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CANCER AND VINYL CHLORIDE - POLYMERIZATION
IMPLICATIONS, PROBLEMS AND NEEDS

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CANCER AND VINYL CHLORIDE - POLYMERIZATION

IMPLICATIONS, PROBLEMS AND NEEDS

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CANCER AND VINYL CHLORIDE - POLYMERIZATION

IMPLICATIONS, PROBLEMS AND NEEDS*

INTRODUCTION

A new occupational cancer has been identified.

The world wide manufacture of polyvinyl chloride now identified with the association of cancer, brings up a tremendous range of human, social and economical problems. The immediate pressing question is whether the cancer observed will be confined to the manufacturing process or also occur in successive lower grades of exposure in the processing and use of vinyl chloride and polyvinyl chloride and whether other types of cancer may subsequently be identified. The potential magnitude of the cancer problem, however, does not rest on vinyl chloride alone, but rather on its role as a possible index cancer chemical - an indicator to a large group of similarly structured chemicals. Should any of these chemicals prove to be carcinogenic, then the magnitude of the risk would extend to an ever widening circle of industries, processes and exposed populations. The degree of validity of these various possibilities must be identified and resolved.

Invariably, whenever a new occupational cancer is discovered

* Submitted for internal discussion and planning on occupational cancer and other health problems, to the Industrial Union Department, AFL-CIO.

it is played down for fear of alarming the workers and the general public. The motivation may be one of not really knowing the facts. Nevertheless, from past experience, what happens is that as further work is undertaken, and information obtained, the problem gets broader and broader with more implications. I think a more straight-forward approach to the workers and the general public is warranted, citing the limitations of what we do not know, clearly indicating what the situation is, what efforts are being developed and carried out to determine the scope of the problem and to correct it.

SCIENTIFIC UNKNOWNNS

This situation, the chance recognition of an occupational cancer by a unique combination of circumstances, clearly demonstrates what is not known about the carcinogenic potential of thousands of industrial chemicals that have been in use for decades and further focuses attention on the total absence of a national concerted study of occupational cancer in this country.

The serious national question that is raised and not resolved - because it is either too shocking to contemplate or because the agencies responsible for the protection of the public are reluctant to open this complex Pandora box - is, in essence, that a national study directed at the industrial environment might uncover a whole series - a succession of occupational cancers, which in turn, would implicate in the distribution of these chemicals, a larger and larger portion of the population exposed to

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past have been responsible for the absence of the necessary investigative studies of the work environment by the Federal Government.

This is a vicious cycle in which the assumptions preclude the studies and, without the data, the assumptions remain. If the studies had been done, the original assumptions would be found to be grossly false and the scientific misunderstanding that has been maintained over the years, would be reversed.

At present the attention is now focused on vinyl chloride and undoubtedly a concerted effort will be undertaken, and must be undertaken. The question I am raising is: must the industrial population and the general public wait until each particular cancer is identified by accident or is forcibly brought to our attention in some other means, before a concerted effort is undertaken to determine the magnitude of the problem, its cause, and control? It would be more appropriate in my opinion, to utilize this observation of occupational cancer to focus attention on the need for a national study by the CDC-NIOSH and the National Cancer Institute and all other agencies, in a concerted effort directed at all suspected carcinogenic agents in the work environment and the development of an industrial epidemiological cancer surveillance recognition system for this purpose.

DURATION OF EMPLOYMENT AND LATENT PERIOD

The implications of the statement that all men who died of angio-sarcoma had at least 15-16 years exposure in the manufacturing of polyvinyl chloride, should be critically assessed. No

one knows at this early stage what combination of length of exposure, concentration or contact with the polyvinyl chloride process will cause the specific angio-sarcoma.

In occupational cancer, the actual exposure in terms of length of employment, may be very small. It is the latent period, that is, the interval period between each exposure and the development of the cancer, that may take many years. In essence, no one knows for the four cases of angio-sarcoma, if the induction of cancer to this type of carcinogenic agent requires relatively few years of exposure and a further latent period of 12 years or more, or whether the induction does require 15 years of exposure.

In my opinion, based on other occupational cancers, it is most unlikely that the carcinogenic dose would require 15 years of exposure. The relatively young ages of the four cases of angio-sarcoma: 37, 43, 50, and 55, and the rapid progression of the cancer once it is identified clinically (six months to three years) indicates a strong carcinogenic agent.

INDUSTRIAL CAUSES FOR CIRRHOSIS OF THE LIVER

The observation among another group of four workers in this small employment group, of cirrhosis of the liver (non-alcoholic), confirmed by eminent pathologists, is very important as another manifestation of occupational disease for those exposed to polyvinyl chloride processes.

The significance of these cases of cirrhosis of the liver is to make the medical profession and the general public more aware

that there are industrial causes for cirrhosis. This observation should further serve to underscore the need for a large scale study to uncover other industrial causes of cirrhosis. The question is, however, how many cases of cirrhosis of the liver due to vinyl chloride and other industrial chemicals, have gone unrecognized?

The additional implications of cirrhosis of the liver are the effect on employability and the life span of the worker. The normal capacity and function of the liver to neutralize chemicals taken into the body are impaired by cirrhosis. Consequently this effect of cirrhosis would severely limit subsequent employability as well as lessen the capacity of the worker to recover from other illnesses or diseases, which may occur in subsequent years.

If, in the subsequent review of microscopic slides of cirrhosis of the liver, there is found an indication in some areas of the liver of atypical cell changes toward malignancy or formation, then cirrhosis of the liver may be seen specifically as an increased risk in the development of liver cancer for the workers exposed. This does not mean, however, in any way, that all cases of occupational liver cancer would require the precursor mechanisms of cirrhosis of the liver or that the two diseases must always be present together. The question and objective remains - what is the minimal induction dose in terms of duration of employment and concentration of exposure to polyvinyl chloride to incite the development of cirrhosis of the liver?

POSSIBLE OTHER HEALTH EFFECTS

Further, no one knows what other types of illnesses or other cancers may occur, consequently, the investigations undertaken should be all-encompassing and of all systems and organs and not confined to angio-sarcoma of the liver. The experimental observations of rats exposed to vinyl chloride, demonstrated cancer of the skin, lung and bone, and in another study, angio-sarcoma.

Although the focus is now on the experimental cancer causing effect, it is very important to note that other pathological changes occur in the brain (degeneration of the nerve cells - cerebellum); severe chronic hepatitis (as well as cirrhosis); interstitial pneumonia; and damage to the kidneys. Further, the skin tumors frequently developed near the ear and submaxillary or the same areas as the salivary glands. It was postulated by the investigators that vinyl chloride may enter the salivary gland system. If this is subsequently confirmed, it raises the question whether tumors of the parotid gland can also occur (as has been demonstrated in the rubber industry).

These various facets are mentioned primarily to broaden the approach undertaken in the evaluation of the health risks involved. The present concentrated attention on angio-sarcoma might inadvertantly miss other related health problems including other organs and systems. Similarly, negative results from a comprehensive study would be more re-assuring than an investigation confined to one organ of the body.

MEDICAL EVALUATION

The actual and potential health effects identified by clinical and experimental observations have clearly established the need for comprehensive medical programs for the protection of the workers in the vinyl chloride and polyvinyl chloride operations.

The Federal Occupational Health and Safety Act requires that the health of the worker not be adversely affected during his employment and this therefore places the responsibility on industry to ensure that no harmful effects do occur as a result of exposures to the various chemicals and work processes involved.

Unless the polyvinyl chloride plant is providing adequate and effective medical examinations, there is really no way of determining whether harm is being done until the harm has become a reality. Similarly, unless medical examinations and special tests are provided periodically, occupational health effects will not be recognized, in particular those that occur as a result of accumulated exposures or peak exposures at different points in time or as a result of changes in the work processes. For vinyl chloride, the range and scope of general and specific tests that should be conducted relative to the specific organs and systems that might be affected, should be given careful consideration. The responsibility for the provision of the tests would rest with the industry.

The recognition of occupational health effects depends upon the physicians and unless they are available to see the workers, to hear and know their symptoms, and provide the examinations and

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special tests, occupational diseases will not be identified at their earliest stages, nor unfortunately, even at the most advanced stages, or at all. The availability and provision of industrial medical services to small plants where such a large portion of the industrial population is employed, and where the hazards may be more common to all the workers, has been a major problem for decades. Invariably the small plants are more susceptible to economic pressures and have the added difficulty in balancing need and cost for medical services and control measures - socio-economic equation.

Arrangements should be made so that all medical observation relative to the health status, and any changes in the status of each worker, should be made available to his personal physician. There must be a certain quality or standard of performance relative to the completeness of the examinations and the types of tests performed and therefore the specification of whatever tests are determined should be clearly delineated. This is particularly important relative to the development of medical services for small plants in which the physicians in general practice, unacquainted with such problems, may be responsible for the conduct of such examinations.

In the briefing session on February 1, 1974, it was reported that approximately 50 workers of the Goodrich Company, Louisville plant, were initially described as having changes in liver function, which in subsequent reviews, all or most were considered to be within the normal range.

The major concern in the clinical evaluation of workers

exposed to vinyl chloride and polyvinyl chloride or other chemicals, is the problem of "observer variation", the differences which occur among different physicians, conducting the same tests on the same or different workers.

"Observer variation" in clinical observations and tests, has been well documented in the interpretation of chest x-rays, pathology slides and clinical examinations. Further, it has also been noted that laboratories vary in the results obtained on blood, urine and tissues, even when the same analytical procedures have been followed on the same sample of a common contaminant (lead).

Consequently, in the present problem of the clinical evaluation of workers (exposed to vinyl chloride processes) which as of now focuses on liver function tests and may involve other organs, alternate approaches should be considered. It would be appropriate to have a series of coordinated procedures in which the specimens and clinical examinations of the workers could be examined at regional medical centres throughout the country, or to one centre such as has been carried out successfully by the Beryllium Registry at Massachusetts General Hospital in Boston.

The Beryllium Registry has demonstrated for years, in its functions, what could be done for vinyl chloride: patients are referred from all parts of the country; the conduct of comprehensive tests of various systems and organs of the body; pathology review and chemical analysis of tissues, etc., all carried out by the same group of physicians, concentrating on the same problem for which comprehensive records are maintained.

For the individual plants, medical examinations by plant.

physicians alone without accurate and complete records, are not effective. In the case of vinyl chloride and polyvinyl chloride, orientation of industrial nurses and physicians to the toxicological and carcinogenic effects of the chemicals in the work environment is essential for them to recognize the occupational health effects. Sickness, hospital and insurance records provide essential links to the medical surveillance of the employees and should be recognized as such. All leaves for sickness and types of illnesses which occur, take on added significance as clues to the health effects in the vinyl chloride or polyvinyl chloride plant. It is essential that the basis for linkage of medical and environmental data be established so that correlations with environmental exposures and specific work processes, and the recognition of an occupational illness, can be made. When a group of workers employed in the same department or work process, exposed to the same chemicals, come down with the same pattern of symptoms or illness, then the essential criteria for the recognition of an occupational disease have been met.

The worker should be informed directly, as is required by the Federal Occupational Health and Safety Act, of the type of harmful effects that may occur with the chemicals he is working with, in this instance vinyl chloride and polyvinyl chloride, and the most effective ways in which the harmful exposures can be controlled and the best ways that he can protect himself. If the worker does not know what kinds of illnesses or injurious effects are caused by the particular chemicals he works with, then he will not be able to recognize the occupational illnesses

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when they do occur. In turn, unless the worker tells his doctor what chemicals and materials he has been exposed to, now and in the past, even his family doctor will not recognize that the illness or disability could be due to his work. The result is that occupational harmful effects are not being identified, recorded, investigated or corrected.

WORK EXPOSURE

Exposure data in terms of air concentration in the work place and other means of exposure (such as due to contaminated work place from breaks in equipment, poor housekeeping, inadequate ventilation and absence of personal protective equipment, etc.) are important in the ultimate correlation analysis of the degree of exposure to polyvinyl chloride and the subsequent health effects.

Precise data on exposure is required as a basis for subsequent resolutions of what health effects occur at different levels of exposure and finally, the exposure data determines the nature, type and comprehensiveness of the control measures required.

The principal exposures of the workers within the polymerization process is to vinyl chloride and polyvinyl chloride. In the Louisville plant, 271 workers are currently employed in a 24 hour continuous operation of the polymerization process (no indication was given of the number of employees who had been formerly employed at some time and left, i.e., of the total employee

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population who had been at risk). According to Dr. M. Johnson, of the Goodrich Company, in the seniority system all new employees were assigned to clean up the insides of the tanks, the operation previously identified as the primary procedure in which acro-osteolysis occurs (changes in the bone of tips of the fingers) where fingers were affected as a result of direct contact with the chemicals. All the employees passed through, and were exposed to, each stage of the work process. The environmental data provided by the companies to their consultants, relative to exposure, was characterized in gross terms similar to: severe, moderate and minimal. Further, the medical programs in the various polyvinyl chloride plants were quite limited.

It was readily acknowledged that employees move from one occupational exposure to another within the same plant, and at different points in time; that individuals who would be recorded as having minimal exposure as of now, may have had extensive exposure before, etc. There was no indication whether any environmental monitoring had been carried out at the other plants, nor any information relative to the degree of accuracy, frequency and thoroughness of what sampling was done.

It was acknowledged by Dr. M. Johnson that past air sampling at the Goodrich Louisville plant, because of diffusion characteristics of vinyl chloride, did not constitute representative samples of air concentration of exposure to the workers. Currently, however, automatic continuous air samples are taken and recorded. Further, in Dr. Johnson's explanation, during the manufacturing processes in the Louisville plant, it is estimated that 6% of the

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polyvinyl chloride in some form, is lost in air and waste disposal, and since this represents a continuous operation, it carries serious implications that warrant investigation.

The unfortunate lesson learned and demonstrated, is that environmental monitoring is extremely important for the company, the worker and the public. The dilemma now posed in the absence of such precise data, is that the information the company, government and scientists need to help resolve the risk factor, is not available. The burden now falls to measuring risk in terms of health effects, measured by crude exposure levels which, as already described, have questionable quantitative validity.

PROBLEMS OF EPIDEMIOLOGICAL STUDY

In referring to the "rarity" of angio-sarcoma (21-28 cases in the U.S. in a specific year, recorded only on the death certificates), this number should not be misinterpreted as an indication that no problem exists. What we may be seeing is the proverbial tip of the iceberg, because of the latent period. What is important is what has not been recorded or recognized. The problems, obstacles and difficulties in the conduct of epidemiological studies of industrial cancer are substantial indeed. When the study is based solely on death certificates and involves a rare type of cancer, the problems of recognition are made even more difficult. When the cancer is confined to a specific histological type, the mathematical odds against the detection of angio-sarcoma by death certificate alone, are tremendous. In

essence, the death certificates alone for the identification of this cancer, would most likely provide "false negative" findings, and reliance solely on the death certificates therefore, would be inappropriate under these circumstances. As of now, based upon the four cases of angio-sarcoma with the latent period estimated at 15 years, if the death certificates are used from the plants which have been in existence for less than 15 years, then the results, if any, will be further diluted.

Some of the basic limitations of the sources of data and information and the variables involved, which would apply to the epidemiological study of angio-sarcoma of the liver, as well as cirrhosis and other health effects, for the plants manufacturing and processing polyvinyl chloride are: a dependence upon pre-existing effective industrial medical programs and supervision, its quality, consistency and adequacy, policies and procedures; the types, accuracy and completeness of necessary records (employment, job changes, exposure measurements in various processes, and medical examinations); retirement policies and the extent of insurance coverage for life, medical and surgical services for the workers while at work and after they leave the plant; the movement of employees to other cities; the extent and percentage of autopsies performed in the community; the availability of hospitals and pathology resources in the community; limitations of what is recorded on the death certificates (beryllium disease was not recorded on the death certificates for 74% of individuals who were previously identified as having beryllium disease); a death certificate may be completed before the

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autopsy is performed, or the microscopic review completed weeks later, with no additional supplementation to the death certificate. Consequently, the cause of death on the death certificate may specify the histological diagnosis, and this type of information would only be available through successive follow-up searches of pathological reports and hospitals. . Workers who died of heart disease may also have had cirrhosis or cancer of the liver, but the cirrhosis or cancer of the liver was not recognized because no biopsy was done while he was alive, nor at death.

It is apparent, in studying cirrhosis of the liver and angio-sarcoma, that many factors are in operation to underestimate what has happened and may be happening. Despite these problems and obstacles, which are formidable indeed for a specific histological type of cancer, epidemiological studies have been successfully undertaken and have identified occupational cancers. There is every reason to believe this can be accomplished with a combination of resources and cooperation.

COMPENSATION CONSIDERATIONS

For the particular cancer now under consideration, I should like to caution that it would be most unwise to confine the recognition of occupational cancer solely to the histological type - angio-sarcoma. If other workers who are exposed to the same work processes of polyvinyl chloride, develop the same disease - cancer of the liver - the cancer should be considered as occupational in origin, regardless of the histological type.

It must be remembered that cancer of the liver itself is an uncommon type of cancer.

In essence, workers should not be denied compensation because of the histological type of the cancer. It is yet possible that other histological types of cancers may develop as well as other health effects. We do know that in other industrial cancers, for example, lung cancers caused by chromate and asbestos, that the histological types of lung cancer are not specific but rather, may be different in workers of the same plant or occupations with the same years of employment. Further, the recognition of cirrhosis of the liver as an occupational disease among polyvinyl chloride workers, makes this disease compensable. Since cirrhosis of the liver is not a rare disease, problems of association and interpretation will be more difficult. Workers at the polyvinyl chloride plants could develop various stages of cirrhosis, depending upon their length of employment and exposure, and not know it and when the condition becomes severe enough to recognize it clinically, the worker may not realize that the disease was due to prior employment at the polyvinyl chloride plant. This is particularly applicable to separated employees, those who leave the vinyl chloride/polyvinyl chloride work for other jobs who develop the illness years later. After so many years have elapsed, this recognition of association of current disease with prior employment, becomes increasingly difficult and consequently compensation claims are not filed or are made difficult, or denied.

The identification of this new occupational cancer focuses

immediately to apply its resources and expertise in epidemiological investigations and to seek such funds, if necessary, to carry out the national study. Resource data should be compiled on all occupations and products in which vinyl chloride and polyvinyl chloride are used to ascertain the range of exposure. The centrifugal distribution from the manufacturing source through all industries, processes and users throughout the country, to identify the populations at potential risk for further study and establish the magnitude of the problem.

- II. That an International Research Committee on Vinyl Chloride and Cancer, be organized with representatives of other countries. The committee would follow the pattern of the previous similar International Committee established for Asbestos and Cancer, which was under the auspices of the UICC (International Union Against Cancer).

The objectives of the committee would be to develop a series of working group panels to plan and coordinate the necessary research and to provide the necessary encouragement and cooperation in a number of essential areas such as:

1. Epidemiology and Clinical - identification of populations at risk, types and levels of exposure, identification of health effects on populations manufacturing polyvinyl chloride, users and consumers in the various countries.
2. Pathology and experimental pathology - to undertake the development of appropriate means to characterize and interpret the diagnoses of angio-sarcoma and cirrhosis and such other pathological changes that do occur in the liver, and in other organs of the body which may be affected as the spleen and the brain, skin, bone, lung, salivary glands, etc.

Angio-sarcoma Registries and Pathology Review Panels.

3. Industrial hygiene, chemistry, engineering - which would be concerned with the problems of identification, evaluation and control of polyvinyl chloride and its decomposition products in every stage of the work processes and community environment.

III. That a Government conference of representatives of all the Federal Agencies who are concerned directly or indirectly with occupational cancer and the study of the industrial environment, be convened so that an evaluation can be made of the resources and funds appropriated, and the nature and extent of the various programs, efforts and funds concerned with the identification and control of occupational cancer.

In this respect, the emphasis on laboratory research alone is not sufficient, although important and serves a particular purpose. The researchers ought to be taken to the work environment. It is there that the health effects already occurring can be properly recognized.

It is readily apparent that the expenditure of funds relative to cancer research can effectively be applied to identify the occupational cancers and their etiological agents within the work environment for the purpose of prevention, in contrast to the expenditure of funds solely for the treatment of cancer. Although the original allocation of funds, as designated, is related to the prevention of cancer, the optimum means of prevention would be through the industrial environment to prevent them from occurring in the first place. It is ironic that tremendous sums of funds are provided to the National Cancer Institute, yet with the accent on prevention, there does not appear to be any organized program for occupational cancer, to identify the causes of cancer in the work place, since Dr. Wilhelm C. Hueper retired a number

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of years ago. Why this is so, and why it has not been changed, is not clear.

NIOSH has a legal capability of obtaining the necessary information in the various industries, and of conducting the epidemiology studies relative to known and suspected carcinogenic agents in the work environment. The question I am raising is whether, in NIOSH, there is an appropriate balance relative to professional efforts and whether the proportion of resources, personnel and funds could more appropriately be directed to the epidemiological program for the identification of occupational diseases - and cancer. In my opinion, the medical epidemiological approach takes precedent, and without such a concerted, broad national effort on a very large scale, the magnitude of the problems that are occurring will never be discovered, recognized or recorded.

IV. That the international unions themselves assume, as their major objective, in conjunction with the universities and medical centres, a concentrated effort to study the cancers which are occurring among members of their union, the relationship to particular occupations, work processes, chemicals and industries.

It is apparent that sole reliance on the government has been ineffective for the study of occupational cancer and other industrial health problems. Despite what efforts might be undertaken now by the government and industry, the industrial union members constitute the largest epidemiological field force in the country.

The objectives go beyond vinyl chloride, to all industrial operations as a fundamental approach of case finding of

further on the need for a re-study of the compensation laws pertaining to occupational cancer and other long term diseases. In particular, my concern is that occupational cancers in general are either not recognized or, when recognized by the individual, his doctor or research group, the identification invariably occurs many years later because the disease itself may require many years for development, and consequently the Statute of Limitations for the filing of workmens' compensation claims, may be exceeded, and the claim denied. I do not believe the worker or his family should be penalized further when an occupational cancer has been identified, just because the circumstances which came about to finally help him recognize that he has an occupational disease, have been so long delayed. In virtually every instance the worker has to be told, and there are very few people telling the worker that he has an occupational cancer. This type of cancer is not readily recognized by the physician in general practice and unfortunately, in many instances, the industry has not helped the worker, rather the position in general has been one of contesting the compensation claims.

RECOMMENDATIONS

- I. That the Government (CDC-NIOSH) take the initiative and conduct its own independent extensive study of the cancer potential and health risks associated with exposure to polyvinyl chloride processes. Further, that the Government (CDC-NIOSH) should undertake such steps as necessary

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occupational health problems. It is highly probable that the first recognition of an occupational disease, including specific types of cancers, may be developed by the workers themselves and serve as the basis for scientific investigations.

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