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REPORT ON A MORTALITY STUDY
COVERING EMPLOYEES OF PVC
FABRICATORS

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Organization for Resources
Courseware, Inc.

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I. OVERVIEW

The mortality study described in this report was undertaken to determine whether there were excessive numbers of deaths attributable to any one cause among employees engaged in the fabrication of products made at least in part of polyvinyl chloride resin. Specifically, it sought to find out if there had been any death in which angiosarcoma of the liver was identified as a cause. Using death certificates, the study examined the cause of death for 4,592 employees who died within the period 1964-1973.

The study was made possible by the financial support of organizations in the plastics industry. Since the risk of vinyl chloride exposure centers primarily in the production process, the opportunity to participate was publicized initially among the producers of vinyl chloride monomer and polymer chloride resins. However, the opportunity was open to fabricators as well.

The organizations sponsoring the study included:

- American Can Company
- B. F. Goodrich Company
- Diamond Shamrock Corporation
- Firestone Tire and Rubber Company
- Johns-Manville Corporation
- Motor Vehicle Manufacturers Association
- Stauffer Chemical Company
- Union Carbide Corporation
- Uniroyal, Incorporated

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In total, 18 companies with a total of 54 plants supplied data. A nineteenth company which provided data was eliminated because its deaths fell outside the study period. Total employment in the plants of the 18 companies approximated 65,000 to 70,000 employees at the end of 1973.

Administration of the study was under the direction of Organization Resources Counselors, Inc. (ORC). Accordingly, ORC identified the possible study population, secured participation, contracted with a nosologist and field workers to obtain needed data, explained the study to insurance carriers and hospital administrators, and provided the staff needed in the preparation of reports. Key personnel who collaborated in the study for ORC were:

Leo Teplow, special consultant to ORC, who directed the feasibility stage.

Leonard Chiazze, Sc.D., then director, Division of Biostatistics and Epidemiology, Department of Community Medicine and International Health, Georgetown University School of Medicine, Washington, D. C., who designed the protocol, provided for computer programming and interpreted the data in the interim report.

Otto Wong, Sc.D., instructor in Community Medicine at Georgetown University, who interpreted the data in this final report.

William E. Nichols, Ph.D., ORC consultant, who served as project manager. He was assisted by other members of the ORC staff, as follows: Wayne T. Brooks, Frances Palladini, Carolyn Sutherland, and Robert H. Willey.

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Clara Walden, an employee of the Department of Health, Education and Welfare at Triangle Park, North Carolina, who contracted as the nosologist.

Claire Goodwin, Registered Records Administrator, assistant administrator of Augusta General Hospital, Augusta, Maine, and Patricia Walker, Registered Records Administrator, then an instructor at Northern Virginia Community College, Annandale, Virginia, who served as field workers.

Warren Holland, instructor in Community Medicine at Georgetown University, who was responsible for computer programming.

David C. B. Smith, who contracted with ORC as expeditor to maintain the flow of records within the processing system.

Assistance in planning and implementation was provided by a steering committee established by ORC and composed of the following representatives of both producers and fabricators:

R. W. McBurney, M.D.
Medical Director
Diamond Shamrock Corporation
Cleveland, Ohio

C. A. Johnson, M.D.
Director, Occupational Safety & Health
The Goodyear Tire & Rubber Company
Akron, Ohio

George Nickel
Safety Manager
Armstrong Cork Company
Lancaster, Pennsylvania

R. N. Wheeler
Assistant Production Manager
Union Carbide Corporation
South Charleston, West Virginia

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The study began in March 1974 and was completed in December 1975. Most of the data were collected and processed in 1974. In October 1975 an interim report was issued analyzing death patterns in 10 of the fabricators.

Companies participating in the study submitted 5,179 death certificates for former employees of fabricating plants. Of these, 587 were excluded because the deaths occurred in 1974 or prior to 1964. Thus the analysis in this report is based on 4,592 death certificates.

No angiosarcoma of the liver was found in the study population. In the conduct of the study, however, ORC also responded to the Center for Disease Control survey of angiosarcoma deaths in the United States. In this process ORC did find five cases of angiosarcoma of the liver, but there was no record that any of the people affected had ever worked for any polyvinyl chloride fabricator.

The data also revealed an important excess in mortality from cancer among both white males and white females. The incidence of liver disease fell within the range of expectation.

The completion of the study was substantially affected by several problems encountered in the data collection process: (1) difficulty in retrieving death records, (2) variety and incompleteness of death certificates, (3) limited retention of death records by employing companies and their insurance carriers, and (4) lack of general hospital

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policy concerning the availability of hospital records for epidemiological or mortality studies. Because of the implications of these problems for future studies, record keeping and its importance are discussed in the concluding chapter of this report.

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II. GENERAL BACKGROUND

In January 1974, B. F. Goodrich Chemical Company disclosed that angiosarcoma of the liver was the cause of death of three employees at the company's Louisville, Kentucky plant. The clustering of three angiosarcomas of the liver, a rare disease, could hardly be regarded as a chance occurrence. Each of the deceased had similar occupational exposures to high concentrations of vinyl chloride in the polymerization stage over a long period. The Goodrich disclosure suggested the possibility of a new occupational disease and a need to reevaluate the standard of the Occupational Safety and Health Administration (OSHA) for occupational exposure to vinyl chloride.

By March 1974, with knowledge of the Goodrich deaths, the National Institute for Occupational Safety and Health (NIOSH) and OSHA had concluded factfinding hearings, a petition had been filed with OSHA for an emergency temporary standard, and NIOSH had recommended a standard that covered virtually all locations manufacturing vinyl chloride, producing polyvinyl chloride, and fabricating or storing the resins.

At that time there were no data from which to determine the prevalence of angiosarcoma of the liver in the plastics industry. On further investigation other cases of the disease were found, but the pattern of occurrence suggested that they were associated with those

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processes which involved high concentrations of vinyl chloride monomer, primarily residues in polymer reactors. Thus there remained the question of possible adverse effects on employees engaged in fabrication where potential exposures were thought to be low and to result only from the release of unreacted monomer trapped in the resin.

Accordingly, representatives of the PVC producers who were members of the ORC Occupational Safety and Health Standards Group asked Leo Teplow, Special Consultant to ORC, about the feasibility of a study of the health risks to employees working with vinyl chloride and polyvinyl chloride. When it was learned that NIOSH was engaged in making a mortality study of employees in vinyl chloride and resin-producing plants, the scope of the proposed study was limited to employees engaged in the fabrication of PVC resin into finished products. The objective was to determine the facts regarding cause of death, based on an analysis of death certificates, and to compare the distribution of causes with published expectation tables.

After exploratory discussions, it was concluded that such a study had merit in adding to the literature in an area that had not been studied and that would probably not be studied by others in the foreseeable future.

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CHARACTERISTICS OF THE VINYL CHLORIDE INDUSTRY

The fabricating companies selected for study are part of the plastics industry and depend to a significant extent on the use of polyvinyl chloride resins as a raw material. Their plants may be involved with any one or all of three stages of vinyl chloride processing:

1. Monomer production. A synthetic chemical, known as chloroethene or vinyl chloride (CH_2CHCl) is formed by the oxychlorination of ethylene and by the hydrochlorination of acetylene. A closed system is used, and employee exposures do not occur routinely.
2. Polymer production. A resin consisting of long molecular chains, is produced by mixing vinyl chloride with catalysts in reactors. Early reactors were open systems, and high exposures are known to have occurred. The deaths disclosed by Goodrich were among employees who had cleaned the reactors.
3. Fabrication. The polymer resin is combined with a variety of other substances to form finished products. Exposure to vinyl chloride is low because it is released only as unreacted monomer that has been trapped in the resin, and this occurs only during heating of the resin. The level of exposure depends on the amount of vinyl chloride gas trapped in the resin. Estimates of such exposure in fabrication ranged from 5-15 parts per million (ppm) at the time this study was started.

There are wide differences in fabrication because of the amount of PVC required for a given product, and the type of resin utilized. For example, the amount of PVC used to produce wide plastic fabrics, using Banburys and calendars, is greater than that in wire coating, using an extrusion die.

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Plants involved at each stage of production may differ widely in characteristics. For example, in the North, polymer plants are usually indoors, but in the South, they are often in an outdoor complex. The age of the facility and vintage of technology may also result in differences in potential exposures.

Since the first commercial use of polyvinyl chloride resins in 1939, the plastics industry has grown steadily. Estimates in early 1974 indicated that the PVC market was in excess of 3 1/2 million tons and that the total employment dependent on PVC was between 700,000 and 2 million people. It is clear that polyvinyl chloride resins play an important part in the economy.

Although the trend has been toward consistent growth, obsolescence of plants and new technologies have brought about retrenchments and plant closings so that local exceptions can be cited to the general pattern of growth. The industry was affected by the recession of the mid 70's, but the magnitude of change varied widely.

CHARACTERISTICS OF VINYL CHLORIDE EMPLOYERS

There are relatively few producers of vinyl chloride monomer; OSHA identified 10 companies with 15 plants in its study of the industry, and they were primarily large chemical or petrochemical companies.

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OSHA identified 22 polymer producers (36 plants), some of which were also monomer producers. All were medium to large companies.¹

Fabricators range from large plants of major companies to very small job shops. Some large companies operate small PVC fabricating plants. Even a large plant, however, may have relatively few employees working in the vicinity where PVC resins are handled. The range in company size, plant size, and number of exposed employees helps to explain the wide variations in estimates of total employment dependent on PVC resins.

Fabrication is geographically dispersed, with at least some plants in almost every state. They seem to be clustered, however, in the traditional industrial states such as New York, New Jersey, Pennsylvania, Michigan, Ohio and Illinois, and in the growing Southeast. The Los Angeles area also has a large number of fabricators. Typical fabrication products include coated wire, upholstery fabrics, floor and wall coverings, pipe and other construction material, toys and recreational equipment, phonograph records, containers and container lining, and a myriad of novelty items.

Inasmuch as the fabrication of PVC resin into finished products is often a part of diversified product lines in a plant, and raw

¹ Occupational Safety and Health Administration (Washington, D. C.), Draft Environmental Impact Statement, Proposed Regulation, Vinyl Chloride, 1974, p. 26.

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materials other than resin are utilized, employees may be exposed to toxic agents other than vinyl chloride. One of the problems in a study of this kind, therefore, is that it is not possible to isolate the effects of a single agent, such as vinyl chloride. Some of the variations from expected experience, reported in Chapter VI, may be due to exposure to vinyl chloride, or one or more other agents, or some combination.

Since the employee population was not homogeneous as to numbers of employees in a plant, age, proportions potentially exposed to vinyl chloride gas, exposure to other possible toxic agents or mixtures of toxic agents, and residence in urban or rural areas, it was accepted at the outset that it might not be possible to draw firm conclusions at the completion of the study regarding the effect of vinyl chloride on the study population. Nevertheless, it was decided that even though limited, the information obtained would be useful in filling the existing factual gap.

CHARACTERISTICS OF FABRICATORS IN THE STUDY

The 18 companies covered in this report range from single plant small companies (one with 70 employees) to multiplant large companies, one of which had over 7,000 employees. Plant size clustered around 300 to 500 employees. The total employment is difficult to determine precisely, but is estimated to have been between 65,000 and 70,000 at the end of 1973.

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Over the study period, plant size was found to have changed drastically in many cases. In one instance, a plant employing 300 employees in 1973 had employed fewer than 10 at the beginning of the study period. At the other extreme, one plant employing 5,000 people in 1964 had only 2,000 in 1973. Some companies had gone out of business. Such developments show not only the rapid changes taking place, but also the difficulty of determining "average" industry employment. Any treatment of an arithmetic mean would lead at best to spurious accuracy. For these reasons, there is little significance in breaking down the study population by plant.

Study plants were located in both urban and small rural communities throughout the country, including New England, the Southeast, Southwest and West Coast, with the bulk of employment in Illinois, Indiana, Maryland, Ohio and Pennsylvania.

The majority of death certificates for the study period were for white males. The study made no attempt to discern current mix of sex or race of employees, but it can be concluded that PVC fabrication employs predominately white males. There are local exceptions, of course, such as inner city plants which have a predominately nonwhite work force or light fabricating plants that are sometimes predominately female. The deaths occurring during the study period reflect hiring practices of two to five decades ago, however, and current employment probably now has more nonwhite and female representation.

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There are no data on turnover or tenure patterns. However, the number of deaths reported in plants where employees were predominately female is less than one would expect from the total plant employment, suggesting that turnover was high. Conversely, the high percentage of deaths occurring after 65 is evidence that employees worked long enough to qualify for paid-up life insurance upon retirement through the 10-year period.

The large plants in the study had full-time medical directors, but small plants, including those of large corporations, provided medical services through local contract physicians. The completeness of medical records varied widely, with no discernable pattern according to either plant or company size.

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