

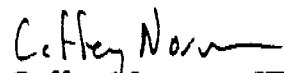
October 15, 1998

PRIVILEGED AND CONFIDENTIAL
ATTORNEY-CLIENT COMMUNICATION

MEMORANDUM FOR THE VINYL CHLORIDE HEALTH COMMITTEE

Re: Response Statement and Talking Points

Attached are a draft response statement, draft talking points, a draft summary of the messages in the talking points, and a draft letter for employees, all for your review and discussion at the meeting tomorrow.


W. Caffey Norman, III

WCN/vsa
Attachments

cc: Wendy K. Sherman

CMA 172073

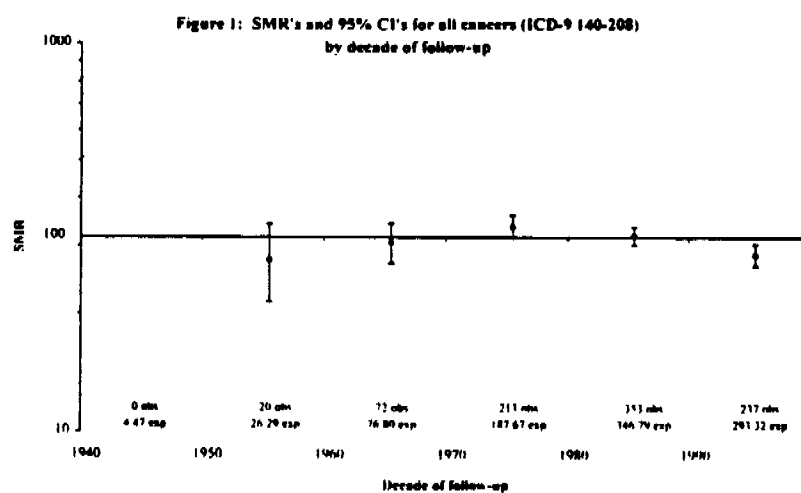
Vinyl Chloride Talking Points
Background and Angiosarcomas

- Vinyl chloride monomer is integral to the production of polyvinyl chloride resin, which is used in manufacturing many plastics. The Vinyl Chloride Health Committee of the Chemical Manufacturers Association represents U.S. producers of vinyl chloride and polyvinyl chloride. The Committee's principal activity is sponsoring scientific studies that will provide information useful in assessing the health effects of vinyl chloride exposure.
- In the early 1970s, epidemiology studies (*i.e.*, studies of exposed worker populations) and studies in laboratory animals established an association between prolonged exposure to high levels of vinyl chloride and angiosarcomas (tumors of the blood vessels) of the liver. This led to world-wide recognition of this important occupational health issue, and the application of improved technology that reduced workplace exposure to vinyl chloride significantly. As a result of these changes, vinyl chloride exposure levels in U.S. workplaces declined to less than 1 part per million by the late 1970s, in accordance with an Occupational Safety and Health Administration standard that remains in effect today. Similar reductions have occurred in other developed countries. Based on experience to date, it is expected that those who first worked in the industry after the strict controls were implemented in the late 1970s have no greater risk of angiosarcomas of the liver than the general population.
- There has been no indication that vinyl chloride or polyvinyl chloride production facilities pose a hazard to the general population. The Environmental Protection Agency (EPA) estimates that the industry has reduced vinyl chloride emissions by 99 percent compared to levels in the early 1970s.

Vinyl Chloride Talking Points
Industry-Wide Epidemiology Study

- All populations or groups have mortality rates from different causes that are higher or lower than expected. Many of these increases and deficits are unrelated to occupation. Epidemiology studies help determine whether any of the increases observed are work-related.
- In order to determine whether there might be an association between vinyl chloride exposure and cancers other than angiosarcomas of the liver, the Vinyl Chloride Health Committee has focused its resources on expanding and updating epidemiology studies of workers exposed to vinyl chloride. An industry-wide cohort mortality study of vinyl chloride-exposed workers was initiated in the early 1970s, by the predecessor organization of CMA. A report of the results of this study was published in 1974. The cohort was subsequently expanded, and follow-up papers were published in 1981 and 1991.
- CMA has continued to fund research on this cohort and a preliminary report of a further update has recently become available. This report confirms the association previously reported between vinyl chloride exposure and angiosarcomas of the liver (see Talking Points: Background and Angiosarcomas).
- The preliminary report of the most recent update shows that the group of workers continues to enjoy better health, as reflected in the patterns of mortality, than individuals in the United States as a whole or in the states in which these employees work. This advantage is evident despite the presence of above-normal rates of death from liver and biliary cancers (reflecting the disproportionately high number of angiosarcomas of the liver). If these excess cancers had not occurred, the overall death rate from cancer among these workers would have been nearly 10 percent lower than normal.
- Researchers in the past have speculated that there might be associations between vinyl chloride exposure and lung cancer, emphysema, and leukemias and lymphomas. The preliminary report of the most recent update, however, clearly indicates that such associations are unlikely.
- Previous updates of the industry-wide cohort study had reported a moderate but statistically significant elevation in mortality from brain cancer. In the most recent report, however, roughly the same number of brain cancer deaths was observed during the update period (1983-1995) as would be expected among a group of this size, age, and geographic location. Whether or not the earlier excess was work-related, it appears that an excess risk no longer exists.

- The recent update indicates for the first time a possible association between vinyl chloride exposure and a diverse group of "connective and soft tissue" cancers, based upon a small number of deaths due to these causes. The observed excess of these tumors might be related to the established association between vinyl chloride exposure and angiosarcomas of the liver, as angiosarcomas occurring outside the liver are classified as soft tissue sarcomas. Very little is known about what causes connective and soft tissue sarcomas, and their relationship to angiosarcomas of the liver provides a possible basis for an association. On the other hand, given the small numbers and the diversity of the connective and soft tissue sarcomas, it is not possible to determine whether the increase was in any way related to vinyl chloride exposure.
- As in most studies of this size, excesses based on small numbers of rare tumors were observed in the preliminary update of the industry-wide cohort. One such excess was mortality due to cancers of the "peritoneum and other digestive organs." The author, however, has indicated that these tumors were broadly distributed by specific cancer site and likely have different causes. In light of the absence of consistency of these cancers, the author advises that this observed excess is unlikely to have any biological significance. Another example is cancers of the tongue. Because little is known about these unusual and rare tumors, additional research would be required to understand their occurrence and whether there is any relationship to workplace exposure to vinyl chloride.
- Presented below is a graph prepared by the author which shows the overall trend in cancer mortality for the group of workers from the mid-1940s to the present. There was an increasing trend in cancer mortality up to the mid-1970s, at which time the trend reversed and cancer mortality has decreased, falling below background levels in the mid-1990s. This coincides with the observation that the higher rate of cancer is associated with workers who began working in the industry in the 1940s and 1950s. This suggests that, whatever the cause of the higher rate, its influence has substantially diminished over time.



- The preliminary results discussed above have been reported to EPA as they have become available. These results remain preliminary and are subject to change, however, until they have been through the scientific peer review process and accepted for publication in a reputable scientific journal.

Vinyl Chloride Talking Points
Case-Control Study

- Separately, CMA has sponsored a case-control study of brain cancer occurrence in a cohort of employees at the B.F. Goodrich Bells Lane Plant, a facility in Louisville, Kentucky manufacturing polyvinyl chloride and other products. These employees have been studied continuously by researchers with the University of Louisville for over 25 years, and the plant is one of the facilities included in the industry-wide cohort study. The objective of the case-control study was to determine whether there is an association between brain cancer and occupational vinyl chloride exposure.
- The case-control study focused on confirmed primary brain cancers (*i.e.*, those that originated in the brain). Estimates of workplace exposure to vinyl chloride and 21 other chemicals were available through the University of Louisville's Occupational Health Surveillance database. A preliminary report of this study concludes that there is no evidence of any association between cumulative exposure to vinyl chloride and brain cancer occurrence in the Bells Lane workforce.
- The preliminary report of the case-control study also includes a secondary analysis showing an association between total duration of employment at the Bells Lane Plant (in *both* vinyl chloride-exposed and non-vinyl chloride-exposed jobs) and brain cancer. The authors deemed this association, although statistically significant, to be of marginal importance. Further study is underway to determine why duration of employment was associated with brain cancer in the secondary analysis, as there does not appear to be a correlation with vinyl chloride exposure.
- The preliminary results discussed above have been reported to EPA as they have become available. These results remain preliminary and are subject to change, however, until they have been through the scientific peer review process and accepted for publication in a reputable scientific journal.