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Total Pages
Including Cover: 6

Client Number: 4590.102

Comments:

This was faxed to the others last evening. I just noticed that my secretary failed to send it to you. Regards.

W. Caffey Norman, III

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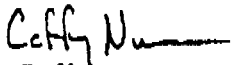
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October 6, 1998

MEMORANDUM FOR MS. PETERSEN AND
MESSRS. COCCO, LOSCOCCO, AND RAMLOW

Re: Talking Points

Attached, for your review and comment, are draft talking points revised to reflect the discussion last Thursday. Please let me know by close of business tomorrow if you have any comments or wish to discuss changes to the talking points before they are circulated for the conference call on Friday.


W. Caffey Norman, III

WCN/vsa
Attachments

cc: Wendy K. Sherman

Discussion Draft

Vinyl Chloride Talking Points
Background and Angiosarcomas

- Vinyl chloride monomer is integral to the production of polyvinyl chloride resin, which is used in manufacturing most 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 proximity to vinyl chloride or polyvinyl chloride production facilities poses a hazard to the general population. The Environmental Protection Agency (EPA) estimates that the industry has reduced vinyl chloride emissions by 99% compared to levels in the early 1970s. EPA is conducting a risk assessment of the effects of vinyl chloride exposure, and to date has found no statistically significant link between occurrences of angiosarcoma and proximity to a vinyl chloride or polyvinyl chloride plant. No other community health problem has been credibly linked to the presence of these production facilities.
- [As part of the product stewardship commitments of its members, the Vinyl Chloride Health Committee recently sponsored a laboratory study to provide information requested by the Agency for Toxic Substances and Disease Registry (ATSDR). This study suggests that vinyl chloride is unlikely to pose a hazard of reproductive or developmental effects to workers or the general public.]

Discussion Draft

Vinyl Chloride Talking Points
Industry-Wide Epidemiology Study

- 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 angiosarcomas of the liver and vinyl chloride exposure (see Talking Points: Background and Angiosarcomas).
- The recent update indicates for the first time a possible association between vinyl chloride exposure and "connective and soft tissue" cancers. 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. However, very little is known about the etiology of connective and soft tissue sarcomas, and it is hoped that the findings in this update will generate important leads for the continued study of these rare cancers. Given the lack of any predominant histological sub-type among the group of deaths due to connective and soft tissue sarcomas, it is difficult to postulate that these outcomes were due to vinyl chloride exposure. On the other hand, their relationship to angiosarcomas of the liver adds to the biological plausibility of an association.
- The preliminary update of the industry-wide cohort also indicates an excess of 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 etiologies. In light of the absence of consistency of these cancers, the author advises that this observed excess is unlikely to have any biological significance.

Discussion Draft

- Previous updates of the industry-wide cohort study had reported a small but statistically significant elevation in mortality from brain cancer. In the most recent report, however, roughly the same number of brain cancer deaths were observed during the update period (1983-1995) as would be expected among a group of this size, age, and geographic location. Continuation of this trend would further attenuate any association between brain cancer in this cohort and vinyl chloride.
- 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.
- The preliminary results discussed above have been reported to EPA as they have become available. These results remain preliminary, however, and should not be relied upon until they have been through the scientific peer review process and accepted for publication in a reputable scientific journal.

Discussion Draft

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. This plant is one of the facilities included in the industry-wide cohort study[, and most of the cancers documented were also counted in the industry-wide 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, carried out by researchers with the University of Louisville, focused on histopathologically confirmed primary cancers of 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 indicates no statistical association between accumulative 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. It is difficult to draw a conclusion from the preliminary report, which states "there is no statistical evidence of any association between the occurrence of brain cancer and exposure to vinyl chloride as measured by the average . . . exposure." The most likely interpretation is that employment at the facility entailed some risk factor associated with brain cancer other than exposure to vinyl chloride.
- The preliminary results discussed above have been reported to EPA as they have become available. These results remain preliminary, however, and should not be relied upon until they have been through the scientific peer review process and accepted for publication in a reputable scientific journal.