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R&S 109619

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Brief Summary

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Firestone
PLASTICS COMPANY

TELEPHONE: 215-326-2000

February 4, 1980

Dr. T. R. Torkelson
The Dow Chemical Company
Health & Environmental Research
9008 Building
Midland, Michigan 48640

R&S 109620

Dear Dr. Torkelson:

Attached is a copy of the "Pasternack—Firestone" cohort study of employees exposed to VCM. This study was part of the presentation Firestone made at the June, 1974 OSHA hearings concerning the proposed VCM standard. As we discussed, one of the criticisms of this study was the selection of tire workers as the comparison group. You will note, however, that Dr. Pasternack also compared the Firestone Plastics Company employee deaths to the relative frequency of specific causes of death among U.S. white males in 1968.

I hope this information will be of value to you. Should you have further questions, I would be happy to attempt an answer.

Sincerely,

Ray Arnold

R. W. Arnold
Technical Manager

RWA:djs

Attachment

EPI FILE

Firestone
PLASTICS COMPANY

TELEPHONE: 215-326-2000

April 4, 1979

Dr. T. R. Torkelson
The Dow Chemical Company
Bennett Building
2030 Dow Center
Midland, MI 48640

Dear Ted:

At the March 30, 1979 meeting of the SPI-PVC Safety Group it was suggested that manufacturers who were in possession of worker epidemiology studies send these data to you. Enclosed is a study by Dr. Bernard S. Pasternack titled "A Proportional Mortality Study of Workers Exposed to Vinyl Chloride 1947-1974." This study was incorporated into the statement presented to OSHA during the June, 1974 hearings.

If you have any questions regarding these data, please do not hesitate to give me a call. Best wishes for a pleasant summer season.

Sincerely,

Russell A. Park

lfc
cc: Mr. T. C. Walker

Mr. John R. Lawrence
Technical Director
The Society of the Plastics Industry
355 Lexington Avenue
New York, NY 10017

Mr. D. C. Nuechterlein
Dow Chemical USA
2020 Dow Center
Midland, MI 48640

Enclosure

R&S 109621

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
U. S. DEPARTMENT OF LABOR
WASHINGTON, D. C.

STATEMENT OF POSITION OF FIRESTONE PLASTICS COMPANY, A DIVISION OF THE FIRESTONE TIRE & RUBBER COMPANY, WITH RESPECT TO THE PROPOSED PERMANENT STANDARD DEALING WITH OCCUPATIONAL EXPOSURE TO VINYL CHLORIDE

WALTER J. CONNOLLY, JR.,
Assistant General Counsel
The Firestone Tire & Rubber Company
1200 Firestone Parkway
Akron, Ohio 44317
(216) 379-7777

Of Counsel:
VEDDER, PRICE, KAUFMAN & KAMMHOLZ
39 South LaSalle Street
Chicago, Illinois 60603
(312) 609-7500

Dated: June 28, 1974

A Proportional Mortality Study of Workers Exposed to Vinyl Chloride 1947-74

0000245

R&S 109623

by

Bernard S. Pasternack, Ph.D.

SUMMARY

The mortality experience of 433 employees who worked at The Firestone Tire & Rubber Company Pottstown complex and died during the period 1947-74 has been examined. Eighty-five of the 433 deceased employees worked in the chemical plant or plastics plant and were exposed to vinyl chloride; the remaining 348 worked in the tire plant and were not exposed to vinyl chloride. Death certificates were obtained for all 433 employees and the cause of death was coded according to the 8th revision of *The International List of Diseases and Causes of Death (1967)* by Michael Baden, M.D. Twelve additional employees have been identified as having died in the period 1947-74 (2 exposed and 10 nonexposed) but cause-of-death information was not available for these employees at the time of this analysis. The 445 employees who died since 1947 includes all workers who died while employed by Firestone or after their retirement. In addition, Firestone identified all of the employees who worked at Pottstown since 1947, had at least three years exposure to vinyl chloride, and terminated for some reason other than death or retirement. Of the 228 employees in this category (out of a total of 750 employees known to have worked in either the chemical plant or plastics plant), Firestone was able to trace all but 18 (8%) and verify that they are

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still alive (207 or 91%) or deceased (3 or 1%). No follow-up was performed on nonexposed ex-employees.

There was an excess of malignant neoplasms in both the exposed and nonexposed employees, and a statistically significant excess in major cardiovascular deaths in the nonexposed employees, compared with the U.S. male population (1968) adjusted for age at death (Table 1). Comparison of the exposed employees with the nonexposed employees shows a slight excess in malignant neoplasms and a small deficit in major cardiovascular deaths in the exposed (Table 2)--neither statistically significant. Further comparisons involving 4 subgroups of the exposed employees (< 10 years work exposure; ≥ 10 years work exposure; "low" level exposure; "medium" level exposure) show no significant differences between observed and expected deaths (Tables 3-8).

Two findings should be stressed:

(1) One death due to angiosarcoma of the liver was confirmed in an employee, classified as having had "medium" level exposure, who died in 1969 at the age of 51--21 years after first exposure to vinyl chloride (with 19.4 years of work exposure). This single angiosarcoma death was the same one previously identified (independently) by Firestone.

(2) The ages-at-death were significantly lower in the exposed employees compared with the nonexposed employees ($P < .05$); the mean (± S.D.) ages of death being 55.3 (± 13.1) - exposed and 59.5 (± 14.6)-nonexposed (Tables 9 and 10). In particular, 21 out of the 22 deaths due to malignant neoplasms (95.5%) for the exposed employees occurred at ages < 65 compared with 44 out of 73 (60.3%) for the nonexposed. This difference is statistically significant at the 0.01 probability level. On the other hand, 32 out of the 46 deaths due to major cardiovascular diseases (69.6%) for the exposed employees occurred at ages < 65 compared with 121 out of 218 (55.5%) for the nonexposed--a

difference that is not statistically significant. Thus, the earlier ages noted for the cancer deaths in the exposed group of employees may not be solely attributable to a presumably younger cohort at risk.

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TABLE 1.-Observed and expected† number of deaths due to selected causes among exposed and nonexposed employees, 1947-74

Cause of death	List No.††	Observed (and expected) deaths	
		Exposed	Nonexposed
Malignant neoplasms	140-209	22(15.4)	73(61.1)
Digestive	150-159	8(4.3)	24(17.5)
Liver	155	1	3
Respiratory system	160-163	8(5.4)	25(19.9)
Urinary organs	188-189	1(0.8)	3(3.5)
Brain	191	1	3
Lymphatic and hematopoietic	200-209	1(2.1)	7(7.8)
Other	—	3	11
Major cardiovascular	390-448	46(41.1)	218(178.5)**
Cirrhosis of liver	571	3(1.8)	4(5.7)
Accidents	800-949	8(8.0)	21(28.9)
Suicides	950-959	0(2.5)	6(8.3)
All other causes	—	6(16.2)	26(65.5)
Total	0-989	85(85.0)	348(348.0)

†Age-adjusted expected numbers determined from relative frequency of specific causes of death among U.S. white males in 1968.

††Eighth revision of *International List of Diseases and Causes of Death, 1967.*

**Statistically significant difference ($P < 0.01$).

TABLE 2.-Observed and expected† number of deaths due to selected causes, with chi-square values, among exposed employees, 1947-74

Cause of death	List No.†	Number of deaths		Mantel-Haenszel summary Chi-square values
		Observed	Expected	
Malignant neoplasms	140-209	22	19.4	0.36
Digestive	150-159	8	6.5	0.23
Liver	155	1	1.0	0.33
Respiratory system	160-163	8	6.8	0.11
Urinary organs	188-189	1	0.7	0.09
Brain	191	1	1.0	0.33
Lymphatic and hematopoietic	200-209	1	1.9	0.00
Other	—	3	2.5	-
Major cardiovascular	390-448	46	50.5	1.08
Cirrhosis of liver	571	3	1.6	0.65
Accidents	800-949	8	6.7	0.18
Suicides	950-959	0	1.1	0.46
All other causes	—	6	5.7	-
Total	0-989	85	85.0	-

†Age-adjusted expected numbers determined from relative frequency of specific causes of death among the 348 nonexposed employees, with adaptation of the Mantel-Haenszel procedure.

‡See footnote, table 1.

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TABLE 3.-Observed and expected† number of deaths due to selected causes, with chi-square values, among employees with < 10 years work exposure, 1947-74

Cause of death	List No.‡	Number of deaths		Mantel-Haenszel summary Chi-square values
		Observed	Expected	
Malignant neoplasms	140-209	16	12.2	1.37
Digestive	150-159	6	4.0	0.71
Liver	155	0	0.6	0.01
Respiratory system	160-163	7	4.5	1.17
Urinary organs	188-189	0	0.8	0.23
Brain	191	0	0.6	0.01
Lymphatic and hematopoietic	200-209	1	1.4	0.02
Other	---	2	0.6	-
Major cardiovascular	390-448	26	31.0	2.10
Cirrhosis of liver	571	1	0.9	0.25
Accidents	800-949	7	4.9	0.87
Suicides	950-959	0	0.8	0.13
All other causes	---	3	3.2	-
Total	0-989	53	53.0	-

†*See* footnote, table 2.

‡*See* footnote, table 1.

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TABLE 4.-Observed and expected† number of deaths due to selected causes, with chi-square values, among employees with ≥ 10 years work exposure, 1947-74

Cause of death	List No.†	Number of deaths		Mantel-Haenszel summary Chi-square values
		Observed	Expected	
Malignant neoplasms	140-209	6	6.8	0.01
Digestive	150-159	2	2.2	0.04
Liver	155	1	0.4	0.05
Respiratory system	160-163	1	2.2	0.26
Urinary organs	188-189	1	0.3	0.08
Brain	191	1	0.4	0.05
Lymphatic and hematopoietic	200-209	0	0.7	0.05
Other	—	1	1.0	-
Major cardiovascular	390-448	20	20.2	0.01
Cirrhosis of liver	571	2	0.5	1.88
Accidents	800-949	1	1.7	0.04
Suicides	950-959	0	0.5	0.00
All other causes	—	3	2.3	-
Total	0-989	32	32.0	-

†*See* footnote, table 2.

†*See* footnote, table 1.

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TABLE 5.-Observed and expected† number of deaths due to selected causes, with chi-square values, among employees with < 10 years work exposure, 1947-74

Cause of death	List No.†	Number of deaths		Mantel-Haenszel summary
		Observed	Expected	Chi-square values
Malignant neoplasms	140-209	16	14.8	0.15
Digestive	150-159	6	5.5	0.00
Liver	155	0	0.7	0.15
Respiratory system	160-163	7	5.2	1.12
Urinary organs	188-189	0	0.7	0.15
Brain	191	0	0.7	0.06
Lymphatic and hematopoietic	200-209	1	0.7	0.28
Other	—	2	2.0	—
Major cardiovascular	390-448	26	26.9	0.04
Cirrhosis of liver	571	1	1.7	0.07
Accidents	800-949	7	5.7	0.48
Suicides	950-959	0	0.0	0.00
All other causes	—	3	3.9	—
Total	0-989	53	53.0	—

†Age-adjusted numbers determined from relative frequency of specific causes of death among the 32 employees with ≥ 10 years work exposures, with adaptation of the Mantel-Haenszel procedure.

†*See* footnote, table 1.

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TABLE 6.-Observed and expected† number of deaths due to selected causes, with chi-square values, among employees in the "low" level exposed group, 1947-74

Cause of death	List No.‡	Number of deaths		Mantel-Haenszel summary Chi-square values
		Observed	Expected	
Malignant neoplasms	140-209	11	10.2	0.01
Digestive	150-159	3	3.4	0.42
Liver	155	1	0.5	0.00
Respiratory system	160-163	4	3.6	0.00
Urinary organs	188-189	1	0.3	0.28
Brain	191	1	0.5	0.00
Lymphatic and hematopoietic	200-209	0	1.2	0.11
ther	—	2	1.2	-
Major cardiovascular	390-448	26	27.6	0.13
Cirrhosis of liver	571	2	1.0	0.35
Accidents	800-949	7	4.6	1.15
Suicides	950-959	0	0.8	0.12
All other causes	—	1	2.8	-
Total	0-989	47	47.0	-

† *See* footnote, table 2.

‡ *See* footnote, table 1.

TABLE 7.-Observed and expected† number of deaths due to selected causes, with chi-square values, among employees in the "medium" level exposed group, 1947-74

Cause of death	List No.‡	Number of deaths		Mantel-Haenszel summary Chi-square values
		Observed	Expected	
Malignant neoplasms	140-209	11	8.6	0.62
Digestive	150-159	3	2.8	0.03
Liver	155	1	0.5	0.00
Respiratory system	160-163	4	2.9	0.14
Urinary organs	188-189	1	0.4	0.03
Brain	191	1	0.5	0.00
Lymphatic and hematopoietic	200-209	0	0.9	0.19
Other	—	2	1.1	-
Major cardiovascular	390-448	20	23.9	1.52
Cirrhosis of liver	571	1	0.5	0.00
Accidents	800-949	1	1.9	0.11
Suicides	950-959	0	0.5	0.00
All other causes	—	5	2.6	-
Total	0-989	38	38.0	-

†*See* footnote, table 2.

‡*See* footnote, table 1.

TABLE 8.-Observed and expected† number of deaths due to selected causes, with chi-square values, among employees in the "low" level exposed group, 1947-74

Cause of death	List No.†	Number of deaths		Mantel-Haenszel summary Chi-square values
		Observed	Expected	
Malignant neoplasms	140-209	11	12.5	0.25
Digestive	150-159	5	4.6	0.00
Liver	155	0	0.5	0.00
Respiratory system	160-163	4	4.4	0.00
Urinary organs	188-189	0	0.6	0.01
Brain	191	0	0.5	0.00
Lymphatic and hematopoietic	200-209	1	0.7	0.28
Other	—	1	1.7	-
Major cardiovascular	390-448	26	24.0	0.48
Cirrhosis of liver	571	2	1.5	0.00
Accidents	800-949	7	5.3	1.01
Suicides	950-959	0	0.0	0.00
All other causes	—	1	3.7	-
Total	0-989	47	47.0	-

†Age-adjusted numbers determined from relative frequency of specific causes of death among the 38 employees in the "medium" level exposed group, with adaptation of the Mantel-Haenszel procedure.

†*See* footnote, table 1.

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Table 9.-Distribution of deaths by age and cause for exposed and nonexposed employees, 1947-74

Cause of Death	List No.†	Group†	Age at Death ≤ 34	35-44	45-54	55-64	≥ 65	Total
Malignant neoplasms	140-209	E	0	3	5	13	1	22
		NE	0	11	15	18	29	73
Digestive	150-159	E	0	1	3	4	0	8
		NE	0	2	6	5	11	24
Respiratory system	160-163	E	0	1	0	6	1	8
		NE	0	5	3	8	9	25
Urinary organs	188-189	E	0	0	1	0	0	1
		NE	0	0	0	1	2	3
Lymphatic and hematopoietic	200-209	E	0	1	0	0	0	1
		NE	0	0	4	2	1	7
Major cardiovascular	390-448	E	0	4	19	9	14	46
		NE	3	13	47	58	97	218
Cirrhosis of liver	571	E	0	0	1	1	1	3
		NE	0	1	2	1	0	4
Accidents	800-949	E	4	1	3	0	0	8
		NE	11	4	5	0	1	21
Suicides	950-959	E	0	0	0	0	0	0
		NE	1	2	1	0	2	6
All other causes	---	E	0	3	1	1	1	6
		NE	3	3	4	2	14	26
Total	0-989	E	4	11	29	24	17	85
		NE	18	34	74	79	143	348

†E = Exposed.
NE = Nonexposed.

†See footnote, table 1.

TABLE 10.-Distribution of age at death by year of death for exposed and nonexposed groups

Year of Death	Group†	Age at Death ≤ 34	35-44	45-54	55-64	≥ 65	Total
1947-54	E	1	0	0	0	0	1
	NE	8	3	11	8	3	33
1955-59	E	1	3	3	1	0	8
	NE	4	7	9	8	17	45
1960-64	E	0	2	10	6	1	19
	NE	2	11	14	16	31	74
1965-69	E	1	3	9	6	3	22
	NE	2	10	23	18	39	92
1970-74	E	1	3	7	11	13	35
	NE	2	3	17	29	53	104
Total	E	4	11	29	24	17	85
	NE	18	34	74	79	143	348

† E = Exposed
NE = Nonexposed

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R&S 109635

MICHAEL M. BADEN, M.D.
520 FIRST AVENUE
NEW YORK, NEW YORK 10016

June 19, 1974

Mr. Arthur Smith
39 South Lasalle Street
Chicago, Illinois 60603

Dear Mr. Smith:

I have reviewed 433 death certificates and the vinyl chloride exposure records of 445 employees identified by the Firestone Company as the total number of workers at the Pottstown complex who have died since 1947. Included are 85 of 87 employees who were exposed to vinyl chloride. Thus 97.3% of all deaths and 97.7% of the vinyl chloride exposed deaths were examined. Hospital records and histologic slide material were reviewed by me when indicated.

The major findings can be separated into four categories:

1. Angioscarcoma: One angiosarcoma of the liver was identified (which I had not known was previously known to Firestone) and no other angiosarcomas were found among the 433 decedents. This tumor occurred in a 51 year old male in the long exposure higher concentration group 21 years after initial exposure. A single tumor, even a rare one such as angiosarcoma of the liver, can occur spontaneously and, by itself, its significance cannot be properly evaluated. However, when considered together with other data presently available which was not known at the time of the death in 1969, including recent animal studies and reports of angiosarcomas in vinyl chloride exposed persons elsewhere, it appears that this angiosarcoma is consequent to the vinyl chloride exposure.

2. Malignancy in general: There was no significant increase in deaths from any specific malignancy in the exposed and non-exposed employees as demonstrated by Dr. Bernard Pasternak's statistical evaluations. A slight excess of cancers of the respiratory and digestive systems present in both groups when compared to the total United States white male population must be further examined as to smoking habits of these groups and other local environmental factors (including fads among physicians in determining cause of death in non-autopsied fatalities.) This examination should include evaluation of Pottstown employees who are still alive. Such evaluation of living employees is also necessary to further evaluate the finding by Dr. Pasternak, on the basis of information presently available, that the mean age of death from all causes of exposed employees (55.3 years) was less than for non-exposed employees (59.5 years). There may be reasons for this difference other than exposure to vinyl chloride.

The median age of death of those dying of cancer in the exposed group (22/85) is the same as the median age of death of those dying of cancer in the non-exposed group (73/348) -- 58 years). There is no greater number of early deaths from cancer in the exposed group. However, in the exposed group the oldest death from cancer was 67; in the non-exposed group 19 deaths from cancer occurred between 71 and 87 years of age. This difference may be an artifact caused by initial population age differences but should be explored further. There is no difference in all causes of death among the 32 decedents exposed to vinyl chloride for more than 10 years as compared to the 53 decedents who had briefer exposure; and among the 22 malignancies in the exposed group there is no difference in type of cancer in those exposed more or less than 10 years (except for the one angiosarcoma in the longer exposed group).

3. Cirrhosis of the liver: The three fatalities attributed to cirrhosis of the liver in the exposed population and four in the non-exposed population may be accounted for on the basis of alcohol comsumption, a highly significant factor in evaluating the etiology of cirrhosis and a factor which is noticably not mentioned in the medical charts I was able to examine.

4. The Tabershaw and Gaffey study: This mortality study, a draft of which I reviewed which may not be the final report, evaluates mortality rates employing data on living as well as dead employees exposed to vinyl chloride in 34 plants. 8384 workers were identified of which 352 were known to have died and 328 death certificates were reviewed (in 1256 or 15% of the workers they had not yet been able to determine whether the individual was still alive). Dr. Tabershaw states that "This is the first epidemiological study which suggests that in humans vinyl chloride may also be associated with cancer of multiple sites." (The only published report he refers to in support of this concern is work by Viola in which "large doses of the chemical in rats produced cancer of the skin, lung and other organs." When Viola's work was reviewed by Maltoni, the latter concluded that these were not primary cancers but were metastases from Zymbal gland tumors which tumors are produced by a large variety of carcinogens and are not specific for vinyl chloride.) Dr. Tabershaw's data suggests that in humans vinyl chloride exposure may cause an increase in cancers of the digestive system (primarily angiosarcomas), respiratory system (primarily lung cancer), brain, unknown sites and in lymphosarcoma:

Lung cancer - this is the most common fatal malignancy in males in the United States; there was a slight excess of this tumor in the Firestone population in both the exposed and non-exposed groups. The significance of this finding can only be evaluated after obtaining adequate smoking histories.

Brain cancer - there was only one death from a brain tumor in the exposed Firestone group and there were three in the non-exposed group. As Dr. Tabershaw indicates deaths diagnosed as due to primary brain cancers may include metastatic cancers from other undiagnosed primary sites, especially from the lung. (In only one of Dr. Tabershaw's six cases is an autopsy listed as having been performed).
Lymphosarcoma - there was only one death from lymphosarcoma indicated on the death certifications in the exposed Firestone group. On further review of this decedent's medical records (after Dr. Pasternak's study was completed) it became apparent that the cause of death was not a lymphoma but rather a metastatic cancer, probably from the trachea. This demonstrates the necessity of not accepting death certificates at face value. Dr. Tabershaw found six lymphosarcomas in his study which apparently was limited to a review of the death certificates.
Cancer of unknown sites - includes many different types of cancer and cannot be evaluated without reviewing each decedent's medical and autopsy records.

The above represents a preliminary evaluation of vinyl chloride exposed and non-exposed employees from the Pottstown Firestone plant who have died. This group should be evaluated together with employees who have not died so that mortality incidences can be determined and maximal information can be obtained. This further study should include information as to smoking and alcohol habits.

The issue of threshold still remains to be resolved but there may be a level beneath which exposure to vinyl chloride is not harmful.

Sincerely,

Michael Baden

Michael M. Baden, M.D.

MMB:fp

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