From: Bernstein, Robert (LNA)
Sent: Thursday, January 04, 2001 3:29 PM
To: Zazenski, Rich (LNA)
Subject: RE: Summary of CRE Meeting - Dec. 15

See my notes below.

-----Original Message-----
From: Zazenski, Rich (LNA)
Sent: Tuesday, January 02, 2001 9:37 AM
To: Turner, Eric (LNA)
Cc: Bernstein, Robert (LNA)
Subject: Summary of CRE Meeting - Dec. 15

At our meeting with Jim Tozzi and Bill Kelly at CRE on Friday Dec. 15th, we discussed the following:

(1) Jim congratulated us for a fine victory but suggested we not get too confident just yet. He confirmed that the talc session was quite an embarrassment for NTP, but that might also motivate them to address the "talc definition issue" with greater resolve.

(2) The fourth NTP review involves the NTP Executive committee. Committee members include the agency heads for:
Agency for Toxic Substances & Disease Registry
U.S. Consumer Product Safety Commission (CPSC)
U. S. Environmental Protection Agency (EPA)
Food & Drug Administration (FDA)
National Cancer Institute (NCI)
National Institutes of Health (NIH)
National Institute of Environmental Health Sciences (NIEHS)
National Institute for Occupational Safety & Health (NIOSH)
Occupational Safety & Health Administration (OSHA)

The protocol for this committee meeting requires the NTP to summarize for the rest of the committee the findings of the first three review groups. Following a discussion, the Executive Committee votes on the substance. Typically, the executive committee meeting is scheduled to start in the morning and conclude by noon during which 8-10 substances will be reviewed. Some substances may get less than 10 minutes of consideration.

(3) Tozzi stated that for the most part, these agency heads do not attend the meeting themselves, but send alternates in their place. Therefore, some lower ranking agency person (who knows nothing about the substances being reviewed) is voting on the recommendation. Consequently, if the NTP wishes to "railroad" a recommendation, they have the forum to do it. Tozzi believes that is what happened to Dioxin where RG1&2 voted to list, Group 3 reversed the recommendation, but Group 4 voted unanimously to list. He said the Group 4 discussion on Dioxin lasted 5 minutes. He reminded us that the other agencies do not have a visible "stake" in this NTP review - such that their final recommendation would not negatively reflect upon their specific agency. Therefore, committee members are inclined to simply vote with the recommendation offered by the NTP.

(4) Tozzi recommended that over the coming months, we target specific individuals at each of the agencies on the Executive Committee who might likely be the attendees for the talc review. Then we select an issue which we want that particular individual to become familiar with before the committee meeting. For example, we target individuals within the FDA and the CPSC to focus on the weaknesses of the epidemiological studies. Then perhaps we target individuals at OSHA and NIOSH for pointing out the irrelevance of the NTP animal study. Etc. ***[Bernstein Robert]*** Can we be specific here? Who does what? You? Tozzi? who?

(5) We enlist the support of senate and congressional representatives from Vermont and Montana to lobby the committee members to "uphold the findings of the BSC Subcommittee and not allow talc to be listed". ***[Bernstein Robert]*** This is good. I have some additional ideas.
I've asked Tozzi to summarize his strategy recommendations to us in a letter.

We (the talc industry) dodged a bullet in December based entirely on the confusion over the definition issue. However, I believe that given the issue at hand, the Draft report can be amended to remove the "fatal flaw assumptions" by accounting for the ambiguities surrounding the content of body powders prior to 1976 in a different context. Essentially, if the report were to be rewritten to state that the possibility of asbestos contamination of cosmetic talc prior to 1976 should simply be accounted for as an additional "confounding" factor in the epidemiology studies, a re-vote for "talc not containing asbestos fibers" would likely go the other way. The additional "confounding" factor might simply reduce the relevance of the human studies from "sufficient" to "limited". "Limited" human studies would most certainly result in a NTP listing recommendation - regardless of the relevance of the animal study. ***[Bernstein Robert]*** Time to come up with more confusion!

As such, I agree that we still have our work cut out for us. Certainly, the December debacle provided us with excellent ammunition for an eventually court challenge should it become necessary. I will provide you with Tozzi's written recommendations as soon as they are received.

Rich Z.