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Many Workers Still Face Health Peril Despite Law

By JANE E. BRODY

The recent discovery of fatal liver cancer among vinyl chloride workers has focused renewed attention of government, labor, industry and medicine on the thousands of known, suspected and as yet unsuspected health hazards that face 60 million working Americans.

Despite the passage three years ago of the Occupational Safety and Health Act, granting every American the right to work without job-induced threats to life and health, the overwhelming majority of workers are not yet protected by the law's provisions. For lack of this protection, hundreds of workers are dying each day from occupational diseases.

The General Accounting Office acknowledges that there has not been nearly enough money and staff allocated to make a dent in the vast problem of occupational health. In addition, fundamental scientific knowledge is lacking upon which to base remedial actions, and without more funds the necessary research is not forthcoming.

Historically, occupational health has been a low-priority item for both government and medicine.

Yet, each year one of every 10 workers suffers a job-related illness or injury. The Public Health Service estimates that prolonged on-the-job exposure to toxic chemicals, dusts, noise, heat, cold, radiation and other industrial conditions each year results in the death of at least 100,000 workers and the development of disabling occupational diseases in 390,000 more.

Researchers in occupational health believe that countless thousands of others succumb to insidious job-related diseases not yet discovered by science.

Industry sources estimate that only between 5 and 15 per cent of workers are covered by comprehensive company medical departments, which have the potential for detecting work-related health threats.

Inadequate Standards

Enforceable Federal standards to protect worker health currently exist for only 430 of the estimated 15,000 chemical and physical agents to which workers are exposed, and experts in occupational health say that most of these standards are inadequate and

For vinyl chloride, for example, the existing Federal standard is 10 times higher than what most industrial users themselves adopted years ago, and is infinitely higher than the zero exposure level that labor and university scientists recommend.

New standards developed under the Federal law are being promulgated by the Department of Labor's Occupational Safety and Health Administration (O.S.H.A.) at a rate of only one a year. At the same time, industry is introducing some 400 new chemicals each year, nearly all of which are untested for possible long-term effects on the workers who handle them.

There is virtually no testing of combinations of substances that by themselves may be harmless but become deadly when combined, although a leading occupational hazard—*asbestos*—is known to greatly increase the risk of lung cancer only in workers who smoke cigarettes.

"The long-term effects of the vast majority of chemical and physical agents used in industry have not been proved, and practically no research is being conducted to find out what these effects are," Dr. Jeanne M. Stillman and Dr. Susan M. Daum state in their new book, "Work Is Dangerous to Your Health."

But Dr. Irving J. Selikoff, director of environmental sciences at Mount Sinai School of Medicine, said, "For scientists to worry about what we don't yet know when nothing is being done about what we already know is a cop-out." He

noted that even if there were enough data to develop protective standards for all known and potential dangers, the Labor Department would be hard put to enforce them with only 600 Federal inspectors and hygienists to canvass nearly five million workplaces.

During its first eight months, O.S.H.A. inspectors visited 17,743 workplaces. At this rate, it would take them more than 200 years to visit each one once. If the staff were expanded to the original projection of 2,000, it would still take about 50 years to complete the rounds of workplaces.

In thousands of plants throughout the country, workers do not even know what chemicals they work with since, to protect trade secrets, the substances are given only code numbers. And unless a Federal standard exists, the company is not required to monitor worker exposure to noxious agents or to perform

periodic medical examinations of those exposed.

"The act has done a great deal to improve the worker's perceptions about the situation, but it hasn't yet done much to improve the situation," said Anthony Mazzocchi, legislative director of the Oil, Chemical and Atomic Workers International Union.

Franklin Wallick of the United Automobile Workers, who wrote a book called, "The American Worker: An Endangered Species," said that for the most part workers are still "the human guinea pigs for industrial processes."

In interviews last week, labor, industry, government and university sources agreed that although the occupational health law was a giant and essential step in the right direction, the realities of current Administration funding have deprived it of much-needed muscle.

Under the act, the National

Institute for Occupational Safety and Health (N.I.O.S.H.) was set up to survey industrial health problems, conduct needed research and develop new standards for known and potential occupational hazards.

But in the wide bureaucracy of the Department of Health, Education and Welfare, the institute has thus far been treated like an unwanted stepchild.

According to a recent analysis by the Government Accounting Office, a meager budget of about \$24-million and a staff limited in size (600) and professional level have severely hampered the institute's potential accomplishments.

As a result, in its first two and a half years, the institute has been able to develop the criteria for only 16 new standards for hazardous materials, although the institute's list of high priority agents exceeds 400.

To handle "emergencies" like vinyl chloride, the institute has been forced to divert funds and personnel from other essential but less immediate tasks, such as developing standards that might head off other vinyl chlorides before workers succumb to their effects.

Last year, the ordinarily sedate and sober director of the institute, Dr. Marcus Key, exploded with exasperation:

"N.I.O.S.H. is not expanding. It is shrinking. It is getting the proverbial meat ax. . . . Our present laboratory space isn't even adequate for any kind of research. It is substandard. . . . We have been frozen on hirings for most of our existence, and we are losing key staff right and left because we don't have the grade points to promote them. . . . I don't think N.I.O.S.H. is a viable organization at this time."

Dr. Key said the situation had not yet improved. "If anything, it's worse," he remarked.

The institute's efforts are not aided by the fact that occupational health has been virtually ignored by the medical profession, which regards it as a less-than-glamorous specialty. Only a handful of universities have departments of occupational health and fewer than a dozen physicians enter the field each year, the majority becoming company doctors.

The institute also faces the scientific problem of how to determine when a substance is safe. As Dr. E. Cuyler Hammond of the American Cancer Society said:

"Negative results in testing a substance for cancer-producing properties are meaningless, and a clever-enough researcher can make almost anything induce cancer in animals, but his findings may have no relevance to human exposure."

Rather than recommending "safe" exposure levels, Dr. Hammond and Dr. Key believe that industry should adopt protective work practices that eliminate worker exposure to all agents—whether or not they have been proved harmful.

Such work practices were recommended by the institute for 14 cancer-causing industrial chemicals covered by an emergency standard issued last spring. The institute advocates a similar approach to vinyl chloride, a gaseous chemical in the plastics industry that in the last month has been linked to angiosarcoma of the liver, an extremely rare cancer, in nine workers at four different plants.

A further problem in gaining worker protection under the act has been the slowness of the Labor Department in issuing new exposure standards and its reluctance to assume full enforcement responsibilities. Thus far, the institute has acted on only two of the institute's 16 proposed standards—*asbestos* and *carcinogens*—and in both cases the action resulted in a weaker standard than the institute had recommended.

Under Administration pressure—and to the distress of occupational health activists—the Labor Department has been seeking to turn enforcement of the Federal regulations back to state occupational safety and health divisions.

Robert E. Nagle, general counsel for the Senate Labor and Public Welfare Committee who is the main author of the Occupational Safety and Health Act, said that the states traditionally have had little interest or expertise in occupational health (as opposed to safety), and that state officials are likely to be more susceptible to pressure from local in-

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vented tube from each engine blows air at very high pressure and forces gravel away from the engine intake.

Other operating problems include temperatures that are 50F to 60F below zero, 60-mph winds, and total darkness in December and January in the High Arctic. Engines on airstrip equipment such as trucks and snowplows are not turned off from Dec. 1 to Mar. 15.

Though the regionals, too, face fuel problems, all are predicting revenue increases this year. They see their biggest growth potential in scheduled passenger service, although no one is scoffing at the big bucks to be made in hauling drilling equipment—and beer—to oil teams in the Arctic or to the off-again, on-again \$6-billion James Bay hydroelectric project in northwestern

PWA ships cattle to the Orient and oil-drilling equipment to the Arctic

Quebec. Nordair flies there from Montreal, and Quebecair operates cargo-only service.

Cattle plane. In the eyes of many industry observers, Pacific Western is the best run of the regionals. Its fleet consists of seven Boeing 737s, with three more on order, plus two 727s, two long-range 707s, five Convair 640s, four Hercules jet-prop freighters, and a few flying boats. PWA's operations range from its scheduled passenger services to shipping cattle to the Orient and extensive relief work in such places as Nigeria and Bangladesh. Scheduled passenger services account for roughly 65% of PWA's revenues, charters for about 10%, and cargo services for the remaining 25%.

Its cattle plane is typical of PWA's willingness to provide specialized services to meet special needs. A conventional Boeing 707-320C, the plane can be equipped with either 13 stalls holding about 85 1,000-lb. cattle or double tiers of pens that will accommodate a great many more smaller animals. Donald N. Watson, PWA president, says that the plane has carried as many as 700 cattle from Toronto to Athens.

The real keys to profits for PWA and the other regionals, however, have been jets and charters. The jets boosted available seat-miles on routes with good load factors, and the charters gave the carriers the capability to use their aircraft more economically.

Keith Miller, executive vice-president of Eastern Provincial Airways, estimates the seat-mile cost on a 109-passenger 737 at 2.2¢ a mi., compared with 5.5¢ for each mile on the 41-seat Handley Page Herald the 737s are replacing. The break-even load factor on the jets is 42%, vs. about 80% on the prop planes. "The stimulation of a 737 is very substantial," Miller says. ■

TECHNOLOGY

Industry's latest cancer scare

The deaths of five workers in ten years seem linked to working on the plastic

Federal officials met last week with plastics industry executives in Cleveland and Washington to try to determine whether the industry has unknowingly been exposing some of its 6,500 blue-collar workers to fumes that can lead to a rare form of liver cancer known as angiosarcoma. The focus was on 28 of the 42 plants in the U. S. that make vinyl chloride or use it to produce polyvinyl chloride resin (PVC), one of the most common plastics.

The hearings grew out of the deaths of four workers over the last six years at a B. F. Goodrich Chemical Co. plant in Louisville, Ky. They could ultimately bring costly new rules for the PVC industry, whose resins are used in such items as pipe, floor tile, phonograph records, and latex wall paints. "Improvements in work practices will probably require a 100% increase in the work force," says Walter B. Connolly, Jr., labor counsel for Firestone Tire & Rubber Co., which operates PVC plants in Pottstown, Pa., and Perryville, Md.

In any case, the current PVC hullabaloo is certain to spark new demands by organized labor for closer examination of the possible long-range ef-

fects on workers of other industrial chemicals. "The cancer took 15 to 20 years to develop," says one federal epidemiologist. Other chemicals could have similar "latency" periods, he says, so there could be more eruptions in the years ahead. "I hope we're not seeing the beginning of a health collapse."

The vinyl chloride case is not the chemical industry's first encounter with OSHA over carcinogenics. Last May the agency invoked emergency standards for 14 chemicals (BW—May 19, 1973). Final rules for these materials went into effect last week, though both industry and labor are suing for judicial review.

The prospect of new, petrochemical versions of such health time bombs as "black lung" and mercury poisoning, makes plastic industry leaders shudder. And indeed, new data presented at the standing-room-only OSHA hearing by Italian researcher Cesare Maltoni, of Bologna's Institute of Cancer, leave little doubt that vinyl chloride is carcinogenic—at least to rats. He exposed 67 rats to air containing 250 parts per million of vinyl chloride off and on for 52 weeks. By the end of 127 weeks, Maltoni reported, two had contracted angiosarcoma and nine contracted other forms of cancer. Many chemical industry executives had downgraded the importance of earlier animal test results because the dosages were mas-

A solvent that crippled chemical workers

Last August, Thomas F. Meade, 22, was stricken with a nerve disease after two years of work at Columbus Coated Fabrics Co., a subsidiary of Borden, Inc., in Columbus, Ohio, that makes vinyl-coated fabrics for luggage and wall coverings. The disease, diagnosed as peripheral neuropathy, left Meade crippled, and today he wears leg braces. He is the most severely affected of some 130 workers at the plant who have suffered symptoms of the disease. The lesser symptoms include weakness and loss of coordination.

When the symptoms became widespread last summer, state health officials tested the nerve responses of the plant's 1,124 employees and told 200 of them to stay home for two months. Many others stayed home, too, out of fear. By December, most employees had returned, and many who had showed neuropathic symptoms appeared well again.

Meanwhile, Ohio health officials had

zeroed in on an ink solvent, methyl butyl ketone, used in applying decorative patterns, as the most likely culprit. While continuing to monitor the plant's air, they banned the use of MBK. The plant's managers have switched to a substitute, improved ventilation, issued respirators to print shop worker and moved lunch areas away from work areas.

But Corwin Smith, president of Local 487 of the Textile Workers Union of America, which represents the plant's workers, is not satisfied. He says that 26 members are still out with the disease, that eight of them are severely crippled, and that three workers whose condition improved are now sick again. On Feb. 9, the local struck the plant as negotiations collapsed on a new contract; one of the union demands was a "proper work environment." Says Smith: "People here don't know whether they will be crippled in the future or not."

sive, on the order to 5,000 to 30,000 ppm.

The bombshell. The cancer crisis hit the vinyl industry just a month ago. Noting an unusual number of liver ailments among the Louisville plant workers, B. F. Goodrich physicians ran blood tests last fall on the 271 workers in the plant's PVC facility and found 55 with apparent liver abnormalities. The company reviewed medical and insurance records and by Jan. 16 had discovered three deaths since 1971 that were attributable to angiosarcoma. Federal health officials estimate the annual death toll in the U.S. from this rare form of cancer at only about 20. On Jan. 29 further review by Goodrich turned up a 1968 death (two more cases, including a 1964 death, were identified this week).

The company's top management had already decided on public disclosure. It reported the situation to the National Institute for Occupational Safety & Health and to the Kentucky Labor Dept. It also began notifying employees in all of its vinyl chloride and PVC operations, and it sent a release to the press. "We are doing our utmost to express our real and serious concern," says John J. Bell, the company's public affairs director, "and yet prevent any undue panic."

NIOSH, which had immediately sent experts to Louisville, held a briefing early last week in Cleveland to tell management and labor leaders in the industry what it knew about the carcinogenic effects of vinyl chloride. And on Friday, many of the same executives showed up in Washington for the OSHA hearing. The federal agency will determine whether the situation warrants either an emergency standard or at least a start on the regular rule-making process.

The attitude of organized labor was a major concern. Anthony Mazzocchi, legislative director of the Oil, Chemical & Atomic Workers, who attended the NIOSH briefing, says: "It's apparent we're dealing with a carcinogen. We want to reduce exposure to zero. But we have a wait-and-see attitude right now."

While the fatalities at Louisville came as a shock to the industry, vinyl chloride has been suspect for a long time. Some 15 years ago Dow Chemical Co., based on its own studies, adopted an average exposure limit of 50 ppm for its workers—well below the 200-

ppm limit recommended since 1972 by the American Conference of Government Industrial Hygienists. In 1970, Italian researcher Dr. P. L. Viola reported that rats exposed to heavy doses of vinyl chloride developed malignant tumors. Several European chemical companies banded together to support research by Maltoni, and in the U.S., the Manufacturing Chemists Assn. began to discuss an industry-wide research program. A year ago, the MCA set up an animal test program that will not be completed until late 1975. The association also contracted with Tabershaw-Cooper Associates, of Berkeley,

nora, Jr., general manager of the Plastics Div. of Diamond Shamrock Chemical Co., which also observes that limit, "there are not enough fumes in the air to smell." Where concentrations are higher, he says, "we have ordered our men to wear gas masks."

Vinyl fumes arise partly from leaks in pipes and valves. But another likely source is the polymerization vessels, when they are opened for cleaning and maintenance. NIOSH officials are concentrating now on the polymerization process, but they plan to extend their studies eventually to monomer production, as well as PVC fabrication and even consumer use of PVC products.

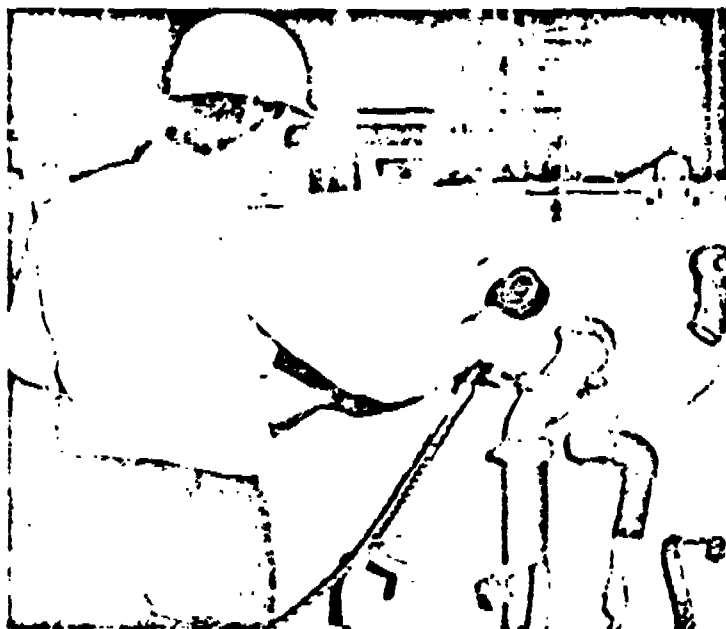
Since safe limits for vinyl chloride are unknown, NIOSH is emphasizing safe work practices rather than arbitrary concentration limits. Its recommendations for the Louisville plant, for example, include such things as overhead cleaning, daily showers and clothing changes for workers, and expanded air monitoring.

Pinning it down. Goodrich's Louisville plant uses about 50 different chemicals, and there is no proof of a direct link between vinyl chloride and the liver cancer cases. But NIOSH officials are certain that the link exists, and the MCA's Johnson concedes that "vinyl chloride is the material of primary

suspicion." Only two other carcinogens, arsenic and thorium-232, are proven causes of angiosarcoma, and medical records on the four Goodrich workers showed no exposure to either.

Both NIOSH and industry officials hope, though, that the link is peculiar to Goodrich's Louisville plant. Says NIOSH Director Marcus M. Key: "We still hold to the possibility that the cause could be a combination of two or three things acting together in the manufacturing process."

The Louisville plant is Goodrich's oldest PVC plant and, unlike most newer plants, is enclosed. It also has a number of older workers on the line. Some workers may have been affected by an epidemic of hepatitis that swept the city a few years ago. A number of other rubber and chemical plants, and their fumes, are located nearby. And the plant is one of the few that uses vinylidene chloride as a copolymerizing agent. Rudolph Jaeger, a physiologist at the Harvard School of Public Health, told the OSHA meeting that test data appear to point to that chemical, too, as a carcinogen.



A B. F. Goodrich safety inspector uses a chemical "sniffer" to check whether vinyl chloride fumes are leaking from a polymerizing reactor.

Calif., to check the available death records of workers at other vinyl plants. "So far," says Kenneth Johnson, MCA technical director, "the results haven't been subjected to statistical analysis."

To Dr. Irving J. Selikoff, the history shows that "our approach to the prob-

NIOSH hopes that the cause is a combination of factors at only one plant

lem was, shall I say, leisurely." Selikoff, director of environmental medicine at New York City's Mount Sinai School of Medicine, has been a frequent critic of industrial health practices, and one chemical executive calls his remark, made at the OSHA meeting, "hindsight."

Belatedly or not, some PVC producers have been tightening up their operations. Goodrich, for example, says it had already done, or was doing, most of the things NIOSH recommended after visiting the Louisville plant, including sticking to a 50-ppm average exposure limit. "At 50 ppm," says Harry Con-

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STATEMENT
OF THE
MANUFACTURING CHEMISTS ASSOCIATION
BEFORE THE
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
ON
POSSIBLE HAZARDS OF VINYL CHLORIDE
MANUFACTURE AND USE
FEBRUARY 15, 1974

The Manufacturing Chemists Association (MCA) is a non-profit trade association having 174 United States member companies representing more than 90 percent of the production capacity of basic industrial chemicals within this country. With respect to vinyl chloride, the subject of this hearing, over 97 percent of the production capacity reported by Chemical and Engineering News in May 1973 was in our members' plants. For the polymer plants, the corresponding figure was then nearly 88 percent.

Vinyl chloride (VC) is a chemical derived ultimately from petrochemical feedstocks and chlorine. Of the 5.2 billion pounds of the monomer produced by U. S. industry in 1972, all but a small fraction -- less than one percent -- was used in the production of various plastics -- primarily polyvinyl chloride (PVC),

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but including a wide variety of co-polymers with other monomers. Among the plastics, only the production of polyethylene exceeds that of PVC.

The importance of PVC production is not measured just by the value of the unprocessed polymer, but more properly by the almost universal dependence of nearly every branch of industrial and commercial activity upon products and components fabricated from this plastic.

With this statement, we are submitting a description of the industry and its products that appeared in the December 1973 issue of Plastics Engineering, and we ask that this reprint be made a portion of the record of this hearing. This report makes it clear that the VC/PVC industry involves a wide variety of chemicals -- initiators, catalysts, plasticizers, stabilizers, antistatic agents, fillers, pigments, and a host of other specialized, but generally very minor, additives. Under such circumstances, the identification of any adverse health effects among the employees of a vertically-integrated VC/PVC plant with a specific causative agent becomes complex.

A few more statistics concerning the industry may be helpful. The U. S. VC/PVC industry has been operating over forty years, and over the past five years has shown an annually compounded

growth rate of 14 percent -- a rate of growth that is expected to taper off only moderately in the next few years, to about 11 percent. U. S. production now represents about one-fourth of the world total.

Synthesis of the monomer is conducted in fourteen U. S. plants, and thirty-seven plants are engaged in polymerization. It is estimated that about 1,500 workers are employed in monomer synthesis, and an additional 5,000 in polymerization operations.

It is difficult to estimate the number of workers employed in converting, molding, and fabricating these polymers, but they are numbered in the tens of thousands, working in thousands of plants. It has been estimated the wholesale value of the annual output of fabricated products is over three billion dollars.

MCA, as a regular and continuing service to its members, has long had active programs in occupational health and safety. Its past and current activities with respect to vinyl chloride are a natural outgrowth of these programs. MCA's Safety and Fire Protection Committee is now in its twenty-eighth year. Among its other activities, it has prepared MCA's highly-respected series of Chemical Safety Data Sheets for commodity chemicals throughout this

period. One on vinyl chloride -- SD-56 -- was first issued in 1954, and was last revised in 1972.

A Medical Advisory Committee was formed in 1946, later reconstituted with the addition of industrial hygiene engineers, toxicologists, statisticians and other specialists in employee health, and renamed the Occupational Health Committee.

Additionally, MCA is prepared to administer special programs on behalf of groups of interested companies, in instances where only a limited number are directly involved.

Thus, in 1966, when companies were alerted by the European reports of an occupational disease among PVC polymerization kettle cleaners, a project was established at the University of Michigan's School of Public Health to determine the nature, extent, and etiology of the condition known as occupational acroosteolysis. The results of this study have been published by Drs. Harold J. Magnuson, Bertram D. Dinman and others, in a series of three papers^{2,3,4} in the Archives of Environmental Health (January 1971). Although the role, if any, of vinyl chloride in the causation of this condition could not be defined, the industrial hygiene controls and improved work practices adopted by the industry have led to a decline to almost zero in the number of new cases of even very mild forms of this disease.

It was in an effort to develop an animal model of this condition that the first observations of possible carcinogenesis by vinyl chloride were made. Dr. P. L. Viola, in a report published in March 1970⁵, reported that rats exposed to 30,000 ppm vinyl chloride vapors for four hours per day, five days per week for a year, showed "degeneration of the skeleton and connective tissue with histopathological pictures similar to those observed in human acroosteolysis of the hands." In his paper, no mention is made of the appearance of any malignant tumors.

A few months later, however, at the Tenth International Cancer Congress⁶, Dr. Viola briefly described observations of malignant tumors in the ear canals of rats subjected to an exposure protocol almost identical with that in his earlier paper. He also reported tumors in the lungs and bones of these rats, but closed his abstract with the specific disclaimer: "No implications to human pathology can be extrapolated from the experimental model reported in this paper."

MCA invited Dr. Viola to come to the United States as a guest of the industry, for a discussion with U. S. occupational health experts. On May 5 and 6, 1971, at a meeting with MCA's Occupational Health Committee, he discussed his more detailed

report then in press⁷, and referred to other studies completed or underway. Dr. Viola spoke of these unreported studies only in rather general terms, and declined to reveal details. He acknowledged that his vinyl chloride was of low purity, but expressed his personal opinion that it was the vinyl chloride, per se, and not any impurities, that was responsible for the pathology he was observing. He claimed to have seen tumors in rats exposed to 5,000 ppm, but expected the results would be negative at half that level. In his opinion, the 500 ppm TLV provided an adequate margin of safety of employees from the tumor induction he had seen in rats at the higher levels. We are not aware of any further publications by Dr. Viola on this subject.

The disparity between Dr. Viola's findings and the relatively low toxicity reported by earlier researchers was immediately recognized. For many years, vinyl chloride monomer was considered to be very low in toxicity, both from single and repeated exposure. Because of its volatility, inhalation was considered the only important route of exposure for workmen. The high flammability of VCM has been considered to be a more serious hazard than inhalation.

From the earliest lists until 1962, the American Conference of Governmental Industrial Hygienists (ACGIH) recommended that the time-weighted average, long-term, 7-8 hour daily exposure

of workmen to vinyl chloride not exceed 500 ppm v/v (1270 mg/m³). This recommendation was based on single exposure studies on animals and on human experience. Recommended time-weighted average concentrations are published by the ACGIH in an annual list of "Threshold Limit Values" (TLV). A TLV was considered by this group to "represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, without adverse effect."

In 1963, the ACGIH modified their recommendation so that 500 ppm was to be a maximum concentration (or ceiling) rather than a time-weighted average. It is this standard that is in the 1970 TLV list promulgated by OSHA on May 29, 1971, as a national consensus standard.

The change from a time-weighted to a ceiling standard was, in part, due to the publication by Torkelson, Oyen and Rowe⁸ of the results of six-month repeated inhalation studies on laboratory animals. These authors reported slight reversible liver injury in rats exposed seven hours per day to 100 ppm, and recommended that the time-weighted average exposure of workers not exceed 50 ppm. This recommendation was not deemed appropriate by Lester, Greenberg, and Adams⁹, however, who did not consider significant injury to have resulted in rats which they had repeatedly exposed to 500 ppm.

In 1970, the ACGIH proposed reduction of their recommended TLV to a time-weighted average of 200 ppm primarily on the basis of work reported by Kramer and Mutchler¹⁰. The authors reported evidence of clinical findings in workers exposed to time-weighted average concentrations of 300 ppm vinyl chloride for many years.

In 1972, the ACGIH took vinyl chloride from the list of Intended Changes and revised the value in their regular list to 200 ppm (510 mg/m³). This value remains the recommended value in the 1973 list. A copy of the documentation for the ACGIH TLV for vinyl chloride is provided as an attachment to this statement.

In view of these developments, it was recommended that MCA convene a conference of vinyl chloride manufacturers to discuss the prospect and feasibility of establishing an industry-supported research program. This meeting, attended by representatives of U. S., Canadian and European firms, took place on November 16, 1971. On the initiative of companies attending, a research project was formed with MCA participating in an administrative role.

A contract with the Industrial BIO-TEST Laboratories, Inc., of Northbrook, Illinois, was signed on February 1, 1973. The complete experimental protocol is submitted as an attachment to this statement. The specific goals in mind were:

1. to attempt to duplicate the European observations with vinyl chloride of a source and quality characteristic of the U. S. industrial product;

2. to extend these studies to two other species of laboratory rodents -- mice and hamsters, to determine whether the responses of rats might be species-specific;

3. to develop dose-response relationships with higher limits of statistical confidence, to permit estimation of potential risks at occupational levels of exposure with greater precision; and

4. to determine what the no-response level is.

In these studies on rats, mice and hamsters, groups of 100 male and 100 female of each species (600 animals at each exposure level) are being exposed to either 0 (control), 2,500 ppm, 200 ppm, or 50 ppm of vinyl chloride monomer, seven hours per day, five days per week, for twelve months. They will then be observed for an additional twelve months (six months for mice). These animals will not have food and water during exposure.

This "lifetime" study is designed primarily as a cancer study and will include only a limited amount of other observations. Because Viola's studies involved simultaneous exposure of food, water, and bedding, a separate group of 100 rats of one sex is being ex-

posed to 2,500 ppm along with their food, water, and bedding. This has been included because of the possibility that a reaction of the vinyl chloride monomer with either the food, water, or bedding may result in a toxic reaction product.

Although animal exposures started in July 1973, equipment problems gave rise to a number of uncertainties that might have compromised the validity of the results, hence the initial group of animals was discarded and a new set procured. The new exposures got underway on September 10, 1973.

Up to this time, no significant results have been observed in this study, nor would the appearance of any tumors be expected in so short a time. We will keep both OSHA and NIOSH informed as this study progresses.

Recognizing that there must always exist a substantial degree of uncertainty in extrapolating the results of animal studies to the evaluation of workplace hazards, MCA has contracted with Tabershaw-Cooper Associates, (TCA) of Berkeley, California, to conduct a study of the causes of death in vinyl chloride and polyvinyl chloride production workers. The objectives are:

1. to compare the mortality of individuals who have worked in vinyl chloride plants with that of the general population, corrected for area, age, and sex;

2. to compare mortality patterns within the population of vinyl chloride workers, based upon estimated occupational exposure; and

3. to compare mortality among vinyl chloride workers with the mortality of other occupational groups which TCA has studied.

This study is now in its eighth month, and a final report is expected to be issued in April. A copy of the protocol is submitted with this statement.

Although the mortality statistics are as yet incomplete, and have not been analyzed, a preliminary review of the current data from all plants, other than the one concerning which the B. F. Goodrich Chemical Company has made a public disclosure, fails to show any obvious departure from the pattern and incidence of the deaths that would be expected among a population of the kind that has been the subject of this survey.

We will, of course, provide OSHA and NIOSH with the final report and alert them promptly should any significant evidence of occupationally-related deaths appear earlier.

MCA's first direct contact with NIOSH specifically on vinyl chloride led to a conference between an industry delegation,

including a European representative, and Dr. Marcus Key and staff on July 17, 1973, at which time the MCA program was presented in some detail, and study protocols, industry statistics, and selected items from the scientific literature were provided.

Under these circumstances, the VC producing and consuming companies participating in the MCA-administered program were understandably greatly concerned when informed on January 22 by the B. F. Goodrich Chemical Company of the events that have led to the hearing now in progress. A meeting of the representatives of these companies was held on January 25 under MCA auspices to receive a comprehensive report from Goodrich, and to plan and implement any necessary steps not only for the protection of their workers, but also to hasten the resolution of remaining uncertainties.

MCA then immediately contacted NIOSH and, both by telephone and by confirming letter, gave assurance of full cooperation and support in their investigation and development of recommendations for the control of hazards from this source.

MCA publicly announced that it is temporarily withdrawing its Chemical Safety Data Sheet for vinyl chloride, which recognized Dr. Viola's work, but stated that "... many years of industrial experience with human exposures to concentrations

frequently far above current standards have not demonstrated any carcinogenicity to humans." MCA will expedite the reissue of this data sheet, revised as necessary to reflect new knowledge concerning possible hazards of vinyl chloride exposures. A copy of a February 6, 1974, news release on the withdrawal is attached.

As discussed herein, manufacturers are aware of the potential hazard of vinyl chloride and, we are informed, are voluntarily taking steps to reduce employee exposure. Substantial research is now in progress, the results of which they believe will provide a firm basis for any standard applicable to VC/PVC manufacture. Therefore, it is their recommendation that OSHA proceed under the provisions of Section 6(b) of the Act.

On behalf of its producer members, MCA pledges full cooperation with both NIOSH and OSHA as they attempt to define the hazards now tentatively identified with vinyl chloride, and develop standards that will assure the safety of workers in this industry.

LIST OF REFERENCES

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6. Viola, P. L.: Cancerogenic Effect of Vinyl Chloride. Presented at the Tenth International Cancer Congress. Houston, Texas (May 22-29, 1970).
7. Viola, P. L.; Bigotti, A.; Caputo, A.: Oncogenic Response of Rat Skin, Lungs, and Bones to Vinyl Chloride. *Cancer Research*. 31, 516-522 (May 1971).
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9. Lester, D.; Greenberg, L. A.; Adams, W. R.: *Am. Ind. Hyg. Assn. J.* 24, 265 (1963).
10. Mutchler, J. E.; Kramer, C. G: Report on Relation of Exposure to State of Health of Dow Chemical Workers, Gordon Conf., Tilton, N. H. (August 1968).

LIST OF ATTACHMENTS

- A) PLASTICS ENGINEERING PRIMER/PVC
Reprint from December 1973 Plastics Engineering
- B) Viola, P. L. - Pathology of Vinyl Chloride
- C) Viola, P. L. - Cancerogenic Effect of Vinyl Chloride
- D) Documentation for ACGIH TLV for Vinyl Chloride
- E) MCA News Release #3791
- F) Revised Protocol for Animal Exposure Studies
Industrial BIO-TEST Laboratories, Inc.
- G) MCA News Release #3814
- H) Protocol for Epidemiology Study
Tabershaw-Cooper Associates, Inc.
- I) MCA News Release #3835

MCA Statement at OSHA Hearings/Vinyl Chloride
February 15, 1974