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Midland, Michigan 48674

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May 23, 1994

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TRIP REPORT - MEETING OF CMA VINYL CHLORIDE RESEARCH COORDINATORS

On Thursday, May 19th, I attended for the first time the meeting of the Research Coordinators group of the CMA Vinyl Chloride Panel in Washington, D.C. The purposes of this meeting are outlined below, but were primarily to forward plans for an update of the industry-wide cohort mortality study, to hear a presentation by Dick Reitz on PB-PK modeling for vinyl chloride (VCM), and to discuss plans for anticipating EPA and ATSDR research agendas for VCM. My trip expenses were paid for by Environmental Affairs, C&PP.

The group endorsed the scope of work for the updated epidemiology study drafted by Greg Bond and myself and our list of suggested potential contractors. A few questions lead to some minor improvements of the scope of work, which I will incorporate into the draft and return to CMA this week. The group also discussed possible cost-sharing formulae, and decided to assign shares of the cost of the study based on 1993 nameplate capacity for VCM. The group also endorsed the concept of an offset of Dow's share for the value of the sweat equity expended and to be expended by Greg Bond and me (in my capacity as project manager for the update).

Dick Reitz's presentation was very good and well-received. His work at Dow and now as a consultant on the uptake and metabolism of VCM are helping to clarify the differences between laboratory animals and humans, in terms that will explain the differences between the carcinogenic risk in humans as predicted by animal models and the actual risk as observed in exposed worker populations.

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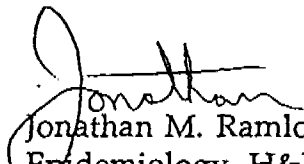
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The ATSDR has designated six critical data needs in their on-going risk profiling of VCM. The EPA intends to address two of these (multigeneration reproductive toxicity via inhalation, 2-species developmental toxicity via inhalation) by rule-making under TSCA. The group explored the possibility of locating existing data (if any) which might address these two issues proactively. I agreed to identify all available Dow study data which might be applicable and briefly review it for the group. I will work with our H&ES repro/developmental people on identifying any such papers or data.

The group discussed an article which appeared in Time magazine on April 25th and mentioned vinyl chloride as a risk factor for lymphoma (in a table, with no discussion in the text). The source for the Time article was given as the American Cancer Society's publication Cancer Facts and Figures. It turns out that the ACS does include VCM as a possible risk factor for lymphoma in one of its summaries. The results of the most recent update of the industry-wide cohort study do not support this, and Sir Richard Doll found little support for the VCM/lymphoma hypothesis in his 1988 review of VCM epidemiology. D. Penney from Vista volunteered to draft a letter to the ACS intended to be sure that they are aware of the current data and their interpretation. The group will review the draft letter and comment in a conference call to be held next month.

Finally, the group elected me the new chair of the Research Coordinators group, to replace Greg Bond. My term as chair will extend through June of 1995. I appreciate the confidence placed in me by the group, and I will do my best to follow through.

Should you wish to discuss any of this material in more detail, please feel free to call me at the number below.


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CHEMICAL MANUFACTURERS ASSOCIATION

Vinyl Chloride Panel

Research Coordinators

Record of Meeting

DATE: November 5, 1993
TIME: 10:30 a.m. - 1:00 p.m.
PLACE: CMA Offices
Washington, D.C.

List of Attendees:

Greg Bond	Dow Chemical
Frank Borrelli	Georgia Gulf
Bob Grahek	GEON
Mark Gruenwald	Borden
James Knaak	Occidental Chemical
Dave Penney	Vista
Bob Ondocsin	CMA
Has Shah	CMA

- 1.0 Dr. Greg Bond was elected Chairman for today's meeting.
- 2.0 The VCRC identified as its objective to discuss the merits and difficulties of updating the Vinyl Chloride Panel sponsored study entitled, "An Update of An Epidemiologic Study of Vinyl Chloride Workers, 1942-1982".
- 3.0 Dr. Has Shah reviewed the CMA Vinyl Chloride Research Coordinator activities since the receipt of the 1986 Final Report, "An Update of An Epidemiologic Study of Vinyl Chloride Workers, 1942-1982". These activities included conducting in 1989 a feasibility survey for the reassessment of liver cancer among vinyl chloride workers that were reported in the 1986 final report. After considerable efforts by an independent contractor, it was determined that a reassessment is not feasible because of difficulties encountered in obtaining slides, tissue blocks, histopathology reports and other pertinent information from hospitals and/or reviewing pathologists. Subsequent to the 1986 final report, Wong et. al. in 1991 published an article in the *American Journal of Industrial Medicine* based upon the 1986 final report. The VCRC identified several concerns regarding the interpretation of the final report data in the Wong et. al. publication and wrote a letter to the Editor of the *American Journal of Industrial Medicine*. Dr. Wong responded to the Letter to the Editor. Both the Letter to the Editor and Dr. Wong's response were published in the journal this year.

cc: Bill Hayes
Ron McCreed
George Dillon
Jonathan Raul
FYI
Any questions
give me a call
Greg

- 4.0 The Research Coordinators discussed the following issues to help them in deciding if an update of the previously completed epidemiology study should be undertaken:

- What additional information can be gained by updating the study?

The additional mortality information by following the 1942-1972 cohort from 1983 to 1992 may help resolve the issue of non-angiosarcoma liver tumors and brain tumors as causes of deaths in the vinyl chloride exposed cohort. There was a general feeling that an update would be useful to resolve these issues.

- Will the raw data from the 1986 study be available to CMA?

Dr. Shah expressed a feeling that the information that was provided by companies to the contractor will be available to companies; however, the death certificate information will not be available to CMA or even the company where the employee worked due to medical confidentiality issues. All data currently are in possession of ENSR. Dr. Bond will prepare a list of questions to be asked of ENSR to ascertain the availability of data either to CMA or the companies. Dr. Bond will forward the questions to Dr. Shah by January 15, 1994. Dr. Shah will discuss the questions with ENSR prior to the next VCRC meeting.

- If the existing epidemiology study is updated, should the study cohort be expanded to include workers who worked in vinyl chloride or related plants from 1973-1992?

VCRC members decided that the current cohort cannot be expanded because that would confound the original study design. Also, a separate study on workers employed in vinyl chloride and related plants from 1973 onward is not feasible at this time because the cohort size and employment duration may not be large enough to generate adequate mortality information for a statistically-sound study. The VCRC agreed to revisit the issue of a new cohort study in one year.

- Are there any recent vinyl chloride epidemiology studies either completed or in progress?

No VCRC member was aware of any recent studies; however, Dr. Shah will conduct a literature review to identify any recent studies. Dr. Shah will conduct this review prior to the next VCRC meeting.

- If a further 10-year update of the CMA sponsored vinyl chloride epidemiology study is to be undertaken, are all necessary data in place to begin such an update?

Dr. Bond will check with the National Death Index office on when all 1992 death certificates may be available from states. Usually, there is a 2 to 2.5 year lag period between the time of death and the time when the death certificates would be available from the states for research purposes. Dr. Bond will forward the lag period information to Dr. Shah by January 15, 1993.

- 5.0 The VCRC agreed to meet in March/April 1994 to review progress of all action items resulting from today's meeting and decide on a course of action.
- 6.0 The VCRC developed a budget of \$24,000 for 1994 for administrative and consultant services. Consultant services would include ENSR's work to respond to CMA inquiries regarding the availability of data from the previously completed study. Dr. Shah will send a commitment form for \$3,000 per company to VCRC members.
- 7.0 The meeting adjourned at approximately 1:00 p.m.

Has Shah

Hasmukh C. Shah, Ph.D.
Manager, Vinyl Chloride Panel

Subject to Approval
November 15, 1993