



Comments to DOL

COMMENTS OF THE
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
ON
THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION'S
PROPOSED RULE; LIMITED REOPENING OF THE RULEMAKING RECORD ON
OCCUPATIONAL EXPOSURE TO FORMALDEHYDE

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29 CFR Part 1910
Docket No. H-225B

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control
National Institute for Occupational Safety and Health

February 9, 1987



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
National Institute for
Occupational Safety & Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati OH 45226

February 9, 1987

Mr. Charles E. Adkins
Acting Director
Health Standards Program
U.S. Department of Labor
Occupational Safety and Health
Administration
Washington, D.C. 20210

Dear Mr. Adkins:

Please find enclosed comments from the National Institute for Occupational Safety and Health (NIOSH) on some of the issues which OSHA reopened the record to have considered on occupational exposure to formaldehyde [51 FR 44796], published December 12, 1986. As we discussed on the phone, it was impossible for me to forward NIOSH's comments by the original date requested, and I am grateful for the extension you granted. Please enter these comments into the record.

If you have any other questions or issues you wish to discuss, please do not hesitate to contact me.

Sincerely yours,

Richard A. Lemen
Director
Division of Standards Development
and Technology Transfer

Enclosure

Enclosures and/or attachments that are not included are available free of charge from the NIOSH Docket Office [513/533-8450].



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

February 9, 1987

Mr. Tom Hall
Docket Office
Docket No. H-225B
Room N-3670
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Dear Mr. Hall:

I and the staff of the National Institute for Occupational Safety and Health (NIOSH) have reviewed the additional material pertaining to the proposed revision of the regulation for occupational exposure to formaldehyde for which OSHA has reopened the record. We would like to offer the following document and comments to supplement the information and testimony we have previously submitted to the record:

- 1) Enclosed as Attachment 1 is a letter sent from J. Donald Millar, M.D., Director, NIOSH, to Vincent T. DeVita, Jr., M.D., Director, National Cancer Institute (NCI), regarding the NCI epidemiologic and industrial hygiene studies of workers exposed to formaldehyde by Blair et al. and Stewart et al., NIOSH's review of these studies for the Occupational Safety and Health Administration (OSHA), and the subsequent communications and comments made regarding NIOSH's review.
- 2) While the report of the occupational epidemiologic study issued by Vaughan et al. did not reveal statistically significant findings of the cancer sites under study, we do not believe this study can be interpreted as negative evidence. Both the report of the occupational epidemiologic study and the companion residential epidemiologic study indicate that the analyses did demonstrate elevations of risk estimates for cancer sites of the upper respiratory system associated with exposure potential to formaldehyde. The occupational study shows statistically nonsignificant excesses in oropharyngeal, hypopharyngeal, and nasopharyngeal cancer when induction time was considered in the analysis. The residential study demonstrated a strong association between nasopharyngeal cancer and a history of having lived in mobile homes, where exposures to formaldehyde have been previously measured. This association was strongest for individuals with the longest residence time in mobile homes. While the

residential study provides only indirect information about any cancer risk associated with formaldehyde, the former occupational study provides limited evidence of an elevation of upper respiratory cancer associated with exposure potential to formaldehyde.

- 3) With regard to the letter of Blair et al., we support Blair et al.'s suggestion submitted to the Journal of the National Cancer Institute, that additional research should be conducted to evaluate the cancer risk associated with the combined exposure to formaldehyde and particulates, but we do feel such a suggestion should not detract from the regulatory process on the control of formaldehyde as a potential occupational carcinogen.
- 4) I would like to take this opportunity to further clarify NIOSH's recommended exposure level. Since NIOSH is not aware of any data that describe a safe exposure concentration to a carcinogen, NIOSH recommends that occupational exposure to formaldehyde be controlled to the lowest feasible concentration.

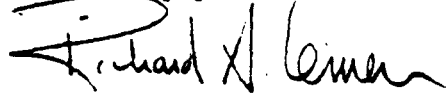
Using the NIOSH Sampling and Analysis Method 3500, the lowest reliably quantifiable level is 2.0 micrograms of formaldehyde per sample. At this level, the lowest reliably quantifiable concentration is 0.1 ppm in a 15-minute sampling period. However, at longer sampling periods, lower concentrations can be quantified. The relationship of lowest quantifiable concentrations using different time-periods of sampling is not directly linear due to flow rate adjustments which must be made to prevent the evaporation of the liquid in the impinger. No more than 100 liters of air should be passed through the sampling media during any sampling period. Due to this adjustment in flow rate, the lowest reliably quantifiable concentration of formaldehyde using a sampling period of eight hours is 0.016 ppm. Documentation further explaining the derivation of this concentration is contained in Attachment 2. Therefore, it is recommended that exposure to formaldehyde not exceed 0.1 ppm for any 15-minute sampling period and 0.016 ppm as an 8-hour time weighted average. Such recommended exposure limits protect against carcinogenic and other health effects of peak and chronic exposure, discussed in earlier submissions to the record.

NIOSH recognizes that in certain occupational environments the lowest reliably quantifiable concentration would be lower than ambient background concentrations when no formaldehyde-producing or -using industrial processes are in operation. In such circumstances, NIOSH recommends that the occupational exposure level should be reduced to the ambient background concentration. This latter consideration is based on the

Page 3 - Mr. Tom Hall

position of NIOSH that workers in any particular occupation should not be required to accept any greater risk than other members of the community experience due to ambient background concentrations.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Richard A. Lemen". The signature is fluid and cursive, with a large initial "R" and a stylized "L".

Richard A. Lemen
Director

Division of Standards Development
and Technology Transfer

2 Attachments

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute for
Occupational Safety and Health
Centers for Disease Control
Atlanta GA 30333

AUG 29 1986

Vincent T. DeVita, Jr., M.D.
Director
National Cancer Institute
National Institutes of Health
Bldg 31, Room 11A52
9000 Rockville Pike
Bethesda, Maryland 20205

Dear Vince:

Your telephone call expressing the desire for a resumption of the usual cordial relationships between NCI and NIOSH was particularly welcome. The inter-Institute debate about the NCI papers by Blair, et al., and Stewart, et al. (viz. Mortality in Workers Exposed to Formaldehyde), and the NIOSH Evaluation of those papers, has, in my opinion, consumed too much time and energy.

After my staff met with Drs. Blair and Stewart on June 6, 1986, and had received Dr. Blair's written comments (dated July 11, 1986), I had hoped we could move on without further comment from NIOSH. Unfortunately, the letter of July 18 from Dr. Richard Adamson of NCI to me (and the OSHA Docket) eliminates that possibility. In the letter, Dr. Adamson labels the NIOSH Evaluation "inaccurate, incomplete, and misleading." To fail to respond to his charge would be inconsistent with my responsibilities as Director of NIOSH.

To satisfy myself on these matters, I sat down with the NIOSH Evaluation and Dr. Blair's written comments, and thoroughly reviewed both, side-by-side, issue-by-issue. (I had previously read the version of Dr. Blair's paper released on or about March 1, 1986.) Frankly, I can see no reason for Dr. Blair's apparent umbrage, nor Dr. Adamson's charge. OSHA asked us to provide a scientific evaluation of the NCI reports, and that is what we did.

In my opinion, the NIOSH Evaluation is straight-forward, reasonable, and accurate. It focuses principally on statistical interpretations, and estimates of exposures, issues that are often topics of scientific discussion in such studies, and issues that are of particular pertinence to OSHA in rulemaking. The Evaluation does not comment on the other issues raised by the public following release of the study in

Page 2 - Dr. Vincent DeVita

March. Indeed, the NIOSH Evaluation seems to me, no more provocative than the comments written by five members of the NCI's own Advisory Panel to the study in the letter by Peters, et al., April 2, 1986. I find nothing in the Evaluation nor in comments by Drs. Blair and Adamson that warrants Dr. Adamson's charge.

On a broader note, there are two other aspects of the debate on which I will comment.

The first is the assertion by Drs. Blair and Adamson that we misrepresented NCI by writing in our Evaluation that the papers by Blair, et al., and Stewart, et al., were "jointly prepared by the National Cancer Institute (NCI), E.I. duPont de Nemours, Monsanto, and the Formaldehyde Institute." Our presumption that this study was collaborative among these parties is easily understood. The title page of the manuscript distributed on or about March 1 refers to each of these parties as well as Westat Inc., and Dynamic Corporation, without distinguishing between them as to degree of involvement or sponsorship. Moreover, a referenced footnote next to the name of author Maureen O'Berg, specifically states that she is "Representing the Health Research Committee of the Formaldehyde Institute." This same designation appears in the version of the paper which appeared subsequently in JNCI (76:6, June, 1986). What conclusions should we have drawn about collaboration? If the interests of the Formaldehyde Institute were not being represented by Dr. O'Berg, what does the footnote mean?

A second issue is the complaint by Drs. Blair and Adamson that NIOSH evaluated only the information in the manuscript released on or about March 1, 1986, and "ignores" the testimony by NCI in OSHA hearings in May, and the version of the paper published in JNCI in June 1986. This complaint is particularly puzzling. Does NCI consider only its type-set version in the June issue of JNCI as "published"? In my view, releasing a report to the news media, as was done by NCI on or about March 1, 1986, is "publication" by definition. Did NCI scientists expect not to be accountable for that version?

We drafted a scientific evaluation of the version released on or about March 1, because that was the version on which OSHA requested our comments. We delayed completion of our Evaluation until after our staff met with Drs. Blair and Stewart, June 6, 1986, to hear their views of our draft. Changes were made in our report as a result of that meeting, though obviously the changes were not enough to satisfy Drs. Blair and Adamson. Our final report was sent to OSHA June 19, 1986; Dr. Blair's extensive written comments (dated July 11) did not reach us until nearly a month later.

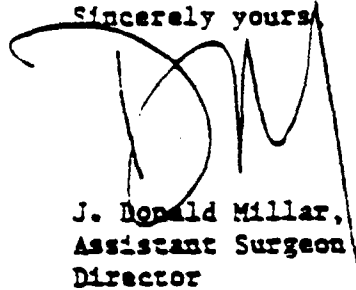
Page 3 - Dr. Vincent DeVita

At this point, I am content to let the NCI papers, the NIOSH Evaluation, and the comments by Drs. Blair and Adamson rest on their respective merits in the OSHA docket. We do not intend to write a rebuttal to Dr. Blair's comments, although, as you might imagine, NIOSH staff were prepared to respond to each point.

Instead, I would like to see us move on. In that light, I am more than willing to meet with you to explore means of assuring the best possible coordination in the future. I understand well, that public scrutiny of studies done in the occupational setting is more intense than that directed to any other form of epidemiology. Hence, I believe it is in the best interest of both NCI and NIOSH, as well as those agencies dependent on our findings, to find ways to assure that important findings are readily and rapidly accepted by those who need to know.

With best personal regards.

Sincerely yours,

A handwritten signature in black ink, appearing to be 'JRM', with a long vertical line extending downwards from the end of the signature.

J. Ronald Millar, M.D.
Assistant Surgeon General
Director