

Testimony Before the Subcommittee on Oversight and Investigations

Ann Marie Cisneros

Good morning Mr. Chairman and members of the Committee. I am honored that you are giving me the opportunity to tell my story.

My name is Ann Marie Cisneros, I am currently an independent clinical research associate. I served in the United States Air Force as a Medical Technologist, have a Bachelors of Science Degree in Occupational Education from Wayland Baptist University and a Masters of Business Administration Degree from Pfeiffer University.

I have worked as a clinical research associate for approximately eight years. My first three years in this industry I spent at PPDI, a Contract Research Organization, where I monitored a number of protocols that included the large Ketek study called Study 3014. At the time of Study 3014, I was a senior clinical research associate and was tasked to assist with the monitoring of Dr. Anne Kirkman-Campbell's site.

Dr. Kirkman-Campbell is currently serving a 57-month prison sentence for fraud associated with Study 3014. In addition she was ordered by the court to pay restitution to the drug sponsor, Aventis, which had paid her \$400 per patient enrolled.

Mr. Chairman, based upon what I observed and learned in monitoring the Kirkman-Campbell site, Dr. Kirkman-Campbell indeed had engaged in fraud. But what the court that sentenced her did not know is that Aventis was not a victim of this fraud. On the contrary. Let me explain.

Even before conducting the Kirkman-Campbell site visit, a number of "red flags" were apparent. I knew that Dr. Kirkman-Campbell had enrolled over 400 patients or 1%

of the adult population of Gadsden, Alabama. (By comparison, another site in Gadsden had enrolled just twelve patients.) In a Quality Assurance audit by Aventis in early 2002 several Informed Consent issues were noted as well as a significant under-reporting of Adverse Events and no reports of Serious Adverse Events. No patients had withdrawn from the study and no patients were lost to follow up, an unusual occurrence given the number of subjects. She enrolled patients within minutes of each other and upwards of 30 patients per day. She enrolled patients at times and on days when the office was closed.

Once we started reviewing patient charts, we discovered that:

- Every informed consent had a discrepancy.
- Most of the consents looked like they had been initialed by someone other than the patient.
- A lot of the consents were dated by someone other than the subject.
- One consent was blatantly forged.
- There were date discrepancies as to when patients were enrolled in the study, had their blood drawn or signed their consent.
- Most patients diagnosed with bronchitis either had no history of the ailment or did not have a “chronic” condition.
- She enrolled her entire staff in the study.

Frankly, all Kirkman-Campbell seemed truly interested in was getting more business from Aventis as an investigator. At one point during my site visit, she told Aventis Project Manager Nadine Grethe that I could only stay if Nadine got her other

studies at Aventis. Nadine must have agreed. It is my understanding that when the FDA audited the Kirkman-Campbell site, she was participating in another Aventis clinical trial.

While at the site, I was so concerned about patient safety I called Copernicus Independent Review Board or IRB to express my concerns and seek guidance. An IRB, which is under contract to the drug sponsor, has as its primary purpose patient advocacy. It is allowed to contact patients directly and is duty-bound to report to the FDA any unanticipated problems involving risks to subjects and serious noncompliance with regulations. I spoke with someone who I understood to be the president of the company and was told that, while she shared my concerns, she preferred to wait and see what actions Aventis took. I never heard from the IRB again. To my knowledge Copernicus never did audit or blacklist the site, or report any irregularities to the FDA.

I e-mailed a summary of my site visit findings to Robert McCormick, head of quality assurance at PPD, and copied Aventis personnel. I also participated in a teleconference between PPD and Aventis at which I discussed issues identified in my site visit. At some point after that I understand that Aventis took site management responsibilities away from PPD because Dr. Kirkman-Campbell would not cooperate with anyone but the sponsor.

I subsequently left PPD but learned that the Kirkman-Campbell site was being audited by the FDA. In preparation for the audit, I was told by a trusted and distressed former colleague at PPD that Nadine Grethe, Project Manager at Aventis coached Dr. Kirkman-Campbell on how to explain away some the site irregularities.

I was called on two occasions by PPD lawyers who reminded me of the confidentiality agreement I signed and advised me not to speak with the FDA without Aventis approval and PPD attorney's present.

In my eight years in clinical research work, this is the only instance I've come across of such abysmal behavior by a drug sponsor. I feel I can speak for those who agonized over this situation when I say we are pleased that Dr. Kirkman-Campbell is serving prison time for her actions. But what brings me here today is my disbelief at Aventis's statements that it did not suspect that fraud was being committed. Mr. Chairman, I knew it, PPD knew it, and Aventis knew it.

Thank you for this opportunity to tell my story.