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Conoco Chemicals Company
A Division of Conoco Inc.
15990 North Barker's Landing Road
P.O. Box 19029
Houston, TX 77224

made

May 2, 1984

Robert Brager
Beverage & Diamond, P.C.
1333 New Hampshire Avenue, N.W.
Washington, DC 20036

Dear Rob:

This is probably more information than you bargained for but I think it will give you a good background and help you understand why vinyl chloride is not the most dangerous material in the world.

Attached is the following:

Attachment A was written by the SPI several years ago. It gives a good overview of the VCM situation.

Attachment B is also an SPI document. I believe that it makes a good argument that the communities near PVC/VCM plants are not at significant risk.

Attachment C is for general reference. It refutes the "myth" that there is a cancer epidemic today in the U.S. The most revealing graph is on page 19: Except for lung cancer (caused by cigarettes) the age adjusted cancer rates are going down.

There are a number of general and specific points that may be valuable to you:

GENERAL

1. There is not a cancer epidemic in this country. In fact, age adjusted cancer rates are going down (except for lung cancer which is largely attributable to smoking, a voluntary risk). There are more cases of cancer today but that's because there are more people and they are living longer.
2. The five leading causes of death - heart disease, cancer, cerebrovascular disease, accidents and chronic obstructive pulmonary disease - claimed the lives of almost 1.5 million Americans in 1979. Almost one-third of the deaths could have been prevented by modifying just three risk factors: smoking, hypertension, and alcohol abuse.

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3. Four of the five leading causes of death are related to smoking. It is estimated that smoking is responsible for 30% of all cancer deaths.
4. To prevent early death our choices are clear. Our limited resources should be allocated where they will do the most good. Comparing the number of premature deaths allegedly caused by "toxic agents" and the number of premature deaths known to result from smoking, alcohol, and hypertension it's clear that it's our lifestyle, not our environment that is the chief villain.

SPECIFIC

1. It is true that some VCM/PVC workers have developed angiosarcoma, a rare liver cancer, however, the bulk of these cancers have occurred in reactor cleaners. They were exposed to extremely high levels of VCM. They actually went inside PVC reactors to chip residue off the walls. There is no evidence of excess liver cancer among workers in plants as they are operated today.
2. Yes, VCM can cause cancer, but that doesn't mean that any exposure to VCM is serious. We are continuously exposed to materials that cause cancer at high levels. Examples:
 - o Extracts of black pepper cause tumors in mice at doses equivalent to 4 mg of dried pepper per day.
 - o Alcohol has long been associated with cancer of the mouth, esophagus, pharynx, larynx.
 - o Burnt and browned material from heating protein during cooking is highly mutagenic.
 - o Coffee is mutagenic. One cup of coffee contains about 250 mg of chlorogenic acid, a natural mutagen. One cup of coffee also contains about 100 mg of caffeine which inhibits DNA repair and can increase tumor yield.
 - o Saccharin has been shown to cause cancer at high exposure levels.
 - o There are carcinogenic compounds in the exhaust from every internal combustion engine.

In summary, we are exposed daily to a great variety of carcinogenic and mutagenic compounds, many of which are naturally occurring and have been a part of man's environment for centuries. We live in a sea of carcinogens and not only are we surviving - we are living longer!

3. The EPA estimated that the average ambient concentration to the five million people who live within five miles of VCM/PVC plants was 17 parts per billion before the VCM regulations were promulgated. These regulations were designed to reduce VCM emissions by 95%, so the exposures today are minuscule.

Robert Brager

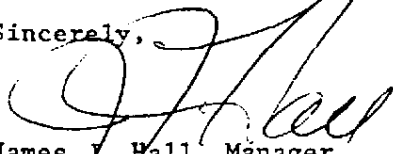
Page 3

May 2, 1984

4. Professor Richard Wilson of Harvard University has calculated that the theoretical risk of living within 5 miles of a PVC plant is equivalent to the risk of contracting cancer from eating $\frac{1}{2}$ tablespoon of peanut butter.

Rob, there is alot more of this type of data available. Let me know if it would be of value to you?

Sincerely,



James J. Hall, Manager
Biomedical & Environmental Affairs

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Attachments

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VINYL CHLORIDE AND OCCUPATIONAL HEALTH

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

The announcement by B.F. Goodrich triggered one of the most intensive investigations in the history of occupational health. It was reported in extreme detail to the American public in literally hundreds of newspaper and magazine articles, in radio shows and television specials, and through rapidly organized medical conferences and regulatory agency hearings. Vinyl chloride even became the subject of a special Congressional hearing.

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

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

- The "epidemic" of angiosarcoma cases predicted by some individuals in 1974 has not occurred. Over the past 16 years there have been a total of 23 deaths from angiosarcoma in six U.S. plants and approximately 48 in other countries.
- Industry opposition to the vinyl chloride standards as originally proposed by the Occupational Safety and Health Administration (OSHA) was based on technical infeasibility, the vagueness of the "no detectable level" proposal, and an over-reliance on animal data. OSHA changed the standards to make them more feasible and subsequent studies have proven the industry's contention that experimental animals are far more susceptible to VCM than are human beings.
- Based on a wide variety of epidemiological studies, the current OSHA standard of 1 part per million in air provides more than an ample margin of safety for industry workers.
- According to experts from Harvard University and the University of Texas, the single study alleging an excess of stillbirths and miscarriages among the wives of heavily exposed vinyl chloride workers is "inadequate," "misleading" and essentially "worthless."

Background

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

Like many other raw materials, VCM had been known for years to have some worker-related problems. It was known by the medical profession to be an anesthetic at extremely high levels; it also

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

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

A 1961 study by the Dow Chemical Company found that long-term exposure of experimental animals to VCM at levels down to 100 parts per million (ppm) resulted in slight liver damage, but a similar study conducted at Yale University found no cause for concern.

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

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

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

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

Cancer Link Discovered

Because of the acroosteolysis situation, industry-sponsored research projects were undertaken both in the United States and Europe in an attempt to discover the exact cause of the disease.

The American study, sponsored at the University of Michigan by the Manufacturing Chemists Association (MCA), was unable to pinpoint the cause in humans but recommended further animal experimentation.

The European study was conducted by Dr. P. L. Viola of the Regina Elena Institute for Cancer Research in Rome, Italy. Dr. Viola, who is also a medical director of Solvay et Cie., a leading European PVC producer, reported at the 10th International Cancer Congress in Houston in May 1970 that he had been able to

produce cancers (but not angiosarcoma) in test animals at extremely high levels (10,000 to 30,000 ppm) of VCM exposure.

Dr. Viola's findings were subsequently published in the Journal of Cancer Research in 1971.

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

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

In the United States the Manufacturing Chemists Association in June 1973 announced that 17 PVC producers had agreed to sponsor a study of all causes of deaths in vinyl chloride workers to be undertaken by Tabershaw-Cooper Associates of Berkeley, California. In February 1973 the industry also contracted with the Industrial Bio-Test Laboratories, Inc. of Northbrook, Illinois, for lifetime chronic inhalation studies using test animals.

Thus, before the middle of 1973, four studies sponsored by the PVC industry were underway at various research facilities around the world, all of them prompted by the Viola findings, which were also industry-sponsored.

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

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

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

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

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

The Government Acts

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

A week later it was discovered that another former employee of the same plant had also died from angiosarcoma. This resulted in an extensive search by the industry through old medical records of other cases. Ultimately, it was determined that over the past 16 years there have been a total of 23 deaths from angiosarcoma in six U.S. PVC plants, and approximately 48 in other countries. The workers' jobs involved cleaning residue of PVC resin from the reactors in which it was produced. Their work thus resulted in high exposure to VCM over a period of many years.

After a special "fact-finding" hearing held in February 1974 OSHA promulgated an Emergency Temporary Standard which lowered the maximum VCM workplace exposure from 500 ppm to 50 ppm. This decision, which was announced on April 5, was based primarily on testimony from Dr. Maltoni at the fact-finding hearing that rats in his research did not develop angiosarcoma at 50 ppm. Only five days later, however, MCA reported to OSHA, NIOSH and the Environmental Protection Agency (EPA) that preliminary results of the Industrial Bio-Test Laboratories animal exposure study showed that VCM could produce angiosarcoma in mice at 50 ppm.

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

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

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

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

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

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

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

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

The new rules, which were scheduled to go into effect January 1, 1975, applied not only to VCM and PVC resin plants but also to processors and fabricators, including firms engaged in "transportation, storage, handling or use" of VCM and PVC resin, unless exposures were found to be below the so-called "action level" of 0.5 ppm.

The industry filed a petition for judicial review of the standards.

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

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

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

Meeting the New Standards

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

The regulations finally promulgated by OSHA, contrary to some reports in the media at the time and to the statements of some individuals even to this present day, were substantially different from those originally proposed. OSHA's change from "non-detectable" to a level of 1 ppm to 5 ppm brought the standard into the realm of technological feasibility, although still extremely difficult and costly to achieve. Since some fluctuation is apt to occur in even the best-controlled plants, the introduction of a peak gave the industry flexibility that was not available under the proposed standard. It introduced a new dimension into the solution of the design and development problems.

In addition, by permitting the use of "gas mask" type respirators at levels below 25 ppm, OSHA eliminated a major compliance difficulty with the standards.

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

Are the Standards "Safe?"

Since 1974, when angiosarcoma of the liver was first identified in PVC workers, numerous animal and epidemiological studies have been undertaken to establish a "safe" level for exposure to vinyl chloride. The results of these studies show that the current OSHA standard of 1 ppm provides more than an ample margin of safety for industry employees.

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

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

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

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

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

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

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

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

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

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

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

-14-

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

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

Non-Carcinogenic Effects

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

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

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

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

Conclusion

Since 1974, when the plastics industry first identified and reported the relationship between vinyl chloride exposure and angiosarcoma of the liver in industrial workers, enormous progress has been made in reducing plant exposures to safe levels. Dr. Irving J. Selikoff, director of the Environmental Sciences Laboratory at the Mount Sinai School of Medicine in New York City, called vinyl chloride one of industry's "success stories." It is, in fact, an excellent case study of how a responsible industry working closely with government and medicine has been able to identify, report and rapidly control a health hazard.

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November 1978

For Additional Information Contact:
The Society of the Plastics Industry, Inc.
355 Lexington Avenue
New York, N.Y. 10017
(212) 573-9400

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Vinyl Chloride and Community Safety.

In February 1974, following the discovery that heavy, long-term occupational exposure to vinyl chloride gas had resulted in an excess of worker deaths from angiosarcoma of the liver, a rare form of cancer, the Environmental Protection Agency (EPA) began investigations to determine if any hazard existed for people living in the vicinity of vinyl chloride or PVC resin plants. After years of intensive investigations, on October 21, 1976, EPA promulgated regulations to reduce community exposure to vinyl chloride by approximately 95 percent. These regulations were immediately challenged in court by the Environmental Defense Fund (EDF), an environmentalist group, with the eventual result that in June 1977 EPA proposed a series of revisions in the existing standards. To date, no final action by EPA has been taken on these proposed revisions.

The controversy over vinyl chloride air emissions has now been going on for more than four years. During this time period, much speculation and misinformation regarding this issue has been generated, with resulting confusion and apprehension in the public mind. It is the purpose of this paper to state the facts regarding vinyl chloride air emissions and to place the issue in its proper perspective.

This paper documents four key points:

- There is no evidence, despite years of investigation, of an excess number of angiosarcoma cases among people living in the vicinity of vinyl chloride or PVC resin plants.

As a result of these findings, the U.S. Occupational Safety and Health Administration in late 1974 announced standards to drastically reduce worker exposure to vinyl chloride. These standards have now been in effect for three years, and VCM exposures in the workplace have been reduced a hundred-fold or more. The Food and Drug Administration is currently considering regulations on the use of PVC food and beverage packaging materials, but the industry has already developed new and better PVC packaging materials to eliminate the possible migration of detectable residual vinyl chloride into finished food and beverage products.

EPA Investigations

Acting under its authority under the Clean Air Act, the Environmental Protection Agency, almost as soon as the then tentative link between vinyl chloride exposure and angiosarcoma was made public, began investigations into whether VCM concentrations in community air constituted a hazard to the health of individuals living in the vicinity of vinyl chloride and PVC resin plants.

As a first step, EPA established a vinyl chloride task force in February 1974. On May 31, 1974, EPA requested emission control data from manufacturers, and on June 11 of that same year the agency announced that preliminary monitoring test results showed "no scientific evidence to indicate that these emissions pose an imminent hazard to people living near these plants..."

The official record of the agency's investigation of vinyl chloride listed 699 documents totaling some 9,000 pages, thus attesting to the extreme care with which EPA went about developing and promulgating its standard on VCM air emissions.

Community Health Risks Extremely Low

In developing its proposed standard, EPA calculated, based primarily on a series of animal studies plus some epidemiological data, that the levels of vinyl chloride existing around VCM and PVC resin plants in 1974, if left uncontrolled, would result in "somewhere between less than one and 10 cases" of angiosarcoma per year among the nearly five million people living within five miles of such plants.

EPA further calculated that the average yearly vinyl chloride exposure of those five million people was 17 parts per billion.

In order to test its risk assessment hypothesis, EPA conducted a survey of all angiosarcoma deaths in the United States between 1964 and 1974. Based on national mortality rates, EPA calculated that there should have been six cases of angiosarcoma among the people living near vinyl chloride plants during that ten-year period "if the presence of the vinyl chloride plant contributed no risk factor pre-disposing people to the disease."

Instead of six cases, EPA found only three. In short, not only was EPA unable to confirm an excess number of cases among people living in proximity to vinyl chloride plants, but the number found was actually less than would have been expected had no vinyl chloride plants existed in those communities at all.

Professor Richard Wilson of Harvard University, for example, has calculated that the risk of living within five miles of a PVC plant for one year is equivalent to the risk of contracting cancer from eating 1/2 of a tablespoon of peanut butter, or to the risk of contracting cancer from increased cosmic radiation during a three-day visit to Denver, Colorado, or to the hazards from smoking 1/15th of a cigarette.

In addition, a report from Ohio that vinyl chloride emissions might result in an excess of birth defects in communities adjacent to VCM or PVC resin plants was proven false by a series of studies conducted by the U.S. Center for Disease Control. Dr. Brian MacMahon, chairman of the department of epidemiology at the Harvard University Graduate School of Public Health, dismissed the Ohio study findings as resulting "from a combination of chance, reporting differentials and epidemiologic gerrymandering." Dr. Thomas D. Downs of the University of Texas Health Science Center was even more emphatic, stating that "it does not seem possible to salvage anything from this study."

New Standards Promulgated

On October 21, 1976, after more than two and a half years of intensive investigation, EPA promulgated national emission standards for vinyl chloride gas and PVC resin plants. EPA also decided, on the basis of extensive research, that emissions from PVC fabricating plants were so minimal to begin with that no restrictions on these operations were necessary.

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EDF Challenges Standard

On November 19, 1976, the Environmental Defense Fund filed suit in the Court of Appeals in Washington challenging the effectiveness of the standards. SPI, and certain individual companies, subsequently filed routine motions to intervene in these court proceedings to protect their interests. Astoundingly, EPA, through its lawyers, opposed industry participation in the case.

Despite an eventual ruling by the court that SPI and the other companies had a legitimate right to intervene in the case, EDF and EPA continued to negotiate in private meetings from which the industry was excluded.

The result of those secret negotiations was a formal agreement on March 24, 1977, between EPA and EDF to propose amendments to the existing vinyl chloride standard which had been promulgated only five months previously. The proposed amendments were published in the Federal Register on June 2, 1977.

Through a series of Freedom of Information Act petitions, SPI obtained documents from EPA showing that since the promulgation of the original standard in October 1976, the agency had received or obtained no new medical or technical information that would justify any changes in the standard. In fact, preliminary results of a new animal inhalation study by Dr. Cesare Maltoni of Italy -- the main reason given by EDF for opposing the standards -- were not only given to EPA by the industry prior to the promulgation of the original standard, but were subsequently described by top EPA medical experts as "not cause for a change in the regulatory approach taken by the agency."

installations was far too high; that the present standard will reduce ambient concentrations far below the EPA estimate; but that the imposition of the proposed amendments would result in little additional reduction.

According to the report: "mean vinyl chloride concentrations on the order of 2.5-4.5 ppb for each unregulated plant are reduced to concentrations on the order of 0.15-0.25 ppb when in compliance with existing standards, and to concentrations on the order of 0.10-0.20 ppb when in compliance with the proposed amendments."

In short, "the further reduction in mean concentrations resulting from implementation of the proposed amendments is less than 0.1 ppb." To put this number in perspective, 0.1 ppb is equivalent to one second in 3.2 centuries or 320 years.

The report concluded, "From the standpoint of ambient air quality measurements, such differences are negligible."

Conclusion

All existing medical and technological data indicate that the EPA standards promulgated in October 1976 provide more than an ample margin of safety for people living in the vicinity of vinyl chloride gas and PVC resin plants. The possibility of even a single individual developing angiosarcoma from these infinitesimal exposures is so remote as to be nonexistent. The proposed amendments would add little or nothing to this already huge margin of safety.

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March 1978

For Additional Information Contact:

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The Society of the Plastics Industry, Inc., 355 Lexington Avenue,
New York, N.Y. 10017 (212) 573-9400.