From: Tonyd92236@aol.com [mailto:Tonyd92236@aol.com]
Sent: Wednesday, February 21, 2007 8:07 AM
To: Kawaley, Bernadette E.
Subject: Re: presentations

Dear Bernadette:

Below is a text of my brief remarks Friday, to the best that I can recreate them. I did not anticipate making any comments, so I did not have a prepared text.

Sincerely,

Wilson DeCamp

Thank you for allowing me the opportunity of making a brief extemporaneous comment.

My name is Wilson DeCamp, and I am from Leesburg, VA. I am a retired FDA chemistry reviewer. I was diagnosed with Parkinson's Disease a little more than two years ago.

Within my experience, I have no reason to question the commitment of FDA to drug safety. I never saw any hesitation to place an investigational application on hold for safety reasons.

Earlier this week, at the 13th Annual Forum of the Parkinson's Action Network, we heard much about developing therapies, including one that had been stopped by the developer for reasons of safety. However, we also heard of an autopsy report from a foreign study of that same therapy that was claimed to show -- for the first time -- pathological evidence of regrowth of dopamine-producing neurons. Clearly, this has not yet, as far as we were told, been submitted to FDA, or published in a refereed journal. However, from discussions at our meeting, we found it frustrating that FDA lacked the authority to require the developer to continue the clinical trials.

Of course, this is not a PDUFA issue. However, I believe that it does describe circumstances that could modify safety concerns, either on the part of FDA or the drug developer.

I respectfully urge FDA to consider how the Agency could be more proactive in situations such as I have described.

Thank you.