

VINYL CHLORIDE AND CANCER --

A STUDY IN PREVENTION

On a bleak Sunday night in January, 1974, a team of doctors told executives of The B.F. Goodrich Company that three polyvinyl chloride workers in its Louisville plant had died in the past two years from a rare form of liver cancer -- angiosarcoma. This portentous finding was the first reported anywhere in the world linking vinyl chloride with human cancer.

The three employees had all worked for years cleaning the interior of reactor vessels that convert vinyl chloride gas into plastic. In so doing, they had inhaled over and over again air containing comparatively high levels of vinyl chloride gas left in the vessels.

Earlier that day, the company's director of environmental health and a consultant on epidemiology and pathology had left Louisville, where they had been conferring with local physicians and pouring over records, and flew in a company plane to Goodrich headquarters in Akron, Ohio.

The two doctors met that same night with top company officials, including the chairman and president. By Monday morning, experts in the company were duly briefed about the hazards of the situation. By midnight Monday these specialists in engineering, environmental controls, medicine, law and public communication formulated the following action plan:

- Dr. Maurice N. Johnson, company director of environmental health, and Dr. Irving Tabershaw of Berkley, Calif, consultant on epidemiology and pathology, would present their data to the National Institute of Occupational

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Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA).

- Dr. John Creech, Louisville plant physician and Phillip J. Lawrence, plant manager, would present the data to the Kentucky Department of Labor.

- The company would release at once all available information to all employees in its five PVC plants and its vinyl chloride monomer plant.

- The company would issue a news release and distribute it not only to Louisville media, but also to media in all plant communities as well as to the national press.

- Customers and competitors were to be advised immediately.

- The company would promptly begin a study of all PVC workers in all plants who had died, as far back as records existed, to learn if there had been other cases of angiosarcoma in the past. Dr. Tabershaw's firm of Tabershaw-Cooper was retained to help in this study.

- Finally, and most important, development engineers and research scientists were instructed to reduce levels of vinyl chloride and worker exposure in all plants as rapidly as possible.

Company officials who had been pursuing vinyl chloride containment programs for several years, realized this final objective would be the toughest part of the problem. The plants were then operating at levels that ran about 50 parts per million vinyl chloride in work atmospheres.

A special group, consisting of those most knowledgeable in each aspect of the problem, met each morning at 7:45 a.m. to exchange information. Plant managers came to the Cleveland headquarters of the chemical division weekly (later every two weeks) to report on progress and discuss new methods of controlling vinyl chloride.

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Within a few weeks NIOSH published emergency recommendations for worker protection. These were strict (some were later found to be unnecessary) and were not mandatory, but Goodrich promptly complied with all of them in all its plants.

In April, OSHA established a temporary exposure level of 50 ppm. Goodrich was already operating at levels that were below that most of the time, but this did not slow its containment programs. The corporate directive was: Get the levels as low as possible as soon as possible.

As shocking as was the first discovery of a link between vinyl chloride and human cancer, it was not the first indication of health problems connected with this gas. In the early 1960's it had been discovered that some workers who cleaned reactors developed a bone degeneration in their finger, called acroosteolysis. Industry had published this discovery, sponsored two university studies on this problem, and had taken steps to protect workers which apparently prevented recurrence. Among these was the Goodrich development of the Hydraulic Reactor Cleaner, a device which cleaned away most of the PVC that remained in reactors after the reaction was completed. This had substantially reduced the number of times men had to go into the vessels to clean them.

It had long been known that at high levels vinyl chloride fumes could have intoxicating or anesthetic effects. Workers were warned of this. In 1949 the Russia

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published a paper showing that workers processing PVC into finished goods (shoes and insulation) had suffered bronchial and liver defects. However, these researchers determined that the defects were caused by a plasticizer in the compound, and not by PVC. Several times since, investigators who may have read only the abstract had incorrectly stated that this report implicated PVC or vinyl chloride only, and not the plasticizer.

OSHA had adopted 500 ppm as the standard for vinyl chloride exposure. This had been the level recommended by the American Conference of Governmental and Industrial Hygienists (ACGIH). However, the Dow Chemical Company had observed liver damage, but not cancer, in rats at lower levels. ACGIH, but not OSHA, changed its standard to 200 ppm in 1972.

In 1969 Dr. P. Viola, in Milan, Italy, was employed by one of the PVC producers in Europe to do further studies on the hand problem (acroosteolysis). He exposed rats over a long period of time to very high concentrations of vinyl chloride in air -- up to 30,000 ppm. Since vinyl chloride approaches its explosive level at these high concentrations, it was never permitted even a decade ago to reach anywhere near these levels in air in plants.

At the conclusion of his studies, Dr. Viola reported that he had observed malignant tumors in several of his rats. It was the first published report of a connection between vinyl chloride and cancer. He presented his report at an international cancer symposium, attended by many U.S. government and private cancer specialists, in Houston in July 1970. His paper was later published in Cancer Research, an international publication, in 1971.

Viola's exposure levels were so high and so prolonged that no similar human exposures had ever been encountered. Nevertheless, Goodrich and other producers began

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to reduce exposure. There was one problem, of course: There were no data to show what a safe level would be.

Goodrich and other producers began discussions in 1972 toward establishing an animal testing program to confirm Viola's results and, if possible, to find a level at which no cancers were observed in test animals. Establishing the criteria for such studies, or "protocols," as scientists call them, is very complicated; as they point out, too many studies of this kind have been incomplete or improperly carried out, so that results were not conclusive.

In the course of this investigation, in late 1972, American producers learned that European producers already had undertaken sponsorship of an animal study by Dr. Cesare Maltoni in Bologna, Italy. A team of American scientists received permission from the European sponsors to observe Maltoni's work. Their objective was to learn his methods and to avoid duplication in U.S. studies. Maltoni agreed, but reserved to himself the right of first publication.

The Americans visited him in January, 1973. Maltoni informed them that he had found malignant tumors in rats at exposures of 250 ppm. He pointed out that his studies were not complete. American producers urged the European sponsors to have these data published, but the sponsors respected Maltoni's prior rights. Upon returning home, the American producers promptly initiated an epidemiological study of U.S. vinyl chloride and PVC workers in the U.S.

U.S. Government scientists also knew of Maltoni's preliminary results early in 1973. At the Second International Symposium on Cancer Detection and Prevention in Bologna, Italy, April 9 - 12, Maltoni showed a table of preliminary results linking vinyl chloride with cancer. Umberto Saffiotti, associate director of carcinogenesis

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at the U.S. National Cancer Institute, was present at the meeting and subsequently discussed the results with Maltoni at his laboratory.

Saffiotti later told a Senate committee that he felt that the work should be included in a "well documented report," to be assessed by a review panel of the World Health Organization's Agency for Research on Cancer. Both Saffiotti and the WHO organization regarded Maltoni's data as preliminary. The WHO group decided to postpone compilation of the definitive review to the next meeting of the committee.

Nevertheless, on April 17, 1973, representatives of the Manufacturing Chemists Association, which was coordinating plans for the two American studies, urged the European sponsors of Maltoni's work to make joint presentations to U.S. and European governments. Permission was granted for U.S. producers in June (Maltoni wanted to complete more work) and NIOSH was asked for a meeting which took place on July 17. At that meeting one European and four U.S. industry representatives presented NIOSH with Maltoni's preliminary findings. No government action was taken on these data at that time.

Meanwhile, U.S. producers continued to follow Maltoni's work and to investigate establishing studies in the United States. Work also continued to reduce exposures in U.S. plants. Goodrich established a task force for this purpose in April, 1973.

One of the most difficult problems was finding reliable monitoring systems which would prove the presence of vinyl chloride in air in work places on a continuous basis. Air samples taken at intervals could be quite accurately analyzed when taken to the laboratory, but vinyl chloride is a gas which dissipates rapidly and the "grab sample" techniques could not really establish high, low or continuing conditions.

One device was tried in August, 1973. It was the portable Organic Vapor Analyzer, an instrument used to detect gas leaks, that measures the levels of all

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organic vapors, down to parts per million, in plant air. (For example, it picked up paint fumes from a nearby plant.) But it will not single out vinyl chloride. However, if vinyl chloride is present, no matter what other gases may be in the air, the OVA will show it. These devices were used to monitor Goodrich's 50 ppm standard.

Late in the summer of 1973, Dr. M.N. Johnson, who had recently been named Goodrich director of environmental health, and Dr. John Creech, physicians for the company's Louisville, Ky., PVC plant, started liver function tests for all PVC employees. Creech had reported that he was seeing more than expected liver problems.

On December 18, Dr. Johnson met with Dr. Creech in Louisville to review results of these tests. In this meeting Dr. Creech mentioned that one of the Goodrich employees had died of angiosarcoma of the liver that spring, and he remembered a similar case a year or so earlier.

Johnson recalled that three weeks earlier he had attended an MCA meeting where an interim report on Maltoni's work was presented. Angiosarcoma had been identified as a type of cancer observed by Maltoni in his rat studies. Johnson and Creech discussed the combined human and animal data and decided immediately to pursue the possibility that the human cases could have been work related. Creech also told Johnson that another employee was terminally ill with liver cancer.

They then began to search records and work histories. The patient in the hospital died on December 19. There was some delay in getting his autopsy report, but when it came in the diagnosis of angiosarcoma was confirmed.

Angiosarcoma of the liver is very rare. There are other forms of liver cancer and liver disease. Drs. Creech and Johnson were sure of their diagnosis, but slides were sent to leading pathological laboratories for confirmation. Meanwhile, Johnson

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began to try to contact the best epidemiological consultant he could find to help him and Creech in looking for other cases. Tabershaw was his man, but Tabershaw was away from his office. Johnson was waiting in Tabershaw's office when he returned on January 16. They left promptly for Louisville, and a few days later presented their data to the Goodrich Management Committee at the Sunday night meeting.

Tabershaw, Creech and plant personnel began searching past records. One of the problems was in death records. Frequently these are quite unspecific as to cause of death. ("Heart failure, complicated by liver cancer." for exaple.) In most cases it was necessary to recover slides, if an autopsy had been done and slides taken. Through this difficult search process, three more past cases were discovered, going back to 1964.

Right after the discovery, Goodrich began medical examinations of all present PVC workers at Louisville, and soon thereafter at all plants. Liver dysfunctions are not uncommon, especially in older men, and several cases were found. An examination procedure was established. The more suspect cases get liver scans, a more detailed process. If these show up positive (a spot on the liver) a biopsy is performed. Through this process Goodrich found that two of its workers had angiosarcoma of the liver. A third was found later. Very early, the company decided that all men with liver problems, even if they had worked in PVC-related operations only a short time, should be moved to other work.

Soon after Goodrich's January announcement, OSHA began to work actively on regulations for PVC and vinyl chloride operations. An investigatory hearing was held February 15 - 20. At this hearing, Maltoni reported that liver cancer had been found in rats at exposures of 250 ppm. Despite considerable emotion introduced into this hearing, and dramatic media coverage, much valuable information on vinyl chloride control was brought out.

On April 5, OSHA issued a temporary emergency standard

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of 50 ppm, and was preparing to issue its proposed permanent regulation. This step, under the OSHA law, would require issuance of a permanent regulation within six months.

Then came another dramatic announcement. In November 1973, Industrial Bio-Test laboratories had begun to conduct industry-sponsored tests with mice. Mice data are less meaningful for human correlation than data from rats, but they are more quickly obtained as the lifespan of mice is shorter. On April 20 this independent laboratory announced that two mice exposed to vinyl chloride levels of 50 ppm, then the OSHA emergency standard, had developed liver angiosarcoma.

The OSHA reaction was swift. On May 10 it promulgated the new proposed permanent regulation. OSHA called for "no detectable" exposure to vinyl chloride, specifying ambiguous test methods that could have been interpreted to mean zero or as high as 1.5 ppm. The proposed regulation also would have required that all workers in PVC polymerization areas wear completely impervious suits with self-contained breathing apparatus.

Despite the considerable progress that was being made in vinyl chloride containment, industry engineers and scientists were unanimous in their belief that this proposed standard could not be met. The only alternative to assure no exposure would be a shut-down of the industry. This would not only eliminate the jobs of nearly 7,000 people in PVC production, but those of thousands more who process PVC into finished goods.

Two weeks of hearings on the proposed standard were held beginning on June 25. One after the other, industry witnesses and consulting engineers testified that the "no detectable" level could not be achieved if production were to continue. The reasons given were fundamental. Vinyl chloride is a volatile gas kept under high pressure in PVC

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plants. It is moved in hundreds of yards of pipe, and also through hundreds of valves, flanges and metering instruments. Because of the high pressure, the smallest aperture in any of these will permit vinyl chloride gas to escape. Zero levels, anywhere in such a plant, were just not possible.

The witnesses also raised serious objections to the protective clothing the proposed standard required. Completely enclosed suits, with self contained breathing supplies, cannot be worn for more than 30 minutes. Not only are they very cumbersome, they are also very hot. One non-industry consultant described them as "instruments of torture." Others described them as definite health hazards to the workers if worn for any length of time.

OSHA took the testimony of industry and consultants more seriously. The regulation was changed. Instead of the "no detectable level," OSHA adopted an exposure standard of 1 ppm on a time-weighted average for eight hours, with 5 ppm for 15 minutes. In place of the impossible self-contained suits, the agency prescribed suitable respirators or face masks.

OSHA mandated continuous monitoring of work areas with detailed records to be kept and made available to both employees and government inspectors at any time. Periodic medical examinations for all PVC and vinyl chloride workers also were required, with records to be kept for 30 years. Employee training programs were ordered.

For the first year, workers were to be provided with respirators, but were not required to wear them unless levels reached or exceeded 25 ppm. Respirators for levels above one part per million would be required beginning April 1, 1976.

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Under the OSHA law, industries or citizens' groups can test a new standard in the courts. Many PVC producers felt that the final regulation, promulgated on October 1, 1974, was still too strict. They petitioned the Federal Court of Appeals in New York City for review. The court upheld the standard in April, 1975.

By this time B.F. Goodrich and other producers had made further progress in containing vinyl chloride. A year earlier Goodrich had started the largest research, development and engineering projects in its history, involving more than 130 scientists and engineers. The object: reduce vinyl chloride in work places, in plant atmospheres and in products as completely as possible.

The company also announced in October 1974 that it would spend \$42 million over a three-year period to meet these objectives.

Many of the problems were enormous, and involved developing technology not previously used in this industry. New systems and new kinds of material had to be developed and tested to prevent leaks in the hundreds of connections in PVC plants.

A major engineering problem was the development of reliable sequential area monitoring systems. Instrument makers cooperated in developing work place air samplers, which would take, analyze and record air samples in many locations in a plant. In addition, the company adapted personal monitoring systems, which would sample all the air a worker breathed during a shift. These samples, analyzed by highly accurate equipment in plant laboratories, could tell just how much vinyl chloride the worker had been exposed to during a shift.

One complicated problem was the selection of respirators which would make it possible for a man to work effectively and comfortably and still be protected from inhaling vinyl chloride. A subordinate problem was to adapt the personal monitoring system to measure the air a man breathes inside his mask.

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Dr. Roger Strassburg, Goodrich's director of environmental affairs, headed this project. "We worked with virtually every known type of respirator or face mask," he said. "We also worked closely with NIOSH in evaluating various types."

Eventually, the company adopted the air-fed mask, which, from a lightweight hose, not only supplies uncontaminated air, but actually pushes any air containing vinyl chloride away from the nose and mouth.

By the time the OSHA regulation went into effect, Goodrich could operate within its limits, but research continued as other problems still had to be solved. On a petition by the Nader-sponsored Health Research Group, the Food & Drug Administration had banned the use of vinyl chloride as a propellant in aerosol cans. The FDA was also looking into the possibility that vinyl chloride could migrate from food packaging materials into food. The Environmental Protection Agency was conducting investigations preparatory to issuing standards on vinyl chloride in air and water surrounding plant areas.

Media and public interest in the subject remained high. Goodrich, from the beginning, had established two information policies. First, any significant developments would be reported promptly to all PVC and vinyl chloride workers. Second, the company would deal candidly and openly with all representatives of the media.

Studies of death records were being carried out not only by Goodrich, but other PVC producers throughout the world. Eventually it was established that, worldwide, 48 PVC workers had died from angiosarcoma between 1961 and 1975. With each announcement, more stories appeared. All major U.S. TV networks carried reports.

Further public alarm was aroused with the report of angiosarcoma cases occurring in people living near PVC plants, but who had never worked in the plants. One

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such case was reported in Niagra Falls, N. Y., and four in Connecticut. The reports were published nationwide.

Not so well publicized, however, were the studies made by the U.S. Center for Disease Control and the National Cancer Institute. None of the publicized cases was found to have been angiosarcoma typical of VC exposure. All were some other type of cancer, and liver cancer is one of the more common forms.

New cases were discovered in a PVC plant in Canada which B.F. Goodrich had purchased in 1972. In 1974, the company had begun the same containment programs there as those being carried out in the U.S. A Quebec pathologist, Dr. Fernand Delorme, had read about the U.S. angiosarcoma cases and started checking cancer deaths in his area. He discovered that four former workers at the PVC plant had died of this disease.

In December 1974, he notified Goodrich Canada, which promptly gave these reports to provincial officials and issued a public announcement. The release was carried by Canadian Press in Canada, and by the Associated Press in the United States.

It was subsequently learned that only one of these men had been a Goodrich employee; all had worked for the previous owners. However, Goodrich also informed U.S. officials at NIOSH and OSHA, and conducted further studies. In the search of records, five more cases were found among men who had worked at the plant under the previous owners. These, too, were reported.

A new question about the relationship of vinyl chloride and human health was raised in the spring of 1975. Dr. Peter Infante, then of the Ohio Health Department, reported at a cancer conference in New York results of a study of birth defects that he had made in three Ohio communities -- Painesville, Avon Lake and Ashtabula -- all of which have PVC plants.

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In all three communities, Dr. Infante found that the number of such defects were higher than the average for the state. He also reported that he had found a higher than normal rate in a community 10 miles from one of the plants. (EPA studies have never found traces of vinyl chloride originating from a plant at this distance.)

Dr. Infante presented his data at a meeting of the New York Academy of Science in April. He concluded his paper with the statement that there is not sufficient evidence to link vinyl chloride to birth defects.

The U.S. Center for Disease Control then conducted its own study. Its report concluded that no relationship could be established between cases of birth defects and vinyl chloride exposure.

These were community studies. Another study was made of wives of workers in a PVC plant in Pennsylvania. The report, made public in February 1976, showed that the wives had experienced a higher number of miscarriages and stillbirths than those of workers in non-PVC operations. The period covered by the report preceded the January, 1974 announcement and the OSHA requirements for exposure reduction.

The question of birth defects or miscarriages, as Infante observed, deserves the further investigation which government agencies are now undertaking.

By early 1975, Goodrich vinyl chloride containment efforts were showing positive results. Vinyl chloride in work atmospheres at all of the company's U.S. plants had been reduced to an average of 6 ppm. The company announced that it could now produce PVC resins containing less than 1 ppm residual VCM. This meant that fabricators of PVC finished products, using these resins, could operate their plants with virtually no detectable vinyl chloride in their work atmospheres.

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Two other major vinyl chloride containment achievements were nearing completion and testing. In September, Goodrich announced that it had designed and was installing new stripping columns. PVC is generally made in a water slurry, which then must be dried. One source of vinyl chloride fumes had been the driers, because some of the gas had remained in the slurry. With the new columns, virtually all of the vinyl chloride was removed. It was not vented to the air, but recovered and recycled for new polymerization. The PVC resin that comes out of the driers had minute traces (less than 1 ppm) of entrapped gas. This is usually broken down by the heat of further processing.

The second development was a new technology resulting from the research and development program which had by then consumed more than 425,000 man hours of the best scientific and technical brains the company has.

This is called the "clean reactor" technology, which prevents most of the PVC buildup in reactors. There was a time when reactors had to be cleaned after every batch. Now, repeated batches could be produced without any entry into the reactor. The company reported it was refining these techniques so that no entry whatever would be required except for maintenance. The company had also learned how to evacuate all fumes from reactors, so that any person having to enter would be completely protected from any fumes.

On December 4, 1975, Goodrich held a press briefing in New York City to announce these developments. Vinyl chloride in all its plants averaged from 1 to 3 ppm. "We are now certain," said Goodrich President John Ong, "that no new cases of angiosarcoma will result from our products or our operations."

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The company also announced that it could meet all present or expected Federal regulations governing vinyl chloride exposure, in plants, in products, or in plant environments. However, Ong stated, the company will continue its research, development and engineering to reduce levels still further. He announced that the company was then starting production at a new PVC plant at Louisville which "will be as good or better than any plant in the country in containment of vinyl chloride."

The vinyl chloride toxicity case has been and is one of the most important and dramatic in U.S. industrial history. Some of the more vociferous writers on the subject have suggested that the PVC industry be banned, regardless of the number of jobs this would eliminate.

But others have taken a more measured view. Dr. Irving Selikoff of New York's Mt. Sinai Institute, a well-known authority in occupational health, was quoted in a recent interview:

. . . he sees the case of vinyl chloride as a "success story."

He says it was a "success for science in having defined the problem; success for labor in the rapid mobilization of concern; success for government in urgently collecting data, evaluating it and translating it into necessary regulations; and success for industry in preparing the necessary engineering controls to minimize or eliminate the hazard."

(Chemical Week, February 25, 1976)

No serious scientist now questions that vinyl chloride is a carcinogen -- that is, it can cause cancer at certain exposure levels. Yet many scientific and medical questions remain. One group of scientists (Gehring and Watanabi) has demonstrated

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that at low levels, vinyl chloride is metabolized (chemically broken down) in the blood, but at high levels it can overload the system and apparently cause the formation of new substances in the body which may be the real cause of cancer.

All of the known angiosarcoma cases among PVC workers occurred among men who had heavy exposure, probably on the average of more than 250 ppm, almost daily over a period of several years. Most of them worked for some period as reactor cleaners. Yet thousands of others have worked in these plants without developing cancer.

Much remains to be learned about this phenomenon, and many studies are under way. At the University of Louisville, under a grant of \$420,000 given by B.F. Goodrich, research into medical detection techniques is being carried out. The University has recently received a grant of \$2,700,000 from the Government's National Cancer Institute to carry on further studies. Several industry-sponsored studies are being coordinated by the Manufacturing Chemists Association. Other industry-sponsored studies are being carried out in Europe.

One point is often missed in this episode. Until recently, all studies in this area have been sponsored by industry, not by government or academia. All public announcements and most of the scientific or technical papers on the subject have been industry authored.

No one has yet counted the millions of dollars that have been spent by industry in containing vinyl chloride. But in the annals of mankind's massive struggle against cancer, prevention of human exposure to vinyl chloride may turn out to be one of the most heroic chapters.

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