

From: Mario Giamei, Jr. </O=FIRST ORGANIZATION/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=MGIAMEL>
Sent: Monday, September 24, 2012 9:13 PM
To: Barry Cadden <bcadden@neccrx.com>
Cc: Robert Ronzio <rrozio@medicalsalesmgmt.com>
Subject: St Thomas Neurosurgical Center

Barry,

Here is an update on the visit I had with St Thomas Surgical Center. I visited the facility around 10:15 AM and the waiting room was unattended and empty. Debra Schaumberg who is my point of contact came in from across the hall and we started to chat about what they were dealing with. She said the health department was investigating the issue with the patient infections and she was sure they were contacting the CDC. She said they were looking at all possibilities. I verified that she had received our testing data which I had forward via email on Friday. At that point a patient came in that had not gotten the message that the procedures were cancelled. Debra took them across the hall telling them the facility was closed due to equipment malfunction. She came back with Cindy who had contacted me on Friday and the Doctor (I believe Dr Culclasure) who is at the center of this situation.

He had several questions. The first was whether we had shipped vials from this lot only to them or to other facilities as well. I told him that we ship medication nationally to over 3000 customers and I am sure many have received methylprednisolone from this lot, with zero issues. He thought we were a small company and did not realize we had a national presence. He wanted to know if doctors were using the 1ml methylprednisolone for joint injections and intramuscular injections. I explained that my best guess is that the majority of the doctors who use the preservative free methylprednisolone use it for similar procedures (ie. ESI) I told him that orthopedic doctors and the like would more likely use preserved methylprednisolone for joint injections. I also pointed out that we provided him with testing and he asked if we test for aspergillus. I told him that questions like that should be directed to Sharon Carter as she had given her phone number to Cindy on Friday. I explained that I am not a clinical person and there is no way for me to answer anything of that nature.

Here is what he told me. He said that they have six patients total that have infections. The first was treated in late July but did not show symptoms until September 7th 2012. The patient was seen at Vanderbilt and was treated and was getting better and I believe he said the patient had been sent home but got worse some days later. This patient was the one confirmed with the aspergillus fungus. He explained to me how the patient could not have just contacted it without it being introduced into his system. He said they were checking all avenues including a discussion with GE on the Omnipaque which they claim they single dose and their provider for preservative free saline. I asked about the lidocaine which Cindy had mentioned to me and he said they weren't too concerned because that was used on the surface or just under the skin but then conceded that could be an issue too. More importantly, he told me that in July, he had treated 309 patients, a colleague had treated about half that and two others treated about 28 each. He generally does most of the procedures at the facility so I suspect that meant August is similar. Of all these patients only Dr Culclasure's patients were among the ones that had been infected. None of the other doctors had any infected patients. They all use the same medications including mostly methylprednisolone although this client does buy some betamethasone from us. Then the doctor expressed concern that only his patients were infected and he began to think about the possible differences in what he does. He said that he thought that the other doctors all use regular epidural needles but he uses a wing needle which has "wings" that he uses to aid with injecting the needle. He also said there was a third type of needle used for transforaminal injections and none of those patients had any infection

issues to date. Then he started to say that the wing needles could potentially have had mold spores in them from the manufacturer and his skin literally began to crawl with goosebumps.

He said that no other patients have been confirmed to have the aspergillus fungus but he assumed they would all show this as the development of all the patients was similar in that they all took some time to show symptoms with the the previously mentioned patient taking the longest and on the other end of the scale one patient showed symptoms within 10 days. He said the good news was that it appears there had been no issues since September 7th. (not sure what he meant by that in terms of the timeline).

Through most of this conversation, I continued to reiterate that I was confident our product was not the issue, that he had testing from us to verify that information which was not available from any other source and that we have no other issues in the entire country on this or any medication. As I left him, I once again advised him to contact Sharon with any questions and he and Debra started to discuss contacting the other doctors to confirm what type of epidural needle they used.

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