CHEMICAL MANUFACTURERS ASSOCIATION

May 22, 1997

Dear Vinyl Chloride Health Committee Members:

Enclosed is the April 23rd Record of Meeting and a conference call scheduling calendar for the month of June. Please complete the calendar and fax return it to us at 703/741-6091. Thank you.

Sincerely,

Cynthia Barrett

Cynthia Barrett
Admin Asst.,
Vinyl Chloride Health Committee

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CHEMICAL MANUFACTURERS ASSOCIATION
Vinyl Chloride Health Committee
Record of Meeting

DATE: April 23, 1997
TIME: 10:00 a.m. EDT

List of Participants:

James Barter	PPG Industries, Inc.
Ed Beeler	GEON Company
Mark Gruenwald	Borden, Inc.
Jim Knaak*	Occidental Chemicals
David Penney	CONDEA Vista Company
Jonathan Ramlow*	Dow Chemical Co.
Jay Strange	Georgia Gulf Corp.
Cynthia Barrett*	CMA
Has Shah	CMA
Wendy Sherman	CMA
Ken Mundt*	Applied Epidemiology, Inc.

* Denotes part-time attendance.

1.0 Approval of February 18th Record of Conference Call and Changes to the Agenda

The Panel approved the February 18, 1997 Record of Conference Call with one change. The change clarified that J. Knaak and Dr. J. Swenberg will soon be finalizing the protocol for the in-life portion of the molecular carcinogenesis satellite study. The protocol for the second half of the study is still under development.

2.0 Update on the Applied Epidemiology, Inc. (AEI) Vinyl Chloride Cohort Study

K. Mundt briefed the Panel on the status of the AEI cohort study. He is working to close a number of data gaps prior to the end of May when the dataset will be closed for analysis. Additional information that comes in after May 31st will be added to the database, however, it will not be included in this study. To prevent confusion over which data were used in the analysis, K. Mundt will append a copy of the dataset to the study so it will be available for reviews and audits. Analysis of the data is expected to take three to four months. K. Mundt reported that the study is close to its original time line and within budget.

3.0 Update on the University of Louisville Brain Cancer Study

K. Mundt also provided an update on the April 18, 1997 meeting with H. Shah, J. Ramlow, C. Tamburro, Tamburro's staff and consultant, R. Buncher. The group discussed concerns with limiting analysis to the Greenberg/Tamburro methodology and the benefits of using multiple analytical techniques to build credibility in the study. C. Tamburro agreed to perform a nested case control as well as a standard cohort

analysis using a Cox regression, logistics regression and SMR analysis. C. Tamburro will provide a revised protocol to CMA by mid-May. When the revised protocol is finalized, W. Sherman will send a copy to H. Checkoway and G. Marsh.

4.0 Update on Huntingdon Life Sciences Vinyl Chloride Developmental, Reproductive, and Molecular Research Studies

J. Knaak briefed Panel members on the April 10th trip to Huntingdon with D. Penney and W. Sherman. During a tour of the facility, the group observed necropsies of dams and fetuses from the developmental study and the weighing of pups and the exposure of dams from the reproductive study. Results of the GC and infra red analysis were discussed along with a review of protocol amendments.

A copy of the final protocol for the in-life phase of the University of North Carolina molecular carcinogenesis satellite studies at Huntington was distributed. The in-life phase of the satellite study is on schedule although no final protocol for the second half of the study had been received from J. Swenberg. J. Knaak will call J. Swenberg to inquire on the status of the second portion of the satellite protocol and to ask for a funding estimate for 1998. The Panel approved $50,000 to cover the cost of the in-life portion of the satellite study at Huntingdon. The Panel also approved a $50,000 gift for J. Swenberg to conduct the second half of his satellite study at the University of North Carolina. W. Sherman will develop a gift letter for J. Swenberg.

W. Sherman distributed copies of a letter to ATSDR informing the Agency of the status of the Huntingdon studies. Progress reports for the developmental and reproductive studies along with a revised study plan were appended to the letter. Starting in April 1997, progress reports will be sent to ATSDR every six months until the final reports are issued.

5.0 Update on the International Life Sciences Institute Genotoxicity Project

W. Sherman briefed the group on the status of the ILSI's project, Use of Non-Tumor Data in Cancer Risk Assessment. A recent progress report from ILSI was distributed to the group. Of the four compounds selected for study (aflatoxin, benzene, butadiene, and vinyl chloride), the case study on aflatoxin was dropped due to insufficient funding. Draft case study reports are expected by the summer of 1997 and will be distributed to Case Study Work Group members for comment. After that review, the studies will be revised and a meeting of all Work Group members and stakeholders, including VCHC members, will be scheduled for the fall of 1997. W. Sherman will contact ILSI and inquire why the use of the PBPK model was not mentioned in the progress report on vinyl chloride.

6.0 Update on EPA IRIS's Pilot Project

In the update on EPA's IRIS Pilot Project, W. Sherman reported on her conversation with A. Mills, the new project manager at EPA. The Pilot is expected to finish this summer, with recommendations for revising the program due this fall. Differences between the regular IRIS program and Pilot project begins with a Federal Register Notice announcing the development of a new or revision of an existing IRIS file, and the addition of a series of peer review panels to evaluate data submitted for inclusion in the

database. According to A. Mills, vinyl chloride is to be submitted for peer review the week of May 12th. W. Sherman will call EPA to get more information on the goals of the peer review process, the criteria for selecting external peer reviewers, opportunities for stakeholder involvement in the Pilot project, and how this project might impact the HEAST tables.

7.0 Update on ATSDR Activities

W. Sherman distributed a draft letter to ATSDR developed by C. Norman to address inaccuracies contained in the draft Vinyl Chloride Toxicology Profile. Members will review the letter and send any additional changes to W. Sherman by May 2nd. W. Sherman will send a copy of the letter to D. Pun and J. Gamble for their comments. W. Sherman will ask ATSDR when the next version of the Toxicological Profile will be released.

Following up on the status of ATSDR's Medical Management Practices Guideline for vinyl chloride, W. Sherman reported that the contractor was not aware of a completion date for the guidelines. W. Sherman will identify and contact the CMA Task Group that was involved in the development of similar Medical Management Guidelines, and determine the status of their activity on this issue.

J. Knaak circulated handouts from an ATSDR-sponsored meeting on the development of Minimum Risk Levels (MRLs).

8.0 Update on the Association of Plastics Manufacturers in Europe (APME) Registry of Angiosarcoma Cases

J. Ramlow agreed to draft comments on the APME registry. D. Lewis, a physician at GEON, will participate in the comment development.

9.0 Selection of a New Committee Chairperson

The Panel nominated J. Knaak to be the next Chairperson of the Vinyl Chloride Health Committee. This motion was made after J. Knaak left the meeting. W. Sherman will call J. Knaak and inquire as to his willingness to serve as Panel Chair.

10.0 Schedule Next Meeting or Conference Call

W. Sherman will circulate a calendar to members to select a date for the next conference call.

Wendy K. Sherman

Wendy K. Sherman
Manager
Vinyl Chloride Health Committee

Subject to Approval

5/21/97

JUNE 1997
Vinyl Chloride Health Comm.

Please Fax to Cynthia Barrett at 703/741-6091

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
9	10	11	12	13
16	17	X 18	19	20
23	24	X 25	26	27
30				

Please Indicate the dates that you are **NOT** available a Conference Call.

SL 109705

CHEMICAL MANUFACTURERS ASSOCIATION
Vinyl Chloride Health Committee
Tentative Meeting Agenda

DATE: April 23, 1997
TIME: 9:30 a.m. - 3:00 p.m. DST
PLACE: Georgetown Conference Room

1.0 Approval of the February 18, 1997 Record of Conference Call

2.0 Update on the Developmental, Reproductive and Mechanistic Research Studies

- 2.1 Huntingdon Life Sciences Developmental and Reproductive Studies — $50,000 approved already for life portion of Swenberg study
- 2.2 University of North Carolina - J. Swenberg Satellite Study — Study 1 May - June 6 — Panel approved $50,000 already in budget
- 2.3 Status of Progress Reports to ATSDR

3.0 Update on the International Life Sciences Institute Genotoxicity Project

4.0 Update on EPA's IRIS Pilot Project — Risk Assessment Review week of 5/12 Will be a peer review workshop later.

5.0 Update on the University of Louisville Brain Cancer Study

6.0 Update on the Vinyl Chloride Cohort Study with Applied Epidemiology Inc.

7.0 Update on ATSDR Activities

Hold back to Wendy Sherman

- 7.1 Status of Comments on the *Toxicological Profile for Vinyl Chloride*
- 7.2 Status of Activity on the Minimal Risk Level for Vinyl Chloride
- 7.3 Status of the Medical Management Practices Guideline

8.0 Financial Update
8.5 Election of Chairman
9.0 Schedule Next Meeting or Conference Call

Subject to Approval

Wendy K. Sherman
Manager
Vinyl Chloride Health Committee

SL 109805

ANTITRUST CHECKLIST FOR CMA MEETINGS

This antitrust checklist is for use by CMA staff and member representatives in the conduct of CMA-sponsored meetings. *Prohibited discussion topics apply equally to social gatherings incidental to CMA-sponsored meetings.* The Checklist is not exhaustive and does not address antitrust issues relating to activities other than CMA meetings. Participants in CMA meetings also should be thoroughly familiar with: (1) "Antitrust Guide for CMA Committee Members;" and, (2) "General Principles Applicable to the Structure and Operations of Committees." Both of these documents may be found in the CMA Directory.

DO

Ensure strict performance in areas of:

OVERSIGHT/SUPERVISION:

- Have a CMA staff representative at each CMA-sponsored meeting (unless an exception has been authorized by the appropriate CMA vice president);
- consult with an attorney of the CMA Office of General Counsel on all antitrust questions relating to CMA-sponsored meetings;
- limit meeting discussions to agenda topics (unless additional topics have been approved by the appropriate CMA staff representative); and
- provide each member company representative and CMA staff representative attending a CMA-sponsored meeting with a copy of this checklist, and have a copy available for reference at all CMA-sponsored meetings.

RECORDKEEPING:

- Have an agenda and minutes which accurately reflect the matters which occur;
- provide agendas and minutes to the CMA Office of General Counsel for review and approval in advance of distribution; and,
- fully describe the purposes and authorities of all task groups, work groups, ad hoc or other standing committee subgroups in the minutes of the appropriate parent committee.

VIGILANCE:

- Protest against any discussion or meeting activities which appear to violate this checklist; dissociate yourself from any such discussion or activities and leave any meeting in which they continue.

DON'T

Do not, in fact or appearance, discuss or exchange information on:

PRICES, INCLUDING:

- Individual company prices, price changes, price differentials, markups, discounts, allowances, credit terms, etc.;
- individual company data on costs, production, capacity, inventories, sales, etc.; and,
- industry pricing policies, price levels, price changes, differentials, etc.

PRODUCTION, INCLUDING:

- Plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and,
- changes in industry production, capacity or inventories.

TRANSPORTATION RATES:

- Rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

MARKET PROCEDURES, INCLUDING:

- Company bids on contracts for particular products; company procedures for responding to bid invitations; and,
- matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

CONSENT DECREE SUBSTANCE:

- Any matter relating to trisodium phosphate (a restriction required by a 1962 consent decree to which CMA is a party).

Revised 3/80 (single page version)
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