

JNJ000004225-JNJ000004230

From: Zazenski, Rich (LNA) [Rich.Zazenski@luzenac.com]
Sent: Monday, February 27, 2006 7:25 PM
To: Mann, Steven [CPCUS]
Subject: RE: Very Important! - Luzenac letter to IARC - Our Conference Call on Monday
Sensitivity: Confidential

I'll call you a little later. I don't think they will issue a press release.

The IARC website update occurred some time between 9:00 and 9:30am EST - which would have been near mid-afternoon in France. I'm not shocked, but a little surprised they didn't take a day or two to rethink their release given the points we made in our letter. In a way, their release (because of what we charged in our letter), may backfire on them if we make 'public' the flaws and outright disregard of their own policies and procedures in this review process. Rest assured, we (I) will explore all possible avenues of challenge - not necessarily expecting a retraction - but to see what sort of political heat (with financial ramifications) that could and should be brought down upon IARC and WHO. This review was a travesty of scientific integrity.

I really think we need to talk to the folks in the FDA about this.....We've already filed a Data Quality challenge with OSHA (last November) regarding their using IARC as an authoritative body for determining carcinogenic substances. OSHA has initially responded that they need another sixty days to evaluate the challenge and their next response date is no later than March 24th. Given the antic's by IARC with this talc review, we believe IARC's applearc is about to tumble. And we fully intend to take this whole story to our legislators. Montana (a state with less than a million people) is the largest talc producing state in the U.S. The two Senators are well aware of what the talc industry means to the state. They will be none too happy to learn of the shenanigans pulled by IARC who receives substantial funding from U.S. taxpayers.

I can't believe the arrogance and insolence of this 'U.N. agency'.

Later,
Rich

From: Mann, Steven [CPCUS] [mailto:SMann@cpcus.jnj.com]
Sent: Monday, February 27, 2006 11:43 AM
To: Zazenski, Rich (LNA)
Subject: RE: Very Important! - Luzenac letter to IARC - Our Conference Call on Monday
Sensitivity: Confidential

Doesn't seem to have helped as website went up this morning. I assume you have seen it. We can talk when you wish.

Do we know if IARC will make a "Press Release"?

Steve

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

From: Zazenski, Rich (LNA) [mailto:Rich.Zazenski@luzenac.com]
Sent: Saturday, February 25, 2006 7:50 PM
To: Mann, Steven [CPCUS]
Subject: FW: Very Important! - Luzenac letter to IARC - Our Conference Call on Monday
Importance: High
Sensitivity: Confidential

Steve - I had to pull the trigger on this just several hours ago. Fortunately, I was able to get permission from my management. Feel free to disseminate this among your management for internal purposes.

Sometimes you have to work the high wireeven if it is without a net.....

Best regards,
Rich

From: Zazenski, Rich (LNA)
Sent: Saturday, February 25, 2006 4:27 PM
To: Goldberg, Gary (RTM); Parr, Adam (RTM); TURNER, Eric (LG CIT); Graham, Robert (RTM); Saperstein, Steve (RTM); Cutler, Kent (LNA); Godell, Ralph (LNA); Argust, Peter (BEU); Hubbard, Sue (BEU); Stockman, Mike (USBORAX); JONES, Laura (LEU); REFREGIER, Michele (LEU); PORTA BONETE, Eric (LEU); Keefe, Susan (RTM); Brown, Judy P. (USBORAX); Sperring, Keith (RTM); Carr, Malcolm (RTM)

Subject: Very Important! - Luzenac letter to IARC - Our Conference Call on Monday
Importance: High
Sensitivity: Confidential

<<IARC letter to Dr Baan - Eric Turner - Feb 25-2006.doc>>
Dear Ladies and Gents:

There have been some developments (and lack thereof) over the last 48 hours that have led us to take some actions over the weekend that we'll discuss during our Monday conference call. Specifically, the delay of an IARC posting of a summary of the review process for Monograph

93 leads us to believe that they may be having difficulties with assembling the language regarding the 2b classification of talc-based body powders. We were instructed that IARC would be posting their summary of the review last Monday or Tuesday.....then it was delayed until possibly Friday (Feb. 24th). As of Saturday afternoon, there have been no updates on the IARC website.

This may be a signal that they are having difficulties regarding the talc classification - and rightly so. Eric Turner had instructed us to compose a letter of 'objection' to IARC as to how the talc review was handled. Originally, Eric suggested that this should be a letter that would come from the Industrial Minerals Associations of Europe and North America. However, in drafting such a letter for IMA submission, it became apparent that since there has been no such pronouncement from IARC as of Friday, February 24th, that perhaps our letter of protest might be most effective if delivered prior to their posting of their decision.

Given the difficulties and time consuming process of getting comments and a consensus from IMA members regarding a letter to IARC, Eric and Gary decided that it would be in the best interests for all if Luzenac took advantage of this window of opportunity to dispatch our letter of protest to IARC this weekend under Luzenac letterhead. Timing may very well be critical here and we cannot afford to pass up this possible opportunity to give IARC further reason to pause.

Hence, attached is a letter from Eric Turner to IARC that was dispatched Saturday afternoon, February 25th. The letter gets right to the point(s) as to why we believe their evaluation of talc was not conducted in a manner that was consistent with IARC's reputation and its policies and procedures.

We have also been in contact the last few days with Dr. Joshua Muscat who was one of our Industry Observers during the IARC proceedings. He has graciously responded to a number of questions we had regarding 'behind the scenes' discussions and issues during the talc review. I've attached his preliminary responses at the end of this e-mail. Dr's. Muscat and Huncharek will be meeting with us next Wednesday (in Washington) to discuss potential new research projects on talc.

The call-in instructions for Monday's call are pasted below followed by Dr. Muscat's responses.

On a personal note, let me just say that it is a pleasure to become part of such a diverse team of talent and expertise. What is really of importance however, is to know that when time is of the essence, we can act swiftly, decisively, and without delay.

Best regards,
Rich

Please join in on the conference call on Monday, Feb 27th to discuss the IARC review of talc:

Time: 4:00 pm France; 3:00 pm UK; 10:00 EST; 8:00 am Denver; 7:00 am Valencia

For those parties calling from the United States & Canada,
dial 1-888-288-9321

For those parties calling from France, dial +33-1-7304-1400

For those parties calling from the United Kingdom, dial +44-207-663-2210

All callers will use the same 6-digit access code when prompted: 531094.

When you hear a tone, you will be connected.

>If by chance another call is already in progress, dial the same main number and use the alternate access code, 892226.

If you have any problems reaching each other, press *0 and an operator will come on the line. For Customer Service at Premiere Conferencing, dial 1-888-605-5061 or 1-719-867-0618. Jeremy Roberts is our account manager at Premiere and his contact number is 1-801-974-3699.

Or, simply call me (Rich) on my cell phone to report a problem 303-956-6131

Rich Zazenski

Hi Rich and Bill,

Let me take a first stab at the questions below, and I will try and fill in more details by telephone.

Thanks

Josh

>>> "Zazenski, Rich (LNA)" 02/24/06 11:04 AM " href="mailto:Rich.Zazenski@luzenac.com

02/24/06 11:04 AM "Rich.Zazenski@luzenac.com" 02/24/06 11:04 AM >>

Questions for the Talc Observers

1. What happened with the translocation (migration) issue? Which subgroup addressed it?

Addressed by the mechanism group. This issue did not come up in the epi working group and was discussed by the mechanism group only for a few minutes at the last day of the proceeding.

2. Were studies showing reduction in ovarian cancers after tubal ligation or hysterectomy argued to support translocation (migration)? If so, by whom?

The answer is yes but I would say it was not the a major factor in the epi working group evaluation (but not insignificant either). Sue Hankinson as the leader of this part brought this up. She is a collaborator with Dan Cramer who thinks this the tubal ligation data is important.

3. What issues were given credence by the epi subgroup? (other than translocation, which it apparently considered significant)

The major issues were the overall increased pattern of elevated risks across the 20 or so epi studies. The subgroup thought that the consistency of these findings ruled out the possibility of bias and confounding.

One of the things that appeared to temper their belief in a possible association was the inconsistent definition of talc terms in these studies (e.g. talc, powder, dusting etc.)

4. Was there discussion of, and any recommendations for, further research?

No

5. What was the final vote on (a) the classification of the human evidence on talc body powder, and (b) the overall evaluation for talc body powder? Who dissented? On what grounds did they dissent? Were there changes in position by any of the voters (e.g., Zu)? Were the issues they raised discussed? If so, what were the majority's responses?

I believe it was 12-3 for the 'limited' classification and 2b for the overall. Dissents were Drs. Wylie, Zu and Dr. Anthony.

There actually was a 2nd vote. Some people had left at that point (Dr. Anthony) and a few others and there was some confusion over the legitimacy of that vote but basically there were no changes as I recall. I sent Bob Glenn an e-mail on this

6. To what extent did Hankinson or others dominate/influence the proceedings? Is this mainly an impression, or is there some way to quantify/objectify the point? Did others appear familiar with the literature and issues regarding ovarian cancer. Was there serious debate and discussion in the subgroup? Do we know what part Hankinson played in authoring the human studies data chapter and the write-up of the subgroup preliminary evaluation of the human studies evidence?

Dr. Hankinson wrote the human studies chapter but the summary was written by another member, in keeping with IARC rules. I can only comment on my impressions of her. She was very fair, but I don't believe her expertise is in this area. She was not really knowledgeable (is that the spelling?) about the biological ways that talc could cause ovarian cancer. She deferred to Cramer's article.

I will talk about the nature of the working group later.

7. Did the epi subgroup vote on an evaluation on the first day?

No. The vote came up later (3rd-4th day).

8. Did Bill Jameson say anything?

He briefly talked about the NTP deferral.

9. Did IARC staff contribute anything significant?

Some did, some didn't. More on this later.

10. How much were the observers allowed to participate?

I was pleased by their acceptance of the Observers participation. Dr. Cogliano was present for most of the epi working group session and no one objected to Observer's comments.

11. Did the subject of the NTP withdrawal and the reasons for it come up?
see above

12. Did any of the participants remark on the lack of gynecologic expertise?

No. I have some comments on the overall structure of the IARC proceedings regarding expertise that will discuss later.

13. Was "the question" on the possibility of asbestos in talc every asked by one of our observers?

The working group members brought this issue up fairly quickly.

14. What exactly was said about the pre-1976 talc issue? Who said what? Did IARC staff say anything?

Different things. It was discussed in terms of the epi studies and that the epi studies could not for the most part differentiate pre from post.

15. What was said about the animal and in vitro evidence regarding talc?

This all came up in the final plenary session the last day (last 2 days). There was some discussion of the animal data. Little on in vitro.

16. What was said about pleurodesis?

Nothing. I requested that the working group review this, which they did. There was a brief discussion on whether medical talc use should get it's own evaluation and the working group concluded that it should not.

Bill, I think this is something we need to talk about this week. I believe that the importance of this info is with respect to the ovarian literature. I discussed the

concept of similar tissue type between mesothelioma and ovarian cancer. This is something that did not make an impression on the working group. To be fair, the process deals with a lot of literature and doesn't really allow for "novel" concepts to be discussed. I think a published review article needs to be done that 'translates' the pleurodesis data to ovarian cancer relevance.

17. Do we have the latest drafts of all the chapters that were made available? (Can IARC write new material to fill-in for points that were discussed but not written up by a subgroup or the plenary? Who writes the final "rationale" section of the monograph?)

There is a pdf file now available. I am attaching that.

18. Were there any indications that "precautionary principle" thinking played a part in the evaluation? (E.g., were there any references to "prudence" or "erring on the side of safety"?)

Yes an no. It depended on the member.

19. How much attention was given to the ovarian cancer issue vs. the inhalation issues?

Both were evaluated. I would say inhalation issue got a fair review.

20. Was there any discussion of the inconsistency between finding inadequate evidence for inhalation exposure and limited evidence for perineal exposure?

Not really. It might have been mentioned once in the epi session but did not come up at plenary. Again, as in the pleurodesis data, this is something that needs to be 'translated.'

See you Tuesday for dinner.

Best,
Josh