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Pennsylvania Woman with Fungal Meningitis Sues Drug Manufacturer

Date of injection, infection predates recall raising questions

RED LION – Penn. — A Red Lion, Pennsylvania, woman stricken with fungal meningitis filed a lawsuit last Friday in federal court against New England Compounding Center (“NECC”), its sister company Ameridose LLC and its sales arm Medical Sales Management, seeking to hold the companies accountable for manufacturing and distributing epidural steroid injections contaminated with fungus and bacteria.

The suit also personally names many of the pharmacists, owners, and leaders of NECC and Ameridose as defendants.

The complaint alleges that on or around Nov. 10, 2011, and on two later occasions, Michele Erkan of Red Lion, Pennsylvania received poisonous epidural steroid injections from a pain-management clinic and developed a high fever, a severe headache, nausea and sensitivity to light some days later. She was subsequently diagnosed with fungal meningitis.

Ms. Erkan’s injections occurred at least 10 months before NECC recalled methylprednisolone acetate suspected to be linked to the fungal infections - raising serious concerns that the problems at NECC and the associated fungal meningitis outbreak began far earlier than the FDA, CDC, or state investigators have suggested. Many cases may have gone undiagnosed or misdiagnosed, her attorney said.

NECC announced the recall of three lots of the medication on Sept. 26, 2012.

“What we’ve learned from the Erkan case is that this contamination could be much broader than NECC admits, and could involve hundreds if not thousands of more patients,” said Thomas Sobol, Erkan’s attorney and managing partner of Hagens Berman Sobol Shapiro’s Boston office.

The suit, filed on Nov. 2, in United States District Court of the District of Massachusetts by the Boston office of Hagens Berman Sobol Shapiro, alleges that NECC’s failure to observe reasonable safety standards in its facilities during the production of injectable steroids, which were distributed to patients across the country, triggered a nationwide fungal meningitis outbreak that has already claimed 28 lives.

The suit also names NECC principal owner Gregory Conigliaro, his sister and pharmacist Lisa Conigliaro Cadden, and Gregory’s brother, Douglas as defendants in the case, along with other family members. The suit also names Medical Sales Management, the sales arm of NECC.

“This is perhaps the most disturbing case of medical product negligence we’ve seen in the years we’ve been helping victims,” Sobol said. “Reports say the vials of medication were so tainted, you could see particulates floating within them.”

After her diagnosis and hospitalization, Erkan continues to suffer severe headaches, hearing and memory loss amid other symptoms. She has been unable to work or care for her family, including her 12-year-old son. Erkan filed the suit on her own behalf and on behalf of her son.

“A mother’s highest duty is to provide for her children and since I had my back injected with those horribly contaminated vials of medicine, I can barely get out of bed, let alone tend to my family,” said Erkan. “They had to know they were cutting corners and putting people like me at risk, and they need to be held accountable for their actions.”

Between Jan. 2012 and Sept. 2012 on at least 26 occasions NECC's internal environmental monitoring program recorded bacteria and mold in the clean rooms used to produce sterile drug products, the FDA claims. Reports also show that a recycling facility next to NECC produced dust and other particles that may have gotten into NECC's HVAC units located on the roof.

Patients who received spinal steroid injections during the last two years may be at risk of contracting meningitis and can contact Hagens Berman to discuss a potential legal claim by calling (206) 623-7292 or by emailing Meningitis@hbsslaw.com. More information about these cases is available at hbsslaw.com/Meningitis.

About Hagens Berman

Seattle-based Hagens Berman Sobol Shapiro LLP is one of the top class-action law firms in the nation, with offices in ten cities. Founded in 1993, we represent plaintiffs in class actions and multi-state, large-scale litigation that seek to protect the rights of investors, consumers, workers and whistleblowers. More information about the firm is available at www.hbsslaw.com.

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