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UNITED STATES DEPARTMENT OF LABOR

Occupational Safety and Health Administration

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INFORMAL FACT-FINDING HEARING ON POSSIBLE HAZARDS OF VINYL CHLORIDE MANUFACTURE AND USE

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The above-entitled matter came on for hearing, pursuant to Notice, at 10:00 a. m.

BEFORE:

GORDON J. MYATT, Administrative Law Judge.

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Conference Room B, Departmental Auditorium
Main Labor Building
14th & Constitution Avenue, N. W.
Washington, D. C.

- - -

Friday, February 15, 1974

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PRE-HEARING CONFERENCE

JUDGE MYATT: Ladies and gentlemen, we are going to have a pre-hearing conference in this matter concerning the possible hazards associated with the manufacture and/or use of vinyl chloride. The purpose of this pre-hearing conference is to go over with you our proposed order of witnesses, to establish certain ground rules, to verify that those that indicated that they wanted to appear are here and will appear and make a presentation, and to determine which of you who are going to simply present written submissions without oral presentation will do so, and then, finally, at the conclusion, we will start the informal fact-finding hearing.

A large number of you have come considerable distances. We're going to try to accommodate you as much as we can in terms of order of appearance and the time that you're going to have available to you.

The Administrative Law Judge who is presiding over this fact-finding hearing is Gordon J. Myatt, M-y-a-t-t.

We also have representatives from the Solicitor's Office, from NIOSH, and also from OSHA.

To my right and to your left will be the table where the witnesses will appear and make their oral presentation.

This pre-hearing conference is being recorded by our official reporter just as the informal hearing will be

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recorded by the official reporter, and that will be the only official record. Those of you who desire copies of the transcript will have to make your independent arrangements with the reporter or talk to the OSHA people.

I have here a tentative schedule of appearances which has been provided by the OSHA people and I am going to read at this point the order in which the witnesses are scheduled thus far.

Once we open the informal hearing, we are going to have a brief submission of exhibits from the representative of the Solicitor's Office into the record, and then we will have the first presentation. Mr. John O'Neill, Chief of the Division of Health Standards of OSHA, has requested approximately five minutes.

The second witness will be Mr. Vernon E. Rose, Acting Assistant Institute Director for Research and Standards Development of NIOSH, and he will be on for approximately 15 minutes.

The third witness will be Prof. Cesare Maltoni from Italy, and his presentation, I understand, will take approximately 45 minutes.

Dr. Maltoni will be followed by B. F. Goodrich's representatives.

We understand that Dr. Irving Selikoff from the Mount Sinai School of Medicine has requested approximately 20

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minutes. He is flying in here -- pardon me -- I hope this isn't indicative of the way the day is going to go. We've already made changes on it.

After Mr. Vernon Rose, who I indicated would be on second, we're going to have Dr. Irving Selikoff from the Mount Sinai School of Medicine. It has been indicated that he is present. He will be on for approximately 20 minutes and he will be followed by Mr. Anthony Mazzocchi, the Legislative Director of the Oil, Chemical and Atomic Workers International Union.

Is Mr. Mazzocchi here?

MR. MAZZOCCHI: Here.

JUDGE MYATT: Mr. Mazzocchi will be followed, then, by Prof. Maltoni, who will have approximately a 45-minute presentation.

After Prof. Maltoni, we have Mr. A. C. Clark, the Vice-President and Technical Director of the Manufacturing Chemists Association.

Is Mr. Clark here?

Following Mr. Clark, then we will have the B. F. Goodrich presentation.

The next order of witnesses starts with Mr. Sheldon Samuels, the Director of the Health, Safety and Environmental Affairs of the Industrial Union Department of the AFL-CIO, who, I understand, will be introducing Dr.

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Henry Anderson of the Mount Sinai School of Medicine and Dr. Thomas F. Mancuso of the University of Pittsburgh Graduate School of Public Health and possibly Mr. Peter Bommarito or Mr. Louis Beliczky, who is the Director of Industrial Hygiene for the United Rubber Workers. And then we will go -- they are going to take approximately 60 minutes.

And then that presentation is scheduled to be followed by Dr. V. K. Rowe, toxicologist, Dow Chemical, who has requested approximately 30 minutes, followed by Mr. Herbert K. Carver, Jr., of Dove Packaging Systems, who has requested ten minutes.

Mr. Richard J. Reynolds, representing Shell Chemical Company, will follow and he has requested approximately 20 minutes, and Mr. Donald Holman of Control Data Corporation has requested ten minutes and will follow Mr. Reynolds.

And Dr. Robert Brookman of Firestone is tentatively scheduled as our last witness, and he has requested ten minutes.

I have just been informed that this tentative order of appearance will be typed up and Xeroxed for you so everyone can have a copy.

Now, are there any other individuals, before we proceed, who have desired to make an oral presentation and have not registered with our folks here in the back?

I'm going to assume by your silence, then, that

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everyone who is going to make a presentation has been registered and has been scheduled.

I might toss this out during this pre-hearing conference for your consideration, that those of you who have your presentation typed and written, should you desire simply to make a submission rather than to give your oral presentation, we would certainly be amenable to that. It would save time -- and it would certainly be in the record, but I don't want to preclude anyone from making an oral presentation if they so desire.

One other thing to be considered now is that under the rules and regulations all exhibits must be in triplicate. So if you're going to make a submission, please have three copies available, or if you don't have three copies available, let's make arrangements for you to get duplicates made of the copy that you're going to submit.

I will also indicate to you at the conclusion of the informal hearing the date until which we will determine to keep the record open so that if you have any further submissions you will have ample time to get them in. We will set that date after a conference with the OSHA people and the Solicitor's representative.

At this point I think the only thing left is to ask if any of you have any questions concerning procedures that we may not have touched upon or any other questions that you

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want to take up at this point before we get into the informal hearing.

If not, we will take a brief recess and we will start promptly at 10:00 -- oh, one other thing before we start. We're going to strictly enforce the no smoking rule in this room.

(Whereupon, at 9:45 a. m., the pre-hearing conference in the above-entitled matter was closed.)

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P R O C E E D I N G S

JUDGE MYATT: The hearing will be in order.

This is an informal fact-finding hearing which is being conducted to give interested persons or organizations an opportunity to present oral or written data, views and/or positions regarding the possible hazards associated with the manufacture and/or use of vinyl chloride.

Notice of this fact-finding hearing was published in Volume 39, No. 21, of the Federal Register on January 30th, 1974, pursuant to the Occupational Safety and Health Act of 1970.

As I indicated during the pre-hearing conference, the Administrative Law Judge presiding at this hearing is Gordon J. Myatt.

It's my function to regulate the course of these proceedings, dispose of any procedural requests and objections, and confine as much as possible the presentations to matters pertinent to the requested information, and, in the exercise of my discretion, determine the extent of any questioning of any witnesses appearing here.

In this regard, I am going to limit the questioning to those individuals or persons representing those organizations who have registered here to give oral presentations. I am not restricting the questioning to the specific individual who is named as the person giving the presentation for a

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given organization. In other words, Shell Chemical is listed here and Mr. Richard J. Reynolds is the one who is going to give the presentation. It need not be Mr. Reynolds asking questions if Shell desires to ask question of any witnesses. Any of the representatives of that organization may ask the questions.

I would suggest, however, in order to expedite these proceedings, that you decide among you of any given organization of company who will be your spokesman. That is a matter for you, who will ask these questions.

I will not, however, allow questions from the floor of any of the witnesses from any individuals who have not signed up here to give an oral presentation.

I also wish to stress at this time that it is not my function to pass on the evidence or the presentations made here; rather, upon the close of this informal hearing and after the receipt of any written data or documents submitted within the time which I shall specify at the time we close, I will certify the complete record to the Assistant Secretary of Labor, Occupational Safety and Health, for his action.

Yes, sir?

DR. JAEGER: Dr. Rudolph Jaeger, Assistant Professor of Toxicology, Harvard School of Public Health.

Your previous ruling excludes me from asking questions of any witness. I am not associated with any group

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but I feel qualified to judge or comment on the scientific merit of information presented here. Am I specifically excluded, sir?

JUDGE MYATT: Yes, sir.

Yes, ma'am?

MS. HRICKO: Andrea Hricko, Health and Research. If I'm also excluded under that rule, I'd like to know on what grounds that decision was made.

JUDGE MYATT: The grounds are that in order to get these proceedings over with and to get the evidence in the record, we cannot allow questioning from people who are not listed here for oral presentation.

Now, if I may continue, as I indicated during the pre-hearing conference, the official reporter makes the only transcript of these proceedings and all oral presentations and examinations will be recorded by the reporter. Copies of all written submissions and documents received in the record and the official transcript will be maintained by OSHA in Room 240 at 1726 M Street, N. W., Washington, D. C.

And, again, any person or persons desiring to purchase a copy of the official transcript should make their own arrangements directly with the reporter.

We have also had a request from our technical people to remind you that when you're up here testifying, these microphones are not the most sensitive, and, therefore,

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we would ask you to speak directly into them because your volume may fade.

We are going to proceed with the informal hearing by first allowing the representative of the Solicitor's Office to introduce certain documents, and then we will proceed with the order of witnesses that I indicated previously during the pre-hearing conference.

MS. GHOLSTON: My name is Evelyn Gholston. I am an attorney from the Solicitor's Office for the Department of Labor.

As Exhibit No. 1 I would like to introduce a copy of the Federal Register notice of the fact-finding hearing on the possible hazards of vinyl chloride manufacture and use which was published on January 30th, 1974, at 39 Federal Register 3874.

JUDGE MYATT: It will be received as Exhibit No. 1.

(Whereupon, Exhibit No. 1 was marked for identification and was received in evidence.)

MS. GHOLSTON: As Exhibit No. 2, I would like to introduce the following notices of intention to appear. The first notice comes from the B. F. Goodrich Company.

JUDGE MYATT: We will classify that as 2(a), and the others alphabetically.

MS. GHOLSTON: The next notice will be 2(a). It's from Vedder, Price, Kaufman & Kammholz, and it's notice of

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intention of Firestone Tire & Rubber Company.

JUDGE MYATT: That's 2(b). The first one, B. F. Goodrich, is 2(a).

MS. GHOLSTON: I'm sorry. B. F. Goodrich will be 2(a) and Firestone will be 2(b).

2(c) would be for The Dow Chemical Company.

2(d) would be from the Oil, Chemical and Atomic Workers International Union for Dr. Irving Selikoff.

2(e) would be from the Oil, Chemical and Atomic Workers International Union, also, for Mr. Anthony Mazzocchi.

And 2(f) is from Wayne T. Brooks, Director of Occupational Safety & Health Services -- excuse me. Mr. Brooks is from the Organization Resources Counselors.

We've just received another notice from the Shell Chemical Company, and that will be 2(g).

JUDGE MYATT: Does that conclude it?

MS. GHOLSTON: That's all.

JUDGE MYATT: All right. Exhibits 2(a) through 2(g) will be received in the record.

(Whereupon, Exhibits Nos. 2(a) through 2(g) were marked for identification and were received in evidence.)

JUDGE MYATT: At this point, then, we will proceed with our scheduled order of witnesses.

Mr. John O'Neill, Chief, Division of Health

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Standards of OSHA.

JOHN O'NEILL

MR. O'NEILL: Mr. Standard, the Assistant Secretary of Labor for Occupational Safety and Health, recognized that a health problem was developing in those areas that used vinyl chloride or manufactured polyvinyl chloride.

In order to develop a posture to determine what the Occupational Safety and Health Administration will do in this case and in order to determine what rule-making should be accomplished, this meeting for fact-finding has been arranged.

I want to emphasize there is no proposal to be discussed. This is simply, we hope, a meeting that will develop the data and the information necessary for OSHA to act.

The notice of the hearing outlines succinctly the type of information that we feel would be most important for our deliberations. These include discussions of the data on the toxicity on the chemicals in question, the technologies involved in their manufacture and use, the employee populations potentialy at risk, epidemiological data indicating the impact of these chemicals upon the work populations, and further information as to the acuteness of this hazard in order to determine whether it should be best handled by an emergency standard or by normal rule-making.

With these few words, I hope that I have put in the

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proper perspective the reasons for this fact-finding group. We hope it will be very fruitful.

JUDGE MYATT: Thank you, Mr. O'Neill.

The next scheduled witness is Mr. Vernon E. Rose, Acting Assistant Institute Director for Research and Standards Development, National Institute for Occupational Safety and Health, known as NIOSH.

VERNON E. ROSE

MR. ROSE: Good morning. I am Vernon E. Rose, Acting Assistant Institute Director for Research and Standards Development of the National Institute for Occupational Safety and Health, or NIOSH, a program of the Center for Disease Control in the Department of Health, Education and Welfare.

We have a statutory responsibility under the Occupational Safety and Health Act of 1970 to, and I quote, "...develop and establish recommended occupational safety and health standards." These recommended standards are then made available to the Occupational Safety and Health Administration in the Department of Labor and serve as the basis for the setting of occupational safety and health standards.

On July 17th, 1973, a meeting was held with certain representatives of the Manufacturing Chemists Association, or the MCA, and members of the NIOSH staff at the request of the MCA. At this time the MCA informed NIOSH of a proposed

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research study to be conducted by an independent laboratory involving the exposure of several rodent species to vinyl chloride vapors at concentrations including 50, 500, and 5,000 parts per million.

The experimental protocol was to include statistically significant numbers of animals of each species including both sexes. The exposure protocol was to be compatible with a normal work week and the duration of exposure and subsequent observation was to be compatible with the normal lifespan of the particular species. Histologic examination of all major organs was to be included and special attention was to be given to behavioral changes and manifestation of lesions.

It is anticipated that the results of this study will be available in eighteen to twenty-four months from the present time.

At the meeting the MCA representatives reviewed the pertinent published accounts of toxicity and tumorigenicity associated with vinyl chloride, including the work of Prof. P. L. Viola published in 1970 and in 1971. Prof. Viola demonstrated the induction of tumors in the skin, lungs, and bone of rats exposed to vinyl chloride at a very high concentration, that is, 30,000 parts per million. He did not find tumors of the liver.

The NIOSH staff considered the proposed study to be

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of excellent design and requested the MCA to keep them advised of the ongoing study as appropriate.

Earlier, on January 30th, 1973, NIOSH had published a request in the Federal Register for information concerning potential hazards associated with occupational exposure to 23 chemical substances and physical agents. Vinyl chloride had been included in this request.

As a result of this Federal Register request and additional independent literature searchers by NIOSH, a bibliography consisting of the pertinent literature has been assembled. Any literature not currently available in NIOSH is being retreived. This bibliography, along with copies of all cited references, will be transmitted to the Department of Labor.

On January 22nd, 1974, representatives from the B. F. Goodrich Chemical Company informed NIOSH that the deaths of several employees of their Lousiville, Kentucky, plant might have been related to occupational exposures. Had not the company taken the initiative it did in following up on suspicions aroused by the occurrence of the rare type of liver cancer, that is, angiosarcoma, discovered in several of its employees at autopsy, it is entirely possible that the significance presently attached to the appearance of these tumors would not have been realized for several more years.

As a result of this information, a walk-through

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survey was conducted on January 24th in the company's facility in Louisville by NIOSH. Also participating in the survey at the specific request of NIOSH were representatives from the Department of Labor of the State of Kentucky, the Occupational Safety and Health Administration of the U. S. Department of Labor, and the Epidemic Intelligence Service of the Center for Disease Control.

As a result of the walk-through survey, NIOSH recommended on January 30th, 1974, that certain monitoring and control procedures of a precautionary nature be instituted at the Louisville facility. A copy of this communication is included as Attachment 1.

On the following day NIOSH also recommended to the MCA that similar precautionary measures be instituted at all facilities engaged in the polymerization of vinyl chloride and requested that MCA disseminate this information to such companies. A copy of this communication is also included as Attachment 2.

On February 1st, 1974, NIOSH and CDC held a briefing for other federal agencies with health research responsibilities, including the National Cancer Institute, the Food and Drug Administration, the National Institute of Environmental Health Sciences, and the Environmental Protection Agency. Also attending the briefing were professional representatives of the Kentucky Department of Labor, the B. F. Goodrich

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Company, and the United Rubber Workers Union.

The briefing involved the medical, epidemiologic, toxicologic, and industrial hygiene findings thus far obtained, and it was concluded that a new occupational cancer had been discovered, that is, angiosarcome of the liver. It was further concluded that this disease was associated with the polymerization of vinyl chloride in the manufacture of polyvinyl chloride and that vinyl chloride was suspected as the prime etiologic candidate among the more than 50 chemicals used in the Louisville, Kentucky, facility. It was announced at the briefing that NIOSH would institute a series of animal-toxicological studies in concert with the National Cancer Institute and accelerate an industry-wide epidemiological study.

Currently, it is estimated that ten companies with fourteen plants and more than 1,500 production workers are involved in producing vinyl chloride monomer. It is further estimated that some 23 companies and 37 plants employing more than 5,000 production workers are involved in the polymerization of vinyl chloride to polyvinyl chloride. It is difficult to estimate the number of workers employed in converting, molding, and fabricating the polymers into finished products, but it is in the order of tens of thousands working in thousands of plants throughout the country. These estimates are based primarily on manufacturing data obtained from the

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1973 edition of the Chemical Economics Handbook published by the Stanford Research Center.

It was disclosed at the NIOSH/CDC briefing that four employees from the Louisville facility of B. F. Goodrich Company had died of angiosarcoma of the liver. Autopsy and/or biopsy material from each of the deceased employees was still available; therefore, an epidemiologist from the Center for Disease Control obtained specimens and slides for independent histologic confirmation of the diagnosis by pathologists at the Clinical Center, National Institutes of Health. In each of the four cases the diagnosis of angiosarcoma of the liver was confirmed. In addition, each of the four liver specimens presented a common nonalcoholic cirrhosis of the liver. A report of the occurrence of angiosarcoma of the liver among polyvinyl chloride workers appearing in the current CDC Morbidity and Mortality Weekly Report is included as Attachment 3.

NIOSH has investigated the number of deaths attributable to angiosarcoma of the liver in the United States and considers the occurrence to be on the order of twenty to thirty each year. It is because of the extremely low incidence of deaths attributable to this disease that the clustering of four cases within a five-year period in the Louisville, Kentucky, facility has been of such great importance.

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During the federal agency briefing, NIOSH and other official agencies were advised by a B. F. Goodrich Company representative as to the status of an ongoing study sponsored by European polyvinyl chloride producers and involving the exposure of small groups of rats to vinyl chloride monomer vapor. Although the results reported were only of a preliminary nature, NIOSH considers that these data, which include histopathologic examination of tissue, identify vinyl chloride monomer as the causative agent in the induction of tumors observed in the test animals, including angiosarcoma of the liver. NIOSH has been advised that the principal investigator responsible for conducting the European studies, Prof. C. Maltoni of Italy, intends to present the results of his investigations to the Occupational Safety and Health Administration during this public hearing.

On February 12th, 1974, NIOSH sponsored a briefing for management and labor representatives from the vinyl chloride and polyvinyl chloride industries. The meeting was held in Cleveland, Ohio, and was attended by approximately 100 individuals. The briefing was conducted by members of the NIOSH and CDC staffs who presented information obtained up to that time concerning the hazards of occupational exposure to vinyl chloride during the polymerization process.

Following review of the problem, NIOSH presented plans for future activities including, number one, development

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of recommended standards; number two, medical surveillance and research programs; number three, industry-wide epidemiologic studies; and, number four, additional toxicologic investigations.

Development of the recommended standard commenced immediately following the NIOSH briefing when members of the NIOSH and CDC staff met with a small group of expert advisors selected from both industry and labor. The purpose of this meeting was the review of the precautionary procedures previously recommended to polyvinyl chloride producers. NIOSH anticipates that such recommendations will be transmitted to the Department of Labor in a few weeks.

Summaries of proposed NIOSH and CDC plans for epidemiologic, medical, and toxicologic studies are included as Attachment 4.

That concludes our formal presentation, and I do have three copies of the presentation to submit.

JUDGE MYATT: All right. The presentation will go into the record as Exhibit 3.

(Whereupon, Exhibit No. 3 was marked for identification and was received in evidence.)

JUDGE MYATT: Are there any questions to be asked of Mr. Rose by those who are going to make oral presentations?

MS. GHOLSTON: Mr. Rose, you mentioned that you made some recommendations to B. F. Goodrich for monitoring. Did

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you recommend any specific type of monitoring?

MR. ROSE: As to the question of whether or not NIOSH recommended specific types of monitoring for materials and hazards in the plant, we recommended that both environmental and personnel sampling be conducted for both vinyl chloride monomer exposure, which would be in the gaseous state because of the pressure of the gas, and, secondly, that measurements be taken for exposures to polyvinyl chloride dust. We did not recommend specific analytical or sampling procedures, but we did indicate that certain staff members of NIOSH in Cincinnati would be available to provide consultation as to appropriate sampling procedures.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Are there any other questions?

Sir, would you identify yourself for the record?

MR. CONNOLLY: My name is Walter B. Connolly, Jr., and I'm labor counsel for Firestone Rubber Company.

Mr. Rose, I'd like to ask you whether or not it is NIOSH's recommendation that standards be implemented in this area pursuant to the regular rule-making procedures provided under Section 6(b) of the Occupational Safety and Health Act.

MR. ROSE: NIOSH considers the situation that has developed in the Louisville facility of B. F. Goodrich to be extremely serious and, indeed, our reaction to the information as presented to us was one of, you might consider, almost a

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crisis response on our part, in that we did send a field team into the plant to observe conditions there, and we have also considered and will implement the studies that I further defined, studies of a research nature.

I am assuming and feel that when we transmit our recommendation to the Department of Labor they will stress a high sense of urgency that rule-making be commenced -- that rule-making be conducted.

MR. CONNOLLY: Thank you.

JUDGE MYATT: Any further questions of this witness?

There being none, thank you, sir.

Our next witness is Dr. Irving J. Selikoff, Director of Environmental Scienes Laboratory, Mount Sinai School of Medicine.

DR. IRVING J. SELIKOFF

DR. SELIKOFF: My name is Dr. Irving J. Selikoff. I'm a Professor of Medicine and Professor of Community Medicine at the Mount Sinai School of Medicine of the City University of the City of New York and Director of its Environmental Sciences Laboratory.

First, I think that this hearing is somewhat of a paradox. Rapidly organized, with an emergency standard being requested, one would imagine that a new, serious problem had been identified and that we are responding to it, and this is partly true. However, equally true is that there has been

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evidence of potentially serious disease among workers engaged in vinyl chloride-polyvinyl chloride manufacture for 25 years which has, for reasons not yet well understood, been incompletely appreciated and inadequately approached by medical scientists and by regulatory authorities. In other words, this is not a new problem. What is new is the vigor and extent of our attention to it.

Thus, for example, acute animal toxicity to vinyl chloride was reported as long as ago as 1938 and important chronic toxicity in 1961. Even more, we didn't need the animal studies to warn us that workers could be harmed in VC-PVC manufacture. As far back as 1949, 25 years ago, liver damage was found in 15 of 48 workers in Russia and disease of liver, skin, and other organs was reported in the next 17 years, not only from Russia but from France and Romania as well. In 1966 and 1967 attention was called to still another lesion, acroosteolysis, an affection of the skin and bones of the hands and feet, and further reports of hypertension, vascular lesions, nervous system and kidney damage and scleroderma later appeared.

Therefore, we have had ample warning that cells, tissues, and organs could be badly damaged during VC-PVC production. Despite this, our approach to the problem, as I said, seems to have been somewhat leisurely.

And we are now galvanized into action. Why?

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Evidently, by the sudden discovery, as Mr. Rose has demonstrated, that VC-PVC exposure cannot only damage, scar or destroy tissue in the liver, bone, nervous system, kidney, and other organs, but that neoplasms can also result.

This change in attitude is fully understandable. Not only is the disease, cancer, more serious, but, once initiated, it is irrevocable and often inexorably fatal.

And, thus, we have a new problem, not merely one in which level of exposure will produce this or that extent of liver cell or skin damage, which could be reversed if our estimates are wrong, but, rather, the question of cancer, an irreversible disease where we can't afford to be wrong.

Now, the cancer that has been identified is one of the type which, unfortunately, is progressive and invariably fatal. Approximately 100 are known to have occurred in medical history. Not one has been cured.

Hemangiosarcoma of the liver has in the past been extraordinarily rare. At the Los Angeles County Hospital only one instance was found in 52,000 consecutive autopsies. Our own experience is similar. At one of the institutions of the Mount Sinai Medical Center, Elmhurst General Hospital, no case has been seen despite the very active medical and surgical services of this thousand-bed hospital. In another of our institutions, the Bronx Veterans Administration Hospital, no case has been seen, despite a search of our files, in 30,000

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consecutive autopsies and 200,000 surgical specimens since 1941. Yet four cases have been described in one vinyl chloride-polyvinyl chloride plant in the United States in which some 250 workers are employed in the VC-PVC operation. This is an extraordinary increase in incidence.

At the same time we should recognize that we know very little yet about the carcinogenic potential of exposures during VC-PVC operations. For example, it is not known whether the hemangiosarcomas will affect only the liver. When this tumor results, let us say, from thorotrast injection, which it can, other tissues and other organs such as bone marrow can be involved. Indeed, we do not know whether hemangiosarcoma will be the only neoplasm associated with exposure in such circumstances.

Experimentally, Viola, with very heavy exposures, has demonstrated that specific skin cancer and cancers of the lung occurred in the animals studied. Experience with other carcinogenic agents has taught us that when a material causes cancer in one organ, it often does in other tissues as well.

On the other hand, in the very short time that has elapsed since we have been alerted to the cancer problem, we have made two key observations. First, just as liver and other organ disease may be found throughout the VC-PVC production industry, hemangiosarcoma will not be restricted to one plant, since it is known that this tumor has also been

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found in Great Britain as well.

A second, even more worrisome observation, has been that the latent period between onset of exposure to the agent and clinical evidence of disease is a long one. The Louisville tumors appeared in workers 14 to 27 years from the onset of their work exposure. This resembles the latent period of thorotrast-induced hemangiosarcoma of the liver where the average latent period has been 21 years. Therefore, uncontrolled exposures in the past are likely to be reflected in the occurrence of tumors in the decades ahead, unless we can learn to reverse the carcinogenic process already presumably underway in the workers involved.

The discovery of vinyl chloride-polyvinyl chloride associated cancer gives added reason for urgent concern, since the tumor joins other serious burdens of such exposure.

Recent studies in Germany have shown that liver damage is far more common and far more serious than we had hitherto expected. Marsteller and his colleagues reported ten weeks ago that in a careful study of 20 workers in a PVC-producing plant, with a range of exposure of from one and a half to twenty-one years, nineteen -- nineteen out of the twenty has some evidence of liver disease, including gross changes of liver and spleen by direct inspection at laparoscopy in fourteen. They operated on these people and in fourteen out of the twenty cases direct inspection of the

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liver and spleen showed disease to be present. Since acro-osteolysis was present in only four, and since enlargement of the liver could be felt by physical examination only in six, it is evident that these gross clinical tests may seriously under-read the extent of liver damage.

In our own studies of a small number of workers of the Goodyear plant in Niagara Falls, we have similarly seen liver changes. We have also found lung changes to be important. These have previously been described and require rapid and careful study.

An important point to make is that we still know very little about the long-term, chronic effects on the various important organs of the body, when they occur and when they don't occur. The occurrence of cancer should not obscure potential damage of serious non-neoplastic disease as well.

I would, therefore, urge that the Department of Labor take immediate measures to control exposures of workers engaged in VC-PVC operations. I have a number of recommendations to suggest which I believe will facilitate such control.

First: Vinyl chloride-polyvinyl chloride exposure should be added to the list of carcinogens promulgated by the Department. It is evident that no threshold is known that would serve to prevent cancer among exposed workmen. Therefore, carefully designed work practices and procedures should

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be identified to govern VC-PVC production. In this regard, we have been impressed, and I'm sure you have been also, with the approach of NIOSH to this aspect of the question so far. Further, it is clear that industry know-how and expertise will be most valuable in the development of the necessary work practices and procedures.

2. The guiding rule for the workers concerned, above and beyond the specific work practices to be developed, should be that no further exposure occur by any route, inhalation, contact or ingestion.

3. It has been pointed out above that we still know comparatively little about the cancer problem and even about the question of chronic organ damage. Therefore, large-scale epidemiological and clinical studies should be mounted as rapidly as possible to determine the full extent and nature of the hazard. These should be broad studies, long-term, generously conceived, and designed to allow us the opportunity for surprises, because we may get some additional surprises.

4. Research should be begun immediately to develop early diagnostic techniques for VC-PVC associated tumors. In this we may have the advantage of knowledge that liver damage will occur before the initiation of the cancer process. Therefore, early diagnosis of VC-PVC disease in general should be looked to, including disease of the lung, skin,

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thyroid, nervous system, liver, kidney, and bladder.

5. It would also be desirable to develop early methods of diagnosis of the tumor, even after it has been initiated. Since it is a vascular neoplasm, it may be that some of our newer techniques of radioactive scanning will allow for such early detection.

6. Simultaneously, programs of therapy should be developed. For example, liver experts should be recruited to look at reversal of liver disease that may occur. Even serious liver disease can sometimes be treated in these patients. We have seen one successful utilization of portal-caval shunts, and we are aware of three others. Similarly, the possibility of the treatment of associated tumors should be investigated as intensively and rapidly as possible.

7. Such early diagnosis and treatment would be expedited and advanced if basic mechanisms of damage could be defined. Here, scientists associated with the National Institute of Environmental Health Sciences could be asked for help.

8. Similarly, the disciplines of experimental toxicology and experimental pathology should be utilized to undertake studies of a basic nature of a different sort. As yet we are uncertain as to which agent or agents are responsible for the toxic and neoplastic effects associated with VC-PVC manufacture. I do know that NIOSH, as Mr. Rose has

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said, considers that vinyl chloride is the heavily suspected agent. We are not sure of this, in my opinion, and I think we should keep an open mind that other agents may be found to be responsible. Therefore, it may be well that laboratory investigations, in addition to epidemiological studies, will make it possible to sort out the effects of various materials and agents.

9. The full extent of the occupational problem should be defined as an urgent matter: are workers exposed to vinyl chloride or polyvinyl chloride in the manufacture of products containing them at risk? We don't know that at this point. In studies to determine the extent of the occupational problem, we can make good use of biochemical and clinical markers, including changes in blood enzymes, clinical findings, lung changes, et cetera.

Now, it may be noted that my recommendations refer to vinyl chloride-polyvinyl chloride production. I have been asked whether regulation should also be promulgated to cover occupational use other than in such production or to consumer products. I would not now recommend this. Our knowledge of health effects is limited to vinyl chloride-polyvinyl chloride production. Now, we should rapidly study whether health effects will be associated with end product or consumer use. Data obtained can then be used to judge whether other

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regulations are needed.

It may turn out that the biological effects are limited to agents present only in vinyl chloride-polyvinyl chloride production. Hopefully this is going to be so, but we don't know.

Now, this meeting takes place at a very solemn moment. In a sense, it not only marks our determination to confront and control a very serious occupational health problem, but it also marks a failure on our part -- failure to protect workers who have every right to expect that scientists, industry, and governmental agencies would protect them against known or suspect hazards. This we failed to do. As a result, what Dr. David P. Rall has called "invisible pollution" associated with what he has called "a new industrial revolution, based on the chemical-process industry," is now becoming visible in terms of disease and death. Our task here today is to address this and to insure that it go no further. No effort should be spared and no control considered too rigorous.

JUDGE MYATT: Thank you, Dr. Selikoff.

Are there any questions of Dr. Selikoff?

MS. GHOLSTON: Yes, I have one.

Dr. Selikoff, you said that there was no known exposure limits. Could you recommend any exposure limits for employees working with PVC and vinyl chloride production?

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DR. SELIKOFF: I could recommend no exposure limits for the prevention of cancer among these workers. There is none known at this time.

MS. GHOLSTON: You mentioned with reference to end products, consumer products, that you would not recommend anything at this time. Are you familiar with any effects of polyvinyl chloride in the end-product stage? For instance, in the meatpacking industry.

DR. SELIKOFF: I have heard reports of this. I have spoken to workers who claim this, but our own studies are not yet at a stage where we can say whether or not the same effects seen in polyvinyl chloride or vinyl chloride workers are seen in the meatcutting industry, the extrusion industry, et cetera.

I think such data are badly needed and should be obtained as rapidly as possible, but at this point in time we should be prudent and limit our activity and judgment to what we already know in the data now at hand.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Are there any further questions? There don't seem to be any.

Thank you, Dr. Selikoff.

Our next speaker making a presentation is Mr. Anthony Mazzocchi, Legislative Director of the Oil, Chemical and Atomic Workers International Union.

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ANTHONY MAZZOCCHI

MR. MAZZOCCHI: My name is Anthony Mazzocchi; Legislative Director of the Oil, Chemical and Atomic Workers Union.

A new occupational carcinogen has been discovered. Thousands of workers throughout the United States are currently exposed to this carcinogen. The responsibility of the Labor Department is clear. An emergency temporary standard must be promulgated immediately.

We have studied the evidence that has been made available and we have concluded that vinyl chloride is a carcinogen. For further analysis on this point we refer you to the testimony presented here today by Dr. Irving Selikoff of the Mount Sinai School of Medicine and Dr. Thomas Mancuso of the University of Pittsburgh.

The fundamental purpose of the Occupational Safety and Health Act is to assure every working man and woman in the nation safe and healthful working conditions and to preserve our human resources. In order to satisfy this Congressional mandate, the Secretary of Labor was delegated the authority under Section 6(c)(1) to establish "...an emergency temporary standard to take immediate effect upon publication in the Federal Register if he determines, (a), that employees are exposed to grave danger from exposure to substances or agents determined to be toxic or physically harmful or from new

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hazards and, (b), that such emergency standard is necessary to protect employees from such danger..."

Therefore, the criteria for granting an emergency standard rests on a twofold evaluation involving a demonstration of a grave danger from exposure to the particular chemical and the necessity of a regulation to afford protection.

It is clear beyond a shadow of a doubt that these two criteria have been met in the case of vinyl chloride. A grave danger exists from cancer, yet industry has failed to protect its employees.

Therefore, the Oil, Chemical and Atomic Workers International Union joins with the Industrial Union Department of the AFL-CIO and hereby petitions the Occupational Safety and Health Administration for an emergency temporary standard on vinyl chloride.

We concur with the IUD that the basis for such a standard must come from the recommendations of the Standards Advisory Committee on Carcinogens that were submitted to the Labor Department on August 27th, 1973.

While these recommendations were developed for a standard on fourteen specific carcinogens, the foundation upon which the Committee based the recommendations is sound for other occupational carcinogens, including vinyl chloride.

Briefly, we would like to highlight some of the

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Committee's recommendations because of their special relevance today:

1. The principle of no measurable exposure or contact by any route, oral, respiratory or skin, to a carcinogen; the use of the most sensitive, feasible, approved, reliable methods of environmental and personnel monitoring; and the ultimate objective of no exposure.

2. Prohibition of open-vessel operations.

3. Providing of all work clothing, protective equipment, and clothing, and work and shower supplies, including towels, by the employer.

4. Extensive requirements for safe work practices, emergency procedure, and training and education.

5. Forwarding of employee medical records to NIOSH upon termination of employment or cessation of business by employer.

6. Confidentiality of medical records.

7. Endorsement of a use permit system as an integral part of the standard.

The Advisory Committee had also planned to develop specific criteria for medical examinations, but it fell short of time. However, such criteria that is applicable to vinyl chloride exposure has been developed by Dr. Henry Anderson, Clinical Consultant to the IUD. We endorse Dr. Anderson's criteria and we request that it be made part of the emergency

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temporary standard.

You may hear testimony today from industry representatives who claim that there is no further verification in their plants of what happened at Louisville. They may also claim that their employees, in any case, are fully protected and, thus, no new standard is needed.

We are skeptical of these opinions. First, we have learned that a recently issued set of NIOSH recommendations on control procedures for vinyl chloride is not being adhered to by the industry. Direct exposure to vinyl chloride still occurs in processing and maintenance operations. You may also hear of industry claims of outdoor operations and so-called "closed processes" that minimize employee exposure. On the contrary, we have found that throughout the chemical industry that these outdoor "closed" processing units allow for considerable exposure to workers from leaks, spills, ruptures, and maintenance work.

Second, industry representatives may site the lack of any epidemiological evidence in their plants as proof that Louisville was an isolated occurrence. One PVC manufacturer, Air Products and Chemicals, Incorporated, at their Calvert City, Kentucky, plant has done just that in a recent 14-page letter to their employees. Air Products failed to tell its employees that the latency period for development of angiosarcoma, from the beginning of exposure to diagnosis of the

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disease, is suspected to be in the neighborhood of 15 years. This Air Products plant, however, is only ten years old and, thus, cancer cases should not be expected until another five or so years have passed. Furthermore, the inherent shortcomings in the use of death certificates in developing epidemiological data must also be understood. Death certificates are well-known to provide false negatives. This is particularly true with angiosarcoma of the liver, which is so rare in the United States that doctors may misdiagnose it. Also, angiosarcoma may have been present at the time of death but may not have been the primary cause of death. These omissions and others point out the shortcomings of relying solely on studies of death certificates to disprove epidemiological experience with angiosarcoma.

We have begun a study of Oil, Chemical and Atomic Worker plants to determine how many make or use vinyl chloride. Initially, we have found several plants and a considerable number of employees involved.

In one of our vinyl chloride polymerization plants, Dr. Irving Selikoff of the Mount Sinai School of Medicine has recently examined a number of workers. His results included gross findings indicative of liver disease and acroosteolysis. These positive findings are an extension of what has been found at the B. F. Goodrich plant in Louisville. These findings further prove that the occupational hazard from vinyl

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chloride is an industry-wide problem.

It is sad to note that only eight months ago the magazine of the plastics industry, Modern Plastics, June 1973, labeled reports of recent animal studies in Italy which found "a disproportionate incidence of skin and organ cancer" as "scare stories." Because of such an industry attitude, OSHA must act by issuing an immediate emergency standard to protect workers.

What we know about the relation between cancer and vinyl chloride is only the tip of the iceberg because of the long latency period. But OSHA can act now to prevent such a carcinogen from being further present in the work environment. Such a standard must eliminate worker exposure to vinyl chloride. There is no known safe or allowable exposure when dealing with a carcinogen. A committee of eight cancer scientists which evaluated the risks of chemical carcinogens for the U. S. Surgeon General in 1970 sharply challenged the concept of a safe dose. "It is impossible," they said, "to establish any absolutely safe level of exposure to a carcinogen for man."

Today, somewhere in the United States a worker is being exposed to vinyl chloride that will someday cause him cancer and a slow, painful death. The Labor Department thus far has responded commendably to this emergency by calling for this hearing within three weeks of its discovery.

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We now ask you to follow through with your responsibilities by issuing and enforcing an emergency temporary standard on this carcinogen.

JUDGE MYATT: Thank you, Mr. Mazzocchi.

Before we go further, we're going to make a change in the so-called updated list which you got. There's a substitution. You'll see No. 12, Mr. Wayne T. Brooks of the Organization Resources Counselors. He has been deleted, and in his place has been substituted Prof. Rudolph J. Jaeger, Department of Physiology, Kresge Center for Environmental Health, Harvard School of Public Health.

In addition, Mr. Mazzocchi, your submission will be Exhibit No. 5.

(Whereupon, Exhibit No. 5 was marked for identification and was received in evidence.)

JUDGE MYATT: For the record, Madam Reporter, Dr. Selikoff's submission is Exhibit No. 4.

(Whereupon, Exhibit No. 4 was marked for identification and was received in evidence.)

JUDGE MYATT: Are there any questions of Mr. Mazzocchi?

Apparently there are none, Mr. Mazzocchi.

We will take at this moment a brief recess before we get to Dr. Maltoni.

(Whereupon, a short recess was taken.)

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JUDGE MYATT: The next oral presentation will be given by Prof. Cesare Maltoni of Italy.

While Prof. Maltoni is coming forward, I might announce to you that more copies of the schedule of appearances are being reproduced. Some of you have asked during the recess whether there will be copies. They are being reproduced and they will be available for you.

Prof. Maltoni.

PROF. CESARE MALTONI

PROF. MALTONI: Probably my English is not so good, so I will go as slowly as I can.

The project of investigating the oncogenic potential of vinyl chloride followed the preliminary results of the pioneering work of Prof. Viola presented at the Tenth International Congress which took place in Houston in 1970 and was then extensively published in "Cancer Research" in 1971.

Prof. Viola's results indicated that the exposure to 30,000 ppm of vinyl chloride four hours a day, five times weekly, for ten months produced tumors in rats. These tumors were interpreted by Prof. Viola as arising in skin, lungs, and bones.

Immediately after the report in Houston, we got in touch with Prof. Viola, who kindly put at our disposal the manuscript of his extensive report still being printed and several slides of the tumors.

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On the basis of Prof. Viola's results and material, we reached the following conclusions: under Prof. Viola's experimental conditions, vinyl chloride definitely showed a carcinogenic effect on rats.

2. 30,000 ppm of vinyl chloride was an extremely high level of exposure.

3. The tumors described as cutaneous were arising in the Zymbal glands, which is a sebaceous gland of the ear duct, which in rats are responsive to a large specter of carcinogens, such as acetyl-amino-fluorene, polycyclic hydrocarbons, aminostilbenes, benzidine, ethyl-carbamate, et cetera.

4. The tumors described as lung tumors were most likely metastases from Zymbal gland carcinomas. The pulmonary neoplastic deposits were in fact morphologically similar to the Zymbal gland carcinomas, and all were observed in animals bearing Zymbal gland tumors, which was an important fact since we know that lungs of rats is extremely resistant to develop cancer.

The need, therefore, emerged for an extensive investigation to further clarify the type and degree of carcinogenic effects of vinyl chloride with particular emphasis on experimental factors related to exposure, such as route, concentration, length, which could give more direct indications about the risk and degree of occupational condi-

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tions.

For these purposes, and since in our country our Institute is particularly oriented towards studies on cancer prevention and control, we were contacted by Montedison Society to undertake the experimental project on the biological effects of vinyl chloride. Montedison was soon joined by ICI, Solvay, and Rhone-Pegil.

To start the operative phase of the research, we needed, first of all, to prepare proper conditions for atmospheric exposure. The studying and building of an apparatus for programmed and controlled exposure took us several months. Such an apparatus makes it possible to deliver concentrations varying from 30,000 ppm to 50 ppm and to treat simultaneously 900 experimental rodents twice daily, so, per day, 1,800 animals. Basically it is built of inoxidable steel and glass.

VC has been supplied by Montedison. Each stock has been analyzed before the use in the chemical research laboratory of Montedison itself.

The experiments are mainly performed on Sprague-Dawley rats; Wistar rats, Swiss mice, and hamsters have also been used. All the animals, except for hamsters, have been bred in our Institute for years and, whatever their use, they are all examined at death by complete autopsy, which means that we know their current pathology quite well.

Thirteen experiments have been started in sequence.

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Some of them were programmed at the beginning; for some others the need appeared on the basis of the first experimental results. The plan of the experiments and the up-to-date situation is shown in the following tables.

(At this point, various slides were shown.)

PROF. MALTONI: Experiment 1 studies the effect of the atmospheric exposure to 10,000, 6,000, 2,500, 500, 250, 50 ppm of VC, four hours daily, five days weekly, for twelve months. Two groups of animals were added as control, one untreated, as for all the following experiments, and one treated with vinyl acetate at 2,500 ppm, under the same experimental conditions. This dose of vinyl acetate appeared to be the maximal possible dose for a chronic exposure.

Experiment 2 was performed to investigate in a larger number of animals the effect of doses among 250 and 50, that is, 200, 150, and 100 ppm, under the same conditions as Experiment 1. It started after it was clear that 250 ppm was still showing oncogenic effects on the basis of the first experiment.

In the last column are shown the weeks from the beginning of the experiment.

Experiment 3 was planned to study the effect of a shorter period of exposure, keeping all the other conditions of Experiment 1.

Experiment 4 studies the effect of the same type of

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exposure as Experiment 1 in another species, that is, mice. The treatment lasted seven months in consideration of the higher mortality and shorter lifespan of the mice of the strain used.

Experiment 5 was undertaken as a pilot investigation for the possible effects of the atmospheric exposure during pregnancy on offsprings.

Experiment 6. We wanted to reproduce the same conditions of Prof. Viola's experiment. That means an exposure to 30,000 ppm.

Experiment 7 was planned to study the effect of the same type of exposure as Experiment 1 in another strain of rats, that is, Wister rats.

Experiment 8 studies the effects of the same exposure as Experiment 1, which means four hours daily, five days weekly, for twelve months, in a third species, that is, hamsters, for the same period as Experiment 4.

Experiment 9 was planned to further assess whether or not inhalation of VC had any effect at a dose level of 50 ppm. The first group we treated in Experiment 1 was with 60 animals. This we thought was not a sufficient large number of animals, and, so, recently we started another experiment in which we put under treatment 300 animals treated with 50 ppm of VC daily, for four hours daily, five days weekly, for twelve months.

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Experiment 10 studies whether a high but short and/or intermittent atmospheric exposure has any effect, and in fact altogether the animals were exposed 100 hours in three different modalities, four hours daily, five days weekly for five weeks; four hours daily, one day weekly, for twenty-five weeks; one hour daily, four days weekly, for twenty-five weeks.

Experiment 11 was performed to evaluate the possible effects of VC by ingestion. The doses have been chosen on the basis of early data on the release of VC by food containers of PVC and following the indications of the EEC.

Experiment 12 was started to assess whether the VC acts on tissues directly or through metabolites, and in fact a solution of VC is directly injected in subcutaneous tissue.

Experiment 13 studies the third general route of exposure -- I'm sorry. Experiment 12 is by endoperitoneal route, which is the third general route. Experiment 13 is by direct injection.

All the animals were kept under observation until spontaneous death and, actually, we were able to (inaudible) a year and a half after the start of this thing. A complete autopsy was made on each animal and histological examination performed on Zymbal glands, interscapular brown fat, salivary glands, tongue, lungs, liver, kidneys, spleen, stomach, different segments of the intestine, bladder, brain, bones of

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the legs and feet, and any other organ with any pathological lesions. All the animals exposed to the highest does, 30,000 and 10,000 ppm, with or without tumors, were examined radiologically during the treatment and/or after the death. Moreover, radiological examinations were made on animals bearing tumors though exposed to the lower doses.

The preliminary results and the other data on the up-to-date situation of the Experiments 1, 3, 5, and 6 are given on the following Tables 2 to 5. For what concerns the other experiments we have still to wait for results, since they started not a long time ago.

This is the first experiment in which I summarize; the rats have been exposed four hours daily, five days weekly, for twelve months, and kept alive until death. The first group is vinyl acetate, 96 animals there treated with 2,500 ppm. No tumor was observed.

In the second group, 10,000 ppm of vinyl chloride, as the other, 69 animals, and we got 13 Zymbal glands carconomas, 3 nephroblastomas, 6 liver angiosarcomas, 5 tumor in other site or type, which I will describe in a moment.

For what concerns 6,000 ppm, we got 5 tumors of Zymbal glands, 3 nephroblastomas, 11 liver angiosarcomas, and 2 tumor other site.

With 2,500 ppm we got 2 Zymbal glands tumors, 6 nephroblastomas, and 9 liver angiosarcomas, and 4 tumor of

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other site.

It seems sort of paradoxical since in this group the number of nephroblastomas are higher than in the other group, but, meanwhile, tumor of the Zymbal glands started quite heavily, tumor of kidney and liver arose after in time.

On 67 animals, 500 ppm, we got 3 Zymbal glands tumors, 3 nephroblastomas, 7 liver angiosarcomas, 3 tumor of other site and/or type.

At the exposure of 250 ppm, we got no Zymbal glands tumors, 5 nephroblastomas, 2 liver angiosarcomas, and 4 tumor other site and/or type.

And, so, the total number of the tumors was 27, 21, 21, 16, 11, and zero in the group with 50 and zero in the group of negative control, so the total number of tumor was 96 over a total number of animals of 577.

I have to say that up to the present moment we have three survivors after 127 weeks from the beginning of treatment in the group of 50, but up to the present moment no tumor appeared in this group.

The tumors are analyzed in the following table, but I prefer to illustrate here the results of these slides. Several of the Zymbal gland carcinomas metastasized to lungs and this was the misinterpretation of lung carcinoma in every experiment.

What concerned nephroblastoma, they metastasized to

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liver, to lung, and to spleen.

For what concerns liver angiosarcomas, these metastasized to lung.

For what concerns the other tumors in other site and of other type, of the five which arose in the second group treated with 10,000 ppm, we observed 2 Zymbal glands adenomas, 1 neurilemmoma of the ear cartilage (inaudible), 1 mammary carcinoma, and 1 cystoadenocarcinoma of ovary.

For what concerns the two tumors which arose in the group treated with 6,000 ppm, we observed 1 angiosarcoma in subcutaneous fibrosing angioma and 1 sebaceous gland carcinoma of the skin.

For what concerns the group treated with 2,500 ppm, we observed 1 Zymbal gland adenoma, 2 intrabdominal angiosarcomas, one next to spleen and one next to ovary, 1 ossifying angiosarcoma of the neck.

For what concerns the group treated with 250 ppm -- no, I beg your pardon. It's 500 ppm -- we got 1 pulmonary angiosarcoma, 1 angiosarcoma of the uterus, 1 minimal deviation hepatoma.

And for what concerns the four tumors in the 250 ppm group, we observed 1 Zymbal gland adenoma, 1 intrabdominal angiosarcoma next to spleen, 1 intrathoracic ossifying angiosarcoma, and 1 salivary gland carcinoma.

They're summarized there, but I already told.

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In this slide is shown the same design experiment, but instead of one year of exposure, here we have four months of exposure, and the animal there kept during all the life-time and we were continuously controlled. Up to the present moment -- after 56 weeks of experiment with four months of exposure, we observed 3 tumor carcinoma of the Zymbal glands and one carcinoma of the Zymbal gland in the group with 6,000. No nephroblastomas and no angiosarcomas and no tumor in other site.

To have a better comparison of the two experiments, I point out that at 50 weeks after the beginning of treatment when the treatment was performed long throughout one year, we observed at the same distance from the beginning of the experiment 11 Zymbal gland tumors instead of three in the first group, one nephroblastoma, one liver angiosarcoma, and three other tumor in other site or type.

In the second group, we have 3 Zymbal gland tumors, one nephroblastoma, three liver angiosarcoma, and one tumor of other site.

For what concerns the third group, we had two Zymbal gland tumors, one nephroblastoma, one angiosarcoma of liver, and one tumor of other site.

For what concerns 500 ppm, we got one Zymbal gland tumor, one liver angiosarcoma.

And for what concerns 250, we have already gotten

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one liver angiosarcoma.

And so it means in reducing the length of exposure the neoplastic response, as much as we may say at 56 weeks, it dropped in a sensible way.

This is the result of the group in which we reproduced the same condition as the other experiment, and over 60 animals treated with 30,000 ppm, all surviving up to the present moment, no weight decrease, no nothing, and so you may follow quite well the sarcogenic effect. We got two tumors of Zymbal glands after 31 weeks. The first arose 22 weeks after the beginning of treatment.

This is the results of part of the experiment to study the exposure of the mother on the offspring during pregnancy. Of a total of 60 breeders, 30 esposed to 10,000 ppm and 30 exposed to 6,000 ppm, 28 are still surviving after 65 weeks. They were exposed for six days, from the twelfth to eighteenth day of pregnancy. No tumor was observed in the mother, but two tumor were observed in the offspring, one in each group. They were not brothers, the two offsprings. They were not from the same mother. And both have a subcutaneous fibrosing angiosarcoma of the same type we observed in the subcutaneous angiosarcoma as I reported..

Zymbal gland carcinomas, liver angiosarcomas and kidney nephroblastomas have never been observed as occurring spontaneously in our breed of Sprague-Dawley rats.

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And now I would like to show many people acquainted with pathology how they look, these tumors.

This is the type of cage, of cell, we used, and this is inside our laboratory.

This is a tumor -- an animal with a Zymbal gland tumor.

This is still more Zymbal gland tumor, and this is -- sometimes it arise a double type of mass. It's still a Zymbal gland tumor.

This is a (inaudible) Zymbal gland tumor.

This is a small Zymbal gland as it is looking normally. It is a (inaudible) low subaceous gland near the ear duct at the limit of the cartilaginous part with the ossified part.

This is a gland as it is looking in an older animal, with a sort of dilatation of ducts and (inaudible).

This is an ossifying carcinoma of Zymbal gland.

This is a solid less differentiated carcinoma of the Zymbal gland.

This is a fully (anaplastic) carcinoma of the Zymbal gland with a very rich (stroma).

This is a polymorphic Zymbal gland carcinoma, and this is (angiocarcinoma) type of Zymbal gland carcinoma.

This is the same type glandular type, very rich in stroma.

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This is as it appeared, the lung metasteses which were misunderstood primary. One of the characters to judge this primary tumor was the angiosarcoma is very frequent also in Zymbal glands.

These are the (inaudible) magnification. This is a metasteses to lung (inaudible) carcinoma with a rich stroma.

This is as it appear kidney nephroblastoma.

Again another kidney nephroblastoma.

Again another nephroblastoma.

This shows quite clearly the picture, the (inaudible) picture of this tumor in which one may see some embryonic-like aspect of (inaudible).

This is better up here.

This is a liver metasteses of nephroblastoma with this (inaudible) slide picture.

This is a spleen metasteses.

This is a lung metasteses nephroblastoma.

This is a magnification of lung metasteses nephroblastoma.

This is an early angiosarcoma of liver. It appears like these red (blips).

This is, again, in the middle of the lobe an angiosarcoma.

This is a larger liver angiosarcoma.

This is a larger liver angiosarcoma.

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This -- it doesn't appear quite right, but many of these angiosarcoma got excluded from the general circulation and so they undergo some degenerative -- and this is one which looks whitish.

This is an angiosarcoma in (inaudible) liver.

This is how it looks morphologically, very well differentiated angiosarcoma. The effect of the angiosarcoma was seen by us some 14 months and I do believe that it has been one of the first times in literature in which one could predict and orient the following epidemiological investigation.

This is again an angiosarcoma of liver.

This is an angiosarcoma in lung primary.

This is a metastetes in lung angiosarcoma.

Again, metasteses of angiosarcoma to lung.

This is associated, angiosarcoma and a nephroblastoma.

Again an association of early angiosarcoma with a quite large nephroblastoma.

This is the subaceous gland carcinoma of the skin.

This is an ossifying angiosarcoma of neck.

The not ossifying part reproduced by (inaudible).

This is the ossifying part, and this is the lung metasteses of the same tumor.

This is again a primary of lung angiosarcoma.

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This is peritoneal angiosarcoma.

Again, peritoneal (inaudible) angiosarcoma.

Again, another peritoneal angiosarcoma.

This is an ovarian angiosarcoma.

This is an equivalent slide.

This is a uterine angiosarcoma, and this is the corresponding slide.

This a subcutaneous angiosarcoma arising in subcutaneous (inaudible), and you will see very nicely the malignant parts and the benign part.

This is (inaudible).

This is salivary gland carcinoma, and this is the corresponding slide.

Three cases of spontaneously occurring Zymbal gland carcinoma -- as I told, Zymbal gland carcinomas, liver angiosarcomas, and kidney nephroblastomas have never occurred spontaneously in our breed of Sprague-Dawley rats.

Three cases of spontaneously occurring Zymbal gland tumors have been recorded in Sprague-Dawley rats in 1962 by Dr. (Fadiman) in Chicago and myself, and I think they are the only three cases of spontaneously occurring Zymbal gland carcinoma ever described in literature.

To our knowledge, no spontaneous nephroblastomas and liver angiosarcomas of rats have been reported in Italy.

As far as we know, kidney nephroblastomas have

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never been reported to be experimentally induced.

As far as liver angiosarcomas are concerned, they have never been experimentally induced in rats. Liver angiosarcomas of a different morphological type and with a much less malignant picture have been described in mice following long-term treatment with ethel-carbamate.

Liver angiosarcomas are quite rare in man. Few cases -- exactly three cases have been reported in humans following medical exposure to radium and thorotrast.

Now our experiments are in progress and I think that the most important part is this one which deals with the long-term exposure to very low doses. I mean 200 ppm, 150 ppm, 100 ppm, and the larger experiment of 50. To wait for the end of the experiment, four months of exposure, and then also to wait for the results of intermittent high doses experiment. (Inaudible) I do believe we have to be careful to look on the effect on oral administration by gavage of control doses because this has a wider implication than merely occupational aspects.

With the corroboration -- we were asked also by Montedison for corroboration on control of exposed workers and we have now several hundred people under such medical control. This medical control consists mainly of a medical examination, radiological examination, and cytological examination of sputum and urinary sediment.

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As much as concerns sputum, we got probably the most interesting results. We have observed in a small part of workers a sort of (metaplastic) lesion of the respiratory (inaudible) of a morphological type. We have a slide I'm ready to present if anybody is interested on it, that we have never observed on other type of (inaudible).

Thank you.

JUDGE MYATT: Professor, would you remain seated?

We're ready to proceed now, if there are any questions.

Mr. Bien?

MR. BIEN: Could you tell --

JUDGE MYATT: Identify yourself for the record.

MR. BIEN: Ching-Tsen Bien, Occupational Safety and Health.

Could you tell the possible concentration level which has no effect (inaudible).

PROF. MALTONI: I don't know if I get your question exactly, but you ask me if I think --

MR. BIEN: It's possible a concentration level which would not induce any cancer.

PROF. MALTONI: As I told you in my report, we didn't get up to now tumor at 50 ppm level, but the group with which we started was in a way limited because there were only 60 rats, and so we now undertook a much larger

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experiment on 300 animals, treated animals, in order to assess in a more definitive way if or not at that dose level in our experimental condition CVM does not produce or does produce tumors.

MR. BIEN: If you can find a level which is safe for the animals, what would the ratio be between this level which would also be safe for human exposure? If you find the concentration at 50 is safe for the animals, what would be the safe level for the human exposure?

PROF. MALTONI: I would say that it is very difficult to -- at such a low dosage to extrapolate at the present moment on rats directly to man. I would say that we are looking now to have further evidence to show that 50 ppm are not carcinogenic for rats, and, so, since the group at starting was too little, we are going now further with this second investigation. We could say that if in this condition we don't get tumor, I think that at that moment we have to start to look how we can extrapolate this data to human situation.

MR. BIEN: On your further study, are you trying to get some primates for your animal experimentation, monkeys, chimpanzees, or not?

PROF. MALTONI: No, no. It is only done on rodents, different types of rodents.

MR. BIEN: Thank you.

DR. KEANE: Dr. Marcus Keane, NIOSH.

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Prof. Maltoni, I'm especially interested in the remarks you made near the end of your presentation recounting the clinical following of exposed workers and finding positive sputum cytology results -- did I understand you correctly?

PROF. MALTONI: No, I worry I didn't make myself clear. We didn't find positive -- to say "positive" would have meant that we find (neoplastic) cell. We did not observe (neoplastic) cell. We observed a kind of metaplasia -- of metaplasia of the respiratory tract epithelium which means to be quite -- I wouldn't say specific, but which we have observed quite rarely in other group of population but which is present in several cases in these exposed people. Metaplasia -- the meaning of metaplasia, (inaudible) metaplasia, it's not so clear in relation to cancer. It doesn't mean the sputum was positive.

I only say we show a kind of change which seemed to be in a way peculiar of this exposure, and if you want to see, I may show to you.

MR. ROSE: Vern Rose from NIOSH.

Did you analyze the purity and/or possible contaminants of the vinyl chloride which you used in the animal experiments that you've described?

PROF. MALTONI: The vinyl chloride, as I told you, it was analyzed in Montedison's experimental unit and their

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impurities were very, very low -- I would not say zero, but near zero.

JUDGE MYATT: Miss Gholston?

MS. GHOLSTON: Could I ask you, are there any regulations in Europe with respect to exposure to vinyl chloride?

PROF. MALTONI: I think that there are rules, and before, it was to keep the exposure below 250 ppm, but I think that recently the recommendation has been adopted, made and adopted to keep as low as possible. Now I think that it's kept below 100 ppm, but orientation is to lower it down under 50.

JUDGE MYATT: Yes, sir?

DR. JAEGER: Dr. Jaeger, Harvard University School of Public Health.

I'm concerned about the purity of vinyl chloride. Although 250 parts per million is a very low level, can you give me any information on the purity, an absolute number -- can you give me any information on possible contaminants, or is there a representative of the laboratory here that can tell us about that?

PROF. MALTONI: I'm sorry, I have not here the (inaudible) of analysis, but I can send you, if you want.

DR. JAEGER: Are you using the same batch throughout your entire study, or is there a variation in the batch?

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PROF. MALTONI: I would say that I think that it is always the same type of vinyl chloride, but it could be, I think, of not great value as much as it is analyzed each time.

JUDGE MYATT: Are there any other questions?

I have been informed that the slides will be photographed and made a part of the record, so that they will be available as a part of this record.

Are there any other questions of Prof. Maltoni?

DR. SELIKOFF: Selikoff of Mount Sinai.

No question, but I rise merely to voice the thanks of the American scientific community for the beautiful piece of work you've done.

PROF. MALTONI: Thank you very much.

(Applause.)

JUDGE MYATT: All right, Professor. Thank you.

The Professor's submission will be, for the record, identified as Exhibit 6, and 6(a) will be the photographs of the slides.

(Whereupon, Exhibit No. 6 was marked for identification and was received in evidence.)

JUDGE MYATT: It is my intention, since we have such a large number who are listed to appear here, to go until approximately 12:30 before we adjourn for lunch.

Accordingly, I'm going to ask Mr. A. C. Clark for the Manufacturing Chemists Association to come forward with

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his presentation.

ALBERT C. CLARK

MR. CLARK: My name is Albert C. Clark. I'm Vice-President and Technical Director of the Manufacturing Chemists Association.

With me here today is Dr. Kenneth E. Johnson, Assistant Technical Director of MCA.

Before beginning my formal presentation, I would just like to comment -- make reference to a comment by Mr. Rose regarding the suggested work practices. Shortly after receiving the communication from Dr. Key, I think you'll be interested to learn that copies of the work practices were distributed to the medical contacts of all MCA member companies, as well as to members of several of the concerned functional committees.

The Manufacturing Chemists Association is a non-profit trade association have 174 United States member companies representing more than 90 percent of the production capacity of basic industrial chemicals within this country.

With respect to vinyl chloride, the subject of this hearing, over 97 percent of the production capacity reported by Chemical and Engineering News in May 1973 was in our members' plants. For the polymer plants, the corresponding figure was then nearly 88 percent.

Vinyl chloride is a chemical derived ultimately

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from petrochemical feedstocks and chlorine. Of the 5.2 billion pounds of the monomer produced by U. S. Industry in 1972, all but a small fraction -- less than one percent -- was used in the production of various plastics -- primarily plyvinyl chloride, but including a wide variety of co-polymers with other monomers. Among the plastics, only the production of polyethylene exceeds that if PVC.

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

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

A few more statistics concerning the industry may

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be helpful. The U. S. VC/PVC industry has been operating over forty years and over the past five years has shown an annually compounded growth rate of 14 percent -- a rate of growth that is expected to taper off only modestly in the next few years to about 11 percent. U. S. production now represents about one-fourth of the world total.

Synthesis of the monomer is conducted in fourteen U. S. plants, and 37 plants are engaged in polymerization. It is estimated that about 1,500 workers are employed in monomer synthesis, and an additional 5,000 in polymerization operations.

It is difficult to estimate the number of workers employed in converting, molding, and fabricating these polymers, but they are numbered in tens of thousands, working in thousands of plants. It has been estimated the wholesale value of the annual output of fabricated products is over $3 billion.

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

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vinyl chloride -- SD-56 -- was first issued in 1954 and last revised in 1972..

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

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

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

It was in an effort to develop an animal model of

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this condition that the first observations of possible carcinogenesis by vinyl chloride were made. Dr. P. L. Viola, in a report published in March 1970, reported that rats exposed to 30,000 ppm vinyl chloride vapors for four hours per day, five days per week for a year, showed "degeneration of the skeleton and connective tissue with histopathological pictures similar to those observed in human acroosteolysis of the hands." In his paper, no mention is made of the appearance of any malignant tumors.

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

MCA invited Dr. Viola to come to the United States as a guest of the industry for a discussion with U. S. occupational health experts. On May 5 and 6, 1971, at a meeting with MCA's Occupational Health Committee he discussed his more detailed report then in press and referred to other studies completed or underway. Dr. Viola spoke of these unreported studies only in rather general terms and declined to

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

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

From the earliest lists until 1962 the American Conference of Governmental Industrial Hygienists, ACGIH, recommended that the time-weighted average, long-term, seven- to eight-hour daily exposure of workmen to vinyl chloride not exceed 500 ppm. This recommendation was based on single exposure studies on animals and on human experience. Recommended time-weighted average concentrations are published by

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ACGIH in an annual list of "Threshold Limit Values." A TLV was considered by this group to "represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, without adverse effect."

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

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

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

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vinyl chloride for many years.

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

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

Subsequently we learned of further work being conducted in Europe and, fortunately, were able to establish and maintain liaison.

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

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

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

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

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

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

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

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

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has studied.

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

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

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

MCA's first direct contact with NIOSH specifically on vinyl chloride led to a conference between an industry delegation, including a European representative, and Dr. Marcus Key and staff on July 17, 1973, at which time the MCA program was presented in some detail, and study protocols, industry statistics, and selected items from the scientific literature were provided.

Under these circumstances, the VC producing and consuming companies participating in the MCA-administered program were understandably greatly concerned when informed on

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January 22 by the B. F. Goodrich Chemical Company of the events that have led to the hearing now in progress. A meeting of the representatives of these companies was held on January 25 under MCA auspices to receive a comprehensive report from Goodrich and to plan and implement any necessary steps not only for the protection of their workers, but also to hasten the resolution of remaining uncertainties.

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

MCA publicly announced that it is temporarily withdrawing its Chemical Safety Data Sheet for vinyl chloride, which recognized Dr. Viola's work, but stated that "...many years of industrial experience with human exposures to concentrations frequently far above current standards have not demonstrated any carcinogenicity to humans." MCA will expedite the reissue of this data sheet, revised as necessary to reflect new knowledge concerning possible hazards of vinyl chloride exposures. A copy of a February 6, 1974, news release on the withdrawal is attached.

As discussed herein, manufacturers are aware of the potential hazard of vinyl chloride and, we are informed, are voluntarily taking steps to reduce employee exposure.

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Substantial research is now in progress, the results of which they believe will provide a firm basis for any standard applicable to vinyl chloride-polyvinyl chloride manufacture. Therefore, it is their recommendation that OSHA proceed under the provisions of Section 6(b) of the Act.

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

Thank you.

JUDGE MYATT: MCA's submission will be Exhibit No. 7.

(Whereupon, Exhibit No. 7 was marked for identification and was received in evidence.)

JUDGE MYATT: Are there any questions of Mr. Clark?

MS. GHOLSTON: Mr. Clark, you said that so far you didn't think that there were adverse health effects that could be attributed to vinyl chloride because of all the different additives that were also involved in the production of vinyl chloride and PVC.

MR. CLARK: Maybe I didn't quite understand you.

MS. GHOLSTON: You said that you did not think you could say outright that there were adverse health effects attributable to vinyl chloride because there were many other additives that could also possibly cause cancer.

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MR. CLARK: Oh. I don't think I said that. I said it was difficult to be specific regarding vinyl chloride.

MS. GHOLSTON: Now, with respect to the other additives, has any effort been made by MCA or any of its members to find out if any of the other additives are carcinogenic?

MR. CLARK: No.

MS. GHOLSTON: The vinyl chloride data sheet that you mentioned earlier, you said it's been withdrawn?

MR. CLARK: Yes.

MS. GHOLSTON: Is this to revise it?

MR. CLARK: Correct.

MS. GHOLSTON: In light of the carcinogenic possibilities?

MR. CLARK: In light of recent developments, that's correct.

I might add that the other recommendations regarding work practices, we still feel is very valid.

MS. GHOLSTON: You also mentioned that you instituted some work practices that led to a decline in the cases -- I think that's what you said -- of cancer. Am I right?

MR. CLARK: Acroosteolysis.

MS. GHOLSTON: How many cases of this, do you know, were there discovered among the member companies?

DR. JOHNSON: I don't have that information with me

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at the present time.

Were the reprints included in the enclosures, Mr. Clark?

MR. CLARK: I don't think so.

DR. JOHNSON: I'll be glad to supply you with a full set of the reprints of the articles by Dr. Magnuson, et al., which is a very comprehensive study.

MS. GHOLSTON: Can you tell me -- you mentioned 500 ppm. Now, do you consider that a safe level of exposure for workers, or would you suggest another level?

MR. CLARK: I'm not prepared to comment on any of that at this time.

MS. GHOLSTON: Can I ask you, you mentioned that you're going to use rodents the same as was used in the older study. Could I ask you, why are you using rodents and not necessarily using primates or other animals?

DR. JOHNSON: It's basically a problem of animal handling difficulties and the expense and space required to get a statistically significant number of the higher species. It requires lifetime exposures to get these cancer studies on a meaningful basis, and the lifetime exposure of a twenty- or thirty-year-old dog or chimpanzee or other higher species gets to be prohibitively expensive and it takes you too long to get answers.

MS. GHOLSTON: Do you think that the rodent body

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and organs are significantly similar to the same organs in the human?

DR. JOHNSON: There certainly are differences. However, the great bulk of experience in carcinogenisists' research has been with the laboratory rodent and, therefore, it is far more convenient for the workers to interpret those results and compare the results they're getting with other studies by staying in these well-studied groups of animals.

MR. GHOLSTON: Specifically, could I ask you if the liver of the rodent is similar to the human?

DR. JOHNSON: Yes, there is a very high degree of similarity, and I believe Dr. Maltoni was discussing earlier the tumors that he found in these rats in his studies were histologically identical with those found in the human cases.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Prof. Jaeger?

DR. JAEGER: May I ask, you stated that you were not conducting studies of other contaminants found in vinyl chloride; you were not assessing their carcinogenesis?

MR. CLARK: That's correct.

DR. JAEGER: But one common constituent of the manufacturing process in vinylidene chloride, a compound that does not currently have a TVL standard, and I believe it was stated on Tuesday that two of the individuals who developed cancer had worked in a vinylidene chloride-vinyl chloride

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process prior to their illness and death. Is there any intention of the industry to study other reactive monomer compounds which may produce cancer in rodents before we find that they produce cancer in man?

MR. CLARK: We have not had, up to this time, any intention to proceed along those lines. What will transpire as a result of the recent discoveries in this incident, I'm not sure.

JUDGE MYATT: Yes, sir?

MR. MAZZOCCHI: Tony Mazzocchi of the Oil, Chemical and Atomic Workers.

Was the MCA aware before today of the documents mentioned in Dr. Selikoff's testimony, the Russian documents and the German documents, and, if so, did they distribute the information from those documents to their members?

MR. CLARK: No, I was not aware of them.

JUDGE MYATT: Are there any further questions?

Let me ask you this: you mentioned that you wanted a copy -- or the reprint made a portion of this record; is that correct?

MR. CLARK: Yes, sir.

JUDGE MYATT: And you're going to supply us with a copy of that, or is it included in the submission?

MR. CLARK: There are nine attachments to my statement, sir, including that.

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JUDGE MYATT: All right.

There being no other questions, thank you, Mr. Clark.

I have twenty-two minutes after 12:00. We're going to take our luncheon break and resume at 2 o'clock with the B. F. Goodrich presentation.

(Whereupon, at 12:22 p. m., the hearing was recessed until 2:00 p. m. of the same day.)

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AFTERNOON SESSION

JUDGE MYATT: The hearing will be resumed.

We have a few more changes. Mr. Donald Holman, the Industrial Hygienist for Control Data Corporation, you can indicate on your list that he will not be making an oral presentation. He has submitted to us a copy of some data he was going to present, and we're going to mark that as Exhibit 8, Madam Reporter.

(Whereupon, Exhibit No. 8 was marked for identification and was received in evidence.)

JUDGE MYATT: That will be in lieu of Mr. Holman's oral presentation.

We also have an additional group to add to the list. Mrs. Andrea Hricko -- how do you pronounce that, madam?

MS. HRICKO: Hricko.

JUDGE MYATT: And Bertram Cottine, representing the Health Research group.

You will list their names as having entered an appearance and, thus, entitled to examine witnesses, although I understand their submission will not be an oral submission but will be a written submission that will be included in the record.

Are the Goodrich people ready? Let's proceed.

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ANTON VITTONE, JR.

MR. VITTONE: My name is Anton Vittone. I am President of B. F. Goodrich Chemical Company, a division of the B. F. Goodrich Company. Our headquarters are 6100 Oak Tree Boulevard, Cleveland, Ohio.

I have prepared a statement from which I will now read and submit for the record of this hearing.

With me to assist in answering questions which may follow this presentation are Maurice N. Johnson, M. D., Director of Environmental Health; Dr. Roger W. Strassburg, Director of Environmental Affairs, and L. B. Crider, Senior Scientist and Specialist in Analytical Chemistry and Monitoring Systems, all of B. F. Goodrich. Their biographies are attached to our written paper.

Over the years our company has sought to maintain a safe working environment through two basic means, containment of potentially or known toxic materials during the manufacturing process and, secondly, protection of our employees through work practices, education, and equipment.

Our efforts to maintain a safe working environment have been in keeping with then known scientific information or data relating to levels of exposure which has resulted in decreasing levels of exposure with time.

Our recent discovery of four deaths from a rare type of liver cancer among employees at our Louisville plant

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was, to our knowledge, the first evidence indicating a possible relationship between human angiosarcoma and chlorinated hydrocarbons used in the production of polyvinyl chloride resins. Our confirmation of the significance of this evidence convinced us that we should report it to our employees and to the federal and state agencies with primary scientific responsibility for occupational health.

Our statement today today will focus on what we have learned about the four deaths at the Louisville plant and our knowledge of previous toxicological data. We will also summarize our program to further safeguard employees now on the job through increased containment of vinyl chloride in processing and reduced worker exposure during all phases of the operation.

The B. F. Goodrich Company began commercial production of polyvinyl chloride resins and compounds in 1937. We currently operate five such plants, at Louisville, Kentucky; Avon Lake, Ohio; Long Beach, California; Henry, Illinois, and Pedricktown, New Jersey, and a vinyl chloride monomer plant at Calvert City, Kentucky. Approximately 1,700 of our employees are engaged directly in these processes. The Louisville, Kentucky, plant is the oldest of our operating polyvinyl chloride resin plants, having initially started production in 1942. We supply finished resins and compounds to about 2,200 domestic customer plants.

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The technologies involved in the production and use of vinyl chloride. There are two types of vinyl chloride monomer processes, acetylene-based and ethylene-based.

B. F. Goodrich has operated both types. Prior to the early 1960's, our principal process of vinyl chloride involved the reaction of acetylene and hydrogen chloride using a Mercuric chloride cataylst deposited on carbon. Starting with a pilot plant at Louisville in 1957 and culminating in a petrochemical complex at Calvert City in 1964, we converted to our present ethylene-based vinyl chloride process.

This consists of three operations: First, reaction of ethylene with chlorine to produce ethylene dichloride; second, thermal cracking of ethylene dichloride to produce vinyl chloride and hydrogen chloride, and, third, reaction of hydrogen chloride with more ethylene in the presence of oxygen to produce more ethylene dichloride. The latter process is known as oxychlorination.

Significantly, the vinyl chloride monomer produced in both processes is distilled to yield commercial vinyl chloride with 99.9 percent purity. The purified vinyl chloride is either pipelined as a liquid under pressure to an adjacent consuming plant or transferred to pressurized tank cars for shipment to other polyvinyl chloride resin plants.

There are four types of polyvinyl chloride

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processes: suspension, emulsion, mass, and solution. B. F. Goodrich Chemical uses the first three types with over three quarters of its production being by the suspension process.

The steps in the process for suspension are: vinyl chloride monomer is received at the plant in pressurized tank cars as a liquid; it is transferred to storage tanks and then piped in a closed system to reactors; water, suspending agents, and catalysts are added to the reactors; polymerization is conducted at controlled temperatures; unreacted monomer is recovered and recycled to the process; water is centrifuged from the stripped polymer slurry and the wet polymer cake is dried; dried polymer is bagged or siloed for bulk shipment or transferred to compound operations.

The emulsion PVC process differs only in the types of emulsifiers and catalysts used in the reactor. Most emulsion PVC processes in our plants are followed by spray drying of the emulsion.

The mass PVC process differs primarily in that it is anhydrous -- no water is used in the polymerization. After unreacted monomer is recovered, the dry powder is packaged.

Compounding. In all of our PVC production plants we convert part of our resins into compounds in powder or cubed form. This compounding operation is the next step towards the finished products. PVC powder is mixed with

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stabilizers, lubricants, and, in some cases, plasticizers in powder mixers of various types. The powder mix is fluxed in internal mixers and subsequently diced or pelletized before packaging for shipment.

B. F. Goodrich toxicity experience. In connection with these processes, our company has had some experiences that we want to review with you in order to complete your understanding of certain factors that prompted us to interpret the most recent events as we did.

In mid-1964, Dr. John L. Creech, our Louisville plant physician, reported that an unusual hand problem had developed among a few employees who entered the polymerization reactors to manually remove the build-up of solid PVC from the reactor walls. This was the first time we encountered a problem anything like this. Dr. Creech's observation was found to confirm European published reports of a similar problem.

We called a meeting with other PVC manufacturers to review the situation and participate with them in an extensive research program through the Manufacturing Chemists Association. We then cooperated in a worldwide investigation of what came to be known as the "hand problem" or acro-osteolysis. Our employees were advised of the problem and a continuing monitoring system of hand x-rays was established at all our plants. These studies of the hand problem

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correlated only with manual cleaning of PVC reactors.

Despite the lack of conclusive evidence as a chemical cause of the hand problem, we initiated an aggressive program to reduce this type of exposure. Goodrich developed a hydraulic reactor cleaning process which is used on all our reactors. The use of hydraulic reactor cleaning reduced substantially the number of entries into reactors and, thus, the manual hand effort, as well as the exposure to vinyl chloride. In the past several years we have observed no new cases of the hand problem.

In May 1970, Dr. P. L. Viola of Rome reported the appearance of tumors in rats exposed to 30,000 parts per million of vinyl chloride vapor in inhalation studies. This level is close to the lower explosive limit of vinyl chloride vapor.

Nevertheless, knowledge of this published information caused the MCA Vinyl Chloride Task Force to initiate a suitable protocol to determine whether tumors could be induced at levels of exposure above or below the 500 parts per million maximum standard then in effect.

In conjunction with the development of this protocol, the MCA task force learned of similar animal research which had been initiated by some European PVC manufacturers some time after Dr. Viola's report.

The MCA animal test program began in September

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1973. In addition, the MCA program was expanded to include an industry-wide epidemiology study now underway.

In January 1973 we intensified air sampling analysis in all our plants to determine more accurately the levels of vinyl chloride monomer exposure. We soon learned that commonly used air sampling techniques were inadequate for fast measurements at low levels for extended periods of time and for determining the cause of any increase in level. Therefore, we investigated all other monitoring techniques, including those being used in other companies, and decided that we needed to develop our own advanced system which would be capable of monitoring at very low levels and over extended periods of time.

While we had been concentrating on reduction of any process loss of vinyl chloride for years, we began a series of special plant manager meetings in mid-1973 to minimize worker exposure to vinyl chloride, to discuss new monitoring systems, and to put into effect new work practices. We established an interim goal of 50 parts per million maximum exposure and are working toward lower levels.

The Louisville situation. In the spring of 1973 Dr. Creech believed that he was observing among some employees an increasing incidence of symptoms normally associated with possible liver ailments. He discussed his concern with Phillip H. Lawrence, manager of the Louisville

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plant, and recommended that liver function tests be initiated among certain groups of the plant's PVC employees.

The company's newly appointed Director of Environmental Health, Dr. Maurice N. Johnson, who is with me today, subsequently went to Louisville and started the testing program involving 271 employees.

The tests which were completed in early December 1973 showed that 55 employees had some evidence of slight liver abnormalities. Because of the known limitations of liver tests, these results were not in themselves a major cause for concern.

On December 18, Dr. Johnson again visited the Louisville plant. He consulted with Dr. Creech on these results and they agreed to retest those employees showing any indication of abnormality. These tests have just been completed and are now being evaluated.

In this meeting Dr. Johnson was informed by Dr. Creech that he had recently learned that an employee died in March 1973 of angiosarcoma of the liver. Dr. Creech also reported that this rare type of cancer prompted him to review medical records concerning another employee and former patient who died of liver cancer in 1971, and that review confirmed it was an angiosarcoma of the liver.

Because of Dr. Creech's growing concern and Dr. Johnson's awareness of other pertinent toxicological studies,

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they reviewed available medical records in the plant and found that another employee had died of an unknown type of liver cancer in 1968. They also learned that another employee was critically ill with a diagnosis of cirrhosis. This man died the following day.

Dr. Johnson returned immediately to Akron for a special meeting with top corporate officers at which the developments at Louisville were reviewed. The decision was made to begin an in-depth investigation with the assistance of outstanding consultants in the field of industrial medicine. Dr. Johnson contacted Tabershaw-Cooper Associates, Inc., of Berkeley, California, because of their reputation and also their involvement in the MCA work that was mentioned earlier. Dr. Johnson met with Dr. Irving R. Tabershaw in California on January 14th and 15th to review all the information then known to the company. Before returning to Akron, Dr. Johnson learned that the cause of the third death which had occurred on December 19th was angiosarcoma of the liver.

Another in a series of top management meetings was held on January 18th to discuss these developments. Dr. Tabershaw flew to Akron for a meeting with corporate and divisional officers on Sunday evening, January 20th.

Because of the possibility that these deaths from a rare type of liver cancer might be work-related, the decision was made to inform the Occupational Safety and

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Health Administration, OSHA, through the Kentucky Department of Labor and the National Institute of Occupational Safety and Health, NIOSH, as well as to provide the essential information to our PVC employees, union officials, and the public.

The initial meeting with NIOSH took place in Washington on January 22nd after Drs. Johnson and Tabershaw returned from a visit to the plant and consultation with Dr. Creech in Louisville on January 21. The notification to OSHA through the Kentucky Department of Labor was made in Louisville by Drs. Johnson and Tabershaw on January 23rd.

A public statement was also released by the company on January 23rd. A second statement was issued to the news media on January 29th immediately after it was learned that a review of autopsy records confirmed the cause of the 1968 death as angiosarcoma of the liver.

During this period, Harry B. Warner, President of B. F. Goodrich, Thomas B. Nantz, Executive Vice-President, and I held private meetings with the families of three of the deceased employees. On the same day, Messrs. Warner, Nantz, and I inspected the Louisville plant to observe current work practices and exposure levels. After these observations and consultation with Drs. Johnson and Tabershaw, we concluded that the existing situation warranted continued operation of the polyvinyl chloride facility.

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Epidemiological studies. We have actively supported and participated in both animal and epidemiological studies through the MCA's Vinyl Chloride Task Group of its Occupational Health Committee.

Because of recent developments, we have expanded the scope of our part of the MCA epidemiology study in order to obtain as in-depth a study as possible of employees exposed to vinyl chloride and related chemicals.

The deceased employees had an average exposure of approximately 19 years to vinyl chloride and ten years to vinylidene chloride. They also had variable exposure times to such volatile organic chemicals as vinyl acetate, methyl acrylate, ethyl acrylate, methanol, and chlorinated solvents.

It would be premature to report on the liver activity tests now in process at all our PVC plants or to provide any statistical analysis of the correlation with chemical exposures. We can tell you that no other cases of angiosarcoma have been found in our preliminary review of death records of employees and retirees from Louisville and our other plants. This review is continuing.

Summary. We have attempted to provide information with respect to our findings of four cases of angiosarcoma of the liver of deceased employees of our Louisville, Kentucky, plant which have brought about this hearing. With respect to Item 6 of the agenda, that is, "whether the avail-

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able information warrants the issuance of an Emergency Temporary Standard or the commencement of a regular rule-making under Section 6(b) of the Occupational Safety and Health Act," we recommend that your agency proceed with the regular rule-making procedure under Section 6(b).

We will do all we can to protect the health and safety of our employees. To help achieve these ends, we have brought exposure levels in all our operations below 50 parts per million on a time-weighted average and are working towards lower levels of exposure. Our plant monitoring procedures are reliable and are being improved. We are in the process of providing liver function tests to all exposed employees. We are implementing most of the temporary precautionary procedures recommended by NIOSH on January 31 at all plants as rapidly as possible. Several recommendations will require further clarification and discussion with NIOSH before implementation. Our medical department is working closely with government and other medical authorities to specify the best possible medical screening and testing procedures.

In summary, the clinical evidence associated with the deaths of four of our employees identifies the need for scientific inquiry beyond the experience of any one company or industry group.

Thank you.

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JUDGE MYATT: Thank you, Mr. Vittone.

Your submission will be admitted into the record as Exhibit 9.

(Whereupon, Exhibit No. 9 was marked for identification and was received in evidence.)

JUDGE MYATT: Are there any questions at this point of the Goodrich representatives?

MR. MAZZOCCHI: Tony Mazzocchi, Oil, Chemical, and Atomic Workers.

I heard reference to a search in the European literature after a relationship had developed between bone disease and PVC exposure. My question is: did the searchers of European literature discover the papers referred to by Dr. Selikoff this morning showing the relationship between liver cancer and PVC and VC?

MR. VITTONE: Do you understand the question?

DR. JOHNSON: You mean at the time the research was done on the acroosteolysis cases? I'm not sure, but they are not in the file, so I presume they did not uncover them.

MR. MAZZOCCHI: Does B. F. Goodrich have a European chemical operation?

MR. VITTONE: Yes, we have a European chemical operation. It's not in the manufacture of polyvinyl chloride. We own part of (Ciago), which does make some

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vinyl (inaudible).

MR. MAZZOCCHI: Do they have a corporate medical department?

MR. VITTONE: I don't understand the question.

MR. MAZZOCCHI: Does the European affiliate have a medical department with an M.D.?

MR. VITTONE: The European facility has medical service through our associates there, HAU, currently KZO.

MR. MAZZOCCHI: What country is that in?

MR. VITTONE: It's in Holland.

MR. MAZZOCCHI: I understand there's a Dutch paper also as to the relation between liver disease and vinyl chloride. Your European medical directors would not communicate with your American company when they discover something that might affect the American operation?

MR. VITTONE: We've been trying throughout these many years to keep abreast of any developments in Europe with respect to this area and we will continue to do so.

MR. MAZZOCCHI: Could you describe for us where monitoring is done in the PVC operation? Is it continuous and how is it performed?

MR. VITTONE: Where what is done?

MR. MAZZOCCHI: Monitoring.

MR. VITTONE: We have two systems we're monitoring currently. We're trying to go to a continuous system. We

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have one such installation at Avon Lake and equipment ordered for all of our plants.

The other system is a spot system where we're employing people constantly checking, spot checking, throughout all floors of the buildings.

MR. MAZZOCCHI: I still have two more questions. Are employees told to monitor the readings at the time they're taken?

MR. VITTONE: They see the readings.

MR. MAZZOCCHI: They see the readings?

MR. VITTONE: That is, the employee who takes them sees the readings. They're available on a chart.

MR. MAZZOCCHI: I understand the daughter of an employee at Louisville, an eight-year-old female, has come down with a liver tumor. Can you tell us something about that, whether that is, in fact, true and, if true, what is the diagnosis of that young girl and also where did her father work in the plant?

MR. VITTONE: Do medical ethics allow you to speak on this subject, Dr. Johnson?

DR. JOHNSON: Yes. I think I can be a bit careful, but there was a child of an employee who was reported to have liver cancer and that has been checked out -- by Dr. (Popper), as a matter of fact -- and it was a liver tumor type other than an angiosarcoma, and I don't know what type

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it was. It was not angiosarcoma.

MR. MAZZOCCHI: Can you tell me where her father worked in the plant?

DR. JOHNSON: I don't know.

JUDGE MYATT: Yes, ma'am?

MS. HRICKO: Andrea Hricko, Health Research Group. Can you submit for the record the exact dates, the month and the year, of the deaths of the former employees?

DR. JOHNSON: Chronologically, 1/7/68, 9/27/71, 3/3/73, and 12/19/73.

MS. HRICKO: And what was the date on which Dr. Creech first found that March '73 case? You mentioned --

MR. VITTONE: The March '73, he reported it to Dr. Johnson, I believe, on December 18th.

MS. HRICKO: That was the first notice you had?

MR. VITTONE: That was the first notice to us. You see, that was not a patient of Dr. Creech's.

MS. HRICKO: The other question I have is in regard to the screening tests you're performing on employees. Can you submit a protocol for those liver function tests for the record?

DR. JOHNSON: At the moment we're doing the standard SMA-12, which includes four things that I think one would call fairly directly related, bilirubin, (inaudible), LDH, and STOT, and, I suppose, some of the other more remote--

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MS. HRICKO: I have one more question. Were any of these employees who died of angiosarcoma of the liver retired employees of B. F. Goodrich?

MR. VITTONE: Not to my knowledge.

MS. HRICKO: Does B. F. Goodrich keep track of their retired employees?

MR. VITTONE: Yes, and that's now we have checked the preliminary report that we have made that we have found none other than the four cases. We're checking the records.

MS. HRICKO: Thank you.

JUDGE MYATT: Miss Gholston?

MS. GHOLSTON: Mr. Vittone, have you done anything to determine where the four employees that died from liver cancer worked with respect to the plant? I mean, did they all work in a common point at one point in time?

MR. VITTONE: Yes, we have checked where they have worked in the plant. They all did work in one particular building at one time, but not their full life history in the plant. There are four polymerization areas at the Louisville plant and these people had worked in more than one. They had worked also in areas outside the polymerization areas.

MS. GHOLSTON: I'd like to ask you: have you noticed or found that there is any difference in the exposure of the employees to vinyl chloride or polyvinyl chloride depending on the stage of production that they're working in?

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MR. VITTONE: Well, not currently. There has been in the past years, and normally in the summertime the level would have been lower than in the wintertime due to less ventilation, closing of windows.

MS. GHOLSTON: Have any of your employees at any of your other plants other than the Louisville plant been found to have died of any other types of cancer other than angiosarcoma?

MR. VITTONE: Dr. Johnson, can you answer that?

DR. JOHNSON: Oh, yes. Over the years, surely.

MS. GHOLSTON: Have you made any connection?

DR. JOHNSON: The distribution, at least superficially, appears to be perfectly normal. Of course, there are too few to be meaningful, and that data is becoming a part of the Tabershaw-Cooper study in order to get enough data together to draw some meaningful conclusions.

MS. GHOLSTON: Are you making any distinction in trying to gather additional information between the vinyl chloride plant at Calvert City, I believe, and your polyvinyl chloride plant?

MR. VITTONE: The vinyl chloride plant at Calvert City has the same program as our polyvinyl chloride plants, as far as studying the employees and the health practices and so forth.

MS. GHOLSTON: Now, with respect to the other

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chemicals that are involved in the processes, are you going to do anything to determine whether or not some of the other chemicals may be carcinogenic?

MR. VITTONE: This is a decision we have not come to yet. The exposure level of other chemicals, of course, is much lower than vinyl chloride, for which they will be, I'm sure, studying the literature.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Yes, sir?

DR. JAEGER: Jaeger of Harvard.

You did comment that all four workers had a ten-year work history with vinylidene chloride?

MR. VITTONE: Yes, I did.

DR. JAEGER: You were making then polyvinyl chloride, polyvinylidene chloride propolymers of polyvinyl chloride?

MR. VITTONE: Yes, it was a propolymer.

DR. JAEGER: Two questions -- one question, really. Vinyl chloride has been acknowledged to be a contaminant of polyvinyl chloride after it has been dried and sprayed or when it's about to be bagged. Is the same thing true of vinylidene chloride? Is it also a contaminant? What I'm asking is: what is the likelihood of vinyl chloride and vinylidene chloride in workers handling the material following polymerization?

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MR. VITTONE: Well, there is some vinyl chloride. I'm not aware of the vinylidene chloride content. I assume Mr. Crider might have some data on that.

MR. CRIDER: No, I don't. I couldn't answer the specific question. I don't know the answer to that right now.

DR. JAEGER: We have heard that vinyl chloride workers have developed angiosarcoma, but the way the story is coming out, we forget the rest, vinyl chloride and vinylidene chloride may develop angiosarcoma.

MR. VITTONE: Yes, there is exposure to other chemicals, as I pointed out in my testimony, to vinyl chloride, to vinylidene chloride, reactors, and so forth.

DR. JEAGER: Could you tell me the amounts of each compound that may constitute the exposure?

MR. VITTONE: It's almost impossible at this point in time to try to determine what the level of exposure was in the last twenty or thirty years, and that's what you're asking me to do.

DR. JEAGER: Your methodology for assessing vinyl chloride concentration in the work area, will it differentiate between vinyl chloride and vinylidene chloride and vinyl acetate and methyl alcohol? What I'm asking you there is: How intensively are you monitoring the exposure of your workers?

MR. VITTONE: The monitoring system we're using

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now will totalize all of those products. We're using a hydrocarbon system. So that when I say under 50 parts per million, the total is under 50.

DR. JAEGER: Thank you.

JUDGE MYATT: Are there any other questions?

Yes, Mr. Bien.

MR. BIEN: Do you have any information regarding the particle size of the polyvinyl chloride tests that you made in the different process areas at the PVC plant? I'm talking about PVC dust.

MR. VITTONE: You're asking for the size of the PVC dust?

MR. BIEN: Right.

MR. VITTONE: This varies with the process. Let's see if Mr. Crider has this in mind.

MR. CRIDER: No -- well, if you take all of the polymers that we make, there's a very wide range of particle size. Right off the top of my head, I couldn't take -- right now, I couldn't take a specific resin and give you a particle size number.

MR. BIEN: I'm talking about airborne dust size. I'm not talking about the size of --

MR. CRIDER: If you're talking about airborne particle size, the answer is I don't know.

MR. VITTONE: It's certainly below 325 mesh. It's

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pretty fine.

MR. BIEN: If you pass it through the screen size (inaudible) the mechanical process. We're just looking for this type information.

MR. VITTONE: Let me understand you correctly. You want information on the particle size of the real fine material?

MR. BIEN: In the airborne stage.

MR. VITTONE: I'm sure we have such data available and we'll make it available to you.

MR. BIEN: During the storage of your final product, like the resins, do you have any measurement of the vinyl chloride concentration in the storage silos or in the packages?

MR. VITTONE: In the storage silo? Yes, we have measurements there. I don't have it handy. But I would say they're probably on the order of a hundred or two hundred, that magnitude, in the silo -- you're talking about the closed silo?

MR. BIEN: You have four major products that you make in the PVC polymerization process (inaudible)?

MR. VITTONE: I don't quite understand your question.

MR. BIEN: During the normal operation you have a different polymerization process, bulk, suspension, emulsion.

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Which products will give the most exposure to vinyl chloride during normal operations, and how do you use them in emergency situations?

MR. VITTONE: You're asking me for exposure levels? I'd have to say that we keep them all within about the same level.

MR. BIEN: Thank you.

MR. VITTONE: There's maybe a difference between one plant and the other, but I don't think it's due to the processes.

JUDGE MYATT: Are there any other questions?

All right, gentlemen. Thank you very much.

The next witness to appear, Mr. Richard J. Reynolds of the Shell Chemical Company.

RICHARD J. REYNOLDS

MR. REYNOLDS: Mr. Chairman, my name is Richard J. Reynolds, Manager of Vinyl Chloride, Shell Chemical Company.

I am accompanied here by Mr. Howard L. Kusnetz, Manager of Industrial Hygiene, Shell Oil Company, and Dr. R. L. Maycock, Manager of Environment and Safety, Shell Chemical Company.

The Shell Oil Company and its division, the Shell Chemical Company, are pleased to be able to participate in this fact-finding hearing on the possible hazards of vinyl chloride manufacture and use. We are especially appreciative

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that the U. S. Department of Labor called this hearing before publishing any proposed regulation.

Shell Chemical Company manufactures vinyl chloride monomer, which we abbreviate VCM, at Deer Park, Texas, near Houston, and at Norco, Louisiana, near New Orleans. We entered the vinyl chloride industry only recently and we produce only the monomer, VCM. Our remarks will be limited to this segment of the industry only.

Shell's facilities comprise large, continuously operating process units closely integrated and requiring minimal manual attention or exposure to feed and product streams. Production in the unit at Deer Park, Texas, was started in August 1971. Production in the Norco unit was started in October 1973. Design production capacity is about 1,200 tons VCM per day at Deer Park and about 1,000 tons VCM per day at Norco.

At Deer Park about twenty persons are involved directly in the day-to-day operation of the VCM unit. Approximately twenty-five additional employees are involved less continually with VCM manufacture during the regular performance of their duties in maintenance, shipping, and supervision. Thus, at Deer Park about 45 workers out of a total chemical plant staff of 1,300 are concerned with VCM manufacture on a regular basis.

At Norco a similar number of direct VCM workers are

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required, but fewer shipping personnel, so about 25 workers of a total chemical plant staff of about 370 are involved on a regular basis with VCM manufacture.

The principal raw materials used in our VCM production units are ethylene and chlorine. At both Houston and Norco the ethylene is received by pipeline. Chlorine at Houston is received by pipeline and at Norco by railroad tank car. Small quantities of dichloroethane are received at both locations by barge to supplement these primary feeds. At Houston small supplemental quantities of hydrogen chloride feed are received via pipeline and tank truck.

The process technology employed at both Shell VCM units was licensed from Stauffer Chemical Company. In this process, about half of the ethylene and all of the chlorine fed are reacted to form the main intermediate, which is 1,2-dichloroethane. After purification, 1,2-dichloroethane is heated in a furnace to form product VCM and the main byproduct, hydrogen chloride. The product VCM is purified to greater than 99.9 percent purity by distillation and stored as a liquid under its own vapor pressure. The byproduct hydrogen chloride is recovered by reaction with the remaining half of the ethylene feed and with air to form additional 1,2-dichloroethane.

Minor byproducts of the process include carbon oxides, chloroform, carbon tetrachloride, ethyl chloride,

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the isomeric dichloroethylenes, the isomeric trichloroethylenes and trichloroethanes, tetrachloroethanes, and the isomeric chlorinated butanes.

The process is a continuous one. The reactants, intermediates, byproducts, and product VCM are contained within the process equipment in a closed system except for a continuous stream of waste process nitrogen which is vented from a high stack after water scrubbing. Occasionally there may be minor vents such as from loading arm drainage or leaks. The process equipment is opened only for maintenance, and then only after washing followed by purging of feed, product, or byproducts contents. Maintenance operations are generally infrequent; maintenance shutdowns are scheduled only once or twice a year.

The general precautions for containing and purging organic materials in large chemical process equipment are well-known to us as a result of our long history of manufacture and handling of flammable materials and chlorinated compounds.

When the process technology was licensed, a substantial compilation of toxicological information on VCM and associated feed and byproduct compounds was received from the licensor. Also we had available considerable other toxicologic information dealing with compounds already handled by Shell Chemical such as chlorine, ethylene, and ethyl chloride.

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This information is available to the public in toxicologic reference works; therefore, we'll avoid requoting it here.

Initial review of the VCM process toxicology information available to us in 1969 and 1970 led us to conclude that additional studies of our own were not required. Thereafter, in a paper delivered at the 1970 International Congress on Cancer by Viola, it was reported that tumor development was observed in rats exposed repeatedly to high concentrations of VCM. The exposure levels in the Viola work, 30,000 parts per million, were grossly in excess of published standards.

Nevertheless, the report raised a new concern as to what hitherto unknown effects might be expected with exposure to lower levels. Thus, we accepted an invitation by the Manufacturing Chemists Association to participate with others in the industry in sponsoring an exposure study to elucidate the possible effects of VCM at much lower levels and to participate in an epidemiology study. These programs were described in detail to you by the Manufacturing Chemists Association today. Shell Chemical has provided financial support and has participated actively in these programs from the outset.

From the time our Deer Park unit began VCM production in August of 1971 until early 1973, periodic spot measurements were made of the ambient plant air in the

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operating unit using standard colormetric VCM detector tubes. All measurements were well below the OSHA 500 ppm ceiling level and the 200 ppm time-weighted average Threshold Limit Value set by the ACGIH in June 1972.

From previous experience with other volatile and flammable materials, we were confident that the plant ambient air contained less than 200 ppm VCM, but this could not be verified because the detector tubes are not sensitive to much lower values. It was apparent that a new analytical method would be required to measure low levels of VCM and also that improved sampling techniques would be required to compensate for the greater effect of variances introduced by weather conditions and sampling locations at low levels. Therefore, a sensitive gas-chromatographic analytical technique for VCM in air was developed and sampling was modified to meet the needs of the situation. A copy of the method is appended to our submission.

Based on a developing concern and with the new analytical tools, our company elected to establish an internal working level of 50 parts per million, eight-hour time-weighted average, maximum exposure to VCM concentrations in air. This level and the possible implications and incentives for minimizing exposure indicated by the Viola work were discussed with our employees in July-August 1973. On August 15th, 1973, we formally advised all of our customers of

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customers of our new working level and the reasons for it. A copy of our letter to our customers is attached.

Along with the new sensitive analytical technique we had our workers periodically wear an improved device for taking a continuous sample over eight hours of the air in worker's breathing zone. Results with the improved sampling and measurement technique showed no values in either VCM plant location exceeding the 50 parts per million VCM eight-hour time-weighted average. Special tests were also made to ascertain the maximum VCM exposure a worker might receive under abnormal conditions at the jobsite. Under some of these conditions, we found values of 100 to 200 parts per emission VCM, but these concentrations persisted only for a short time. Based on these tests, additional precautions and directions were put into practice.

In 1973 we began a program of medical surveillance of VCM workers who would be regularly assigned to jobs involving potential or regular exposure to VCM. Twenty-five workers at Norco were given the examination described below. Forty-two examinations will have been given at Deer Park when the current examination cycle is complete.

The annual examination provides for: (1) medical history; (2) physical examination by a physician; (3) laboratory blood studies including RBC, hematocrit, hemoglobin, WBC, differential count, and platelet count; (4) SMA-12 blood

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chemistry including serum bilirubin; (5) routine urine examination; (6) 14 by 17 P-A chest x-ray.

Based on existing knowledge, with the very low accumulated exposure of our workers to VCM, we would not expect these examinations to provide any data beyond that establishing a baseline for subsequent medical history. In fact, to date we have found no liver damage or cancer among the Shell participants. Although we have not been onstream long enough to have meaningful epidemiological data of our own, Shell Chemical is a financial supporter of the Manufacturing Chemists Association epidemiology study contracted to Tabershaw-Cooper Associates and described to you today.

In addition to the above actions, we continue efforts to locate and curtail emissions, should they be found, throughout our process units and associated loading areas.

With respect to Item 6 in the notice of this hearing, Shell Chemical would favor the route of the regular rule-making under Section 6(b) of the Occupational Safety and Health Act for a VCM standard as opposed to an Emergency Temporary Standard. The rule-making procedure would allow the orderly development of data.

Thank you very much for the opportunity to appear.

JUDGE MYATT: All right, sir. Shell Chemical Company's exhibit will be designated Exhibit No. 10.

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(Whereupon, Exhibit No. 10 was marked for identification and was received in evidence.)

JUDGE MYATT: At this point are there any questions?

MS. GHOLSTON: Has there been any change in the purity of the vinyl chloride that you used at the beginning up until now?

MR. REYNOLDS: No, our standards have always been 99.9 percent plus purity.

MS. GHOLSTON: With respect to any other chemical that may be involved in your process, are you looking to see if any other chemical might be a cause of cancer?

MR. REYNOLDS: As I mentioned earlier, we don't have our own toxicological studies, animal studies, of what's going on in our operations. I would say that we would support and feel that it would be advisable for the industry broadly to support additional studies and we would be glad to participate in that support.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Yes, sir?

MR. ROSE: Mr. Rose from NIOSH.

Concerning the new environmental sampling system that you've gone to to replace the detector tubes, first of all, I assume it's an environmental sampling as opposed to personal sampling?

MR. REYNOLDS: It's both.

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MR. ROSE: It's both. Is this grab samples that are then analyzed in the gas chromatograph or are these --

MR. REYNOLDS: Well, we have done both studies. We feel that the most reliable indication at any point is given by the worker-carried apparatus which continuously pumps air for the duration of his exposure and collects it in a huge bag, and then this bag is taken to the laboratory and analyzed and it permits a pretty thorough analysis. It gets around the problem of differences owing to wind shift. It would be difficult for us to say -- we're in an open place -- where is the best place or the best five or six places to locate a detector. We just don't know where to put them.

MR. ROSE: One last question: you said he carries a sampling bag which collects the eight-hour sample. What's the bag made out of, the material, and have you run tests to determine the diffusion coefficient or loss through the bag material for vinyl chloride monomer?

MR. KUSNETZ: Yes, the bag is teflon and the tests have been done on diffusion, on bag memory, on other loss. Essentially, it's a personal sampler which can be run any period of time up to eight hours, and, so, you get a true breathing zone representative integrated sample of the individual worker.

JUDGE MYATT: Are there any other questions?

MR. MAZZOCCHI: Tony Mazzocchi, Oil, Chemical and

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Atomic Workers.

Have your employees, vinyl employees, ever been told of the possible relationship between VCM and cancer?

MR. REYNOLDS: Yes, they certainly have. As I mentioned, last July we mentioned to all the workers the Viola work -- of course, the Viola work didn't mention liver cancer, but we did warn the people that this was a very great unknown area and we were concerned about the possibility, and that's why we called the meeting, to solicit their cooperation with us to do some of the personal sampling.

MR. MAZZOCCHI: My question was: was any specific reference made to liver cancer and VCM?

MR. REYNOLDS: Oh, yes. The day the Wall Street Journal article appeared announcing the disclosure by B. F. Goodrich Company, one of our plant managers tacked the copy of the Wall Street Journal on the bulletin board so that all could see it, and the assistant department manager in our VCM unit met every shift who came into the plant that day and told them of the article and re-emphasized the need for precautions.

MR. MAZZOCCHI: Prior to the Wall Street Journal article which appeared, no mention was made of the relationship -- possible relationship between liver cancer and VCM?

MR. REYNOLDS: We suggested there may be evidence -- there was no evidence of liver cancer before the Viola

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article, but in animals -- weren't there animal tests? -- I'm sorry, maybe I don't understand your question.

MR. MAZZOCCHI: I understood the reply, so let me--

JUDGE MYATT: Let's go to the next question, please.

MR. MAZZOCCHI: Are employees told of the monitoring results by the unit employees monitoring the results after the analysis is made?

MR. REYNOLDS: Yes. Each employee -- the ones who wear the personal monitoring device receives the results that he produced during the time that he wore the device.

MR. MAZZOCCHI: After it goes through analysis, then he's told?

MR. REYNOLDS: Yes.

MR. MAZZOCCHI: Does Shell release to the physician of the employee's designation the results of the physical examinations that you give these employees?

MR. REYNOLDS: The employees are told the results of the physical examinations individually.

MR. MAZZOCCHI: And you release this information to the designated physician if the employee so requests it?

MR. REYNOLDS: Yes, we have.

MR. MAZZOCCHI: I have just one other question. I'm not quite clear. Was a liver scan given as part of that protocol? I might have missed it.

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MR. KUSNETZ: No, the liver tests were the SMA-12s -- were included in the SMA-12s.

JUDGE MYATT: Yes, sir?

MR. COTTINE: I'm Bertram Robert Cottine. I'm from Health Research Group.

Mr. Reynolds, you mentioned the MCA epidemiological study. Could you indicate to us the cost of that total study and the participation of Shell in it in terms of its part? In other words, the cost of the total study and your contribution.

MS. GHOLSTON: I object. I don't see the relevancy of the cost to this proceeding.

JUDGE MYATT: I agree. I'm sorry, sir, but I'm not going to require him to answer the question. That has no bearing on the issue before us.

MR. COTTINE: What is the nature of review of the participant companies over the course of that study? What type of review committee is established and are you a participant or do you know the participants?

MR. REYNOLDS: Yes, we are a participant. We know the participants. But I think that is a more proper question for the MCA. I defer....

MR. COTTINE: Your Honor, could we request that he provide us as much information as he, of his own knowledge, knows regarding the conduct of those committees? The

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protocol review is extremely important to the subsequent results in the proceeding.

JUDGE MYATT: It would seem to me that that's more properly directed to MCA.

MR. COTTINE: Your Honor, as you well know, we were not capable of cross-examining this morning by virtue of your ruling.

JUDGE MYATT: Have you made a request of MCA?

MR. COTTINE: No, we have not.

JUDGE MYATT: I would suggest you do that.

MR. COTTINE: On August 15th, 1973, you mentioned that you advised your customers of your new working level and you briefly stated the rationale. What was the nature of your previous communication with your customers and what did you advise them regarding the vinyl chloride and polyvinyl chloride?

MR. REYNOLDS: All our previous advice was based on the then published standard, which was the OSHA 500 standard, and the recommended ACGIH 200 standard.

MR. COTTINE: Did that include any printed material of your company regarding those particular standards?

MR. REYNOLDS: Material Safety Data Sheets were available. I can't say precisely who got what.

MR. COTTINE: Have you submitted those particular Safety Data Sheets for the record?

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MR. REYNOLDS: I have submitted our latest Safety Data Sheet as part of our record.

MR. COTTINE: May we respectfully request that you submit the earlier Safety Data Sheets as a part of the record?

MS. GHOLSTON: Could I ask Mr. Cottine what the purpose of the earlier data sheet would be?

MR. COTTINE: Yes. We would like to know the comparison between the two different safety data sheets and the rationale in terms of the health hazard involved.

MS. GHOLSTON: Then could I ask a question of the witness?

The previous data sheet, did it have any reference to the carcinogenicity of the vinyl chloride or was it based on the toxicity?

MR. REYNOLDS: The previous sheets were based on the previous information which was known to me. The latest sheet does specifically mention the Viola study and the potential dangers.

MS. GHOLSTON: Do you have any objection to introducing them?

MR. REYNOLDS: I am willing to introduce our latest safety data sheet, and I think I must say that we should revise even that sheet in the light of the B. F. Goodrich results, and, so, I'll introduce the sheet that we have and tell you that we're going to revise it further to more

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specifically indicate what B. F. Goodrich has told us today.

JUDGE MYATT: What is the position of the Solicitor in regard to the prior safety sheet?

MS. GHOLSTON: As far as we're concerned, it would be information, but he's indicated that as far as a carcinogistic, it has no bearing. However, for our purposes, we might like to look at it.

So, unless you have a specific objection to introducing it -- and I don't think you stated one --

MR. REYNOLDS: I'll have to reply to you in writing on that subject, if you please. I don't know what our availability is.

MS. GHOLSTON: That's fine. I don't know about Mr. Cottine.

MR. COTTINE: I would request, Your Honor, to have it submitted, but if you do it voluntarily....

I have one further question. Now, you have already the August 15th, 1973, advice as part of the record; that is correct?

MR. REYNOLDS: Yes.

MR. COTTINE: Will you be submitting as a part of the record any subsequent revisions?

MR. REYNOLDS: Would you please say your question again?

MR. COTTINE: You noted that after the B. F.

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Goodrich testimony of this afternoon that you would probably be revising the August 15th, '73, letter to your customers. Are you submitting that revision?

MR. REYNOLDS: If that would be of interest to the group here, we would. I think we feel compelled to do so.

MR. COTTINE: Thank you.

JUDGE MYATT: Yes, ma'am?

MS. HRICKO: Andrea Hricko.

You said that you monitored from '71 until August of '73 (inaudible), and then on August 15th of '73, you revised your sheet to your customers describing your new working level, why you changed it. I don't understand what prompted the revision, why you lowered the working level.

MR. REYNOLDS: I'll try and respond, if I understand the thing. The thing that prompted us to revise our own internal thoughts and notify our customers was a general developing concern, much of which was shared by other people who participated in the MCA study. We elected, in view of this rising concern and uncertainty, to review our standard and we went back to the basis, the TVL documentation basis, which was set forth in their establishing the lower level of 200 parts per million TLV. In examining the background cited by that background -- in that ACGIH background study, we noted that it referred to recommendations in the literature varying all the way from 50 parts per million to 500, and

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since we didn't know anything further, we elected to take the more conservative level, and that's why we decided to take the 50 level, and that is so stated in our letter which is appended to our submission.

MS. HRICKO: Thank you.

JUDGE MYATT: Are there any further questions?

All right, gentlemen. Thank you.

Our next presentation is going to be rather lengthy, so we're going to take a five-minute recess.

(Whereupon, a short recess was taken.)

JUDGE MYATT: Let's come to order, please.

For the benefit of those who are going to have to catch planes or leave for other reasons, we are in the process of determining a date which we are going to keep the record open. At this moment that date has not been established. It will be before this hearing is adjourned, and any further submissions which the parties would like to be included in the record, you are to address to the Occupational Safety and Health Administration, Room 240, 1726 M Street, N. W., Washington, D. C. Zip 20210.

But again I repeat that before this hearing is concluded, we will establish a date to which we are going to keep this record open for any additional submissions.

All right. The next group testifying consists of Mr. Sheldon Samuels, Director of Health, Safety and

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Environmental Affairs of the IUD, AFL-CIO. Accompanying him will be Dr. Henry Anderson, Mount Sinai School of Medicine, Dr. Thomas F. Mancuso, University of Pittsburgh Graduate School of Public Health, and Mr. Louis Beliczky, Director of Industrial Hygiene, United Rubber, Cork, Linoleum and Plastic Workers, AFL-CIO.

Gentlemen, proceed.

SHELDON SAMUELS

MR. SAMUELS: Thank you.

Let me say I have no introductory remarks per se, but I would like to note that if a unique tumor had not been involved, as was noted earlier this week, the effects that we've been discussing all day would still not be noted and no action taken. It seems that we pay the price each day in lives and lost production for our continual neglect of systematic research and case finding.

I'd like to introduce Dr. Thomas F. Mancuso, who on February the 1st represented our Department in a meeting noted earlier by Mr. Rose as a consultant to the Industrial Union Department, on my left, and on my right, Mr. Louis Belicsky, who is, as you have noted, the Director of Industrial Hygiene for the United Rubber Workers. He attended that meeting, also, representing his president, Peter Bommarito, who is the chairman of the committee on the health and safety of workers of the Industrial Union

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Department.

And on my far right is Dr. Henry Anderson, who is a clinical consultant to the Industrial Union Department and, as has been noted, is on the staff of the Mount Sinai School of Medicine.

Dr. Mancuso will begin for us.

THOMAS F. MANCUSO, M.D.

DR. MANCUSO: I'm Thomas F. Mancuso, Research Professor of the University of Pittsburgh Graduate School of Public Health.

A new occupational cancer has been identified. The presentation I am making is at the request of the Industrial Union Department of the AFL-CIO. I prepared the following statement in support of their request for an emergency temporary standard to be issued by the Occupational Safety and Health Administration.

It is my considered opinion that appropriate steps be taken to provide for immediate protection of the workers exposed during the manufacturing processes concerned with the polymerization of vinyl chloride.

I have also made additional recommendations for consideration by the Secretary of Labor.

The worldwide manufacture of polyvinyl chloride, now identified with the association of cancer, brings up a tremendous range of human, social, and economical problems.

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The immediate pressing question is whether the cancer observed will be confined to the manufacturing process or also occur in successive lower grades of exposure in the processing and use of vinyl chloride and polyvinyl chloride and whether other types of cancer may subsequently be identified.

The potential magnitude of the cancer problem, however, does not rest on vinyl chloride alone, but, rather, on its role as a possible index cancer chemical as an indicator to a large group of similarly structured chemicals. Should any of these chemicals prove to be carcinogenic, then the magnitude of the risk would extend to an ever widening circle of industries, processes, and exposed populations. The degree of validity of these various possibilities must be identified and resolved.

Invariably, whenever a new occupational cancer is discovered, it is played down for fear of alarming the workers and the general public. The motivation may be one of not really knowing the facts. Nevertheless, from past experience what happens is that as further work is undertaken and information obtained, the problem gets broader and broader with more implications. I think a more straightforward approach to the workers and the general public is warranted, citing the limitations of what we do not know, clearly indicating what the situation is, what efforts are being

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developed and carried out to determine the scope of the problem and to correct it.

The scientific unknowns. This situation, the chance recognition of an occupational cancer by a unique combination of circumstances, clearly demonstrates what is not known about the carcinogenic potential of thousands of industrial chemicals that have been in use for decades and further focuses attention on the total absence of a national concerted study of occupational cancer in this country.

The serious national question that is raised and not resolved, because it is either too shocking to contemplate or because the agencies responsible for the protection of the public are reluctant to open this complex Pandora box, is, in essence, that a national study directed at the industrial environment might uncover a whole series, a succession of occupational cancers, which in turn would implicate in the distribution of these chemicals a larger and larger portion of the population exposed to the risk of cancer. It is my understanding that there never has been any legal requirement that the industrial chemicals in the work environment be tested for their cancer-producing effects. With thousands of industrial chemicals involved, conservatively estimated at 20,000, the real carcinogenic potential of these chemicals acting alone or in combination with each other has never been established.

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Further, there are indications that previous methods of testing industrial chemicals may not have been adequate nor sufficiently sensitive nor were all the substances tested for carcinogenic effect. At this point I should like to make the difference between testing for toxicologic effect and for carcinogenic effect, and invariably in the past the primary emphasis was relative to the toxicological effect. In addition, they were invariably tested as a single chemical rather than in combination of chemicals used in the work environment.

The short-term laboratory experiments previously used and the primary use of ingestion or injection in experiments rather than inhalation exposure, which is the particular means of exposure to the worker, have definite limitations as accurate assessments of cancer risk to the worker.

Invariably, the chemicals tested in animal experiments are at room temperature, yet when these chemicals are used in industry, they may be subjected to heat and may change their composition or unite with other chemicals in the work atmosphere to form new chemicals whose carcinogenic and toxicological potentials have not been identified. No one really knows the carcinogenic potential of the complex occupational environment in the United States.

In the face of these scientific unknowns, how can anyone arbitrarily assume, as has been consistently done in

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the past, that occupational cancer is a minor problem? Such arbitrary assumptions in past have been responsible for the absence of the necessary investigative studies of the work environment by the Federal Government.

This is a vicious cycle in which the assumptions preclude the studies, and without the data the assumptions remain. If the studies had been done, the original assumptions would be found to be grossly false and the scientific misunderstanding that has been maintained over the years would be reversed.

At present the attention is now focused on the vinyl chloride process and undoubtedly a concerted effort will be undertaken and must be undertaken. The question I am raising is: must the industrial population and the general public wait until each particular cancer is identified by accident or is forcibly brought to our attention in some other means before a concerted effort is undertaken to determine the magnitude of the problem, its cause, and control? It would be more appropriate, in my opinion, to utilize this observation of occupational cancer to focus attention on the need for a national study by the Center for Communicable Disease -- the Center for Disease Control, NIOSH, and the National Cancer Institute, and all other agencies in a concerted effort directed at all suspected carcinogenic chemicals in the work environment. In addition,

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the development of an industrial epidemiological cancer surveillance recognition system for this purpose is required.

Duration of employment and latent period. The implications throughout this testimony -- the implications of the statement that all men who died of angiosarcoma had at least fifteen to sixteen years of exposure in the manufacturing of polyvinyl chloride should be critically assessed. No one knows at this early stage what combination of length of exposure, concentration or contact with the polyvinyl chloride process will cause the specific angiosarcoma.

In occupational cancer, the actual exposure in terms of length of employment may be very small. It is the latent period, that is, the interval period between each exposure and the development of the cancer, that may take many years. In essence, no one knows for the four cases of angiosarcoma if the induction of cancer to this type of carcinogenic agent requires relatively few years of exposure and a further latent period of twelve years or more or whether the induction does require fifteen years of exposure.

In my opinion, based on other occupational cancers, it is most unlikely that the carcinogenic dose would require fifteen years of exposure. The relatively young ages of the four cases of angiosarcoma, 37, 43, 50, and 55, and the rapid progression of the cancer once it is identified clinically, six months to three years, indicates a strong carcinogenic

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agent and/or in conjunction with some other harmful chemical agent.

Industrial causes for cirrhosis of the liver. The observation among another group of four workers in this small employment group of cirrhosis of the liver, non-alcoholic, confirmed by eminent pathologists, is very important as another manifestation of occupational disease for those exposed to polyvinyl chloride processes.

The significance of these cases of cirrhosis of the liver is to make the medical profession and the general public more aware that there are industrial causes for cirrhosis. This observation should further serve to underscore the need for a large scale study to uncover other industrial causes of cirrhosis. The question is, however, how many cases of cirrhosis of the liver due to vinyl chloride processes and other industrial chemicals have gone unrecognized.

The additional implications of cirrhosis of the liver are the effect on the employability and the lifespan of the worker. The normal capacity and function of the liver to detoxify chemicals taken into the body are impaired by cirrhosis. Consequently, this effect of cirrhosis would severely limit subsequent employability, as well as lessen the capacity of the worker to recover from other illnesses and diseases which may occur in subsequent years.

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If, in the subsequent review of microscopic slides of cirrhosis of the liver, there is found an indication in some areas of the liver of atypical cell changes toward malignant formation, then cirrhosis of the liver may be seen specifically as an increased risk in the development of liver cancer for the workers exposed. This does not mean, however, in any way that all cases of occupational liver cancer would require the precursor mechanisms of cirrhosis of the liver or that the two diseases must always be present together. The question and objective remains: what is the minimal induction dose in terms of duration of employment and concentration of exposure to VC and PVC to incite the development of cirrhosis of the liver?

Possible other health effects. Further, no one knows what other types of illnesses or other cancers may occur. Consequently, the investigations undertaken should be all-encompassing and of all systems and organs and not confined to angiosarcoma of the liver. The experimental observations of rats exposed to vinyl chloride demonstrated cancer of the skin, lung, and bone, and in another study angiosarcoma. And now, with the information provided this morning so excellently, the information relates to cancer of the kidney, and it indicates the importance of studying other systems of the body.

Although the focus is now on the experimental

cancer-causing effect, it is very important to note that other pathological changes occur in the brain, degeneration of the nerve cells, of the cerebellum; severe chronic hepatitis, besides the cirrhosis; interstitial pneumonia, and damage to the kidneys, and it is also possible that coronary heart disease or some type of heart disease may be involved.

Further, the skin tumors frequently developed near the ear and submaxillary or the same areas as the salivary glands. It was postulated by the original investigators that vinyl chloride may enter the salivary gland system. If this is subsequently confirmed, it raises the question whether tumors of the parotid gland can also occur, as has been demonstrated in the rubber industry -- and this has been confirmed now by the testimony this morning, that cancer of the parotid gland has been observed in animals.

These various facets are mentioned primarily to broaden the approach undertaken in the evaluation of the health risks involved. The present concentrated attention on angiosarcoma might inadvertently miss other related health problems including other organs and systems. Similarly, negative results from a comprehensive study would be more reassuring than an investigation confined to one organ of the body.

Medical evaluation. The actual and potential

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health effects identified by clinical and experimental observations have clearly established the need for comprehensive medical programs for the protection of the workers in the vinyl chloride and polyvinyl chloride operations.

The Federal Occupational Health and Safety Act requires that the health of the worker not be adversely affected during his employment and this, therefore, places the responsibility on industry to ensure that no harmful effects do occur as a result of exposures to the various chemicals and the work processes involved.

Unless the polyvinyl chloride plant is providing adequate and effective medical examinations, there is really no way of determining whether harm is being done until the harm has become a reality. Similarly, unless medical examinations and special tests are provided periodically, occupational health effects will not be recognized, in particular those that occur as a result of accumulated exposures or peak exposures at different points in time or as a result of changes in the work processes. For vinyl chloride, the range and scope of general and specific tests that should be conducted relative to the specific organs and systems that might be affected should be given careful consideration. The responsibility for the provision of the tests would rest with the industry.

The recognition of occupational health effects

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depends upon the physicians and unless they are available to see the workers, to hear and know their symptoms, and provide the examinations and special tests, occupational diseases will not be identified at their earliest stages nor, unfortunately, even at the most advanced stages or at all.

Arrangements should be made so that all medical observations relative to the health status and any changes in the status of each worker should be made available to his personal physician. There must be a certain quality or standard of performance relative to the completeness of the examinations and the types of tests performed and, therefore, the specification of whatever tests are determined should be clearly delineated.

It is essential that the basis for linkage of medical and environmental data -- for the individual plants, medical examinations by medical physicians alone without accurate and complete records are not effective. It is essential that the basis for the linkage of medical and environmental data be established so that correlations with environmental exposures and specific work processes and the recognition of an occupational illness can be made. When a group of workers employed in the same department or work process, exposed to the same chemicals, come down with the same pattern of symptoms or illnesses, then the essential criteria for the recognition of an occupational disease have

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been met.

The worker should be informed directly as is required by the Federal Occupational Health and Safety Act of the type of harmful effects that may occur with the chemicals he is working with, in this instance vinyl chloride and polyvinyl chloride, and the most effective ways in which the harmful exposures can be controlled and the best ways that he can protect himself. If the worker does not know what kinds of illnesses or injurious effects are caused by the particular chemicals he works with, then he will not be able to recognize the occupational illnesses when they do occur. In turn, unless the worker tells his doctor what chemicals and materials he has been exposed to, now and in the past, even his family doctor will not recognize that the illness or disability could be due to his work. The result is that occupational harmful effects are not being identified, recorded, investigated or corrected.

Work exposure. Exposure data in terms of air concentrations in the workplace and other means of exposure, such as due to contaminated workplace from breaks in equipment, poor housekeeping, inadequate ventilation, and absence of personal protective equipment, and so forth, are important in the ultimate correlation analysis of the degree of exposure to polyvinyl chloride and the subsequent health effects.

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Precise data on exposure is required as a basis for subsequent resolutions of what health effects occur at different levels of exposure and, finally, the exposure data determines the nature, type, and comprehensiveness of the control measures required.

The unfortunate lesson learned and demonstrated is that environmental monitoring is extremely important for the company, the worker, and the public. The dilemma now posed in the absence of such precise data is that the information the company, government, and scientists need to help resolve the risk factor is not available. The burden now falls to measuring risk in terms of health effects measured by crude exposure levels which, as already described, have questionable quantitative validity.

Problems of the epidemiological study. In referring to the "rarity" of angiosarcoma, such as twenty-one or twenty-eight cases in the U. S. in a specific year recorded only on the death certificates, this number should not be misinterpreted as an indication that no problem exists. Actually, it is a problem of a latent period and what is important is what has not been recorded or recognized. The problems, obstacles, and difficulties in the conduct of epidemiological studies of industrial cancer are substantial indeed. When the study is based solely on death certificates and involves a rare type of cancer, the problems of

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recognition are made even more difficult. When the cancer is confined to a specific histological type, the mathematical odds against the detection of angiosarcoma by death certificate alone are tremendous. In essence, the death certificate alone for the identification of this cancer would most likely provide "false negative" findings, and reliance solely on death certificates, therefore, would be inappropriate under these circumstances. As of now, based upon the four cases of angiosarcoma with the latent period estimated at fifteen years minimum, if the death certificates are used from the plants which have been in existence for less than fifteen years, then results, if any, will be further diluted.

There are a substantial number of basic limitations relative to epidemiological studies which I have in the document submitted for the report. I shall just highlight several of them. One relates to limitations of the death certificates themselves; the movement of employees to other cities; the extent and percentage of autopsies performed in the community; the availability of hospitals and pathology resources in the community; the limitations of what is recorded on the death certificates -- for example, in the case of beryllium disease, 74 percent of the individuals who were previously identified as having beryllium disease were not recorded on the death certificate; a death certificate may be completed before the autopsy is performed, or the

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microscopic review completed weeks later with no additional supplementation to the death certificate. Consequently, the cause of death on the death certificate may not specify the histological diagnosis, and this type of information would only be available through successive follow-up searches of pathological reports in hospitals. Workers who died of heart disease may also have had cirrhosis or cancer of the liver, but the cirrhosis or cancer of the liver was not recognized because no biopsy was done while he was alive nor at death.

And I should like to add parenthetically that one should be careful in evaluating the heart -- questions of heart disease because of some previous experimental work.

It is apparent in studying cirrhosis of the liver and angiosarcoma that many factors are in operation to underestimate what has happened and may be happening.

For the particular cancer now under consideration, I should like to caution that it would be most unwise to confine the recognition of occupational cancer solely to the histological type angiosarcoma. If other workers who are exposed to the same work processes of polyvinyl chloride develop the same disease, cancer of the liver, the cancer should be considered as occupational in origin regardless of the histological type. It must be remembered that cancer of the liver itself is an uncommon type of cancer

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It is yet possible that other histological types of cancers may develop, as well as other health effects. We do know that in other industrial cancers, for example, lung cancers caused by chromate and asbestos, that the histological type of lung cancer are not specific, but, rather, may be different in workers of the same plant or occupations with the same years of employment.

Recommendations: 1. That the Government, referring to the Center for Disease Control and NIOSH, take the initiative and conduct its own independent extensive study of the cancer potential and health risks associated with exposure to polyvinyl chloride processes. Further, that the Government should undertake such steps as necessary immediately to apply its resources and expertise in epidemiological investigation and to seek such funds, if necessary, to carry out the national study.

2. That an International Research Committee on Vinyl Chloride and Cancer be organized with representatives of other countries. The committee would follow the pattern of the previous similar International Committee established for asbestos and cancer which was under the auspices of the UICC, the International Union Against Cancer.

3. That a Government conference of representatives of all the federal agencies who are concerned directly or indirectly with occupational cancer and the study of the

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industrial environment be convened so that an evaluation can be made of the resources and funds appropriated and the nature and extent of the various programs, efforts, and funds concerned with the identification and control of occupational cancer.

The fourth and final recommendation is that the international unions themselves, with whatever systems may be provided by the Secretary of Labor -- that the international unions assume as their major objective in conjunction with the universities and medical centers a concentrated effort to study the cancers which are occurring among members of their unions, the relationship to particular occupations, work processes, chemicals, and industries. The objectives go beyond vinyl chloride, to all industrial operations as a fundamental approach of case finding of occupational health problems.

Thank you.

JUDGE MYATT: Thank you.

MR. SAMUELS: I'd like to insert in the verbal record at this point to complement the testimony of Dr. Mancuso the following statement of the Surgeon General dated April 22nd, 1970: "No level of exposure to a chemical carcinogen should be considered toxicologically insignificant for man. For carcinogenic agents a safe level for man cannot be established by application of our present knowledge. The

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concept of socially acceptable risk represents a more realistic notion."

In the Occupational Safety and Health Act of 1970 the concept of socially acceptable risk is expressed in the concept of technical feasibility. We caution the Secretary to make no decision on any other basis. The past pattern of making these decisions on the basis of micro-micro economic studies is inadequate.

Mr. Beliczky.

LOUIS S. BELICZKY

MR. BELIZCKY: The --

MS. GHOLSTON: Could I ask --

JUDGE MYATT: No, not at this point.

MS. GHOLSTON: The reason I wanted to ask him now was not to get so far from the statement that he couldn't....

JUDGE MYATT: I understand. Not at this time.

MR. BELICZKY: I'm Louis S. Beliczky, Director of Industrial Hygiene for the United Rubber Workers International Union.

I am presenting this testimony to the Judge and the Secretary for Mr. Peter Bommarito, President of the United Rubber Workers International Union.

Section 6(c)(1) of the Occupational Safety and Health Act of 1970 instructs the Secretary to provide an emergency temporary standard if he determines, one, that

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employees are exposed to grave danger from toxic substances or agents and, two, that an emergency standard is necessary to protect employees from such danger.

The Director of the National Institute for Occupational Safety and Health has declared, in Cleveland on February 12th, 1974, that, based on information related to him by the B. F. Goodrich Company and his own investigation, the cause of at least four deaths due to angiosarcoma of the liver among former employees of the company's plant must be presumed to have an occupational cause. At an earlier meeting on February 1, 1974, he stated that "on the basis of medical, epidemiologic, and toxicologic findings thus far, it would appear that a new occupational cancer has been discovered associated with the polymerization of vinyl chloride in the manufacture of polyvinyl chloride. Vinyl chloride is the chief suspect..."

Approximately ten corporations and at least 6,500 production workers, organized by affiliates of the Industrial Union Department, are directly involved in vinyl chloride synthesis and its polymerization.

A task force of NIOSH, industry, and labor specialists convened on February 12th by the Director of NIOSH agreed that the process of vinyl chloride polymerization, including the production of vinyl chloride itself, must be presumed to be carcinogenic and that action should be

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taken for the sake of prudence in the public interest.

Actually, as the medical literature attached will indicate, vinyl chloride has been regarded by responsible investigators as highly toxic and probably carcinogenic in man for some time. Industrial practice at the B. F. Goodrich plant in Louisville and elsewhere has aimed at achieving one-tenth of the special limit value used by the Occupational Safety and Health Administration. Even that level does not meet criteria established by the Secretary of Health, Education and Welfare for exposure to a carcinogen.

Therefore, it is clearly the responsibility of the Secretary to determine that employees are exposed to grave danger in the polymerization process by which polyvinyl chloride resin is produced.

Based on information supplied by the B. F. Goodrich Company, an investigation of their plant in Louisville, Kentucky, and other information interim work practice standards have been transmitted to the company and to the Manufacturing Chemists Association. There is no indication that all these recommendations are being universally implemented, no determination that they have even been distributed to all plants, and there is no means by which employees can participate in or initiate compliance with these recommendations. Therefore, an enforceable regulation is necessary to ensure that employees are

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protected from such danger as vinyl chloride and its polymerization process.

Thus, the issuance of an emergency temporary standard by the Secretary is imperative.

Urgent action by the Secretary is necessary. As investigation proceeds in other countries and in plants other than that in Louisville, we are discovering diseases of the liver that are likely precursors to latent and developing cancer. Additional deaths from liver cancer are being uncovered that must be attributed to exposure during the production of polyvinyl chloride resin.

The probability exists that reduction in exposure among diseased workers will reduce the risk of liver cancer and that the identification of these workers may save their lives.

The Standards Advisory Committee on Carcinogens appointed by the Secretary proposed a scheme on August 23rd, 1973, that still represents, in our opinion, the best thinking applicable to the control of any carcinogen. We recommend that the Secretary accept that report, and it's attached, with the following changes appropriate to this situation; these are some of the changes:

The word "purpose." The purpose of this standard is to prevent any worker contact or exposure to vinyl chloride during its production and polymerization as detected

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by the most sensitive, feasible sampling and analytical methods available.

A change in scope and application. This section applies to any workplace in which the carcinogen is manufactured, processed, used, repackaged, released, handled or stored.

A change in terminology. Eliminate Subsection 1 and retain the balance of this subsection.

Another change in requirements for areas containing carcinogens. Eliminate Subsection 1, "or decontaminated" in (d), Subsection (2)(ii), "close to the point of exit" in (d)(2)(vi).

Because of the volatility of vinyl chloride, we do not believe that the installation of special shower facilities is necessary. Changes to reflect this would be appropriate. The medical requirements of the Advisory Committee need to be amended. Our recommendations are those of Dr. Anderson, clinical consultant to the Industrial Union Department, who will make his presentation after this.

We believe that all of the appropriate, specific interim recommendations transmitted by NIOSH to MCA be included with the recommendations of the Advisory Committee on Carcinogens.

Furthermore, in view of the information supplied us by industry representatives on February 12th, 1974, that

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500 to 3,000 parts per million of vinyl chloride may be entrapped in the polyvinyl chloride resin prior to packaging and shipment, it is essential that the concentration of vinyl chloride in the resin be reduced to less than 0.01 percent as quickly as possible.

Vinyl chloride, the monomer of polyvinyl chloride, is a gas with known anaesthetic effect in high concentrations. At the same high levels it is known to sensitize the heart resulting in fatal arrhythmias. There are at least two fatalities in acutely exposed workers reported in the literature. Dizziness, headache, disorientation are symptoms which may be the alarm sign for acute overexposure.

The chronic effects of vinyl chloride have been studied by Torkelson, et al., on laboratory animals, rats, rabbits, guinea pigs, and dogs. The results, published in 1961, emphasized the effects on the liver and kidney at concentrations of 500, 200, and 100 parts per million. The conclusion of that study stated, "Repeated exposure to vinyl chloride at concentrations considerably below the level that has been considered safe for human exposure, 500 parts per million, has been shown to have an effect on the liver and kidney of laboratory animals."

It was recommended that daily exposures should be limited to 100 parts per million, although this level would not offer any margin of safety. Industry sources claim that

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they have been successful in achieveing levels of 50 parts per million for many years in accordance with the preferred industrial hygiene practice of providing a margin of safety. The threshold limit value suggested by the ACGIH was maintained at 500 parts per million until recently when it was reduced to 200 parts per million. Five hundred parts per million is the current OSHA standard.

At this point we wish to commend Dr. Cesare Maltoni for his clarifying presentation this morning. His comments certainly affirmed our thinking regarding the carcinogenicity of the polyvinyl chloride polymerization process.

Before I conclude, I'd like to enter for the record the testimony that was submitted by International President Bommarito on September 11th, 1973, just a portion on the testimony regarding a standard for carcinogens, the closing of his remarks: "We demand the absolute need of a permit system for the effective implementation of an enforceable standard. I must emphasize the Standards Advisory Committee's recommendation: 'A use permit system shall be initiated as an integral part of the permanent standard to provide for effective regulation of conditions and practices concerning carcinogens to enhance the implementation of the standard.'

"II. The need of a National Registry of exposures

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to carcinogens. NIOSH's assistance in this area is envisioned."

Items I and II as mentioned here are also strong recommendations in Report VII of the ILO's 58th Session regarding the "Control and Prevention of Occupational Cancer.

Thank you.

JUDGE MYATT: For the record, Madam Reporter, Dr. Mancuso's statement will be Exhibit No. 11, the combined statement of Mr. Beliczky and Dr. Anderson will be designated as Exhibit No. 12, and the report of the testimony read by Mr. Beliczky will be designated Exhibit No. 13 in the record.

(Whereupon, Exhibits Nos. 11, 12, and 13 were marked for identification and were received in evidence.)

JUDGE MYATT: All right, Dr. Anderson.

HENRY ANDERSON, M. D.

DR. ANDERSON: I am Dr. Henry Anderson, Clinical Consultant, Industrial Union Department.

It is necessary that an effective medical examination protocol be established rapidly to provide a uniform means of initial and continuing surveillance of all workers in vinyl chloride and polyvinyl chloride operations.

It is recommended that a specific set of clinical and laboratory examinations be required periodically for every VC and PVC industrial worker. The following protocol

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of minimum medical surveillance requirements was developed in cooperation with the Mount Sinai School of Medicine, Environmental Sciences Laboratory. The protocol was carefully designed not to exceed the service capabilities of local community facilities. It is recognized that there are tests which are more specific, but which are not universally available. It is suggested that where available such tests would be incorporated by individual examining units.

The following protocol is recommended as the minimum acceptable initial and continuing periodic examination for all VC and PVC operation employees:

No. 1, history. The understanding of the natural evolution of disease associated with VC and PVC production will be aided by systematic, periodic records. Accurate records will help clarify the possible interrelationships of the various multiorgan-system clinical entities already described in the world literature, such as Raynaud's phenomenon acroosteolysis, cirrhosis, and other liver disease, pulmonary fibrosis, thrombocytopenia, and now hemangiosarcoma.

Thus a comprehensive work history covering all past and present employment with specific job descriptions and exposures, a complete medical history covering all organ systems, and all pertinent chemical environmental agents must be carefully recorded.

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A standard questionnaire and examination form should be developed and its use required so that examinations and records will meet a uniform quality. Such a form will assist the examining physicians who are not trained occupational medicine specialists.

No. 2, physical examination. Each worker should have a thorough, complete physical examination of all organ systems and have specific parameters properly recorded on the required examination form. Continuing periodic examinations should also be made.

No. 3, X-ray examination. It is recommended that each individual have a periodic 14 by 17-inch PA chest X-ray and X-rays of both hands. These should be read by experienced radiologists.

No. 4, pulmonary function tests. Vital capacity and one-second forced expiratory volume measurements should be recorded.

Blood tests. A complete blood count and platelet count should be done. An automated battery of SMA-type determinations of SGOT, SGPT, alkaline phosphatase, LDH, albumin, bilirubin, cholesterol, uric acid, glucose, BUN, and calcium should be included.

Urinalysis. Routine screening tests for glucose, blood, and protein should be done.

It is understood that where facilities are readily

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available to do more specific tests, they should be incorporated so that the examining physician has the best possible information available. The examining physician should add all available tests he feels would be useful.

It is recommended that the worker be given this protocol of examinations every six months. After the initial history, an interval history can update the record.

If a test is abnormal, it is recommended it be repeated within one month and if the abnormality persists, it should be further investigated using additional appropriate tests.

It is recommended that upon individual authorization, all company medical records be made available to his personal physician.

It is important that there be a continuity in the worker's occupational health record and that the employer be required to store an employee's record even after the termination of his employment.

The rapid development of medical knowledge and new laboratory technology prompts the recommendation that at least every three years NIOSH convene an advisory committee of qualified medical experts to review the continuing applicability of the clinical laboratory tests, examination procedures, and X-rays which are the established minimum requirements under the OSHA standard. Acting upon their

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evaluation and suggestions, the Department of Labor would then revise the medical surveillance requirements. This will permit the use of the best available newly developed techniques, as well as protect the worker from tests which are proven to be no longer of diagnostic value.

It is anticipated that data gathered from the rapid implementation of this examination system, coupled with information arriving from ongoing environmental monitoring and epidemiological clinical studies, will help establish -- and animal studies -- will help establish the basis for prevention and control of these occupational health hazards.

JUDGE MYATT: All right. Now we'll hear from the representative of the Solicitor's Office.

MS. GHOLSTON: I have a question for Mr. Mancuso -- excuse me, Dr. Mancuso.

In the beginning of your testimony you mentioned inhalation and ingestion tests, but I believe you distinguished between them by saying that one was more similar to the conditions of the worker --

DR. MANCUSO: Inhalation is. I was pleased to see in the experiments which are now underway and the studies which were done by Dr. Viola that they did use inhalation experiments, but if you will study the experimental literature, however, it's amazing, really, the majority -- the greater percentage of the majority purely for economic

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reasons, the animals were rarely tested by ingestion, feeding them, and also by injection. Inhalation experiments, of course, are much more costly, but the ingestion and the injection experiments really do not parallel what the worker does. His primary mode of exposure is inhalation, but also by contact through absorption through the skin.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Anything further?

MS. GHOLSTON: Nothing.

JUDGE MYATT: Yes, sir?

MR. CONNOLLY: I'd like to address this question to the entire panel -- I'm Walter Connolly with the Firestone Rubber Company.

Mr. Mazzocchi, earlier this morning, did not give any indication that there were any deaths that resulted in the same type of problem that B. F. Goodrich has come in contact with. Does anyone on the panel know of any other deaths that we are not familiar with in the industry that would relate to this particular problem?

MR. SAMUELS: We are now investigating some reports that are, so far, unconfirmed and Dr. Anderson has, in addition to that --

DR. ANDERSON: I believe Dr. Selikoff mentioned this morning that he had been given a personal communication from some doctors in England that they do have one additional

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case of angiosarcoma.

MR. CONNOLLY: To your knowledge, there are none in the United States?

DR. ANDERSON: None yet.

MR. CONNOLLY: I presume that the unions involved, not only OCAW, but the AFL-CIO unions, would have come in contact with such a problem through workmen's compensation cases.

MR. SAMUELS: First of all, we have not yet completely studied the population risk, so the fact that we have not yet had brought to our attention cases doesn't mean anything. The state of workmen's compensation, as you, I'm sure, know is such that what you don't reveal or have revealed through that process is also meaningless for purposes of medical investigation.

MR. BELICZKY: I'd like to respond to that question. First of all, I think it's a loaded question -- and I know why as well as you do.

Secondly, as far as workmen's compensation claims at the present time related to the production of the polyvinyl chloride resin and the relationship to either liver disease or to angiosarcoma of the liver probably hasn't entered the minds of too many people because it hasn't been published as such. So, therefore, any basis for claims or comments or getting conclusions regarding workmen's

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compensation is certainly not the direction to go at the present time.

MR. CONNOLLY: I have one final question --

DR. MANCUSO: Can I add to that question? It's a very important question because as far as I'm concerned it should be put to rest. Under no circumstances should anyone use the workmen's compensation claims as an index of what in the world happened to the industrial population. In the first place, the worker doesn't even recognize an occupational disease when he sees one. In the second place, the general practitioner doesn't recognize it. Consequently, it doesn't come to a compensation claim. So I would say, even in this particular case, which is very difficult, it would be very foolish and unwise to use that as an index.

MR. CONNOLLY: One final question: as Mr. Mazzocchi correctly prognosticated, corporations have testified that to their knowledge there are no deaths other than the ones at the B. F. Goodrich plant. Can any conclusions be drawn from the fact that Firestone's facility has utilized this material over the past 27 years and no deaths have occurred comparable to the type that B. F. Goodrich has come in contact with that might be relevant to this hearing?

DR. MANCUSO: You were saying you have a plant that's been in operation for 26 years?

MR. CONNOLLY: Twenty-seven years utilizing this

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material.

DR. MANCUSO: The question would relate to how well the medical records were kept and what kind of medical surveillance was done.

I'd like to ask you a specific question: one is, what kind of continuous environmental or medical surveillance system exists in Firestone, and how do you trace all the employees, and do you know or does your company know what happens to each individual after he is separated from employment and what his health effects or what diseases subsequently occur? If you do not know and you have no surveillance system for that purpose, then there's no way for you to determine that no deaths have occurred due to this particular disease.

MR. CONNOLLY: I think Mr. Beliczky can attest to the study that we have at the North Carolina Medical School. However, since we're not submitting testimony today, I just asked: are there any conclusions you can draw from the fact that no deaths have occurred at Firestone that we know of --

MR. BELICZKY: Since you already mentioned my name, and you mentioned the URW, and you mentioned an occupational health program, any conclusions you reach are very, very premature. It's unfortunate that you have to talk about deaths, because nothing can be done about the poor souls who have passed away. But I can inform you now that I know of

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people in your plant that have serious liver disease which could eventually lead to death, so I wouldn't embellish comments, as you have made, to say that you do not have a problem, and that the problem that you do not have is related to the fact that you don't have deaths.

So, again, I would be awfully careful when we talk about the people who work in your plant and their exposure, because I've been to that plant. I know the concentration of some of the exposures in the plant. I know that some of the people have high concentrations, high enough that they became narcotized during and after their exposure.

So, again, I don't like to have anyone base any judgment on the fact that you don't have a problem because you haven't had a death at the plant directly related to angiosarcoma of the liver. I'm sure that death certificates have not been properly filled out to date, will be.

I don't want to involve the University of North Carolina at this point.

MR. CONNOLLY: I think Firestone is not overly enamoured by any of the results that have emanated from this hearing, but we would assume --

JUDGE MYATT: Mr. Connolly, I'm going to cut you off on that. That is not pertinent to what we're doing. It should be fact-finding, and now you're interjecting Firestone's situation, but that isn't helping us in this

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fact-finding situation. You can discuss that with Mr. Beliczky at another time.

MR. CONNOLLY: We're willing to present evidence at this hearing, this fact-finding hearing, relative to the points that he mentioned --

JUDGE MYATT: Firestone is listed on here.

MR. CONNOLLY: I'm talking about later. We're not going to testify today.

I'm asking whether or not the URW or the AFL-CIO has testimony they're planning to present relative to the Firestone situation.

MR. BELICZKY: Not at this time. If I would have, I would have presented it.

JUDGE MYATT: All right. Are there any other questions of these gentlemen?

Gentlemen, thank you.

Dr. Jeager, would you have time enough, if we took you out of turn, to give your oral presentation?

All right. We're going to make a modification here in an effort to accommodate Prof. Jaeger, who has a flight scheduled out of National at 5:15. He says he has a brief presentation that he feels he would like to give, and then we will get to Dr. V. K. Rowe.

PROF. JAEGER: My name is Rudolph Jaeger. I live in Westwood, Massachusetts. I hold a doctorate, a Doctor of

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Philosophy in biochemical toxicology. I am a member of the faculty of the Harvard School of Public Health.

My statement is prompted by the earlier ruling that questioners -- questions may only be asked by participants or their representatives.

I represent no one but myself. I am an inhalation toxicologist and a consumer of plastic products. My deposition which I have given to Ms. Goodell relates to the evaporation of a plasticizer from heated polyvinyl chloride meat wrapping film.

While this problem is currently the subject of a NIOSH study, the cause of "meat wrappers' asthma" is not yet known.

Angiosarcoma in PVC polymerization workers is being studied as a result of the association of this occupation with the death of four workers and the apparent pre-illness conditions of four more persons. While there appears to be little doubt that vinyl chloride monomer is a carcinogen to rats, the human carcinogenic potential of this substance or any other substance should not have to be evaluated in man.

The predictive science of experimental toxicology has been with us for some time. It is sad that humans had to prove Dr. Viola to be correct.

While I must caution myself about the danger

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implicit in self-serving statements, I must address myself to three areas. First, the possibility exists that polyvinyl chloride resin or compounds or similar materials may contain an agent admitted to be carcinogenic; second, the possibility exists that polyvinyl chloride or propolymers of vinyl chloride by virtue of their use may release substances known to be carcinogenic; third, the possibility that reactive polymeric monomers may, like polyvinyl chloride, produce cancer in workers exposed to such agents should be considered.

It is my contention that we must exonerate of carcinogenic potential all finished polyvinyl chloride materials available to the consumer. This must be done immediately and with a zeal consistent with our concern for the public health. All workers at each stage of PVC processing must be similarly protected.

With respect to the possibility that PVC use or disposal may result in the release of a carcinogen, research in this area should be intensified. The possible pyrolytic evolution of vinyl chloride from PVC materials must be determined. Examples of this are large-scale municipal incineration of plastics and the cutting of polyvinyl chloride meat wrapping film with an electrically heated hot wire.

Lastly, the possible carcinogenic hazard of other

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plastic monomers cannot be laid aside. For instance, vinylidene chloride is a more potent pathotoxin than vinyl chloride, both acutely and chronically. It is used in the manufacture of vinyl chloride-vinylidene chloride propolymers. However, there does not currently exist, to my knowledge, a published lawful TLV for this agent, much less an assessment of its carcinogenicity.

In conclusion, I don't wish to be identified as an alarmist; rather, I would close on the words of a famous scientist who was asked his thoughts when he observed an interesting phenomenon, "I didn't think, I investigated."

JUDGE MYATT: Are there any questions of Prof. Jeager?

Thank you, sir.

All right, Dr. Rowe, if you will.

DR. V. K. ROWE

DR. ROWE: Your Honor, I am V. K. Rowe of the Dow Chemical Company. Currently I am a research scientist concerned with the over-all, broad aspects of Dow's health and environmental research. Prior to being named to this post in late 1973, I was director of our toxicology laboratory and industrial hygiene research.

I shall summarize for the record the following: (1) scope of the vinyl chloride industry; (2) the basic toxicological information; (3) the health parameters studied

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in vinyl chloride workers; (4) our industrial hygiene experience in all of our plants; (5) analytical and monitoring procedures; (6) items found effective in maintaining safe operations; and finally, (7), some suggestions for the future.

I believe it will be apparent that the industry learning curve for vinyl chloride is advancing.

1. The scope of the vinyl chloride industry. Dow Chemical USA began producing vinyl chloride monomer on a very limited scale in Midland, Michigan, in 1939 and production remained relatively low throughout the war period. In 1946 production of vinyl chloride began in our Texas division at Freeport, Texas. Capacity was expanded at this location through 1956.

In 1958 our second monomer plant was brought on stream at Plaquemine, Louisiana, and a third was added in 1969 at our Oyster Creek Division.

In 1952 Dow was one of seven U. S. producers of vinyl chloride monomer as reported in the first U. S. Tariff Commission report on vinyl chloride. Today there are ten producers of vinyl chloride monomer, Dow being one of the large merchant suppliers. In addition to producing monomer, Dow operates a small polymerization plant.

The quantity of vinyl chloride produced in the U. S. has grown quite rapidly. Production increased from

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approximately 321 million pounds in 1952 to a billion pounds in 1960, two billion in 1965, four billion in 1970, to an estimated 5.3 billion in 1973. This monomer growth rate illustrates the high demand for the plastics produced from vinyl chloride -- and I have a table which I shall not read into the record giving you this kind of data. It will be in my submission.

Vinyl chloride is the second largest volume monomer produced in the United States. There are two commercial processes, which have been discussed and in the interest of brevity since they are already read into the record, I will avoid discussing them.

However, I would like to point out that the principal process used by Dow is the one which involves the thermal dehydrohalogenation of ethylene dichloride.

Vinyl chloride is one of the purest organic compounds produced commercially. A typical analysis of vinyl chloride produced by Dow shows less than 20 parts per million of total organic impurities. These trace impurities are acetylene, 1,3-butadiene, methyl chloride, and vinyl acetylene.

Nearly all the vinyl chloride monomer shipped by Dow is uninhibited; however, a small amount is inhibited with 25 to 75 parts per million phenol. The phenol is subsequently removed by the use of a caustic wash.

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I wish to emphasize the diversity of plant and process operations in producing and using vinyl chloride. Commercial plants for producing vinyl chloride range in capacity from modest size up to several hundred million pounds. Some of these plants are new, some are fifteen to twenty years old.

There are three distinctly different polymerization processes which have also been described previously, suspension, emulsion, and bulk processes.

I will cite many of our plant practices, but strongly recommend that OSHA recognize the diversity of monomer manufacturing and polymerization operations when they consider the establishment of a workplace standard or standards. Other producers and processors will have different types of jobs, different equipment, and different engineering, monitoring, and procedural approaches. Dow strongly believes that a standard should emphasize in objective terms what is to be accomplished so that a number of engineering and procedural approaches may be employed under the standard depending on the particular plant situation.

The toxicology of vinyl chloride. Earliest studies on vinyl chloride were limited to acute exposures, as typical of the toxicity studies of the day. These observations led to its consideration even as a surgical anesthetic. Generally, these studies showed vinyl chloride to be low in acute toxicity, to be anesthetic in action, and

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to have little capacity to cause liver injury from exposures of a few hours. Mastromateo, et al., 1960, and Lester, et al., 1963, reported on acute exposures of animals and humans.

With respect to humans, they reported very little effect until exposure concentrations approached 10,000 parts per million when dizziness was reported after five minutes of exposure. In animal work, no deaths occurred in rats exposed for a half to two hours to 100,000 parts per million and exposures to 150,000 to 200,000 parts per million for a half to two hours caused anesthetic deaths, as did higher concentrations for shorter periods of time.

I have also a table entitled "Acute Inhalation of Toxicity for Vinyl Chloride," which I will not attempt to read in as it is a part of the record.

In the exposures to high levels of animals, lung congestion and edema were present after 42 minutes of exposure to 150,000 parts per million, but according to Lester, Greenberg liver and kidney injury were not apparent.

Since 1962, numerous non-U. S. articles on vinyl chloride have appeared, particularly in the Russian literature. Several of these studies involved acute exposures and the observed effects were generally subtle changes. I am well-aware, however, that there are reports that indicate low concentrations having caused a variety of changes. I would like to add here that these changes need

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to be evaluated, the report needs to be evaluated because there is no data that I have to permit me to evaluate the quality of the work that was done.

The chronic toxicity of vinyl chloride has been studied by several investigators. Torkelson, Oyen, and Rowe, 1961, reported their results, and these again have been read into the record several times today, so I will only briefly comment that we had very minimal effects -- slight effects at 200 parts per million, very little at 100 -- as a matter of fact, it consisted of slight liver and weight increases in rats, with no effect on dogs, guinea pigs or rabbits exposed six months, seven hours a day, to 100 parts per million, and we detected no changes whatsoever in any of the four species after six months of exposure to 50 parts per million.

We concluded that the exposure should be limited to less than 100 parts per million with a time-weighted average not to exceed 50 parts per million.

And again, as pointed out previously, Lester, Greenberg, and Adams took exception to the conclusions of Torkelson, et al., and recommended 500 as a time-weighted average exposure. They cited for their reasons one table entitled "Result of Repeated Seven-Hour Exposure of Male and Female Rats to Vinyl Chloride." They exposed these animals to 50,000 parts per million for 19 days and observed in-

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coordination, normal hematology, increase liver weight, normal gross pathology, slight liver histopathology. And at 20,000 parts per million for 90 days they had normal hematology, increased liver weight, normal gross pathology, slight liver histopathology, which was considered to be within normal limits.

Because of these conflicting reports, the TLV Committee of the ACGIH in 1963 chose to change their TLV from 500 ppm as a maximum time-weighted average for industrial exposure to 500 ppm as a ceiling value.

Because of the report of acroosteolysis in humans, Prof. Viola of the Regina Eleva Institute for Cancer Research in Rome, Italy, attempted to produce the disease in animals, and the results of his work have also been read in, so I won't take the time to do it.

The report by Viola, et al., is apparently the earliest and only publication in which carcinogenic activity has been ascribed to vinyl chloride -- that is, up until the report we heard this morning. Although there are possible deficiencies in Viola's study, such as the quality of the vinyl chloride sample used in the study, the presence of food and bedding in the exposure chamber, and the excessive exposure concentration used, the report nevertheless gave rise to serious concern and resulted in the initiation of additional animal studies and epidemiological studies which

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are currently underway and which were described by the Manufacturing Chemists Association in testimony this morning.

In summary, we could say that the acute effects from short-term exposure occur at high environmental concentrations; chronic or long-term effects occur at moderate concentrations. The most sensitive toxicological response observed to date is the effect upon the liver. The central nervous system effect in human beings is related to concentration, and here, again, the tests involved will dictate what that level is.

We are submitting in triplicate -- we are submitting triplicate copies of the toxicological literature on vinyl chloride for OSHA reference, and this is Appendix 1 of my testimony which you have.

Now to the health parameters studied in our workers. Dow is cooperating with the Manufacturing Chemists Association which has retained Tabershaw-Cooper Associates to do an industry-wide study of the health of workers exposed to vinyl chloride. Currently, we have approximately 320 employees in vinyl chloride operations. We have submitted to Tabershaw-Cooper employee records covering 916 personnel who have been involved in vinyl chloride operations over the years. This study is incomplete and will be reported at the appropriate time. However, we can make the following preliminary comments on the health parameters of Dow vinyl chloride

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workers.

Preliminary data from Dow manufacturing units reveal no deaths due to cancer of the liver.

Preliminary data likewise reveal no deaths due to cirrhosis of the liver, and we have had no cases of acro-osteolysis.

At the present time, we are unaware of any living employee who has been exposed to vinyl chloride suffering from cancer of the liver. Likewise, we know of no case of cirrhosis of the liver in employees exposed to vinyl chloride. However, this information is incomplete and it is being subjected at the present time to critical research.

Preliminary studies in two major manufacturing locations with the longest history of vinyl chloride production reveal no increase in abnormal liver function tests above that expected in a similar unexposed population.

C. G. Kramer, M. D., and J. E. Mutchler published in the American Industrial Hygiene Association Journal in 1972 a study of vinyl chloride workers in one location. Findings suggest that repeated exposure to vinyl chloride at time-weighted average levels of 300 parts per million or above for a working lifetime together with a very low level of vinylidene chloride may result in slight changes in certain physiological and clinical laboratory parameters. The possibility of some impairment of liver function must be

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considered even though no overt clinical disease was evident in any of the individuals studied. This study showed a definite dose-response correlation between the intensity of exposure and the deviation from normal values.

We will continue to cooperate with the Manufacturing Chemists Association in the Tabershaw-Cooper studies. Additional in-depth studies will be continued within the various manufacturing units of the company and will be reported upon when completed.

Industrial hygiene measurement of vinyl chloride in workplace air. Dow has monitored the workplace environment by a variety of techniques, including: (A) continuous monitoring of representative or selected workplace areas by a combustion-conductivity analyzer; (B) "grab" samples of workplace air collected in impervious plastic bags or activated carbon "slugs"; analysis of such samples is now by gas chromatography, but years ago analysis was by determination of total chloride or by infrared spectroscopy. (C) personnel monitors based on absorption on activated carbon slugs, followed by gas chromatographic analysis.

Our monomer plant No. 1 started operation in 1946. Historically, spot sampling was conducted. Loading of tank cars, collection of samples for product assay and distillation operations were the only tasks which needed attention in the early operation of this plant.

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In 1972 an extensive industrial hygiene survey was conducted. Multiple grab samples were collected in impervious plastic bags and analyzed by gas chromatography. The four control operator classifications had time-weighted average values between .2 and 1.3 parts per million. Maintenance employees had time-weighted average values of 1.7 parts per million and the supervisory employees had a TWA of 1.3 parts per million. The loading operations had a TWA value of 45 parts per million and the laboratory employees who collect samples from storage tanks had a TWA of 14 parts per million.

Personnel monitoring is presently being carried out on a systematic and periodic basis in this production unit. In 1973 all TWA values were below 10 parts per million except for the laboratory employees who had TWA exposures of up to 30 parts per million, a level well below our industrial hygiene guideline of 50 parts per million.

Monomer Plant No. 2 started operation in 1958. Limited surveys were conducted in 1955 and revealed time-weighted averages ranging from 9 to 60 parts per million. An in-depth survey was carried out in 1973. All TWA values were below ten except for the laboratory employees. Their values were between ten and fifteen parts per million.

Monomer Plant 3 began operation in 1969. In a 1973 personnel monitoring study, TWA values ranged from less than one part per million to ten parts per million.

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Our Polymer Plant No. 1 was operated from 1946 to 1972. Between 1950 and 1959 several industrial hygiene surveys were conducted. A number of job classifications, polymerizer operators, drier operators, monomer still operators, and monomer transfer operators, had workplace environmental levels ranging from 50 to 385 parts per million vinyl chloride. After installation of a continuous analyzer for the workplace air in 1959, improvements were achieved. Vinyl chloride TWA values ranged from 25 to 85 during the period of 1960 to 1967.

Our present polymerization plant, Polymer Plant No. 2, began operation in 1953. Historically the TWA values have been decreased over this period of time. In the early history, TWA values of 105 to 240 parts per million were observed. During '73 similar values for vinyl chloride in the air were in the one to twenty-five parts per million range.

We emphasize that there is some variation in TWA values from day to day for a given type of operation. For example, operators involved in pumping reactors showed values ranging from 1 to 34 parts per million. Similarly, three operators involved in loading operations had TWA values ranging from 8 to 31 parts per million. We encourage recognition that such variations will occur in normal day to day operations involving transfer of monomer.

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We are including reports on a number of our industrial hygiene monitoring studies as written supplements to this statement and they are labeled Appendix 2.

In summary, the industrial hygiene data shows that levels of exposure below 50 parts per million are obtainable in both producer and user plants of vinyl chloride. It must be noted, however, that with the older plants the achievement of such goals may be difficult and in all probability will require modifications that will take time to accomplish.

Safety in the vinyl chloride industry. The operation of a safe plant involving the handling of toxic, hazardous materials revolves around a number of factors:

1. Establishment of safe, practical, allowable environmental levels.

2. Implementing appropriate engineering and operating procedures to achieve or better these levels.

3. Providing analytical monitoring capability to insure the environment is maintained below the established levels and to detect excursions above such levels.

4. Initiating appropriate corrective action when breakdowns occur and guideline environmental levels are exceeded.

Developing and supporting an appropriate medical surveillance program.

Dow has a safety philosophy that the safety of our

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employees, our customers, and our neighbors is of prime and utmost importance. This safety philosophy permeates our operations. To achieve our general safety goals for vinyl chloride operations and to achieve a goal that industrial exposure to vinyl chloride should be kept below 50 ppm on a time-weighted average, we have implemented the following design and engineering principles for vinyl chloride operations:

1. Processing systems are closed with no open vessel operation.

Current buildings where vinyl chloride is manufactured or polymerized are open to the atmosphere or have ventilation to minimize concentration build-ups.

3. Engineering design emphasizes reasonable process automation and reasonable remote operation in order to minimize personnel exposure.

Vent exhaust systems are selectively located to minimize the possibility of personnel exposure.

And the number and quantity of samples for control analyses are minimized.

Careful application of the above principles has led essentially to the attainment of our goal of TWA values of less than 50 parts per million in our operations.

We believe that good operating procedure must be tailored to each specific plant, that plant size and the

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nature of the process and the plant location all will influence the exact procedures to be carried out. I will mention a few of the more important operating procedures and techniques involved in one of our monomer production plants to illustrate the complexity of good plant operation.

1. Employees are familiarized with emergency procedures and signals. For example, wind directional signals, horn emergency calls, and evacuation routes.

2. Collection of analytical samples of vinyl chloride from storage tanks involves a closed-loop sampling system in order to return vinyl chloride to the process rather than venting vapor in the workplace environment. Laboratory samples of vinyl chloride are handled in hoods and sample cylinders are grounded when discharged. On-line gas chromatography is being used extensively to monitor product purity and process operation. This has reduced markedly the number of manual sample collections required, and this has occurred over the last few years.

Specially designed vapor equalizing lines connected back to the storage tank are employed in the loading of tank cars.

4. Environmental monitoring of air is being conducted by a number of techniques. Gas detector alarms are located throughout the plant at a number of strategic locations to warn of any flammable concentrations. Portable

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detector instruments are available for checking plant areas or process equipment prior to non-routine operations and procedures. Air quality surveys were conducted in Monomer Plant No. 1 in 1971 and in the first quarter of 1974. A continuous analyzer system for twelve strategic locations in the plant will be installed. This will provide continous background information and provide instantaneous signals for any unusually high concentrations that might occur due to leaks, spills or other non-routine situations.

In our polymerization operations we have not had problems of worker illness from the cleaning of polymerization vessels. We utilize high pressure water jets after each polymerization reaction to prevent polymer build-up. Our emulsion polymerization kettles require manual clean-out every two or three months. After water cleaning of the vessel, all lines are blanked to prevent any material from entering the vessel and the atmosphere is tested for oxygen supply and a continuous vinyl chloride monitoring probe is put into the vessel. Concentrations must be below 50 parts per million prior to vessel entry. Air purge is maintained on the vessel during the cleaning operation.

Analytical methodology. Four methods are available for environmental monitoring of air for the presence of vinyl chloride: (1) conbustion-conductivity, gas chromatography, infrared spectrophotometry, and flame ionization

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spectrophotometry.

Gas chromatography is very specific, but requires about ten minutes per sample. Flame ionization detectors have no specificity-responding to all carbon-carbon or carbon-hydrogen bonds, but are portable and the measurement is instantaneous. The combustion-conductivity method responds to any material which burns to produce ions. It responds rapidly. Infrared analyzers are very specific, respond quickly, and are portable. All of these techniques have adequate sensitivity, detecting concentrations of as low as one part per million.

Personnel monitoring is achieved through the use of absorption tubes filled with activated carbon. The absorbed chlorinated hydrocarbons are determined by gas chromatography after thermal release or extraction by carbon disulfide.

At Dow most of our environmental monitoring has been with combustion-conductivity analyzers. We have used these analyzers for continuous monitoring since 1959 with excellent results.

And now for recommendations for government-industry action.

Dow urges OSHA to recognize the voluntary industry action to lower the levels of exposure to vinyl chloride and the leaf role of industry in obtaining data on the vinyl chloride problem.

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Dow believes the industry recognizes the need to maintain environmental levels below the OSHA standard of 500 ppm and even below the ACGIH recommendation of 200 ppm.

Dow believes that it is industry's and government's responsibility to inform all employees or persons working with vinyl chloride about its hazards and to develop and implement training programs to help prevent overexposure and insure proper reaction in emergency situations. We believe informed employees will cooperate in eliminating over-exposure and suggest methods for improvement.

Based upon the medical and toxicological data available to us at this time, Dow believes that an eight-hour TWA of 50 ppm is a satisfactory environmental standard for vinyl chloride.

Dow is supporting and actively cooperating in long-term inhalation, metabolism, and epidemiological studies in order to obtain the most precise data possible relating to the potential for occupational health assessment.

(A) We will strongly support industry-government evaluation of the data as it becomes available.

Results of the epidemiological survey of vinyl chloride workers initiated about a year ago by MCA via contract with Tabershaw-Cooper will be available in the near future. It seems reasonable to expect that these results will provide additional and substantive basis for rule-making.

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Dow believes rule-making should not be based on conditions that existed in the past but should be based on conditions as they exist now. Based on NIOSH activity and on widespread voluntary actions by industry, we believe there is no need for a temporary emergency standard. Realistically, we believe a temporary emergency standard would result in polarization rather than constructive definition of areas of concern and constructive problem solving.

We believe most users/producers of vinyl chloride have or will soon have the capability to maintain an eight-hour time-weighted average of 50 parts per million or below. Therefore, we suggest that steps be taken in order to develop the standard in a reasonable way.

In order to asses the state and magnitude of the problem, we suggest that each producer/user of vinyl chloride complete an industrial hygiene survey of his operations and a medical survey of vinyl chloride workers within three months and report the results of each survey to NIOSH and OSHA.

If the survey reveals TWA's in excess of 50 ppm, the manufacturer or processor should immediately take steps to reduce exposure by operational and/or engineering changes and require the use of appropriate respiratory protection by his employees likely to be exposed to such levels.

If the medical surveillance program indicates

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abnormalities that could be attributed to excessive exposure to vinyl chloride or a condition that could reasonably be expected to be aggravated by continued work with vinyl chloride, that person might well be removed to another job not involving such exposure. We recommend NIOSH assistance in defining the priority of health parameters for this study.

Dow supports OSHA's establishment of a permanent health standard for vinyl chloride by regular rule-making procedures.

And we recommend that the standard state what should be accomplished, leaving the "how-to-achieve compliance" to individual plant implementation.

Thank you, sir.

JUDGE MYATT: Thank you, Doctor.

We are going to mark as Exhibit 15(a) Dr. Rowe's statement, "Toxicological Data and Industrial Experience with Vinyl Chloride," 15(b) Appendix No. 1, the published references to the biological effects of vinyl chloride, and 15(c), Appendix No. 2, the industrial hygiene surveys involving vinyl chloride.

(Whereupon, Exhibits Nos. 15(a), 15(b), and 15(c) were marked for identification and were received in evidence.)

JUDGE MYATT: We are also going to mark, Madam Reporter, as Exhibit 14 an article by Dr. Jaeger, which I

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understand a copy has been supplied to you.

(Whereupon, Exhibit No. 14 was marked for identification and was received in evidence.)

Now, are there any questions?

MS. GHOLSTON: I have a question with respect to your medical surveillance. You stated that you didn't find any liver cancer or cirrhosis of the liver. As part of the medical surveillance, were you looking for these?

DR. ROWE: Yes, ma'am. We have a rather sophisticated medical department in all of our -- our two major production areas. Medical surveillance is a real serious thing with us. One of the things that go along with that, I think, we would like very much to implement some of those last suggestions I made, if people from NIOSH and other agencies, interested people, would get together to attempt to develop the best protocol that their collective thoughts can produce rather than any one single one.

MS. GHOLSTON: Thank you.

JUDGE MYATT: Yes, Mr. Bien.

MR. BIEN: Could you give us some information regarding the toxicity of polyvinyl chloride at this time?

DR. ROWE: I have not conducted any studies on polyvinyl chloride -- we have not.

JUDGE MYATT: Is there anything else?

MR. BIEN: No, sir.

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JUDGE MYATT: Yes, Mr. Beliczky.

MR. BELICZKY: I just wonder if I could ask V. K. is he has any idea of how much VC is in the polymer after the polymerization reaction, maybe put into bags, barrels, shipped, put into boxcars.

DR. ROWE: Lou, I don't know. I don't know whether the information is available or not. I haven't looked into this. However, I am certain that the amount that's going to be there will depend upon the intensity of the degassing process in the final steps of polymerization, and I'm sure that there are many variations to this and I can't tell you what ours runs, and I don't know what other people's do either.

MR. BELICZKY: We heard Dr. Maltoni this morning talk about certain kinds of carcinogenic responses in animals to various concentration exposures to vinyl chloride, and I think he did mention that he did find some carcinogenic response in 100 parts per million. In relating this -- this is an animal, and we are concerned about human beings. What degree of surety do you have or confidence in a level of 50 parts per million?

DR. ROWE: I was not aware that Prof. Maltoni mentioned any positive effect at 100. I could stand corrected. I'm not sure that I understood everything he said. But I don't believe -- I didn't hear that and I didn't see it on

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the tables.

MR. BELICZKY: It was either 100 or 200. I'm not quite sure.

DR. ROWE: 250, I think he did.

JUDGE MYATT: Yes?

MR. SAMUELS: Dr. Rowe, first let me say that if your other colleagues in the industry had followed your advice in 1961 following the publication of your paper, we perhaps would not be faced with this crisis. Nevertheless, you were a member of the Standards Advisory Committee on Carcinogens, and I wonder why you choose to handle this carcinogen any differently than the carcinogens approach as described by the Committee, namely, the purpose of this standard -- and I'm quoting from the Committee report -- "The purpose of this standard is to prevent any worker contact or exposure to any of the listed qarcinogens" -- it could be vinyl chloride or the process of polymerization -- as detected by the most sensible, feasible sampling and analytical methods available. The vote on that was fourteen to nothing.

DR. ROWE: Well, Sheldon, I don't want to get into all the arguments and the discussions that went on at the Advisory Committee on Carcinogens, but there was a matter of timing when that was developed and we were coming back to discuss some other matters later on as to how that should be implemented, and we were not able to do that at the end, so

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that stands as a part of the record, a part that I would not concur to completely.

I think we want to reduce these, but I do feel that there is a reasonable level -- and you asked me about why I feel the way I do. I feel that from my knowledge of some of the things that have gone on there must have been a rather severe exposure, very severe exposure, of people many years ago that we are seeing the results of today.

Our experience, which is just as long, but under control conditions, we have not seen this. Now, we have looked at almost everybody we can find. We have a few people who yet -- we're going to have to have some help through Social Security numbers or other means to find them. We have all the people who are retired; we know all those. We have our own people; we know the people who have died. There are a few who have worked a very short time and quit or left for other reasons, and those are the ones that we don't have. So I can't be completely conclusive in my remarks that we have not had any, but I don't believe so.

MR. SAMUELS: Can I ask this further question, then? I will admit to the theoretical possibility that 50 parts per million or some other parts oer million, some other level, some other dose relationship might be safe, but until that's shown and proven, do you think it's prudent to take the risk with the lives of thousands of workers?

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DR. ROWE: I don't believe that there is that great a risk, if we control our concentration during this interim period during which we're developing, I think, very significant data, and that's why I feel that we ought to go ahead in a practical way because it would be absolutely catastrophic to the whole affair if we were to have to go down to none. It would be essentially impossible continuing operations --

MR. SAMUELS: We're not talking about none. We're talking about methods that are already feasible for detection and we've been told by the industry that your methods of analysis, using the shelf instruments, instruments that can be purchased off the shelf of vendors, will enable you to measure concentrations of vinyl chloride in the range of ten to thirty parts per million. So we're not talking about none. We're talking about your doing what's feasible in terms of measurement.

DR. ROWE: I thought that's what I was trying to recommend.

MR. SAMUELS: Well, you recommended fifty.

DR. ROWE: Anything below that --

MR. SAMUELS: We're saying it should be tied not to the assumption of the TLV, which has not been demonstrated -- in fact, it has not been demonstrated -- but , rather, to the method of measurement, and if some instrument manufacturer develops a more sensitive instrument, then we expect you to

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achieve that level of detectability.

DR. ROWE: I think that is quite an ideal situation because the challenge of any analytical -- good analytical man in instrumentation can extend that by orders of magnitude with just a matter of a few months or a year's research. We've seen this when it is absolutely necessary to do so. So that's kind of -- you run out of space, Mr. Samuels.

JUDGE MYATT: Yes, ma'am?

MS. HRICKO: Dr. Rowe, you said that Dow has very carefully controlled the levels of vinyl chloride at these various plants since they started their operations, yet you stated that Plant 2 started up in 1958 and you did a spot survey in 1965 at a level showing that they were all under 60; then you did a more in-depth survey in 1973 showing that all values except for lab personnel were under ten. I can only assume from the way you presented the data that there was not continuous monitoring from 1958 to 1973. If there wasn't and there were only these surveys done in those two years, how can you assume that the levels of vinyl chloride did not have great excursions during those years?

DR. ROWE: I said what I said because I can't produce data to demonstrate what happened during those years. I know what happened, but I don't have data to prove it.

MS. HRICKO: Was there continuous monitoring?

DR. ROWE: The monitoring was done and the people

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in the plant -- this is recorded right in the plant and there are such volumes of paper that are generated on a day-to-day basis that if everything was right, they threw them in the waste can.

MS. HRICKO: So there was continuous monitoring. You just happened to pick out '65 and '73 as examples?

DR. ROWE: I did pick out some examples, yes. These are ones that we have records for and documentation in our files.

MR. BELICZKY: Of the methods that you described for monitoring, which of the methods could go down to one part per million?

DR. ROWE: I think any one of them can.

MR. BELICZKY: Can the flame ionization procedure distinguish, let's say, between vinyl chloride and vinylidene chloride?

DR. ROWE: I'm not an analytical man or a spectroscopist here, Lou. I think it can. I think it's quite highly specific.

The thermal conductivity -- the combustion-conductivity unit will not, of course.

MR. BELICZKY: Since you've never thought of really going beyond -- let's say below 50 parts per million. I'm now thinking of one part per million. Do you conceive of any real technical difficulty in going down to a tenth of a part

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per million if one part per million is easily achievable -- in instrumentation.

DR. ROWE: In instrumentation? No, that's no problem.

JUDGE MYATT: All right. Are there any further questions of Dr. Rowe?

Thank you very much, Dr. Rowe.

We have remaining Mr. Herbert Carver of Dove Packaging Systems Division of Franklin Electric and Dr. Robert Brookman, Manager of Research and Development of Firestone.

Is Mr. Carver here? Step up, please, sir.

What I propose to do is to continue on. I know it's after 5:00 -- it's only five after. I'm assuming that with only two individuals left to make a presentation that we can conclude this by 6 o'clock, if you'll bear with us.

Mr. Carver.

HERBERT K. CARVER, JR.

MR. CARVER: My name is Herbert K. Carver, Jr. I am employed as a design engineer with Dove Packaging Systems Division of Franklin Electric, headquartered in Fallsington, Pennsylvania, with a mailing address of Box 666, Levittown, Pennsylvania, 19058.

Dove manufactures packaging, weighing, and labeling equipment primarily for exposure in the supermarket

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industry.

One of the long-established product lines is console and table-top hand wrapping stations used by supermarket personnel to manually overwrap meat and produce. The overwrap packaging material is roll stock plastic films such as polyethylene and polyvinyl chloride.

Briefly, the Dove manual overwrap operation includes wrapping the film around a tray-held product, thermally severing the film web, heat sealing the bottom of the package, and, in the case of shrink films, thermally shrinking the film around the package.

Several years ago we started a project to develop a means to reduce the visible quantity of "smoke" released in the high-temperature, hot wire thermal severing of the film. This led to the issuance of a patent to us which basically involves the regulation of the severing wire's temperature below the combustion point of the film. This way the film is softened and then severed mechanically by the force exerted by the operator who is performing the wrapping.

To us, as chemical laymen, the reduction of visible smoke indicated a step in the right direction. Our intuitive feeling on this point seems somewhat justified based on the results reported in the Health Hazard Evaluation Determination, Report 72-53, issued in September 1973 by the U. S. Department of Health, Education and Welfare, Hazard

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Evaluation Services Branch of NIOSH, Cincinnati, Ohio. This report generated from a request of an authorized representative of the supermarket meat wrapping employees for an investigation regarding employee exposures to the potentially toxic substances emitted from thermal decomposition of polyvinyl chloride packaging films.

Following are some excerpts from this report which led us to this belief: "...the production of both HCl and airborne particulate increase with increasing wire temperature ...machines with low temperature cutoff wires are to be preferred..."

Further, as mentioned in the subject NIOSH study, there are differences of opinion on the exact nature of the emissions and inconclusive results concerning the effects of these emissions on the operator performing the wrapping. However, it would seem that a temperature-controlled film separation technique, as recommended in the NIOSH study, is a step in the right direction.

The use of such a technique would maximize the utilization of established wrapping methods and equipment. Also, it should minimize the wrapping speed reduction and film waste indicated with other cutting techniques, such as knives. In these days of reported declining supermarket meat room profits and petrochemical shortages, such points must be seriously considered.

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Being a supplier of hand-wrapping equipment, the Dove Packagaing Systems Division is continually concerned with providing acceptable and efficient equipment to the supermarket industry. For some time Dove hand-wrap stations have been equipped with a controlled low temperature thermal cutoff mechanism and it is our goal to equip all remaining newly built models with a similar mechanism.

We offer whatever help we can to resolve this question.

Further, it it is determined that the thermal products of "hot wire" cutting of PVC film are potential health hazards, we offer the use of our low temperature technique and/or equipment to OSHA and NIOSH as a baseline for the development of a specific standard.

In closing, to all participants in this hearing, as well as those not in attendance today, please be advised and assured that we have a serious interest in the resolution of this concern.

For the Dove Packaging Systems Division of Franklin Electric, I submit this statement for the OSHA record.

JUDGE MYATT: All right. The statement will be received as Exhibit 16.

(Whereupon, Exhibit No. 16 was marked for identification and was received in evidence.)

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JUDGE MYATT: Are there any questions of Mr. Carver? Thank you, Mr. Carver.

Dr. Robert Brookman -- I'm sorry. I didn't notice your final note. I'm tired, too.

Firestone does not intend to make a presentation.

Do we have any others?

MS. FERRONE: Not that I know of.

JUDGE MYATT: That, then, concludes all of the individuals that have entered an appearance and indicated that they would make a presentation.

I had a discussion with the OSHA people and the representative from the Solicitor's Office. I will keep the record open for written submissions until March 8th, 1974. All documents should be recived by that date, which is a Friday, by the Occupational Safety and Health Administration, Room 240 -- and again I repeat the address -- 1726 M STreet, N. W., Washington, D. C., Zip 20210.

Yes, sir?

A VOICE: Will these written depositions be included in the transcript of this meeting?

JUDGE MYATT: They will not be in the transcript. They will be part of the official record which will be certified to the Assistant Secretary, but they will not be in the transcript. However, they will be incorporated later -- I don't know. The expert is shaking her head "no," so the

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answer is no.

A VOICE: Thank you.

JUDGE MYATT: I want to thank all of you for your attendance and your cooperation in this matter, and I would also like to thank all of the staff people and the representative from the Solicitor's Office, OSHA, NIOSH, and et cetera.

This hearing is officially adjourned.

(Whereupon, at 5:15 p. m., Friday, February 15, 1974, the hearing in the above-entitled matter was adjourned.)

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CERTIFICATE OF REPORTER

I hereby certify, as the stenographic reporter, that the foregoing proceedings were taken stenographically by me and thereafter reduced to typewriting by me or under my direction; that this transcript is a true and accurate record to the best of my ability.

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By: Leah S. McClure

Leah S. McClure
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