

DAVID H. WEGMAN, M.D.
18 PERKINS STREET
ARLINGTON, MASS. 02174

September 20, 1974

Donald Boyd
Office of Standard Development
Room 610
1726 M Street, N.W.
Washington, D.C.

Dear Mr. Boyd:

Enclosed is my report on the medical and biologic hazards of exposure to vinyl chloride. It is based on all the material which was sent me and which I frankly found overwhelming. At your suggestion I have made the report brief and in summary form. It would seem that this is the organization of the large volume of material which will prove most useful to you at this point in the development of the vinyl chloride standard. I hope this assumption is correct, for a complete epidemiologic and medical evaluation of the information regarding vinyl chloride would be long, detailed, technical and would most likely bury the essential conclusions.

As I read through the testimony and accompanying documents (some of which arrived only the beginning of this week), I was dismayed at the amount of repetitious material and information of little use. There was, in sum, only limited information available which was original, based on sound principles of medicine and epidemiology and useful for my report.

You will remember I attempted to elaborate on some of my findings during the meeting with Mr. Stender. His question regarding the scientific certainty for the identification of a specific number was distressing. I am afraid that there is no data upon which to suggest, with certainty, a specific number which I or anyone else can assure you will be a safe exposure level. I urge you to plan reconsideration of this standard in three years when studies which have only now begun will have provided us with a better foundation. I fear, however, that an accurate answer to Mr. Stender's question will never be known.

As I understand it you did not wish me to suggest specific language for the standard and I have not. I have, however, added brief comments on non-medical sections of the proposed standard which appeared pertinent.

I do not envy you the task before you. Please let me know if any further information would prove useful. If elaboration of any section of my comments is desired I can be reached by phone at 617-727-3982.

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I was not provided any specific instructions regarding submission of expenses. I have enclosed a cost account for my trip to Washington and my airplane ticket receipt. Will you let me know how payment for expenses and services will be made?

Sincerely yours,

David H. Wynn, MD

130W 1476

RECOMMENDATIONS FOR A VINYL CHLORIDE STANDARD
BASED ON BIOLOGIC AND MEDICAL DATA

A review of the data made available through the Hearings and other published material leads to the recommendation of an exposure to vinyl chloride of no greater than 1 ppm. This conclusion is based on the following facts.

1. A review of the animal studies of which we have preliminary results makes it clear that at least two species are subject to tumors following long term exposures to vinyl chloride. It is generally accepted that these animals develop tumors at levels as low as 50 ppm. The dose-response relationships are still being explored as experiments at lower exposures have been initiated. In addition multiple tumor sites have been observed in exposed animals. It would appear, that not much more is to be expected from this resource as the animal lifetime is short and the numbers necessary for significant tests are becoming large. In summary, the animal data support three major conclusions: a) multiple species are susceptible, b) multiple organs are at risk of cancer in the animals and c) levels as low as 50 ppm are not safe.

Extrapolation to man from animal studies is extremely difficult but we must consider man at least as susceptible to vinyl chloride as the animal species. Although not often used, extrapolation by way of a safety conversion factor is possible.

From these data alone a level of 0.5 ppm is suggested.

2. Four studies of mortality have been reported which have reasonable designs and are sufficiently free of design bias to warrant further review. Unfortunately several reported studies looked only for angiosarcoma rather than seeking all disease which might be in excess. Others were too heavily biased by large numbers of recent employees to allow any conclusions to be reliably drawn.

a. Dr. Wagoner of NIOSH has completed 70% of a study of persons who died having worked at Pottstown or Louisville. This group was selected for 5 years of exposure and at least ten years since onset. Already excessive liver, brain, lung and blood tumors are evident.

b. Dr. Nicholson's study of the Niagra Falls plant is defined in the same fashion. Liver cancer is excessive and there is a suggestion of brain and blood tumors being excessive.

c. Dr. Monson's study of Louisville workers shows two important results. The multiple organ involvement is again noted with liver, biliary tract, lung and brain cancer. A disturbing additional finding is that a trend is revealed which shows an increase in proportion of cancer over time.

d. Dr. Tabershaw's study is of a large part of the industry. This study suffers from too many recent employees who have not been employed long enough to be affected. The analysis underrepresents those who died as follow-up was not complete. Even so, the results suggest increased lung, brain, blood and digestive system cancer.

In summary, the human mortality data demonstrate a rising number of deaths due to cancer and many different types of cancer associated with work exposure to vinyl chloride.

3. Non-malignant disease. Studies by Dr. Lange in Germany suggest that exposures to vinyl chloride experienced in the manufacturers who use only the finished resin (approximately 5-10 ppm on average) are associated with multiple organ disease. They have preliminary evidence of a chronic liver disease, splenomegaly and thrombocytopenia. Dr. Selikoff's studies in Niagra Falls are showing evidence of liver disease, splenomegaly, pulmonary ventilation defects and peripheral vascular disease. There is no accurate measure of dose associated with these acute and chronic changes.

4. Mutagenic effects. There is preliminary evidence in a study of chromosomes of 11 vinyl chloride workers compared with ten controls that chromosome changes are present con-

siderably more frequently than expected. In addition, Swedish laboratory tests have shown mutagenesis in an animal test system.

In summary the animal studies make clear that any human exposure level must be less than 50 ppm. How much less than this appears indicated by the human studies on malignancy, non-malignant disease and mutagenesis. There is no single material currently in use which has been shown to affect as many different parts of the body with such devastating impact as vinyl chloride. Were it possible to eliminate it from the market, this would be by far the wisest choice. If it must be used, human exposure must be kept to the absolute minimum. Exposure to more than 1 ppm is not medically defensible.

COMMENTS ON OTHER PORTIONS OF THE STANDARD

1. The variance system, not a staged standard, should be used to allow introduction of technological controls.
2. A list of required medical screening tests and procedure needs to be included or most physicians will be left not knowing what is sufficient.

3. Medical records and monitoring results must be maintained not only for the lifetime of an exposed individual but should be maintained afterwards. Were such information available now, well after the deaths of past vinyl chloride workers, we would be much better informed about this problem.
4. A full face canister respirator should be permitted for specified uses for limited time periods. Shortcomings of current respirators could be alleviated if manufacturers have an incentive.
5. Signs and labels. Vinyl Chloride is not a cancer-suspect agent, it is a recognized carcinogen and should be labeled as such.