Message

From: HEYDENS, WILLIAM F [AG/1000] [/O=MONSANTO/OU=NA-1000-01/CN=RECIPIENTS/CN=230737]
Sent: 2/9/2016 11:43:08 PM
To: Ashley Roberts Intertek [redacted]@intertek.com]
Subject: RE: summary article
Attachments: Summary Manuscript Draft 2 0 Feb 5 2016_jfa_wfh.docx

Ashley,

OK, I have gone through the entire document and indicated what I think should stay, what can go, and in a couple spots I did a little editing. I took a crack at adding a little text on page 10 to address John's comments about toxicologists' use of Hill's criteria – see what you think; it made sense to me, but I'm not sure if it will to others - please feel free to further modify and/or run by Gary.

After you have looked through this, let's discuss.

Thanks,

Bill

From: Ashley Roberts Intertek [redacted]@intertek.com]
Sent: Monday, February 08, 2016 3:15 PM
To: HEYDENS, WILLIAM F [AG/1000]
Subject: FW: summary article

Hi Bill,

Please take a look at the latest from the epi group!!!!

Can you call me once you have digested this.

Plaintiff Exhibit
0368

Thanks

Ashley

Ashley Roberts, Ph.D.
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From: John Acquavella [[redacted]@gmail.com]
Sent: February-08-16 4:00 PM
To: Ashley Roberts Intertek
Subject: summary article

Ashley:

Let me start by saying that I share your goal of having complete expert panel authorship on the summary article. I've had some initial correspondence from the panelists about the summary article and the consensus is that they will not be authors on an article that has inflammatory comments about IARC. Assuming those inflammatory comments were carried over from the animal carcinogenicity and genotoxicity articles, I'm sure the epi panelists would not want to be associated with those articles either.

To achieve the complete authorship goal, an extensive revision of the summary article is necessary. To facilitate, I've edited the entire summary article to take out most of the inflammatory statements about IARC. The view of the epi panelists is that the inflammatory comments are not necessary and will cause readers to disregard the outstanding scientific work that was done by the panels. Inflammatory statements will certainly

cause IARC and IARC's vocal supporters to push back hard to defend their evaluation and discredit Monsanto's expert panel process and panelists. I think you have seen the recent article in which many well known epidemiologists banded together to defend IARC (see Pearce et al. 2005 attached). Our strongest point is the quality of our scientific reviews, not disparaging the IARC process or the work of monograph 112 workgroups. To the extent that there are inflammatory comments about IARC in the articles by the other panels, I suggest you work with the authors to remove them.

In addition, I noted the following in my review of the summary article:

- Hill's criteria are misapplied by the toxicology panels. Please review applications of Hill's criteria with Doug Weed who is an expert on the intended meaning of each criterion. It will detract from the toxicology arguments to misuse these criteria. I suggest you also ask Doug to look at the animal carcinogenicity and genotoxicity articles to make sure that Hill's criteria are cited appropriately.
- With respect to exposure, I think the margin of safety is underestimated in various sections of the article because the RfD is a daily dose and the applicator exposures are very infrequent. I addressed this in an article in Annals of Epidemiology in 2003 that was the work of an ECPA taskforce. See reference below and article attached.

I expect to have specific suggestions from the epi panelists later this week. I will compile the unique suggestions and send them on to you asap.

Regards,

John

Acquavella JF, Doe J, Tomenson J, Chester G, Cowell J, Bloemen L. Epidemiologic Studies of Occupational Pesticide Exposure and Cancer: Regulatory Risk Assessments and Biologic Plausibility. Annals of Epidemiology 2003; 13: 1-7.