CHEMICAL MANUFACTURERS ASSOCIATION

July 11, 1995

Dear Vinyl Chloride Health Committee Members:

The following items are enclosed:

1) the June 7, 1995 Record of Meeting;

2) interim report #1 (July 1, 1995) on the Update of Mortality Among Vinyl Chloride Workers;

3) preliminary protocol for Vinyl Chloride: Combined Inhalation Two Generation Reproduction and Developmental Toxicity Study in CD Rats. Caffey Norman informs me that ATSDR/EPA did not review the protocol on June 15 as originally scheduled. No new date for an ATSDR/EPA meeting is established yet. I will keep you informed on reproduction and neurotoxicity data needs issues as I receive new information;

4) Proposal for Prioritizing Candidate Agents for Consideration Under Proposition 65 by the OEHHA Science Advisory Board. Please note that vinyl chloride is (i) on the Tier 1 Agents list for screening by OEHHA for availability of data to begin prioritization; and (ii) on the Proposition 65 Priority List - Candidate Agents Under Consideration for Developmental and Reproductive Toxicity Evaluation. I will contact the appropriate Cal EPA personnel to discuss the status of vinyl chloride on both lists and to establish a liaison with them for future consideration; and,

5) the June 23, 1995 letter from the Goodyear Tire and Rubber Company in response to Lillian Kelly's January 27, 1995 letter to me. Ms. Kelly identified the factory she referred to in her January 27 letter (copy attached) as a Goodyear plant. I therefore contacted Michael Smith to follow-up on the issue of alleged environmental concentration. Mr. Smith sent the enclosed June 23 letter to Ms. Kelly with a copy to me.

On a separate issue, I contacted Ms. Kelly to see if Richard Reitz can make a presentation at the public workshop on vinyl chloride risk assessment in a residential community immediately adjacent to a closed hazardous waste landfill. Ms. Kelly did not consider this specific public workshop an appropriate forum for a highly technical presentation, but she promised to make the Cal EPA risk assessment available to us for comments prior to its finalization. I will distribute Cal EPA's risk assessment to the Committee as soon as I receive it.

If you have any questions, please call me at (202) 887-1192.

Sincerely,

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

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CHEMICAL MANUFACTURERS ASSOCIATION
Vinyl Chloride Health Committee
Record of Meeting

Date:	June 7, 1995
Time:	10:00 a.m. - 3:00 p.m.
Place:	CMA Offices Washington, D.C.

List of Attendees:

James Barter	PPG Industries
Ed Beeler	The GEON Company
Mark Gruenwald (PT)	Borden Chemicals and Plastics
James Knaak	Occidental Chemical
Caffey Norman	Patton, Boggs LLP
David Penney	Vista Chemical
Jonathan Ramlow	Dow Chemical
Kim Reed	CMA
Has Shah	CMA

1.0 Has Shah and Jonathan Ramlow reported on the response from ATSDR to the Committee's proposal to conduct a combined reproductive and developmental effects study. ATSDR agreed to the Committee's proposal. The Committee will submit a protocol to ATSDR within the next week including rationale for excluding parameters that the Committee believes are not necessary for the study. The Committee also will include dose levels in the protocol. The Committee will request that ATSDR contact EPA to discuss the Agency's request for a neurotoxicity study. The Committee believes that a neurotoxicity study would not produce necessary exposure information. The Committee will work with ATSDR to resolve the neurotoxicity issue before the study begins. ATSDR representatives will meet to discuss the Committee's protocol on June 15.

The Committee reviewed the draft cover letter to ATSDR prepared by Caffey Norman and the protocol for the reproductive and developmental effects study. Mr. Norman will finalize the letter and send it to Dr. Shah for his signature. Dr. Ramlow will finalize the study protocol for submission to ATSDR.

2.0 The Committee discussed the *Pesticide and Toxic Chemical News* article by James Cogliano of EPA on the health effects risk assessment of vinyl chloride. Dr. Shah will contact Dr. Cogliano to identify studies and the methodology EPA has used in its risk assessment of vinyl chloride. Dr. Shah also will follow-up with Dr. Cogliano on the possibility of modifying the Heast table on vinyl chloride.

3.0 The Committee reviewed the proposal from James Swenberg of the University of North Carolina to conduct a series of studies on the formation and repair of

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DNA adducts induced by vinyl chloride that will provide molecular dosimetry information relevant to risk assessment. According to Dr. Swenberg's proposal, these studies would be conducted in a manner that will complement the two generation reproductive and developmental toxicity study. Committee members will review the proposal for discussion on a conference call in the next few weeks.

4.0 The Committee reviewed the ongoing risk assessments at EPA and Cal EPA. Dr. Shah will contact Lillian Kelley of Cal EPA to request that Richard Reitz and a Committee member be allowed to make a presentation at the upcoming risk assessment workshop on vinyl chloride. Dr. Shah also will contact the Proposition 65 staff at Cal EPA to request that Cal EPA hold their risk assessment of vinyl chloride until after the Committee's reproductive and developmental effects study is completed.

5.0 Dr. Ramlow reviewed the status of the Vinyl Chloride Epidemiology Study Update underway at Applied Epidemiology Inc. AEI has received several boxes of records and histories from the previous study from ENSR. However, ENSR is experiencing problems in locating some of the death certificates from the previous study. Dr. Shah and Dr. Ramlow will work closely with ENSR to ensure the transfer of the data to AEI as soon as possible. Dr. Shah and Dr. Ramlow also are working with several states to receive permission for the transfer of death certificates from ENSR to AEI. Of the 40 states in questions, 26 have given permission. Dr. Shah has submitted an application to the National Death Index to facilitate receipt of death certificates since 1982 from individual states. A response from NDI is expected by the end of August. In addition, Dr. Shah and Dr. Ramlow are working with Dr. Whorton of ENSR to resolve contractual problems in the transfer of the data tapes.

Committee members should contact Ken Mundt of AEI with contacts within their companies for tracking employee vital status information.

Dr. Shah will have a list of the original study cohort sent to Jim Barter.

6.0 Dave Penney informed the Committee that Vista has sponsored a literature review on brain cancer and vinyl chloride. The review was performed by Ken Mundt and is presently undergoing peer review. Mr. Penney will contact Dr. Mundt to discuss the possibility of sharing the draft manuscript with the Committee.

7.0 The Committee discussed the Proposal for a Brain Cancer Case Control Study submitted by Carlo Tamburo of the University of Louisville. Dr. Ramlow will draft a list of questions in response to the proposal including:

- Have you established a working network with the three BFGoodrich branch companies?

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- What information do you need from the three companies?
- What are the evaluations? What period of time do they cover? How will the data differ or overlap?
- Do you still have copies of reviewer comments from previous studies?
- Will networking with AEI be useful?
- What resources will be needed to complete the proposed work within one year?

Ed Beeler will arrange a meeting between Dr. Tamburo and Dr. Ramlow to discuss these and other questions and to develop a possible course of action. Dr. Ramlow also will discuss the University of Louisville's ability to comply with CMA's Guidelines for Good Epidemiology Practices for Occupational and Environmental Epidemiologic Research. A list of questions will be provided to Dr. Tamburo prior to the meeting.

8.0 Dr. Shah distributed the Committee financial statement.

Hasmukh Shah

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

Subject to Approval

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