*Statement of*

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*Department of Health, Education, and Welfare*

*Before the Subcommittee on the Environment of*
*the United States Senate Commerce Committee*

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15. Supplementary Notes

16. Abstract (Limit: 200 words) This testimony before the Subcommittee on the Environment concerned epidemiological studies dealing with the effects of vinyl-chloride (75014) exposures in the workplace. This substance has been shown to induce toxic effects including hepatic damage and acro osteolysis. On discovering its association with angiosarcoma of the liver, NIOSH met with other agencies having health research responsibility on February 1, 1974. Four working groups were formed: epidemiology, toxicology, industrial hygiene, and analytical methods, to draft plans to address this issue. A selection was made of facilities to be investigated in the epidemiologic aspect of this study, with the criteria being that the facility had been engaged in the polymerization of vinyl-chloride for at least 15 years, that it had a sizable work force, that it was located in a state with an ability to facilitate vital status ascertainment, and that it had an inhouse medical program. During the period from 1950 to 1973, a total of 109 deaths were observed among the vinyl-chloride polymerization workers; 105 would have been expected. The only disease category in which the deaths noted exceeded those expected was in the cancer deaths, a 57 percent increase over that expected. A NIOSH/CDC Surveillance Network has been established for identifying cases of angiosarcoma of the liver in vinyl-chloride polymerization workers. Statistics were provided with the testimony.

17. Document Analysis a. Descriptors

b. Identifiers/Open-Ended Terms NIOSH-Publication, NIOSH-Author, NIOSH-Testimony, WAGONER-J-K, Cancer-rates, Risk-factors, Worker-health, Plastics-industry, Liver-damage, Liver-cancer, Carcinogens, Chlorinated-hydrocarbons, Toxic-effects

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*INTRODUCTION*

*I am Dr. Joseph K. Wagoner, Director of the Division of Field Studies and Clinical Investigations, a program in the National Institute for Occupational Safety and Health (NIOSH), Center for Disease Control (CDC), Department of Health, Education, and Welfare. Under the Occupational Safety and Health Act of 1970 we have responsibilities to undertake industry-wide studies of the effects of chronic or low level exposure to industrial materials, processes and stresses on the potential for illness, disease or loss of functional capacity in aging adults.*

*Although for several years vinyl chloride (VC) had been known to induce toxic effects including hepatic damage and acro-osteolysis, a lesion of the bones of the hand and foot, its potential for liver cancer was not realized until quite recently. On January 22, 1974, the National Institute for Occupational Safety and Health (NIOSH) was informed of several deaths due to angiosarcoma of the liver among former employees of the B. F. Goodrich vinyl chloride polymerization facility in Louisville, Kentucky. This clustering of four angiosarcomas of the liver within a five year period at one vinyl chloride polymerization facility was extremely unusual in view of the rarity of this tumor as reported in the Third National Cancer Survey.*

*In recognition of the urgency and potential seriousness of the problem, NIOSH-CDC held a briefing on February 1, 1974, for other federal agencies with health research responsibility. Included in this meeting were representatives of the National Cancer Institute, the National Institute of*

Environmental Health Sciences, the Food and Drug Administration, the Environmental Protection Agency and the Office of the Assistant Secretary for Health, Department of Health, Education, and Welfare. Following the general briefing, NIOSH-CDC convened four working groups (epidemiology, toxicology, industrial hygiene, and analytic methods) to draft plans for addressing this emerging international epidemic.

My comments today will be restricted to the mission and status of the NIOSH-CDC epidemiology program for vinyl chloride. The recommendations set forth by the epidemiological working group are shown in attachment A.

In brief, the charge to the NIOSH-CDC epidemiology program was as follows: one, to undertake an investigation of mortality and morbidity among current and past employees at VC polymerization facilities, and two, to establish a surveillance network for the identification, review and work-up of cases suspected of or certified as having angiosarcoma of the liver.

MORTALITY AND MORBIDITY INVESTIGATIONS

Initially criteria were established for selection of facilities to be investigated. Those criteria in decreasing order of priority were that the facility:

1. had been engaged in the polymerization of vinyl chloride for at least fifteen (15) years,
2. had a sizable work force,
3. was located in a state with demonstrated ability to facilitate vital status ascertainment and
4. had an inhouse medical program.

Because of time and manpower constraints, epidemiologic results reported today will include only two vinyl chloride polymerization facilities.

Since cancer is an insidious disease, often taking many years to become clinically manifest, the study was restricted to those individuals having achieved five or more years of employment and ten years since onset of initial employment in departments directly related to vinyl chloride polymerization. After these exclusions, the final study cohort consisted of 930 white males. Follow-up of all study cohort members was attempted from the time of termination of employment to December 31, 1973. Vital status ascertainment was made through records maintained by government agencies. In spite of this follow-up program, 285 individuals (31 percent of the study members) were lost to observation. All individuals not located are considered to be alive in the following analysis, thus making conservative any findings of increased mortality among the study cohort. Comparison was made between the observed risk of death and the expected risk based on mortality rates for the general white male population of the United States.

Results

During the calendar period of 1950-1973, a total of 109 deaths was observed among vinyl chloride polymerization workers, whereas 105 would have been expected (Table 1). The overall number of deaths of these workers is just slightly greater than expected, although this could change as the vital status of the lost to follow-up group is determined. Deaths due to each

of the specific causes are not much different than would be expected in all but one disease category - cancer. At this stage of our research, a fifty-seven percent increase in deaths due to cancer beyond what would have been expected has already been observed. When one looks at the make-up of these excess cancer deaths in Table 2, it is seen that they are not limited to any single organ system. An excess cancer mortality is observed for the respiratory system, the blood forming tissues, and the brain and central nervous system. The number of deaths from liver cancer in this population was almost twelve times the number expected. Strikingly, the majority of these excess cancer deaths did not occur until fifteen or more years after first exposure to vinyl chloride. This latent period is consistent with other observations on occupational cancer.

Three points in particular are noteworthy about this study. First of all, the overall mortality risk is at variance with an industry sponsored study of vinyl chloride polymerization employees which showed a deficit in total mortality because of a disproportionate number of recently hired employees. Secondly, the results of this study are consistent with a mortality study by Mt. Sinai School of Medicine at another vinyl chloride polymerization facility showing excess cancer and excess total deaths using the same study criteria as NIOSH-CDC. Finally, these results corroborate the animal experimental findings of Dr. Maltoni showing multiple organ involvement.

Medical surveys of vinyl chloride polymerization facilities have been scheduled for early fall 1974.

*LIVER ANGIOSARCOMA SURVEILLANCE NETWORK*

*The NIOSH-CDC Surveillance Network thus far has identified twenty-one (21) cases of angiosarcoma of the liver in vinyl chloride polymerization workers (Table 3). Fourteen (14) of these cases are reported from the United States and seven from other countries. Case number 8 is most noteworthy. This individual's lifetime work history has been reconstructed. As can be seen in Table 4, this individual's only known exposure to vinyl chloride was at the B. F. Goodrich vinyl chloride polymerization plant during 1950-1954. Eighteen years later, at the age of forty-one, this individual died of angiosarcoma of the liver. This single case suggests that the carcinogenic process, even in the absence of continued exposure, is irreversible.*

*Within the past two months, several deaths from angiosarcoma of the liver have also been identified in individuals with potential exposure to vinyl chloride in other than the vinyl chloride polymerization processes (Table 5). One individual worked in a vinyl chloride monomer production plant, one filled pesticide spray cans with vinyl chloride propellant and two persons worked in vinyl cloth plants. A detailed occupational history of the vinyl cloth plant worker in Glasgow is shown in Table 6. In addition, two cases have been identified in individuals having lived in close proximity to facilities using vinyl chloride or polyvinyl chloride (PVC).*

*In conclusion, the NIOSH-CDC investigation into vinyl chloride points out the importance of industrial studies for identifying potential carcinogenic hazards which may extend into the general population, and the need for pretesting chemical substances by animal bioassay methods.*

Table 1

OBSERVED AND EXPECTED DEATHS AMONG SELECTED EMPLOYEES
OF TWO VINYL CHLORIDE POLYMERIZATION FACILITIES
1950 - 1973

| CAUSES OF DEATH | OBSERVED | EXPECTED | STANDARD MORTALITY RATIO |
|---|---|---|---|
| TUBERCULOSIS | 0 | .74 | -- |
| CANCER | 31 | 19.74 | 157† |
| VASCULAR LESIONS AFFECTING CNS | 6 | 6.45 | 93 |
| DISEASES OF HEART | 43 | 46.12 | 93 |
| NON-MALIGNANT RESPIRATORY DISEASE | 6 | 5.12 | 117 |
| CIRRHOSIS OF LIVER | 2 | 3.21 | 62 |
| VIOLENT DEATHS | 8 | 11.00 | 73 |
| ALL OTHER KNOWN CAUSES | 12 | 13.04 | 92 |
| UNKNOWN CAUSES | | | |
| TOTAL | 109 | 105.42 | 103 |

† SIGNIFICANT AT $p < 0.05$

Table 2

EXPECTED AND OBSERVED DEATHS FROM VARIOUS CANCER CAUSES
1950 - 1973

| YEARS SINCE ONSET OF EXPOSURE IN THE SELECTED DEPARTMENTS | PERSON YEARS AT RISK | ALL CANCER | | LIVER CANCER | | BRAIN CANCER | | RESPIRATORY SYSTEM CANCER | | LYMPHOMA & LEUKEMIA | | RESIDUAL CANCER | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | EXP. | OBS. | EXP. | OBS. | EXP. | OBS. | EXP. | OBS. | EXP. | OBS. | EXP. | OBS. |
| 10 - 14.9 | | 4.91 | 6 | .12 | 0 | .22 | 0 | 1.50 | 3 | .61 | 1 | 2.46 | 2 |
| 15 - 19.9 | | 6.30 | 11 | .17 | 3* | .25 | 1 | 2.08 | 3 | .67 | 2 | 3.13 | 2 |
| 20 - 24.9 | | 5.81 | 11 | .15 | 3* | .20 | 2* | 1.99 | 4 | .55 | 1 | 2.92 | 2 |
| >25 | | 2.72 | 3 | .07 | 0 | .06 | 1 | .92 | 0 | .24 | 0 | 1.43 | 1 |
| TOTAL | 9731 | 19.74 | 31* | .51 | 6** | .73 | 4* | 6.49 | 10 | 2.07 | 4 | 9.94 | 7 |
| Standard Mortality Ratio | | 157 | | 1,176 | | 548 | | 154 | | 193 | | 70 | |

* Significant at $p < 0.05$
** Significant at $p < 0.01$

TABLE 3

LIVER ANGIOSARCOMA CASES AMONG VC POLYMERIZATION WORKERS

| 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 4

CASE NUMBER 8 from Table 3

EMPLOYMENT HISTORY

| DATE | OCCUPATION |
|---|---|
| 2/14/46 - 3/7/47 | Military |
| 3/7/47 - 4/16/48 | Unknown |
| 4/16/48 - 4/6/50 | Military |
| 11/11/51 - 11/12/52 | Chemical helper at a vinyl chloride polymerization plant |
| 11/12/52 - 7/1/53 | Chemical operator at a vinyl chloride polymerization plant |
| 7/1/53 - 3/7/54 | Chemical helper at a vinyl chloride polymerization plant |
| 3/7/54 - 6/13/54 | Chemical operator at a vinyl chloride polymerization plant |
| 6/13/54 - 7/14/55 | Unknown |
| 7/14/55 - 6/30/63 | Military |
| 6/30/63 - 8/1/63 | Unknown |
| 8/1/63 - 2/17/67 | Military |
| 2/17/67 - 3/27/69 | Unknown |
| 3/27/69 | Deceased |

TABLE 5

LIVER ANGIOSARCOMA CASES AMONG NON-VC POLYMERIZATION WORKERS

| COUNTRY | DATE OF DEATH | YEARS AFTER FIRST EXPOSURE | YEARS OF EXPOSURE | AGE AT DIAGNOSIS | NOTES |
|---|---|---|---|---|---|
| UNITED STATES | 1973 | -- | -- | 47 | Accountant at vinyl cloth plants |
| WEST GERMANY | -- | 14 | -- | 43 | Filled pesticide cans with VC propellant |
| UNITED KINGDOM | 1970 | 24 | 11 | 55 | Vinyl cloth plant |
| SWEDEN | 1972 | 27 | 23 | 61 | VC monomer production plant |

TABLE 6

CASE NUMBER 3 from Table 5

EMPLOYMENT HISTORY

| DATE | OCCUPATION |
|---|---|
| 1928-1941 | Worked at factory producing resin covers for furniture and patent leather for shoes |
| 1941-1946 | Navy |
| 1946-1957 | Returned to previous employment where PVC had been introduced during his absence into the plant and was employed pouring PVC-oil mixtures onto fabric bases for covering material |
| 1957-1964 | Barman - no history of alcohol abuse |
| 1964-1969 | Fibrous glass worker |
| 1970 | Deceased |

ATTACHMENT A

# MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

TO : Director, NIOSH
Thru : Director, OHSB

DATE: February 4, 1974

FROM : Deputy Associate Director for
Medical Affairs, Cincinnati Operations

SUBJECT: Recommendations from the Epidemiology Work Group, PVC

Following the general orientation to the health problems associated with the production of polylvinylchloride (PVC), the epidemiology work group composed of Drs. Lloyd, Adamson, Falk, Flynt, Johnson, Mancuso, Wagoner and myself met Friday afternoon, February 1, to consider the two charges which you gave to the Working Group, to wit,

1. Review the MCA study in detail, and
2. Make recommendations as to what the Federal Government can do to expedite, enlarge or supplement that MCA epidemiological study to develop further information on the problem as soon as possible.

It was agreed in the epidemiology work group that:

1. There appears to be a major health problem in the production of PVC from the monomer vinyl chloride (VC);

2. In consideration of the potential scope and seriousness of this problem that NIOSH/CDC take the leadership in the government to attack the problem, assign it top priority and immediately to provide or seek the necessary personnel and funds for implementation. This implementation shall include cooperation with interested groups in government, industry, labor, and elsewhere;

3. The Division of Field Studies and Clinical Investigations (DFSCI) within NIOSH/CDC take the lead in undertaking such steps as necessary to determine the full extent of the mortality and morbidity associated with VC exposure, for industrially exposed occupational groups.

There appear to be four groups of individuals potentially at risk from exposure to VC and where exposure and health effects should be evaluated:

1. Production of the monomer VC;
2. The conversion of VC to PVC, both as pure PVC and as polymers containing other substances;
3. The use of PVC in the production of other products; and
4. Consumer uses of PVC products.

In the light of the unusual frequency of angiosarcoma of the liver in a single polymerization facility, first priority should be given to early ascertainment of the disease experience of Group 2 above.

The immediate program should have the following elements:

1. DFSCI/NIOSH in cooperation with the office of Health Surveillance and Biometrics (HSB) would be involved in:

   a. Assisting Tabershaw, Cooper and Associates in any way possible to complete the study of the B.F. Goodrich PVC operations in Louisville, given no restrictions as to confidentiality except as provided under the Public Health Service regulations (Such assurances were given verbally by Drs. Johnson and Tabershaw.);
   b. A governmentally-sponsored epidemiological study, to begin immediately, of the health hazards associated with the production of PVC in 2-4 plants (other than the Louisville operation) with the longest production experience with, preferably, pure PVC (no co-polymer); and
   c. A determination of the extent of use and distribution of PVC among users of the polymer to estimate the exposure to VC or PVC under such circumstances.

   These actions are to proceed apace and concurrently.

2. OHSB will develop information regarding the potential occupational exposures to VC and PVC through governmental and non-governmental channels.

3. CDC will follow through with its surveillance program for the identification, review, and workup of cases certified as having angiosarcoma on death certificates.

4. NIOSH through the Office of the Director, immediately solicit certain information from other Federal agencies (representatives of which were not in attendance to our work group):

   a. The magnitude and distribution (both past and present) of VC in aerosol sprays from the Food and Drug Administration;
   b. The present use and distribution of VC - containing household products from the Consumer Production Safety Commission; and

c. A letter to be written to the National Cancer Institute alerting them to the problem of hepatic angiosarcoma following VC exposure and requesting that they alert the various cancer registries and other interested groups. In addition, this group of organizations could provide valuable information regarding the extent and geographic distribution of liver cancer in this country.

5. Our concern with citizen exposure to VC in drugs and cosmetics, food and in air and water should be conveyed to the representatives of the various governmental agencies involved.

William S. Lainhart

William S. Lainhart, M.D.

cc: Dr. Fairchild
Dr. Craft
Dr. Adamson
Dr. Falk
Dr. Flynt
Dr. Johnson
Dr. Mancuso
Dr. Wagoner