From: Lee, Bonnie on behalf of OC GCP Questions
Sent: Thursday, April 25, 2002 11:12 AM
To: **[Redacted]**
Subject: RE: Conflict of Interest in Clinical Trials
[Redacted], Please see below for answers to your questions.

Bonnie

Bonnie M. Lee
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-----Original Message-----
From: **[Redacted]**
Sent: Tuesday, April 23, 2002 3:00 PM
To: 'OC GCP Questions'
Subject: RE: Conflict of Interest in Clinical Trials

[Redacted],

Thank you very much for you prompt and helpful response. I will review all suggested and attached documentation.

I do have more specific questions.

Does the FDA define or interpret "conflict of interest" and if so how?
In the preamble to FDA's 1981 IRB regulations, 46 FR 8942 at Comment 60, it states "FDA believes that the IRB or the institution should determine what constitutes a conflicting interest." The regulations at part 54 address different disclosure amounts--but amount above those indicated do not necessarily represent a "conflict of interest", rather they are amounts that need to be disclosed because they may be a source of "bias" in clinical trials.
If a pharmacist, who is also an IRB member, votes on a protocol in which his pharmacy is paid for services is this a conflict?
A pharmacist can be a valuable member of the IRB and if he is simply performing his responsibilities as the institution's pharmacist, he may not have a conflict of interest. However, if the pharmacist has an integral role in the conduct of the study (e.g., blinding medications, etc.), then it is up to the institution to determine whether he has a conflict of interest and would therefore be precluded from participating in the review of the particular study.
If the PI's father is the chairman of the IRB and voted on the PI's protocol, is this a conflict? Yes.

[Redacted] disclosed in the ICF that he had a financial interest in the drug being provided to [Redacted]. This is a conflict of interest, but because it was disclosed, is it considered acceptable to the FDA? No. There has been a lot of discussion about whether disclosure is sufficient, or whether there is a need to manage or eliminate conflicts of interest once they reach a certain point. I believe that there is consensus that disclosure, alone, is not enough. The Departmental guidance document, I believe, discusses this in further detail. Additionally, guidance on financial interests has been put out by the AAU and the AAMC--you ought to look at these as well.

Does the FDA require compliance with the Declaration of Helsinki, 2000, item 22, regarding conflict of interest? FDA's regulations only address the Declaration of Helsinki in 21 CFR 312.120 (acceptance of foreign studies for drugs) and in 21 CFR 814.15 (for medical devices). The versions referred to in the regulations are the 1989 version (for drugs) and the 1986 version (for medical devices). For further information on this, you can read our guidance document at:
http://www.fda.gov/cder/guidance/fstud.htm

Thanks again,

[Redacted]