

ENVIRONMENTAL PROTECTION AGENCY

In the Matter of:

PUBLIC HEARING ON

VINYL CHLORIDE

February 3, 1976
Room 3395
401 M Street, S.E.
Washington, D. C.

The above-described hearing convened,
pursuant to notice, at 9:00 o'clock a.m.

BEFORE:

RICHARD DENNEY, Chairman

JACK FARMER

SUSAN WYATT

DR. JOHN KNELSON

DR. WILLIAM MARCUS

DR. ROBERT McGAUGHY

DR. ARNOLD KUZMACK

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P R O C E E D I N G S

1
2 CHAIRMAN DENNEY: Will the meeting please come
3 to order?

4 Good morning, I am Dick Denney of the Office
5 of General Counsel of the Environmental Protection Agency.
6 I would like to welcome you on behalf of Russell Train
7 our Administrator and thank you for your interest in this
8 proceeding.

9 Robert Strelow who is the Assistant Administrator
10 for the Office of Air and Waste Management Programs will
11 make a statement to start the hearing off.

12 MR. STRELOW: Good morning. I will be responsible
13 for recommending to the Administrator the final standard
14 which EPA should promulgate to regulate vinyl chloride
15 emissions to the air.

16 I would like to welcome you to this hearing to
17 consider whether vinyl chloride is a hazardous air pollutant,
18 and if so, what standard should be adopted to limit its
19 emissions.

20 Most of EPA's efforts to prevent air pollution
21 have focused on pollutants that are very widespread in our
22 environment and for which there is a substantial amount of
23 information. For such pollutants, national ambient air
24 quality standards have been established. The public issues
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1 associated with these pollutants are well known. They
2 include such matters as use of stack gas scrubbers by
3 utilities, auto emission standards and transportation
4 control plans.

5 EPA also has the authority under the Clean Air
6 Act to directly regulate the emissions of hazardous air
7 pollutants that are less generally pervasive but which may
8 threaten health in localized concentrations around emission
9 sources. Vinyl chloride is this type of pollutant.

10 It is a relatively new pollutant, its dangers have only
11 very recently become known.

12 For those reasons EPA has less of a data base
13 with respect to vinyl chloride than for some of the more
14 widespread pollutants. Our limited information on
15 vinyl chloride is a matter of concern to EPA.

16 EPA was faced with a choice of either not
17 regulating emissions of vinyl chloride until further
18 information could be gathered or regulating vinyl chloride
19 now on the basis of the limited information available to us.
20 We believe that vinyl chloride should be regulated now.

21 We do know that vinyl chloride is a carcinogen
22 that has caused disease and death to workers exposed to
23 relatively high levels of this chemical. We do not know
24 the extent to which the lower levels that are present in
25 the general environment around production facilities

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1 constitute a danger to health. However, because vinyl
2 chloride is a carcinogen, any level of exposure probably
3 carries some risk.

4 Carcinogens are believed to have latency periods
5 as long as 20 years from initial exposure to the occurrence
6 of the disease. Polyvinyl chloride production has only
7 recently been undertaken on a large scale. Only about ten
8 of the approximately 40 polyvinyl chloride plants are
9 20 years old or older, and the oldest one is 40 years old.

10 The first report of the risks of vinyl chloride
11 was in 1974. These factors are relevant to why there is
12 limited information available on the effects of vinyl
13 chloride. These factors are also relevant to why EPA
14 believes it should take action now.

15 However, in view of the information presently
16 available, EPA does not believe that it is appropriate
17 at this time to set such a stringent standard that it would
18 effectively ban all production of vinyl chloride. Vinyl
19 chloride has many important uses in our society. There
20 are no present substitutes for some of these uses.

21 The emission limitation that EPA is proposing
22 to promulgate for vinyl chloride should reduce ambient
23 levels to well below those levels at which cancer has been
24 observed to be induced in animals and well below those
25 levels to which occupational workers who contracted cancer

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1 are believed to have been exposed.

2 I believe that participation by both environ-
3 mentalists and industry at this hearing should provide
4 useful information to assist us in evaluating the
5 approach which we have proposed for this pollutant.

6 Prior to making my recommendation to the
7 Administrator concerning a final regulation for vinyl
8 chloride, I will review the hearing record as well as
9 the written comments received in response to EPA's
10 proposed regulations.

11 Thank you.

12 CHAIRMAN DENNEY: Thank you, Roger.

13 This hearing is intended to provide opportunity
14 for interested persons to state their views or arguments,
15 or to provide information as to, first, whether vinyl
16 chloride when emitted to ambient air may cause or contribute
17 to irreversible or incapacitating illness?

18 If so, second, what standards should be adopted
19 to regulate such emissions of such a pollutant?

20 The Administrator is required, under Section
21 112 of the Clean Air Act to establish air quality standards
22 at the level, which in his judgement, provides a margin
23 of safety to protect the public, unless on the basis of
24 information presented at this hearing he finds such
25 pollutant is not a hazardous air pollutant.

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1 Accordingly, participants in the hearing are
2 requested to identify specifically the portions of their
3 presentations, if any, which are directed to the issue of
4 whether the pollutant in question, vinyl chloride, is or
5 is not a hazardous pollutant as defined in Section 112(a)(1)
6 of the Act.

7 There will be, I believe, five parties presenting
8 testimony at these hearings. Following each statement,
9 the panelists, the people you see here, may ask questions
10 of the witnesses. Any questions that other participants
11 in this hearing may have for a witness should be submitted
12 to me in writing, and I will request the panelists to ask
13 the questions.

14 Should we, in the questioning of any witness,
15 request additional material or answers in writing, we
16 request it be submitted to EPA not later than February 23rd
17 of this year.

18 Additionally, all witnesses will be permitted to
19 submit post-hearing comments to EPA if they wish.

20 The comment period does not close until February
21 23rd on the EPA proposed regulation, so, of course, any
22 member of the public may submit written comments up until
23 February 23rd.

24 This hearing is an informal hearing, technical
25

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1 rules of evidence will not apply. Any motions or requests
2 for rulings or procedural points should be directed to me.

3 The panelists in this hearing, starting on my
4 left are first, Jack Farmer and Susan Wyatt from the
5 Office of Air and Waste Management. Dr. John Knelson from
6 the Office of Research and Development. Dr. William Marcus
7 from the Office of Toxic Substances. Dr. Robert McGaughy
8 from the Office of Research and Development and Dr. Arnold
9 Kuzmack from the Office of Planning and Management.

10 The order of the presentations at the hearing
11 today are first, and I would like to go through the list
12 before anybody comes up.

13 First, I would like EDF, the Environmental Defense.
14 Fund to testify.

15 Second, will be the Society for the Plastics
16 Industry.

17 Third will be Dow Chemical.

18 Fourth will be Diamond Shamrock.

19 Fifth will be Air Products.

20 I would like to begin now with the witness from
21 the Environmental Defense Fund who I understand is to be
22 Barry Castleman.

23 Would you come forward, Barry, and sit in the
24 middle chair of the witness table on my right.

25 Incidentally, before Barry starts to testify,

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1 we have received from some of those testifying, copies
2 of their presentation. We would suggest that you talk
3 to the people who are giving the testimony if you would
4 like additional copies.

5 You can, of course, ultimately get copies
6 from EPA, but we will have to reproduce them, so, if you
7 want any copies now please talk to the people who are
8 giving the testimony.

9 Barry, are you ready?

10 MR. CASTLEMAN: Yes.

11 STATEMENT OF BARRY I. CASTLEMAN, ENVIRONMENTAL
12 DEFENSE FUND.

13 MR. CASTLEMAN: Good morning. I am Barry
14 Castleman, a consultant to the Environmental Defense Fund.
15 EDF is a nonprofit public interest organization with a
16 membership of some 40,000 scientists, lawyers and
17 citizens nationwide. Since its inception in 1967, EDF
18 has been actively involved in actions aimed at reducing
19 the involuntary exposure of the public to carcinogenic
20 pesticides DDT and aldrin/dieldrin, are examples of EDF
21 successes in halting widespread exposure of the public
22 to carcinogenic chemicals.

23 Before we get to vinyl chloride, I would like to
24 talk about the level of exposure of cancer in general.

25 Cancer has reached epidemic proportions in the

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1 United States. The rate of increase appears more rapid
2 than either the rate of increase of population, or the rate
3 of increase in the total death rate. Today, one in every
4 four Americans contracts cancer during his lifetime, and
5 two-thirds of these die from the disease. In 1973, there
6 were over 600,000 new cases of cancer, and approximately
7 350,000 deaths. Cancer is a leading cause of premature
8 death in the United States

9 The economic impact of cancer is massive. The
10 direct and indirect costs of cancer, including loss of
11 earnings during illness and during the balance of
12 normal life expectancy, have been estimated at a total
13 of \$15 billion for 1971.

14 Although less certainty exists on the role
15 of most environmental contaminants in human cancer than
16 say, cigarette smoking, drugs and occupational airborne
17 particles, a recent Presidential panel concluded that:

18 "Cancer incitements by so far unrecognized
19 chemicals combine to form a threat to health
20 that may well be of at least the same general
21 size as the three major threats just described
22 [i.e., cigarette smoking, alcohol abuse, and
23 choice of dietary composition]. These chemicals
24 may be natural or synthetic."

25 Although most of the evidence for the effect

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1 of environmental carcinogens on man has come with industrial
2 exposure to high levels of these carcinogens, most cancer
3 experts agree that the low levels of carcinogens to which
4 the general population is exposed are responsible
5 for the majority of human cancers.

6 Although others would argue that the levels of
7 these chemicals in the environment are too small to be of
8 significance to the general population, the scientific
9 evidence simply does not support this viewpoint. For example,
10 the chemical aflatoxin is known to cause cancer in man,
11 and in experiments on trout, it was shown to produce liver
12 tumors when present in feed in concentrations as low as
13 400 parts per trillion; even at this low level, its
14 carcinogenic effect was enhanced by addition of various
15 non-carcinogenic oils to the diet.

16 Similarly, dieldrin, a chlorninated hydrocarbon
17 pesticide now banned by EPA, still used in Brazil and other
18 countries, has been found to be carcinogenic in the lowest
19 concentrations tested, 100 parts per billion.

20 Therefore, lacking scientific evidence that a
21 threshold existed for any chemical carcinogen, the Ad Hoc
22 Committee on the Evaluation of Low Levels of Environmental
23 Chemical Carcinogens reporting to the Surgeon General in
24 1970 concluded that:

25 "No level of exposure to a chemical carcinogen

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1 should be considered toxicologically insignificant
2 for man."

3 This report, though five years old, was cited
4 in the EPA report for the Vinyl Chloride Regulations.

5 It is with a recognition of these facts that
6 I would like to address the proposed standard for emission
7 of vinyl chloride into air.

8 First, it is necessary to retrace both the
9 development of medical knowledge and EPA regulations with
10 respect to vinyl chloride in order to appreciate the problems
11 raised by vinyl chloride and to establish plans for reacting
12 to the next vinyl chloride.

13 We all recognize that vinyl chloride is one
14 of hundreds of widely used chemicals that were never
15 pre-tested on laboratory animals for chronic toxicity
16 prior to being introduced commercially. Due to the long
17 latency period for the induction of cancer and the
18 fact that chemically induced diseases have received
19 inadequate study, it would be most fortuitous if
20 vinyl chloride's longterm health dangers were unique.

21 In May of 1974, an international conference
22 was convened by the New York Academy of Sciences to review
23 the health hazards posed by exposure to vinyl chloride.
24 This followed by four months the first announcement that
25 angiosarcoma of the liver, an extremely rare and always

A. D. ... C.

1 mutagenic effects were also associated with exposure to
2 vinyl chloride. In the summer of 1974, Dr. Peter Infante,
3 who is currently with the National Institute for Occupa-
4 tional Safety and Health, observed an excess rate of serious
5 birth defects in residents in Ohio counties with plants
6 emitting vinyl chloride.

7 The central nervous system birth defects noted
8 commonly result in death during infancy. A more recent
9 report from Norway, though including a small number of
10 cases, also linked these same types of birth defects to
11 neighborhood exposure to vinyl chloride. While neither
12 of the above reports is conclusive, taken together they
13 support the hypothesis that vinyl chloride air pollution
14 can produce central nervous system birth defects.

15 Mutagenicity, as distinct from teratogenicity,
16 was indicated in studies by Dr. F. deSerres of the
17 National Institute of Environmental Health Sciences, on
18 the effects of vinyl chloride on salmonella - liver microsome
19 systems.

20 In addition, Dr. Irving Selikoff, of the
21 Mount Sinai School of Medicine reported data suggesting a
22 higher than normal rate of stillbirths and miscarriages
23 among wives of vinyl chloride workers and a high incidence
24 of abnormal chromosomes among the workers themselves.
25 This was when EPA was starting to take action for same.

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1 This was in 1974.

2 By August of 1974, EPA had sampled the air
3 around a dozen vinyl chloride and polyvinyl chloride plants.
4 Grab samples contained up to 33 parts per million of
5 vinyl chloride and 24-hour samples ran as high as one
6 part per million. Thus, the cumulative exposure of the
7 neighbors of these plants to vinyl chloride were comparable
8 to the present workplace standard for a 40-hour week.

9 Yet, in a letter of reply to Dr. Albert Fritsch,
10 Director of the Center for Science in the Public Interest
11 and myself, the Administrator of the EPA, Mr. Train,
12 alluded to this monitoring data on vinyl chloride by saying:

13 "Following an assessment of this preliminary data,
14 it was determined that there was no scientific
15 evidence to indicate that vinyl chloride emissions
16 pose an imminent hazard to people living near these
17 plants."

18 I was amazed at this. Fifty parts per million
19 in test animals and 35 parts per million outside the
20 plant, and this is not construed to be a hazard. This
21 purports to have scientific merits.

22 Are there any scientists on the panel who would
23 like to explain the scientific merit? I would be interested
24 in hearing that later on.

25 Usually occupational exposure standards are at

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1 100 times as high as the concentrations allowed by
2 environmental standards. This is just for a general
3 workplace.

4 In September, 1974, Mr. Train presented EPA's
5 vinyl chloride Task Force Report, saying that available
6 control technology could reduce vinyl chloride emissions
7 from polyvinyl chloride plants by 75 percent and from
8 vinyl chloride monomer plants by 90 percent.

9 However, five months later, Don Goodwin, Director
10 of Emission Standards and Engineering Division, EPA,
11 described the situation existing at that time as follows:

12 "Generally speaking, the industry is presently
13 controlling the vinyl chloride emissions to the
14 extent that it is economical to do so. That is, the
15 recovered vinyl chloride will pay for the control
16 equipment that is installed. At this stage of our
17 investigation, it is our opinion that neither the
18 polyvinyl chloride nor the vinyl chloride monomer
19 plants are presently controlled to the extent that
20 available control technology will permit."

21 The equipment had been installed at that time, and
22 this equipment paid for itself in productivity.
23 The EPA painstakingly compiled a best available
24 technology standard after observing the industry through
25 1974. Through almost all of 1975, the standard was examined

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1 by people in the EPA and other governmental agencies, by
2 industry and possibly members of the public, this is
3 an extremely lengthy review and I think it is very
4 important to try to put regulations out and somehow
5 shorten this review process. Possibly have some of the
6 review going on after a proposal is issued, or at least,
7 after a substance is declared to be hazardous.

8 Now, another year has passed with industrial
9 application of controls plodding along at the snail's
10 pacedictated by the economics of product recovery that pays
11 for itself. It is 1976, but we still do not have any
12 state or national emission standards, and much of the
13 technology in use today resembles the best pastry in the
14 bakery that they will let you have for free.

15 Had EPA declared vinyl chloride a hazardous air
16 pollutant in June of 1974, the final standards would have
17 been due by June of 1975. The public would have been
18 spared an additional year of unregulated emissions
19 from the 58 largest sources of vinyl chloride air pollution
20 in the country, and the state of development of engineering
21 controls would have been more advanced a year ago than it is
22 today.

23 Under the Clean Air Act, the EPA had the authority
24 to force the United States vinyl plants to close until
25 air pollution controls could be installed. Why did

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1 EPA not at least declare vinyl chloride a hazardous
2 air pollutant in 1974 so that the industry would have
3 been required to install integrated systems for control
4 of emissions both inside and outside of these plants?

5 We hope that EPA will do its job better
6 and faster for the next vinyl chloride.

7 I don't think vinyl chloride is in any way
8 unique. I think a lot of chemicals have been intro-
9 duced the same way, and there are others coming along
10 that may be discovered to have the same hazards.

11 Now we will get to the proposed standards.

12 As EPA has recognized, the major issue raised
13 by the setting of an emission standard for apparent non-
14 threshold pollutants, such as vinyl chloride is,
15 and that is EPA's term, how far exposures should be reduced
16 to provide an ample margin of safety. That is the crux
17 of this issue.

18 What is the social acceptable risk. Do you dare
19 risk any level of exposure?

20 EPA accepts the notion that operation of
21 vinyl chloride plants has increased the risk of cancer
22 among plant neighbors, and that the risk is roughly pro-
23 portional to the level of emissions.

24 The calculations contained in the Quantitative
25 Risk Assessment report by Dr. Arnold Kuzmack and Dr. Robert

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1 McGaughey indicate that current levels of air pollution
2 cause one to 20 cases of cancer per year among vinyl
3 chloride and polyvinyl chloride plant neighbors. With
4 95 percent emission reduction, the linear model predicts
5 less than one case of cancer per year.

6 However, since there are factors in the EPA
7 risk calculations that tend to underestimate the risk as
8 well as over-estimate it, I think it is important to
9 emphasize that we have to put a firm upper limit on what
10 the risk is. We have to know that there are not going to
11 be much more than so many cases that are going to occur,
12 given the risk of exposure.

13 For example, the estimates are based solely on
14 post-natal exposure, and possible exposure of the fetus
15 through transplacental transfer is not considered. Likewise,
16 the possible synergistic effects between vinyl chloride
17 and other toxic materials to which we are exposed has not
18 been evaluated.

19 The animal inhalation tests upon which the
20 risk estimates are based were tests with rats exposed to
21 vinyl chloride in an otherwise chemically restricted
22 environment. In contrast, people are subjected to many
23 other chemical exposures, such as to polychlorinated
24 biphenyls, PCB's. Half of the United States population
25 is believed to have accumulated one to three parts per

1 million of PCP's in their fatty tissues. These compounds
2 are similar to DDT and other chlorinated pesticides,
3 Their metabolism activates specific liver enzyme systems,
4 enabling the liver to more readily metabolize such
5 chemicals as vinyl chloride.

6
7 Apparently it is the metabolite in vinyl chloride,
8 and not vinyl chloride itself. The body, in the course of
9 digesting and metabolizing it causes cancer and so the
10 PCB's might make us more susceptible to cancer from a
11 given dose of vinyl chloride than otherwise would be
12 predicted.

13 Using the EPA figures, we can calculate the
14 lifetime cancer risk for near neighbors of vinyl chloride
15 emission sources, having qualified the EPA risk model
16 that tests have been done. Our estimates assume an annual
17 average value of 323 parts per billions for vinyl chloride
18 concentration near a single, average polyvinyl chloride
19 plant; a 40 year period-at-risk; and EPA's figures of risk
20 equal to 0.15 cases of all types of cancer, 0.071 cases
21 of liver angiosarcoma per million people per year per
22 parts per billion of continuous exposure.

23 The 40-year period of risk assumes all exposures
24 is post-natal, and can account for a lifetime, near-
25 continuous residence within one-half mile of the plant.

Of course, a number of people live near more than

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1 one vinyl chloride emitting plant. Fully 46,000
2 currently live within one-half mile of at least one
3 polyvinyl plant, according to an American Public Health
4 Association survey conducted for EPA.

5 We thus calculate the lifetime cancer risk for
6 near neighbors to be about 1/500 at 1974 emission levels.
7 With a 95 percent reduction in emissions, this risk would
8 be expected to be reduced to 1/10,000.

9 The present risk would be something in between.

10 According to Dr. Marvin Schneiderman, National
11 Cancer Institute statistician who raised some hard questions
12 about a socially acceptable risk at the New York Academy's
13 vinyl chloride conference in 1974, "When people talk about
14 levels they 'can live with,' they must be reminded that
15 these could be levels that other people might die from."

16 I think what we are raising here is who is
17 setting standards and who is taking the risk, and how
18 can we get the people who are taking the risk into the
19 standard setting process?

20 I would suggest that hearings be held in Houston,
21 for one thing, and possibly in other places which are large
22 sources of vinyl chloride, so people who are taking the
23 risk can be apprized to the extent possible, so that they
24 know what the risk is, and what we don't know about the risk.

25 I think they may have some input as to whether it

Alice Rosalinda Commanu

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1 is a socially acceptable risk.

2 Dr. Schneiderman said at the conference, he
3 gave us some figures for what might be considered an
4 acceptable risk. EDF does not proscribe to Dr. Schneiderman's
5 figures, but I do introduce them, because Dr. Schneiderman
6 is an expert.

7 Dr. Schneiderman said, for example, "with
8 materials now in the environment and of substantial economic
9 importance, limiting the risk of one in a million, reducing it
10 in subsequent years to one in ten million, and then to
11 one in 100 million, may be appropriate. The setting of a
12 limiting risk level should be an open market operation."

13 Is it worth a one in 10,000 chance, which might
14 be one in 1,000,000, but might also be one in 1,000 of cancer
15 to a plant neighbor who derives no direct economic benefit
16 from the plant's operations? Is it still worth it if the
17 still-inestimable increased risks of cancer, stillbirth,
18 malformed birth, and miscarriage are attendant on the
19 prospect of having children?

20 Should the neighbors of vinyl chloride and poly-
21 vinyl chloride plants be required to accept these risks
22 in order to keep down the price of phonograph records,
23 or to provide society with substitutable products like
24 ,polyvinyl chloride beach balls?

25 The difficult problem of determining socially

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1 acceptable risks must be approached in terms of a benefit/
2 risk calculation. In our view, Congress did not intend
3 EPA to regulate hazardous air pollutants with merely the
4 best available technology. Technology is in its infancy
5 which may or may not provide the statutorily required "ample
6 margin of safety."

7 Nor did Congress expect EPA summarily to
8 close down entire industries emitting hazardous pollutants
9 without regard to the value to society of the products of
10 such industries. Thus, if a socially acceptable risk is
11 to be determined, it must be justified by the social
12 importance, that is, the benefits to society of the article
13 whose production entails that risk.

14 This view is supported by the recommendation
15 of the National Academy of Sciences in its recent study enti-
16 tled, Decision Making for Regulating Chemicals in the
17 Environment, that in cases such as vinyl chloride:

18 "Once the Government has made a reasonable
19 case that the challenged use of an existing chemical
20 created an excessive hazard to human health or to the
21 environment, the burden of producing evidence should shift
22 to the proponent of use, who must then make an appropriate
23 showing that continued use is desirable."

24 In formulating the proposed standard, however,
25 EPA appears to have lost sight of the predominant purpose

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1 of Section 112 of the Clean Air Act, which is to protect
2 public health against hazardous air pollution emissions.

3 After deciding to perform a benefit/risk calcu-
4 lation which, by definition, takes economic factors into
5 consideration, EPA appears to have accepted at face value
6 the industry's projection of the economic impact of a zero
7 emission level. Thus, EPA reaches the wholly economically-
8 based conclusion that "setting zero emission limits would
9 be neither desirable nor necessary."

10 EPA alleges that, "the purpose of the proposed
11 standard is to minimize risk to public health by establish-
12 ing an emission standard which will reduce emissions to the
13 level attainable with best available control systems."

14 But, the economic evidence offered in support
15 of the standard clearly indicates that no serious evaluation
16 of the desirability of continuing all existing uses of
17 vinyl chloride was made, and an estimated annual growth
18 rate of ten percent in the industry was apparently accepted
19 without question.

20 Certainly, any valid attempt to determine "socially
21 acceptable risk" would have to take the foregoing factors
22 into consideration.

23 EPA assumes that a worst case economic impact
24 would be experienced under a more stringent standard, and
25 that the proposed standard will minimize risks to health.

Ann. D. Sullivan, C. Sullivan

1 Neither of these assumptions is well supported in the
2 Standard Support Document.

3 In the first place, the Standard Support
4 Document includes a table of uses of polyvinyl chloride,
5 about 97 percent of the vinyl chloride produced in the
6 United States is used to make polyvinyl chloride.

7 the table lists pounds consumed for each use, and
8 remarks on substitutes available for each. EPA acknow-
9 ledges that substitutes exist for "approximately 85 percent
10 by weight" of present polyvinyl chloride uses. It is
11 clear too, that there must be substitutes for some of the
12 uses listed as having none.

13 Obviously, one of these is PVC's for credit
14 cards, and I can't imagine that this country would have
15 any shortage of credit cards if PVC was banned.

16 Substitutes have a way of coming into existence
17 quickly, as was the case when widely used asbestos insulation
18 was banned by EPA. It is noteworthy that EPA lists credit
19 cards as one of the fastest-growing markets for PVC, with an
20 annual growth of 19 percent per year and 1974 consumption
21 of 22 million pounds, 10 million kilograms.

22 In addition to EPA's table of PVC product uses
23 and replacements, an industry-sponsored report lists several
24 pages of products made from polyvinyl chloride dispersion
25 resins. These resins are most difficult to strip of residual

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1 vinyl chloride monomer, and appear to be the most polluting
2 polyvinyl chloride resins to manufacture.

3 Only one product is listed as having "no known
4 substitute," a paste used for highway bridge surface repair.
5 I am not familiar with this product, but it may be an
6 example of a product the manufacture of which might be
7 justified in terms of what good it does for society, and
8 apparently it is not a substitutable product. On the
9 other hand, it might turn out to be substitutable.

10 At first glance, the only apparent cost of
11 substitutes for PVC products appears to be an increased
12 cost for the product's users. But this cost must now be
13 measured against previously unrecognized and patently
14 unacceptable costs to workers and to community health and
15 safety.

16 Although the consumer/taxpayer pays some of the
17 costs of a disabled or deformed victim of vinyl chloride
18 toxicity requires extensive treatment and hospitalization,
19 these costs are not perceived as added costs for consuming
20 vinyl plastics.

21 More important, these costs are never assessed
22 in full to the companies that make vinyl chloride and
23 polyvinyl chloride, and to the extent that these costs
24 are not internalized, society in general and some of us
25 much more than others, subsidizes these industries and

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1 other hazardous industries.

2 Is it then reasonable to accept the toll of pre-
3 ventable disease that is associated with providing society
4 with polyvinyl chloride garden hose, disposable diapers,
5 ladies fashion boots, traffic "safety" cones, mats, toys
6 and foamed-back football fields?

7 We acknowledge that some substitutes for polyvinyl
8 chloride have received little study and may be hazardous
9 to produce. Other substitutes, such as asbestos cement
10 pipe, which is not the only substitute available for PVC
11 pipe are known to be hazardous to manufacture. In many
12 cases, however, substitutes are available which are safer
13 to make and use than PVC.

14 If, in fact, such a vast number of actual and
15 potential substitutes for PVC are available, why will
16 imposition of a more stringent emission standard necessarily
17 have such a devastating economic impact?

18 With respect to health risks, it is clear that
19 a 95 percent reduction of vinyl chloride emissions should
20 reduce the risk of adverse health effects. Whether this
21 reduction will, in fact, minimize health risks, especially
22 in the context of an industry whose every product, and whose
23 ten percent annual rate of growth EPA seems to have
24 accepted as necessary and desirable, is a wholly separate and
25 unanswered question.

1 We believe that Section 112 requires more
2 protection of public health than the proposed standard
3 will provide, especially in view of the evidence that
4 PVC products also cause adverse health effects which have
5 not yet been mentioned.

6 Clearly, the 6,500 workers in vinyl chloride
7 and polyvinyl chloride polymerization plants and about
8 350,000 works in PVC fabrication plants take substantial
9 risks from exposure to vinyl chloride. But there are others,
10 too, including 75,000 to 1000,000 meat wrappers, many of
11 whom are exposed to fumes from cutting PVC wrapping with
12 a hot wire. The fumes, mostly hydrogen chloride, have caused
13 a new disease called "meat cutter's asthma".

14 In addition, a study just published by the
15 Director of the Washington, D. C. police and firemen's clinic,
16 ascribes severe respiratory damage and possible coronary
17 damage to inhalation of fumes from burning PVC plastic
18 articles.

19 These are hazards not only to firemen, but,
20 of course, to people trapped in buildings that catch fire.

21 Over the past six years, 191 D. C. firemen
22 were injured and one was killed by hydrogen chloride gas
23 produced by the combustion of PVC. One of the authors
24 of the article, Dr. Victor Esch, said that plastic fumes
25 today outdo smoke as a fire danger. The potential danger

Anna R. Manning, Chairman

1 from fumes released by burning plastic furnishings, wiring
2 and clothing present a special fire hazard to most of
3 us in homes and places we work.

4 Finally, a new study about to be released by the
5 National Institute for Occupational Safety and Health,
6 shows an increased rate of miscarriages among wives of
7 workmen exposed to vinyl chloride. The control group,
8 which had a rate one half or one third as high, consisted
9 of the wives of rubber workers. This indicates that one
10 of the prime substitutes for PVC is less of a mutagenic
11 threat than vinyl chloride.

12 The many disbenefits of VC production continue
13 to require a vast expenditure of government resources.
14 EPA will have to devote substantial resources to enforcing
15 a national emissions standard. Air monitoring and engin-
16 eering appraisals are needed for expanding the regulations
17 to cover additional sources of VC air pollution, sludge
18 disposal sites, PVC fabrication plants, ethylene amine
19 plants and others. EPA's Office of Solid Waste Management
20 meanwhile grapples with the problem of dealing with a mount-
21 ing volume of PVC trash.

22 The United States Department of Agriculture
23 is also concerned about VC air pollution. Livestock
24 graze near some sources of VC emissions, and VC may
25 accumulate in the fat of these animals. We understand

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1 that EPA has been in contact with the Department of
2 Agriculture and the Food and Drug Administration on this
3 matter and that studies are in progress.

4 I would be very interested in knowing, if you
5 could tell me, what the update situation is about what we
6 know about vinyl chloride and livestock.

7 The Food and Drug Administration last September
8 proposed to ban all rigid PVC plastic food-contact articles,
9 and announced at that time that it was considering a ban
10 on PVC pipe for supplying drinking water. Vinyl Chloride
11 was banned as a propellant in aerosol products by EPA,
12 FDA and the Consumer Product Safety Commission. The
13 last of these agencies then had to defend its actions
14 in court when manufacturers sued.

15 I think it is getting to be a major part of the
16 Government rule-making function to defend its rules in
17 court against a challenge.

18 We challenge you in courts sometimes too, but
19 we don't have the resources to do it as often as we would
20 like.

21 CHAIRMAN DENNEY: Your challenges have not been
22 all together ineffective, I might add.

23 MR. CASTLEMAN: The U. S. Department of Labor
24 has, like EPA, had to commit a major share of its scant
25 resources to developing and enforcing a standard to protect

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1 workers from vinyl chloride. Additional resources
2 were necessary to defend the workplace standard all the way
3 to the Supreme Court. Industry unsuccessfully challenged
4 the part per million limit for 8-hour average exposure as
5 unjustifiably stringent and technologically infeasible.

6 But the burden imposed by vinyl chloride is not
7 borne by the government's understaffed regulatory agencies
8 alone. Research programs of the National Institute for
9 Occupational Safety and Health and the National Institute
10 of Environmental Health Sciences have been likewise affected.
11 Major studies will be going on for years to try and map
12 the extent of the problem and seek solutions.

13 Is there any way we can diagnose angiosarcoma
14 before a fatal tumor develops. We would like to find out
15 just what this vinyl chloride problem is.

16 Most of our health research agencies are critically
17 short of the funds and people necessary to keep up with
18 urgent research needs in areas long recognized. The appearance
19 of vinyl chloride on the scene thus diverts major resources
20 from other essential research and regulatory programs, with
21 the result that the public pays with a lot of tax dollars
22 and an unknown amount of prolonged danger from exposure to
23 other toxic substances.

24 As the foregoing discussion indicates, there is
25 much evidence which would support imposition of a more

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1 stringent emission standard for VC. This would include
2 zero emissions for substitutable uses of PVC plastics, and
3 incentives for developing substitutes for currently
4 non-substitutable uses. Not only is the alleged economic
5 impact of a stricter standard greatly overstated, but
6 the basis for concluding that application of the best
7 available technology to reduce emissions will provide the
8 ample margin of safety required by Section 112 is speculative
9 at best.

10 We emphasize that best available technology is
11 not synonymous with an ample margin of safety. If
12 ample in this case must be defined in terms of a
13 socially acceptable risk, we urge EPA to redetermine that
14 risk by giving greater weight to the very real health costs
15 involved, and by making a more objective assessment of the
16 potential economic impact which is likely to occur given
17 the availability of substitutes for PVC. The statute
18 requires no less.

19 We would like to talk a little bit about engineering
20 comments, most of which we will submit in the next three
21 weeks.

22 In Baltimore they were making a rocket fuel as
23 most of you know, which used dimethyl nitrosamine as
24 an intermediate. Dimethyl nitrosamine is one of the
25 family of carcinogens which is very much exploited. It

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1 has carcinogens, mutagens, just about every animal specie
2 that has ever been tested -- And, yet, we don't know
3 what these things do to man.

4 As we know vinyl chloride will cause cancer
5 in man, and when it was discovered that there were nitrosamines
6 the ambient air in Baltimore, the air pollution officials
7 in the City of Baltimore, brought enough pressure on the
8 plant to force its closing. This plant manufactures a rocket
9 fuel for the airports, which the Air Force describes as
10 a critical national security airport.

11 At the time the Air Force maintained there was
12 no substitute route for making this hydrogen fuel.

13 Now that this plant is going to be closed because people
14 in Baltimore just don't like the idea of taking the risks
15 of this kind, it is one part per billion, as long as they
16 can find any of them, they were advised this was an
17 acceptable risk.

18 This is apparently a pretty essential product
19 and the Air Force spent \$12 million to renovate the plant
20 and to install the best available control technology. Now
21 the National Cancer Institute is going to study another
22 way of making rocket fuel which has come along which
23 doesn't use dimethyl nitrosamines.

24 We will send in detailed engineering comments
25 on the proposed standard in the next three weeks. Obviously

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1 it will be necessary to see that plants emitting vinyl
2 chloride are stringently controlled, as the phasing out of
3 these vinyl products takes place.

4 Some of the topics we will address are, the
5 use of energy-efficient incineration to minimize VC
6 emissions from oxychlorination vents at ethylene dichloride/
7 VC plants; the use of scrubbers on such incineration
8 systems to control air emissions of hydrogen chloride;
9 monitoring and record keeping; elimination of relief
10 valve discharges to the ambient air; the need to develop
11 information on sources not included in the proposed
12 standards; and the need for a formal commitment to
13 review the standard one year after promulgation, in the
14 light of information not available in time for the
15 current rulemaking.

16 That concludes what I have to say.

17 CHAIRMAN DENNEY: Thank you very much. Before
18 I ask if any of the -- The purpose of this hearing is
19 to get information from those who testify and not to debate
20 the standard. This is also not the forum which EPA will
21 use to respond to any criticisms or questions or comments
22 on our standards. We will have to do that next year with
23 our final rulemaking, and we will do so.

24 With that in mind, I would like to start and
25 find out if any of the panelists here have any questions.

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1 Jack, do you?

2 MR. FARMER: No, I do not.

3 CHAIRMAN DENNEY: Susan?

4 MS. WYATT: Yes, I do.

5 Mr. Castleman is correct, there are some
6 substitutes for many of the PVC products, but unfortunately
7 a lot of these don't have some of the more desirable
8 characteristics of PVC.

9 For example wood and rubber used in the construc-
10 tion industry, I am concerned that industry will probably
11 develop other substitutes besides these, and I wanted
12 to ask Mr. Castleman if he knows of any existing mechanism
13 by which we can assure these substitutes developed are not
14 worse than vinyl chloride itself?

15 MR. CASTLEMAN: Well, you can set up several
16 classes of substitutes. You can set up substitutes which
17 are obviously safe, much safer to produce, and which are
18 relatively readily available.

19 I would think, for example, the use of aluminum
20 for credit cards. There are lots of things you can see
21 that can be substituted that are available. Maybe cast
22 iron for polyvinyl chloride pipe, and then there are the
23 classes of products which we are not too sure of, but it
24 now appears, for example, that at least the rubber workers
25 that we used as a control group for the vinyl workers, have

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1 less of a mutagenic risk. We can verify that they have
2 less of a carcinogenic risk, and of course, the same
3 would apply for neighbors of the plants.

4 So, I think you can set up several classes of
5 products, the ones you know that have safe substitutes
6 that are relatively readily available, and those where
7 substitutes are a little harder to bring into existence,
8 and then there are those where substitutes are questionable
9 in terms, highly questionable, or not very highly question-
10 able, in terms of manufacturing them. And, timetables
11 can be established for accomplishing all of these in an
12 attempt to minimize economic dislocations.

13 We are in a position where, I think, we have hope
14 for ourselves by depending upon over 4 million tons a year
15 for PVC Plastics. We keep digging ourselves into this
16 and we will get ourselves into a ten billion a year dependency
17 on the stuff, or we can look for a way to get around this.
18 It is not a real dependency, an apparent dependency. In
19 terms of health it is very real.

20 CHAIRMAN DENNEY: Dr. Knelson, do you have any
21 questions.

22 DR. KENLSON: Yes. I have several questions.

23 I would like to ask Mr. Castleman, in your
24 introductory comments you mentioned that cancer has reached
25 epidemic proportions in the country. To me this implies

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1 there has been a changing experience in neoplastic disease
2 occurrence, probably specific neoplastic disease.

3 Can you comment on this, your data, to substantiate
4 this?

5 MR. CASTLEMAN: We saw a brief rise of five
6 percent, but now that seems to be less than a five percent
7 rise in the subsequent data.

8 We saw a small jag in the increase of cancer
9 in the country, and it is this hard to appraise that
10 at this time. There are increasing levels of cancer
11 of certain types. There is occupational, there is lower
12 intestinal tract cancer which seems to be a matter of
13 changing diet.

14 DR. KNELSON: You were relating the change in
15 neoplastic disease experience of cancer incidence in the
16 country. I think the general industrialization process
17 in the United States. Therefore, we would expect a long-
18 term, very definite trend, relatable to this change in
19 industrialization.

20 Would you like to comment on that?

21 MR. CASTLEMAN: Certainly. The use of pesticides,
22 the wide use of pesticides like chlorinated compounds,
23 have been banned because they cause cancer. It started
24 about 20,30,40 years ago, but really took off after World
25 War II. I think we now are only beginning to see the

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1 incidence of disease that has been produced by introducing
2 these chemicals as haphazardly as we can, and scaling up
3 our production.

4 DR. KNELSON: I think it is a very good comment.
5 I would like to ask another specific question.

6 Did you say that you feel cancer is the leading
7 cause of premature death, or a leading cause?

8 MR. CASTLEMAN: I can't think of any larger
9 cause of premature death, but, of course --

10 DR. KNELSON: Can you tell us how you define
11 premature?

12 MR. CASTLEMAN: If you have a bunch of asbestos
13 workers, let's say, and I am sure some of them smoke,
14 and a lot of them get lung cancer. One out of five.
15 But, still the risk of getting cancer, even for those
16 who smoke is about ten times as high as it would be for
17 smoking alone.

18 That means one out of ten who get lung cancer
19 are dieing before their time, that is for smoking, that
20 is a premature death.

21 DR. KNELSON: You mentioned the concept of
22 no permissible level of certain environmental factors.
23 Would you like to comment on what you mean by a permissible
24 level?

25 MR. CASTLEMAN: Well, we are talking about setting

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1 a zero emission standard of the manufacture of substitutable
2 uses. For other uses, uses which like the highway paste,
3 may have some great value to society and which may not
4 be substitutable with other materials, there may be some
5 social acceptable risk for the manufacture of these things.

6 But, again, I emphasize these people who are taking
7 them should be told what is going on, and asked if it is
8 an acceptable risk.

9 In the City of Baltimore, if you take one in a
10 million as a figure to consider as an acceptable risk,
11 George Ferrary had to think about -- He is in a city of
12 one million people in Baltimore -- and he had to think of
13 whether one in a million was an acceptable risk in terms
14 of losing one of the residents of that city.

15 When you think of it in those terms, maybe it is
16 a little bit less acceptable versus when you think about
17 your chances are one in a million, which are pretty good
18 odds.

19 When you are making a decision as a public health
20 official, you are making it from the other side.

21 DR. KENLSON: We are talking about acceptable
22 risks. These are cogent comments, but I would like you to
23 comment more on your concept of zero emissions or no
24 permissible level.

25 How do you determine what is zero emission? This

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1 is a function of technology. You cannot say zero emission --

2 MR. CASTLEMAN: I know, and you can't say zero
3 risk as long as there are going to be emissions of things
4 like vinyl chloride.

5 DR. KNELSON: I wonder if you would redefine your
6 concept a little bit? What non-zero levels would you think
7 are permissible, since zero is a concept, perhaps, but it
8 is not attainable.

9 As I say, the amount of any particular constituent
10 in the atmosphere is a function of technology to measure.

11 MR. CASTLEMAN: I am not talking about a zero
12 emission level. I am talking about zero, which would be
13 accomplished by a phasing out of the industry to the extent
14 we can do it and as fast as we can do it.

15 Zero emissions in the past have also been described --
16 or zero exposure, has often been described as measured
17 by some instrument such as a part per million.

18 We are not talking about that kind of zero.

19 DR. KNELSON: One final question. You mention
20 the observation of chromosomal abnormality in plant workers.

21 Would you give us your impression of the relevance
22 of this kind of finding?

23 MR. CASTLEMAN: Well, in light of the increased
24 rates of miscarriages that were observed in the wives of
25 these workers, which is in a report which will be published

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1 this week, something that Infante is working on now, I think
2 you have a very strong reason to suspect that this material
3 is a mutagenic that causes genetic damage to persons who
4 are exposed, and that this translates itself.

5 DR. KNELSON: Is it correct to assume then that
6 you are equating the chromosomal aberrations with a mutagenic
7 ergo, future teratogenic effect?

8 MR. CASTLEMAN: Not necessarily. That is usually
9 a test for carcinogenicity I realize. I thought you were
10 talking about the fact that the workers seem to have more
11 than their share of chromosome breaks, which was observed
12 by biological tests, more of a carcinogenic test.

13 DR. KNELSON: What I was trying to get from you
14 is your concept of the relevance of these chromosomal
15 aberrations, and the relevance of this occurring to the
16 other kinds of occurrences that you mentioned, such as
17 increased screening systems.

18 I would like to have you comment on the relation-
19 ships between these bioindicators. I think the relationship
20 is a good one for discussion. One that must be scrutinized.

21 MR. CASTLEMAN: I would prefer to send in comments
22 on that later on, because the people who are most expert
23 in that are not here today.

24 CHAIRMAN DENNEY: Dr. Marcus, do you have any
25 questions?

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1 DR. MARCUS: Do you know of any evidence of the
2 increased risk in the general population, other than the
3 studies that have been done in work?

4 MR. CASTLEMAN: Aside from the fact that there
5 were apparently two neighborhood cases with no known
6 occupational exposure, no I don't.

7 DR. MARCUS: I would like to say that EPA
8 investigated very carefully those cases, and we consulted
9 with our expert doctor, Hans Popper of Mount Sinai, and
10 it was his expert opinion that these people did have
11 angiosarcoma that was of a different type than that caused
12 by vinyl chloride monomer, and I must say, to date we
13 do not have any evidence that angiosarcoma has been
14 produced by vinyl chloride monomer in the general population.

15 MR. CASTLEMAN: I think it is important to
16 realize that only about one-fourth of the present PVC
17 plants were operating 20 years ago. The latency of this
18 disease is 20 years or more, and of these ten plants,
19 at least one-fourth of the present level of plants, which
20 is about ten, the total production rate is one-tenth of the
21 rate it is today. The population may also have been thinner
22 around the plants than it is today.

23 So, if you look at the present situation in terms
24 of how many people lived near the plants of a certain
25 size, it bears little resemblance to the situation 20

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1 years ago.

2 The mortality experience that we observe today
3 started 20 years ago. I don't think the absence of
4 cases is any proof of anything. Wouldn't you agree with
5 that?

6 DR. MARCUS: In general I would say that is a
7 very cogent comment. The only thing here is that vinyl
8 chloride happens to offer us a unique opportunity to
9 see an extremely rare cancer, which we can say is maybe
10 due to the substance in question, rather than an increased
11 rate of cancer, which is a very difficult thing to assess.

12 That is why I say, I was hoping somebody would
13 have some information about VCM induced angiosarcoma in
14 the general public, because we have not been able to find
15 it as yet.

16 MR. CASTLEMAN: I talk to the same people you do.

17 CHAIRMAN DENNEY: Dr. McGaughy.

18 DR. MC GAUGHY: I just have one short question.

19 We are interested in getting as accurate a
20 picture as we can as to what the risk is to the population
21 due to vinyl chloride exposure. You mentioned there
22 were two or three factors that we have not considered.

23 Mainly the carcinogenicity of vinyl chloride and
24 other chemicals and the transplacental effects that might
25 caused to expectant mothers.

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1 I would appreciate, in your eventual comments,
2 if you could tell us, if you can, what these studies are.
3 Just inform us as to what risk these effects would have.

4 We have been trying to get evidence on this,
5 and we have had a very hard time getting a realistic
6 estimate of what these effects are. So, if you could provide
7 that, we would be very grateful.

8 MR. CASTLEMAN: I wish I could. I can provide
9 you certain information between the activity of PVC's
10 in the body and vinyl chlorides, but I think my point was,
11 it is very difficult to make these kinds of quantitative
12 estimates, and there are certain factors which -- It is
13 just impossible to know the size of when you make these
14 calculations. So, you have to qualify the calculations
15 by saying that.

16 DR. MC GAUGHY: We would appreciate, at least
17 your viewpoint on the uncertainties about this.

18 CHAIRMAN DENNEY: Dr. Kuzmack.

19 DR. KUZMACK: I have a few questions, somewhere
20 along those lines.

21 You state that the estimates of one to 20 cases
22 do not give a firm limit of the risk, which I certainly
23 agree with.

24 Elsewhere in this statement you suggest that it
25 could be, of course, ten times higher than that. That gives

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1 me some problems. It seems to me at some point if the
2 risk was sufficiently greater than what we are estimating
3 we would see a lot of cases of angiosarcoma around the
4 plants, even taking into the account the lower production
5 levels in the past.

6 Do you have any idea as to what -- At what
7 increased level you would expect to be able to demonstrate
8 the cases around the plant?

9 MR. CASTLEMAN: No, I don't. I didn't give that
10 much thought into calculating this. I just took the
11 figure of one chance in a thousand just to measure the
12 possible uncertainty if we are going to be appraising people
13 in the plants what their risk is.

14 DR. KUZMACK: You mentioned the one in 500 chance
15 of getting cancer for a near neighbor. Considering the
16 chance of getting cancer is something on the order of one
17 out of five, do you believe that an increase from one out
18 of five, to one out of 500 is a sort of increase that,
19 in fact, concerns people, that people will change where they
20 live as a result of that?

21 MR. CASTLEMAN: If you are putting it to them
22 that they are taking one chance of five hundred of dying
23 before their time, it is not just what they die of but
24 when they die.

25 DR. KUZMACK: There seems to be some conflicting

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1 evidence as to how people evaluate these risks.

2 MR. CASTLEMAN: I think the public has certain
3 difficulties comprehending hazards they can't see.

4 DR. KUZMACK: Your alternative recommendation is
5 that certain uses of vinyl chloride be phased out over
6 a time period as substitutes are available and can be
7 evaluated.

8 MR. CASTLEMAN: Yes.

9 DR. KUZMACK: Do you believe that Section 112
10 gives EPA that authority?

11 MR. CASTLEMAN: Yes.

12 DR. KUZMACK: I think it would be desirable, if
13 in your written comments, you go into a detail on that.

14 MR. CASTLEMAN: We can certainly provide that.

15 DR. KNELSON: I neglected to ask you one technical
16 question.

17 I was kind of shocked about 33 parts per million.
18 Could you give us the average time, the circumstances
19 surrounding the reflection of that sample.

20 MR. CASTLEMAN: I believe that was a one hour
21 sample. If you check the Task Force report, you can see
22 what reasoning there was. I think that was a sample for
23 one hour average in time.

24 CHAIRMAN DENNEY: Mr. Farmer, I believe you
25 have a question?

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1 MR. FARMER: Yes.

2 Mr. Castleman, I just want to make sure I
3 understood what you were basically recommending. I under-
4 stand what you are basically recommending is what we should
5 do is more or less assess the products and uses and determine
6 whether the substitutes would have less of an environmental
7 impact than vinyl chloride.

8 And, if we determined that the alternates, like
9 aluminum instead of PVC for credit cards have less of
10 an environmental impact, we should ban further use, their
11 use, and the ones we do determine are socially acceptable,
12 and there is no substitute, then the type of standard
13 we have proposed would be applicable for the production
14 of polyvinyl chloride for those kind of end products: is
15 that right?

16 MR. CASTLEMAN: That is pretty much it. It is
17 not just environmental impact. We are also talking about
18 health as well.

19 MR. FARMER: What factors would you recommend we
20 consider in evaluating the environmental impact of the
21 substitutes as compared to the environmental impact of
22 polyvinyl chloride?

23 MR. CASTLEMAN: Primarily, you are concerned with
24 the air pollution hazards?

25 MR. FARMER: We would be concerned with all factors,

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1 and that was what I was after.

2 MR. CASTLEMAN: Some of the factors you might
3 consider -- Would you consider air pollution to be something
4 that comes from the combustion of these things, because
5 if you do, you would maybe be concerned with the health
6 hazards, the final end uses.

7 It is not a simple appraisal to make. I would
8 really like to sit down with you sometime and work out
9 a little better what we think, what kinds of criteria should
10 be established. What we are looking for in ways of
11 eliminating this kind of risk people have been running,
12 living next to these plants, and perhaps taking a cancer
13 risk.

14 CHAIRMAN DENNEY: I would like to ask a couple
15 of questions.

16 One is, I would like to expand a little bit on
17 what Mr. Farmer asked you and you were just talking about.

18 It seems to me if we have learned anything from
19 the environmental movement, any dislocations are apt to have
20 unforeseeable prohibitions or unforeseeable effects.

21 To the extent you are suggesting we actually go
22 down and devote agency resources to making each polyvinyl
23 application, and then to evaluate the possible adverse
24 environmental and other consequences of each of those, I
25 am not quite sure how we would do that.

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1 If you are suggesting, and this is going to
2 be my question, are you suggesting we simply, for instance,
3 if we had it your way, should we ban this starting a year
4 from now? The reason I ask this, is the central concern
5 I have, if we say within a year, whatever time thing you
6 want to talk about, immediately switch over and say from
7 now on no more polyvinyl chloride pipes, credit cards,
8 insulation and so on, and various other uses, is it your
9 opinion if you had to make that judgement now that we
10 would be clearly better off, or we could be better off,
11 or you think there is some reasonable way we could conduct
12 studies, and all of these things to insure that we don't
13 end up with a worse problem than we have now?

14 MR. CASTELMAN: I think you would be definitely
15 better off. I think you can, again, establish classes of
16 products for which the decision is a lot easier than others.

17 Where you have some difficulty deciding whether
18 the substitute is really something you would want to go
19 with, then you could call for more information from the
20 industry by way of the usual announcements and rulemaking
21 procedures.

22 CHAIRMAN DENNEY: I am somewhat doubtful that
23 we can do that particularly, because we are constantly
24 learning new things as with vinyl chloride as we had
25 anticipated when we started out.

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1 MR. CASTLEMAN: A lot of the substitutes are
2 going to be the same thing over and over again. Once you
3 make the decision you have got a pretty good idea. When
4 you see the same substitute coming up it can be applied.

5 I don't think the job is as awesome as it might
6 look at first.

7 CHAIRMAN DENNEY: For instance, in vinyl chloride,
8 they are saying now one of the problems in regulating it
9 is that we do have limited information, that there is a
10 20 year latency in the period of cancer, that the oldest
11 plants are 40 years old and most of them are less than
12 20 years old, so we are just now finding out the hazards
13 of it. We do have some kind of idea of what those hazards
14 are. We do have some idea, certainly not a firm upper
15 limit, about the cancers we are talking about and what some
16 of the impacts are.

17 I am wondering about the wisdom of saying we
18 know there are some hazards, we think we are controlling
19 them rather tightly right now, and we could possibly
20 ratchet them down even more in the future, at this time,
21 sometime.

22 Is it not possibly wiser from an environmental
23 point of view to consider that, to take the evil we know
24 now, to figure out how much to cut it down now, before
25 we immediately cut it out wholesale in the environment and

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1 perhaps wait another 20 years to find out they are even
2 more hazardous than the vinyl chloride?

3 MR. CASTLEMAN: Your point is well taken. There
4 are obviously going to be some materials you want to be
5 careful about in not bringing it into use. But, I think
6 with a lot of these other things, many of them we have had
7 longer experience than we have had with vinyl chloride,
8 and we have a fairly good idea of what the health impacts
9 are.

10 CHAIRMAN DENNEY: Is there any lower level of
11 risk at which it would not suggest that idea that vinyl
12 chloride should be banned? I mean, considering first off
13 we would have to go through this process of finding sub-
14 stitute products -- And, the obvious dislocations and
15 hardships to workers -- Is there any level of risk, one
16 risk of cancer in 100 in the United States, is there any
17 level of risk which you would not consider a wise risk?
18 The ultimate banning of vinyl chloride.

19 MR. CASTLEMAN: We do understand that there is
20 a risk in everything, and we are not asking you to eliminate
21 risks. We are just asking you to choose among the risks
22 that are available.

23 I do not think we can speak to an exact number.
24 I point out again that Dr. Schneiderman said, that one
25 in a million was about as much risk as you should take for

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1 an existing product in wide use. Near neighbors of vinyl
2 chloride plants are taking, as near as I can guess, one
3 in 10,000, which is substantially greater. That is cancer.

4 We are now talking about these other effects
5 on the unborn. If there was an advocate for the unborn
6 who came to these hearings, I am sure he would tell you
7 to ban vinyl chloride.

8 CHAIRMAN DENNEY: Why don't we start with Dr.
9 Kuzmack and work our way back.

10 DR. KUZMACK: Just to follow up on the line
11 of questioning, I see a practical problem with this approach
12 in that a particular monomer plant does not produce for a
13 particular use. It just produces the stuff and ships it
14 to fabricators which means we cannot eliminate a particular
15 use by setting a limitation on a plant.

16 We think it would be stretching it legally to
17 say that Section 112 standard would consist of banning
18 use of PVC in credit cards and have you. Your reaction
19 to that?

20 MR. CASTLEMAN: You are not an attorney and neither
21 am I. Why don't we let the attorneys handle that question?

22 DR. KUZMACK: You also talk about an emission
23 standard for sewer, and that is a problem.

24 MR. CASTLEMAN: This is more of a legal question.
25 I am not an attorney, I don't think I can give you the most

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1 qualified answer that the Environmental Defense Fund could
2 offer you on it.

3 CHAIRMAN DENNEY: Dr. McGaughy?

4 DR. MC GAUGHY: No questions.

5 CHAIRMAN DENNEY: Dr. Marcus?

6 DR. MARCUS: Mr. Castleman, I would like you to
7 tell me what your scientific qualifications are so that
8 I may be aware of them?

9 MR. CASTLEMAN: I am a chemical engineer, and
10 I also have a Master's degree in environmental engineering
11 which I got -- I got a air pollution fellowship from HEW,
12 and I worked in air pollution control in the State of
13 Maryland, and I have also worked as a process engineer
14 in the chemical industry for a number of years.

15 DR. MARCUS: I would like to make a couple,
16 just kind of factual remarks, about the polyvinyl chloride.

17 Over the past year industry in their response
18 to our activities has reduced, to the best of my knowledge,
19 the amount of unreacted vinyl chloride monomer which we
20 know to be the problem. Not vinyl chloride per se, from
21 something in the order of 4,000 parts per million, from
22 the latest reports I have received, to below 100 parts
23 per million, and for most parts below 50 parts per million.

24 MR. CASTLEMAN: This is not the dispersion rate
25 for the others.

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1 DR. MARCUS: The fact that dispersion resins has
2 been brought up is interesting.

3 We have initiated a study to determine whether
4 there were, in fact, any dangers to the general public
5 in products from which are made, using dispersion resins.
6 And, to date, we have found to look at a large number of
7 products, and are only able to find a very little amount
8 in parts per billion in one unusual circumstance.

9 It is our best opinion now that while dispersion
10 resins would seem to be the most likely place to find a
11 problem, we indeed investigated and found none.

12 Secondly, I would like to address the area of
13 fire. The industry itself looked at it a while back and
14 actually conducted experiments, as I recall, with animals
15 using various proportions of vinyl chloride, wood and other
16 things you might find in a fire. And, came to the con-
17 clusion that while vinyl chloride perhaps offers some
18 danger in a fire, by far the greatest amount the fireman
19 finds in a home or in a business so to speak is due to
20 carbon monoxide that comes from incomplete combustion of
21 wood and wood products in that area.

22 While you make a large point of it in your presenta-
23 tion, I feel I would like you to give us, if you could,
24 a little more information on how you reach that conclusion?

25 MR. CASTLEMAN: Well, I was speaking a little bit

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1 with one of the authors of the article on the District of
2 Columbia Firemen, and I think it would be best if I sent
3 you a copy of that article.

4 This doctor is a surgeon. He found vinyl chloride
5 combustion products to be very dangerous. Whether he means
6 more dangerous than carbon monoxide, I would assume, because
7 I am assuming, that is true.

8 CHAIRMAN DENNEY: Dr. Knelson.

9 DR. KNELSON: An unrelated point I wanted to
10 respond to. You made the comment that you felt if there
11 was an advocate in the room for the unborn he would
12 certainly advise the banning of vinyl chloride production
13 in the country. Is that correct?

14 MR. CASTLEMAN: Yes, it is a correct quote, yes.

15 DR. KNELSON: It so happens I am a pediatrician,
16 and I specialize in diseases of the newborn, and it also
17 happens that I have looked very closely into the entire
18 vinyl chloride issue with real concern, and cannot, as
19 an advocate -- I believe I am an advocate for children --
20 and certainly for the unborn child, cannot advise the
21 Administrator today to ban vinyl chloride in the country
22 based on what I know.

23 CHAIRMAN DENNEY: If there are no further
24 questions? One more question, Dr. Marcus.

25 DR. MARCUS: We have gone round and round about

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1 substitute testing. My office in EPA, the Office of Toxic
2 Substances, is faced with this problem; should toxic
3 substances control legislation be passed?

4 I might say, it is not a simple question, it
5 is a very difficult one to answer, and answer both candidly
6 and correctly.

7 I would like to say that from the point of
8 view of what we know now, and that is far more than what
9 we know of other substitutes that might be proposed, I
10 think that vinyl chloride is easier to live with than
11 something that might do a better job, but then we don't
12 really have the same information or history of exposure.
13 And, to say that it is easy to test substitutes might be
14 correct, but to suggest that we so test everything that
15 might be used to rule out things like cancer and other
16 morbidity problems, is not a very inexpensive project.

17 Since we know what is going on with vinyl chloride,
18 I don't think one would like to suggest that we stop
19 an industry in which there are 3,000,000 employees
20 directly or indirectly involved and try something new.

21 MR. CASTLEMAN: If you mean indirect employees
22 which constitute most of those employees, you are talking
23 about people who, say, put plastics on automobiles, I
24 don't think we are going to stop making automobiles, or
25 that those people are going to be laid off.

Announcing Program

1 Obviously substitutes will come into existence
2 and we can get a pretty good idea of the time it would
3 take for substitutes to come into existence.
4

5 Vinyl Chloride is remarkable in the hazards it
6 poses. It is recognized by the fact that EPA has declared
7 only four hazards air pollutants since the Clean Air
8 Act was passed. There are a whole lot of things going
9 around that are as bad as vinyl chloride in the context
10 of thinking about substitution. That is a point to make.

11 CHAIRMAN DENNEY: I would like to thank you,
12 Mr. Castleman. I would like to take about a 15 minute
13 break here, in order not to violate the anti-trust laws.

14 I understand another network wants to set up.
15 I don't know where they are from. I think they are from
16 Nebraska from the logo.

17 We will meet back here. We will start again at
18 20 minutes to 11.

19 (Short recess taken)

20 CHAIRMAN DENNEY: I think we will start up now.
21 If anyone in the hall is interested in coming in, now is
22 the time to do it.

23 The next witness is Mr. Ralph Harding of the
24 Society of the Plastics Industry, and I would appreciate
25 it if the gentlemen accompanying Mr. Harding, or Mr.
Harding himself, will introduce the people accompanying him

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1 and sitting with him at the witness table.

2 Is everyone ready to go? All right, Mr. Harding,
3 would you please lead off and introduce the people with you.

4 STATEMENT OF RALPH L. HARDING, JR., PRESIDENT
5 OF THE SOCIETY OF THE PLASTICS INDUSTRY

6 MR. HARDING: Thank you, Mr. Denney.

7 Laides and gentlemen, I am Ralph Harding, Presi-
8 dent of the Society of the Plastics Industry, SPI. I am
9 accompanied by Mr. Albet J. Beveridge of the firm of
10 Ruckelshaus, Beveridge, Fairbanks and Diamond, our special
11 counsel, and Mr. Robert W. Laundrie of General Tire Company,
12 Chairman of our Technical Committee.

13 On behalf of the Society I will comment on
14 EPA's proposed Vinyl Chloride Air Emissions Standard.
15 Specifically, I will describe how the Vinyl Chloride and
16 Polyvinyl Chloride Producers Group of SPI intend to respond
17 to the proposed Standard; our reaction to the Standard;
18 and in the industry's position on methodology used by
19 EPA in developing the Standard.

20 Let me summarize our position right now. We
21 will do our best to meet the Standard. We do want to urge
22 the making of constructive changes in the proposal and will
23 do so in our written comments to be filed on February 23.

24 SPI is the trade association for the plastics
25 industry. Our 1200 member companies and 52 operating units

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1 include producers of plastics raw materials, resins,
2 modifiers, adjuvants, machinery and mold builders; and
3 the Society also includes processors and converters of the
4 resins into end products.

5 We estimate that SPI membership represents 95
6 percent of the plastics materials and machinery produced in
7 the U.S.A and about 75 percent of domestic processing
8 volume. The Society's concern with polyvinyl chloride
9 begins with the manufacture of vinyl chloride monomer,
10 VCM, and carries forward through its polymerization into
11 polyvinyl chloride, PVC, and the various conversion processes
12 to its multitude of end uses and ultimately to its
13 recycling or disposal.

14 In 1975, total pastics production is estimated
15 at 22.1 billion pounds of which polyvinyl chloride
16 accounts for 3.7 billion pounds. In the United States
17 there are 17 vinyl chloride monomer producing plants and
18 41 polymerization plants. Twenty-two companies represent-
19 ing over 99 percent of VCM and PVC capacity are active
20 members of SPI's VCM and PVC Producers Group.

21 Polyvinyl chloride is the second most widely
22 used plastics product in the United States. It is a solid,
23 produced by several different polymerization processes.
24 The sold source of PVC is vinyl chloride monomer, a gaseous
25 chemical derived from petroleum or natural gas and chlorine.

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1 Although I know the panel fully understands this,
2 I think there are some in the room that need it clearly
3 understood that VCM is a gas and PVC is the solid. The
4 plastic derived therefrom.

5 PVC is used in a vast array of industrial and
6 consumer products. While there may be substitutes for
7 many of PVC's end uses, in some areas, such as blood bags
8 and surgical/medical tubing, polyvinyl chloride is
9 indispensable. The availability of PVC has made possible
10 the advancement and development techniques which are
11 essential to modern blood technology and the treatment of
12 kidney disease.

13 The belting industry has stated that there is
14 no acceptable substitute for conveyor belting made from PVC,
15 which would affect industries that range from coal mining
16 to grain and processed food handling.

17 In other areas, PVC has become vitally important;
18 for example, in packaging uses and commercial and industrial
19 wire and cable insulation. PVC's resistance to fire, water
20 and solvents as well as its own chemical inertness have
21 made it invaluable.

22 As to other uses of PVC, it is uncertain whether
23 substitutes are available; more critically, do we not know
24 the time necessary for their development and whether they
25 possess the same valuable characteristics as PVC?

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1 Moreover, It is unknown whether potential substitutes may
2 themselves pose a threat to public health.

3 Originally it was our hope to be able to provide
4 detailed comments on the proposed Standard and the
5 accompanying Standard Support and Environmental Impact
6 Statement, The Scientific Technical Assessment Report on
7 Vinyl Chloride and Polyvinyl Chloride and the Quantitative
8 Risk Assessment for Community Exposure to Vinyl Chloride.

9 The proposed Standard was not published until
10 December 24, 1975, and the supporting documentation
11 was not available to us in time to circulate prior to the
12 week of January 5, 1976. Only then were our VCM/PVC
13 producers in a position to begin analyzing EPA's material.

14 In addition, The Quantitative Risk Assessment
15 Document is a new document which we were unaware EPA was
16 preparing and it requires substantial time and expertise
17 to offer informed comment.

18 Therefore, because of the timing of this hearing,
19 my comments will necessarily be general. We plan to submit
20 extensive written comments on the technical, legal,
21 health and economic aspects of the proposed Standard
22 before the February deadline.

23 Major areas of concern appear to be: One,
24 inclusion of small research and development facilities within
25

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1 the Standard. Two, certain reporting and recordkeeping
2 requirements, and three, especially, the absence of
3 existing technology to strip some dispersion resins to the
4 level proposed in the Standard.

5 In addition, some member companies are planning
6 to submit their own detailed comments on issues raised by
7 the Standard and the supporting documents.

8 As I stated at the outset, our VCM/PVC producers
9 will do their best to meet the stringent requirements of
10 the proposed United States Environmental Protection Agency
11 Standard for vinyl chloride. As estimated by the
12 Administrator, this will entail a cost of about \$200
13 million with an annual operating cost of \$70 million. Our
14 preliminary analysis indicates that these estimates are
15 low. Although the costs are great, our industry as a
16 matter of principle is dedicated to assuring that the public
17 health will not be jeopardized by the manufacture of vinyl
18 chloride monomer or polyvinyl chloride resin.

19 One aspect of the proposed Standard deserves
20 special comment at this point. EPA chose to regulate
21 vinyl chloride under Section 112 of the Clean Air Act.
22 This action requires emission standards for hazardous air
23 pollutants to be set at levels which in the judgment of the
24 Administrator provide an ample margin of safety to protect
25 public health. Despite the fact that no demonstrable health

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1 risk to the public who live in the vicinity of our plants
2 has been shown, the Administrator is of the opinion that
3 a safe level cannot now be conclusively determined.

4 Under these circumstances EPA has a number of
5 choices including deferring action until it has more
6 facts; banning the substance; or requiring the installation
7 of control technology to reduce vinyl chloride emissions
8 with or without reference to cost.

9 We commend the Agency for considering costs,
10 although we believe that it has not adequately weighed
11 them against the actual benefits likely to be achieved in
12 protecting the public health.

13 In considering whether to ban vinyl chloride,
14 EPA was faced with a substance that is apparently a human
15 carcinogen at high occupational exposure levels which
16 existed in some plants prior to the imposition of
17 the OSHA Standard, and a carcinogen at lower exposure levels
18 in test animals, but which has no demonstrable health
19 effect at the extremely low levels found in the ambient air.

20 In addition, polyvinyl chloride has many
21 beneficial uses and its production and further use in
22 various applications involves over two million jobs.
23 Given the absence of knowledge of any adverse health effects
24 of vinyl chloride at the very low levels found around the
25 manufacturing facilities, EPA decided that a total ban

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1 would represent a cost to society that could not be
2 justified.

3 EPA's decision to utilize a control technology
4 alternative involves a further consideration of cost.
5 The Agency has taken costs into account in setting the
6 proposed Standard only when "costs appear to be grossly
7 disproportionate to the emission reduction achieved."

8 EPA rejected a "fine balancing of costs against
9 benefits" in setting a best available control technology
10 standard.

11 As we have stated, at this point we believe that
12 in view of the lack of any demonstrable health risk at
13 the extremely low levels of vinyl chloride in the ambient
14 air, the Agency should have undertaken a more careful
15 balancing of the costs of each specific control requirement
16 against the emission reductions likely to be achieved.

17 We urge EPA to attempt this balance before
18 promulgating a final regulation in this case. We also
19 believe EPA should apply the same methodology in the
20 future when regulating substances posing problems similar
21 to vinyl chloride.

22 We want to support the proposed Standard and we
23 will offer a number of constructive suggestions regarding
24 the Standard itself, the Standard Support and Environmental
25 Impact Statement, the Scientific Technical Assessment

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1
2 Report, and the Quantitative Risk Assessment for Community
3 Exposure to Vinyl Chloride.

4 Our initial review of these documents dis-
5 closes what appear to be errors, inaccuracies and unjusti-
6 fied conclusions which should be corrected before the Stand-
7 ard is finally promulgated. These problems will be addressed
8 in our written submissions and in those of the individual
9 companies.

10 The proposed Standard becomes effective 90 days
11 after promulgation. A waiver of up to two years to
12 comply can be granted by the Administrator. In light of
13 the lead time necessary to develop additional technology,
14 to order new equipment and to have it installed and
15 demonstrated, some companies will undoubtedly require this
16 additional time in which to comply with the proposed standard.

17 SPI also takes this opportunity to commend the
18 Agency for adopting an approach which allowed an open
19 exchange of information between the technical people of the
20 Agency, the industry and other interested parties. This
21 approach to developing a standard which involves complex
22 technology is sound and we encourage its use in the future.

23 We also encourage the Agency's utilization of a
24 quantitative risk assessment analysis in determining the
25 appropriate Standard. Even though we have major difficulties

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1 in this instance with the published document, the
2 underlying concept is worthwhile.

3 The Administrator of EPA has discretion under the
4 Clean Air Act to determine which chemicals he believes
5 may be hazardous to the public health. He admits his
6 uncertainty about the potential environmental threat posed
7 by vinyl chloride and concedes that there is no demon-
8 strable health risk to the people who live near vinyl
9 chloride or polyvinyl chloride plants.

10 To fill in the gaps of our health effects knowledge,
11 we believe he has an obligation to establish a procedure
12 whereby the Agency can gather additional information.
13 We strongly urge the U. S. Environmental Protection Agency
14 to provide leadership in implementing a thorough, coordinated,
15 joint labor-management-citizen and government research
16 program to give clearer answers to continued questions
17 about the health effects of vinyl chloride including
18 whether there is a safe "threshold" level for vinyl chloride
19 in the atmosphere.

20 The problems associated with suspected carcinogens
21 with no established thresholds are simply too important
22 for each affected group to pursue its own limited goals and
23 to have the medical facts clouded by emotional claims.
24 There are important studies which we understand have been
25 undertaken by Dow Chemical Company which Dr. Perry J. Gehring

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1 will describe in some detail and we are hopeful that these
2 and similar efforts can be continued and encouraged by the
3 Government.

4 The industry has participated in preliminary
5 steps to establish a comprehensive, coordinated research
6 program. Frankly, we had hoped the Agency's response to
7 obvious research needs would have been more aggressive and
8 we hope that it will adopt the recommendation of the
9 office of Air Quality Planning and Standards and the Office
10 of Air and Waste Management on September 30, 1974, to
11 "initiate a research program to develop more definitive
12 data on the human health effects of vinyl chloride in
13 the general population and on ambient air concentrations
14 of vinyl chloride."

15 Thank you for affording the Society this opportunity
16 to appear.

17 CHAIRMAN DENNEY: Thank you, Mr. Harding.

18 Jack, do you have any questions?

19 MR. FARMER: I would just like to urge SPI in
20 submitting their detailed information, that they address the
21 question of the substitute that Mr. Castleman brought up
22 earlier.

23 I think this is an area we have not had a very
24 good handle on, and there have been a lot of discussions
25 about that. So, any information, as detailed as possible on

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1 substitutes and possible problems, or other information,
2 about substitutes for PVC, I think will be helpful to
3 us.

4 MR. HARDING: This is putting us in a somewhat
5 difficult position since I do represent all plastics, and
6 I would like to think my interest is balanced.

7 On what criteria do you want the question of
8 substitution considered, and what specifically do you ask
9 us in this connection?

10 MR. FARMER: I would not limit the substitute
11 list to merely plastics. We are talking about material
12 besides plastics, and I appreciate your position in terms
13 of representing all plastics industry, but I think it
14 would be very helpful to us to address the substitute
15 question. If we knew more about the uses of PVC's and then
16 the possible substitutes for PVC in all these end use
17 applications.

18 MR. HARDING: If you accept the promise that there
19 is always a substitute for everything, where do we go?
20 There is a substitute for everything including me
21 and thee, sir.

22 MR. FARMER: I have been hearing there are some
23 uses for PVC for which there are some substitutes.

24 CHAIRMAN DENNEY: Me and thee may not have some
25 of the adverse environmental effects.

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1 Ms. Wyatt, do you have any comment?

2 MS. WYATT: You mentioned the costs that would
3 be incurred because of the Standard. Could you tell me
4 about what percentage of those costs will be incurred
5 because of the OSHA standards?

6 MR. HARDING: No, I cannot. I think it is a
7 premature number at this point. Nor have we attempted
8 as an industry association to do more than help the
9 companies supply you with information on that score directly.
10

11 I think that they are interrelated. I do not
12 think they are ready yet to be able to ascribe which costs
13 to which standard, and there are other standards. The
14 Food and Drug matter coming up relative to the monomer
15 content in the product which is involved here.

16 MS. WYATT: I was wondering, did they not have
17 conveyor belts before PVC was produced?

18 MR. HARDING: Yes, I believe they did, but I think
19 it was demonstrated its particular worthiness in this
20 application.

21 Sure, they had metal conveyor belts, and yet
22 it has many desirable characteristics that are needed by
23 the people who make use of conveyor belts.

24 CHAIRMAN DENNEY: Dr. Knelson?

25 DR. KNELSON: Thank you. I have several questions
I would like to pose.

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1 The first fundamental one. What is your criteria
2 establishing the carcinogenic property of a compound? I
3 am prompted to ask the question by your comment in your
4 presentation here concerning the "apparent carcinogenicity"
5 of VC monomers?

6 MR. HARDING: I think our position on this
7 subject will become more clear to you when you hear what
8 Dr. Gehring has to say.

9 DR. KNELSON: Do you have any further response
10 to that question?

11 MR. HARDING: At this point I think no, because
12 his comments will bear directly upon some aspects of that.

13 DR. KNELSON: All right, I get to ask the
14 question again.

15 MR. HARDING: Perry will be happy to answer it.

16 DR. KNELSON: On page two you talk about the
17 indispensability of PVC in the blood transfusion technology,
18 blood bag, surgical/medical tubing and so forth.

19 I am not exactly ancient, but there was a time
20 we did not use this polyvinyl chloride for these things.
21 I would like to have you elaborate on this.

22 MR. HARDING: Far be it for me to tell a doctor
23 how it works, but I think that in the matter of transfusing,
24 the use of this particular type of tubing is made far
25 safer and far more effective, and in the case of blood bags,

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1 the whole blood bag system is built around the use of
2 these plastics.

3
4 DR. KNELSON: I know. The glass bottle industry
5 was built around the availability of glass.

6 I don't think that is the issues. What is so
7 special about this particular material?

8 MR. HARDING: I think that you have a tremendous
9 added factor of safety.

10 DR. KNELSON: What are these factors?

11 MR. HARDING: For one thing, the blood bags
12 don't break when you drop them, and I think that, again,
13 indispensibility is always a relative matter.

14 DR. KNELSON: What is Tygon?

15 MR. HARDING: It is a form of PVC.

16 DR. KNELSON: Teflon certainly is not?

17 MR. HARDING: No, teflon is not.

18 DR. KNELSON: What are the -- You talk about
19 the kidney disease treatment that is dependent upon PVC
20 for the artificial dialysis machines we are using.
21 What are these membranes made out of?

22 MR. HARDING: I will have to file an answer to
23 that question.

24 DR. KNELSON: I don't think they are made out
25 of PVC. The first ones were made out of cellophane.

MR. HARDING: PVC has certain characteristics

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1 that are considered for these types of applications.

2 DR. KNELSON: On page eight you say the
3 Administrator admits his uncertainty about the potential
4 and environmental threat posed by vinyl chloride.

5 I would like to comment on that. We always
6 have a certain level of uncertainty. We always wish
7 we had better data for any regulatory decisions made.
8 But, I believe the translation of this could be, admitting
9 doesn't
10 uncertainty/mean admitting no problem exists, and I do
11 not believe that is the interpretation, or that interpretation
12 can be applied.

13 MR. HARDING: It admits there is an uncertainty,
14 I think. This is why we go on to say some of the things
15 that follow.

16 DR. KNELSON: I think we could probably preface
17 every comment we make about regulatory decisions of the
18 agency with the statement there is some uncertainty.

19 MR. HARDING: This whole point made here would
20 support what follows concerning the needs.

21 DR. KNELSON: As a research administrator I
22 heartily endorse your recommendation.

23 CHAIRMAN DENNEY: Dr. Marcus.

24 DR. MARCUS: I find it interesting you find there
25 is no demonstrable health risk to the people who live near
vinyl chloride or polyvinyl chloride plants.

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1 Now, that is not such a very pat statement if
2 one listens to Drs. Wagner and Infante who seem to imply
3 that in Plainville, Ohio -- And, we have found recently
4 in the first week of December, I think it was, in Norway,
5 that there was an increased level of birth defects of
6 women who live within two to five miles of vinyl chloride
7 monomer plants. The nature of these birth defects was
8 central nervous system.

9
10 The thing I find, as the vinyl chloride coordina-
11 tor for the Agency particularly interesting was that
12 the birth defects were of the same type as those found
13 here in the United States as was found in Norway.

14 I also find that three times the expected level
15 here in the United States -- Two times the expected level
16 in Norway, is not being able to say a non-demonstrable
17 health effect.

18 I would also ask the question, why does industry
19 leave it to Government to do these kinds of studies?
20 Why hasn't industry taken the lead and looked in the
21 environment? Why must the Office of Toxic Substances
22 conduct these kinds of things in the community?

23 I feel it is part of the industrial responsibility
24 to look around the communities they work with and go
25 about and see if there is any problem, because we are
now involved in a rather expensive and difficult decision to

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1 look at communities in which vinyl chloride monomer
2 exposure would be the greatest.

3 Secondly, to define the population at risk and
4 to, thirdly, look carefully at medical help to determine
5 whether there has been any morbidity.

6 I don't think the only reason one regulates
7 is that people will get cancer or are dying in the streets.
8 I would hope that you could answer why industry has not,
9 at least you, have not looked at this?

10 MR. HARDING: I would be glad to take first --
11 I think there are four questions there.

12 I don't have, myself, the knowledge to comment
13 on the Norway study. I believe you have some -- A report
14 by CDC on the studies in Ohio where they concluded
15 differently from Dr. Infante. I believe there is also
16 another study that is being referred to, which is not
17 yet published, and we have not had the privilege of
18 seeing it as some other people have apparently, relative
19 to a study jointly conducted by industry, labor, government,
20 to further investigate the area that Infante talks about.

21 Again, by hearsay, I understand that report
22 does not come up with very alarming information, but I
23 think this is an area where both the record of this hearing
24 and the situation needs to have further information.

25 With regard to the studies you are referring to,

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1 let me just partly remind you, sir, that it was the
2 industry supported research that discovered the problem
3 in the first place.

4 Furthermore, we have proposed and there is
5 discussion underway, we have proposed that there be
6 joint industry-government-labor-public studies.

7 We are not asking the Government to pay for all
8 of it. We are being, very, sort of, if you will, restrained
9 in promoting this. We want this work to go ahead and
10 we would rather not have it be anything but joint, a joint
11 sponsorship. In today's climate, if industry were to pro-
12 pose and finance and announce these studies unilaterally,
13 today's climate makes it likely that the findings would
14 not be accepted, and we think the subject is too important
15 for a discussion of methodology, and indeed, the facts
16 covered by this study, there will always be a discussion
17 of interpretation. But, we think it is much more important
18 that we get on with the work.

19 We aren't asking the Government to do it all.
20 We are asking the Government to help see it is brought
21 about.

22 DR. MARCUS: Do you recall when you were first
23 informed about the Maltoni studies, and we were first
24 informed of the dates, to your knowledge?

25 MR. HARDING: This whole timetable, this whole

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1 chronology has been rehashed and rehashed and rehashed, in
2 and out of the press. Are you asking me when I was
3 first informed?

4 DR. MARCUS: No, when Maltoni first informed
5 industry and industry first informed EPA?

6 MR. HARDING: Maltoni, as I recall, first
7 announced that he had some rats with tumors and I hope
8 I will be allowed to correct this because I am doing this
9 from memory rather than notes. But, it was in the spring
10 I believe of 1972. Is that right, 1972?

11 A VOICE: Three.

12 MR. HARDING: Three, all right. No, a study
13 at a seminar in Italy when a number of people from both
14 industry and Government were present. That was the
15 first announcement of the subject, and nobody really took
16 it too seriously at that time. It was just a preliminary
17 finding. I am trying to work back.

18 I think it had to be in the spring of 1972.
19 But, in any case, this study had been going on. It is
20 the kind of study, as you well know, where preliminary
21 findings are not particularly valuable. It is just to
22 carry it forward.

23 He was not originally going to announce anything
24 until about 1975 on this study.

25 DR. MARCUS: I would like to say something in

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1 defense of industry which is kind of an unusual position.
2 But, it is not the position of the United States Government
3 a priority to eliminate data conclusions or studies
4 done by industry because they are done by industries.

5 I might compliment Dr. Gehring's studies, they
6 are very well done. We accept that data, and in part
7 most of the conclusions, the same is true of Haskall
8 Laboratories and other places, because done by industry does not
9 make it unacceptable to the United States Government.

10 We have now a plan in our Office in which we
11 have engaged the industry, the Society for the industry
12 and Government, and State Governments, to look at the
13 particular problems, so we can work together.

14 My question is why, when industry found out there
15 was a possible problem, didn't they initiate this kind
16 of study. And, I hope in the future should something else
17 come along that we will not have to go through the bureau-
18 cratic process to do that. It just takes us too long.

19 MR. HARDING: The industry did announce it.
20 The industry did start it. Almost all the work on vinyl
21 chloride has been financed and sponsored by industry.
22 Hindsight makes it very clear a lot of things could have
23 happened sooner. But, in terms of what was found out
24 and done about it, we moved pretty fast, and we have not
25 really tried to hide the subject either.

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1 DR. MARCUS: I never meant to imply that.

2 MR. HARDING: I know that. I think we tend to
3 agree. I think we are reaching the same point that
4 more data, more understanding is needed, and we are
5 hopeful this can be done on a cooperative, joint-basis.

6 DR. MC GAUGHEY: I would like to follow up
7 on this last point you made.

8 In your conclusion you mentioned that several
9 research studies on the health effects on the population
10 of vinyl chloride are needed, and I am wondering --
11 First of all, I would be very anxious to see detailed
12 statements of just what studies you think should be done.

13 Secondly, I was wondering whether or not
14 you think -- I would like to get your ideas on whether
15 you think these studies are necessary before we promulgate
16 the regulations.

17 In other words, how long do you think we should
18 wait to get these studies, or do you think our current
19 information is adequate to set the standards?

20 MR. HARDING: I do not think it is our intention
21 to put these studies in front of the promulgation of the
22 regulations.

23 DR. MC GAUGHEY: You do not see these as affecting--

24 MR. HARDING: I think it is a matter of getting
25 more and better information, so we all understand the

1 methodological problems in trying to answer a question
2 like that, and how would you propose going about it?

3 MR. HARDING: Again, I think this is what this
4 group is attempting to study, and in today's time with
5 the measuring techniques available, and the vaguaries
6 of the kinds of data that are being developed, we are
7 never going to get the finite absolute answer, but we
8 should get a little closer.

9 We are talking about methodology and we are
10 talking about more studies along these lines. Dr. Gehring
11 is going to talk about this.

12 Again, with the protocol, and the priorities,
13 if you will, a matter of joint development so that we
14 can in effect study your data versus our data. Not between
15 Government and industry, and get on with knowing more.

16 DR. KUZMACK: Your feeling then, the study on
17 the metabolism of the substance in the body is one of
18 the main sources of shedding light on the threshold question?

19 MR. HARDING: I do, but perhaps others are
20 going to add that there are other studies that are equally
21 valuable.

22 DR. KUZMACK: I think one of the problems we run
23 into in this sort of thing is that you start testing
24 animals at very low levels, it requires thousands and
25 thousands of animals to really get anything, and it is

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1 really questionable about the feasibility of that sort of
2 thing.

3 MR. HARDING: I agree.

4 CHAIRMAN DENNEY: Are there any other questions?

5 Dr. Knelson.

6 DR. KNELSON: We have been talking about joint
7 research by industry and Government agencies and Government
8 institutions, either conducted jointly or shared.

9 There is coming into existence in Research Park,
10 North Carolina, some research. Is SPI becoming involved
11 with this?

12 MR. HARDING: I think all the members of that
13 company are members of our organization and there is
14 liason already established. We will not be, per se, a
15 sponsor, but through our joint membership there will be
16 a close relationship, keeping in mind that most of our
17 concerns are involving the plastics industry beyond when
18 the material becomes ready for shipment.

19 There are other segments of the chemical industry
20 which have concerns primarily back into the chemical
21 process. So, yes, there is going to be --

22 There are high hopes in our whole industry about
23 the value that lies ahead from the kind of work that will
24 be done by the Chemical Institute, the Institute of Toxicology.

25 DR. KNELSON: You say that although the costs are

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1 great, the industry as a matter of principle, is dedicated
2 to health of the population and that it not be jeopardized
3 by polyvinyl chloride or polyvinyl chloride resin.

4 I am sure you would make the same statement
5 with regard to any of the products, not just PVC; is that
6 correct?

7 MR. HARDING: Sure.

8 DR. KNELSON: Would you care to comment on your
9 Society's position vis-a-vis pending toxic substance
10 legislation?

11 MR. HARDING: I am not an expert on this subject,
12 having been otherwise involved, but I would say that
13 the plastics industry recognizes a need for some control
14 being exercised in this area.

15 At the same time, we recognize a balancing need
16 not to stifle the introduction and development of new
17 materials. That some of the control being proposed are
18 extremely arduous and we think unnecessary.

19 So, we are looking for a more modern approach
20 to this.

21 CHAIRMAN DENNEY: Dr. Marcus?

22 DR. MARCUS: Would you please identify the areas
23 of 776 which you feel are far too restrictive?

24 MR. HARDING: May I comment in writing to you
25 on this, please?

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1 MR. BEVERIDGE: May I say this is far beyond the
2 bounds of these particular hearings, Dr. Denney.

3 The question was asked which particular portions of
4 the toxic substances bill Mr. Harding finds too restrictive,
5 and may I address a procedural motion, if you will, to you
6 to say it is far outside the bounds of this particular
7 hearing.

8 MR. DENNEY: Yes.

9 MR. BEVERIDGE: And, if we want to respond, we
10 will respond to it in writing.

11 MR. DENNEY: You do not have to respond to that.
12 Your views were solicited, but you are not bound to respond
13 to that. If you care to submit it, you may.

14 DR. MARCUS: I would like to explain why I asked
15 that question. It seems to me you have had a particular
16 exposure to what can happen, should a chemical be introduced
17 and then there be a very unfortunate set of circumstances
18 set into motion.

19 I was hoping to benefit by your experience with
20 your response. I will be looking forward to your written
21 response.

22 MR. HARDING: Acknowledged.

23 CHAIRMAN DENNEY: I have one question. It is
24 a tough question I think, but I would like to hear your
25 response to it.

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1 Why should a person who does not bear the direct
2 or even indirect benefits from an activity have to suffer
3 any risk from an activity?

4 MR. HARDING: That gets right to the heart of
5 the whole thing, doesn't it?

6 CHAIRMAN DENNEY: I think it does. I would
7 like to hear your response.

8 MR. HARDING: Say it again, please.

9 CHAIRMAN DENNEY: Why does a person who does not
10 derive benefit from an activity be subjected to any risk
11 from that activity? Specifically, someone who lives near
12 a vinyl chloride plant who may be subjected to a relatively
13 low risk, have to bear any risk, if he does not benefit
14 in any way from that plant?

15 MR. HARDING: We are not in a position in industry
16 today to make sure that those risks are kept at the minimum.
17 But, I think that individual has to recognize a part of
18 a society beyond the community in which he lives.

19 This cuts into the whole question of how we
20 deal with clean air and clean water and the substances that
21 are injected therein.

22 I don't think you can justify undue exposure and
23 there is a need to clean up and to protect people, but
24 I think the approach the agency is taking in vinyl chloride
25 is to minimize the risk, take it to the 95 percent below

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1 what it was, and to decide that this is a socially acceptable
2 risk.

3 I think we are engaged in that kind of discussion
4 whether we realize it or not, all day, every day, in
5 everything we do, including watching our children walk
6 off to school.

7 CHAIRMAN DENNEY: Let me say I agree. It is
8 a very central question that enters into all of our activities,
9 I want to emphasize I do not think it is unique to vinyl
10 chloride. I just wanted to get your reaction to it.

11 I might have one further question.

12 If no one else has any further questions, thank
13 you, Mr. Harding, I appreciate it and the gentlemen with
14 you.

15 Will the gentlemen from Dow Chemical please come
16 forward?

17 Hopefully there will be no technical difficulties,
18 but there are some technical complications. Some slides
19 were planned to be shown directly behind us, on us, or
20 under us. I am not sure what happened. We possibly
21 should start to see if we can get them up here, before the
22 Dow people start their presentation, and then we will
23 know whether we are going to have problems.

24 Would someone please project one slide up? Can
25 the panel members move out of the way? Is that relatively

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1 clear? Would people rather have more lights? Are you
2 satisfied with this?

3 Before we begin I would like to ask, first off,
4 approximately how much time do you anticipate you will
5 need to give your testimony, leaving questions aside?

6 MR. GEHRING: One-half hour.

7 CHAIRMAN DENNEY: All right, one-half hour for
8 Dow, and it is my understanding and I hope people here will
9 correct me if I am wrong, that Air Products and Diamond
10 Shamrock are planning to appear, but very briefly, a total
11 of five or ten minutes. Is that incorrect?

12 A VOICE: That is correct as to Air Products.

13 CHAIRMAN DENNEY: How about Diamond Shamrock?

14 A VOICE: Also correct.

15 CHAIRMAN DENNEY: What we will try to do then is
16 try to complete the hearings this morning. We should be
17 done at 12:30 at the latest, but we will try to wrap it
18 up this morning.

19 The witness for Dow, I believe is Dr. Gehring.

20 DR. GEHRING: Yes.

21 CHAIRMAN DENNEY: Would you please introduce the
22 gentlemen with you, not on the panel. Dr. Marcus wears
23 many coats.

24 STATEMENT OF P. J. GEHRING
25 DOW CHEMICAL, USA.

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1 DR. GEHRING: First of all, I am Dr. Gehring,
2 and I am the Director of the Toxicology Research Laboratory
3 of Dow Chemical. On my left is Mr. Paul Hill who is
4 an employee with the Dow Chemical Company.

5 I assume I do not have to introduce Dr. Marcus.

6 CHAIRMAN DENNEY: He shouldn't be taking a job
7 with industry.

8 DR. GEHRING: I have a slight cold, so if I am
9 not talking loud enough raise your hand and I will try
10 to conform to your desires.

11 The purpose of my testimony is to inform you of
12 studies being conducted in the Toxicology Research Labora-
13 tory of the Dow Chemical Company on the fate of vinyl chloride
14 in the body and how the results of these studies relate
15 to assessing the potential hazard of low level exposures
16 to vinyl chloride. These studies have been supported in
17 part by the Manufacturing Chemists Association as well as
18 The Dow Chemical Company.

19 The studies I will describe are referred to
20 technically as the Pharmacokinetics of Vinyl Chloride.
21 Pharmacokinetics is the study of the dynamic process involved
22 in the absorption, distribution, metabolism and elimination
23 of chemicals from the body.

24 Toxicity, including carcinogenesis, is caused
25 by the presence of a specified amount of a chemical or

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1 its degradation product in tissues and cells; and subse-
2 quently reversible or irreversible reactions of these
3 materials with cellular tissue components.

4 In essence, toxicity is a measurement of what
5 selected doses of a chemical or its degradation product
6 do to the cell, a tissue or the body. Pharmacokinetics
7 quantitates the presence of the chemical or its degradation
8 product in the cell, a tissue or the body. Knowledge
9 and consideration of both are inextricably associated in
10 utilizing the results of toxicity evaluation of high doses
11 to predict the hazard of low doses.

12 To illustrate further my point, Slide 1 shows
13 a typical dose response curve for the percent of individuals
14 in triangles in a population responding adversely in some
15 manner to selected doses of a chemical. The sigmoid curve
16 represents a response of a population described by a normal
17 or Gaussian distribution. These adverse responses are
18 discernible over only a range of doses represented by
19 the solid line because the investigator is limited by the
20 number of individuals he can include in such a study.

21 It should be emphasized that in theory the
22 tails of the sigmoid curve never reach zero on the low
23 dose side and never 100 percent on the high dose side;
24 that is, the curve approaches zero and 100 percent
25 asymptotically.

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1 The adverse effect, cancer as well as other untow-
2 ard effects, will occur in theory no matter how low the
3 dose if the population is sufficiently large. However, for
4 most adverse effects, experience leads us to conclude
5 that there is a dose below which adverse effects will not
6 occur; that is there is a threshold, because drinking two
7 one-fifths of alcohol over a short period of time would kill
8 some people, we do not conclude that one drop of alcohol
9 will kill some.

10 This is another effect I would point out, that
11 alcohol is also responsible for the production of liver
12 cancer.

13 A simplistic scenario is that for a faster runner
14 to pass a slower one, he needs to traverse one-half the
15 distance between the two, then one-half that distance and
16 so on; one mathematical theory suggests the faster runner
17 can never pass the slower.

18 However, definitive observation leads us to
19 reject that simulation. Unfortunately, such definitive
20 observations are nonexistent for carcinogenicity and I believe
21 will remain so for a long time.

22 In the case of carcinogenicity, stochastic,
23 guess work by definition, statistical projects are made from
24 the range of doses over which an increased incidence of
25 cancer can be perceived to predict what percent of individuals

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1 may respond at lower doses. The a priori assumption for
2 making such projections is that the chemical is handled
3 the same by the body as the dose decreases. If the dynamics
4 for the fate of the chemical change, such extrapolation is
5 not valid.

6 Conceptually, it is not surprising that the
7 toxicity, including carcinogenicity of a chemical is
8 expressed only after the detoxification process of the body
9 are overwhelmed. In such cases, the response of the
10 population may be more accurately described by the other two
11 dash lines in the lower left-hand corner.

12 That is, you do get a bending off of the predicted
13 dose response.

14 Having provided the above background, I will proceed
15 to describe the results of studies which show that the
16 dynamics of the fate of vinyl chloride in the body change
17 with dose and exposure levels. Initially, the motivation for
18 these studies was the results of Maltoni which suggested
19 strongly that the incidence of cancer in rats exposed to
20 50 parts per million was less than that predicted from
21 exposures to levels ranging from 250 parts per million
22 to 10,000 parts per million.

23 I would also like to indicate that this has also
24 been a particular research development of ours.

25 In the initial studies, we exposed four rats

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1 these studies, it was concluded that vinyl chloride monomer
2 is metabolized or degraded readily at low concentrations
3 and that the primary pathway for degradation is swamped at
4 concentrations exceeding 220 parts per million.

5 Another objective means of demonstrating that
6 the pathway for the metabolism or degradation of chemicals
7 may be overwhelmed is to administer potential inhibitors
8 of its metabolism.

9 The next slide, Slide 4, shows that the adminis-
10 tration of 5ml/kg 95 percent ethanol inhibits profoundly
11 the metabolism of vinyl chloride monomer by rats exposed to
12 an initial concentration of 50 parts per million ethanol
13 but not of rats exposed to approximately 1,000 parts per
14 million.

15 In other words, here we have an inhibitor which
16 has a profound effect on one pathway and a less dramatic
17 effect on another pathway.

18 In other studies, we found that SKF-525A inhibited
19 by approximately 20 percent the metabolism of VCM by rats
20 exposed to initial concentrations of approximately 1,000
21 parts per million, but caused no inhibition in rats exposed
22 to initial concentrations of less than 100 parts per million.

23 Again, indicating there is a divergence of pathways,
24 two different pathways involved.

25 The results of these studies led to the conclusion

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7 that VCM must be metabolized by at least two different
8 pathways. The primary pathway for metabolism is overwhelmed
9 as the exposure concentration is increased until at concentra-
10 tion exceeding 220 parts per million, the secondary pathway
11 predominates.

12 Slide 5 illustrates my point. It is in somewhat
13 a more simplistic fashion. In this slide is shown a barrel
14 with two slits in it and the amount of material coming into
15 the barrel increased as you go from A to B to C to D, and
16 of course, at some point it is just dripping in. The one
17 slit will handle the elimination of the material, but if you
18 increase this to very large levels the capacity of this
19 slit is overwhelmed and it begins to flow out of the other
20 slit in the barrel.

21 So, basically, we are interested in what is the
22 relationship of these two slits to the toxicity and perhaps
23 carcinogenicity of vinyl chloride.

24 In subsequent studies, we were fortunate to have
25 radioactively tagged Carbon 14 to follow the fate of VCM.
This facilitated greatly following the disposition of the
administered VCM.

Slide 6 shows the percent of C-14 activity
eliminated via various routes following different single-oral
doses of VCM in corn oil to rats. The C-14 activity expired
consisted of $^{14}\text{CO}_2$ and $^{14}\text{C-VCM}$. The C-14 activity found in
urine, feces and carcass and tissues represents nonvolatile

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1 metabolites of VCM.

2 The key item to notice in this slide is that the
3 dose is increased from 0.05 and 0.10 mg/kg to 20 and 100
4 mg/kg, the percent expired as VCM increases markedly while the
5 other parameters, particularly urinary excretion of the C-14
6 activity, correspondingly decrease.

7 Again, this demonstrates that the primary
8 route for the elimination of vinyl chloride from the body is
9 dose depending; that is, the primary route is overwhelmed
10 and more begins to spill out via other routes, the upper slit
11 in the barrel.

12 Since urinary and pulmonary excretion of vinyl
13 chloride was dramatically altered as the dose increased from
14 one to 100 mg/kg, the question is raised whether these processes
15 of elimination may be a function of dose. This question
16 can be examined via elucidating the rates of elimination.

17 Slide 7 shows a plot of the logarithm of the
18 C-14 activity eliminated via the urine as a function of
19 time. Since the slopes or rates of elimination are unchanged,
20 it must be concluded that urinary excretion of nonvolatile
21 metabolites of VCM is unaltered by dose.

22 Slide 8 shows similarly the expiration of vinyl
23 chloride per se following various doses. Elimination follow-
24 ing 0.05 or one mg/kg occurred in accordance with a first-order
25 rate of mono-exponential process.

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1 When 100 mg/kg was given the elimination was
2 biexponential. The rates or $t_{1/2}$ time for elimination are
3 indicated in the figure; those correspond to those reported
4 for blood by Withey, the Canadian Food and Drug.

5 These results are indicative of a material which
6 is bound reversibly to some site in the body having a finite
7 capacity. As the dose increases, the availability of these
8 binding sites decreases and the chemical is free to find
9 its way to other sites as well or to be eliminated.

10 Thus, it may be concluded that the expiration of vinyl
11 chloride monomer following different doses indicates that
12 the pulmonary excretion of vinyl chloride monomer is not
13 a rate limiting step. Even more important, the data indicate
14 that the state in which vinyl chloride monomer exists in
15 the body changes with dose.

16 Slide 9 summarizes the dose-dependant excretion
17 of vinyl chloride via urinary excretion, solid line, and
18 pulmonary elimination, broken line.

19 The area demarcated by the rectangle represents
20 that range of doses over which distributive or metabolic
21 saturation occurs. It is noteworthy that in ongoing
22 carcinogenicity studies, Maltoni has reported an angiosarcoma
23 of the thymus in a rat given 50 mg/kg per day and one of the
24 liver in a rat given 16.6 mg/kg per day. No tumors have,
25 as yet, occurred in rats given 3.3 mg/kg per day.

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1 Although the data collected from studies in rats
2 given oral doses of vinyl chloride elucidate the dose-
3 dependent fate of vinyl chloride, these hearings are
4 more concerned with inhalation exposure.

5 Slide 10 depicts the fate of C-14 vinyl chloride
6 in rats exposed for six to ten hours or 1,000 parts per
7 million. Immediately following the exposure, the rats
8 were placed in cages providing for collection of C-14
9 activity in the expired air, feces and urine over the
10 subsequent 72 hours as can be seen. As in the experiments
11 in which oral doses were given, the presence of C-14 activity
12 expired as VCM increased as the exposure increased.

13 Also to be noted in this slide is that the percent
14 of C-14 activity found in the tissues and carcass increases
15 slightly as the exposure is increased from ten to 1,000
16 parts per million, although not statistically significant,
17 if you look at carcass and tissues, you can see the percent
18 increase from 13.8 to 13.48 percent.

19 I would not request that anyone attach a great
20 deal of significance to this, except this is a rather
21 remarkable finding, because a much larger fraction of the
22 vinyl chloride was expired as vinyl chloride per se.
23 So it is not normalized for the actual amount.

24 This may mean that a larger fraction is being
25 bound to the macromolecules of tissues. This aspect is being

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1 investigate currently since such reactivity may explain
2 carcinogenesis.

3 The two subsequent slides show the elimination of
4 C-14 nonvolatile metabolites in the urine and vinyl chloride
5 monomer per se in the expired air. This is the elimination
6 in the urine. You can see again these processes go on
7 about the same rate regardless of exposure, and this is
8 the expiration of vinyl chloride in the air.

9 Again, these results support the conclusions of
10 previous studies, one, that the fate of vinyl chloride
11 monomers changes with dose and, two, that this occurs because
12 the primary pathway for the metabolism of vinyl chloride
13 monomer is saturated at high doses or exposures.

14 Since the metabolism of vinyl chloride monomer
15 appears to occur via, at least, two saturable pathways,
16 a considerable effort has been made to elucidate the
17 metabolites of vinyl chloride.

18 Already it has been demonstrated that a measurable
19 amount of vinyl chloride was metabolised to the end-product
20 of mammalian metabolism, that is, carbon dioxide.

21 Using high pressure liquid chromatography, three
22 major metabolites have been isolated from urine. Two of
23 the three have been identified by gas chromatography-mass
24 spectroscopy. These are shown in Slide 13.

25 Metabolite A is N-acetyl-S (2' hydroxyethyl)

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1 cysteine. Metabolite B is thiodiglycolic acid. Together
2 these metabolites comprise 50 to 60 percent of the
3 radioactivity found in urine. Both of these metabolites
4 are likely formed from the compound shown at the bottom,
5 2-hydroxyethylcysteine.

6 At one point in time, it appeared that the third
7 major, metabolite in urine, comprising about 30 percent
8 of the radioactivity, was this compound, shown at the bottom.
9 Even though some analytical comparisons between the
10 isolated metabolite and 2-hydroxyethylcysteine favored this
11 conclusion, others failed to establish identity.

12 Another way of saying this is that we conducted
13 one to many experiments.

14 The finding of these metabolites of vinyl chloride
15 in the urine indicates that vinyl chloridemonomer is
16 transformed in the body to a reactive intermediate metabolite.
17 This reactive metabolite is detoxified by reaction with
18 glutathione, a tripeptide containing glutamic acid and
19 glycine as well as cysteine.

20 Subsequently, the glutamic acid and glycine moieties
21 of the tripeptide are cleaved and the cysteine conjugate
22 of the reactive metabolite of vinyl chloride is either
23 acetylated or further oxidized and excreted as the
24 aforementioned metabolites.

25 Before leaving the subject of metabolism, it is

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1 important to state that the metabolites of VCM were not
2 changed either qualitatively or quantitatively as the dose
3 or exposure level was increased.

4 Since evidence has been presented showing that
5 there are at least two pathways for the metabolism of
6 vinyl chloride monomer, this indicates that both pathways
7 produce reactive metabolites leading to the same end
8 products. Our initial work and subsequently that
9 of others, and I refer to that in the document by Kappus
10 et al, 1975; Bolt et al, 1975 and Barbin et al, 1974, which
11 indicates that one pathway involves oxidation of vinyl
12 chloride monomer by microsomal enzymes to chloroethylene
13 oxide. The other pathway, yet to be identified, is, we
14 feel, the primary pathway at low doses or exposure levels;
15 it is blocked by administration of ethanol and is very likely
16 located in the soluble fraction of the cell.

17 Reactive intermediates produced by the latter
18 pathway are less likely to induce toxicity or cancer because
19 critical macromolecules--protein, DNA, RNA -- are less
20 proximate to the site of their formation. This concept
21 however, I concede is speculation at this time.

22 Now, I want to return to a subject which is
23 less speculative. As I indicated previously, the reactive
24 metabolites of vinyl chloride monomer are detoxified by
25 reaction with glutathione. This is very important because

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1 it has been demonstrated that when high doses of some
2 chemicals, for example bromobenzene and acetaminophen are
3 given the glutathione is used up at a faster rate than it
4 can be produced by conjugation with the reactive intermediates.

5 As the level of glutathione in the liver is
6 progressively depleted, the reactive metabolites react with
7 macromolecules such as protein, DNA, RNA, leading to
8 toxicity, Gillatte, 1974a and 1974 b, two articles. Generally,
9 it is accepted that at least one mechanism for chemical
10 carcinogenesis occurs via such reactions.

11 To assess the effect exposures to vinyl chloride
12 may have on hepatic glutathione levels, rats were exposed
13 to concentration of 10, 50, 150, 250, 1,000 or 2,000 parts
14 per million for durations of one to seven hours. The results
15 are shown in Slide 14.

16 Exposure to 150, 250, 1,000 or 2,000 parts per million
17 vinyl chloride monomer caused a progressive depression of
18 the hepatic nonprotein sulfhydryl content; the hepatic
19 nonprotein sulfhydryl content is primarily glutathione.

20 Exposure to 50 parts per million for seven hours
21 produced a small and inconsistent depression. There was
22 a considerable variability because we showed the number
23 of rats in this concentration and some showed it and some
24 didn't.

25 No depression was observed in rats exposed to ten

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1 parts per million vinyl chloride monomer. These
2 results indicate there is a measurable biological threshold
3 for the depression of hepatic glutathione levels induced
4 by exposures to vinyl chloride. Unequivocal depressions are
5 produced by concentrations exceeding 50 parts per million,
6 while exposure to 50 parts per million seem to be a transi-
7 tion zone and exposure to ten parts per million causes no
8 depression.

9 How do these results relate to the carcinogenicity
10 of vinyl chloride? In the studies of Maltoni and Lafemine,
11 1975, the reported incidence of angiosarcoma of the liver
12 in rats exposed four hours a day, five days a week to 2,500
13 or 6,000 parts per million was 22 percent. The incidence
14 in rats exposed to 500 and 250 parts per million were,
15 respectively, 12 and seven percent. Reference to the
16 figure indicates that the depression of the hepatic non-
17 protein sulfhydryl content observed after four hours of
18 exposure coincides with the increased incidence of
19 angiosarcoma.

20 In the study of Maltoni and Lefemine, 1975, an
21 incidence of two percent angiosarcoma of the liver
22 occurred in rats exposed to 50 parts per million vinyl
23 chloride monomer. As I indicated previously exposure to
24 50 parts per million for seven hours caused a small and
25 inconsistent depression of the hepatic nonprotein sulfhydryl

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1 content.

2 I also indicated that this exposure appeared to
3 be in the transition zone of the threshold for this bio-
4 logical effect. In a recent publication by Maltoni, Ambio,
5 Volume 5, 1975, not only the incidences of angiosarcomas of
6 the liver were given but also the latency periods for their
7 development were provided. The latency periods were 64,
8 70, 78, 81 and 79 weeks in rats exposed to 10,000, 6,000,
9 2,500, 500 and 250 parts per million respectively.

10 So, you can see, they are pretty much the same.
11 The latency period was the same regardless of exposure
12 level.

13 However, in rats exposed to 50 parts per million,
14 the latency period was 135 weeks. Indeed, tumors were
15 discovered in these aged rats when they were killed at the
16 end of the study. Since the tumors in the former groups
17 of rats were discovered as they died spontaneously, the
18 discrepancy is even greater than the values indicate.

19 the latencies for the development of other types
20 of tumors showed the same discrepancies. Consideration of
21 these results leads me to conclude that in rats exposure to
22 50 parts per million vinyl chloride monomer four hours a
23 day is in the threshold transition zone for not only
24 hepatic nonprotein free sulfhydryl depression but for tumor
25 induction as well.

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1 In summarizing the studies on the pharmacokinetics
2 and metabolism of vinyl chloride, the data indicate that
3 the fate of vinyl chloride in rats is a dose-dependent
4 process following either single oral administration
5 and after inhalation exposure. More importantly, it appears
6 from the data available that a correlation exists between
7 doses of vinyl chloride monomer that cause tumors and those
8 that saturate metabolic or detoxifying pathways.

9 The primary detoxification pathway for vinyl
10 chloride which appears saturable at high dose levels,
11 involves conjugation of its reactive metabolites with
12 nonprotein sulfhydryl groups. Therefore, it seems reasonable
13 to postulate that as the nonprotein sulfhydryl groups are
14 depleted, reactive metabolites may be free to react with
15 other macromolecules DNA, RNA, Protein, lipids, resulting
16 in toxicity and carcinogenicity.

17 Recent reports have demonstrated that in the presence
18 of fortified microsomal enzyme preparations reactive metabolites
19 of vinyl chloride monomer are produced which covalently
20 bind to rat liver microsomes protein sulfhydryl groups,
21 RNA and adenosine of DNA.

22 Inclusion of glutathione in the system will
23 decrease or preclude these reactions depending on the
24 concentration. It is highly significant that exposure to
25 ten parts per million vinyl chloride for seven hours caused

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1 no depression of hepatic nonprotein sulfhydryl content.

2 This indicates that there is a threshold of exposure
3 in rats where the ability to replace sulfhydryl groups
4 is not overwhelmed and physiologic defense mechanisms
5 remain fully operative. Furthermore, this suggests
6 that thresholds exist for toxic effects which are expressed
7 with greater intensity as this protective mechanism is
8 depressed. Studies currently in progress are designed to
9 characterize the macromolecular binding of vinyl chloride
10 monomer to protein and Nucleic acids following exposure
11 to various concentrations of 14 C-vinyl chloride monomer.

12 Finally, I want to reemphasize strongly that stochastic
13 statistical projections utilizing data collected from
14 rats exposed to concentrations exceeding 100 parts per
15 million are invalid for predicting the hazard of lower
16 levels exposures. Such projections violate the a priori
17 assumption that the dynamics governing the fate of the
18 compound are unaltered.

19 Our pharmacokinetic studies on the fate of
20 vinyl chloride monomer show that the dynamics for its
21 disposition change as the dose or exposure level is increased.
22 Also demonstrated was a threshold for the depression of
23 hepatic glutathione.

24 Finally, the discrepancy between the latent
25 period for tumor development in rats exposed to 50 parts

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1 per million vinyl chloride and the latent periods for
2 those exposed to higher levels indicates a threshold for
3 tumor development exists.

4 Thank you.

5 CHAIRMAN DENNEY: Thank you. I was saying many
6 of the same things to my wife this morning.

7 (Laughter)

8 CHAIRMAN DENNEY: Have you any questions of
9 Dr. Gehring?

10 Mr. Farmer, do you have any questions?

11 MR. FARMER: No.

12 CHAIRMAN DENNEY: Ms. Wyatt?

13 MS. WYATT: No.

14 CHAIRMAN DENNEY: Dr. Knelson.

15 DR. KNELSON: Were you the one that I get to
16 ask what the criteria for carcinogens are?

17 DR. GHERING: I guess I am the one you are going
18 to ask that of.

19 I think these are under much debate, as you know.
20 I feel that I have very little -- Well, the criteria are
21 whether an agent administered to an animal or an individual
22 will cause cancer. Simply that is it.

23 Now, that defines, for me at least, the potential
24 to produce cancer with that particular given dose. That
25

1 does not indicate that lower doses will have the same
2 sort of activity.

3 DR. KNELSON: That is a very simplistic definition
4 of carcinogenises. So, let's get into the meat of it
5 very quickly, and in the interest of time I will ask
6 a few pointed questions.

7 You made a great -- Admitted a lot of the varying
8 latent period with varying doses in these studies. At the
9 lowest level it took a long time, a long latent level.
10 At the higher dosage there wasn't much latent period.
11 Did that surprise you?

12 DR. GEHRING: No, it does not.

13 What did surprise me though, there is something
14 that did surprise me, and I tried to point that out and
15 I will reemphasize it again.

16 The fact that the dose levels of 200, 5,500, 6,000,
17 10,000 and so on had latent periods which were identical.
18 There would be no differences in the latency periods,
19 whereas this one was quite different. So, that really
20 indicates to me at least, that the mechanism is changing
21 dramatically, and to make projections to me, one should
22 utilize -- One cannot throw out the high dose data. You
23 should use all of the data, and I think one of the most
24 valuable projections at this point in time is using that
25 data and finding out what the deviation at the lower levels

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1 means.

2 DR. KNELSON: All right. Now, at the low dose
3 level there is a long latent period. What were the tumors
4 that were discovered in the mice?

5 DR. GEHRING: These were rats.

6 DR. KNELSON: The rodents. When they died finally,
7 and were autopsied?

8 DR. GEHRING: One had an angiosarcoma of the liver,
9 and one had an ephoblastoma (Ph.)

10 DR. KNELSON: Do you think that tumors that
11 occur spontaneously in an experimental animal, when that
12 spontaneous occurrence is speeded up, does that constitute
13 in other words; earlier induction of an otherwise spontaneously
14 occurring tumor? Does this constitute carcinogenises?

15 DR. GEHRING: That one is a very difficult one to
16 answer obviously, because you could be potentiating the
17 effects, latent effects, of viruses in laboratory animals.

18 DR. KNELSON: I am just asking you whether you
19 think that is a valid test for carcinogenises?

20 DR. GEHRING: Yes, I think it is something for
21 you to look at, definitely.

22 DR. KNELSON: You would just as soon put off getting
23 a tumor, wouldn't you?

24 DR. GEHRING: Yes, of course, but again, I emphasize
25 that in the case of rodents, and I think this has very

1 little to do -- I am not questioning the angiosarcoma
2 production in these rodents, or the fact that it was produced
3 by vinyl chloride, but to keep the issue open, I think the
4 speeding up of tumors -- For example, let me point this
5 out. If you reduce the dietary intake of rodents you
6 tremendously delay by one-third, you tremendously delay,
7 the reduction of spontaneous tumors induction.

8 Does this tell us we eat too much and ought to
9 reduce our dietary intake by one-third?

10 DR. KNELSON: I assume the controlled and VC
11 dose rats had the same diet?

12 DR. GEHRING: I am not questioning the data that
13 have been gathered in this study. I am just saying --
14 I was responding to your question of what I feel.

15 DR. KNELSON: Do you think transformation of a
16 benign tumor into a malignant tumor is related to an
17 environmental fact constitutes carcinogenesis?

18 DR. GEHRING: I would say yes.

19 CHAIRMAN DENNEY: Dr. Marcus.

20 DR. MARCUS: A very interesting paper.

21 I would like to ask just a few simple questions.
22 Do you think that exposure of animals to 24 hours a day,
23 seven days a week, would change what you see in terms of
24 glutathione content in the liver -- Let's say the vinyl
25 chloride?

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1 DR. GEHRING: That is a very difficult question
2 to answer. I do not, from the data we have, for example,
3 you can see that seven hours exposure at the one dose level
4 ten parts per million, did not preclude replacement of
5 the glutathione level.

6 I assume the time sequence there is one that
7 is a very difficult one -- Well, it is not difficult to
8 estimate, we just haven't done it.

9 DR. MARCUS: Do you think that --

10 DR. GEHRING: It changes spontaneously incidentally.
11 You are looking at a running target so to speak.

12 DR. MARCUS: What animals were exposed to vinyl
13 chloride, let's say, and not fed, starved, would they have
14 a higher induction rate of tumors than those who are
15 well fed?

16 DR. GEHRING: I would expect yes. If what I feel
17 is the case, that glutathione is the detoxifying, the
18 length of detoxification, that not feeding the individual
19 or lowering the glutathione content by various means would
20 increase susceptibility.

21 DR. MARCUS: So, vinyl chloride monomer at low
22 doses made the animals somewhat sick, and they do not eat,
23 and their susceptibility increases?

24 DR. GEHRING: I would say that would be the case,
25 but when you say low doses, I would like to have that

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1 quantitated.

2 DR. MARCUS: Below 50 parts per million, for argu-
3 ments sake.

4 DR. GEHRING: I would question whether that dose
5 level makes them sick.

6 DR. MARCUS: I was getting to the human case in
7 which you have a person who might be more than just a
8 moderate drinker of alcohol. Would that have any effect
9 on the glutathione content level?

10 DR. GEHRING: I believe it would.

11 DR. MARCUS: Would that person then be at a greater
12 risk than you and I?

13 DR. GEHRING: I believe that is the case.

14 In fact, Dr. Selikoff -- I certainly fall into that
15 category -- but at any rate, Dr. Selikoff has publicly said
16 that there appears to be an increased level of angiosarcoma
17 in people who imbibe more than the normal population.

18 DR. MARCUS: I think that study has not been
19 published, but Lillis is involved.

20 DR. GEHRING: He made the statement publicly.

21 But, again, those were high level exposures. They
22 were not these exposures that we are talking about, or
23 addressing our attention to.

24 DR. MARCUS: What I am trying to point out specifically,
25 studies of this nature are important, but I would like to know

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1 what you think about exposing animals, let's say, in utero,
2 suppose somebody lives near a vinyl chloride plant and
3 there is one part per million of vinyl chloride in the air,
4 or maybe less, or more maybe, and the lady is pregnant
5 and the child grows up in that atmosphere. Do you think
6 he is a greater risk than an exposed child?

7 DR. GEHRING: I do not think he is. That is the
8 answer to your question. I don't think that he is.

9 DR. MARCUS: I do not remember what the glutathione
10 content in the liver was --

11 DR. GEHRING: I think there is more to it than that.
12 You are assuming the metabolic capacity of the mother to
13 handle this material is not predominating. Right now we
14 do not have data on the transplacental transfer of vinyl
15 chloride.

16 Whether any gets there? I am sure some does, a
17 few molecules. But, how much this is?

18 One thing I have not related here, but it is known
19 we have conducted in our laboratories studies on the --
20 in rodents again -- actually rabbits, rats and mice on vinyl
21 chloride. The effect on the embryo and fetal development,
22 and these will be reported and submitted to you, but there
23 were no effects.

24 Now, insofar as carcinogenicity, I believe Dr. Maltoni
25 has some studies and the results are not completed at this
time.

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1 DR. MARCUS: I am trying to get at the difficult
2 question of 24-hour exposure. Has Dow done any studies
3 in the carcinogenic area below the 50 parts per million
4 over the two years that Maltoni is talking about?

5 DR. GEHRING: The answer is no.

6 DR. MARCUS: Can you tell us why he did not initiate
7 that?

8 DR. GEHRING: I can tell you why we didn't. We
9 had other materials in the chambers at the time. It was
10 a matter of assessing priorities for a particular material.

11 More importantly, we did not know what studies
12 to initiate. We wanted to get some parameters to decide
13 studies that would give us answers. To just pile in
14 a bunch of animals at just less than 50 parts per million,
15 would be an absolute exercise in futility.

16 You cannot do it statistically unless you understand
17 what the basics are that are going to allow you to interpret
18 such data when you get it. It is a moot point.

19 We really do not have -- I have some ideas now what
20 types of studies could be instituted to provide that
21 final link to cancer, but that has only been gleaned
22 through what we have done.

23 DR. MARCUS: That was precisely what I was trying
24 to get at. Now that we have this kind of information, when
25 do you think using that particular design -- When do you

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1 expect it to be controlled?

2 DR. GEHRING: This is again a guesstimation, I
3 grant you. If our data are correct I feel that none would
4 be seen at ten, and I may be wrong.

5 DR. MARCUS: I just found it interesting, the
6 question I am trying to ask you is Maltoni only went down
7 to 50, and I don't know why.

8 DR. GEHRING: He has subsequently gone down more,
9 because in retrospect he would have loved to have gone
10 down lower.

11 DR. KNELSON: One think I have to say, don't forget
12 about the big number problem. We keep talking about the dose
13 rates and the latency periods, and we are talking about
14 risk rates of one in a million. So, we have got to use
15 extrapolations, unless you are prepared to set megamillions
16 experiments.

17 DR. GEHRING: I am not suggesting that at all.

18 DR. KNELSON: I want to inject this note of caution
19 into the discussion here, because we put ten rats in a
20 cage at ten parts per million for their lifetime, and you
21 don't see any angiosarcoma. You and I know it does not
22 mean --

23 DR. GEHRING: Absolutely. May I respond to that
24 one thing.

25 Unfortunately, neglected in assessing the risk of

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1 vinyl chloride to workers is the fact that, I believe, in
2 every case of angiosarcoma there were other signs or
3 other disease states present.

4 We have also, in our studies at Dow which have
5 been published, have examined the liver function of workers
6 and found that one of the most sensitive parameters was the
7 clearance and an aggression analysis was done on this.

8 I think the animal studies have been, in Maltoni's
9 case, I feel leave that point unanswered. What was the state
10 of the animal otherwise? Was there other concurrent or
11 concomitant disease states? This is tremendously valuable
12 in estimating risks of a particular disease, that is,
13 cancer, and I don't know where it lies right now.

14 Does it represent the most sensitive parameter
15 or does it fall to the right of the dosage required to cause
16 other disease states?

17 DR. KNELSON: Are you saying that you think vinyl
18 chloride monomer is related to a variety of tumors, a
19 variety of neoplasms, not just cancer of the liver?

20 DR. GEHRING: I think your document will show that.

21 DR. KNELSON: And, other diseases in addition?

22 DR. GEHRING: As you well know, scleroderma,
23 juvenile sclerosis.

24 DR. KNELSON: I want that in the record.

25 Do you think that cancer is a multi-factorial disease

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1 or do you think it is a single bullet, single target?

2 DR. GEHRING: I think it is multi-factorial.

3 DR. KNELSON: So, you must place chemical carcino-
4 genises along with all of the other factors that may be
5 related to the induction of cancer in people?

6 DR. GEHRING: Yes.

7 CHAIRMAN DENNEY: I would like to request Dr. Marcus
8 and other people who have questions, because of the time,
9 if possible to try to keep them to a minimum, or to
10 request that the answer be submitted in writing.

11 I also think the issues are highly technical.
12 We don't have a simultaneous translator. I have just
13 learned angiosarcoma and I am still practicing carcinogenicity.
14 so I think the technical answers will have to be answered,
15 but in writing.

16 DR. MARCUS: One short question, non-technical.

17 In your report you mentioned there were two pathways.
18 Is it your professional opinion that one pathway shuts off
19 and turns on, or do they operate simultaneously?

20 DR. GEHRING: I think the lower pathway, and the
21 primary pathway for metabolism, we feel is in the soluble
22 portion of the cell. We do not feel at this time it is
23 related to microsomal metabolism, and this one predominates
24 at lower exposure levels, whereas, we know and it is
25 better established that the microsomal oxidation of vinyl

1 chloride, very likely the chlorethylene oxide is another
2 pathway. This one appears to be much lower, and when
3 you say "shuts off", obviously there are always going to
4 be a few molecules that get through.

5 Enzymes, even though one is much faster than the
6 other, the other enzyme is still going to get a few molecules
7 through. So, when you say complete shut down, that is
8 a different thing than I am implying by a threshold.

9 I am implying great changes in rate, and in the
10 degree of importance of that particular enzyme.

11 CHAIRMAN DENNEY: Dr. McGaughy.

12 DR. MC GAUGHY: I have a question about your
13 attitude towards these studies as they relate to what is
14 standard.

15 There are several chemicals which have been known
16 to be protected by glutathione in the body, and probably
17 there are other chemicals that do not act by that mechanism,
18 although I cannot reel off a list of them and which
19 category.

20 Suppose, I do not know what the situation is at
21 Dow, but suppose you were responsible for the health of the
22 Dow workers, and suppose you were screening a bunch of
23 substances. If you found a substance that reacts like
24 this where glutathione acts as a protection, if you were
25 confronted with a substance like this, would you feel much

1 safer in recommending exposure to the workers than with
2 another substance that did not show this protecting mechanism?

3 In other words, how does this relate to your
4 occupational standards? I was wondering how you would trans-
5 fer this break point into metabolic conversion at 220 parts
6 per million?

7 I wonder if you can transfer that into any kind
8 of standards for the workers?

9 DR. GEMRING: The metabolic break point in one case, I
10 said it was above 100 from the pharmacokinetics analysis.
11 From the standpoint of the glutathione levels, somewhere
12 around 50.

13 How do you transform this to your workers? That
14 is very difficult. One of the difficulties, I think, and
15 one of the things that has not been considered adequately
16 is that the people, at least, appear to be less susceptible
17 than do some of the rodents species to vinyl chloride,
18 and there could be much argument on this, but, for example,
19 exposure to mice to 500 parts per million of vinyl chloride
20 causes death in a considerable fraction of them.

21 So, if, obviously, rodents are not responding, mice
22 in this case are not responding as people do to vinyl
23 chloride, where we would have discovered that 500 parts per
24 million has an untoward effect a long time ago. When you
25 say, what does it mean to me, I certainly would not recommend

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1 that a major detoxification mechanism, glutathione, I
2 would certainly not recommend that exposures exceed those
3 necessary to deplete this should be incurred.

4 But, how you translate that from rat to mouse and
5 finally and ultimately to the one of importance, man, is
6 a difficult procedure, and each and every chemical is
7 different.

8 DR. MCGAUGHY: Suppose you had a chemical -- Would
9 you feel the workers would be more endangered to that
10 chemical --

11 DR. GEHRING: It is very difficult. Are you talking
12 about the same effect -- I am having difficulty with the
13 meaning of your question.

14 In this particular case, glutathione apparently
15 lays around in the body and is there to pick off materials.
16 Things that can alkalanate DNA, that can alkalanate protein
17 can alkalanate RNA, and it is almost like an immune
18 mechanism.

19 If you get an excessive amount of alkaline materials
20 formed, it picks it up. This can be both natural and
21 synthetic type materials.

22 Now, not all alkalanate materials go through the
23 reaction with glutathione predominantly. Some of them,
24 for example, apoxides, apoxides of aromatic compounds, the
25 primary pathway might be by an apoxide on apoxidies, so it

1 goes entirely in a different direction.

2 I do not really know how to answer your question
3 using the vinyl chloride examples by saying all chemicals
4 fall in that area. They do not. They do not metabolise
5 that way.

6 DR. MC GAUGHY: We had not known about your study
7 demonstrating change in the metabolic mechanism.

8 DR. GEHRING: It is interesting, because it was
9 given at the New York Academy of Science almost a year and
10 a-half ago, and it has been published in at least two
11 journals.

12 DR. MC GAUGHY: It is easy to make a linear projection
13 and if this mechanism you have come up with is valid for
14 human exposure, then perhaps you overestimated it.

15 But, I would just like to know what your attitude
16 is towards risk.

17 DR. GEHRING: Toward risk, I think you have to
18 get the best hard data you have available and put this in
19 a pot and then you go over on the other side of it, and you
20 say, well, for example, if a chemist comes into me at the
21 Dow Chemical Company and says, I have Product X here, not
22 product, but a new chemical, I don't know what the heck
23 it is going to do, I don't know what it is used for, what
24 is an acceptable measure of exposure. Well, if there is
25 no benefit whatsoever, there is/acceptable measure of exposure.

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1 The question you are asking is, you have put the
2 hard data in and really what you have to ascertain is when
3 is the break in that tremendous increase of costs for
4 control going to occur. That is the area that you are
5 really dealing with in the assessment.

6 DR. MC GAUGHY: Fine.

7 CHAIRMAN DENNEY: Dr. Kuzmack.

8 DR. KUZMACK: I just have a few questions.

9 As I understood from your response to Dr. Marcus
10 when you talk about a threshold, you do not mean a level
11 below zero where carcinogenicity can occur, but just that
12 the rate of occurrence would be a lot less?

13 DR. GENRING: Well, biological processes do not
14 stop, they go on, and you don't have an abrupt situation.

15 The thing that does happen, however, is as I
16 indicated before, that the relative importance changes
17 tremendously, so when they begin to be much lower in
18 importance then you get a change.

19 For example, in Maltoni's study where the latency
20 period dramatically changed, something happened. They
21 are different populations, and so the way I interpret that,
22 at least at this point in time, is that Maltoni's data
23 itself indicates there is something going on to change that
24 latency period.

25 It makes it extremely longer, and, in fact, those

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1 animals, like I said, were extremely aged rats, and Albert
2 Aitshuler has also looked at this. So, there is a threshold.
3 So, even if we lived hundreds and thousands of years, I
4 suspect under those cases that the one molecule approach
5 might be more appropriate.

6 DR. KUZMACK: Or if you had hundreds and millions
7 of people exposed.

8 DR. GEHRING: As long as you take into account
9 that the threshold is a change in rate and you cannot make
10 statistical projections when you have definitive evidence
11 showing that the incidence at those levels apply to lower
12 levels.

13 DR. KUZMACK: What is the nature of the evidence
14 that suggests it is the upper pathway or the higher dust
15 pathway that involves the carcinogenics?

16 DR. GEHRING: Well, one, you have Maltoni's data
17 which correlates pretty well. Two, is the production of
18 chlorethylene oxide above the upper pathway. At least
19 some people have felt this gives the right type of reaction.

20 Those are the primary evidence. That doesn't
21 mean to say -- And, of course, the incidence the correlation
22 is beautiful between the predominance of the upper pathway
23 and the incidence of disease.

24 DR. KUZMACK: What experiments would you suggest that
25 would confirm or disprove the hypotheses that below this

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1 level you would expect --

2 DR. GERRING: I don't believe in mega-animal
3 experiments. Right now the types of studies we are involved
4 in is to determine what the macromolecular binding of the
5 reacting metabolites is, and whether this changes with dose.
6

7 Unfortunately, vinyl chloride, it isn't --
8 particularly when you get up to the upper pathway -- it
9 isn't all that metabolised that fast, so the amount of
10 radioactivity you can actually use is somewhat limited.
11 But, we are pursuing that aspect.

12 We are pursuing another aspect to delineate not
13 only the microsomal metabolism of this material, or the
14 extra microsome, and we think that is quite important,
15 because this is the one we feel is most likely by ethanol.
16 It is also located in the area of the cell which allows
17 more detoxification.

18 Now, the ultimate thing to do is to tie this in
19 with carcinogenicity. You will never do this in an absolute,
20 direct fashion.

21 We look at it as links in a chain. First we saw
22 the two differences in pathways, the subsequent aspect was,
23 let's look at the detoxifying systems and find out if it is
24 depleted, and this also accords you another aspect. It
25 shows you that accretation has occurred.

Then the next one is the macromolecular binding

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1 and finally, the real last link that I feel is feasible,
2 I feel, would be to administer both materials which augment
3 and those which inhibit selectively those pathways and
4 find out whether or not you increase the incidence
5 of cancer above the background of controls.

6 It is still indirect, but I do not think we will
7 ever do better than that in our lifetime.

8 CHAIRMAN DENNEY: All right, I would like to go
9 on then to the next witness. I thank you very much, Dr.
10 Gehring, for appearing.

11 DR. GEHRING: Thank you.

12 CHAIRMAN DENNEY: Diamond Shamrock is the next
13 witness, Mr. Connors, I believe.

14 I believe you are Mr. Connors of Diamond Shamrock.
15 Would you please introduce yourself.

16 STATEMENT OF HARRY CONNORS, DIAMOND
17 SHAMROCK CORPORATION

18 MR. CONNORS: Yes, my name is Harry Connors. I am
19 Vice President of the Industrial and Plastics Unit of
20 Diamond Shamrock Corporation.

21 Diamond Shamrock is a major producer of PVC
22 resins at plants in Delaware City and Deer Park, Texas.
23 We employ over 500 people -- Excuse me, may I interrupt to
24 say that Mr. Robert Hill, senior counsel in our Law Department
25 is with me.

We employ over 500 persons in our PVC plants and

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1 probably somewhere over 600 people, Diamond employees are
2 directly or indirectly supported by the PVC business.
3 In addition, a subsidiary is engaged in fabricating PVC
4 products, and we have recently announced our intention to
5 build a vinyl chloride monomer plant.

6 You can see that Diamon Shamrock's involvement with,
7 and interest in vinyl chloride monomer is substantial and
8 significant. The capital cost to Diamond to bring its
9 PVC plants into compliance with the OSHA standard on vinyl
10 chloride and the anticipated EPA and FDA requirements
11 on VCM and PVC will exceed \$15 million. This does not
12 include the cost of water treatment facilities in our PVC
13 plants nor added cost for our proposed VCM plant.

14 We are a member of SPI and we support the SPI
15 position stated by Mr. Harding earlier this morning, but
16 would like to emphasize to things further.

17 First, we are naturally very concerned with the
18 Administrator's designation of vinyl chloride as a hazardous
19 air pollutant. Of course, we realize that the statutory
20 framework within which he proposed to act requires that such
21 designation precede any further regulatory action.

22 Nevertheless, it is our opinion that no evidence
23 has yet been produced which demonstrates that vinyl chloride
24 in the concentrations found in the ambient air, has, in fact,
25 caused any kind of injury.

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1 What has been established is that vinyl chloride
2 is hazardous to workers exposed regularly to very high
3 concentrations over a period of many years. That evidence,
4 together with inconclusive animal test data, provides the
5 basis for the Administrator's conclusion that a risk to the
6 general public may exist. The distinction is an important
7 one, since the regulatory measures proposed will result in
8 significant economic impact.

9 Secondly, the Agency has rejected a fine balancing
10 of costs against benefits, choosing instead to require that
11 the best available technology be employed to reduce vinyl
12 chloride emissions. The difference may be substantial.

13 While exact costs cannot now be established, it is
14 generally agreed, I think, that compliance with the proposed
15 regulations will cost at least \$200,000,000, estimated by
16 the Agency, plus the additional expenditure of at least
17 \$70,000,000 annually. And, we think also it will probably
18 be more.

19 This additional expenditure has to reduce the
20 ability of our industry to attract capital, unless we can
21 increase our prices in the neighborhood of ten percent,
22 which is clearly inflationary.

23 While the Agency clearly has the duty to protect
24 the public against known hazards, it has another duty to the
25 public as well. We believe that, even when dealing with a

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1 known hazard, the Agency has a responsibility to engage
2 in that very fine balancing which it has here rejected.
3 Certainly, when the subject of such regulation has not been
4 established to be a hazard, even greater care is warranted.

5 In conclusion, let me say that Diamond Shamrock
6 expects to maintain its plants in compliance with all
7 Government regulations and, assuming our ability to raise
8 prices, we will be able to provide the capital necessary to
9 maintain our PVC plants in operation if this proposed
10 standard is finally adopted.

11 Furthermore, because of the Agency's commendable
12 procedure of making drafts of their proposals available for
13 study and comment before publication, we can even now advise
14 that, technically, the standard, for the most part is feasible
15 for our plants.

16 We deplore, however, the inflationary effect and
17 the waste that will be involved in a significant portion of
18 these huge expenditures for little discernible benefit.
19 We also cannot agree that it is correct to label vinyl
20 chloride as a hazardous air pollutant in the concentrations
21 found in the ambient air surrounding VCM or PVC plants.

22 We will be submitting detailed written comments
23 of a supplementary nature on the proposed standard and
24 supporting documents which time did not permit us to have
25 prepared for this hearing.

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1 Thank you.

2 DR. KNELSON: Just for my own instruction, you
3 mentioned a cost of \$16 million for your implementation
4 of the requirements. What fraction of the total capital expend-
5 tures of your company does that represent?

6 MR. CONNOR: Of the total capital expenditures
7 of our company, of course, this would be expended over
8 a couple of years. It would be in the five to ten percent
9 range.

10 DR. KNELSON: Five to ten percent. Over what
11 period of time would that \$16 million be amortized?

12 MR. CONNOR: It would be amortized in general,
13 over a two year period.

14 DR. KNELSON: In other words, you have to reinstall
15 this step every ten years?

16 MR. CONNOR: Yes. As a matter of fact, on the
17 average that is probably too long a period. Some of the
18 facilities to which we will be adding this equipment,
19 probably will not have a life of ten years. They have
20 already been in operation for ten years, so ten years would
21 be an exaggeration, I think, on the average.

22 DR. KNELSON: You mentioned the inflationary
23 pressure of something like ten percent. By that you mean
24 the price of the resin will be increased by ten percent
25 as a result of this capital outlay?

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1 MR. CONNOR: It will be necessary to do so in
2 order to continue in business.

3 DR. KNELSON: Most of us don't buy PVC resin
4 by-products. Could you give me an example of how the ten
5 percent increase in the raw material would increase the
6 price of the product, to the end-user, the consumer is
7 really interested in? How much would it influence the
8 cost of the phonograph record?

9 MR. CONNOR: A phonograph record is largely PVC
10 resins, so that it would increase the raw material cost
11 of the resin the full ten percent.

12 What that would translate into in the selling
13 price, I cannot tell you. Obviously a smaller percentage.

14 DR. KNELSON: A much smaller percentage?

15 MR. CONNOR: Yes.

16 DR. KNELSON: If it cost me \$4.98 now, it might
17 cost me a couple of more cents. That is what I would have
18 to pay for the assurance of this benefit?

19 MR. CONNOR: However, there are other products
20 that would be greater. Such things that do not have a high
21 input of let's say art, as your phonograph record has.

22 CHAIRMAN DENNEY: Dr. Marcus.

23 DR. MARCUS: In your costing have you figured
24 in how much money you would be saving by recovering
25 distributing operations?

Am. Electric Company

1 MR. CONNOR: We would obviously gain some return.
2 But, the return is negative.

3 In other words, we are spending more to recover a
4 pound of monomer than is the value of that monomer. That
5 doesn't mean the recovery material doesn't have a value,
6 but we spend more to get it than it is worth. Even if we
7 project the cost by increasing the energy costs.

8 DR. MC GAUGHY: What would your net figure be?

9 MR. CONNOR: For \$70 million, I would have to
10 reserve a positive comment on that? I will have to check
11 that. I think it is probably before the value of the
12 recovery monomer.

13 DR. MC GAUGHY: One point of clarification.
14 The \$16 million what fraction of that is due to EPA, and
15 what fraction is due to the OSHA requirements?

16 MR. CONNOR: Those things are hard to separate.
17 But, I will make an honest effort. We think that something
18 more than half of that, but less than three-quarters would
19 be required for EPA.

20 DR. MC GAUGHY: Thank you.

21 CHAIRMAN DENNEY: I have one question.

22 I asked Mr. Harding how the industry can justify
23 imposing any risk on somebody who does not derive benefit
24 from an activity. You suggested, and we have problems with
25 that question, I think in general it seems it is being done

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1 indeed promulgates regulations. But, I am concerned about
2 your suggestion -- I am wondering about your suggestion
3 that we do a more finally tuned benefit cost analysis, which
4 is by no means a novel suggestion.

5 I am simply wondering how we do that. It is one
6 thing to say at some point it doesn't really warrant for
7 instance, quadrupling the cost of utility power to reduce
8 one common, coal to use an example, at some point there is
9 a gross disproportion.

10 For instance, if you could in some way quantify
11 a health effect to be worth \$100 to the person who has it
12 in lost wages, pain or whatever, would you then say an
13 industry should not spend more than \$101 to protect that
14 person, and if it is \$99, that person is lucky, and if it is
15 \$101 it is too bad for him.

16 There is no reason to make industry spend more
17 than his benefit.

18 I am wondering if you have a suggestion. If you
19 have an involved response to that, I would appreciate it
20 in writing, but if you have a quick answer on how we would
21 go about conducting such a balancing?

22 MR. CONNOR: I am very afraid I do not have a
23 quick or an involved answer.

24 What you are referring to, I think, fundamentally
25 is we feel with an unproven risk, an unproven hazard, that

James R. Conner, Chairman

1 one must proceed cautiously.

2 We agree with the necessity for looking at the
3 problem for controlling major abuses, but whether one cost
4 of going from reducing, let us say, just as an example, the
5 ambient air concentration from two parts per million to
6 one part per million, in view of the available data on hazards,
7 and, in fact, the preponderance of data which would indicate
8 that the hazard was not excessive, it is probably ridiculous.

9 That does not mean that one doesn't continue
10 to watch developments, and if data develops at a later
11 date, additional concern on health hazards would be worth-
12 while.

13 CHAIRMAN DENNEY: What you are suggesting is
14 not that we do a fine tune cost benefit, but rather we
15 over estimated the health risk considerably.

16 I ask this, because I have yet to find anybody
17 who has really been able to come up with a really helpful,
18 so-called fine tune benefit balance. We have talked to
19 a lot of people and we have been in litigation with a lot
20 of people who have suggested we ought to do more.

21 MR. CONNOR: We could make some specific suggestions
22 on specific technical points in our written submission.

23 DR. MARCUS: One simple question.

24 If there is a proven health hazard in some
25 particular chemical you do manufacture, how would you go

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1 about identifying the people who are harmed by it?

2 MR. CONNOR: I think I should defer to my legal
3 representative. I don't think you can answer that broadly.

4 Again, I think that a product that vinyl chloride
5 is of benefit to society and that, therefore, all members
6 of society are benefiting from it whether or not they happen
7 work in a PVC plant or not, because it is reducing their
8 cost-of-living, or increasing their standard of living.

9 Now, whether they should have correcting indemni-
10 fication I think it's very moot, and this would be true
11 of any chemical unless there was gross negligence involved.
12 Gross and willful negligence. That is another matter.

13 CHAIRMAN DENNEY: Thank you very much.

14 Our next witness is Air Products, and I believe
15 you are Mr. Shenk.

16 Mr. Shenk is the last person asked to testify.
17 Mr. Shenk, would you please introduce yourself?

18 STATEMENT OF RAYMOND SHENK, ATTORNEY
19 AIR PRODUCTS AND CHEMICALS, INC.

20 MR. SHENK: My name is Raymond Shenk, and I am
21 a n attorney representing Air Products and Chemicals, Incorporated.
22

23 Although we had asked for time at this hearing to
24 present our oral testimony on the propriety of the Agency's
25 action in designating vinyl chloride a health hazard, we

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1 have determined that the short interval between publication
2 of the proposed standard and this hearing is insufficient
3 for us to make a thorough analysis of the voluminous
4 documents issued by EPA in support of its action affecting
5 vinyl chloride.

6 Accordingly, we have determined not to present
7 any oral testimony at this hearing. We will devote our
8 energies to the preparation of detailed written comments
9 which we will be submitting to the Agency later this month.

10 Thank you.

11 CHAIRMAN DENNEY: Thank you.

12 I will simply assume there are no questions.

13 Thank you all very much for participating in
14 hearing. We appreciate having you.

15 (Whereupon, at 12:45 p.m. the hearing was
16 concluded)

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