March 6, 2007

Joe Barton
U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

Dear Representative Barton,

Enclosed are answers to questions submitted to me by you in regards to the hearing entitled, "The Adequacy of the FDA to Assure the Safety of the Drug Supply" that took place on Tuesday 13, 2007. Thank you for your continued interest in this subject. Please do not hesitate to contact me for further inquires.

Respectfully,

Ann Marie Cisneros

1251 NW MAYNARD RD. #184
CARY, NC 27513

1. As of what date do you believe that Sanofi-Aventis ("Aventis") first knew that the problems at Dr. Kirkman-Campbell's site constituted fraud?

   I believe Aventis concretely knew of the fraud when their own QA auditor, Rhanjan Khosla, audited the site. That was a few weeks before my visit to the site in February of 2002.

   a. What is the basis for your belief that Aventis knew the problems at Dr. Kirkman-Campbell's site constituted fraud?

      The fraud was blatant, there was no attempt by the Investigator to cover it up. Most research professionals and especially employees of a Quality Assurance department receive some level of fraud training. For Aventis to claim they didn't recognize the sort of oddities described below constituted a suspicion of fraud makes them either incompetent or not completely honest.

      Please remember that Aventis was never tasked with the responsibility to PROVE fraud; the requirement is to report to the FDA any site where fraud is merely SUSPECTED.

   b. Please identify the particular circumstances, problems, or events that you believe constituted fraud and of which Aventis knew?

      These events individually might have equaled GCP deviations as is being claimed by Aventis. However, collectively, the evidence is overwhelming the site was committing fraud.

      - ***The number of patients enrolled, 407 with no sub-Investigator and only 3 study coordinators.***
      - ***Forged consents.***
      - ***Every informed consent was either initialed or dated by someone other than the patient. (It is NEVER acceptable to forge anything on an Informed Consent)***
      - ***Medical Charts consisting of one or two pages.***
      - ***Every patient completing the study, adhering to all study visits, being 100% compliant with study medication.***
      - ***Overwrites of dates and adding study diagnosis in different color ink than what was used for the initial visit in the medical chart.***
      - ***The office staff would not speak with the monitors.***

- ***Enrollment of patients within minutes of each other, on times and days the office was closed and enrolling patients when the site was completely out of study drug (meaning sick patients would have to come back at a later date to pick up the study drug)***
- ***Patients diagnosed with Acute Exacerbation of Chronic Bronchitis that had never had bronchitis or a limited history not meeting "chronic" definition.***
- ***The first several hundred patients were enrolled with primarily Acute Sinusitis; when enrollment was closed for that indication, the Investigator's remaining hundred or so patients all had AECB. You would expect to see the enrollment pattern intermingled, not all one group and then the other.***
- ***Significant under-reporting of Adverse Events and Serious Adverse Events given the number of subjects. This was an indication that she was not following the patients after they started taking the study medication.***

c. Please identify the Aventis employees who were on notice of the fraud you describe in response to Question 1 (b).

Nadine Grethe
Rhanjan Khosla
Rhanjan's boss (head of QA department)

d. Please identify the employee of Pharmaceutical Product Development, Inc. ('PPD") who were on notice of the fraud you describe in response to Question 1 (b)

The following PPD employees diligently reported the fraud:

Beth Heding, CRA
Abby Wear, CRA
John Reynolds, MD

The following PPD employees were also aware of the fraud:

Stephanie Love, CRA
Robert McCormick, Head of QA
Roxann Evans, Project Manager