

VINYL CHLORIDE AND OCCUPATIONAL HEALTH

In January 1974 the B.F. Goodrich Company announced publicly that the plant physician at its Louisville, Kentucky, polyvinyl chloride (PVC) resin plant had identified three cases of angiosarcoma of the liver, an extremely rare type of cancer, among long-term plant employees. The company said it suspected that vinyl chloride monomer (VCM), the gaseous industrial chemical from which PVC resin is produced, might be implicated in the three deaths.

The announcement by B.F. Goodrich triggered one of the most intensive investigations in the history of occupational health. It was reported in extreme detail to the American public in literally hundreds of newspaper and magazine articles, in radio shows and television programs. A highly organized medical conference was held in Washington, D.C., and vinyl chloride even became the subject of a Senate subcommittee hearing.

It is the purpose of this report to review the events of the last several years, to place vinyl chloride and exposure to them in perspective, and to discuss the current state of knowledge.

- The PVC industry has been the subject of the medical research community for many years, and, in fact, was the first to be investigated. In industry, the focus was on the health of workers next to nothing about the health effects of vinyl chloride.

- ## Background

The main ingredient is vinyl chloride, a gaseous industrial chemical. It is mixed with a catalyst, plus chlorine. It is then combined with a solvent and chloride resin is produced. This is called polymerization. The process for manufacturing PVC was first discovered in 1936 in Germany. Since then, similar processes have been used to make PVC resin in the United States.

Like many people who have been known for years to have some water-related problem, the medical profession to be an anesthetic at extremely high levels, it also

presented flammability and explosion risk potential. However, controls were devised for these problems.

Information on possible long-term health effects of VCM exposure was admittedly scanty and incomplete during the 1940s '50s and '60s. The first inkling of a potential problem was a 1949 study of 73 workers in a Russian plastics fabricating firm. The study indicated evidence of hepatitis among the workers but concluded that this was due to exposure to a polychloro-biphenyl (PCB) plasticizer used in the factory and not to VCM. Much was made of this study by professional activists following the discovery of the vinyl chloride cancer link, but apparently no one in the American medical community -- governmental, industrial or private -- was aware of the study prior to 1974.

A 1961 study by the Dow Chemical Company found that long-term exposure of experimental animals to VCM at levels down to 100 parts per million (ppm) resulted in slight liver damage, but a similar study conducted by the National Institute for Environmental Health Sciences (NIEHS) found no such effects. The NIEHS study was a cause for concern.

From 1951 to 1961, the National Institute for Occupational Safety and Health (NIOSH) conducted a maximum time-weighted average (TWA) study of VCM exposure by the American Chemical Society (ACS) and the American Industrial Hygiene Association (ACGIH) after careful review of all available data on the subject. ACGIH is a professional organization devoted to technical and administrative aspects of occupational health and safety protection.

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One of its principal functions is the promotion of standards and techniques in industrial health. Thus the standard was not an arbitrary one, but was set after professional evaluation of all available data. In 1963, the ACGIH recommended a ceiling of 500 ppm for vinyl chloride. This same level was adopted in 1971 by the newly created Occupational Safety and Health Administration (OSHA).

In 1966 a reversible disease of the bones of the fingers called acroosteolysis was discovered among some heavily exposed reactor cleaners. Prompt and appropriate industrial hygiene efforts by the industry quickly eliminated the problem.

Strangely enough, it was the industry's search for an answer to the cause of acroosteolysis that eventually led to the discovery of the carcinogenic risk of vinyl chloride.

Cancer Link Discovered

Because of the acroosteolysis situation, industry-sponsored research projects were undertaken in the United States and Europe in an effort to determine the cause of the disease. The American study was headed at the University of Michigan by the Manufacturer's Association, which was unable to pinpoint the cause of the disease and recommended further experimentation.

The European study was headed by Dr. Regina Elwood of the Regina Elena Hospital in Rome. Dr. Viola, who is also a medical director at the IRI, a leading European firm, reported at the 1970 International Cancer Congress in Houston in May 1970 that he had been able to

produce cancers (but not angiosarcoma) in test animals at extremely high levels (10,000 to 30,000 ppm) of VCM exposure. Dr. Viola's findings were subsequently published in the Journal of Cancer Research in 1971.

While no notice of Dr. Viola's findings was taken by any government agency involved in worker health, the PVC industry both in the United States and in Europe began plans for more extensive animal studies at levels of exposure more likely to be encountered in actual plant situations. Epidemiological studies of plant workers were also planned.

The European animal inhalation study was conducted under the direction of Dr. Cesare Maltoni of the Instituto di Oncologia and Centro Tumori in Bologna, Italy. In addition, two European PVC producers undertook studies of workers who had been exposed to VCM at high and sustained levels.

In California, the American Lung Association in June 1971 requested that the state health department sponsor a study of all workers in the state who had been exposed to VCM. The study was undertaken by the University of California at Los Angeles, California. In February 1972, the state health department, through the Industrial Bio-Test Center, requested that the state health department sponsor a study of all workers in the state who had been exposed to VCM for lifetime chronic exposure.

The state health department, through the state health department, sponsored by the PVC industry, the state health department, through the state health department, around the state health department, through the state health department, which were also industry-sponsored.

Because the European research had gotten underway earlier than the efforts undertaken in America, some preliminary results of Dr. Maltoni's study became available in early 1973. Accordingly, a technical delegation from the U.S. PVC industry visited Dr. Maltoni in Italy in January of that year to review the progress of his research. The American team learned that Dr. Maltoni had detected a variety of tumors in test animals at concentrations as low as 250 ppm.

The American PVC industry then requested a meeting with the National Institute of Occupational Safety and Health (NIOSH) to call the Maltoni results to the attention of the U.S. government. The meeting was held in July 1973 and included discussions of various kinds of cancer that Dr. Maltoni had found. NIOSH requested that the industry be informed as the research progressed.

Industry representatives were informed of some of his preliminary results. Industry representatives were also informed that NIOSH representatives were aware of the results.

Thus, both the government and the industry, as well as NIOSH, were aware of the results. This did not result in any action being taken. It is not surprising that Maltoni's findings were not taken into account. Results from the industry showed

no excess of cancer or any other disease among the workers, and (3) angiosarcoma had not yet been discovered among industry workers.

The Government Acts

In addition to its public announcement on January 22, 1974, regarding the three angiosarcoma deaths, B.F. Goodrich also notified officials of NIOSH as well as Kentucky state medical officers.

A week later it was discovered that another former employee of the same plant had also died from angiosarcoma. This resulted in an extensive search by the industry through old medical records of other cases. Ultimately, it was determined that over the past 16 years there have been a total of 23 deaths from angiosarcoma in six U.S. BFG plants, and approximately 42 in other countries. The workers' jobs involved cleaning residue of BFC resin from the equipment in which it was produced. While working, this resulted in high exposure to VCM over a period of several years.

After a "fact-finding" hearing held in February 1974 OSHA issued an Emergency Temporary Standard which lowered the maximum allowable exposure from 100 ppm to 50 ppm. This decision was announced on April 1, and based primarily on testimony presented at the fact-finding hearing that rats in his research did not develop angiosarcoma at 100 ppm. Only five days later, however, NIOSH reported to OSHA, NIOSH and the Environmental Protection Agency (EPA) that preliminary results of the Industrial Bio-Test Laboratories animal exposure study showed that VCM could produce angiosarcoma in mice at 50 ppm.

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This was subsequently confirmed by Dr. Maltoni on his rat experiments in June. On May 10, therefore, OSHA proposed a permanent worker standard which would reduce in-plant exposure to the "no detectable level" and require complete impervious suits and self-contained breathing equipment.

Shortly before this, on May 7, MCA publicly announced the preliminary results of the Tabershaw-Cooper worker survey which showed that workers exposed to VCM had overall cancer death rates comparable to those of other U.S. industrial groups and lower than those of the general public.

Public hearings, up till then the largest ever held by OSHA, began in Washington on June 25. The industry's position was essentially that the OSHA proposal was unrealistic because (1) it relied too heavily on animal data, even though more relevant human mortality data were available; (2) its requirements were far in excess of what was felt to be realistically required to protect employees; and (3) attainment of the proposed "no detectable level" was not considered to be feasible, employing the then existing control technology.

The industry also recommended the adoption of a higher standard, to be achieved with phased reductions over a number of years. During the hearings, evidence was presented which clearly showed that the cancer deaths from vinyl chloride were a result of conditions existing a decade or more before exposure levels were in the hundreds, if not thousands, of parts per million. Data developed by the Dow Chemical Company showed no excess mortality

from any cause among long-term workers exposed to levels below 200ppm.

Despite the evidence presented at the hearings, on October 1, 1974, the agency announced a permanent standard for VCM which called for reducing exposure levels to 1 ppm averaged over an eight-hour day, with peak exposure levels not to exceed 5 ppm as measured over any 15-minute period.

The standard further said that, during the first year, employers were to provide respirators for employees exposed to between 1 and 25 ppm, but that it was up to the employee whether he wanted to wear it or not. At exposures above 25 ppm, wearing of respirators was mandatory. After January 1, 1976, wearing of respirators would be mandatory for all workers whenever levels exceeded the 1 ppm and 5 ppm levels. On the other hand, regulations as to the types of respirators to be used at low levels of exposure were made less strict.

The new rules, which were scheduled to go into effect January 1, 1975, applied to all VCM and PVC resin plants but also to processors of VCM and PVC resin, including firms engaged in "transportation, storage, handling of VCM, PVC and PVC resin, unless exposures were found to be below the so-called "action level" of 0.5 ppm.

The industry has been asking for a review of the standards.

In January 1975 the Court of Appeals in New York upheld the OSHA standards. It declared that OSHA is not restricted to setting standards that are feasible with known technology, but that it is permissible to set "technology forcing" standards that

may be achievable at some undetermined time in the future with technology as yet undeveloped.

Because of the judicial proceedings, the implementation date for the standards was delayed until April 1, 1975.

Meeting the New Standards

Long before the standards went into effect, industry members had been actively seeking new means to reduce worker exposure. The industry's opposition to the "non-detectable" proposal had been based principally on the virtual technical impossibility of achieving this standard and on the impracticality of using air respirators that would be unsafe, uncomfortable and would inhibit workers from moving around on the job.

The regulations finally promulgated by OSHA, contrary to some reports in the media at the time and to the statements of some individuals even to this present day, were substantially different from those originally proposed. OSHA's change from "non-detectable" to a standard of 100 ppm allowed the standard into the realm of the achievable, though still extremely difficult. The change from "non-detectable" to 100 ppm is apt to occur in many other areas. The introduction of a new standard that was not available previously introduced a new dimension into the problem of recent problems.

In addition, the regulations required the use of type respirators at levels above 100 ppm. This created a major compliance difficulty with the standards.

While the new standards did result in the closing of a handful of plants, the industry's all-out effort to meet the OSHA requirements resulted in technological progress that PVC producers themselves did not feel was possible at the time of the hearings. The industrywide cost of compliance has run between \$300 and \$400 million in capital expenditures, with many additional millions being expended yearly in operating expenses. The achievements in reducing exposure have to date far surpassed the expectations of industry executives and technical experts alike.

Are the Standards "Safe?"

Since 1974, when angiosarcoma of the liver was first identified in PVC workers, numerous animal and epidemiological studies have been undertaken to establish a safe level for exposure to vinyl chloride. The available studies show that the current OSHA standard provides an ample margin of safety.

Because the latency period for angiosarcoma of the liver is 40 years, it is not possible to conduct long enough studies to establish a safe level of exposure of the effect.

In general, the available studies show that the current OSHA standard provides an ample margin of safety for nor any other PVC workers. The available studies of intermediate level of exposure show that the current OSHA standard provides an ample margin of safety for the exposure extended over long periods of time. Other studies

have estimated the long-term exposure levels of the 23 confirmed U.S. angiosarcoma cases at between 350 and 1,600 ppm. The median length of exposure for these cases was 18 years.

The single largest study conducted to date was that undertaken by Tabershaw-Cooper Associates and subsequently expanded upon by Equitable Environmental Health, Inc. This study examined the mortality experience of 10,173 workers with at least one year of occupational vinyl chloride exposure and analyzed the cause of death of 707 workers in the study population. As is common for healthy industrial populations, the results showed a 20-30 percent lower than normal death rate from all causes among the workers, whether high or low, or long- or short-term exposure. Cancers of the digestive system (primarily angiosarcoma), respiratory system, and cancers of "unknown" site were slightly elevated in the high-exposure category, but the increases were not statistically significant. Brain cancer was increased in the high-exposure group but the increase was not related to duration of exposure, according to the investigators.

A similar study was conducted by the National Cancer Institute and PVC resin workers. The results of this study showed that there was "no evidence" that exposure to vinyl chloride caused cancer.

A study of the mortality experience of workers in a single PVC plant showed that there was no significant increase in overall deaths or in deaths from cancer. However, there was an increase in deaths from cancer in the intermediate exposure group and a decrease in deaths from cancer in the high-exposure group.

Epidemiological studies by Nicholson et al. and by Waxweiler et al. were of limited value in determining a "safe" level for

vinyl chloride exposure since no attempt was made to assess the exposures of the workers studied.

In addition, a study by Organization Resources Counselors of more than 4,100 deaths among PVC fabrication workers discovered not a single case of angiosarcoma. Workers in PVC fabrication, it should be pointed out, were, even in the past, exposed to far lower levels of vinyl chloride than were their fellow workers in the VCM and PVC resin industries. Accusations by the Environmental Defense Fund that this study demonstrated an excess risk of breast cancer from low-level vinyl chloride exposure were proven false when it was found upon re-examination that only two of the 44 cases of breast cancer in the study had "definite exposure" to vinyl chloride.

Animal inhalation studies, on the other hand, have produced angiosarcoma in test animals at levels as low as 1 ppm. This has prompted Dr. David R. Miller, director of the National Institute of Environmental Health Sciences, to conclude that vinyl chloride may be as much as 100 times more potent in animals than it is in man. This conclusion is based on the work of Gehring et al., who found that the liver of the rat can detoxify vinyl chloride at a rate of 100 mg per kg per day. This rate of detoxification appears to be a "threshold" or no-effect level. For this reason, the biological data suggest that the standard for humans should be of 1 ppm. This standard is based on the fact that angiosarcoma will not occur in the future due to the fact that it has not occurred in the past. However, it appears reasonable to conclude that

employees who work their entire lifetime at a level of 1 ppm will have no greater risk of contracting angiosarcoma than workers who were never exposed to vinyl chloride at all.

With regard to the question of whether vinyl chloride is capable of causing cancers other than angiosarcoma, the evidence is far from conclusive. Nonetheless, even if future research shows this supposition to be correct, the reduction in exposure to 1 ppm will undoubtedly have taken care of this problem as well.

Non-Carcinogenic Effects

In early February 1976 Ralph Nader's Health Research Group released to the press the text of a study scheduled to be printed in the April 3, 1976, issue of The Lancet. The study, by Dr. Infante et al., was conducted at a single PVC resin plant in Pennsylvania. It purported to show that the wives of workers exposed to heavy concentrations of VCM had a statistically significant increase in the number of stillbirths and miscarriages compared to the wives of workers exposed to levels of no VCM.

The Society of the Plastics Industry, Inc. (SPI) engaged eminent scientists, Dr. Brian MacMahon, professor of the Department of Epidemiology, Harvard University, and the Graduate School of Public Health, and Dr. Thomas D. Downs, professor of Biometry, University of Texas Health Science Center, and colleagues -- to undertake independent reviews of this study.

Both Dr. MacMahon and Dr. Downs were highly critical of the analytical methods used. Dr. Downs said that the "misleading conclusions" drawn by the authors were brought about through the

"selection and use of their control group." Dr. MacMahon called the data "worthless," the analysis "naive" and the test "inadequate and misleading." "In short," he said, "this paper is strewn with evidence of carelessness and incompetence and deserves, in my opinion, no consideration whatsoever in weighing the question of whether there is or is not a genetic risk associated with exposure to VCM."

Conclusion

Since 1974, when the plastics industry first identified and reported the relationship between vinyl chloride exposure and angiosarcoma of the liver in industrial workers, enormous progress has been made in reducing plant exposures to safe levels. Dr. Irving J. Selikoff, director of the Environmental Sciences Laboratory at the Mount Sinai School of Medicine in New York City, called vinyl chloride one of industry's "success stories." It is, in fact, the only major toxic substance responsible in industry for which the responsible industry has been able to identify a safe level of exposure and has been able to identify a safe level of exposure.

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