

summary of Conference Call.eml.txt

Subject:
Re: Summary of Conference Call
From:
"Tom Beauchamp" <beauchat@georgetown.edu>
Date:
Tue, 8 Feb 2005 09:41:14 -0500
To:
"David Wegman" <david_wegman@um1.edu>, "Ellen Eisen" <Ellen_Eisen@um1.edu>, "Ellen Eisen" <eeisen@hsph.harvard.edu>
CC:
"Noah Seixas" <nseixas@u.washington.edu>, "Mark Cullen" <MRCULLEN@aol.com>, "Jon Samet" <jksamet@jhsph.edu>, "David Wegman" <David_Wegman@um1.edu>

David:

This is a follow-up to my earlier letter to you.

Somewhere between ?misleading? and ?disingenuous? has red-flag written all over it.

I assume from your letter that you want to recommend that it is inappropriate to say ?...no human health effects.? If we are to write up something on this point, perhaps the nature of the inappropriateness should be explained. The fact that an elevated LDL is a health effect gives you one ground of inappropriateness: The claim of no health effects is not supported by available facts (factual inappropriateness). However, you may also mean that such a statement is misleading, whether intentionally or not, and it is unacceptable to mislead in this way (moral inappropriateness).

Let's assume that this study was inadequate to determine either causation or lack of causal influence by PFOA. Since that's the central question, any plan for further study must be designed to examine a specific and relevant hypothesis about causality. In the absence of such study, it would seem that the central question is being avoided.

Assuming that we are all agreed on something like the above, what's next? Did you discuss the next move in your conference call? What are the official responsibilities of our committee at this point? Is Robin aware of these judgments?

I am sorry to have to play catch-up.

Tom

----- Original Message -----

From: David Wegman
To: Ellen Eisen ; Ellen Eisen ; Tom Beauchamp
Cc: Noah Seixas ; Mark Cullen ; Jon Samet ; David Wegman
Sent: Friday, February 04, 2005 1:12 PM
Subject: Summary of Conference Call

Dear Ellen and Tom,

Sorry you couldn't be with us on the phone call today. I wanted to summarize what was said.

First, all four of us were concerned that the employee letter was somewhere between ?misleading? and ?disingenuous?. We were unanimous in believing that, contrary to the statement at the start of the letter, we believe that the results do show a ?health effect?. While this is not equivalent to disease, it is certainly not appropriate to say ?...no human health effects?. An elevated LDL is a health effect. This study could determine neither that it was ?caused? by PFOA nor that it was not caused by PFOA. The letter indicates a plan for further study but that further study is the community study which, unlike our recommendation that the

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findings be used to propose and undertake a study to examine a specific hypothesis about causality, the community study can be expected not to be informative on this issue.

Furthermore, the later statement in the letter (that the abnormal results were only in the highest group) was considered by us all to be misleading. Each decile had some significantly elevated values. The only way to say that elevated LDL occurs just in the highest decile is to rely exclusively on John Green's model, while that modeling approach may be defensible, it is not standard, by any means, and a linear model is likely to fit the data equally as well (I can't recall if we already know it does). Jon Samet had asked last meeting and in messages after the meeting to have the standard approaches performed as well. They may be doing this for the final report but these results do not appear to have been included in the way that the letter was crafted.

Second, there was concern that the ERB was indirectly invoked as having participated in "...a rigorous review process by noted health experts..." while we were involved, our review did not appear to achieve the result of influencing the plan on communicating results. We did, specifically, recommend release to EPA and that was done. But by implication, that EPA release was needed because of demonstrated health effects, a fact not communicated in the letter. We are concerned that we are being invoked inappropriately (although anonymously).

Third, there was concern that a letter such as this should have been vetted by the ERB. Mark pointed out that communication of positive results as a result of a study that Yale was involved in was closely reviewed by their IRB. Therefore, there was a general concern about how and when we are being sought for advice and counsel. He had offered to be available (on behalf of the ERB) and was not contacted.

The plan is for me to talk to Robin and tell her about our discussion. I will ask her a) to address developing a correction in the communication to the employees (its not her responsibility but she is our contact) and ask that we be involved in that correction, b) to clarify what our role is (and will be) for vetting communications to workers and/or the public, and c) to assure us that the analyses we think essential are to be included in the final report.

The plan is for me to do this by phone, not on paper, but, if we are dissatisfied with the response, then a formal communication may be in order.

If you have any thoughts before I communicate with Robin, let me know. I probably won't get to it until a week from now because I leave the country on Saturday and return Sunday. But I think it is important to communicate to Robin as soon as possible.

and toby ?us? but not of release

Regards,

David

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