



DOW CHEMICAL U.S.A.

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cc: Roy Gottesman, SPI
Bill Maberry, ICD, 2020
Ron Taylor, ICD, 2020
Chris Wren, ICD, 2020
Art Link, ICD, 2020

RE: REVIEW OF SPI WHITE PAPERS ON VCM

Stan,

With one exception the attached six papers on VCM have been used by the Society of the Plastics Industry (SPI) for the last several years as a general response to all inquiries on the subject. The exception is the paper by Barr of Air Products which is dated 1983.

As a member of SPI's Vinyl Institute Communications committee, I volunteered to have these papers reviewed by knowledgeable Dow people in answer to the questions:

1. Should the five White Papers be scrapped and discontinued, or should they be updated for continuing use?
2. Can Barr's paper be used as a more current response in lieu of the others?

In the meanwhile, Roy Gottesman has removed the papers from circulation. Would you bring to bear the right Dow people on this subject so we can resolve the matter in the Society's best interests. I'll be happy to attend any discussion on the subject.

Thanks,

Tom Sinclair, Manager
Communications
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att.

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 specials, and through rapidly organized medical conferences and regulatory agency hearings. Vinyl chloride even became the subject of a special Congressional hearing.

It is the purpose of this paper to review the events of the last four years regarding vinyl chloride and to place them in perspective. It documents five key points:

- The PVC industry has sponsored the majority of the medical research on vinyl chloride conducted to date, and essentially all of it conducted before 1974. In fact, were it not for the actions taken by the PVC industry from 1970 onward, we might still know next to nothing about the health effects of vinyl chloride.

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The "epidemic" of angiosarcoma cases predicted by some individuals in 1974 has not occurred. Over the past 16 years there have been a total of 23 deaths from angiosarcoma in six U.S. plants and approximately 48 in other countries.

- Industry opposition to the vinyl chloride standards as originally proposed by the Occupational Safety and Health Administration (OSHA) was based on technical infeasibility, the vagueness of the "no detectable level" proposal, and an over-reliance on animal data. OSHA changed the standards to make them more feasible and subsequent studies have proven the industry's contention that experimental animals are far more susceptible to VCM than are human beings.
- Based on a wide variety of epidemiological studies, the current OSHA standard of 1 part per million in air provides more than an ample margin of safety for industry workers.
- According to experts from Harvard University and the University of Texas, the single study alleging an excess of stillbirths and miscarriages among the wives of heavily exposed vinyl chloride workers is "inadequate," "misleading" and essentially "worthless."

Background

The sole source of PVC is vinyl chloride monomer, a gaseous industrial chemical derived from petroleum or natural gas plus chlorine. It is the raw material from which polyvinyl chloride resin is made by a process called polymerization. The process for manufacturing PVC in large vessels or reactors was discovered in Germany in the 1930s and similar processes have been used to make PVC resin in the United States ever since.

Like many other raw materials, VCM had been known for years to have some worker-related problems. It was known by 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 at Yale University found no cause for concern.

From 1951 to 1962 a safety standard of 500 ppm as a maximum time-weighted average was recommended for worker exposure by the American Conference of Governmental Industrial Hygienists (ACGIH) after careful study of all available medical data on the subject. ACGIH is a professional governmental organization devoted to technical and administrative aspects of worker health 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 lead to the discovery of the carcinogenic risk of vinyl chloride.

Cancer Link Discovered

Because of the acroosteolysis situation, industry-sponsored research projects were undertaken both in the United States and Europe in an attempt to discover the exact cause of the disease. The American study, sponsored at the University of Michigan by the Manufacturing Chemists Association (MCA), was unable to pinpoint the cause in humans but recommended further animal experimentation.

The European study was conducted by Dr. P. L. Viola of the Regina Elena Institute for Cancer Research in Rome, Italy. Dr. Viola, who is also a medical director of Solvay et Cie., a leading European PVC producer, reported at the 10th 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 Istituto 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 the United States the Manufacturing Chemists Association in June 1973 announced that 17 PVC producers had agreed to sponsor a study of all causes of deaths in vinyl chloride workers to be undertaken by Tabershaw-Cooper Associates of Berkeley, California. In February 1973 the industry also contracted with the Industrial Bio-Test Laboratories, Inc. of Northbrook, Illinois, for lifetime chronic inhalation studies using test animals.

Thus, before the middle of 1973, four studies sponsored by the PVC industry were underway at various research facilities around the world, all of them prompted by the Viola findings, 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 keep it informed as the research progressed.

In April 1973 Dr. Maltoni also announced some of his preliminary results at a medical meeting in Italy at which representatives of the U.S. government were present.

Thus, by July 1973 at the latest, the U.S. government, as well as at least some portions of the American PVC industry, were aware of Dr. Maltoni's preliminary findings. That this did not result in great alarm in either government or industry circles is not surprising considering the fact that (1) Dr. Maltoni's findings were only preliminary and not final, (2) early results from the European and American epidemiological studies showed

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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. PVC plants, and approximately 48 in other countries. The workers' jobs involved cleaning residue of PVC resin from the reactors in which it was produced. Their work thus resulted in high exposure to VCM over a period of many years.

After a special "fact-finding" hearing held in February 1974 OSHA promulgated an Emergency Temporary Standard which lowered the maximum VCM workplace exposure from 500 ppm to 50 ppm. This decision, which was announced on April 5, was based primarily on testimony from Dr. Maltoni at the fact-finding hearing that rats in his research did not develop angiosarcoma at 50 ppm. Only five days later, however, MCA 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 employee health, and (3) attaining the proposed "no detectable level" standard was not considered to be feasible, employing the then existing control technology.

The industry, therefore, recommended the adoption of a higher numerical standard, with phased reductions over a number of years and revisions of the other requirements.

During the hearings evidence was presented which clearly showed that the employee deaths from angiosarcoma were a result of conditions existing a decade or more ago when exposure levels were in the hundreds, if not thousands, of parts per million. Data developed by the Dow Chemical Company showed no excess mortality

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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 not only to VCM and PVC resin plants but also to processors and fabricators, including firms engaged in "transportation, storage, handling or use" of VCM and PVC resin, unless exposures were found to be below the so-called "action level" of 0.5 ppm.

The industry filed a petition for judicial 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 level of 1 ppm to 5 ppm brought the standard into the realm of technological feasibility, although still extremely difficult and costly to achieve. Since some fluctuation is apt to occur in even the best-controlled plants, the introduction of a peak gave the industry flexibility that was not available under the proposed standard. It introduced a new dimension into the solution of the design and development problems.

In addition, by permitting the use of "gas mask" type respirators at levels below 25 ppm, OSHA eliminated 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 results of these studies show that the current OSHA standard of 1 ppm provides more than an ample margin of safety for industry employees.

Because VCM has been in use in industry for upwards of 40 years, sufficient numbers of people have been exposed long enough to make epidemiological studies reliable indicators of the effects of VCM at various levels of exposure.

In general, these studies showed no excess of cancer nor any cases of angiosarcoma among workers exposed to low or intermediate levels (below 250 ppm) of vinyl chloride even if the exposure extended over long periods of time. Other studies

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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 excesses were not statistically significant. Brain cancer was increased in the study population but the increase was not relatable to vinyl chloride, according to the investigators.

A similar study conducted in Great Britain of 7,717 VCM and PVC resin workers showed similar results, except that there was "no evidence to support the suggestion" that vinyl chloride caused cancers other than angiosarcoma.

A study by Ott, Langner and Holder conducted at a single PVC plant in the U.S. found no angiosarcomas and no excess of overall deaths or deaths from cancer in either the low or intermediate exposure groups. A slight excess of cancer deaths in the high-exposure category was noted, however.

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 5 ppm. This has prompted Dr. David Rall, director of the National Institute of Environmental Health Sciences, to conclude that vinyl chloride may be as much as 500 times more carcinogenic in animals as it is in man. This position is supported by research conducted by Gehring et al. which shows that the body's defensive mechanisms can detoxify limited amounts of vinyl chloride that find their way into the system. It would appear, therefore, that a "threshold" or no-effect level exists for vinyl chloride. The epidemiological data suggests that this level is far greater than the OSHA standard of 1 ppm.

This is not to say that occasional cases of angiosarcoma will not occur in the future due to the heavy exposures of a decade or more ago. However, it appears reasonable to conclude that

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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 little or no VCM.

The Society of the Plastics Industry, Inc. (SPI) engaged eminent scientists -- Dr. Brian MacMahon, chairman of the Department of Epidemiology, Harvard University 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."

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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, an excellent case study of how a responsible industry working closely with government and medicine has been able to identify, report and rapidly control a health hazard.

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