

1 industry.

2 A That last one was a study of the employees of the
3 factory, the plant in which Messrs Wallace and Dendinger worked.

4 Q Have you reviewed that study?

5 A I have studied the report, yes.

6 Q And that was the report prepared by Dr Shindell?

7 A Yes.

8 Q Did you know of Dr Shindell before you saw his report?

9 A No.

10 Q Going back for a minute to Dr Chiazze, were you aware
11 that Dr Chiazze's initial work was paid for by the Trade Industry
12 for the PVC manufacturers of the United States?

13 A I cannot recall that but if he says it, I am sure it
14 was.

15 Q And your suggestion with regard to the conclusions or
16 hypotheses that Dr Chiazze derived from his study, was that they
17 should be further analysed and were, and that further research
18 should be done?

19 A Yes.

20 Q Are you aware of any efforts by the American PVC
21 industry to sponsor further studies of PVC fabrication employees
22 in the light of the results reported by Dr Chiazze in his 1981
23 work?

24 A I have no idea what they have done, I am not in touch
25 with the industry.

URL 11612

1 Q Was your recommendation, however, that follow-up
2 studies be done?

3 A I think that would be a reasonable thing to do, yes
4 and Dr Shindell, of course, could be cited, I suppose, as one
5 such study.

6 Q Then let us talk about Dr Shindell's study. Do you have
7 a copy of that with you, doctor?

8 A I could get it, yes. (Pause) Yes, I have.

9 Q I would like to direct your attention if I could to
10 Table II in Dr Shindell's study that appears at page 12. Do you
11 have that in front of you, sir?

12 A Yes.

13 Q What is your understanding as to the job categories
14 in which Mr Wallace and Mr Dendinger were employed?

15 A My understanding is that they were employed in the
16 categories described there as inspection shipping - - no, I am
17 sorry, coating and finishing.

18 Q Your understanding is that both---

19 A I am sorry, I think I may be wrong on this. I thought
20 one was inspecting, was he not?

21 Q Let me make a representation.

22 A Can you remind me?

23 Q It is my understanding that Mr Wallace was classified
24 as a coating finishing employee and Mr Dendinger was classified
25 as an inspection shipping employee.

URL 11613

1 A In other words I was right in both cases but for the
2 wrong reasons.

3 Q I suppose so. What I would like to do doctor, is to
4 have you contrast the Shindell study with the Chiazze study.
5 How would you classify this study that Dr Shindell did in terms
6 of epidemiologic categories?

7 A This is a cohort study and as such is the type of study
8 that one likes to carry out to test a hypothesis.

9 Q One of the hypotheses that Dr Chiazze proposed in his
10 1981 article was that there was an increase in the proportion
11 of total cancer deaths among white male PVC fabrication employees?

12 A Yes.

13 Q So one of the follow-ups that you would have suggested
14 to confirm or disprove Dr Chiazze's hypothesis was the cohort
15 study done by Dr Shindell?

16 A Yes.

17 Q What I would like to do, Dr Doll, is to have you look
18 at Table II and the total cancers reported in the coating finishing
19 and the inspection shipping categories, in which my clients
20 decedents worked. If we can take the coating finishing category
21 first in which Mr Wallace was employed and determine the total
22 number of cancers that would have been expected in a general
23 population, we could take that by adding the 1.4 expected
24 respiratory cancers and the 2.47 expected other cancers. Would
25 that be correct?

JRL 1614

1 A Yes.

2 Q Could we go off the record for just a minute, please?

3 (Whereupon there followed a discussion off the record)

4 BY MR DELLI BOVI:

5 Q Dr Doll, referring to Table II in Dr Shindell's study
6 and the two categories of employees which Mr Dendinger and
7 Mr Wallace worked, there are data reported in both of respiratory
8 cancers and other cancers, correct?

9 A Yes.

10 Q And these are categories that were set up by Dr Shindell
11 for purposes of his analysis?

12 A Yes.

13 Q I would like to direct your attention to the exhibits
14 that we have on the easel which I will mark as Plaintiffs Exhibit
15 Doll 3. I would like, if you would, to refer to the respiratory
16 cancer deaths and the other cancer deaths in the job classifi-
17 cations in which Mr Wallace and Mr Dendinger were classified and
18 tell me whether or not the figures that are on Exhibit 3 are
19 identical to those appearing in Dr Shindell's study?

20 A Yes, they are.

21 Q What I would like---

22 A I have not checked the addition but I am assuming the
23 addition is correct.

24 Q I hope so. What I would like you to do, Dr Doll, is
25 to do something Dr Shindell did not do in his study and that is

URL 11615

1 to determine in terms of total cancers in the job categories in
2 which Mr Wallace and Mr Dendinger were employed, the significance
3 of the observed deaths, versus the expected deaths. Would you
4 be able to do that, sir?

5 A I would have to look at the tables of significance.
6 From my general experience I would guess the coating and finishing
7 one was not significant statistically, but the inspection and
8 shipping was, but that is a guess and I would have to look at
9 the table. You can doubtless tell me.

10 Q Let me go back to the findings that Dr Shindell came
11 to himself. With regard to the respiratory cancers among the
12 coating and finishing employees, Dr Shindell calculated the
13 expected deaths at 1.4, correct?

14 A Yes.

15 Q What does that indicate, doctor?

16 A That had the people in those particular sections of
17 the industry died at the same rate as the people of the same
18 ages in the United States as a whole, from respiratory cancer,
19 that 1.4 of them, if you can accept 0.4 of an individual, would
20 have died of respiratory cancer.

21 Q As opposed to the 1.4 expected deaths, Dr Shindell
22 reported actual deaths among employees at the plant where my
23 clients' decedents worked?

24 A Yes.

25 Q Did Dr Shindell determine that that number of observed

URL 11616

1 deaths versus the number of expected deaths was statistically
2 significant?

3 A Yes, he said it was but when I looked it up in my
4 tables I found it was not but it is a quibble because it is
5 round about 5% probability and whether it is 4% or 6% is scientifi-
6 cally of trivial importance. Actually, I make it nearer 6% than
7 4%.

8 Q And that means what, doctor?

9 A That means to have observed four or more deaths from
10 respiratory cancer in that particular group of people of those
11 ages over that period in the United States would have turned up
12 only about once in twenty such groups that you looked at.

13 Q Next I would like to direct you to the inspection and
14 shipping category of employees in which Mr Dendinger worked and
15 to the other cancers. According to Dr Shindell's method of
16 classification, would those other cancers include the colon
17 cancer from which Mr Dendinger died?

18 A Yes.

19 Q In that category, Dr Doll, one would have expected,
20 assuming the death rate from these other cancers among inspection
21 shipping employees at Chrysler, was the same as that among a
22 comparable general population, 1.95?

23 A Yes.

24 Q And in fact at Chrysler there were five employees who
25 died of cancers other than respiratory cancer?

URL 11617

1 A Yes.

2 Q Is that number again, Dr Doll, statistically signifi-
3 cant?

4 A This time I have no difficulty in agreeing with
5 Dr Shindell.

6 Q In terms of testing Dr Chiazze's 1981 hypothesis of
7 an increase in overall cancers among PVC fabrication employees,
8 is it fair to total these four categories of employees to arrive
9 at sum total figures?

10 A No.

11 Q Why is that, doctor?

12 A Because you have subscribed the population and picked
13 out some groups with higher mortalities than other groups. You
14 have left out the production and maintenance group which did not
15 show such an excess. It showed, I think, 4 cancers against 3.72
16 expected and you left out the management and clerical group
17 which showed no cancers against 1.79 expected and when you sub-
18 divide and look at a number of separate groups, then inevitably
19 you are going to find some with statistically significant
20 excesses. Had the prior hypothesis of Dr Chiazze been that
21 people in the coating finishing and inspection shipping groups
22 had a higher than expected mortality from cancer, then that would
23 be a fair thing to do, but it was not. It was that all the
24 employees of the PVC fabrication industry had an excess and,
25 therefore, you have to look at the total. Again, you get your-

UPL 11618

1 self into a situation in which you create another hypothesis
2 when you find an excess in some subdivisions. You find now an
3 excess in the coating finishing and inspection shipping divisions
4 and that constitutes a new hypothesis which will have to be tested
5 by further experience of those workers. I would like to carry
6 that a little further because in testing a hypothesis I think
7 it is important that you take into account the area in which the
8 people were working. Dr Chiazze's hypothesis was based on the
9 workers in, I think, seventeen plants, but my memory may be
10 fallible about that, scattered throughout the United States and
11 he, therefore, very properly or reasonably took the whole of the
12 United States mortality experience as a standard to compare with
13 it. If, however, you are looking at a plant in Ohio, then you
14 need to see what the mortality from cancer is in Ohio, how that
15 compares with the rest of the United States. I have not got the
16 figures for that, it is a highly industrialised State or part
17 of it, I believe is and I would expect the expected mortality
18 from cancer to be higher than is estimated from the national
19 United States rates.

20 Q To a significant degree?

21 A Yes.

22 Q Have you been presented with data for Ohio by any of
23 the PVC manufacturers?

24 A No.

25 Q Did you consider the cancer deaths reported at the

JRL 11619

1 Chrysler facility by Dr Shindell in coming to the opinions that
2 you have suggested today?

3 A Dr Shindell's paper was not available at the time I
4 made my review.

5 Q When did you first see Dr Shindell's paper?

6 A About two weeks ago, one week, ten days ago.

7 Q In terms of Mr Dendinger and Mr Wallace, I take it you
8 do not have an opinion as to the cause of either gentleman's
9 cancer?

10 A No.

11 Q Were you provided with any information about their age,
12 at the time of death, their diet, their family history or known
13 history of cancer, their inhalation of tobacco smoke, if any,
14 or their use of alcohol, if any?

15 A Yes, some limited data. Certainly precise data for
16 age and some details for the other things that you mention but
17 none of them in fact are relevant or would be regarded as
18 relevant to the aetiology of their conditions. When I say that,
19 I do not mean diet is not relevant to the aetiology of cancer of
20 the colon, all I mean is the sort of information that could be
21 given about the individual would not affect my assessment
22 because one cannot really assess an individual's diets sufficiently
23 precisely to be of any value on deciding if it is a cause of his
24 cancer.

25 Q In terms of your opinions that you have expressed today,

JHL 11620

1 you have not relied on the Shindell study at the Chrysler plant,
2 the Chiazze study of PVC fabrication employees, the Molina study
3 of PVC fabrication employees, is that correct?

4 A No. I have certainly taken them all into full account
5 and weighed the evidence that they have produced before
6 expressing my opinion which is an opinion based on all the data
7 I have seen including the data which you have provided me with
8 and which I was provided with in the last few months.

9 Q What determined whether or not a particular study made
10 your list of references at the conclusion of your paper?

11 A Whether it was relevant to the conclusions which I
12 reached in it. I did not list quite a number of studies which
13 I read, including the Chiazze study because I did not think it
14 was relevant to the conclusion which I reached.

15 Q Your belief then was that Chiazze was not relevant?

16 A I thought that Chiazze's study was not helping in any
17 way assess what the effects of vinyl chloride were.

18 Q That Molina was not relevant?

19 A Molina was definitely not relevant.

20 Q And Shindell was not relevant?

21 A Shindell I only recently took into account in expressing
22 my opinion today.

23 Q The report with the review that you authored and
24 appeared in the Scandinavian journal, was commissioned by the
25 Manufacturing Chemists Association?

URL 11621

1 A It depends what you mean by "commissioned". If by
2 "commissioned", you mean was I paid to do it, the answer is no.
3 If by "commissioned" you mean was I asked to do it in an
4 honorary capacity, the answer is yes. I said I was glad to do
5 it, it was an interesting and important subject and I would do
6 it on the understanding they made a contribution to a charity
7 which I named. So, depending what you mean by "commissioned",
8 there is my answer.

9 Q And, if you do not mind my inquiry, could you tell me
10 the amount of the contribution MCA agreed to pay?

11 A Oh, I will have to look it up. It might have been
12 \$10,000, 7,000. It was not paid to me, it was paid to the
13 charity.

14 Q Can you tell me for certain whether or not the study
15 was commissioned before or after 1985?

16 A No, I cannot. I think it was before, probably. I know
17 it was about two years before I could start on it. I did the
18 work in 1986. I would guess it was 1984 I was asked to do it
19 but it might have been 1985.

20 Q Could you tell me, doctor, precisely what assignment
21 you received from the MCA?

22 A I cannot remember the exact wording. It was about
23 three lines to review the evidence on the effect of vinyl
24 chloride on man with specific reference to whether there was any
25 increase of any cancer other than angiosarcoma of the liver.

UPL 11622

1 I think that was the way it was put.

2 Q Do you know whether or not that study was sought by
3 the MCA after Mr Dendinger and Mr Wallace filed their litigation?

4 A I have no idea. I do not know when they filed it.

5 Q Of the four major studies that your article reviews,
6 three were - at least at the time you wrote the article - un-
7 published?

8 A Yes. They are published now.

9 Q Are all four of the studies that you have reviewed
10 published?

11 A No, the American study, to my knowledge, has not been
12 published yet although I believe it is available to anyone who
13 asks for it.

14 Q How did the United States study come to your knowledge?

15 A It came to my knowledge because when I started doing
16 the review I was dealing with a lot of separate papers about
17 populations exposed to vinyl chloride in the United States and
18 there was one of them done by an American organization, I forget
19 the name, Equitable and Environmental Health Inc., that covered
20 a substantial number of plants and there was a follow up study
21 to this by a man beginning with C---

22 Q Cooper?

23 A Cooper, and I wondered whether the individual studies
24 reported by other authors were included in these two studies.
25 Clearly, in a review you do not want to add in the same amount

URL 11623

1 of data three or four times as reported by different people.
2 It is important you only include one set of data on one occasion,
3 so I enquired of the chemical industry through the Imperial
4 Chemical Industries in England, whether I could be told whether
5 these studies of Cooper and Tabershaw and Gaffey covered the
6 other studies and I was told that they did and then I was told
7 also that another study was being carried out and I said that
8 a follow up study was being carried out and I said it is silly
9 for me to give an opinion until I had seen the follow up study,
10 so I waited till I had seen the follow up study. I made the
11 same inquiries in England. I had a report of Fox and Collier
12 of the British Industry and I wrote to the Health and Safety
13 Executive in England to ask if they were doing any further
14 studies and they told me there was this government study that
15 covered the whole industry in England and I said: "I must wait
16 and have the results of both these studies before I can give an
17 opinion." Could we go off the record for a moment while the
18 refreshments come in?

19 MR DELLI BOVI: Yes, why don't we go off the record.

20 (Whereupon there followed a short adjournment)

21 BY MR DELLI BOVI:

22 Q Dr Doll, I am going to hand you what I have marked as
23 Plaintiffs Exhibit 4. Would you review this document and tell
24 me whether or not this is a copy of the study that is cited in
25 your review that was prepared from the Chemical Manufacturers

URL 11624

1 Association. (Document handed to the witness)

2 A Yes, that is the one.

3 Q To your knowledge, that study remains unpublished?

4 A Yes. What I am saying by that is I do not know if it
5 is published.

6 Q One of the other studies referred to in your references
7 as reference 16 is a 1978 study by Equitable Environmental
8 Health entitled: "Epidemiological Study of Vinyl Chloride
9 Workers: Final Report to Manufacturing Chemists Association."
10 Do you have a copy of that report with you this afternoon?

11 A No, I do not have a copy of that with me. This was
12 subsumed in this later report and it is a long time since I read
13 it. It is not relevant to my review.

14 Q So, among the references that you cited in your review
15 are references that are not relevant to it?

16 A I cited and gave reasons why I have not included them,
17 saying the data in it has been subsumed in the later one, but
18 I cited it because otherwise people might have wondered why I
19 did not mention it.

20 Q Where did you obtain the 1978 Equitable Environmental
21 Health Report?

22 A I cannot remember now. I am guessing, probably from
23 Imperial Chemical Industries or I might have had it from Cooper
24 himself. I think that was the one that Cooper published, was
25 it not?

URL 11625

1 Q Was that study, to your knowledge, ever published?

2 A Not to my knowledge, no.

3 Q Imperial Chemical Industries---

4 A Wait a minute. We have got Cooper as a separate one,
5 have we not?

6 Q Yes.

7 A Now, this one, I think that was a preliminary report
8 to Cooper so Cooper would be regarded as the publication of
9 number 16. I think that is right. So, the answer, therefore,
10 would be yes it was published if I am correct, but I really have
11 to check to make sure I am being correct on that. Earlier
12 observations, that is right. Yes, yes. Without going back and
13 looking at the data, my recollection is that 12 was the publi-
14 cation in effect of 16, but I would not want to swear to it
15 without checking.

16 Q Dr Doll, can you tell us what a carcinogen is?

17 A I wish I could. What one means by a carcinogen is
18 any agent which will cause cancer in any animal if that animal
19 is exposed to it in any conditions the experimenter likes to
20 think. An agent capable of causing cancer in some circumstances.

21 Q Is vinyl chloride a carcinogen?

22 A Yes.

23 Q What is a human carcinogen?

24 A A human carcinogen is a carcinogen shown to cause cancer
25 in humans.

JRL 11626

1 Q Is vinyl chloride a human carcinogen?

2 A Yes.

3 Q What is a mutagen?

4 A That is very much more difficult to define because it
5 has a very wide connotation of meanings given to it by different
6 workers. Essentially, it is something which damages the DNA in
7 a cell, causes the DNA which is the material that holds all the
8 codes as to how that cell is to operate, which causes that DNA
9 to be altered in some way.

10 Q Is vinyl chloride a mutagen?

11 A Yes.

12 Q Is it your understanding that prior to the 1970 work
13 of Professor Viola, there were a large number of studies done
14 concerning the acute, the sub-acute and the chronic health effects
15 on humans of over exposure to vinyl chloride?

16 A Yes.

17 Q Could you outline for us some of the acute, the sub-
18 acute and chronic effects of exposure to vinyl chloride that were
19 reported prior to 1970?

20 A The first effect, of course, is just unconsciousness,
21 if it is a sufficiently high dose of the gas, but once the con-
22 centration to which individuals are exposed is kept down to
23 lower levels, then it is found that chronic exposure at these
24 lower levels would cause some damage to the liver, they would
25 cause damage to the terminal phalanges, the bones in the fingers.

URL 11627

1 I forget the technical term - acro-ostiolysis. Also that it would
2 have some effect on the circulatory system, producing symptoms
3 that are known medically as Raynaud phenomena. Those are the
4 principal effects I can recall.

5 Q Do you recall whether or not much of the work done into
6 the health effects of exposure to vinyl chloride prior to 1970
7 was done in the Eastern European nations?

8 A I know of one report from the Soviet Union, but no,
9 I am afraid I cannot answer that.

10 MR BUNDA: I am going to interpose an objection that
11 the cross examination is going beyond the scope of the
12 direct examination.

13 BY MR DELLI BOVI:

14 Q Have you looked into the history of the medical and
15 scientific articles dealing with the toxicity of vinyl chloride
16 as part of your assignment for the CMA?

17 A Only levels below those which produce the so-called
18 vinyl chloride syndrome which I did not think was necessary for
19 me to investigate because that was well established and as far
20 as I knew was agreed by everybody and not controversial but
21 I certainly looked to see if there were any other long term effects
22 on individuals which would show up in mortality rates from
23 diseases other than cancer.

24 Q Is it your understanding that evidence of the carcino-
25 gency of vinyl chloride was first reported by Professor Viola

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1 in 1970?

2 A Yes.

3 MR BUNDA: I would like to interpose a continuing
4 objection on the basis the cross examination is going beyond
5 the scope of direct examination.

6 BY MR DELLI BOVI:

7 Q I would like to hand you, doctor, a series of medical
8 journal articles and have you identify them for me, if you would.
9 Can we go off the record for just a second while I find them.
10 Never mind, I have them.

11 MR BUNDA: I would like to go off the record for a
12 second.

13 (Whereupon there followed a discussion off the record)

14 MR BUNDA: I am also going to object to the introduction
15 of these exhibits or the showing the witness these exhibits
16 in their present form since they have stickers all over them
17 and I think that that is prejudicial. If you have any clean
18 copies I have no objection to the doctor being questioned
19 about those.

20 MR DELLI BOVI: I have no clean copies.

21 MR BUNDA: Then I object.

22 BY MR DELLI BOVI:

23 Q Doctor, I show you Exhibit 5. You can feel free to
24 ignore all stickers on there other than those that refer to your
25 testimony. (Document handed to the witness)

UPL 11629

1 MR BUNDA: Objection, I move to strike.

2 BY MR DELLI BOVI:

3 Q Have you seen that document before in that form or any
4 other form?

5 A Yes, I believe this is one of the documents I was
6 provided when I was asked if I would give evidence in this case.
7 I had not seen it before then.

8 Q The first time you saw Dr Viola's 1970 publication in
9 the Italian medical journal was in 1985?

10 A No, I said 1988, just a week or so ago. I had not
11 thought it necessary to look for this article as I knew, of
12 course, Dr Viola's publication of 1971 and it seemed to me that
13 subsumed the earlier evidence and I did not think it necessary
14 to go to the preliminary report in 1970.

15 Q Well, Dr Doll, you had to have seen that document prior
16 to 1988.

17 A Did I? Yes.

18 MR BUNDA: Objection. Argumentative.

19 BY MR DELLI BOVI:

20 Q Is it your testimony you first saw that article this
21 year?

22 A I am confused slightly. I think there is an article
23 by Viola of 1971.

24 Q That is correct, in Cancer Research.

25 A As far as I can recall I have only read Viola's article

URL 11630

1 of 1971 before this last few weeks. I saw no reason for looking
2 up Viola's article of 1970 and I am not aware of having seen it
3 before.

4 MR BUNDA: I am also going to interpose an objection
5 on the basis there has been no other occasion that that
6 document is in the form in which it appeared in the Italian
7 journals. My understanding is that it is a translation and
8 on that basis I believe the questions are improper because
9 they infer that that is a copy of the form in which the
10 articles were published and I think that is not borne out
11 by the facts. So I do not have to continue to object, I
12 believe there will be a second article following the
13 objections which I made with regard to the stickers and with
14 regard to the fact it is a translation, also applies to that
15 article, also authored by Dr Viola.

16 BY MR DELLI BOVI:

17 Q I would like to refer you to an article you co- authored
18 in 1985. Would you take a look at that and indicate whether your
19 first reference in that 1985 work was to Dr Viola's 1970 publi-
20 cation, in the medical journal article. (Document handed to the
21 witness)

22 A Yes, it was.

23 Q So, you were aware as early as 1985 of Dr Viola's 1970
24 publication?

25 A Oh, I have been aware of it earlier than that but as

URL 11631

1 I said, I did not regard it as necessary to read it, as Dr Viola
2 published a paper in 1971 which was the definitive results of
3 his study and I based all my conclusions on Viola's 1971 paper.
4 This was a paper jointly by myself and three other colleagues
5 and they doubtless thought if you are referring to Viola it was
6 only reasonable to give the first reference to Viola, but the
7 one that I read and studied is the 1971 one.

8 Q When were you first aware whether or not you read of
9 the findings reported by Dr Viola in 1970?

10 A I cannot recall that I was aware of them reported in
11 1970. I was aware of them reported in 1971 - - oh, I suppose
12 in 1975. When did I first start getting interested in vinyl
13 chloride? When I gave a paper, joined in a discussion at the
14 New York Academy of Sciences which must have been in the mid 1970s.
15 I cannot remember the exact year, but I would say 1974 or 1975
16 I was aware of the 1971 paper.

17 Q What about the 1970 paper?

18 A It must have -- it was drawn to my attention when I
19 read the 1971 paper because there was the reference presumably
20 in it but I cannot recall having seen it until this last week
21 or two.

22 Q Would you take a look at Professor Viola's 1971 document
23 and see if there is in fact any reference to his 1971 publication?
24 (Document handed to the witness)

25 A No, there is a reference to his 1969 one, which I had

UHL 11632

1 heard of, of course.

2 Q Have you ever reviewed that publication, sir?

3 A No, because I have worked with Maltoni who continued
4 his work and Maltoni told me all about the work and I had,
5 therefore, known about this work, Viola's since the middle 1970s.

6 Q Do you know whether Dr Viola in his 1969 presentation
7 at the International Cancer Congress in Tokyo discussed the
8 subject of carcinogenicity of vinyl chloride?

9 A I cannot answer that with certainty. My belief is that
10 he reported it in 1969. That is my understanding but I could
11 not be held to that.

12 Q Whether or not it was reported in 1969, certainly by
13 1970 Dr Viola had authored a publication in one of the Italian
14 medical journal articles, dealing with the carcinogenicity of
15 vinyl chloride in animals?

16 A I dare say.

17 Q You, however, were not aware of either his 1969 or his
18 1970 publication until some years later?

19 A I was not aware of it until after the occurrence of
20 the two or three cases of angiosarcoma in the Goodyear works
21 in the early 1970s.

22 Q If the Goodyear angiosarcoma deaths were announced in
23 1974, then you would not have been aware of Dr Viola's 1970 paper
24 until that time?

25 A That is right, yes.

JPL 11633

1 Q Is Cancer Research a European publication? —

2 A No.

3 Q Where is that published?

4 A The United States.

5 Q Are you aware of any evidence of an effort by the
6 polyvinyl chloride industry in the United States to hide
7 Dr Viola's 1970 publication from its customers, from the United
8 States government and from the general public?

9 A No.

10 Q Would you regard such an effort, if it occurred, as
11 evidencing a lack of corporate responsibility on the part of
12 vinyl chloride and polyvinyl chloride manufacturers ---

13 MR BUNDA: Objection. Dr Doll, wait a second, let me
14 interpose an objection on the basis it is speculative and
15 is not based on any facts which are properly in evidence.
16 You can go ahead and answer the question if you recall what
17 it is.

18 BY THE WITNESS:

19 A No, it is too hypothetical for me to give any answer
20 to.

21 BY MR DELLI BOVI:

22 Q Then, Dr Doll, I would like to make the question some-
23 what more concrete. Would you look at Plaintiffs' Exhibit Doll
24 6, please and tell me whether you have seen this document or
25 reviewed this document before? (Document handed to the witness)

URL 11634

1 MR BUNDA: Again, I am interposing an objection on the
2 basis it goes beyond the scope of the cross examination and,
3 further more, it is irrelevant.

4 BY THE WITNESS:

5 A I am very happy to answer it because I have never seen
6 it before.

7 BY MR DELLI BOVI:

8 Q I would like you also to take a look and tell me whether
9 you have seen, prior to today, Plaintiffs' Exhibit 7 which is
10 entitled: "Cancerogenic Effect of Vinyl Chloride, P.L.Viola
11 (Regina Elene Institute for Cancer Research) Rome, Italy,
12 presented at the Tenth International Cancer Congress, Houston,
13 Texas. May 22-29, 1970".

14 MR BUNDA: Can I see that please? (Document handed
15 to counsel) Again I am going to interpose an objection on
16 the basis that this document contains multiple stickers and
17 is prejudicial in its presentation. Furthermore, it appears
18 to be a summary and it is difficult to determine where it
19 comes from. So, I object on the basis of authenticity as
20 well.

21 BY MR DELLI BOVI:

22 Q Have you seen Plaintiffs' Exhibit 7 before today?

23 (Document handed to the witness)

24 A Well, I find that difficult to answer because I attended
25 this conference, in fact I gave the opening lecture at it and

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1 it is possible this is a photocopy of an abstract, in which case
2 I might have seen it, but I cannot recall having seen it and my
3 interest in vinyl chloride as a carcinogen only arose in 1974
4 or so when I heard about the angiosarcoma cases, so whether I
5 saw it or not I do not know. It is possible I did, but it
6 certainly made no impact on me if I saw it.

7 Q You indicated earlier that you had not seen Plaintiffs
8 Exhibit Doll 6 before. Is that correct? (Document handed to
9 the witness)

10 A I indicated that. I would like to read it again just
11 to make quite sure that I am not misleading you. (Pause) No,
12 I am not aware of ever having seen that before.

13 Q You were a professor of epidemiology at Oxford College,
14 1970, 1971, 1972, 1973 and during those years you had not seen
15 Dr Viola's 1970 article. It had not come to your attention
16 during those years?

17 A I was actually a professor of clinical medicine techni-
18 cally but my research was all in the field of epidemiology. I
19 was au fait as I taught with the cancer research work throughout
20 the world. I discussed many carcinogens with many cancer research
21 workers and I can never recall anybody mentioning vinyl chloride
22 as a carcinogen at all until after the angiosarcoma cases occurred
23 in the Goodyear works.

24 Q In 1974?

25 A In 1974, yes. I certainly would not claim to have been

UHL 11636

1 completely up to date and obviously I was not, but there were
2 a lot of things going on and certainly in the cancer research
3 world generally, vinyl chloride was not being discussed as a
4 potential hazard.

5 Q Please do not infer from my question that I am finding
6 any fault at all in that fact but the fact is that you were an
7 expert in epidemiology in the early 1970s and prior to 1974 none
8 of Dr Viola's work or Dr Maltoni's work had come to your attention?

9 A That is true, yes. Of course, there were many, many
10 animal carcinogens which had not been drawn to my attention at
11 the same time.

12 Q Do you feel, Dr Doll, as a physician, that when a man-
13 ufacturer of a product learns of studies that indicate a potential
14 cancerogenic problem with that product, that they have a duty
15 to disclose that information to their workers and to their
16 customers?

17 MR BUNDA: Objection. I am going to interpose an
18 objection on the basis it is speculative, it is a vague
19 question, it improperly states the facts of the situation
20 and further more, is irrelevant to this particular case.

21 BY THE WITNESS:

22 A My answer to the question would be I cannot give an
23 answer to it because it depends upon the situation. I am very
24 much opposed to frightening people unnecessarily. If you asked
25 me whether on the basis of such findings, inquiries should be

UPL 11637

1 made as to whether there were any hazards to humans, but I would
2 say unhesitatingly yes, but the question of disclosure is always
3 a very difficult one. There are so many things which can cause
4 cancer in certain circumstances, and one has to, as a research
5 worker, use your judgment as to what is proper information and
6 what is scaremongering and I would not feel that I could pass
7 judgment on actions taken many years ago on the basis of a
8 totality of evidence of which I am not wholly aware.

9 BY MR DELLI BOVI:

10 Q Do you regard Dr Maltoni's 1970 and 1971 publications
11 which has been marked as Doll Exhibits 5,7 and which I will mark
12 as Doll Exhibit 8---

13 MR BUNDA: Hang on. Did you miss-state yourself. You
14 mentioned Dr Maltoni. Did you mean Dr Viola?

15 MR DELLI BOVI: Dr Viola.

16 MR BUNDA: What is the exhibit number?

17 MR DELLI BOVI: 5, 7 and 8.

18 MR BUNDA: Again I object to the numerocity of the
19 exhibit numbers.

20 BY MR DELLI BOVI:

21 Q Do you regard those documents, Dr Doll, as documents
22 calling into serious question the carcinogenicity of vinyl chloride.
23 (Documents handed to the witness)

24 A I regard the one in 1971 in Cancer Research as so doing.
25 The others I regard as preliminary reports and I think one would

U/RL 11638

1 be unwise to draw any conclusions, any important conclusions from
2 them but the paper in 1971 by Viola, Bigotti and Caputo is
3 certainly an important paper to which attention should be paid.

4 Q Is your understanding that Dr Viola, at the time he
5 authored these papers, was employed by one of the European PVC
6 manufacturers?

7 A I have no idea who he was employed by. I know
8 Dr Maltoni personally but I do not know Dr Viola, I have never
9 met him.

10 Q You indicate in your 1985 publication: "The idea that
11 vinyl chloride might cause cancer was first suggested by Viola
12 in 1970 as a result of experiments in rats". Correct?

13 A Yes, I said that but clearly it is wrong because he
14 reported it in 1969, verbally, did he not, at the Houston
15 conference.

16 MR BUNDA: I am going to object and move to strike.
17 I think the Houston conference is 1970.

18 THE WITNESS: Ah, 1970.

19 BY MR DELLI BOVI:

20 Q Tokyo was 1969?

21 A 1966. I do not know what conference that was. The
22 cancer conference was Tokyo, 1966.

23 Q The 16th Congress on Occupational Health.

24 A Oh, I did not know anything about that conference.

25 Q You indicated earlier that you were not aware of any

URL 11639

1 efforts by any PVC manufacturers in the United States to keep
2 the 1970 findings of Dr Viola from being published in the United
3 States?

4 A Yes.

5 Q Is it your belief, Dr Doll, that the PVC manufacturing
6 industry after the publications of Dr Viola in 1970 and 1971,
7 had an obligation to disclose Dr Viola's findings to their
8 employees and to their customers?

9 MR BUNDA: Objection, I think it calls for speculation,
10 it is a vague question, it is over broad and it is irrelevant
11 to this case and mischaracterizes the information which is
12 in evidence and the status of the situation which existed
13 in 1970.

14 BY THE WITNESS:

15 A I do not think I could give an answer about what
16 happened at that time. I was not aware of what was going on and
17 it would be too speculative.

18 BY MR DELLI BOVI:

19 Q Dr Doll, I am not asking you to tell me or to tell this
20 jury what happened. What I am asking you as a physician special-
21 ising in epidemiology, whether, based on the 1970 and 1971
22 studies of Viola, the PVC industry had a duty to disclose those
23 findings to its customers and to its employees?

24 A I cannot answer that question because I am a scientist,
25 not a politician and I spend my time trying to decide what data

URL 11640

1 means. I do not tell people what they should do and I cannot
2 express an opinion on what people should have done or what people
3 should do now. It is not my line.

4 Q You do not, in your capacity here at Oxford, advise
5 industry or the Government on whether they should or should not
6 disclose particular epidemiological data?

7 A No, I do not think so. I am trying to think if I do.
8 I just publish my results in the scientific press and I think
9 that is the responsibility of the scientist. Then, other people
10 have to decide what they do about it. I remember when we first
11 discovered that smoking caused cancer of the lung, we were always
12 being asked what the Government should be doing about it and we
13 said: "That is nothing to do with us." It took them seven years
14 to tell the public that smoking caused cancer of the lung and
15 I did not express an opinion on that.

16 Q Did you feel, based upon the initial results of your
17 studies, that the public had a right to know what you found out?

18 A I do not feel things - - well, that is not true, I
19 obviously do as a human being, but I try not to feel anything
20 on a scientific matter as that can prejudice my scientific judg-
21 ment as to what the cause of disease is. I try to keep quite
22 separate from that field. I try to do work to find out what
23 causes disease, publish it openly and then it is for others to
24 decide what should be done, not for me.

25 Q I would like to read you an excerpt from Plaintiffs'

URL 11641

1 Doll Exhibit 6. I am going to represent ^{to} you that this was an
2 internal memorandum prepared by R.N. Field of Union Carbide, as
3 the result of a meeting of the Occupational Health Committee of
4 the Manufacturing Chemists Associations. The date of the memor-
5 andum is November 23, 1971. "Publishing of Dr Viola's work in
6 the United States could lead to serious problems with regard to
7 the vinyl chloride monomer and resin industry. These are as
8 follows:- 1) The Delaney amendment bans the use of any material
9 in food that can cause cancer. 2) A law exists in Pennsylvania
10 banning carcinogens from the air i.e. the allowable threshold
11 limit is zero. 3) The present political climate in the United
12 States is such that a campaign by Mr R. Nathan and others could
13 force an industrial upheaval, via new laws for strict interpre-
14 tation of the pollution and occupational health laws." Did the
15 CMA, when they furnished you with materials for you to review
16 in connection with your 1988 review in the Scandinavian medical
17 journal, ever furnish you with a copy of that memorandum, sir?

18 A No.

19 Q Are you aware of any efforts by the polyvinyl chloride
20 industry between 1970 and 1974 to make publicly known or to make
21 known to their customers or to make known to their employees,
22 the findings of Dr Viola?

23 A No.

24 Q Are you aware of any efforts by the polyvinyl chloride
25 industry in the United States between 1970 and 1974 to conduct

UPL 11642

1 epidemiological research of PVC fabrication employees, following
2 the findings of Dr Viola.

3 MR BUNDA: I am going to interpose an objection to the
4 whole line of questioning as I have done before, on the
5 basis that it is irrelevant. I am also going to object on
6 the basis that there is no foundation having been laid that
7 this witness has any knowledge about this area of inquiry
8 at all and I move to strike the whole line of questioning.

9 BY THE WITNESS:

10 A I can answer it very simply, I do not know anything
11 between 1970 and 1988, I am just not aware of what the American
12 industry has been doing apart from what is published.

13 BY MR DELLI BOVI:

14 Q Dr Doll, you presented a discussion paper to the New
15 York Academy of Sciences in 1975, did you not, at a conference
16 specifically held to discuss the carcinogenicity of vinyl chloride?

17 A Yes. I think my paper was a summing up, was it not.
18 A conclusion to the discussions.

19 Q I am going to hand you what I will mark as Plaintiffs'
20 Exhibit Doll 8. Could you identify that document, please, sir?
21 (Document handed to the witness)

22 A Yes. This is a report of my discussion and my contri-
23 bution to the discussion.

24 Q That was at a conference discussing the carcinogenicity
25 of vinyl chloride approximately a year after the public announce-

URL 11643

1 ment of the Goodrich angiosarcoma deaths?

2 A I cannot remember the whole discussion. Certainly
3 vinyl chloride was part of it but I do not remember whether
4 there were other things discussed or not. I have a very poor
5 memory of the discussions. I only remember that in the report
6 of it I was made to say something which I did not say but that
7 is another matter.

8 Q Sure, and that particular point had nothing to do with
9 vinyl chloride?

10 A Not that point, no.

11 Q In fact, that point is corrected in that exhibit?

12 A Yes.

13 Q That exhibit reflected your presentation in 1975 and
14 does so accurately?

15 A Yes.

16 Q Is it your opinion that for any human carcinogen, in-
17 cluding vinyl chloride, there is a safe level of exposure at
18 which no potential carcinogenic effects will occur?

19 A That is something I wish I could answer. I really have
20 not got an opinion on that. In cancer research we work on the
21 assumption that unless there are strong reasons otherwise, we
22 postulate that an effect is produced proportional to dose down
23 to vanishingly small levels but whether this is so or not is a
24 matter of great debate and which we really have no firm scientific
25 evidence one way or another. We act on the assumption in the

JRL 11644

1 same way as we are acting on the assumption now that other people's
2 tobacco smoke in a room will cause a risk to the people who are
3 not smoking, but the scientific proof that this is so is such
4 that I really have not got an opinion. What I have is a working
5 rule, but not an opinion.

6 Q What is your working rule?

7 A The working rule is to assume that there is an effect
8 proportional to dose down to vanishingly low levels, given that
9 the material is a mutagen. If it is not a mutagen, then my
10 working rule would be that is probably not the case and there
11 would be a threshold below which it had no effect.

12 Q Vinyl chloride is a mutagen?

13 A Yes.

14 Q Therefore, your working rule is what?

15 A My working rule is that you would assume there was an
16 effect proportional to dose down to vanishingly small levels.
17 A vanishingly small effect but an effect.

18 Q A vanishingly small effect with regard to the general
19 population, exposed, but a very---

20 A Yes.

21 Q But a very real effect for that person who develops
22 the cancer?

23 MR BUNDA: Objection, calls for speculation. You can
24 go ahead and answer.
25

URL 11645

1 BY THE WITNESS:

2 A Yes, this is true, but I believe society has to accept
3 that there is such a thing as a negligible risk, otherwise
4 society is not possible to run, it becomes socially impracticable.

5 Q Let us have a look at vinyl chloride in this concept
6 of no safe level. You are aware, are you not - - let me back
7 up one step. There are many types of cancer?

8 A Yes.

9 Q One of which is angiosarcoma of the liver?

10 A Yes.

11 Q Angiosarcoma of the liver is an exceedingly rare cancer?

12 A Yes.

13 Q And occurs approximately to one person out of every
14 10m or 20m?

15 A Approximately once to every 10m each year. That is,
16 once to every 10m in a population in a year, yes.

17 Q You are aware of studies, are you not, postulating
18 increased risk of cancer from vinyl chloride at exposure levels
19 in the parts per billion?

20 A No. Oh, I am aware of some evidence that there may
21 have been some cases produced in the surroundings of some
22 factories in New York State where the concentrations to which
23 people were exposed were of the order of parts per billion.
24 Whether they really did cause cancer or not is difficult to say.
25 What I have said and my policy in interpreting such data and,

UFG 11646

1 of course, this is coming up at the present moment in regard to
2 clusters of leukaemia in regard to nuclear installations, first
3 of all you have to decide is there a greater instance of this
4 particular type of cancer in that neighbourhood. If you come
5 to the conclusion there is a greater one than it would be
6 reasonable to expect, you then have to say, well, what could it
7 be due to and it is very easy to jump to a conclusion that it
8 is due to a particular factory or a particular amount of waste
9 that is being released, environmental pollution, just on the
10 grounds that that material is known at high dose levels to
11 cause some cancer. But, to conclude that the two are connected,
12 you have to have some evidence that the amounts to which the
13 people are exposed might reasonably be thought to produce the
14 effect that is observed, otherwise you may be blinding yourself
15 to some other causes and I can only conclude that the effect is
16 due to the postulated pollutant if one can decide on the basis
17 of the totality of the evidence available that the sort of hazard
18 observed is of the order of magnitude of the sort of hazard that
19 might be anticipated, so that the situation, the problem in each
20 case is a difficult one which needs a lot of evidence. I left
21 it open in relation to vinyl chloride and the vinyl chloride
22 producing plants because we have not yet got sufficiently clear
23 evidence of the dose to which people are exposed that have
24 produced the measured risk we have been able to measure in the
25 industry concerned.

UPL 11647

1 Q It is your opinion, however, that vinyl chloride as a
2 carcinogen and as a mutagen is capable of producing cancers at
3 exposure levels in the parts per billion?

4 A No, I would not express it as my opinion. I would
5 express it saying it is my belief we have to consider that as
6 a possibility.

7 (Whereupon there followed a short adjournment)

8 BY MR DELLI BOVI:

9 Q Dr Doll, are you aware of any human carcinogens that
10 Hermon Dendinger or Fred Wallace were exposed to at Chrysler
11 other than vinyl chloride?

12 A I am not sure. Was not one of them exposed to ethylene
13 dioxide? I am not sure. I have not looked into it.

14 Q Have any of the polyvinyl chloride manufacturers that
15 are Defendants in this case presented you with any evidence in-
16 dicating Mr Dendinger or Mr Wallace were exposed to any other
17 human carcinogen?

18 A I should need to refresh my memory, to look at the
19 papers I have had.

20 Q You indicated in your 1975 presentation to the New
21 York Academy of Sciences: "Cancer is a process in which several
22 factors are likely to participate. A particular chemical carcin-
23 ogen is only one factor which interacts with a number of others
24 that may depend on the environment or on the functional state
25 of the body, and a simple linear relationship with one factor

URL 11648

1 "may be seen in all sorts of complex situations." Do you agree
2 with that statement today?

3 A Yes and no. I would not put it quite in that form
4 today. At that time I wrote that I was fairly confident in my
5 own mind that there was a real effect creating a risk of cancer
6 down to vanishingly low levels. In the past twelve or thirteen
7 years I have learnt more about the repair mechanisms of the cell
8 and I would be more open minded now as to whether that actually
9 was the position or not. I would still say that that is a
10 possibility but I will be much more open minded to the possibility
11 that the human body was capable of dealing with very small
12 amounts of carcinogen and thereby repairing the damage done than
13 I was in 1975.

14 Q By the time you made that presentation in 1975, dozens
15 of workers exposed to vinyl chloride had already died of angio-
16 sarcoma of the liver?

17 A I do not think that is quite true, is it. I would
18 have thought it was under 20 by 1975, but we have the register
19 of cases. That will tell us how many there were. How many were
20 there?

21 Q There were 23 by the end of 1974 and I do not think
22 we can tell from the way the data is presented how many there
23 were in 1975.

24 A That is what I said. Not dozens but of the order of
25 20 is I think what I said.

JPL 11649

1 Q At your presentation in 1975 you were critical, were
2 you not, of the polyvinyl chloride industry's lack of monitoring
3 its work force over years prior to 1975?

4 A Yes, I had been critical of many industries at their
5 failure to maintain on-going studies or cohort studies of their
6 work as I had been teaching this for the last thirty years.
7 Whether the industry was in fact, had in fact started one then,
8 I do not know. The Tabershaw and Gaffey study, when that was
9 first commissioned, I cannot remember now, but it was certainly
10 my view at that time that the industry ought to be organising
11 a cohort study of its workers.

12 Q By 1968 or 1969, when Herman Dendinger first came to
13 work at Chrysler, there had already been within the industry
14 9 angiosarcoma deaths?

15 A That certainly was not known at that time.

16 Q But was that not precisely the point you were making,
17 that if the industry had done these cohort studies and follow
18 ups of their workers, that they may well have discovered years
19 prior to 1974, the carcinogenicity in humans of vinyl chloride?

20 A That was a criticism I made of industries throughout
21 the world, not specifically of the vinyl chloride industry.
22 Their behaviour was no different from all industries in all
23 major countries. Some industries do no cohort studies at all.
24 In the Soviet Union they do not do any at all and I have been
25 nagging them for years that they should.

JRL 11650

1 Q Let me read a small excerpt from your 1975 presentation
2 and afterwards my question will be if you still subscribe to
3 this statement today. "I should like to re-emphasise a point
4 that has already been made several times in this conference;
5 that is, the one made by Dr Schweitzer when he said that all
6 responsible industries - certainly all those that are large
7 enough to employ a doctor - should maintain an on-going perspec-
8 tive study of the health of their working force. That does not
9 mean keeping an eye on them while at work only; it means keeping
10 an eye on them when they leave if they have been employed in
11 the industry for (say) five or more years. Professor Schilling
12 and many other people have been urging this for a long time.
13 How we can have a situation in which a new risk is discovered
14 in a major industry and then have to set up a prospective study
15 to find out what is actually happening to process workers is
16 incomprehensible to me."

17 A Yes, I have been teaching that since the middle 1950s.

18 Q You referred in your direct examination to an article
19 - - maybe you did not. One you wrote in 1986 called: "Cancer
20 - a preventable disease" and that was a presentation that you
21 made to the Royal Society of Medicine ?

22 A Yes.

23 Q I would like to read to you from page 20 of your
24 presentation in 1986 that dealt with animal studies. My question
25 will be the same as it was with the last paper, that is whether

URL 11651

1 you subscribe to that statement today. "Animals, however, vary
2 greatly in the way they absorb, metabolise and respond to
3 different chemicals and there are no observational data to
4 justify such an assumption. That is not to say that we should
5 ignore the results of laboratory tests in small rows, as there
6 are sufficient grounds for believing that agents that cause
7 cancer in one animal are quite likely to do so in others and it
8 would be criminal to allow anyone to be exposed unnecessarily
9 to a new chemical that was found to be a powerful carcinogen
10 in several animal species just because there was no human
11 evidence."

12 A Yes.

13 Q With respect to the cancer sustained by Fred Wallace,
14 the mucoepidermoid cancer, you indicated that you did not believe
15 that vinyl chloride was the source of that cancer because such
16 cancers had not been produced in animal experiments?

17 A Yes and not in humans, in the human population or
18 animal experiments .

19 Q Those were two different grounds for your opinion?

20 A Yes.

21 Q And you have reviewed the pathology report for
22 Mr Wallace to know what cancer he died from?

23 A Yes.

24 Q I would like to refer you to Dr Viola's 1971 paper and
25 the summary which reads in part: "The cutaneous tumours which

URL 11652

1 "always appeared/ⁱⁿ the area in which submaxillary and parotid
2 glands are located, have been histologically recognised as
3 epidermoid carcinomas, papillomas, and mucoepidermoid carcinomas."

4 A Yes.

5 Q At page 518 of his 1971 article, Dr Viola states, does
6 he not: "A few tumours showed little nests of isolated pale
7 cells of three types; mucin-producing cells (originating from
8 the duct epithelium of sweat glands or salivary glands); squa-
9 mous cells; and intermediate cells with minor tendencies to-
10 wards differentiation."

11 A Yes.

12 Q Was it your understanding that Mr Wallace died of a
13 poorly differentiated squamous cell, mucoepidermoid carcinoma---

14 A Yes, that is of a different organ to the ones that
15 Viola is describing. Viola's description has been discounted
16 since 1974, when it was appreciated that the tumours that Viola
17 was describing were not tumours that had anything to do with the
18 salivary glands at all but they were related to a zimal gland
19 of rats which is a serpaceous gland and has no relationship what-
20 soever to a salivary gland. This is uniformly accepted by
21 every cancer research worker to whom I have spoken. At the time
22 Dr Viola made his first observations he was not very experienced
23 with the rat pathology and he attributed them incorrectly. His
24 error has been corrected ever since 1974 and it is not questioned
25 now.

JHL 11653

1 Q Have you reviewed other scientific articles or case
2 studies associating buccal cavity or cancers of the pharynx with
3 exposure to vinyl chloride?

4 A I have read one article relating a cancer of the buccal
5 cavity to someone who chewed plastic. That is the only article
6 which I could think of which might be relevant to your question.

7 Q Did Tabershaw and Gaffey report an excess of buccal
8 cavity and cancers of the pharynx in 1974 MCA study?

9 A That is quite possible but I would not pay any
10 attention to that because I looked at their longer follow-up
11 when they had the more complete data, that is preliminary data
12 and their final data do not show any excess tumours in that cate-
13 gory. There may be one excess compared to the expected, I can-
14 not remember. 15 as compared to 13.5.

15 Q Have you referred or been furnished for your review
16 prior to today, with any portions of the hearings held by the
17 Occupational Health and Safety Administration in the United
18 States relating to regulating vinyl chloride following public
19 announcement of the Goodrich cancer deaths in 1974?

20 A Frankly, I find them too tedious to read and I never
21 read those hearings, I prefer to read the basic science on which
22 they are supposed to be based.

23 Q Do you know Mr Thomas Mancuso of the Pittsburgh School
24 of Public Health?

25 A Yes, I do.

UHL 11654

1 Q Are you very familiar with work in areas of beryllium?

2 A Yes and several other areas.

3 Q Do you regard him as an expert in the area in which
4 he practises?

5 A No, I regard him as a very unreliable person.

6 Q I would like to refer you to a portion of Dr Mancuso's
7 testimony before the Occupational Health and Safety Administration
8 and I would like to know after I read that extract whether or
9 not you agree with it. "Further, the skin tumours frequently
10 develop near the ear and submaxillary or the same areas as the
11 salivary glands. It was postulated by the original investigators
12 that vinyl chloride may enter the salivary gland system." Do
13 you have opinion on whether vinyl chloride or its active meta-
14 bollites, enter the salivary system in humans?

15 A I should be surprised if they do. I do not see why
16 they should go up against the saliver, but I do not know of any
17 results analysing the saliver in the salivary glands so I have
18 not any positive evidence but it seems an unlikely thing.

19 Q "If this/^{is} subsequently confirmed, it raises the question
20 whether tumours of the parotid glands can also occur as has been
21 demonstrated in the rubber industry and this has been confirmed
22 now by the testimony this morning that cancer of the parotid
23 gland has been observed in animals."

24 A Well, he is incorrect in talking about it being observed
25 in animals. He is basing himself on the erroneous reports of

URL 11655

1 Viola and I am not aware of any excess of cancer of the parotid
2 glands in the rubber industry. Certainly none of the very
3 detailed studies that have been carried out in this country in
4 the rubber industry have shown any such effect.

5 Q How rare a cancer is a parotid gland carcinoma?

6 A I cannot give you a figure but it is a rare cancer.

7 Q There was a statistically significant increase in the
8 deaths for parotid gland cancers at the Chrysler plant in Ohio,
9 was there not, Dr Doll?

10 MR BUNDA: Objection.

11 BY THE WITNESS:

12 A Not to my knowledge. Was there? I have seen no
13 evidence of that.

14 BY MR DELLI BOVI:

15 Q How is a parotid gland cancer classified under the
16 ICDA8?

17 A It is classified with the cancers of the buccal cavity
18 and pharynx.

19 Q Do you know whether a parotid gland carcinoma has its
20 own number?

21 A It has a sub-number, a fourth digit number. I think
22 it is separate from the submaxillary gland. It is a fourth digit
23 number I believe.

24 Q Are you aware of any attempts by Tabershaw and Gaffey
25 or by any of the other scientific investigators, to break out

UHL 11656

1 from the category of buccal cavity and cancers of the pharynx,
2 parotid gland cancers, so as to report those results separately?

3 A No.

4 Q You do not know then whether or not there may, within
5 that group of buccal cavity and cancers of the pharynx, be an
6 excess of parotid gland carcinomas based on the form on which
7 the data has been presented to date?

8 A No. One can be sure it is not a big excess but you
9 cannot be sure that within that group there was not three or four
10 cases.

11 Q And that brings me to the United States study that you
12 reviewed versus the United Kingdom study. In the United States
13 study, the organisation hired by the MCA only broke down the
14 number of cancers into about 33 categories?

15 A I do not know about only, it seems to me a very large
16 number. It was a very good effort to break them down to as many
17 as that.

18 Q Did not the United Kingdom study use 68 separate cancer
19 categories for reporting purposes?

20 A No, they had 68 different causes of death but nothing
21 like so many cancers. I think there were probably less cancers
22 than in the American study but of the same order.

23 Q Did the United States study report an increase in the
24 total number of cancers among the polyvinyl chloride workers
25 study?

UPL 11657

1 A Total number of cancers you said?

2 Q Yes, sir.

3 A The answer is no - - sorry, the answer is yes in
4 comparison with the United States. 383 against 343. 383 against
5 341-73. I must correct that, I am sorry. That is not what they
6 reported. That is the adjustment that I made. They reported
7 less than that. I increased the amount to take account of the
8 deaths of unknown cause. I forget now precisely how many they
9 reported. It could only have been about 360, I should think.
10 What I did was to say, well they were not able to find out the
11 cause of death of about 7% of the men that died and whereas they
12 of course, included them in the total deaths when comparing the
13 total 1500 deaths against the expected 1700, they did not in-
14 clude them in the individual causes and whether it is justifiable
15 or not to assume that the deaths for which they did not discover
16 a cause were evenly distributed, were equally distributed among
17 all causes in the same way as the deaths for which they did
18 discover a cause, is, of course, anybody's guess. What I did
19 was assume they were and add those deaths on so as to get a
20 worst possible place and that is the figure that I published,
21 but it is not the figure that they reported. That may not be
22 clear. I would be very glad to elaborate on that if that is
23 a confusing point.

24 Q No, I understand what you are saying, Dr Doll. In
25 terms of other cancers, did the United States study indicate a

URL 11658

1 statistically significant increase?

2 A I do not think they did for any other cancers. I am
3 just refreshing my memory. Apart from the liver, of course.

4 Q Would you look at pages 71 ---

5 A Yes, the brain is down here. Significant excess of
6 cancers of the brain. I am not sure about lympho-reticulo
7 sarcoma. That might be significant.

8 Q On page 71 of your paper on other cancers, do you show
9 a statistically significant excess?

10 A Page 71 is not referring to the American study, is it?
11 You are talking about cancer of the lymphatic---

12 Q No, I am referring to the other cancers, right-hand
13 column, page 71 about two-thirds of the way down?

14 A Ah, yes. Fine. This was the summation, not from the
15 American study, this was the summation of the four studies which
16 I regarded as providing the really important evidence, the main
17 contribution of which came actually from the United Kingdom
18 study. The American study did not show a significant excess of
19 this group of other and unspecified cancers. The four studies
20 added together does and as you will see in the report, I thought
21 the most likely explanation of this was the mis-diagnosis of a
22 few cases of angiosarcoma of the liver which would have appeared
23 as secondary liver cancers.

24 Q Your studies showed an increase in the rate of lung
25 cancer to those who were heavily exposed?

URL 11659

1 A It depends what you mean by "increased" . Not, I think,
2 a significantly increased one. The lung cancer mortality as a
3 whole amongst the vinyl chloride exposed workers was almost
4 precisely what was expected on national data, though I think
5 national data are very hazardous to use in comparison with
6 observed deaths from lung cancer because the mortality rate does
7 vary so from one part of the country to another and I do prefer
8 to use regional rates but when you broke the lung cancers down
9 to groups of people employed for a longer period against shorter
10 period or observed more than twenty years after first employment
11 compared with those observed for shorter periods, sooner after
12 first employment, then you invariably got a higher mortality in
13 the groups that one might regard as the more likely to show an
14 excess, but the differences in total were not such as to lead
15 to a clear evidence of an excess from lung cancer but just to
16 suggest that there might be such an excess.

17 Q Did the German and Swedish studies, were they consistent
18 with that?

19 A No. I will have to refresh my memory. The German one
20 was not, if I remember rightly, but I will have to check. Where
21 are we now. No, the German one did not show an excess, that was
22 23½ against 24½ expected. The Norwegian and the Swedish ones
23 did, from tiny numbers, both added together, was 5 against 4½
24 - - 8 against 4½ expected and the Italian did not show any, so
25 when you added the four studies together you got an observed of

URL 11660

1 31½ - the half comes in because of some of the adjustments the
2 Germans made against an expected of 30.7, so I would say the
3 subsidiary studies really supported the idea there was no excess
4 from lung cancer but I do not think you should put too much
5 weight on the subsidiary studies. I regarded them as subsidiary
6 studies because so much of their period of observation were at
7 a time before any occupational cancer could be expected to occur
8 that is to say the first twenty years after observation and the
9 evidence from the studies is really scientifically trivial. The
10 only thing of any importance amongst them is that they did show
11 that angiosarcoma were occurring in all these plants. That is
12 the only thing I put my money on.

13 Q You say angiosarcomas occur in cases with nine years'
14 latency?

15 A Not angiosarcomas. One.

16 Q And you have seen angiosarcomas with exposures of less
17 than fifteen years?

18 A Yes much less than fifteen years.

19 (Whereupon there followed a short adjournment)

20 BY MR DELLI BOVI:

21 Q Dr Doll, if a chemical is found as a result of animal
22 studies to be a potential carcinogen, do you have an opinion as
23 to whether the manufacturer of a product that contains that
24 chemical has responsibility to disclose to its customers that
25 that chemical is in its product?

UPL 11661

1 MR BUNDA: Objection.

2 BY THE WITNESS:

3 A That is an impossible question to answer. It depends
4 on circumstances too much.

5 BY MR DELLI BOVI:

6 Q Do you know whether or not any polyvinyl chloride
7 manufacturer in the United States prior to 1974 disclosed to its
8 customers that its product contained vinyl chloride?

9 A I know nothing about what the polyvinyl chloride man-
10 ufacturers disclosed to its customers in 1974 or 1988. I am not
11 aware of their activities.

12 Q Dr Doll, are people in the United States continuing
13 to die from cancers that they contract as a result of occupational
14 exposure to vinyl chloride?

15 A Oh, of course.

16 Q In terms of angiosarcoma deaths, how many have we seen
17 to date, reported cases?

18 A Worldwide or in the United States?

19 Q Worldwide.

20 A Worldwide, something of the order of 120.

21 Q Do you have an opinion or have you expressed an
22 opinion as to how many more angiosarcoma cases we are likely to
23 see as a result of occupational exposure to vinyl chloride?

24 A Yes.

25 Q What is your opinion, sir?

URL 11662

1 A I said that I thought it might be something of the
2 order - I am speaking from memory - 250, but I might be out by
3 50.

4 Q So your opinion then in terms of angiosarcoma deaths,
5 is that we have not yet reached the halfway point?

6 MR BUNDA: Objection. I am going to object again to
7 this questioning on the grounds that it exceeded the scope
8 of direct examination and also on the basis of relevancy.

9 THE WITNESS: Where does this put me in relation to
10 answering questions. We do not have a judge to say he
11 objects to the question or not.

12 MR DELLI BOVI: For the purposes of the questions, you
13 answer my question regardless of his objection---

14 THE WITNESS: And subsequently?

15 MR DELLI BOVI: They decide if the question will stand
16 or not.

17 THE WITNESS: Would you repeat the question?

18 BY MR DELLI BOVI:

19 Q Certainly. In terms of the number of angiosarcoma
20 deaths that you would anticipate would result from occupational
21 exposure to vinyl chloride, we have not yet reached the halfway
22 point?

23 A I think that is probably true, yes.

24 Q If, in fact, vinyl chloride causes cancers in humans
25 other than angiosarcoma of the liver, there may in fact have been

URL 11663

1 many more people who have died and will continue to die-as a
2 result of occupational exposure to that chemical. ;

3 MR. BUNDA: I am going to object again on the same
4 grounds as before and also because it calls for speculation.
5 So that I will not be interrupting the tape constantly, I
6 am going to have a continuing objection to this line of
7 question.

8 BY THE WITNESS:

9 A My estimate is there will be no such deaths occur in
10 the future.

11 BY MR. DELLI BOVI:

12 Q On what do you base that opinion, doctor?

13 A I base that opinion on a mixture of animal evidence
14 and human evidence of what we have seen to date of people that
15 have been heavily exposed to vinyl chloride.

16 Q The studies that you have referred to in your review,
17 include only employees that worked in the PVC industry for one
18 year or more?

19 A Yes, I think that is true. I am just wondering, I
20 think some of the studies included people for shorter periods
21 but I tried to exclude them and I think I did in the principal
22 studies.

23 Q What is the reason for using a one year minimum employ-
24 ment period as opposed to say, three months?

25 A It is a matter of practicality. There is a big turn-

URL 11664

1 over in many industries and the turnover occurs in the early
2 period. By the time people have been employed for a year they
3 are likely to stay for a good deal longer and if you have a
4 shorter period, a much shorter period, you are likely to under
5 estimate the effect that you will observe by including a lot of
6 people with very short periods of exposure. It is a matter for
7 arbitrary decision just which people you should include. Some-
8 times people go so far as to include only people who had five
9 years exposure. I have done that in some studies and it was
10 done in one of these vinyl chloride studies. Some people include
11 people that have had only one day's employment. I personally
12 think that is a very unwise thing to do because you have a very
13 big turnover of short term employees who give you very little
14 details about the effects of short term exposure and make the
15 study very, very difficult to do because you are tracing very
16 mobile people. There is a third reason. People who change
17 their jobs very quickly are a very unrepresentative group on the
18 population and there are a number of studies recently that have
19 suggested as a group they have more accidents, more cirrhosis
20 of the liver, various diseases because of their personal charac-
21 teristics. My general rule is to take a year as a practical
22 working rule. That avoids the big turnover of very short term
23 employees but does not reduce the size of the population too
24 much, but it is an arbitrary decision and I would go with other
25 people using other cut off periods.

LRL 11665

1 Q Does the use of a substantial shorter cut off-period
2 in a minimum period, say, three months, for example, have the
3 effect of diluting the potential effects from exposure to the
4 chemical in question?

5 A That is my belief although not all epidemiologists
6 would take that view.

7 Q And you are aware that in this case, Dr Shindell's
8 study of the Chrysler employees used a three months minimum
9 employment duration rather than one year or more?

10 A Yes.

11 Q It is your opinion then that that would have the effect
12 of diluting the effects from exposure?

13 A I would think it would.

14 Q Let us take a look also at the cut off period for the
15 study. It is your opinion, of course, that occupational cancers
16 have a latency period?

17 A Yes.

18 Q That is, that they take and may take many years between
19 the time of initial exposure before the cancer manifests itself?

20 A Yes.

21 Q Is it, therefore, important when you are doing an
22 epidemiologic study, to use a cut off date, a sufficient number
23 of years prior to the time you do your research in order for the
24 latent effects of exposure to the potential carcinogen or mutagen
25 in issue to manifest themselves?

JRL 11666

1 A You can do it that way, yes. I certainly think there
2 is not much point in including people that started to be employed
3 just in the last year or two. A better thing, of course, to do
4 is when you present your results, to present them separately
5 for people that have been observed in the first five years of
6 their employment, five to nine years afterwards, ten to twenty
7 years afterwards et cetera. That is the best thing to do and,
8 of course, it is because of this that I have put so much more
9 stress on the four principal studies because they are all studies
10 in which a very substantial number of observations were made on
11 people more than twenty years after their first exposure and
12 many of the other studies that I did not include, including
13 Dr Chiazze's study where they know nothing about the study of
14 exposure, time since first employment, these will all be affected.
15 They will all be affected by the high proportion with the short
16 time since first exposure. That is really equivalent of saying
17 they are not really relevant evidence. Occupational studies,
18 unless you have a type of cancer which appears very quickly as,
19 for example cancer of the bladder did following exposure to
20 naphthylamine, the evidence within the first ten years, even
21 within the first fifteen years, the first employment does not
22 tell you much about cancer hazards.

23 Q Would you agree that the incorporation into an epidemio-
24 logic study of recently employed members of a cohort also has
25 the effect of diluting the effects of exposure to the chemical

JRL 11667

1 in question?

2 A Yes, it certainly does though, of course, a lot of
3 people will include them because they will have in mind continu-
4 ing the study for longer and you already have them included.
5 If you begin by excluding them, then in ten years' time when you
6 want to do a follow-up, you suddenly find you have not got some
7 of the people you would like to have in, so most people, when
8 doing an epidemiologic study, do include people who have been
9 employed relatively recently so that they have the material
10 prepared for a continuation study.

11 Q But in terms of the reporting of the analysis that
12 recently employed portion of the cohort would be separately
13 analysed?

14 A That is right.

15 Q Again, if we look at Dr Shindell's study, have you
16 learnt that he included in his study, individuals first employed
17 potentially as little as 90 days before the cut off period?

18 A I cannot remember honestly whether he did that.

19 Q If he had done that, would that also have the effect
20 of diluting the effects of exposure to the chemical in question?

21 A Yes, but of course, it does not imply that he would
22 necessarily have observed a greater risk if he had cut them off
23 because I do not think from memory that he described exactly
24 the date of first employment of all the people, but if he did,
25 then that is a bald point.

UPL 11668

1 Q Have you ever attempted to analyse the fourteen cancer
2 deaths in the job categories in which Messrs Dendinger and
3 Wallace were employed, to determine the latency period?

4 A My understanding is that none of them are likely to
5 have had a long enough latent period to be of any interest, but
6 I must check, I am not sure of the details of this study.

7 Q Incidentally Dr Doll, that binder of material you are
8 going through, could you tell me where that came from?

9 A Yes, this was provided for me by the attorneys for the
10 defence.

11 Q What does that binder consist of?

12 A It consists of 26 different sets of papers including
13 most of the ones which you have discussed with me today.

14 Q Could I see it please?

15 A Yes. (Document handed to counsel)

16 Q Did you review all of the materials contained in this
17 binder?

18 A If by that do you mean have I read them before today,
19 yes.

20 Q And are the opinions that you have expressed today
21 based in part on your reliance on the materials contained in
22 this binder?

23 A No. My opinions that I have expressed today are based
24 essentially on the review which I carried out and has been
25 published in April, but of course, to that I have had to add

UPL 11669

1 the details about Mr Wallace and Mr Dendinger which I knew
2 nothing about. I have refreshed my memory about the early papers
3 of Dr Viola and there are one or two new ones like the one of
4 Dr Shindell you have talked about and there are some reports of
5 the industrial hygiene reports of the amount of vinyl chloride
6 detected, I think, by NIOSH inspectors in the Chrysler plant,
7 but I need to refresh my memory as to who exactly made those
8 measurements. I think those are the principal new bits of
9 evidence that they drew to my attention.

10 Q One of the documents in that binder is the Molina
11 Swedish study from 1981?

12 A Yes.

13 Q Does that study report: "An elevated risk of morbidity
14 and mortality from tumours in the digestive organs"?

15 A Yes, if you remember, we discussed that before and I
16 included in my review and decided it was a paper that was too
17 unreliable to mean anything. The digestive organs that it refers
18 to there, I think, I forget the exact number, but it does not
19 separate out - - no, I cannot comment on that without refreshing
20 my memory, but my view is that that paper is not really, cannot
21 really be regarded as evidence. There are too many weaknesses
22 in the paper.

23 Q Rendering your opinions with regard to the aetiology
24 of the cancers of Fred Wallace and Herman Dendinger, or your
25 opinions relating to the potential implication of vinyl chloride,

URL 11670

1 did you rely at all upon the indexes or summaries of their
2 depositions that were provided to you and that you read?

3 A No, no. I would not feel able to do that without
4 seeing the entire thing.

5 Q You are aware of the 1984 article by Maltoni that is
6 not cited in your review, reporting angiosarcoma cases among
7 workers in the PVC fabrication industry?

8 A No, I had not come across that until I was sent that
9 report. That was news to me.

10 Q Did you receive this document after you authored your
11 report that appeared in the Scandinavian journal?

12 A Yes. I would not have included it anyway - - yes, I
13 would have included the statement that there were angiosarcomas
14 reported in that plant, but I was not covering fabricators and
15 so the probability is that I would not have included anyway,
16 but I had not seen it. When was it published?

17 Q 1984. Did you personally review or conduct the
18 literature review for the report that you authored or did you
19 have a research assistant perform that task for you?

20 A No, I did it myself which is to say, of course, one
21 also made use of the automated techniques which medical libraries
22 provide for you.

23 Q In forming the opinions you expressed regarding the
24 cancer sustained by Fred Wallace and Herman Dendinger, did you
25 rely at all on the industrial commission reports that are

JRL 11671

1 contained in the binder that Mr Bunda presented to you?

2 A No, I based my opinion entirely on the fact that those
3 two types of cancers are not seen in people heavily exposed to
4 vinyl chloride and not produced by vinyl chloride in animal
5 experiments.

6 Q In connection with your assumptions concerning the
7 vinyl chloride levels in the workplace at Chrysler, did you
8 rely at all on the letters of August 25, 1986 and April 7, 1987
9 by Jack Peterson?

10 A That is the only information I have had. I think those
11 are the only ones in that book, are they not? I have had no
12 other information other than what is provided in that book about
13 the levels at Chrysler works.

14 Q Is it important for an epidemiologist who is investi-
15 gating a particular chemical, not to establish preconceived
16 notions or assumptions as to what cancers that chemical can and
17 cannot produce?

18 A Yes.

19 Q Have you read at all prior to today, the sworn testi-
20 mony of Dr Shindell?

21 A No.

22 Q Have you been furnished prior to today with his testi-
23 mony?

24 A No.

25 Q Have you read prior to today, the sworn testimony of

UPL 11672

1 any witness in this case?

2 A No.

3 Q Have you read prior to today the sworn testimony of
4 Herman Dendinger and Fred Wallace?

5 A No.

6 Q In the Environmental Health Associates Study of 1986
7 - and I would like you to refer to your report if you would, at
8 page 62, the right-hand column - it indicates that he studied
9 a total of 10,173 men?

10 A I am sure that is right but I cannot see where you are
11 pointing---

12 Q The first paragraph of the United States study.

13 A Page 62, I am sorry I was looking at 63. Yes.

14 Q That was his cohort?

15 A Yes.

16 Q Included in that 10,173 men were 1,176 men in five
17 plants that produced homopolymers and copolymers with or without
18 vinyl chloride monomer or polyvinyl chloride?

19 A Yes.

20 Q Is that correct?

21 A Yes.

22 Q So at least potentially incorporated into his data of
23 a cohort of 10,173 men, were 1,176 men that may not even have
24 been exposed to the chemical?

25 A I think that is unlikely the way it is phrased:

URL 11673

1 "with ~~or without~~", but I am afraid you would have to ask a more
2 exper~~imental~~ chemist than myself as to the implication of the
3 homopolymers and copolymers.

4 Q If we look at page 1 of your review, did all four of
5 the principal studies you relied on, the United States, the
6 United Kingdom, the Canadian and the Italian study show an
7 increase above the number expected of the number of observed
8 cancers in the polyvinyl chloride workers?

9 A In comparison with the national expected, yes. The
10 Canadian was not the national expected, it was the Quebec
11 mortality rates.

12 Q But each of the studies showed an increase in the total
13 numbers of cancers?

14 A Yes.

15 Q Dr Doll, do you know why, in terms of the United States
16 figures, in Table I there is no data presented at all with respect
17 to liver cancers?

18 A Yes. The authors were working with a particular ICD
19 category in which liver and gall bladder were put together as
20 one in the ICD category but they did, of course, publish
21 separately a listing of the 39 cases, using the 7th revision,
22 that they were using, they had not got the separate numbers,
23 they had not got the separation of liver and gall bladder and
24 that is a weakness of their study, but I think we can assume that
25 the deaths were practically all cancers of the liver. The expected

URL 11674

1 deaths for cancer of the liver, I think I am right in saying,
2 were not available separately from the American data at that
3 period, but that may be wrong.

4 Q If we look at Table 4, did the results of the four
5 principal studies, United States, United Kingdom, Canada and
6 Italy, show an increase above that expected for cancers of the
7 mouth and pharynx in the polyvinyl chloride and vinyl chloride
8 workers?

9 A They showed 18 deaths against 16.6 expected.

10 Q For a PMR of 109?

11 A Yes.

12 Q If we go down to Table 5 which reports the studies from
13 Germany, Norway, Sweden and Italy, encompassing 14 plants, did
14 those four studies combined reveal an increase above the number
15 expected of digestive system cancers excluding cancer of the
16 liver?

17 MR BUNDA: Objection. I am going to object to the form
18 of the question on the basis that when we are talking about
19 an increase you have to have a data point from which you
20 show an increase. I think it is a mischaracterisation of
21 what the table shows. The table shows there is a greater
22 number but I do not know if that is an increase or decrease.

23 BY THE WITNESS:

24 A The table showed a greater number but the excess was
25 smaller than the deficiency in Table 4 in the principal studies

URL 11675

1 to which you have not drawn my attention which, of course, was
2 125 deaths against 166.4 expected. When you combine the two,
3 you get an observed which is less than that expected.

4 BY MR DELLI BOVI:

5 Q One of the problems ^{with} these studies, when they are
6 combined, is that the researchers have not reported their results
7 in a uniform consistent manner?

8 A That is one of the difficulties that one has in
9 combining them and one of the reasons why several of the sub-
10 sidiary studies were regarded as subsidiary. The Swedish study,
11 for example and the Norwegian study, both report their data in
12 such an incomplete way they could not be usefully used, whereas
13 the three of the principal ones reported them in a very detailed
14 way. The Canadian one was not as detailed as one would like.

15 Q The Canadian one only dealt with a total of twenty
16 deaths?

17 A Yes.

18 Q And the Canadian one was even less than the total
19 number of cancer deaths at Chrysler?

20 A Yes.

21 Q The Italian study only dealt with 30 deaths?

22 A Yes, but they are both good and important studies in
23 the sense that they had observations on people more than 25 years
24 after they were first employed and they both had cases of angio-
25 sarcoma of the liver in them so they were relevant to include

UPL 11676

1 and it would have been improper to have excluded them. Although
2 the numbers are small, they are of real value in that they
3 report relevant data.

4 Q In terms of the angiosarcoma deaths in the United
5 States, you indicated in your 1985 article in British Journal
6 for Industrial Medicine that 23 of the 33 cases that had been
7 reported to date in the United States involved just two factories.
8 Could I refer you to that document. (Document handed to the
9 witness)

10 A Yes.

11 Q Have any of the PVC manufacturers disclosed to you at
12 which of their facilities these large increases in the angio-
13 sarcoma deaths were experienced?

14 A I am afraid I cannot answer that question. I cannot
15 remember whether it is in the angiosarcoma register or not. It
16 has not been a question I have been asked.

17 Q Let me combine that point, that is the concentration
18 of angiosarcoma deaths at a relatively small number of plants,
19 with the differences in the results of the data you have reviewed.
20 Some show an increase in brain cancer, some show an increase in
21 thyroid cancer, some show an increase in melanomas, some show
22 an excess in the digestive system, some show an excess in lung,
23 some do not. Could those differences and the seeming irrecon-
24 cilability of all the data, be due to what you described in one
25 of the articles we talked about earlier as the need to consider

JRL 11677

1 each facility and the cohorts exposure and the peculiarities of
2 those facilities or the peculiarities of the particular vinyl
3 chloride or polyvinyl chloride resin produced or used by those
4 facilities into account?

5 A No, that is not the natural interpretation. The
6 natural interpretation is this is exactly what you would expect
7 to find if you look at 25 different reports and look at 25
8 different cancers in each of them. I guarantee whatever the
9 chemical was, if you looked at as many different cohorts as have
10 been looked at in relation to vinyl chloride and looked at as
11 many different cancers in them, you would find precisely this:
12 It is inevitable. This is exactly what chance means. If you
13 look at 25 different types of cancer, one will show a signifi-
14 cant excess by chance. That is the definition. If you look at
15 20 plants and 20 factories, then you are going to get 20 times
16 that number of excesses and they will all be different. If you
17 want to find an excess which you are going to relate to the
18 particular conditions of the plant, you want to show that it is
19 consistent in other plants that have the same chemical exposure,
20 you want to show it occurs at the right time after exposures
21 and it is concentrated on people who have had longer rather than
22 shorter terms of exposure. All these are things you take into
23 account. What you have described is what I would expect to find
24 in any series of studies no matter what chemical you were looking
25 at, irrespective if it was not a carcinogen.

QAL 11678

1 MR DELLI BOVI: Could we go off the record for just
2 a minute?

3 (Off the record)

4 BY MR DELLI BOVI:

5 Q Finally, Dr Doll, there are a number of exhibits that
6 I would like you to identify for me. I understand that a number
7 of those are your only copy and I will be more than happy to
8 substitute a copy of that document for the original but I would
9 like to get the documents marked so we are clear what we do and
10 do not need copies of.

11 A May I just ask. Will you pay for the photocopying of
12 them or who shall I charge?

13 Q Absolutely, I shall be more than happy to, as well as
14 the time of who does it for me. Would you first identify
15 Exhibit Doll 9. (Document handed to the witness)

16 A Yes.

17 Q What is that?

18 A A version of the United Kingdom report which has been
19 published in the Scandinavian journal, Work, Environment and
20 Health in June this year, provided me by Dr Jones in January,
21 1987. I see that it says the version I received in 16th January.
22 It is not the press version and I cannot guarantee that it is
23 precisely the same as that on which I based my final conclusions.
24 but it is certainly near enough it.

25 Q Did you indicate in your review who commissioned

URL 11679

1 Dr Jones to conduct that study?

2 A Yes, this was carried out by the Government, I suppose
3 the equivalent of NIOSH. Our health and safety executive.

4 Q Would you identify Plaintiffs' Exhibit Doll 10, please?

5 (Document handed to the witness)

6 A Yes, this is a translation of an Italian article that
7 I arranged to have. The Italian article was sent to me by ICI
8 in this country, it had not been published at the time, it has
9 subsequently been published in English, but I have not got a
10 copy of the English translation, only of the one I had made
11 personally.

12 Q ICI is a European ---

13 A ICI is a big chemical industry that makes polyvinyl
14 chloride.

15 Q Do you know Dr David Duffield?

16 A No.

17 Q Plaintiffs' Exhibit Doll 11 contains a number of your
18 publications that I have requested, does it not? (Document
19 handed to the witness)

20 A Yes.

21 Q Your preference is that we not mark the originals of
22 those publications but you will provide me at my expense with
23 copies of the publications that are listed on that exhibit?

24 A Yes indeed, they are my only copies of my own work and
25 I prefer not to have them marked, but I am very happy to let you

UPL 11680

1 have copies. Do you want copies of the two books?

2 Q I have reviewed them earlier. I do not have a need
3 for copies of either of those.

4 A If you could be so good as to initial or that is not
5 necessary. I am sure you will accept my withdrawal of the
6 appropriate two?

7 MR DELLI BOVI: Certainly.

8 MR BUNDA: Rather than sending them directly to
9 Mr Delli Bovi, since we are attaching the list, let us
10 attach the articles to the transcript. So, why don't you
11 provide them to the Court Reporter and she can attach them
12 to the transcript.

13 THE WITNESS: Whatever you suggest.

14 BY MR DELLI BOVI:

15 Q Finally, Plaintiffs' Exhibit Doll 12 is a binder of
16 materials that were presented to you for your review and which
17 you have in fact reviewed concerning this case?

18 A Yes.

19 MR DELLI BOVI: That is all I have, Dr Doll. Thank
20 you.

21 RE DIRECT

22 BY MR BUNDA:

23 Q I have a couple of questions. I realise the hour is
24 late and we are all tired doing this but I just want to go over
25 one or two things. I would like to refer you if I could to the

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1 1981 study done by Dr Chiazze. Do you have that before you,
2 that is Exhibit 2.

3 A Well, we have it in here so I can look at it here.

4 Q Let's make sure we have the exhibit. Do you have that?

5 MR DELLI BOVI: Certainly I have a pile of materials
6 here.

7 THE WITNESS: I have it here, Exhibit 2.

8 MR DELLI BOVI: Do you mind, we have three copies of
9 this study, could I have one of them please? (Document
10 handed to counsel) Thank you.

11 BY MR BUNDA:

12 Q Did Dr Chiazze when he was doing this study, attempt
13 to determine whether or not those people that he studied in the
14 cohort deaths that he looked at, whether or not all of those
15 people had had exposure to vinyl chloride?

16 A No. In fact, it is quite clear that a lot of them
17 had not.

18 Q How can you tell that? For example, look at Table
19 5, please.

20 A Yes, that is the table I had in mind where 61% of the
21 women with breast cancer had no exposure and 72.4% of the
22 controls also selected from women who had died of other diseases
23 had had no exposure and another substantial proportion who had
24 had improbable exposure.

25 Q Of the cohort or deaths that you looked at in your study

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1 did those people all have exposure to polyvinyl chloride or
2 vinyl chloride?

3 A Well, there is a possibility that a few did not that
4 worked in these plants producing homopolymers and copolymers.
5 I am not quite sure whether they have exposure. Some of them
6 may not have, but the great majority of all the others certainly
7 did have. I would have to check my memory on the United Kingdom
8 study as to whether there were any that had no exposure. I am
9 not quite sure.

10 Q So would it be improper to compare the Chiazze study
11 with your study in terms of comparing the number of deaths?

12 A Oh completely improper. They bear no relation to one
13 another as far as hazards of vinyl chloride are concerned.

14 Q Getting back to the Chiazze study for just a second,
15 why were those particular people in Table 5 looked at to deter-
16 mine their exposure?

17 A If I may elaborate, my previous answer ---

18 Q Oh, I am sorry.

19 A I was checking on the United Kingdom study and all
20 5,500 men who were employed had potential exposure to VCM for
21 25% of the work week. I thought that was the position but I
22 wanted to check. Sorry, what was the first question?

23 Q Getting back to the Chiazze article of those people
24 in Table 5 that we looked at before, what was the reason why
25 the exposure information was determined for them?

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1 A Because there was an excess, a higher proportion of
2 deaths were attributed to breast cancer among the female workers
3 than would be expected if the distribution had been the same
4 as deaths in the United States as a whole and he wanted to in-
5 vestigate this further and he did the proper thing for an epidem-
6 iologist to do in this situation which is to do a nested case
7 control study, that is to say one in which you make special
8 inquiries about the affected patients and then you choose a group
9 of other people who did not develop the same disease but who
10 were matched in certain respects, same age and similar charac-
11 teristics like that and compare the exposures of these two groups.
12 That is what Dr Chiazze did.

13 Q What happened when he did that?

14 A Well, he found that of those with possible or definite
15 exposure there were 4.5% of women who died of breast cancer and
16 a possible or definite exposure in 7.5% in their matched controls.
17 In other words, a higher proportion had had possible or definite
18 exposure in the women that did not develop breast cancer but
19 both proportions were extremely small.

20 Q It also showed, did it not, that a large percentage
21 of women who had breast cancer had no exposure?

22 A It did. 75% had no exposure or improbable exposure.

23 Q What effect did that have on the hypothesis that vinyl
24 chloride was somehow related to breast cancer?

25 A Oh, I think it made it quite clear that it was not

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1 related in any way.

2 Q During the cross examination we heard in the discussion
3 of this article about a significant statistic with regard to
4 all cancers and large intestine cancers. This breast cancer
5 statistic was also deemed important by Dr Chiazze at first, was
6 it not?

7 A Yes.

8 Q Is this case control study which he thereafter did,
9 an example of the pitfalls that you can run into if you jump
10 to conclusions about proportionate mortality results?

11 MR DELLI BOVI: Objection, leading. You can go ahead
12 and answer.

13 BY THE WITNESS:

14 A I think it was a perfectly natural thing to do if you
15 were wanting to see whether the findings that you had found from
16 a proportionate mortality ratio study did have any significance
17 in relation to the exposure to which the individuals were con-
18 cerned. In this case it said certainly as far as the breast
19 cancer was concerned, exposure of vinyl chloride was irrelevant.

20 Q Similarly we have no information available concerning
21 whether those people who were shown as having colon cancer in
22 the study, had any exposure to vinyl chloride?

23 A No such information.

24 Q Dr Doll, you were also asked how payment was made by
25 the CMA to you after you were asked to do this comparison study

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1 which was recently published and you indicated a donation was
2 made to charity. Do you recall that?

3 A Yes.

4 Q Can you please explain to the jury what is the relation-
5 ship or how payment is being made to you as far as your consul-
6 tation for the Defendants in this case?

7 A In the same way. I have always refused to take money
8 from industry for any purpose in order to retain my independence
9 and I made it a condition of appearing as a witness in this case
10 that the normal consultation fee should be paid to charity and
11 not to me directly.

12 MR BUNDA: Thank you, sir. That is all the questions
13 I have.

14 FURTHER CROSS EXAMINATION

15 BY MR DELLI BOVI:

16 Q I would like you to assume that the trade industry
17 for polyvinyl chloride manufacturers in the United States,
18 Chemical Manufacturers Association, the Manufacturing Chemists
19 Association sponsored and paid for Chiazze's initial work. As
20 a result of that, would the raw data from Chiazze's original
21 work be in the possession of that industry?

22 MR BUNDA: Objection, there is no foundation laid
23 whether he has such knowledge.

24 BY THE WITNESS:

25 A It depends on the conditions under which Dr Chiazze

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1 undertook the work. If I were to have undertaken the work,
2 although as I pointed out I have never undertaken work for pay-
3 ment by industry, the condition would be I would be entitled
4 to publish anything I wished about the data, it would be for
5 me to dispose of. If that was Dr Chiazze's case, I just do not
6 know.

7 BY MR DELLI BOVI:

8 Q Are you aware of any efforts by the American polyvinyl
9 chloride manufacturers industry to sponsor a follow-up study
10 of Chiazze's proportional mortality ratio study of PVC fabri-
11 cation employees to test his hypotheses regarding the statisti-
12 cally significant increases in all cancers, large intestine
13 cancers and other unspecified cancers in both males and females?

14 A I think your question includes a few postulates which
15 I would not accept but perhaps it is not necessary for us to
16 go over that. It is a question of the use of the term "statisti-
17 cally significant increases."

18 Q Statistically significant proportional distributions?

19 A Thank you. It is a point of some substance. No, I
20 have no knowledge of what the PVC fabrication industry in the
21 United States is doing at all in regard to anything.

22 MR DELLI BOVI: Thank you.

23 FURTHER RE DIRECT

24 BY MR BUNDA:

25 Q Doctor, I have one more question addressed to the last

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1 question put to you. The continuing updating and following of
2 the workers in the polyvinyl chloride manufacturing industry,
3 the people who make polyvinyl chloride and the people who make
4 vinyl chloride and the Tabershaw and Gaffey study updated by
5 Cooper and updated again by the MCA, would that or would it not
6 be relevant to the same question regarding issues raised in the
7 Chiazze study?

8 A I do not have in mind what issues were being raised
9 by the last question, but it seems to me a comparable question,
10 yes.

11 Q I am sorry, what I meant by the issues raised were
12 the concerns concerning intestinal cancer, proportional increases
13 in total cancer and questions concerning breast cancer. Would
14 those be addressed by the study involving polyvinyl chloride
15 manufacturers done by the MCA?

16 A Insofar as there was any suggestion that those cancers
17 were produced by exposure to vinyl chloride, yes.

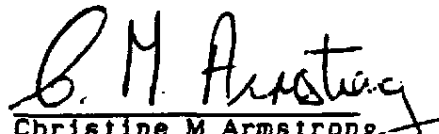
18 MR BUNDA: Thank you.

19 (Whereupon the deposition concluded at 6.40pm)
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CERTIFICATE OF COURT REPORTER

I, CHRISTINE MARY ARMSTRONG, Accredited Court
Reporter, do hereby certify that I took stenotype notes
in the foregoing deposition and that the transcript
thereof is true and accurate and executed to the best
of my skill and ability.


Christine M Armstrong
Tennyson & Company

17th August 1988

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CERTIFICATE OF WITNESS

I hereby declare that the foregoing is a transcript of my deposition; are the questions asked of me and my answers thereto; that I have read same and have made the necessary corrections, additions or changes to my answers that I deem necessary.

In witness thereof, I hereby subscribe my name this _____ day of _____, 198__.

PROFESSOR SIR RICHARD DOLL

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ERRATA

Correction

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