



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,

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

Enclosure

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.

Vinyl Chloride Health Committee

ROCC 1/19/96

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- 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



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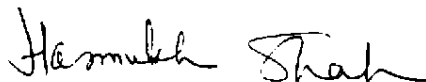
and decided to place the study with Huntington Life Sciences, Inc. The protocol that was peer reviewed had been submitted by The Dow Chemical Company.

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,

A handwritten signature in black ink, reading "Hasmukh C. Shah". The signature is fluid and cursive, with the first name "Hasmukh" and last name "Shah" clearly distinguishable.

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

Enclosures

cc: W. Caffey Norman, Esq.

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CHEMICAL MANUFACTURERS ASSOCIATION

March 11, 1996

Dear Vinyl Chloride Health Committee Members:

The following items are enclosed:

- 1) February 9, 1996 letter to David Siegel regarding the reports submitted to the California Office of Environmental Health Hazard Assessment;
- 2) the Committee's comments on ATSDR's Toxicological Profile for vinyl chloride. These comments were prepared by Tom Downs of Patton Boggs, LLP, based on comments from PPG Industries, Inc., Dow Chemical Company, Occidental Chemical Corporation, and Vista Chemical Company; and,
- 3) the Committee's comments on ATSDR Medical Management Guidelines for vinyl chloride. These comments were prepared by Tom Downs based on comments from Dow Chemical Company and PPG Industries, Inc.

I will schedule a conference call in the near future to brief the Committee on the status of discussion with ENSR research proposal from Dr. Swenborg, the Memorandum of Understanding with ATSDR, EPA's Risk Assessment of vinyl chloride, and other issues.

I look forward to talking with you soon.

Sincerely,

Jon Burch for

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

Enclosure



CHEMICAL MANUFACTURERS ASSOCIATION

Vinyl Chloride Panel

Health Committee

FAX

January 25, 1996

TO:	Heather Burleigh-Flayer	PPG Industries	412/434-2137
	Jim Barter	PPG Industries	412/434-2137
	Ed Beeler	GEON	216/930-3034
	Ron Gilbert	Westlake	713/963-1540
	Mark Gruenwald	Borden	614/225-7638
	James Knaak	Occidental	716/286-3141
	Caffey Norman	Patton Boggs	202/457-6315
	Dave Penney	Vista	713/588-3478
	Dave Pun	Formosa	201/716-7283
	Jonathan Ramlow	Dow	517/636-1875
	Jay Strange	Georgia Gulf	504/687-0294

FROM: Has Shah CMA

RE: The Conference Call on January 29, 1996

MESSAGE

The next Vinyl Chloride Health Committee conference call has been **rescheduled for Monday, January 29, 1996, at 3:00 p.m. EST.** We will discuss the following items on that call:

- 1.0 Selection of Contract Laboratory for the Combined Reproduction and Developmental Toxicity Study
- 2.0 Draft Response to ATSDR's Toxicology Profile for Vinyl Chloride
- 3.0 Update on Negotiations with ENSR on Contractual Obligations

SENDER: Elena Howell

PHONE: 703/741-5638

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JS.*

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CHEMICAL MANUFACTURERS ASSOCIATION

Vinyl Chloride Panel

Health Committee

FAX

January 17, 1995

TO:	Jim Barter	PPG Industries	412/434-2137
	Ed Beeler	GEON	216/447-6459
	Ron Gilbert	Westlake	713/963-1540
	Mark Gruenwald	Borden	614/225-7638
	James Knaak	Occidental	716/286-3141
	Caffey Norman	Patton Boggs	202/457-6315
	Dave Penney	Vista	713/588-3478
	Dave Pun	Formosa	201/716-7283
	Jonathan Ramlow	Dow	517/636-1875
	Jay Strange	Georgia Gulf	504/687-0294

FROM: Has Shah CMA

RE: The Conference Call on January 19, 1996

MESSAGE

A proposal from Carlo Tamburo for the Study of Brain Cancer in Vinyl Chloride Exposed Workers is enclosed for your review prior to our conference call on January 19, 1995, at 2:30 p.m. EST. A copy of the agenda for the call also is enclosed.

SENDER: Elena Howell

PHONE: 703/741-5638

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*See PLS notifies Elena
that due to travel schedule
I will not be available
THX
EHS*

CMA IS MOVING!

EFFECTIVE JANUARY 1996, OUR NEW ADDRESS WILL BE: 1300 WILSON BOULEVARD • ARLINGTON, VIRGINIA 22209

2501 M STREET, NW, WASHINGTON, DC 20037 • TELEPHONE 202-887-1100 • FAX 202-887-1237



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CHEMICAL MANUFACTURERS ASSOCIATION
Vinyl Chloride Health Committee
Conference Call
Tentative Agenda

Date: January 19, 1996

Time: 2:30 p.m. ET

- 1.0 Approval of November 30, 1995, Record of Conference Call**
- 2.0 Status of Vinyl Chloride Epidemiology Update Study.**
 - 2.1 Negotiations with ENSR - Mike Druckman, Jonathan Ramlow and Has Shah.**
 - 2.2 Status of The Study at Applied Epidemiology, Inc. - Kenneth Mundt, Jonathan Ramlow, and Has Shah**
- 3.0 Discussion of proposals from Dow Chemical, CIIT, and Huntingdon for the combined Reproductive/Developmental Effects Study - All**
- 4.0 Review of the Revised Draft Memorandum of Understanding between ATSDR and CMA - Caffey Norman**
- 5.0 Review of Status of Commitments for the Vinyl Chloride 1996-1997 Research Program - Has Shah**
- 6.0 Discussion of Molecular Toxicology Research at the University of North Carolina at Chapel Hill - Jim Knaak, Jim Barter, and Jonathan Ramlow**
- 7.0 Review of Draft Comments on the ATSDR Toxicological Profile - Jim Barter, Jim Knaak, and Jonathan Ramlow**
- 8.0 Discussion of the Draft ATSDR Vinyl Chloride Medical Management Guidelines - All**
- 9.0 Discussion of the Vinyl Chloride Brain Cancer Case Control Study Proposal from Carlo Tamburo of the University of Louisville - Jonathan Ramlow, Ed Beeler, and Has Shah**
- 10.0 Strategy Discussion to respond to California EPA's Draft Addendum Health Risk Assessment of Ambient Fugitive Vinyl Chloride Emissions from a Landfill Site - All**
- 11.0 Set a date for the next Vinyl Chloride Conference Call or meeting**