



Air Products and Chemicals
INC.

CHEMICALS GROUP

Five Executive Mall, Swedesford Road, Wayne, Pa. 19087

RD 0002006545

PLASTICS DIVISION

10 January 1975

A. R. Adams, General Manager
Tel: (215) 687-6150
Twx:

Mr. Ralph L. Harding, Jr.
The Society of the
Plastics Industry, Inc.
250 Park Avenue
New York, New York 10017

Dear Ralph:

Please find enclosed correspondence from Dr. B. G. Greenberg, Dean-- School of Public Health, University of North Carolina. The estimated budget for the Feasibility Study of Cancer Mortality and Morbidity among vinyl chloride exposed workers is significantly higher than that authorized by the full membership of the Ad Hoc Committee of VCM and PVC Producers. Before formally inviting Dr. Greenberg to conduct the Feasibility Study (as outlined in your draft letter to him dated December 19, 1974) I feel we must obtain support from the full Committee to fund this project. I am sure you understand Air Products' position on the necessity of this study.

- A. We believe that there is a need to develop a statistically meaningful vinyl chloride dose response curve for humans.
- B. That such a study must be designed and carried out by an agency whose credentials are unquestioned and the reliability of the data will be accepted on a worldwide basis.
- C. That there is a need for this study irrespective of the status of various pending legislative actions.

I have requested from Dr. Greenberg authority to circulate the proposal to the voting representatives of the Ad Hoc Committee of VCM and PVC Producers.

Very truly,

A. Ross Adams

ARA/d6

Enclosures

cc: Mr. R. Fleming

THE UNIVERSITY OF NORTH CAROLINA
AT
CHAPEL HILL

27514

SCHOOL OF PUBLIC HEALTH
OFFICE OF THE DEAN

anna-
make up for Stenberg
Committee + RF +
Ralph Harding.

TELEPHONE
AREA 919, 966-1753

January 3, 1975

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Dr. A. R. Adams
Air Products and Chemicals
Chemicals Group
5 Executive Mall
East Swedesford Road
Wayne, Pa. 19087

JAN 06 1975

A. ROSS ADAMS

Dear Ross:

In reply to the draft letter of December 19, 1974 from Ralph L. Harding, Jr., I enclose a proposal for a feasibility study to investigate mortality and morbidity data from workers exposed to vinyl chloride. The proposed budget for the feasibility study is \$72,971 - considerably more than our earlier "off-the-cuff" estimates. The higher estimate is the result of three factors. Firstly, based on our experience in setting up the occupational health study for the chemical rubber union-management contract, our advisors state that the feasibility study will require a minimum of two full time research associates for eight months, and ten percent time of three senior level faculty for the same period. This amount of effort is necessary if we are to obtain a good grasp of the data base for a dose-response study, and produce a report that includes a sound study protocol as well as intelligent cost estimates. Secondly, because of the large number of plants potentially involved in a full scale study, we allocated considerable funds for travel and per diem expenses. Thirdly, since a substantial amount of personnel effort will be required, we must negotiate this feasibility study as a regular University contract, thereby incurring the usual 48.12 percent overhead expense on direct salaries. I am reluctant to handle this large a contract as a letter of agreement outside of the University channels.

I believe that the importance and scope of the full scale study deserves a well planned and carefully researched feasibility effort. By allocating an adequate amount of personnel effort to the feasibility study, we can be much more realistic about the limitations of a full scale study and, hopefully, save the industry the burden of investing in a poorly planned research endeavor.

I will be happy to discuss personally with you any aspect of our proposal and I look forward to your reaction to the attached research plan.

Sincerely yours,

Bernie

B. G. Greenberg
Dean

BGG/fwa
Enclosure - Proposal for Feasibility Study
cc: Dr. Carl M. Shy

Ross - I am notifying you of what the feasibility will cost at this early stage, in case SPI want to back down before sending the formal letter.

LIVER ANGIOSARCOMA CASES AMONG
VC POLYMERIZATION WORKERS²

Case No.	Country	Date of Death	Years after First Exposure	Years of Exposure	Age at Diagnosis
1	West Germany	1969	11	11	39
2	United States	Alive	12	12	45
3	United States	1971	14	13	37
4	West Germany	1971	14	14	40
5	United States	1968	15	15	44
6	United States	1961	15	15	41
7	United States	1968	17	17	54
8	United States	1969	18	4	41
9	Sweden	1970	19	18	43
10	United States	1969	20	15	50
11	United States	1964	20	18	52
12	United States	1973	22	16	51
13	Norway	1972	22	21	56
14	United States	1970	23	23	60
15	United States	1968	24	18	45
16	United Kingdom	1972	26	20	71
17	United States	1973	28	28	59
18	United States	Alive	29	17	43
19	United States	1974	30	30	52
20	Czechoslovakia	Awaiting Details			
21	Czechoslovakia	Awaiting Details			

Table 2. A COMPARISON OF MORTALITY STUDIES AMONG VINYL CHLORIDE WORKERS

Comparison	Study				
	Tabershaw/ Cooper	Dow	NIOSH	Nicholson	Monson
Number of Plants	33	1	2	1	2
Study Population					
a) Yrs. exposed	1 yr or more	1 yr or more	5 yrs or more	5 yrs or more	No Restriction
b) Onset since first exposure	No restriction	No restriction	At least 10 yrs	At least 10 yrs	No Restriction
c) Size of cohort	8,384	522	930	257	--
d) No. successfully followed up	7,128 (85%)	505 (97%)	645 (69%)	255 (99%)	--
e) No. of deaths	352	88	109	24	161
SMR's or Relative Risk					
All causes of death	75	91	103	126	--
All cancers	110 (total 114 (only those with 5 yrs or more exposure)	84 (total) 250 (only those with high exposure with at least 15 yrs after onset of exposure)	157**	231	150*
Multiple cancer sites suggested	Yes	Yes	Yes	Yes	Yes
Angiosarcoma of the liver found	Yes	No	Yes (?)	Yes	Yes

* Statistically significant at $p < 0.05$ ** Statistically significant at $p < 0.01$

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1. Classification of exposure levels according to process

<u>Process</u>	<u>Exposure Levels by Job</u>		
	Low	Middle	High
A. Monomer manufacture			
B. Polymer manufacture	"	"	"
C. Fabrication of end products	"	"	"

Note: A full time employee (industrial hygienist) x 8 months will be required to obtain familiarity with these process and job classifications. The researcher will determine the feasibility of obtaining substantiating measurements of vinyl chloride especially at various fabricating operations.

2. Computation of number of workers within each process and job category, and inventory of medical records available in each plant. Feasibility and methods to obtain death records on retirees and industry drop-outs must also be investigated. This function will also require a full time employee (epidemiology associate) x 8 months.

3. Each of the above employees will be required to spend considerable time visiting industry headquarters and plant locations. Fifty percent of the employees time will be spent in the field, for a total of 170 man-days of per diem. Each of the two employees are likely to make 3 trips/month, for a total of 48 trips.

4. Evaluation of data sources identified by the above researchers and planning, design and protocol development for a full scale mortality and morbidity survey. This effort will require 10% of the time of each of three senior level persons: a biostatistician, epidemiologist and industrial hygienist.

5. The final product of the feasibility study will be a written report on the data sources, quality of data, research design including a protocol, level of effort and cost of conducting the mortality and morbidity survey of vinyl chloride exposed workers.
6. The estimated time interval for performance of the feasibility study, from contract award to completion of the final report, is eight months.

The feasibility study will be conducted by a research team consisting of a principal investigator, a research assistant, and a research coordinator.

The principal investigator will be responsible for the overall management and coordination of the study. The research assistant will be responsible for the collection and analysis of data. The research coordinator will be responsible for the day-to-day management of the study. The study will also require the services of a statistician, a biologist, and a chemist. The principal investigator will also be responsible for the preparation of the final report.

The research team will be composed of the following individuals: the principal investigator, the research assistant, the research coordinator, the statistician, the biologist, and the chemist. The principal investigator will be responsible for the overall management and coordination of the study. The research assistant will be responsible for the collection and analysis of data. The research coordinator will be responsible for the day-to-day management of the study. The statistician will be responsible for the statistical analysis of the data. The biologist will be responsible for the biological aspects of the study. The chemist will be responsible for the chemical aspects of the study.

The study will require the services of the following personnel: a statistician, a biologist, a chemist, and a research assistant. The principal investigator will be responsible for the overall management and coordination of the study. The research assistant will be responsible for the collection and analysis of data. The research coordinator will be responsible for the day-to-day management of the study. The statistician will be responsible for the statistical analysis of the data. The biologist will be responsible for the biological aspects of the study. The chemist will be responsible for the chemical aspects of the study.

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IV. Estimated Budget for Feasibility Study

I. Salaries

1. Senior level faculty consultants in epidemiology biostatistics and industrial hygiene @ 10% level for 8 mos. each = 2.4 man mos.	\$ 10,000
2. Two field investigators (industrial hygienist and epidemiology associate) @ 100% x 8 mos. = 16 man mos. @ \$15,000 per year	20,000
3. Secretary @ 40% level x 8 mos = 3.2 man mos. @ \$7,000 per year	2,240
4. Clerk @ 20% level x 8 mos. = 1.6 man mos. @ \$7,000 per year	<u>1,120</u>
Subtotal	\$ 33,360

II. Fringe benefits @ 15% of salary \$ 5,004

III. Travel

1. 170 man-days @ \$35 per diem	\$ 5,950
2. 48 trips @ \$200 travel fare/trip	<u>9,600</u>
	\$ 15,550

IV. Miscellaneous expenses

1. Telephone, duplicating, office supplies, computer services	\$ 3,000
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V. University overhead @ 48.13% of direct salaries \$ 16,057

Estimated Total Budget \$ 72,971

APPENDIXLITERATURE REVIEW ON VINYL CHLORIDE INDUCED CANCERS IN HUMANS

In January 1974, the B.F. Goodrich Company in Louisville reported to the National Institute of Occupational Safety and Health that three deaths from hemangiosarcoma of the liver had occurred in polyvinyl chloride production workers (JL Creech, J. Occup. Med 16:150-151, 1974). Subsequently a total of 15 cases of hemangiosarcoma of the liver was identified among workers with a history of occupational exposure to vinyl chloride.

These associations are significant because of the experimental evidence that Vinyl chloride, administered to rats and mice at concentrations of 50ppm and greater, induced angiosarcoma of the liver, and other tumors including pulmonary adenomas and mammary carcinomas (in mice) and zymbal gland carcinomas and nephroblastomas (in rats). (References: C. Maltoni, Envir. Res 7:387-405, 1974; P.L. Viola, Cancer Res. 31:516-519, 1971).

Prior to these observations, vinyl chloride has been treated as a relatively innocuous gas. Exposure to high concentrations exceeding 500ppm resulted in a mild anesthetic action and a reversible lung irritation. In 1971, the threshold limit value was lowered from 500 to 200ppm, based largely upon the increased occurrence of acroosteolysis in occupationally exposed workers and evidence of liver toxicity in animals. Shortly after the discovery of the human carcinogenic properties of vinyl chloride, the TLV was lowered to 50ppm, and an ultimate limit of 1ppm was proposed.

Under contract from the Manufacturing Chemists Association, Tabershaw and Gaffey (J Occup. Med 16:509-518, 1974) computed mortality rates of workers from 33 plants who had worked for at least one year in a job involving exposure to vinyl chloride.

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Eighty-five percent of workers, or 7128 individuals, were traced, and standardized mortality ratios were computed against the mortality experience of U.S. males of the same ages. Overall mortality of the study population was significantly lower (75% of expected) than that of the U.S. male population. However, for several malignant neoplasms the SMR increased with increasing exposure (measured by level, duration, or both). In the high exposure group with 5 or more years of exposure, the SMR for total malignant neoplasms was 141; for malignant neoplasms of digestive organs and peritoneum: 151; for malignant neoplasms of respiratory system: 144; for malignant neoplasms of other and unspecified sites: 204; and for lymphomas: 222.

Workers with low estimated exposure levels were found to have SMRs less than 100 for all cancers except those of the buccal cavity and pharynx (SMR=30) and of other and unspecified sites (SMR=146). However, cancer of the buccal cavity did not correlate with duration or intensity of exposure. The authors concluded that mortality from digestive and respiratory cancer, cancer of other and unspecified sites, and lymphomas appeared to be related to duration and intensity of exposure. About 40% of the observed deaths in the category of "other and unspecified" cancers were due to brain cancer. With the exception of buccal cavity and "other and unspecified" cancers, workers having lower level exposures to vinyl chloride revealed SMRs less than 100 for all cancerous and non-cancerous causes.

The distribution of causes-of-death among 161 deceased workers in two plants, a vinyl chloride monomer and a polymer manufacturing plant, were compared with proportional mortality ratios for U.S. white males (Monson, Lancet ii:397-398, 1974). A 50% proportional excess of deaths due to all cancers was found, with the greatest excess in cancers of the liver and biliary tract, lung and brain. These data were supportive of findings from the larger study by Tabershaw and Gaffey.

had worked for at least one year in a job involving exposure

Current manifestations of angiosarcoma of the liver are generally the result of high occupational exposures beginning 15-20 years ago. Table 1 (taken from an unpublished EPA report on vinyl chloride) provides data suggesting a latent period of 11-20 years between first exposure and clinical manifestation of tumor. This latent period suggests that the full impact of vinyl chloride exposure may not be realized for 10 or more years, unless current reductions in occupational exposure exert an immediate beneficial effect.

With respect to general community exposures, two confirmed angiosarcoma cases have been reported from Connecticut (EPA report, op. cit.), one in a 73-year old man who had lived his entire life within 2 miles of an electrical products factory which processed electrical insulation made of polyvinyl chloride. The other case was an 83-year old woman who resided for 35 years within one-half mile of the vinyl chloride products plant. The old age and long-term low level exposures of these non-occupational cases suggest that low level exposures may not be entirely innocuous and that the latent period may be greatly increased under these circumstances.

Ben Holder of the Dow Chemical Company (testimony presented at public hearing on the proposed standard for occupational exposure to vinyl chloride, U.S. Dept. of Labor, Washington, D.C., June 25, 1974 -- cited in EPA report, op. cit.) reported results of a long-term mortality study of 594 chemical workers exposed to vinyl chloride between 1942 and 1960. Each job classification was assigned a vinyl chloride exposure rating based on actual air measurements. A low exposure group consisted of persons with time weighted average concentrations below 25ppm vinyl chloride, an intermediate group with 25-200ppm exposures, and a high group with 200-300+ppm exposures. The authors concluded that an apparent increase above expected (U.S. white male mortality rates) in overall malignancy rates occurred only in the high exposure group. Angiosarcomas were not found at any level of exposure. However assignment to exposure groups was determined

by the highest exposure experienced for one or more months. Only 19 of 163 members in the high exposure group had high level exposures for 10 or more years. Therefore the group as a whole had time weighted average exposures below 200ppm. However, the low exposure group should have included only individuals with exposures less than 25ppm.

Nicholson and colleagues (Mortality Experience of a Cohort of Vinyl Chloride-Polyvinyl Chloride Workers. Paper presented at a Working Group on Toxicity of Vinyl Chloride - Polyvinyl Chloride sponsored by the New York Academy of Sciences, New York City, May 10-11, 1974) identified a cohort of 257 individuals with at least a five year history (subsequent to 1946) of occupational exposure to vinyl chloride in a polymerization plant. All individuals employed in the plant from 1946-1963 and meeting the above criterion were included. The mortality status of these individuals was evaluated from the 10th year of their employment through April 1974; 255 men, or 99% of individuals, were traced. No measurements of actual exposures were available and no effort was made to categorize level of exposures. A total of 24 deaths was identified, 25% above expected (U.S. white male population). Cancer deaths were 131% in excess, and included three confirmed cases of angiosarcoma, one brain cancer and two lymphomas. The study cohort was relatively young at the time of entry to the study, since over half of the men were under age 37 at entry.

NIOSH conducted a study of mortality and morbidity among 930 current and past employees at two vinyl chloride polymerization plants (reported in EPA report, op. cit.). The study population was restricted to workers with 5 or more years employment who had been employed in the polymerization process at least 10 years prior to the study. Unfortunately 31% (285 individuals) were not successfully contacted, and these individuals were conservatively assumed to be alive. In spite of this assumption, a

significant 57% excess in cancer deaths above expected (U.S. white male population) was observed. Excess deaths were found for cancers of the liver, respiratory, hematopoietic, brain and central nervous systems. Liver cancers were 12 times expected. The majority of cancer deaths (25 of 31) did not occur until at least 15 years following first exposure to vinyl chloride.

The attached Table 2 is taken from the previously cited EPA report and summarizes the findings of the above described studies.

The attached Table 2 is taken from the previously cited EPA report and summarizes the findings of the above described studies. The study population was restricted to workers who had been employed in the polymerization process at least 10 years prior to the study. Unfortunately 312 (28%) individuals were not successfully contacted, and these individuals were conservatively assumed to be alive. In spite of this assumption, a

Table showing the excess of mortality and morbidity data. The current and past exposure to vinyl chloride polymerization process reported in EPA report, 11/11/77. The study population was restricted to workers who had been employed in the polymerization process at least 10 years prior to the study. Unfortunately 312 (28%) individuals were not successfully contacted, and these individuals were conservatively assumed to be alive. In spite of this assumption, a

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Proposal for a Feasibility Study
of Cancer Mortality and Morbidity Among Vinyl Chloride Exposed Workers

I. Objectives

In this feasibility study, investigators from the University of North Carolina would obtain information from operating plants concerning existing records and data that would be required (1) to classify vinyl chloride exposures of workers by process (monomer or polymer manufacture or fabrication of end products) and by job within each plant, (2) to compute mortality rates for specific disease categories among actively employed, retirees and drop-outs from the industry. From these data sources the investigators would determine the cost and feasibility of mortality and morbidity surveys of vinyl chloride exposed workers at all stages of vinyl chloride manufacture and fabrication into end-products, and would develop a protocol for such surveys, if deemed to be feasible.

II. Background

Five mortality studies of vinyl chloride exposed workers have been conducted to date. These studies are summarized in the appendix to this proposal. The important points to note from these studies are the following:

1. Most tumors were manifested 11 to 20 years after onset of exposure to vinyl chloride.
2. Excess deaths are not attributable only to angiosarcoma of the liver, but include cancers of the respiratory and hematopoietic systems and brain.
3. Some angiosarcomas (two, to date) may be attributable to low level non-occupational exposures. The possibility of excess lung cancers, lymphomas and brain cancers associated with low level occupational and non-occupational exposures must be seriously considered.

E. G. Greenberg
Dean

BGG:fm
Enclosure - Proposal for Feasibility Study
cc: Dr. Carl M. Sky

4. Clear excesses of cancer mortality were demonstrated only in persons with exposures exceeding 100-200ppm, when such measurements were available to categorize work exposures.

III. Scope of Work

A. The following factors must be considered in a mortality study of vinyl chloride exposed workers:

1. Date of onset of exposure to vinyl chloride; age, race and sex of exposed person.
2. Duration of employment in vinyl chloride process.
3. Estimates of exposure level for each job classification in the vinyl chloride process, including monomer, polymer and fabrication processes.
4. Measurements of vinyl chloride concentrations to substantiate some of the above work exposures.
5. Measurement of vinyl chloride concentrations in various polyvinyl chloride fabricating processes.
6. Important covariate information: smoking history, alcohol history, history of chronic respiratory disease and liver disease, history of exposure to solvents in other jobs and in home hobbies.
7. Death records of persons who died while employed or after retirement.
8. Names of individuals who left the industry before retirement, and follow-up contact with these individuals.
9. Validation of liver and other gastrointestinal deaths by pathological tissue examination.

B. In the proposed feasibility study, investigators would ascertain data sources, quality of data, level of effort and cost of obtaining information on the factors

identified above (in III A). Specifically, the following activities would be undertaken:

1. Data analysis: The data may be attributable to low level non-occupational exposures. The possibility of excess lung cancer, hepatoma and renal cancers associated with low level occupational and non-occupational exposures must be seriously considered.

THE
UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 74-2071

OIL, CHEMICAL AND ATOMIC WORKERS
INTERNATIONAL UNION, AFL-CIO,

Petitioner,

v.

PETER J. BRENNAN, SECRETARY, UNITED
STATES DEPARTMENT OF LABOR, and
JOHN H. STENDER, ASSISTANT SECRETARY OF
LABOR FOR OCCUPATIONAL SAFETY AND
HEALTH,

Respondents.

PETITIONER'S OPPOSITION TO MOTION OF FIRESTONE
PLASTICS COMPANY AND UNION CARBIDE CORPORATION
TO DISMISS PETITION FOR REVIEW

Firestone Plastics Company, a Division of The Firestone Tire & Rubber Company ("Firestone"), and Union Carbide Corporation ("Union Carbide"), filed a joint motion to intervene in the above case on January 13, 1975, and simultaneously filed a Motion to Dismiss the Petition for Review. As grounds for dismissal, Firestone and Union Carbide allege that since petitioner's principal place of business and general offices are in Denver, Colorado, this Court lacks venue under section 6(f) of the Occupational Safety and Health Act, 29 U.S.C. §655(f)(1970).

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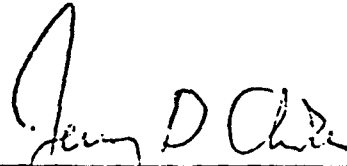
Section 6(f) of the Act states in pertinent part:

"Any person who may be adversely affected by a standard issued under this section may at any time prior to the sixtieth day after such standard is promulgated file a petition challenging the validity of such standard with the United States Court of Appeals for the Circuit wherein such person resides or has his principal place of business, for a judicial review of such standard" (Emphasis added.)

The Motion to Dismiss totally ignores the statutory language providing for the filing of a petition for review in any Circuit wherein the petitioner "resides." The Supreme Court has held that an unincorporated association, such as a labor union, "resides" for venue purposes wherever it is "doing business" and not just where it maintains its principal place of business. Denver & Rio Grande Western Railroad Co. v. Brotherhood of Railroad Trainmen, et al., 387 U.S. 556 (1967).

The petitioner, Oil, Chemical and Atomic Workers International Union, does business in the judicial district of this Court. It maintains offices at 1126 Sixteenth Street, N. W., Washington, D. C. 20036. It has a full-time staff at that office, and transacts business in the District of Columbia on behalf of its members. It therefore "resides" within the District of Columbia.

WHEREFORE, the Motion to Dismiss should be denied.



Jerry D. Anker
Lichtman, Abeles, Anker & Nagle, P.C.
1730 M Street, N. W. - Suite 900
Washington, D. C. 20036

January 22, 1975

Attorney for Petitioner

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Petitioner's Memorandum in Opposition to the Motion of Firestone Plastics Company, A Division of The Firestone Tire & Rubber Company, and Union Carbide Corporation to Dismiss Petition for Review Filed by Oil, Chemical and Atomic Workers International Union was served by first-class mail, postage prepaid, this 22nd day of January, 1975, on the following counsel:

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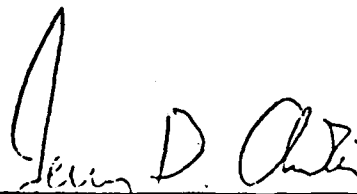
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