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VINYL CHLORIDE AND CANCER,
A STUDY IN PREVENTION

Sunday night in a blizzard in January is not the normal time for a high-level corporate conference. But there was no time for delay. Pathologists had just confirmed to executives of The B.F. Goodrich Company that three of its polyvinyl chloride (PVC) workers had died in the past two years from a rare form of liver cancer -- angiosarcoma.

A company plane had flown Dr. Maurice N. Johnson, company director of environmental health, and Dr. Irving Tabershaw, a consultant on epidemiology and pathology, from Louisville, Ky., where they had spent several days meeting with Louisville physicians and searching all available records. The diagnoses had been confirmed. The three patients had all worked for a number of years in cleaning the insides of reactor vessels where vinyl chloride gas is converted into plastic. They had breathed air containing comparatively high levels of vinyl chloride gas, left in the reactors, many times.

The discovery was the first reported anywhere in the world that vinyl chloride had been connected with human cancer. The date was Jan. 20, 1974.

Board chairman O. Pendleton Thomas, then president Harry B. Warner, and John D. Ong, then vice chairman of the board and later president, along with other executives, listened to all the reports. All experts in the company who could be directly involved with some phase of this problem were to be informed as early as possible Monday morning, and were to meet Monday night with recommendations for action. Dr. John Creech, the Louisville plant physician, and Phillip J. Lawrence, the plant manager, were to be flown up from Louisville for this meeting. The meeting was set for 7 p.m.

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It lasted until nearly midnight. For one thing, the weather had delayed the flight, and Creech and Lawrence were late. The meeting was somber, but calm. All the company's top experts -- in engineering, environmental control, medicine, law, employee and public communications were present. All questions were answered and all recommendations heard. Then immediate action decisions were made. They included the following:

Such information as the company had would immediately be given to all employees in the company's five PVC plants and one vinyl chloride monomer plant. Drs. Johnson and Tabershaw would go to Washington the next day to present the data to the National Institute of Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA). Dr. Creech and Lawrence would, also the next day, give the data to the Kentucky Department of Labor. The Company would also issue a news release and distribute it not only to Louisville media, but to media in all plant communities and national media. All customers and competitors also would be advised.

At the same time, the company would promptly begin an epidemiological study, actually a mortality study, of all PVC workers in all plants who had died, as far back as records would go, to learn if there had been any other past cases. The firm of Tabershaw-Cooper was engaged to help in this study.

Engineers and research and development were instructed promptly to begin every effort to reduce levels of vinyl chloride and worker exposure in all plants as quickly and as much as possible. This was the hardest part of the problem, because Goodrich had been conducting programs of this type for several years. The plants were ^{when is this} then operating at levels usually ^{around} below 50 parts per million of vinyl chloride in work atmospheres, and a number of experienced engineers felt they had levels as far down as they knew how to go.

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"hard problem" in mind
"important thing" Mr. Lawrence

The company also established a group of the leaders in each field dealing with the problem. They were called the "briefing group," and were to meet every morning at 7:45 to keep each other informed of daily developments and progress. Plant managers came into the Cleveland headquarters of the Goodrich chemical division weekly, later every two weeks, to report progress and discuss new methods of controlling vinyl chloride.

Very promptly NIOSH published emergency "recommendations" for worker protection. These were strict (some were later found to be unnecessary) and were not mandatory, but Goodrich promptly instituted all of them. ^{Q - even the unnecessary ones} Shortly thereafter, OSHA established a temporary exposure level of 50 ppm. Goodrich was already operating with levels below that most of the time, but this did not slow its containment programs. The 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 fingers, called acroosteolosis. 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 which 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. *How* In 1949 the Russians published a paper showing that workers processing PVC

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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 only read the abstract had incorrectly stated that this report implicated PVC or vinyl chloride only, and not the plasticizer.

When OSHA was established in 1970, it adopted the standard for vinyl chloride exposure at 500 ppm, which had been the level recommended by the American Conference of Governmental and Industrial Hygienists (ACGIH). However, the Dow Chemical Company had observed liver damage in rats at lower levels. *→ and recommended reduction of exposure to 50 ppm* ACGIH, but not OSHA, changed its standard to 200 ppm. Goodrich and many producers adopted this new standard. *yale*

In 1971 Dr. P. Viola, in Milan, Italy, had been employed by the PVC industry 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 -- 30,000 ppm. Since vinyl chloride is approaching its explosive level at these high concentrations, it is never permitted 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 is the first published report of a connection of 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 *May*, 1972. His paper was later published in CANCER, an international publication.

Viola's exposure levels were so high and so prolonged that no similar human exposures had ever been encountered. But Goodrich and other producers immediately began programs to reduce exposure as much as possible. The 200

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*not till after the
visit to Maltoni*

ppm level was abandoned, and the company established 50 ppm as its standard. 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, on establishing an animal testing program to confirm Viola's results and, if possible, to find a level where no cancers were observed in test animals. Establishing such studies, or "protocols", as scientists call them, is very complicated, and, 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 sponsored a 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. For the first time, Maltoni told them he had found malignant tumors in rats at exposures of 250 ppm. Maltoni 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.

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 to 12, Maltoni showed a table of preliminary results linking vinyl chloride with cancer. Umberto Saffiotti, associate director of carcinogenesis at the U.S. National Cancer Institute, was present at the meeting and subsequently discussed the results with Maltoni at his laboratory.

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*You are leaving out the
part on agreements not to disclose
until confirmed*

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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 to be preliminary. The WHO group decided to postpone compilation of the definitive review to the next meeting of the committee.

Nevertheless, on April 17 representatives of the Manufacturing Chemists Association, which was coordinating plans for American studies, urged the European sponsors of Maltoni's work to make joint presentations to U.S. and European governments. Permission was granted for the U.S., and NIOSH was requested to set up a meeting. They were unable to do this until 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 on this.

One of the most difficult problems was finding reliable monitoring data 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 then "grab sample" techniques could not really establish high, low or continuing conditions.

One device was tried in August, 1973. It is the portable Organic Vapor Analyzer, an instrument used to detect gas leaks. It will measure the levels of all organic vapors, down to parts per million, in plant air. (For example,

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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 were used to monitor Goodrich's 50 ppm standard.

In November, 1973, Dr. Creech, who had heard of the Maltoni and Viola work, had begun to check records of workers at the Goodrich PVC plant at Louisville. He reported to Dr. Johnson that he thought he was seeing more than normal liver dysfunctions. Johnson had just come from an MCA meeting where Maltoni's latest results had been reported. For the first time he had heard about the diagnosis of angiosarcoma. He visited Creech. After going over the data, he asked Creech if he had ever seen a case of angiosarcoma.

"Yes," Creech replied. "One of my patients -- one of your employees -- died of angiosarcoma of the liver in March. I think there was another case in Louisville in 1972. Right now I have a terminal patient with liver cancer in the hospital."

They began then to search records and work histories. The patient in the hospital died on Dec. 18. 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 began to try to contact the best epidemiological consultant he could find to help him and Creech in looking of other cases. Tabershaw was his man, but Tabershaw was on vacation. Johnson was in his office when he

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I don't think this is who I happened to see

returned on Jan. 16. They returned immediately to Louisville, and a few days later, presented their data to the Goodrich Management Committee at the Sunday night meeting.

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 example.) 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 exams 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. 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 present workers had angiosarcoma of the liver. (A third was later found.) Very early, ^{in 1964} the company decided that all men with liver problems, even if they had worked there 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 Feb. 15 to 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 standard 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.

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Then another dramatic announcement was made. Industrial Bio-Test laboratories was conducting industry-sponsored tests, begun in November 1973, with mice. Mice data are not as meaningful for human correlation as rats, but are quicker, because 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 quick.

On May 10 they promulgated the new proposed permanent regulation. It called for "no detectable" exposure to vinyl chloride, specifying ambiguous test methods which 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 must wear completely impermeable suits, with self contained breathing apparatus.

Despite considerable progress being made in vinyl chloride containment, industry engineers and scientists were unanimous in their belief that this proposed standard ^{if no detectable exposure} could not be met. The only alternative, and assurance of ^{detectable} no exposure, would be a shutdown of the industry. This would not only eliminate the jobs of nearly 7,000 people in the PVC production business, but thousands more who processed PVC into finished goods.

Hearings on the proposed standard were held from June __ to July __. One after the other, industry witnesses and consulting engineers testified that the "no detectable" level could not be accomplished and continue to operate. The reasons given were fundamental. Vinyl chloride is a volatile gas, kept under high pressure in PVC plants. It is moved in hundreds of

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no detectable exposure

yards of pipe, and through literally 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 second major point was 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, but very hot. One non-industry consultant described them as "instruments of torture." Others described them as being definite health hazards to the workers if worn for any length of time.

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

Continuous monitoring of work areas was required, 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 mandated.

For the first year, workers were to have respirators available, but were not required to wear them unless levels reached or exceeded 25 ppm. Respirators are required for any levels above one part per million 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 the final regulation, promulgated on Oct. __, 1974, was still too strict. They petitioned the Federal court of appeals for review. The court upheld the standard in April, 1975.

By this time B.F. Goodrich and other producers had made considerable progress in containing vinyl chloride, but many problems yet remained. 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 had also announced 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 continuous monitoring systems. Instrument makers cooperated in developing continuous work place air samplers, which would take, analyze and record air samples in many places 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 over a shift.

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A complicated aspect was the selection of respirators which would make it possible for a man to work but protect him from inhaling vinyl chloride. 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 different types."

One step was the adaptation of the personal monitoring system so that it would measure air a man breathed inside his mask. Eventually, the company adopted the air-fed mask, which, from a light-weight hose, supplied uncontaminated air, but actually pushed any air containing vinyl chloride away from his nose and mouth.

By the time the regulation went into effect, Goodrich could operate within its limits, but work continued. 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 around plants.

The media and the public kept up a running interest in the subject. Goodrich, from the beginning had adopted two information policies. First, any significant developments would be reported to all PVC and vinyl chloride workers as promptly as possible. Second, the company would deal openly with all representatives of the media.

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Studies of death records were being carried out not only by Goodrich, but other producers throughout the world. Eventually it was learned that about 40 PVC workers had died from angiosarcoma around the world between 19__ and 1975. With each announcement, more stories appeared. All major U.S. TV networks carried reports.

More 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 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. 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. B.F. Goodrich had purchased this plant 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 had been 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 Associate Press in the United States.

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It was learned that none of these men had been Goodrich employees. 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 for previous owners. These also 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, called a press conference to announce results of a study he had made in three Ohio communities, Painesville, Avon Lake and Ashtabula, of birth defects.

In all three communities, Dr. Infante said he had 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.) When asked, Dr. Infante declined to give high and low rates for the state, or conditions in any other communities where rates were high.

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 on this subject. Its report stated that the study could not establish any relationship between cases of birth defects and vinyl chloride exposure.

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

The question, as Infante observed, deserves further study. Government agencies are now conducting such studies.

By early 1975, Goodrich vinyl chloride containment efforts were showing positive results. Vinyl chloride in work atmospheres at all 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. 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.

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. A 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 which comes out of the driers has minute traces (less than 1 ppm) of entrapped gas. This is usually broken down by the heat of further processing.

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The second development is a new technology result of the research and development program which had by then consumed more than 425,000 manhours of the best scientific and technical brains the company has.

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

On December 4 Goodrich held a press briefing 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."

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 industry be banned, regardless of the number of jobs this would eliminate.

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But others have taken a more measured view. Dr. Irving Selikoff on New York's Mt. Sinai Institute, a frequent critic of industry, had this to say in a recent interview:

But 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, Feb. 25, 1976)

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

No studies have yet demonstrated that animals, exposed to less than 50 ppm over their lifetimes, have developed angiosarcoma or other cancers, although studies are being conducted.

All the known angiosarcoma cases among PVC workers occurred among men who had heavy exposure, probably on the average of more than 500 ppm, almost daily over a period of several years. Most of them worked for some period as reactor cleaners. Thousands of others have worked in these plants without developing cancer.

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Much remains to be learned about this phenomenon, and many studies are underway. At the University of Louisville, under a grant of \$420,000 given by B.F. Goodrich, research into medical detection techniques and other phases is being carried out. The university has recently received a grant of \$2,500,000 from the Government National Cancer Institute to carry on further studies. Several industry-sponsored studies are being carried out, 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 fairly recently, all studies in this area have been sponsored by industry, not 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 that have been spent by industry in containing vinyl chloride. But in the great human struggle against cancer, the vinyl chloride episode may turn out to be one of the great chapters in prevention.

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