

Attachment 2



FORMALDEHYDE INSTITUTE

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April 21, 1981

Miss Mary Martha McNamara
Bushnell, Gage, Reizen and Byington
1111 Nineteenth Street, N.W.
Washington, D. C. 20036

Dear Mary,

Thank you for forwarding a copy of the testimony given by Drs. Infante and Kang at the Consumer Product Safety Commission Public Hearing on Proposed Regulation for Urea Formaldehyde Foam Installation, March 20, 1981. Although the contents of the testimony were far from accurate, I am not surprised at the tone established during the testimony. I was quite surprised, however, when they stated that their "views do not necessarily represent those of our employment agency (OSHA)." Drs. Infante and Kang's opinions were quite implicit during our meeting in December with OSHA to discuss the NIOSH Bulletin entitled "Formaldehyde: Evidence For Carcinogenicity." In particular, they refused to even consider a more comprehensive, balanced review of formaldehyde toxicity for the Bulletin and rejected outright all constructive comments. These views were further supported by Mr. Froines.

In view of the credentials presented by Drs. Infante and Kang, I was dismayed to read their interpretation of the findings taken from a National Cancer Institute Study entitled "Proportionate Mortality Among New York Embalmers." Drs. Infante and Kang stated that

"The most significant finding was an unusually high proportion of deaths from skin cancer, about 2.5 times greater than the expected (8 observed vs. 3.2 expected deaths). The study also presents suggestive evidence for the development of skin cancer in relation to the degree of formaldehyde exposure and latency."

If Drs. Infante and Kang would have conducted an appropriate review of Dr. Walrath's study, they would have found that eight skin cancers were uncovered during the research, four were classified as malignant melanomas, three as squamous cell carcinomas and one was unclassified. There are distinct differences of origin and histopathologic structure between these malignancies, and they

should not be added to determine excess cause-specific mortality. Although the study would be more complete if the pathologic diagnoses of the malignant melanomas were available, a skin cancer excess appears only when these distinctly different malignancies are combined. In summary, there is no suggestive evidence for the development of skin cancer following formaldehyde exposure when these distinctly different skin cancers are properly characterized.

The authors further state that "organs that are targets of carcinogenicity may vary greatly in different species and under different exposure conditions" and use as examples, benzidine and bis(chloromethyl) ether (BCME) which have no relationship to formaldehyde. Numerous animal studies indicate that the upper respiratory tract is the primary target for action by formaldehyde. This is further confirmed through metabolism studies which have shown that toxic metabolites do not appear to be formed in animals or humans and that both endogenous and exogenous formaldehyde are rapidly metabolized to formate. The formate can enter the one carbon pool where it provides a source of carbon for the essential amino acids used for protein synthesis.

It also should be noted that several studies have been conducted using hexamethylenetetramine (HMT) which decomposes in an acid media to release formaldehyde and ammonia. No treatment-related tumors were observed in mice or rats administered HMT in drinking water for 60 weeks or 104 weeks, respectively. Evidence for transplacental carcinogenicity was not observed in a subsequent study in which rats were given 2% HMT in drinking water over three consecutive generations. The lack of a toxic response, including tumorigenicity, further supports contentions that the tumorigenic effects of formaldehyde are exhibited only on tissue which is directly assaulted with formaldehyde such as the upper respiratory tract (nasal epithelium) in animal inhalation studies.

Drs. Infante and Kang state in the final paragraph of testimony that during a meeting in Lyon, France in February The International Agency for Research on Cancer (IARC) concluded "that available data from humans are insufficient to allow evaluation of the carcinogenicity of formaldehyde." IARC has established stringent criteria for evaluating research to determine the potential carcinogenicity of compounds. Preliminary drafts from IARC have actually concluded that there is limited evidence for the carcinogenicity of formaldehyde in experimental animals and that on the basis of all available data which included the conflicting results from three epidemiology studies, no evaluation could be

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made of the carcinogenicity of formaldehyde to humans. It is quite obvious that this prestigious organization is waiting for the published results of current research. It is not relying on preliminary or cursory information.

The results of carcinogenic evaluations produced by The International Agency for Research on Cancer have generally been well received by the scientific community. It is imperative that IARC remain independent and unencumbered by the activities of regulatory agencies. I, therefore, question the wisdom, motives and insistence of Dr. Han Kang to vote on the issue of the potential carcinogenicity of formaldehyde when in fact he was involved in regulatory activities at both CPSC and OSHA. Such actions serve only to foster a misimpression that IARC acts as an instrument for regulatory activities. I welcome your suggestions to insure the independence of evaluations conducted by agencies such as IARC.

Sincerely,



Joel R. Bender, Ph.D., M.D.
Medical Committee Chairman
The Formaldehyde Institute

JRB/egg