March 20, 1980

To: Vinyl Chloride Project Panel

Gentlemen:

Enclosed is a copy of a communication to Mr. Frank D. Kover that serves as a letter of transmittal for the report from Experimental Pathology Laboratories, Inc. (EPL) entitled "Vinyl Chloride Pathology Report". Please note the last paragraph of the letter and the fact that CMA has not attempted to evaluate the report as a Section 8(e) TSCA report because CMA does not have a reporting obligation under Section 8(e).

Also enclosed is a record of the Panel meeting held on March 18, 1980.

A copy of the EPL report is being sent to all Panel members who were unable to attend the March 18 meeting.

Sincerely,

J. T. Seawell
Project Administrator
Vinyl Chloride

JTS:db

Enclosures

BY MESSENGER

CHEMICAL MANUFACTURERS ASSOCIATION

March 19, 1980

Mr. Frank D. Kover - TS 792
Chief
Chemical Hazards Identification
Branch
Assessment Division
Environmental Protection Agency
401 M Street, S.W.
611 East Tower
Washington, D.C. 20460

Dear Mr. Kover:

On January 14, 1977, Mr. Albert Clark forwarded to Mr. Robert McGaughy of EPA, on behalf of the Manufacturing Chemists Association (now the Chemical Manufacturers Association), a copy of the protocol and the 23-month status summary for the Association-sponsored research on vinyl chloride at Industrial Bio-Test Laboratories (IBT). Mr. Clark stated in that letter that the final report was expected to be submitted soon, and when available, would be forwarded to the Agency.

As you know, all testing undertaken at IBT has come under a cloud. In particular, serious flaws were discovered in the vinyl chloride study, and no final report of the IBT study was ever issued. The Association undertook to determine whether the vinyl chloride study could be validated through an audit of the pathology by Experimental Pathology Laboratories (conducted by Dr. William Busey). Dr. Busey subsequently submitted a report of his audit to the Association on January 9, 1979. It was reviewed by an Association task force and, because it was part of a larger audit (including a review of compliance of IBT with good laboratory practices), was not further distributed at that time. Unfortunately, because of the interim change in the management of the Association and the extraordinary increase in the scientific work of the Association caused by the Toxic Substances Control Act and related environmental legislation, we failed to send it to the Agency as a follow-up to Mr. Clark's letter of January 14, 1977.

CMA 008062

Recently, the Association has established a task force to oversee and coordinate all scientific testing projects. In the course of reviewing existing projects, this group discovered that we had not made Dr. Busey's audit report on the vinyl chloride study available to the Agency. Accordingly, I am enclosing a copy of the audit report as a follow-up to Mr. Clark's letter of January 14, 1977.

As shown in the interim report sent to the Agency in January, 1977, three suspect brain tumors were noted in male rats at the high dose level. These brain tumors, plus one at the lower dose level, were confirmed by pathology subsequently conducted by IBT and then by Dr. Busey. Unfortunately, not all of the brain specimens were retain d by IBT and not all retained specimens were examined. The Association has therefore concluded to determine whether additional information can be obtained from whatever brain specimens remain at IBT from this highly-flawed study by conducting histopathological examination of all remaining brain tissues. We have not identified any other findings that would appear to warrant further attempts to salvage other information from this study.

We apologize for failing to follow-up on Mr. Clark's earlier letter, and wish to assure you that we will, in the future, keep you apprised of any additional relevant information as it becomes available to us.

While CMA does not itself have a Section 8(e) reporting obligation, and while it appears that this information would not be reportable under Section 8(e) in any event, pursuant to our earlier commitment we are submitting it to the Agency.

Sincerely yours,

Hasmukh Shah

Hasmukh C. Shah, Ph.D.
Director, Special Projects

cc: (with enclosure)
Mr. Robert McGaughy
Office of Research &
Development
Environmental Protection Agency

Chemical Manufacturers Association

Record of Meeting

VINYL CHLORIDE PROJECT PANEL

March 18, 1980

Washington Hilton Hotel — Washington, D. C.

MEMBERS PRESENT:

W. M. Smith	Air Products & Chemicals, Inc.
H. W. Blakeslee	CertainTeed Products
T. R. Torkelson	Dow Chemical Company
T. J. Benya	Ethyl Corporation
R. Park	Firestone Plastics Co.
M. N. Johnson	BFGoodrich Company
Z. G. Bell	PPG Industries, Inc.
R. N. Wheeler	Union Carbide Corporation
J. T. Seawell	CMA Staff

PRESENT BY INVITATION:

C. R. Hopper	Gulf Oil Chemicals Co.
J. P. Murphy	Stauffer Chemical Co.
R. M. Walter	Firestone Plastics Co.
H. Shaw	CMA Staff
R. W. Hill	Diamond Shamrock
G. K. Hatfield	Diamond Shamrock
J. Hanson	Dow Chemical Co.
D. F. Zoll	CMA Staff
E. Frost	CMA Staff
W. Busey	Experimental Pathology Labs., Inc.
W. F. Carroll	Firestone Plastics Co.
R. T. Gottesman	Tenneco Chemicals, Inc.

MEMBERS ABSENT:

J. T. Carter	BP Chemicals, Ltd.
W. Bittenbender	Borden Chemical
F. Kennedy	Continental Oil Co.
R. W. McBurney	Diamond Shamrock

J. Lynch	Exxon Chemical Co.
R. W. Laundrie	General Tire & Rubber Co.
J. Gabbett	Georgia-Pacific Corp.
C. A. Johnson	Goodyear Tire & Rubber
R. B. Judge	W. R. Grace & Company
P. Cohen	Great American Chemical Co.
R. L. Gibson	Gulf Oil Chemicals Co.
R. J. Abramowitz	Hooker Chemicals & Plastics Corp.
G. Roush	Monsanto Company
A. G. Wheeler	ICI Americas, Inc.
S. K. Law	Keysor-Century Corp.
R. L. O'Connell	Olin Corporation
R. Brookman	Pantasote Company
V. L. Kirkland	Shell Chemical Co.
J. Stauffer	Stauffer Chemical Co.
P. M. Reed	Tenneco Chemicals, Inc.
W. D. Harris	Uniroyal, Inc.

1.0 Edmund Frost, Esq., summarized the purpose of the meeting and briefly described the history of the Panel's research project with Industrial BIO-Test and an audit of the study by the Experimental Pathology Laboratory (EPL).

2.0 Following a discussion of EPL's January 9, 1979 "Vinyl Chloride Pathology Report" a motion was made, duly seconded and passed to submit the Report forthwith to the U. S. Environmental Protection Agency.

3.0 Following a discussion of the research project conducted by Industrial BIO-Test, a motion was made, duly seconded and passed to immediately conduct further pathologic analysis of all remaining brain tissue salvageable from the study.

4.0 Following discussion of CMA's efforts to terminate the Industrial BIO-Test contract and to seek reimbursement of funds, it was the consensus of the Panel that no additional efforts were required at this time and that the CMA Legal Department would handle the remaining aspects of the matter.

J. T. Seawell
Project Administrator
Vinyl Chloride

JTS:md

Record Subject to Approval

March 20, 1980

J. Lynch	Exxon Chemical Co.
R. W. Laundrie	General Tire & Rubber Co.
J. Gabbett	Georgia-Pacific Corp.
C. A. Johnson	Goodyear Tire & Rubber
R. B. Judge	W. R. Grace & Company
P. Cohen	Great American Chemical Co.
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