



APR 22 1980

CHEMICAL MANUFACTURERS ASSOCIATION

April 1, 1980

To: Vinyl Chloride Project Panel

Subjects: I . Additional Histopathologic Examination of Brains
from the IBT/VC Study

II. Validation of Exposure Chamber Concentrations,
During IBT/VC Study by Means of G. C. Strip Chart
Examinations.

Gentlemen:

As a result of Panel action on March 18, 1980, (please refer to page 2, Item 3.0 of the Record of Meeting), Dr. William Busey will perform additional histopathologic examinations of brains from the IBT/VC study. Dr. Busey's work will involve:

- Five trained histology personnel on his staff
- On-location tissue accountability, search and retrieval at IBT facilities at Northbrook, Illinois.
- All material requiring histologic preparation (wet tissues and/or paraffin blocks) will be processed in Dr. Busey's laboratories, Experimental Pathology Laboratories, Inc. (EPL), Herndon, Virginia, onto microscopic slides.
- At least three sections will be processed from each brain retrieved from IBT/Northbrook.
- A detailed reading of each slide will be performed by Dr. Busey, and a final report will be prepared by Dr. Busey detailing his findings.

EPL charges for the work described above will be \$16,460.

Pursuit of the validation of chamber concentrations during the last six months of exposure will involve random studies of at least 10% of all G. C. strip charts. The Audit Task Group advises CMA that third

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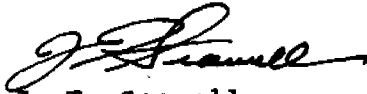
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party validation readings should be made of the IBT/G.C. strip charts. Bob West Associates gave CMA an estimate of \$4,000 for validation readings of at least 10% of the strip charts; however, a contingency of at least \$2,000 should be included. A contingency is necessary since we should assume that G. C. recordings for VC exposures will be similar to those observed during earlier sample validation readings made during the trichloroethylene audits. ←

Funds remaining from the IBT/VC study will cover the two studies described above. It is not anticipated that additional funding will be required unless findings by Drs. Busey and West indicate the advisability of further studies. In this event, Panel authorization will of course be secured.

Work on both of these studies will begin as soon as possible. Should you wish to comment on these two actions please contact Dr. Shah or the undersigned immediately after receipt of this letter.

Sincerely,


J. T. Seawell
Project Administrator
Vinyl Chloride

JTS:md

cc: Audit Task Group

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CHEMICAL MANUFACTURERS ASSOCIATION

May 7, 1980

Mr. Richard L. Davis
Director
Health Management Services
Environmental Health Associates, Inc.
2150 Shattuck Avenue
Suite 414
Berkley, California 94704

Dear Mr. Davis:

The following summary is being presented in order that a revised or modified bid/proposal can be prepared by Environmental Health Associates, Inc., (EHA) that reflects recent action of the Vinyl Chloride Panel and Research Coordinators. Wherever possible, Panel actions are summarized according to major sections of your bid/proposal of January 15, 1980. To facilitate subsequent reference, the following sections and subsections are numbered:

1.0 Evaluation of the Current Data Base

1.1 In the light of our recent discussions it appears advisable that at the earliest possible time EHA give the Panel a written opinion on the exact current status of the data base. As you indicated, before a "Brain Case Control Study" or a "Five-Year Epidemiological Update" can be conducted, the data base must be augmented.

1.2 Panel action relevant to EHA's assessment and/or evaluation of existing data was as follows:

"We agree that Environmental Health Associates (EHA) be authorized to examine the current records, prepare a protocol for a five-year update, and conduct a reanalysis of death certificates according to the EHA letter proposal dated January 15, 1980."

2.0 "Brain Case Control Study" (BCCS)

2.1 After EHA has completed necessary assessment of the data base that pertains to the BCCS, the Panel confirmed its earlier position by voting:

EHA will be requested to prepare a protocol and a cost estimate for a "case control study" of

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cancers of the central nervous system.

- 2.2 The Panel confirmed an earlier stipulation that the protocol prepared by EHA for the BCCS will be open for bids in addition to the EHA bid.

3.0 Study Plan A

- 3.1 The Panel is in agreement on proceeding with Study Plan A described on pages 6, 7 and 9 of EHA's letter-proposal dated January 15, 1980.
- 3.2 As you reemphasized during your telephone call of May 6, 1980, the development of an accurate estimate of the probable cost to perform the five-year follow-up requires more precise information than is now available.

4.0 Study Plan B

Introductory Comment As discussed with you, the following summary of Panel action on Study Plan B is presented in an effort to assist you during the preparation of your modified bid/proposal. The preceding comment is relevant because the Panel voted to hold Study Plan B in abeyance for consideration at a future date.

- 4.1 Study Plan B should be modified by identifying the plants as follows:

Group I - Vinyl Chloride Monomer
Group II - PVC By Dispersion or Emulsion Processes
Group III - All Others

- 4.2 Under Study Plan B, EHA is to be requested to clarify the comment "...secure complete job histories for the approximate 3,300 cohort members with incomplete job histories". EHA is to characterize the deficiencies that exist in these 3,300 cohort members.

5.0 Study Plan C

Panel members expressed the opinion that there is little likelihood that Study Plan C will contribute anything new. They estimated that Study Plan C will not yield meaningful data until 10, 20 or perhaps 25 years hence.

6.0 Request for EHA's "Opinion and Position" on Mortality Study Based on Type of Plant Production

The Panel requests that EHA present its "Opinion and Position" on analyzing data in terms of those plants producing:

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Calcutt, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100

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- (1) Vinyl Chloride Monomer
- (2) Emulsion or Dispersion Polymers (excluding latex),
- (3) All Others

The analysis(s) to treat "significant differences with respect to mortality at a cost not to exceed \$10,000".

Please contact me immediately should any item in this letter need clarification.

Sincerely,



J. T. Seawell
Staff Advisor
Vinyl Chloride

JTS:md

cc: Dr. H. C. Shah
Dr. T. R. Torkelson

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Vinyl Chloride Payments to IBT

4 - 16 - 73	18,625	
7 - 16 - 73	18,625	
7 - 16 - 73	5,000	
10 - 10 - 73	18,625	60,875
12 - 10 - 74	37,250	
12 - 10 - 74	5,000	42,250
2 - 25 - 75	18,625	
5 - 14 - 75	18,625	37,250
01 - 76	7,840	
2 - 02 - 76	20,000	
4 - 29 - 76	1,610	29,450
		169,825

1976	186,807
1977	205,488
1978	226,037
1979	248,640
1980	273,505

Interest 103,680

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CHEMICAL MANUFACTURERS ASSOCIATION

June 27, 1980

Mr. Fred R. Current
Corporate Attorney
Industrial Bio-Test
Laboratories, Inc.
1810 Frontage Road
Northbrook, IL 60062

Dear Fred:

As per our telephone conversation, I have enclosed EPL and Bob West audit reports. The total cost of the study to date is \$248,639 and can be broken down as follows:

\$169,825	Payments to Industrial Bio-Test
20,147	Payments to Experimental Pathology Labs
4,000	Payments to Bob West Associates
54,667	Administrative Expenses
<u>\$248,639</u>	TOTAL

Mr. Frost and I look forward to seeing you on July 16, 1980.

Sincerely,

Hasmukh Shah

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

HCS:am

Enclosures

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CHEMICAL MANUFACTURERS ASSOCIATION

August 8, 1980

Mr. Fred Current, President
Industrial Bio-Test Laboratories, Inc.
1810 Frontage Road
Northbrook, IL 60062

Dear Fred:

I was out of the office for the last couple of weeks and so apologize for not forwarding to you the information you requested during our meeting on July 16, 1980. The total cost to conduct the study at IBT and the estimated interest are summarized below:

\$169,825	Payments to IBT
20,147	Payments to Experimental Pathology Labs
4,000	Payments to Bob West Associates
9,908	CMA administrative expenses from 1973 to 1977
29,759	CMA administrative expenses from 1978 to present
15,000	Estimated expenses incurred by Panel members during various audits and related activities from 1978 to present
103,680	Estimated interest from 1976 to present
<u>\$352,319</u>	TOTAL

Please do not hesitate to call me if you need additional information.

I look forward to a mutually agreeable settlement of this issue.

Thank you.

Sincerely,

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

cc: Dr. Ted Torkelson
Dr. Zeb Bell
Mr. Roger Lockhead

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VINYL CHLORIDE AUDIT TASK GROUP

May 1980

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