From: Lee, Bonnie
Sent: Wednesday, October 20, 2004 9:48 AM
To: [Redacted]
Subject: FW: Re Your IRB COI Question

[Redacted] , Here's another attempt at sending this response to you. I hope this works!

My best,

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

-----Original Message-----
From: Lee, Bonnie
Sent: Wednesday, October 20, 2004 9:13 AM
To: [Redacted]
Cc: Lepay, David
Subject: Re Your IRB COI Question

Dear [Redacted] ,

David Lepay asked me to respond to your inquiry (below). In response to your question, and based on your description of the situation (again, below), I don't think that you could be considered to have an "unmanageable conflict of interest" that would prevent your involvement as an unaffiliated voting member to this IRB. There are two sides to the potential conflicts that probably should be considered. The first you have considered: that is, the need to *not* participate in the review of protocols from your company. The second, you may not have considered: that is, whether there is a conflict in reviewing other company protocols for potential products that could be in direct competition (if approved) with products from your company. I don't know whether the latter is as significant (since it could, in theory, influence a negative decision), but I think it ought to be considered in determining what protocols you may need to limit your involvement. I hope this is helpful to you.

In the future, if you have inquiries you may want to send them to our general GCP mailbox: GCPquestions@oc.fda.gov.

Bonnie

Bonnie M. Lee
Associate Director for Human Subject Protection Policy
Good Clinical Practice Program, FDA

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From: [Redacted]
Sent: Friday, October 15, 2004 10:49 AM
To: 'david.lepay@fda.hhs.gov'
Subject: IRB COI question

Hi David, hope you are doing well. I left [Redacted] in August and retreated
back to industry. In addition to my "day job" I am a certified IRB professional ("CIP") through [Redacted] . I have been serving on a

medical
IRB for 3 years (as an affiliated member at [Redacted]).

I have another opportunity to serve as a voluntary unaffiliated member on
another local academic medical center here in [Redacted] . The question has come up as to whether my career (as an employee in Pharmaceutical Industry) would be considered an unmanageable conflict of interest. Naturally I would not participate in the review, deliberations or
voting of [Redacted] (or it's business partners) protocols (and frankly we don't
really run any protocols with them). Besides, this institution has several
IRBs so in the event that a future protocol should make it's way there it
could easily be sent to one of the other boards.

Since I would not want to potentially expose this organization to issues in
the event of an FDA inspection, the ultimate question is whether FDA OGCP's
would view my participation on an IRB as an unmanageable conflict of interest that should prohibit my involvement as an unaffiliated voting member. I would be grateful for your response.

Warmest Regards

[Redacted]