



CHEMICAL MANUFACTURERS ASSOCIATION

March 26, 1996

Dear Vinyl Chloride Health Committee Members:

The following items are enclosed:

- 1) the January 19, 1996 Record of Conference Call; and,
- 2) the cover letter to William Cibulas. The attachments which are discussed in the letter are not included in your package. Once the MOU with ATSDR is final, we will send you a complete package.

Please call me at 703/741-5637 if you have any questions.

Sincerely,

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

Enclosure





CHEMICAL MANUFACTURERS ASSOCIATION

March 22, 1996

BY COURIER

William Cibulas, Ph.D.
Chief
Research Implementation Branch
Division of Toxicology
Agency for Toxic Substances and Disease Registry
1600 Clifton Road, N.E., Mailstop E-29
Atlanta, Georgia 30333

Re: MOU for Vinyl Chloride

Dear Dr. Cibulas:

By letter dated November 8, 1995, you indicated that the revised protocol for the combined two-generation reproduction and developmental toxicity study of vinyl chloride that we submitted on October 23, 1995 was satisfactory. Thank you for confirming as well that the Environmental Protection Agency would not be requiring additional neurotoxicity data on vinyl chloride.

You asked that we complete a memorandum of understanding (MOU) for the combined inhalation two-generation reproduction and developmental toxicity study and forward it to you. Our counsel has made a number of minor revisions to the model MOU you provided. A redlined version, showing the revisions, is enclosed. A clean copy of the MOU also is enclosed.

In addition to the MOU, we are submitting a study plan setting forth the schedule for conducting and reporting the study. Also attached to the MOU is the final protocol. You will note that it is in a somewhat different format from the protocol submitted for peer review, but it is essentially the same study. The reason for the different format is that we solicited bids from several contractors

William Cibulas, Ph.D.

March 22, 1996

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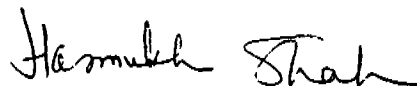
and decided to place the study with Huntington Life Sciences, Inc. The protocol that was peer reviewed had been submitted by The Dow Chemical Company.

I should also note that the protocol attached to the MOU may be revised slightly in the next few weeks to include additional subgroups of animals in the exposure chambers. These animals may be used for molecular research unrelated to the reproduction and developmental toxicity study that is the subject of the MOU. If a decision is made to add additional subgroups, a revised version of the protocol will be submitted to you. We did not think, however, that this should slow the process for getting a signed MOU in place.

Should you or your colleagues at the Agency for Toxic Substances and Disease Registry (ATSDR) have any comments on the enclosed MOU, I suggest that you contact our counsel, Caffey Norman, at 202-457-5270.

Your letter of November 8 also made reference to additional opportunities for collaborative research on vinyl chloride, specifically with regard to chronic-duration studies by inhalation. I suggest that we discuss ATSDR's needs in this respect in greater detail as part of a continuing dialogue on the reproduction and developmental toxicity study that will shortly be underway.

Sincerely,



Hasmukh C. Shah, Ph.D.
Vinyl Chloride Panel Health Committee

Enclosures

cc: W. Caffey Norman, Esq.

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CHEMICAL MANUFACTURERS ASSOCIATION
Vinyl Chloride Health Committee
Record of Conference Call

DATE: January 19, 1996
TIME: 2:30 p.m. EST

List of Participants:

Jim Barter	PPG Industries, Inc.
Ron Gilbert	Westlake Polymers
Mark Gruenwald	Borden, Inc.
Ken Mundt	Applied Epidemiology, Inc.
Caffey Norman	Patton Boggs, LLP
David Penney	Vista Chemical Company
David Pun	Formosa Plastics
Jonathan Ramlow	Dow Chemical Company
Jay Strange	Georgia Gulf Corporation

Elena Howell (p/t)	CMA
Has Shah	CMA

- 1.0 The November 30, 1995, record of conference call was approved as written.
- 2.0 The Committee discussed the status of the Vinyl Chloride Epidemiology Update Study. Jonathan Ramlow visited AEI, and reported on the progress Ken Mundt is making in reconstituting the information.

Dr. Mundt informed the Committee that extending the study from 1992 to 1994 could be done at a cost of approximately \$9,500. The Committee agreed to extend the study.
- 3.0 The Committee discussed the Brain Cancer Case Control study proposal from Carlo Tamburo. The Committee, with the exception of one member, agreed to support the study with a budget of \$150,000. Dr. Shah will ask Dr. Tamburo to start working on the study protocol. The member not voting in support will make a decision on supporting the study at a later date.
- 4.0 The Committee decided to postpone the decision on the proposals from Dow Chemical, CIIT, and Huntingdon for the combined Reproductive/Developmental effects study.
- 5.0 The Committee approved the revised draft Memorandum of Understanding between ATSDR and CMA for the combined two-generation reproduction and developmental effects study in rats.

- 6.0 The Committee discussed the molecular toxicology research at the University of North Carolina at Chapel Hill. Has Shah will ask Jim Knaack for justification for the study, and how the data may be used.
- 7.0 Dr. Shah reminded the Committee to send in their comments on the ATSDR Toxicological Profile. Dr. Shah will compile the comments when he receives them. The Committee decided to coordinate its activities on this profile with the Vinyl Institute.
- 8.0 Dr. Shah reminded the Committee that comments on the ATSDR Medical Management Practices Guidelines should be submitted to CMA by mid-February.
- 9.0 Dr. Shah will submit the Rietz and Clewell manuscripts on vinyl chloride risk assessment to CalEPA on behalf of the Panel.
- 10.0 The next conference call is scheduled for January 29, 1996, at 1:30 p.m. EST.



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

Subject to Approval