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HEALTH, SAFETY AND ENVIRONMENT -
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REBUTTAL OF EDF'S SUBMITTAL
TO EPA ON VCM STANDARDS

This information acknowledges your memo of October 13, 1977, in reference to the above subject. Apparently EDF would like to re-trace and up-date the state of medical knowledge concerning vinyl chloride which, under the Clean Air Act, is to serve as a basis for EPA's regulatory actions. The following are my impressions:

1. While many of the VCM references at higher dose levels may be very valid, some of the low-dose, short-time exposure data needs to be seriously evaluated for accuracy in the conclusions. This should especially be noted on the basis of the poorly designed Infante study noted in the literature (P.F. Infante, Oncogenic and Mutagenic Risks in Communities with Polyvinyl Chloride Production Facilities, 1975, ANN. N.Y. ACAD. SCIENCES, 49-57.)
2. Certainly literature presenting cases of angiosarcoma that have been "environmentally induced" are open to question based on selection of the population examined and a notable lack of information concerning possible etiologial alternatives.
3. In reference to mutagenic studies, there is certainly a question of what one can consider reliable data when testing is performed on a bacterial system versus a mammalian study. In reference to mammalian studies, certainly the unpublished work of Dr. Maltoni, who reported the induction of mammary carcinoma in rodents at levels of 1 ppm, is important. However, more data must be obtained utilizing mammalian species at other selected dose-time concentrations. Additional information must also be elicited on the species population from which experimental animals are selected in order to rule out an unusually sensitive species.
4. There is not any conclusive animal study, or human study, that reveals that there is not a level or threshold under which harmful effects such as cancer will not occur.
5. There is no reason to believe from any of the studies of either recent or past origin that a dose-time response does not exist. As a scientist, one cannot generally consider it prudent to assume that there is "no threshold" for chemical carcinogens. In fact, it is most likely there is a threshold below which the body is able to handle small amounts of vinyl chloride without adverse effects. Obviously if this is the case, there is no reason to believe that carcinogens pose a threat to human health at slightly higher exposure levels over a relatively brief period of time.

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6. Statements such as, "the risk of actually developing cancer following only a brief (environmental) exposure (to a carcinogen) is very real," cannot be proven and reveal a lack of understanding concerning delineation of persons in high-risk cancer groups. From a review of multiple literature sources, the so-called "environment" is implicated in a large percentage of cancers. This "environment" appears to include all elements influencing cancer incidence originating wholly or largely outside the body. Thus, many authors have concluded that "environmental cancers" are induced or related to our personal habits and lifestyle as well as things beyond our personal control. The leading known causes of cancer in the United States are clearly extrinsic. Tobacco and alcohol use and nutritional factors appear to be important contributors to "environmental cancers," accounting for well over half of all cancer deaths*. One must also consider the ten percent plus of all cancer cases which apparently have hereditary factors**. Only if these things are considered can a sensitive approach to cancer etiology and control be reached.

These are the Corporate Medical Department's impressions on the EDF's comments. Please notify me if further discussions are indicated.

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* Wynder, Ernst L, M.D. and Gori, Gio B., M.D., "Contribution of the Environment to Cancer Incidence: An Epidemiologic Exercise," Journal of the National Cancer Institute, April, 1977.

** Fraumeni, Joseph F., Jr., Persons at High Risk of Cancer: An Approach to Cancer Etiology and Control, Academic Press, Inc., New York, 1975.