→ M.R. ChudKowski

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EXHIBIT tabbies 17

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Dear Steve:

As I had informed Mike Chudkowski and Don Jones, I was out of town at (800)452-8127 from Monday through Friday. Therefore I could not return your call to Richland earlier. Upon my return last night, I found your message and a couple of faxes from J&J.
In summary, I plan on arriving Monday evening, June 27, at the Holiday Inn in RTP. My flights and arrival time are still uncertain as my travel agency is closed today. Bill Ashton suggested a "post-mortem" meeting Tuesday evening at the Holiday Inn which, in my opinion, is a good idea (I had recommended a post-mortem for the FDA workshop on 2/1/94). I plan on flying back Wednesday morning.
In response to your request for questions and comments for Dr.Heller, I am submitting the following for your consideration.

Comments

- To correct any preconceived ideas and apprehensions that Dr.Heller et al might have regarding the talc industry, it should be pointed out right at the beginning -- to set the tone for the meeting -- that the industry has a hard-earned reputation for corporate/civic responsibility, as evidenced, for example, by J&J's attitude and action during the Exedrin scare a number of years ago.
- Regarding Dr.Gordon's question why the industry is interested in their findings: Obviously, any findings, even if only tangentially involving biological effects of cosmetic talc, must be of great and immediate interest to the industry, last but not least because of its corporate/civic responsibility.

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- Member companies of CTFA have in-house research laboratories staffed by qualified scientists who are spending professional life-times investigating highly specific talc-related issues. It is logical to use the readily available expertise of these specialists to assist in evaluating relevant published studies and analyzing/interpreting their results and, most important, to assist in designing future studies for maximal scientific relevance and validity.

Questions

- Were the talc particles in Dr.Heller's study on or in ovarian tissue?
- By which methods were the particles identified as talc?
- In addition to qualitatively analyzing for talc, was a quantitative analysis conducted? If so, which method was used? What were the results?
- Were qualitative and quantitative analyses made for particles other than talc? If so, which method(s) were used? What were the results?
- Do Dr.Heller et al have a hpothesis on how inert particles without locomotion of their own and unable to respond to chemotactic stimuli can migrate from the perineum/vagina to the ovaries, breaching the formidable cervical barrier and "swimming upstream" through the oviducts?
- Were there any lesions of the examined ovarian tissues? If so, which types? Specifically, was there fibrosis? If not, why not?
- What are the medical histories of the women involved in Dr.Heller's study? Nullipara? Multipara? Lacerated cervices? Vulvovaginal diseases? Ages and bodyweights?
- What is the history of talc use in these women? Frequency of use? How used? For how long?
- Has there been talc found on/in ovaries of women who have not used talc?

If more studies on talc issues are to be conducted, I have repeatedly recommended a study examining human ovaries. However, for such a study to be efficient and scientifically meaningful it should, in my opinion, be conducted in a coordinated way on a larger scale (involving several preferably research/teaching hospitals) according to a detailed standard experimental protocol designed by a multidisciplinary group of experts thoroughly familiar with relevant issues (including industry scientists), and executed by well-trained clinical personnel cognizant of the issues and pitfalls (e.g. potential contamination problems). Given this situation, such a study should probably best be conducted under the auspices of a federal agency such as the FDA, given FDA's interest in cosmetic talc issues.

Whether or not the talc industry should financially support in part or fully any such effort is a different question. It can be plausibly argued against such support that (a) it is the government through the FDA which apparently sees the need for more studies and therefore it is they who ought to pay for them, and (b) if the industry supports such a study it a priori might be labeled "bought" by the industry and its results dismissed by some of the industry's critics. On the other hand there are, of course, also reasons in favor of industry's support.

Sincerely

Dr.Alfred P.Wehner

cc: W.H.Ashton
M.R.Chudkowski
D.F.Jones

Mac

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Personal Information