From: Toth-Allen, Jean
Sent: Tuesday, August 01, 2006 8:38 AM
To: [purged]
Cc: CDER DRUG INFO
Subject: Ethics and clinical trials

Dear Mr. [purged]Hancock:

Your inquiry was forward to us for response. Please excuse the delay in responding.

The ethics of performing research on human subjects has been an on-going discussion internationally for many years, but particularly since World War II and the Nuremberg trials. Such documents as the Belmont Report in the United States and the international Declaration of Helsinki, which has seen several updates, provide basic historical precedents. The organization, Public Responsibility in Medicine and Research (PRIMR), whose website is http://www.primr.org, is also a good source of information in this regard. You can also find some useful references on the President's Council on Bioethics website, http://www.bioethics.gov/.

Hope this information is useful.

If you need further information and/or have additional questions, please submit them once again to the official GCP mailbox, gcpquestions@oc.fda.gov, in lieu of responding to my personal e-mail address.

Sincerely yours,

Jean Toth-Allen, Ph.D.
Good Clinical Practices Program
OSHC, Office of the Commissioner, US FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

----Original Message-----
From: [purged]
Sent: Monday, July 17, 2006 10:46 AM
To: CDER DRUG INFO
Subject: DrugInfo Comment Form FDA/CDER Site

Name: [purged]

E-Mail: [purged]

Comments: Hello. My name is [purged] and I am a student at [purged]. My undergraduate degree is in Bioethics from [purged] and I am currently doing research in the hopes of combining my two areas of

interest.

I have a question about which I believe someone in your office might be able to point me in a helpful direction. I have come across a situation in which a European pharmaceutical company is requesting permission to run a test very similar to a phase I clinical trial. What is unusual in this instance is that the drug to be used in the trial has already been approved and is being tested solely for the purpose of establishing in vivo patent infringement. I am familiar with the belief that clinical trials should not be conducted when the root of such testing is purely legal (or in other cases economic), but I am unable to find sources in which this belief is expressed. Might someone know where I could find such sources? And more importantly, are clinical trials with the goal of proving things other than a drug s safety or efficacy approved? Why or why not?

I hope I haven t burdened you with too many open-ended questions and would greatly appreciate any advice you might have to offer, although I do understand that your time must be extremely limited.

Thank you so very much for your consideration,
[purged]