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CENTRAL RESEARCH & DEVELOPMENT DEPARTMENT

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FOR
TOXICOLOGY AND INDUSTRIAL MEDICINE

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RECEIVED

May 4, 1982

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CMA PANEL ON VINYL CHLORIDE
(Ref.: Our telephone conversation of 4/28/82)

As we discussed, I am enclosing the information from CMA on the formation of a new panel to monitor programs on vinyl chloride monomer and PVC resin. If we at Haskell Laboratory can be of any assistance, please let me know.

Henry J. Trochimowicz, Sc.D.
Manager, Toxicology Division

HJT/cgs
Enclosure

SAL 000080710

Vinyl Chloride - SPAG Review

1.0 Charters

a. Panel Charter

The Program Panel will be concerned with vinyl chloride monomer and polyvinyl chloride resin. The Panel will develop a program that examines the possible health effects of vinyl chloride through toxicological research and human (epidemiological) studies. The testing program will include appropriate monitoring to ensure adherence to sound scientific practice and compliance with prevailing regulations. The Program Panel will review and evaluate the results of all studies.

Consistent with CMA practices and policies, the Program Panel wil represent the interests of the Chemical Manufacturers Association (CMA) before Federal agencies in all matters relating to safety and health issues arising out of the production, reaction, release, packaging, storage, handling or use of vinyl chloride.

The Program Panel will also be responsible for certain administrative matters, including the election of officers, deciding the basis for sharing the cost of the program among the participating companies, designation of appropriate task and/or working groups, and liaison with interested non-participating parties.

The Program Panel will function as a special committee under CMA's bylaws, and as such will be subject to the Special Programs Guidelines.

b. Research Coordinators Charter

The Vinyl Chloride Research Coordinators, operating within the Charter of the Vinyl Chloride Program Panel, will provide interpretation of available data on the toxicology of vinyl chloride. The coordinators will advise the Panel on appropriate studies, both in the areas of toxicological research and human studies, required to expand the data base. The Group will provide the necessary protocol design or protocol review and will conduct or make provision for appropriate monitoring and auditing of all research programs.

2.0 Uses

Manufacture of polyvinyl chloride and copolymers; organic synthesis; adhesives for plastics.

3.0 Background and Objectives

a. Introduction

CMA has had a long-standing interest in vinyl chloride monomer. In the early 1960s, the then Manufacturing Chemists Association arranged for a study at the University of Michigan on acroosteolysis (softening of finger tip bones) in VCM/PVC workers. The findings were published by the American Medical Association in the January 1971 issue of "Archives of Environmental Health".

In 1971, at the recommendation of MCA's Occupational Health Committee, U.S. VCM/PVC producers were approached with the proposal that they might wish to support a research program to answer questions on vinyl chloride carcinogenesis raised by Dr. Viola's studies at the Regina Elena Institute for Cancer Research in Italy. A conference of interested member companies was held in November 1971; twenty producers were represented. An ad hoc planning group for vinyl chloride research (precursor to the present Vinyl Chloride Research Coordinators) was formed at the conference to provide review of research proposals and funding requirements. By early 1972, it was established that seventeen companies would support a vinyl chloride research program. The group of sponsoring companies, known then as the "Technical Task Group on Vinyl Chloride" was the first Vinyl Chloride Program Panel. The objective of the Task Group (Panel) was to expand the toxicology data base, thereby lending support to certain health and safety issues surrounding exposure to vinyl chloride monomer in the workplace.

b. Research Programs

i. IBT Study

A research contract was negotiated with Industrial Bio-Test Laboratories in February 1973 to conduct a chronic vinyl chloride inhalation study in rats, mice and hamsters. IBT submitted interim reports to CMA during the course of the two-year study but issued no final report. Subsequent audits by both CMA and third parties found irreparable deficiencies in the study. CMA entered into negotiations for settlement with IBT last year and an agreement was reached. Companies participating in the research program will be refunded on the same pro-rated basis as they contributed to the program.

ii. Dow Studies

In 1974, the Program Panel agreed to fund a teratology study in mice, rats and rabbits to be conducted at Dow Chemical Research Laboratories. Results were published in a March 1977 issue of "Toxicology and Applied Pharmacology". The data indicated that vinyl chloride did

not cause significant embryonal or fetal toxicity and was not teratogenic in any of the species at the concentrations tested (up to 2500 ppm).

A contract was executed with Dow in November 1976 to conduct a pharmacokinetic/metabolism study of vinyl chloride in rats. This research was an extension of similar studies being performed at Dow. A summary of the research was submitted to CMA in May 1977.

iii. University of Louisville Research Program (Phase VII)

In 1975, the emphasis on research shifted from toxicological investigations to one more directly related to the early diagnosis and clinical management of vinyl chloride injuries resulting from past industrial exposure. Accordingly, the Panel approved support of a grant to the University of Louisville for the development of "Research Techniques and Methods for Detection and Prevention of Carcinogenesis in Industrial Workers". Support of the research continued and two further agreements were signed with the University in 1978 and 1979. Final reports for the first and second years were received; the third is anticipated shortly. Continued funding of this program by the Panel is not likely.

iiii. Epidemiology Studies

A contract was awarded to Tabershaw Cooper Associates, Inc. (TCA) in June 1973 to conduct an epidemiology study of vinyl chloride workers. A final report issued by Equitable Environmental Health Associates (successor to TCA) included 10,173 individuals. Brain tumor incidence was found to be in excess but did not apear to be related to either the duration or intensity of exposure to vinyl chloride. Weak associations between vinyl chloride exposure and malignancies at other sites were noted. EEH suggested that the cohort be studied again five years hence, since observation time would be extended and more deaths available for analysis.

4. Membership

See attachments A, B and C.

5. Research Programs
a. Completed studies (See attachment D).

b. Future studies

The Program Panel has considered a proposal from Environmental Health Associates, Inc. (EHA) to update the 1978 EEH epidemiology study (see above). In this study,

work histories of the 10,173 member cohort will be updated through December 1979. Twenty companies are supporting this program (re: Vinyl Chloride Program Panel - Phase VIII). A budget has been established and a contract agreement with EHA will be drawn up shortly. Of particular interest in this study is whether or not the brain tumor incidence remains in excess. Also, are the associations seen in the earlier study strengthened or weakened?

6. Advocacy

Although there has been limited activity, advocacy has not been emphasized by the Panel. This is partially the result of the extremely close liaison of the members of the Panel with the Vinyl Chloride Health and Safety Committee of the Society of the Plastics Industries, Inc. This arrangement has appeared to work well and at the present time increased advocacy is not anticipated.

Several regulatory issues remain, however:

1. EPA is currently considering lowering the air standard for vinyl chloride. The Environmental Defense Fund is involved in these negotiations.

2. The FDA has delayed action on a request for approval of PVC liquor bottles.

3. OSHA appears interested in PVC dust and in vinyl chloride itself. However, no notice has been published and no time table has been established.

7. Key Issues

A small number of key issues remain, but it should be emphasized that because of the high visibility of vinyl chloride, these issues can change rapidly and dramatically.

1. Whether single exposures to vinyl chloride are capable of causing cancer is an important question. The study sponsored by CPSC, at Edgewood Arsenal, purports to have shown a positive effect from single exposure. Study conditions and the type of response were questionable, but adverse publicity may result when the report is published.

2. Vinyl chloride has been shown to cause other cancers in animals besides angiosarcoma. Human data is inconsistent; with some studies positive and others not.

3. Scientific quality of the proposed epidemiological study is critical. It is essential that the study be acceptable by current scientific standards.

Furthermore, it is essential that the study population include all those eligible from the Tabershaw Cooper study, so as to maintain the cohort. This may require liaison with companies who have lost interest in vinyl chloride as a product, but still have former employees that were in the original cohort.

4. The EPA air standard may be an issue, depending upon the pressure placed on that Agency by the Environmental Defense Fund.

5. Transportation accidents are a possibility. This may present an emotionally charged situation for activists.

8. Liaison

Liaison has been and continues to be an important activity. The relationship to the SPI has been very effective, primarily because of the significant overlap in committee membership.

Liaison with European countries was extremely active and still continues at a lower activity. Several European based companies are represented on the Panel and many Panel members have European affiliates. The four European companies sponsoring Dr. Maltoni's studies have been most helpful. Working primarily through ICI (Dr. David Duffield and later Dr. John Stafford) we have succeeded in transmitting information rapidly between our groups.

9. Controversial Issues

None.

10. Financial Status

(See attachments E, F and G).

11. Critical Dates

June 1981 - start of vinyl chloride epidemiology study update (Environmental Health Associates, Inc.).

Spring 1983 - epidemiology study completed.

May 15, 1981 - final report on University of Louisville study expected.

12. Future Needs

None.

13. Summary.

The Panel has undertaken several animal studies to expand the toxicological data base on vinyl chloride monomer. These phases of the program were completed and it is not anticipated that the Panel will sponsor further research in this area. The University of Louisville Program is winding down and continued funding of this research is unlikely. At the moment, the Panel's attention is focused on human studies and the use of epidemiological research to clarify the relationship between the etiology of certain diseases and vinyl chloride exposure.

The Panel's pursuit of an advocacy program has been limited. Members of the Program Panel have maintained a close liaison with the VC Health and Safety Committee of the Society of the Plastics Industries, Inc. (SPI), the lead organization in the vinyl chloride advocacy area. Several regulatory issues do remain and the Panel will continue to maintain interest through its association with SPI.

ATTACHMENT A

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ATTACHMENT II

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 1961 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.

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

PVC producers unfortunately

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.

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

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

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

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

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

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

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

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

Meeting the New Standards

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

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

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

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

Are the Standards "Safe?"

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

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

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

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

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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ATTACHMENT III

VINYL CHLORIDE: RISKS AND BENEFITS

The use of chemicals in our society is so common that we tend to take their benefits for granted. Chemicals play an essential role in modern agriculture, industry and public health. Today's style of living depends on chemicals and would be inconceivable without them.

But as our ability to make and use chemicals grows, so does our concern for their possible undesirable effects. When we learn of possible harmful effects of a chemical which is performing very useful functions, we are faced with several alternatives. Should we ban it altogether? Should we carefully restrict its use? Should we continue to use it without restrictions since only "possible" harmful effects have been suggested? To help us select the best course of action, we should examine both the risks and benefits involved. With this information, we are in a better position to make a rational decision rather than one based on intuition.

This background paper discusses risks and benefits for one chemical --vinyl chloride--and documents the following four key points:

- Vinyl chloride monomer, the raw material used to make polyvinyl chloride plastics, offers many benefits which make it virtually indispensable in our society.

- Industry workers are working in a safe environment. Based on a wide variety of epidemiological human health studies, the current Occupational Safety and Health Administration (OSHA) vinyl chloride standard provides a wide margin of protection for the industry's workers.

- Current standards limiting emissions ensure that public health in communities surrounding VCM plants is being adequately protected. There is no evidence of an excess number of cases of angiosarcoma of the liver (a rare form of cancer) in communities surrounding vinyl chloride plants and no evidence that public health will be materially improved by a further tightening of the Environmental Protection Agency (EPA) standards limiting vinyl chloride emissions.

- One of the most outstanding applications for PVC is in food packaging. There is no reasonable likelihood of vinyl chloride monomer getting into the diet from polyvinyl chloride packaging materials. Even if this monomer did migrate from the package into the food, there is no scientific evidence showing that residual vinyl chloride monomer at the levels found in PVC food packaging products is carcinogenic.

The Vinyl Chloride Industry

Polyvinyl chloride (PVC) is produced from vinyl chloride monomer (VCM), a gaseous industrial chemical, by a process called polymerization. Important for making industrial and consumer products for over 35 years, PVC has grown to be the second most widely used plastic in America. Production in 1978 by 21 U.S. manufacturing companies was 5.7 billion pounds, an 8 percent increase over the 5.3 billion pounds produced in 1977.

Because of its versatility, PVC has important applications in building and construction, the motor vehicle industry, apparel and home furnishings, phonograph records, plastic pipe and communications equipment as well as in miscellaneous products from bottles to meat wrappings and from credit cards to medical tubing.

About 1,500 U.S. workers are engaged in producing vinyl chloride monomer and 5,000 are involved in polymerization of the gas into PVC. In addition, an estimated 700,000 men and women have jobs involving the manufacture of products from PVC. They work for the transporters, processors and fabricators who mold, extrude or otherwise form PVC resin into finished plastic products.

One way to measure the impact of the vinyl chloride industry on our economy is to look at what would happen if companies in the PVC resin industry were forced to shut down production. When the Occupational Safety and Health Administration in 1974 announced that it proposed to replace the vinyl chloride monomer Emergency Temporary Standard of 50 parts per million (50 ppm) with a permanent "non-detectable" tolerance level, the companies in the PVC resin industry stated they would be unable to meet the newly proposed standard. The research firm Arthur D. Little, Inc. was then commissioned by The Society of the Plastics Industry, Inc. (SPI) to identify and estimate the loss in employment and domestic production that would be generated by such an event.

The conclusions reached in the Arthur D. Little analysis were that "an immediate shutdown of all PVC resin plants and the subsequent unavailability of PVC resin could result in a loss of between 1.7 and 2.2 million jobs in consuming and related industries and a loss of domestic production value of $65-90 billion annually."

When OSHA changed its proposal from "non-detectable" to exposures that would not exceed 1 ppm average for an eight-hour period, the standard became technologically feasible, although still extremely difficult and costly to achieve.

In brief, vinyl chloride monomer and its polymer, PVC, have become virtually indispensable in our society today, a clear indication of the many benefits this versatile chemical has brought to American life.

Vinyl Chloride and Health

While the social and economic benefits of vinyl chloride are one side of the coin, on the other side are the possible harmful health effects from high dosage exposure to the chemical. In recent years, concern has been expressed by the manufacturing companies, their employees, the government, scientists, environmentalists and the media about the safe manufacture and use of vinyl chloride. This concern has been in three general areas.

- Occupational health -- the effect on workers in vinyl chloride monomer plants and PVC polymerization plants.

- Community health -- the effect on residents in areas surrounding vinyl chloride monomer manufacturing and polymerization plants.

- General public health -- the effect through possible ingestion of foodstuffs packaged in bottles or various types of wrappings made of PVC.

The Occupational Health Question

In January 1974 three cases of angiosarcoma of the liver, an extremely rare type of cancer, were discovered among workers exposed over a period of many years to high concentrations of vinyl chloride monomer. Ultimately, extensive research has shown that 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. As a result of these findings, OSHA in late 1974 announced regulations to drastically reduce worker exposure to vinyl chloride.

The new limitations set exposures so as not to exceed one part of vinyl chloride per million parts of air (1 ppm) averaged over an eight-hour day. To put these infinitesimal figures into perspective, one part per million in distance is approximately the same as one inch in 16 miles; in time, one minute in two years; and in weight, one ounce in 32 tons.

The new regulations greatly reduced occupational exposure to vinyl chloride. From 1951 to 1974 the recommended maximum average for worker exposure was 500 ppm. In 1974, OSHA issued an Emergency Temporary Standard reducing the exposure to 50 ppm where it remained until the 1 ppm standard took effect in April 1975.

When angiosarcoma of the liver was found in PVC workers in 1974, a number of steps were soon taken reducing occupational exposure and an extensive series of tests on animals was started. Retrospective studies were made of liver angiosarcomas contracted by vinyl chloride workers. In addition, comparison studies were made of causes of death between vinyl chloride workers and the general population.

A quantitative risk assessment for community exposure to vinyl chloride was made for the Environmental Protection Agency. Professor Richard C. Wilson of the Harvard University Department of Physics, in reviewing the analysis, stated that the EPA report was based primarily on early animal studies and, when compared with later epidemiological data, was "more pessimistic than need be."

Two recent industry studies administered by the Chemical Manufacturers Association (formerly the Manufacturing Chemists Association) examined the effects on rats of exposure to vinyl chloride. The results of the effects on rodents were then extrapolated to humans with appropriate adjustment for metabolic factors. Based on the studies it was predicted that there would be one to two angiosarcomas if 100 million workers were exposed to 1 ppm of vinyl chloride (the current standard) daily for 35 years. Since there are no more than 6,500 VCM and PVC polymerization workers in this country, the real lifetime risk is almost zero. To put this into further perspective, the

Statistical Abstract of the U.S. and Mortality Tables show the lifetime accident risk for railroad workers is 12 in every 100,000, and for commercial airline pilots is six in every 100,000.

In citing risk levels, it is sometimes overlooked that a risk level is not constant. For example, a risk level of one in one million means that the actual risk could vary anywhere from zero up to one in one million as the upper limit.

Numerous studies have been undertaken in the past five years to identify a "safe level" for occupational exposure to vinyl chloride. The results of these studies show that the current OSHA standard of 1 ppm provides an ample margin of protection to the health of industry employees.

The Community Health Question

In February 1974, following the discovery of worker deaths from angiosarcoma, the Environmental Protection Agency began studies to determine if any health hazard existed for people living in the vicinity of vinyl chloride monomer or PVC resin plants.

After nearly three years of investigation, on October 21, 1976, the EPA promulgated regulations to reduce vinyl chloride

emissions (and, consequently, community exposure) by approximately 95 percent. EPA had estimated the five-mile radius annual average of vinyl chloride to be 17 parts per billion (17 ppb) in 1974. Its new regulations were intended to reduce these exposure levels to less than one part per billion when the industry reached full compliance in 1978.

The two model EPA calculations, which estimated that the average vinyl chloride exposure for the 4.6 million people living within five miles of VCM and PVC resin plants was 17 parts per billion (17 ppb), were later revised to estimate exposure levels of less than 10 parts per billion (10 ppb).

In the rule-making process, SPI and various companies in the industry submitted medical, technical and legal data to EPA. Included was a report to SPI by the environmental consulting firm of Dames and Moore which established that the original EPA estimate of 17 ppb of vinyl chloride as a yearly average exposure within five miles of vinyl chloride installations was far too high. The actual average exposure levels today are in the range of 0.2 ppb, according to the Dames and Moore study.

While the risk of angiosarcoma to the community resident by this exposure to VCM is very low, its meaning can only be grasped by a comparison with other risks. For example, the theoretical risk of cancer from exposure to VCM is less than

that of annually smoking 1/15 of a cigarette, drinking 1/3 ounce of wine or 1-1/2 cans of diet soda or eating 1/2 tablespoon of peanut butter.

In brief, all existing medical and technical data indicate that the EPA standards, originally promulgated in October 1976, provide an ample margin of protection to community health in the neighborhoods around vinyl chloride monomer and PVC resin plants.

The Vinyl Chloride Migration Question

The vinyl chloride migration issue arose in 1973, when a manufacturer of distilled alcoholic beverages reported to the U.S. Treasury Department's Bureau of Alcohol, Tobacco and Firearms (BATF) the presence of vinyl chloride in gin and vodka packaged in experimental PVC bottles. As a result of the report, the BATF allowed the experimental bottle permit to expire and permanent authority was not granted for the further use of the bottles for alcoholic beverages. The Food and Drug Administration (FDA), which is responsible for "alcoholic foods," then proposed a regulation banning the use of PVC for packaging all alcoholic foods but reaffirming its

"prior sanctions" for all other uses. In addition, FDA intensified its study of the question of vinyl chloride migration from food packaging.

In July 1975, the Health Research Group, a Ralph Nader affiliate, petitioned the FDA to ban all PVC food packaging materials completely. The FDA responded by proposing a ban on all rigid and semi-rigid PVC products. In doing so, however, the FDA stated that it had reason to believe there was "no migration" from plasticized PVC film, can and cap liners, coatings, gaskets or flexible tubing and would reaffirm its "prior sanctions" for their continued use.

Through intensive effort by the plastics industry, the residual VCM in rigid and semi-rigid products has been reduced from as much as 500 ppm to as low as 2 ppb. Furthermore, at these levels, recent data indicate that the remaining 2 ppb vinyl chloride monomer is so tightly bound in the polymer matrix that migration is impossible. Therefore, a finding of "non-detectable" with an analytical method sensitive to two parts per billion (2 ppb) should assure virtually absolute safety.

Although it has been suggested that general public exposure may occur through ingestion of residual vinyl chloride monomer which may have migrated from PVC food containers to the food or drink, the data cited above indicate this does not happen today.

In short, there is no scientific evidence showing that vinyl chloride monomer at the levels potentially found in PVC food packaging today poses any risk. FDA currently is reassessing its previously expressed position regarding proposed regulations for the use of PVC in food packaging.

Comparing Risk and Benefit

The importance of having some type of risk/benefit calculation was clearly stated in 1976 in a report by the Federation of American Scientists as follows:

> "There is needed some simple measure of cost and benefit that would make widely different risk situations comparable so as to attempt to maintain, in different areas, roughly similar standards for spending government and industrial funds to save lives. Without such a standard, as economists will sense immediately, cancer-avoiding expenditures cannot be spent efficiently. And, in addition, the public will have the greatest difficulty distinguishing minimal risks from large ones."

In his risk/benefit analysis of vinyl chloride, Prof. Wilson asks two questions: (1) "Is the risk worthwhile to society or to the individual worker?" (2) "At what costs can we reduce the risk further and is this worthwhile?"

As we have seen, the lifetime risk of contracting liver cancer from occupational exposure to vinyl chloride is about one in 100 million. The risk for a community resident living near a vinyl chloride plant is one possible cancer case per century

and is even less than that for the potential ingestion of vinyl chloride monomer from PVC food packaging materials. To reduce the hazards of vinyl chloride to current levels, the industry has spent close to $1 billion. To reduce the present infinitesimal risks by an additional factor would cost between three and four times as much as already spent. This could not be justified for the minute, if not theoretical, benefits that would be gained.

To Sum Up

All existing medical and technical studies for vinyl chloride indicate that the present OSHA and EPA standards provide an ample margin for safety for workers and for people living in the vicinity of vinyl chloride monomer and PVC resin plants. Studies also show there is no reasonable likelihood of vinyl chloride monomer getting into the diet from PVC food packaging.

In brief, when risk and benefit are compared for vinyl chloride, the data clearly show that occupational, community and public risks from inhalation and ingestion are very small compared to the many benefits that vinyl chloride and polyvinyl chloride provide to our society today.

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