

31, 1994

Note to: Sally Carr

From: John Bailey

A handwritten signature in cursive script, appearing to read "John Bailey".

Re: Manuscript for Talc Workshop

Please find attached a copy of my opening remarks for the talc workshop. Please feel free to read this over and make any corrections/changes that serve to make it clearer.

Also, after thinking about our discussion yesterday concerning the release of the transcript, it would be nice if we could edit this some since its very rough in places. Unfortunately, I don't have the time to do this. Is there any way we can get at least a minimum editing to polish it up somewhat?

Finally, could you please send me a list of who has (and has not) submitted manuscripts for publication in the journal?

Thanks - John Bailey (202-205-4530).

Good morning and welcome. My name is John Bailey and I am the Director of FDA's Office of Cosmetics and Colors. I would like to welcome you to the Workshop on "Talc: Consumer Uses and Health Perspectives."

I look forward to a stimulating program today and will start off with a question, that is - why a workshop and why on talc? Two recent events have focused attention on the safety of talc as used in consumer products. The first was the completion, in 1992, of a long-term inhalation carcinogenicity study of talc by the National Toxicology Program.

This study, using cosmetic grade talc, reported the following results: That, under the conditions of the study, there was some evidence of carcinogenic activity in male rats, there was clear evidence of carcinogenic activity of talc in female rats, and there was no evidence of carcinogenic activity of talc in male or female mice.

The second event was the publication in the July, 1992, issue of the Journal of Obstetrics and Gynecology of an article by Bernard L. Harlow et al. entitled - "Perineal Exposure to Talc and Ovarian Cancer Risk."

In this epidemiology study the authors concluded that a lifetime pattern of perineal talc use may increase the risk of epithelial ovarian cancer. The authors went on to note that this use of talc is unlikely, however, to be the etiology for the majority of epithelial ovarian cancer cases.

Talc has a long history of use in a wide variety of consumer products. That goes without saying. It has use in virtually all product types that are regulated by the Food and Drug Administration. These uses include foods, drugs, principally the OTC drugs, cosmetics and medical devices, and many of these applications are certainly going to include inhalation exposure, perineal exposure and in many cases both.

Clearly the findings of these two recent studies have raised serious concerns about whether or not the use of talc in FDA-regulated products is safe. The agency must consider, within the differing legal schemes that apply, whether or not the risk is sufficient to warrant control through issuance of regulations.

However, any efforts to measure risk requires a clear understanding of the strengths and weaknesses of the evidence and its relevance to human use and exposure. Further, a clear understanding of the significance of the scientific evidence is a requirement in any risk communication efforts. This

workshop is being held to provide a forum for discussion of the uses, toxicology and epidemiology of talc by experts in the relevant scientific and medical disciplines and other interested persons.

This workshop is not, nor can it be, a forum for reaching a consensus or recommendation about what specific regulatory action is appropriate for FDA to take with regard to different product categories it regulates. However, I think it is reasonable to expect by the end of the workshop, to have a discussion or to even reach a consensus of the many scientific and medical experts that are participating in and attending this meeting, about the relevance of the recent reports to the safety of talc to human health risks.

Because of the complexity of the toxicological and epidemiological issues, the approach developed for the workshop combines detailed discussions of the individual studies on the safety of talc with broader discussions on inhalation toxicity, ovarian cancer and methods of epidemiology.

We are fortunate to have available a highly qualified faculty of scientific and medical experts that will provide 2 days of stimulating and highly relevant presentations and discussions. In particular we are fortunate to have with us Dr. Gary Boorman of NIEHS who will talk about the NTP study and Dr.

Bernard Harlow of Brigham & Women's Hospital to present on their epidemiology work.

In addition to the individual presentations scheduled, each session will conclude with a panel discussion that includes not only the speakers but, also, additional participants representing the consumer perspective, as well as industry and academia viewpoints.

Please keep in mind that this is a workshop. A workshop, as opposed to a symposium or seminar, is by nature more interactive. The panel discussions will, I think, provide an opportunity for the audience to ask questions or debate issues, and I strongly urge you to take advantage of this extraordinary opportunity.

Today's session will concentrate on inhalation toxicity of talc. We will begin by focusing on the nature of the ingredient that is talc - that is - what is talc?; how is it manufactured?; what is its composition?; what are the quality control issues associated with its manufacture? and so forth.

Next, the regulatory status for various product categories will be reviewed. This will be followed by a discussion of inhalation toxicity, the 1992 NTP

inhalation studies and the relevance of animal tests to man.

I will provide, if time permits, at the end of each presentation an opportunity for questions. You will notice at your seats that there is a black button. If you have a question, push the black button and speak into the microphone, and then after you are finished, turn it off so that we don't catch your papers ruffling and so forth.

Our first speaker this morning is Stephen Gettings. Dr. Gettings received his Ph.D. in biochemistry in 1985, from the University of Surrey, Surrey, England. Subsequently he served as senior toxicologist in the Department of Pharmacology, University of Louisville, School of Medicine and the University of Texas Health Science Center at Dallas in the Biochemistry Department. He joined the Cosmetic, Toiletry and Fragrance Association as senior toxicologist, and at present he is the Director of Toxicology at CTFA. Dr. Gettings will speak this morning on Talc Characterization and Consumer Uses.