

Vermillion, Terry

From: West, Robert
Sent: Monday, July 28, 2003 10:57 AM
To: Vermillion, Terry
Cc: Niemiec, Michael; Bourne, David
Subject: Per your request

I had a conversation this morning with Dr. Soreth, Mark Goldberger, and Ed Cox regarding Dr. Campbell and Aventis. I briefed them on the entire investigation involving Campbell and what Aventis knew before they submitted their NDA. I suggested to them that it was absolutely necessary for this agency (FDA) to inspect other clinical sites that participated in the clinical trial. I proposed to them that we establish a criteria for inspection (PI that enrolled more than 100 patients) and immediately inspect those sites. I also suggested that these sites be inspected unannounced and with the understanding that fraud could be detected. I explained that it was my opinion that these sites could not be inspected normally. We have to go in to prove or disprove fraud not whether or not the PI was in compliance with the protocol. I told them that it was my feeling that Aventis knew sites were suspect but they did nothing to prove or refute their suspicions. I told them that it was my opinion that Aventis disregarding the safety of the patients with hopes that FDA would approve their product. I also told them that I know they have a shortage of personnel but I think we have to take the necessary steps in order to protect the consumer. I am not interested in whether or not this drug works or doesn't work. I am only interested in whether or not PIs and Aventis blatantly disregarded the obvious. This is the key to whether or not we have any action against Aventis or other PIs.

I would like to propose the following. I am willing to be involved in any action you deem appropriate.

I feel that all suspect sites and those sites that have 100 patients or more be inspected. This could be done by Bimo personnel or by OCI agents. If regulatory inspects, they can issue a notice of inspection and move forward. If OCI agents examine documents, we would have to either get the PI to voluntarily release all documents or we would have to get a US Attorney's Office interested for the purpose of issuing subpoenas for those documents. These documents would include CRFs, Source documents etc. This would probably involve establishing a mini-task force.

The first step has to be establishing criteria for inspection. The next step would be obtaining the documentation associated with the clinical trial and then interviewing a random sample of those individuals enrolled. We are not going to pursue Aventis unless we (FDA) take the necessary steps.

I think the three individuals from CDER understood my feelings and opinions but I don't know whether or not the necessary steps will be accomplished.

Robert J. West
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