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Meningitis outbreak: Nashville clinic provided patients' names

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Vials of injectable steroid made by New England Compounding Center implicated in a fungal meningitis outbreak. / Minnesota Department of Health / File / AP

Written by
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The Tennessean

A salesman for the drug company blamed for a nationwide fungal meningitis outbreak told an official at a Nashville clinic last year that because of pressure from regulators, patients' names would have to be provided when placing orders from the company, but it didn't matter if people named were the ones actually getting the shots.

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Dr. John Culclasure's account of the conversation became public in

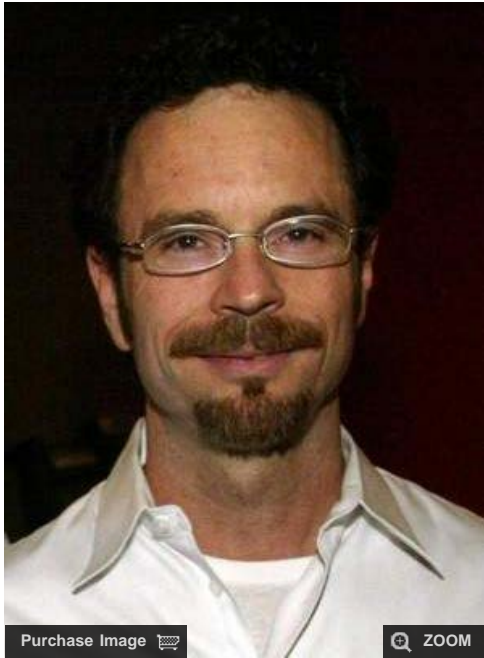
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a court filing this week even as a congressional committee was discussing proposed legislation to prevent another outbreak like the one that has taken 55 lives, 15 of them in Tennessee.



Dr. John Culclasure / File / The Tennessean

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Whether patient-specific prescriptions were provided to the now-shuttered drug compounding company has become a critical issue in the ongoing criminal investigation. Regulators have charged that the New England Compounding Center routinely shipped thousands of drug vials without legally required patient-specific prescriptions.

According to the filing, staffers at the Saint Thomas Outpatient Neurosurgical Center — where Culclasure was medical director — subsequently simply submitted daily lists of patient names with their orders, but on at least one occasion did not do so. NECC filled the order anyway. The salesman had told the clinic that the Massachusetts pharmacy board was insisting on patient names.

Clinic officials had noted that it would be impossible for them to predict in advance which patients would actually get the injections, but the salesman told them “that was fine because NECC just needed a list of patient names.”

Other details in the filing include an account of a face-to-face encounter between NECC salesman Mario Giamei and clinic officials on Sept. 24, 2012, just as the outbreak was unfolding.

Giamei, who had stopped by on his way to a Memphis conference, was questioned by clinic officials about the fungal meningitis outbreak, but he was “adamant that the problem could not have come from NECC.”

“This could not possibly be coming from us,” the salesman insisted, according to the filing.

“Mr. Giamei stated that NECC complied with applicable sterility procedures and had a state-of-the-art facility.”

Later inspections found numerous sterility problems at NECC, including unopened vials of fungus-tainted steroids.

George Nolan and William Leader, attorneys for Wayne Reed, filed Culclasure's responses to interrogatories as part of a motion to compel clinic officials to respond to unanswered questions. Reed, who suffers from Lou Gehrig's disease, lost his wife, Diana, to the meningitis outbreak.

Lawyers for the clinic have refused to answer several questions, contending that the information sought is exempt from disclosure under state and federal laws.

Just four days before Giamei's September visit, a staffer at the Nashville clinic called the salesman and questioned whether "there had been any other reports of patients with meningitis."

The salesman subsequently emailed the clinic sterility test results from the three lots that became the subject of a nationwide recall.

The filing does not make clear when the clinic began ordering methylprednisolone acetate, the steroid blamed for the outbreak, from NECC, but an account of phone calls about pricing shows that the drug was being purchased from NECC by February 2012.

In April, the filing shows, NECC informed the clinic that it would have to order at least 500 vials at a time in order to get the \$6.50 per unit price. The clinic "ordered 500 vials from that point on."

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