

From: Barbara Warren [REDACTED]
Sent: Thursday, September 30, 2010 1:11 PM
To: Bryan Bower; Paul J. Bembia
Cc: Anne Rabe; Diane D'Arrigo; Joanne Hameister
Subject: Re: Phase I Study Process

Dear Bryan Bower & Paul Bembia,

We are in the process of putting together additional comments on this Process. However, there are some outstanding items that we would appreciate having resolution on.

We sent comments on the CSAP, Characterization, Sampling and Analysis Plan, and we have been given vague answers about when the plan might be modified and to what extent our comments will be addressed. There was some suggestion that other Phase I studies might handle some of the issues we raised. While other groups supported CEC comments, because of the short time frame we were operating under we did not have the time to gain supporters. However, it appears that DOE is not in any rush to finalize the CSAP.

We believe this Plan is a critical starting point for all the subsequent studies that are done.

We really need a more specific and detailed response, so that we can then include anything that is not being addressed in the CSAP into our recommendations for Phase I studies.

More recently we sent a joint letter regarding the Proposed Independent Scientific Panel, which relates to the Phase I study process. We have heard no response.

Thank you for your attention.

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