

Bourne, David

From: West, Robert
Sent: Thursday, June 19, 2003 2:50 PM
To: Bourne, David
Subject: RE: Dr. Campbell

Attachments: RE Reschedule Meeting.txt



RE
ule Meeting.b

I have provided the AUSA with the prosecution report and we are schedule to indict Campbell at the end of July 2003. I spoke with the AUSA today and we will draft the indictment the 2nd week-of July. I am still looking into whether or not Aventis (Corporation) or Aventis personnel deliberately provided false information to the FDA. I think that we should provide the Center with the interviews we conducted along with the prosecution report so they can initiate disqualification proceedings against Campbell. If we don't provide them with the results of our investigation, I don't think they can proceed with disqualification based solely on the 483 that was issued by CSO Smith during her inspection.

In order to proceed with Aventis or at least Aventis personnel, I believe that other PIs need to be inspected to see if there was a pattern of falsification. If other PIs were falsifying their clinical studies, I think we would have a better chance proving Aventis personnel knew of the falsification and submitted the NDA even though they knew of the fraud. The Center needs to inspect those PIs that enrolled a large number of patients. When the protocol was written, Aventis figured that 50 patients would be the average. If a PI enrolled over 100, I believe they should be looked at very closely. If the PI enrolled employees, their families, themselves, this is a red flag for fraud.

We also need someone from the Center to be prepared to testify at the GJ and/or Trial regarding the application process. They do not need to testify about the safety and/or effectiveness of the drug. They need to be able to articulate the entire process.

Once we indict Campbell, I do believe she will talk about her involvement and maybe she will provide enough evidence to prove that Aventis or Aventis personnel knew of the fraud. If this takes place, then I think we can pursue the corporation either in Alabama or New Jersey where the corporation is located.

I am forwarding an attachment I received from AUSA Henry this morning. He has a few questions which we will resolve before the GJ. We have received additional e-mails from Aventis; however, I have not seen any evidence so far that they purposely submitted fraudulent information to the FDA. They have acknowledged that there were suspicions but nothing concrete. It is my opinion that they did not take the necessary steps in order to prove or refute the suspicions. I don't know whether or not that falls in the criminal category. (Lack of due diligent) I think the Center needs to seriously take the necessary steps to conduct inspections of those high enrollee clinical sites and I think this needs to be accomplished rather quickly. Memories will fade if the inspection process is not initiated. During the inspections, patients need to be contacted to verify their participation. CSOs can not just review documents. Verification is essential.

Robert J. West
Special Agent
Nashville Domicile
New Orleans Resident Office

-----Original Message-----

From: Bourne, David
Sent: Thursday, June 19, 2003 1:22 PM
To: West, Robert
Cc: Niemiec, Michael; Messa, Ronald; Aspinwall, Greg
Subject: Dr. Campbell

Bob,

HQ is being queried by the center and ORA concerning the status of the Dr. Campbell investigation. The questions are: has the investigation expanded to include others beyond Dr. Campbell and what is the status of the investigation with regard to Dr. Campbell.

I know we are on the verge of indicting Campbell, but I'd like you to send me an email, one that I can forward to Terry V who will in turn forward to ORA and the center.

Tell me that information on the case and the status that you don't have a problem with the center being aware of.

David W. Bourne
Special Agent in Charge
Miami Field Office
865 SW 78th Ave, Suite 201
Plantation, FL 33324
(954) 476-5415
Fax: (954) 476-5435