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Report/Article Title In the Circuit Court, Twentieth Judicial Circuit of Illinois, St. Clair County, Frances E. Kemner, et al., Plaintiffs, vs. Monsanto Company, et al., Defendants, No. 80-L-970, Before the Honorable Richard P. Goldenhersh, Judge, Report of Proceedings, April 24, 1984, Jury Trial

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1 IN THE CIRCUIT COURT FOR THE TWENTIETH JUDICIAL CIRCUIT
2 ST. CLAIR COUNTY, ILLINOIS
3

4 FRANCES E. KEMNER, et al.,)
5 Plaintiffs,)
6 vs.) No. 80-L-970
7 MONSANTO COMPANY, et al.,)
8 Defendants.)
9

10
11 Before the HONORABLE RICHARD P. GOLDENHERSH, Judge
12

13 REPORT OF PROCEEDINGS

14 JURY TRIAL

15 April 24, 1984
16

17 APPEARANCES:

18 MR. REX CARR and MR. JERRY SEIGFREID, Attorneys at Law,
19 On Behalf of the Plaintiffs;

20 MR. KENNETH R. HEINEMAN, Attorney at Law,
21 On Behalf of the Defendant, Monsanto Company;

22 MR. ALBERT SCHOENBECK and MR. STEPHEN M. SCHOENBECK,
23 Attorneys at Law,
24 On Behalf of the Defendant, Norfolk and Western Railroad.

DONNA F. BREWER, CSR
Official Court Reporter

I N D E X

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In Chambers Conference 2

WITNESSES CALLED ON BEHALF OF THE PLAINTIFFS:

ELLEN SILBERGELD

Cross Examination by Mr. Heineman 10

E X H I B I T S

DEFENDANT MONSANTO COMPANY'S EXHIBITS: MARKED ADMITTED

No. 76 50 . . .

No. 77 63 . . .

1 BE IT REMEMBERED AND CERTIFIED that heretofore, on
2 to-wit: Tuesday, April 24, 1984, being one of the regular
3 judicial days of this Court, the matter as hereinbefore set
4 forth came on for hearing before the HONORABLE RICHARD P.
5 GOLDENHERSH, Circuit Judge in and for the Twentieth Judicial
6 Circuit, State of Illinois, in St. Clair County Building,
7 Belleville, St. Clair County, Illinois, and the following
8 was had of record, to-wit:

9 * * * * *

10 (The following proceedings were held in chambers
11 out of the hearing and presence of the jury.)

12 MR. CARR: Judge, I have just this morning between
13 ten after nine and now scanned the decision laying on my desk
14 in the Lowe cases. I am not familiar with it except by
15 certainly some highlights. This motion they are presenting
16 this morning, obviously we need to consider what reply to make
17 to it. I am certainly not prepared to address any of its
18 points. And I would suggest that we do it later on this week
19 after I have had an opportunity to consider it and, if necessary,
20 file something in reply to it. I don't know if it's necessary
21 now. Certainly, there is nothing we can do here this morning,
22 because I am not prepared to respond to it.

23 THE COURT: I haven't read this opinion either yet.
24 It was just handed to me. I hadn't gotten a copy of it

1 yesterday. Do you have any objection to putting it off a couple
2 days?

3 MR. ALBERT SCHOENBECK: Judge, first of all, I
4 would request that the court record show that the Motion to
5 Reconsider the Court's Rulings on Motions to Dismiss on the
6 Ground of Forum Non Conveniens and to Consolidate Causes of
7 Action for Trial be shown as being filed as of this time as
8 of today's date.

9 THE COURT: Absolutely.

10 MR. ALBERT SCHOENBECK: I would like to confer just
11 a moment with my co-counsel in regard to the request to
12 delay consideration of the motion to reconsider if I may do
13 that now.

14 THE COURT: Sure. I am talking of a delay of a couple
15 days basically.

16 MR. ALBERT SCHOENBECK: Do you have a date in mind?

17 MR. CARR: No, I just got it.

18 MR. ALBERT SCHOENBECK: I understand. I mean a
19 date by which you would want to have this matter considered
20 by the Court.

21 MR. CARR: No, I would have to be able to read it,
22 read the opinion and consider -- the opinion is that thick.

23 MR. ALBERT SCHOENBECK: It's 66 pages.

24 MR. CARR: I am not going to entertain it idly.

1 I would say at least a week.

2 THE COURT: Do you want to confer?

3 MR. ALBERT SCHOENBECK: Yes.

4 (A short recess was taken.)

5 MR. ALBERT SCHOENBECK: If the Court please, in light
6 of Mr. Carr's request that consideration of Norfolk's motion
7 to reconsider be delayed for a period of a week so that he and
8 the Court and everyone may consider the effect that the decision
9 in the Lowe cases will have upon the litigation in which we
10 are now in trial, defendant Norfolk will now move for a continuance
11 of the trial of the Kemner cases for a period of one week so
12 that we may all consider the ramifications of the Lowe as
13 it affects Kemner. And in support of that motion I would say
14 this, there obviously is a tremendous impact by virtue of
15 this case upon the Kemner litigation.

16 Just briefly in the opinion in Lowe, the Court found
17 four major areas of error. First, Forum Non Conveniens;
18 second, consolidation of 47 cases for a single trial; third,
19 erroneous dismissal of the counterclaims of Norfolk against
20 the co-defendants on the products liability indemnity; and
21 fourth, the wrongful discharge of two of the jurors during the
22 trial of the case. The first three of the grounds which the
23 Appellate Court has held to be reversible error are all
24 squarely in this litigation here and now.

1 And we are appreciative of the time of the Court,
2 the time of the jurors, the expense of the parties, the burden
3 upon the judicial system of the county. And all of these
4 factors would mitigate for a continuance of the case in order
5 that we may proceed in an orderly fashion and in order that the
6 Court may be fully apprised before determining whether the
7 Kemner case should or should not go forward. Otherwise, we
8 would be in the posture of spinning our wheels for a full
9 week incurring great inconvenience to many, many people,
10 the system itself and great expense to all of the parties.
11 And, therefore, we orally move for a continuance for a period
12 of one week until your Honor and plaintiffs' counsel have
13 had the opportunity to study this opinion and make a determination
14 as to what should be done under the circumstances.

15 MR. CARR: If I might respond to that, Judge. You
16 have at least two days more with Dr. Silbergeld?

17 MR. HEINEMAN: I think that's right.

18 MR. CARR: All right. Dr. Silbergeld has an
19 extremely important meeting that she has to attend on
20 Thursday and Friday of this week. She is chairman of some
21 E.P.A. committee that is going to make some kind of ruling on
22 some kind of toxic substance is what they are going to do.
23 And she has to be there Thursday and Friday of this week. I
24 don't see any reason for postponement for the purpose of

1 Mr. Schoenbeck's statement. This trial should go forward and
2 go on. Of course, we ultimately take that position. I have
3 not much worry that our case is easily distinguishable
4 from the Lowe case. But that's another matter.

5 As kind of a compromise position, the two days that
6 we have -- today is Tuesday and Wednesday -- two days more of
7 Dr. Silbergeld, recess Thursday and that will give me three
8 days to study this opinion. Friday we come back here and
9 argue this motion. I will be prepared to argue it Friday.
10 We have Thursday off to do what I want to do with response
11 to it; come in Friday and we will argue the motion Friday,
12 and will serve Dr. Silbergeld. We have her here at considerable
13 expense to us. Certainly two days more of testimony will be
14 helpful. And then we will know -- Friday the Court can
15 make its decision Friday or Saturday or whenever it wants to
16 as kind of a compromise to serve all parties.

17 THE COURT: Any problem with that, gentlemen?

18 MR. HEINEMAN: Are you talking about there be no
19 evidence on Thursday or Friday?

20 MR. CARR: That's correct.

21 MR. HEINEMAN: So, we are talking about Tuesday
22 and Wednesday.

23 MR. CARR: Yes.

24 MR. HEINEMAN: Your Honor, our position, of course,

1 would be to join with the railroad in its motion with respect
2 to this continuance for a week during which time obviously
3 we would want to make an additional motion ourselves with
4 respect to a continuation of the case pending the finality of
5 the decision in the Fifth District in Lowe. In any event,
6 our position, your Honor, is that it would clearly be, in our
7 view, a waste of everybody's time. I understand there has
8 I am sure been some expense in Dr. Silbergeld coming out here
9 today. The problem, of course, is that there is going to be
10 considerably more expense to the plaintiffs for her testifying
11 over the next two days. As I understand it, she charges them
12 \$1,000 a day. And she would have that travel expense no matter
13 what. My view would be it would be a great deal -- it would
14 be of benefit to all the parties in terms of saving expenses
15 of the parties, saving expenses of the tax payers, saving a
16 burden on the jury to just put -- to call a halt until Friday
17 when this Court has a chance to rule on these motions and restart
18 the thing on Monday. And let the jury go home for a week or
19 go back to work or whatever they are able to do. Because,
20 your Honor, obviously, there is an expense to the county. There
21 is a burden to the jurors. And if this thing is going to be --
22 I am sure that Mr. Carr is going to consider this opinion very
23 carefully in the meantime. And if there is going to be an
24 opportunity to -- if there is a chance that this case is going

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to stop at this point, it certainly makes -- seems to make good sense to me not to have everybody spinning their wheels in the meantime and generating a lot of expense, both for the plaintiffs and for the defendants. And, therefore, we would join in the railroad's motion to just put this thing off until Friday and the Court has a chance to rule on the motion.

MR. CARR: Your Honor, we already have the witness here. The jury is here. I have not the least doubt but what our position would be strongly so that this case should go forward. We should utilize the witness here. We should utilize time of counsel that is here. That would be a complete waste to judicial time to lose these two days. And why lose it? Nothing is to be gained by doing it. We have already got the expense of one day already. The expert witness and the jurors and counsel are already here for this day. One more day. . And if we proceed, it's one more day that the case will be shorter in point of time and serve everybody and less expense.

THE COURT: I don't know what the ultimate disposition of this motion is going to be. We are already behind schedule. I would prefer to go these two days and we will set this up for Friday morning to argue it assuming everyone can be ready at that time, both Mr. Carr and you, if you plan to file motions. We can discuss that later today or tomorrow morning.

1 But we are already running behind schedule, anybody's schedule.
2 So, I think we are going to go.

3 MR. CARR: Could I ask if Monsanto is going to file
4 a motion that we have it tomorrow morning so I will have two
5 days to consider it before we argue on Friday?

6 MR. HEINEMAN: Fine.

7 THE COURT: Okay. Let's go in.

8 (The following proceedings were held in open
9 court in the presence and hearing of the jury.)

10 THE COURT: Morning. Gentlemen, before we start,
11 could I see you at the bench for a moment, please?

12 (A discussion was held at the bench out of the
13 hearing of the jury and off the record.)

14 THE COURT: Ladies and gentlemen, I am sorry for
15 the delay. We had a matter to take up in chambers. Before
16 we start, in keeping with the policy that we have had of
17 trying to notify you somewhat in advance of times that we will
18 not be in session, this Thursday and Friday due to circumstances
19 we will not be in session. So, we will have court today and
20 tomorrow and then we would ask you to come back Monday. So,
21 I just wanted to let you know so you had time to plan whatever
22 you can plan. Welcome back. Mr. Heineman, you may
23 proceed.
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ELLEN SILBERGELD

resumed the stand, having been previously duly sworn, was further examined and testified as follows:

CROSS EXAMINATION

BY MR. HEINEMAN:

Q. Doctor, I know you will recall that when we left off on Thursday -- was it Thursday?

THE COURT: I think it was.

MR. HEINEMAN: Q. When we left off on Thursday, we were talking about the studies on soft tissue sarcoma. And I wanted to discuss briefly with you, Doctor, what you told us at that time with respect to soft -- to case control studies versus cohort studies. There was a distinction made between the first three studies that we talked about which were Hardell, Hardell and Smith. Let me turn that a bit so you can see it. Can the jury see that? Okay. Hardell, Hardell and Smith were case control studies, correct?

A. I believe so.

Q. Then we started talking about cohort studies thereafter.

A. That's right.

Q. Now, Doctor, isn't it proper toxicological procedure that when case control studies indicate an association or a relationship that the proper procedure is to follow them up with cohort studies which are more reliable?

1 A. Well, that's an epidemiologic issue, not a toxicologic
2 issue primarily, Mr. Heineman. And I am not certain I would
3 say a cohort study is necessarily more reliable. They ask
4 different questions and they get different kinds of answers.
5 Sometimes they can be put together. But it's not really an
6 issue of reliability. It depends very much on the kind of
7 question you are asking as to which sort of study is the most
8 useful.

9 Q. Doctor, let me direct your attention to a book on
10 epidemiology by Brian MacMahon and Thomas Pugh of the Department
11 of Epidemiology of the Harvard University School of Public
12 Health. I direct your attention to a paragraph on page 43
13 where they discuss --

14 MR. CARR: Could you establish the authoritativeness
15 of the text first, Mr. Heineman, before you ask questions
16 about it?

17 MR. HEINEMAN: Q. Doctor, are you familiar with
18 this book?

19 A. I am.

20 Q. Would you consider it authoritative in the field
21 of epidemiology?

22 A. I consider it an authoritative source in the field
23 of epidemiology, yes.

24 Q. All right. That paragraph -- let me read it to you

1 and make sure I read it accurately. It's noted there on page 43.

2 "A case control study is usually less costly than a cohort
3 study in terms of both time and resources and is therefore
4 frequently undertaken as a first step to determine whether
5 or not an association exists between the suspected cause and
6 effect or to select between several hypotheses that may
7 explain the observed characteristics of the disease. Cohort
8 studies may then be undertaken to gain added confidence in
9 the existence of a relationship and to measure more accurately
10 its strength." Did I read that accurately, Doctor?

11 A. You did.

12 Q. All right. Do you agree with Professors MacMahon
13 and Pugh in that statement?

14 A. To a great extent. Not completely. I think this
15 is slightly taken out of context, Mr. Heineman, because they
16 are talking about cases -- they use the example of lung
17 cancer. They are talking about those conditions where first
18 off one has the choice of a variety of experimental designs.
19 This book and other authorities in the area of epidemiology
20 go on to stress, as I tried to describe last week, that when
21 you are dealing with rare diseases, which unfortunately
22 lung cancer is not -- but rare diseases like the soft tissue
23 sarcomas or inherited porphyrias, then there is more strength
24 in a statistical sense to using the case control method.

1 So, it's not always the case first off that one of these can
2 be used sequentially with the other; nor is it always the
3 case that all kinds of study designs in epidemiology are
4 equally appropriate.

5 Q. Would you then agree that in instances in which the
6 form of cancer is less rare that you would follow -- it would
7 be appropriate to follow case control studies with cohort
8 studies?

9 A. I would really have to know first off a great deal
10 about the results of the case control study, the size of the
11 population available to study, the amount of time that has
12 elapsed, the types of other variables and factors which might
13 be intervening in order to answer that question.

14 I am involved in a very big exercise on this very
15 issue for the Clean Air Science Advisory Committee for the
16 E.P.A. right now. It's not a simple answer.

17 Q. So, you couldn't say one way or the other. It may
18 be or it may not be.

19 A. No, one can say one way or another, but it's very
20 dependent on the facts of the case. One can't make a kind of
21 general, easy comment on the subject. These are difficult
22 technical issues.

23 Q. All right. So that in these particular cases, the
24 case control studies are situations in which someone has

1 discovered a group of people that manifest a symptom or a
2 condition, correct?

3 A. That's right.

4 Q. And then they go back and they try to find out what
5 it is that might have caused that symptom or condition.

6 A. That's right.

7 Q. And they do that by asking questions to determine what
8 similarities there might be between the backgrounds of the
9 individuals being studied.

10 A. That's right.

11 Q. And as you told us before, what they come up with is
12 essentially an association, something whereby that no scientist
13 can really say for sure that yes, this is the cause and that
14 is the result. What you come up with is an association.

15 A. An association is what scientists call for sure.

16 Q. All right. Now, Doctor, didn't you just tell us the
17 other day when you were referring to this diagram of yours
18 that all the scientists can tell you is association and that
19 they can't tell you absolutely, positively cause and effect?

20 A. We had a long discussion about that which I tried
21 to explain that's the whole nature of science; that all it
22 does in any field is to show correlations and associations
23 which occur at a better than chance rate. That's all that
24 any science can do.

1 Q. All right. Now, the difference then in a cohort
2 study is you take people that you know have been exposed to
3 something or you believe have been exposed to something and
4 you study them to see if you find the things that you think
5 might be associated with that, is that correct?

6 A. That's right.

7 Q. All right. And the group of people that you study
8 depends on the group that is presented to you in terms of
9 what the exposure is. It may be nineteen hundred and something
10 as in the Riihimaki study. It may be 64 as in one of the
11 other studies depending upon the group that has been exposed.

12 A. That's right.

13 Q. So, in the cohort study you work with the exposed
14 group that you have.

15 A. That's right.

16 Q. And you study them and you write down whatever it is
17 that you find.

18 A. That's right.

19 Q. I hope the jury will excuse my walking around here.
20 I can't find a place to put anything.

21 Let me direct your attention, Doctor, to the
22 Pazderova or Jirasek study which we talked about before which
23 is among the exhibits in front of you. I don't remember the
24 number.

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MR. STEPHEN SCHOENBECK: Sixty-nine.

MR. HEINEMAN: Sixty-nine? Thank you.

Q. Now, this is a ten year study done in Czechoslovakia, done of only 55 people, correct?

A. That's right.

Q. All right. Now, one of the things that she looked for in this study, as I perceive it, was carcinogenicity; isn't that right?

A. They looked at cause of death in these persons that died. It's not clear they specifically did an examination of morbidity for cancer. The emphasis of this paper was primarily on neurotoxic and liver disfunctions. I am checking this to make sure I am correct. But that is my recollection of this paper, Mr. Heineman. It was not really an examination of cancer.

Q. But one of the things they found, one of the things they looked for, if you will look at page 10 -- it's a paragraph that we have dealt with previously. It begins "In recent years" right here.

A. Yes, as I said, they did look at the people who died. But it doesn't indicate they looked for morbidity in terms of cancer, Mr. Heineman.

Q. All right. They did find two cases of lung cancer.

A. That's what it states, right.

1 Q. And she does not report finding any cases of soft
2 tissue sarcoma, does she?

3 A. No, but as we discussed earlier, this was a follow-up
4 of a very small number of the original exposed group. And
5 she goes on to state because of the small number of persons
6 in the group no definite conclusions can be drawn. I would
7 agree with that.

8 Q. She does say it is a small group. It is the group
9 that she has, but it's a small group. And she finds no
10 soft tissue sarcoma in that group.

11 A. She finds no deaths associated with soft tissue
12 sarcoma. It's not clear to me whether they looked for
13 disease. So, that makes it a little bit different again
14 from those other studies, but that's a patchwork collection
15 of things there, so --

16 Q. It's a patchwork collection of studies. It sure is.
17 Now, if you would look, please, at the May study of the
18 British workers exposed in the Coalite incident in the
19 United Kingdom, in Great Britian. And there we were talking
20 about exposure levels, as I recall, of something like a
21 million parts per billion in the Coalite plant.

22 And, again, I think that May found no death from
23 cancers at all in that group. And, again, it is a group of
24 79 workers.

1 A. That's right.

2 Q. Okay. And if we then look at Theiss which is a
3 review of 74 people. There is a, if you look at Table II on
4 page 183 -- he specifically lists soft tissue sarcoma,
5 does he not?

6 A. That's right.

7 Q. And he found none.

8 A. Yes. I think if you look at this table though, you
9 will see the extraordinary weakness of this process that we
10 are going through right now. If you look at the expected
11 death rates in that table for the populations in his three
12 control groups -- two control groups; one of them he has no
13 available data -- you will see that the expected rate is
14 infinitesimal. And I think that should indicate really how
15 unscientific this process we are engaged in right now is,
16 Mr. Heineman.

17 Q. Doctor, what you are pointing out there is that
18 soft tissue sarcoma is sufficiently rare in the population;
19 that in the control groups there were very, very low expected
20 incidence.

21 A. .02.

22 Q. Right. And he found none. Which if it's only .02
23 it's not surprising that he finds none, correct?

24 A. This indicates, Mr. Heineman, you could have a very

1 large increase, up to a fifty-fold increase in the rate and
2 not detect a soft tissue sarcoma if you want to play numbers
3 games. And I think that shows why MacMahon and others would
4 not recommend these small cohort studies as means of
5 detecting this disease.

6 Q. In this particular disease.

7 A. That's right.

8 Q. It's a very difficult thing. Because it's rare --

9 A. It's not difficult. It is inappropriate.

10 Q. But if it's all you have --

11 A. It is not all we have, Mr. Heineman. You have got
12 the three studies at the top which were done properly.

13 Q. We will get back to those in a minute, Doctor.

14 A. But you are diluting them out by these inappropriate
15 studies which were not under -- the authors of these studies --
16 I think it's important to point out for their scientific
17 reputations -- did not attempt to draw the conclusions you are
18 trying to draw, because they knew that by their study design
19 they couldn't answer these questions.

20 Q. Now, Doctor, it is a fact that Dr. Thiess when he
21 did this study looked for cancers in this exposed group,
22 didn't he?

23 A. We are talking about soft tissue sarcomas here,
24 Mr. Heineman, a type of cancer.

1 Q. That is one of the cancers he specifically looked
2 for, isn't it?

3 A. Well, I think you ought to read the discussion here
4 to understand what he is talking about in terms of what he
5 did and the power which he places very appropriately in certain
6 of his findings and not in others. He listed -- indeed, he
7 listed every single one of the cancers that was found for the
8 dioxin group for completeness of the record. But he is not
9 attempting to make any finding of importance at all in terms
10 of the rates.

11 Q. He even listed traffic accidents.

12 A. That's right. Every cause of death.

13 Q. All right. But one of the things he listed was
14 something that didn't even occur, isn't it? One of the
15 things he listed was something he specifically looked for
16 and found none. And that was soft tissue sarcoma, isn't
17 that right?

18 A. Well, I am not sure he specifically looked for it.
19 He had the death certificates and he broke out some of the
20 ICD classifications of cancer.

21 Q. And one of the classifications that he put down on
22 his chart to make sure that whoever read this paper would know
23 that he looked for soft tissue sarcoma and found none.

24 A. Let's see if he explains why he did that.

1 Q. I'm sorry. Are you still looking for --

2 A. No, I have satisfied my curiosity.

3 Q. All right. Now, if we go to the Bond, Ott study,
4 Doctor, published in the British Journal of Industrial Medicine
5 in 1983 and look at Table 5 on page 322, again we find that
6 he looked specifically for malignant neoplasms of connective
7 and other soft tissues, CDI No. 171, correct?

8 A. That's right.

9 Q. And in the exposed group, in the TCP cohort, he found
10 none, whereas in the control group he found one.

11 A. That's right.

12 Q. And in the 2,4,5-T cohort in the exposed group he
13 found none and in the control group he found none.

14 A. That's right.

15 Q. All right. Now, if we look at Riihimaki -- this is
16 the Finnish study of 1,971 male workers, correct?

17 A. (No response.)

18 Q. Yes? 1,971 workers?

19 A. 1,926 it seems to say, but that's not important.

20 Q. All right. If you look at Table 3 on page 781, this
21 scientist again lists soft tissue sarcoma as one of the
22 specific types of cancer looked for. Only expects to find
23 .1, which demonstrates it's a very rare disease, but finds
24 none, correct?

1 A. That's right. Also demonstrating it would take over
2 a ten-fold increase to show one case.

3 Q. All right. And that Table 3 is after a ten-year
4 latency period, correct? Do you see in the paragraph just
5 above the table?

6 A. Yes.

7 Q. Then if we look at the Center for Control Disease
8 study and the Missouri Dioxin Health studies, we look at
9 page 33. This was again done in 1983. Note in the fifth line
10 of the first full paragraph on that page -- let me start a
11 little bit above that. Start at the beginning of that
12 sentence. It says, "Of the five cases of cancer reported,
13 three in the high risk group and two in the low risk group,
14 difference not significant at the .05 level. None of the
15 cancers were soft tissue sarcomas." Correct?

16 A. That's right.

17 Q. Now, and this was a study done again in 1983.
18 Now, Doctor, why is it that these case control studies are
19 being done where they are looking specifically for soft tissue
20 sarcoma? Is it because of these case control reports by
21 Hardell?

22 A. These aren't case control studies down here.

23 Q. I know.

24 A. I don't understand what you are saying.

1 Q. My question is --

2 A. Which case control studies?

3 Q. -- in the cohort studies, why is it that they are
4 looking specifically for soft tissue sarcoma? Is it because
5 of these reports by Hardell and they are trying to substantiate
6 what Hardell has found?

7 A. No, I don't think so. I think it's -- first off,
8 they are not looking specifically for soft tissue sarcoma.
9 If they were, they would employ a different experimental
10 design. Because as most of them note, it would be extraordinary,
11 given the size of their populations, if they were to find soft
12 tissue sarcoma. It would indicate an extraordinary effect;
13 although one that would probably not be able to be calculated
14 because the populations are so small. I think they are
15 noting it as any scientist would note based on the fact that
16 the issue has been raised, just as, for instance, before
17 Hardell's studies when the work of Kociba and others
18 at Dow Chemical had showed the very great power of TCDD to
19 cause cancer in animals. Many of these studies and others
20 we haven't cited did indicate they looked at the records
21 for cancer. That's a customary thing in science. But I don't
22 think you should take these studies and change their intent
23 to suggest that they were in any way specifically designed
24 in response to Hardell's study to try and refute or add to the

1 evidence. Because I think most of these authors are very
2 reputable scientists, excellent epidemiologists, some of
3 them, including Dr. Ott from Dow. And they would in no way
4 consider the design of their experiments would allow them to
5 add in a scientific sense to the findings of Hardell and
6 Smith, which were specifically designed to answer that question.
7 I think it's a very profound misunderstanding of epidemiology
8 and scientific design to suggest that what you have got down
9 here at the bottom of your exhibit in any way bears on what
10 is at the top part of the exhibit. They are really two different
11 categories we are talking about here. Apples and oranges
12 again, Mr. Heineman.

13 Q. All right. But, Doctor, each of these renowned
14 epidemiologists has done a study, a cohort study, in which
15 they have taken a group of exposed people and they have tried
16 to find out what cancers these exposed people have come up
17 with.

18 A. Among other things.

19 Q. Among other things. We haven't gotten to the other
20 things yet. We are going to do that too. But the point is
21 they are looking for everything they can find that these
22 people have come up with.

23 A. Yes, but the major point is that they are well aware
24 of what they can find. Sometimes you can look for things

1 very hard, but given the circumstances you are in, you might
2 not be able to find it. If you are in a room with the lights
3 turned off, which is certainly analogous to looking for a
4 very rare disease in a group of 60 or 80 people -- if you
5 are in a room with the lights turned off, you are not going
6 to find it.

7 Q. I understand your opinion, Doctor. But the thing
8 that I am concerned about is if these people -- they are not
9 publishing this stuff out of just a joke or for the heck of it.
10 I mean they are telling you what they found in the cohort
11 study that they have done. And it's for scientific purposes,
12 isn't it?

13 A. That's right.

14 Q. And they want to tell the world what indeed people
15 exposed to a million parts per billion of dioxin have come
16 down with. Isn't that right? At least the group that they
17 looked at.

18 A. Well, first off, your assumption is of the exposure.
19 Very few of these papers have any quantitative assessment
20 of the exposure, Mr. Heineman. And, secondly, I think most
21 of these papers are also very careful to tell the world
22 what they haven't found or what they could not find given the
23 size of their population. I think it's very important to add
24 that in. I don't think it's correct to mischaracterize the

1 intent of these authors. And that is what you are doing by
2 trying to compare cohort and case control studies. I know it
3 sounds like a lot of epidemiologic jargon, but it's very
4 important.

5 Q. All right. Doctor, I understand what you are saying.
6 And I understand that you believe that these -- that the Hardell
7 studies reveal more --

8 A. No.

9 Q. -- than these studies do.

10 A. No. What I am trying to say is that based on the
11 question being asked -- and this is how scientists perceive.
12 The first thing you try to do is really formulate your
13 question in a clear sense. What am I trying to find out?
14 And then try to figure out, how can I answer that question?
15 And it doesn't do much good to have a question and then go out
16 and pull in all kinds of irrelevant evidence. Doesn't work
17 in law either. You have to have a way of looking for the
18 answer which suits the question. And that's what I am saying
19 is going on here.

20 Q. But would these -- are these epidemiologists just
21 trying to fool us?

22 A. No, Mr. Heineman. They are asking questions and
23 attempting to answer them that are appropriate to the cohort
24 design. They are not trying to go further than that. Only

1 you are trying to do that.

2 Q. And they are trying to report what they have found.

3 A. And what they cannot find.

4 Q. Exactly.

5 A. And one of the things that many of them state is
6 that they cannot make a statement about cancer itself.

7 Pazderova says that. She can't make any conclusions on cancer.
8 Others say given the short latency times they can't make final
9 conclusions. Riihimaki says given the absence of information
10 on dosage I can't make conclusions. They are very careful
11 to limit what they can say. And that is what is being omitted
12 in our discussion right here.

13 Q. But there are some of them like Dr. May in Great
14 Britian who had the Coalite exposures and said he found no
15 cancers at all.

16 A. That's right. But he has a very short period of
17 follow-up compared to Hardell. And based on what we know of
18 the mechanisms of action of the substance, one would expect
19 a latency period probably in excess of ten years for the
20 soft tissue sarcomas. So, there is nothing in May -- which
21 again is a small group also. There is nothing in May that
22 is inconsistent with either the reports of Hardell or with
23 what we know of the mechanism of action of dioxin and chemical
24 carcinogens as a class and also of the pathologic development

1 of this type of tumor, the soft tissue sarcoma group.

2 Q. So, it's not inconsistent?

3 A. These are not inconsistent studies. You haven't
4 really set up a dichotomy here. You have set up a mixed bag.
5 But when you start to look through them very carefully, you
6 can see that they are not inconsistent findings.

7 Q. So, it's not inconsistent?

8 A. They are different questions. They are different
9 answers.

10 Q. So, just because Hardell in their case control study
11 where they found people who had already had soft tissue sarcoma
12 and then went back and asked questions about their background,
13 that would not be inconsistent with studies where they found
14 people that were actually exposed to something and then looked
15 at them to see what in fact they came down with. That is
16 not inconsistent?

17 A. No. It is inconsistent to take those two studies
18 from different approaches and attempt to state that they both
19 give the same answers to the same questions. That is
20 inconsistent.

21 Q. And as a matter of fact, some of these studies -- all
22 of these authors are saying -- all they are saying is that, "I
23 looked at this group of people that were exposed to this
24 chemical." Some of them have the amount and some of them don't.

1 But they look at the group and they said, "This is what I
2 found in the group that I looked at."

3 A. But most of them go on to say, "This is what I
4 could find given the size and the time." And that's what you
5 are leaving out here.

6 Q. Doctor, let's look at the Ranch Hand study, Defendant's
7 Exhibit 67. Page 18, Table 20. Now, this again is the study
8 of those people, the Air Force personnel involved in loading
9 and spraying Agent Orange, correct?

10 A. That's right.

11 Q. And this was a group of people who served in Vietnam
12 during the period from 1962 until 1971.

13 A. I think it was a narrower group than that. Because
14 the use of Agent Orange was not until later in the war. If
15 it goes through 1962, then it's a very diluted group. I know
16 that is an issue that some epidemiologists have raised that
17 the Air Force did include people who could not have been
18 exposed to Agent Orange and claimed they were and thus
19 kind of knocked out their study. If that's true --

20 Q. You think it's narrower than that?

21 A. Well, if they did go back to 1962, it's a totally
22 invalid study. I hope that's not true, because it certainly
23 was a lot of work by the government.

24 Q. We are talking about the dates of service here, Doctor.

1 A. Well, since --

2 Q. If you look at page 1, right at the beginning, the
3 very second page of the exhibit. Right here. It's a method
4 by which they selected who the people were.

5 A. Well, that is -- I know this is an issue that has been
6 raised by Dr. Sturgeon, Dr. Schneiderman and others as to
7 whether or not the Ranch Hand personnel that the Air Force
8 has studied really were exposed to Agent Orange. Because
9 I believe according to Dow Chemical and Monsanto, Agent Orange
10 was not used in Vietnam by the Air Force or anyone else in
11 the U.S. Military very substantially until 1978 or '79.
12 Excuse me, '68 or '69. So, if they are going back to '62
13 to pick up people, that is very inappropriate.

14 Q. Would it be inappropriate if these people were still
15 there in '68 or '69?

16 A. No, if they had served through that period. But
17 that has been a problem people have identified with this
18 study to try and figure out exactly whether the classification
19 was correct.

20 Q. Now, is that a problem that people have picked out
21 who have disagreed with the results of the study?

22 A. No, certainly not. As a matter of fact, the second
23 part of the Ranch Hand study, as you may know, contains a
24 number of very significant health effects. So that actually,

1 given the two studies, mortality and morbidity, there is
2 evidence for both sides, if you care to characterize them that
3 way. The concerns I think have been raised by epidemiologists
4 who are worried about the ability to decipher what went on
5 in the study. And as you may know, this study has been
6 criticized when it was designed by the National Academy
7 of Sciences and by the Public Health Services.

8 Q. All right. Let's look at this study in any event
9 done by the Air Force. Actually it wasn't. There was an outside
10 review team on this study, wasn't there, Doctor?

11 A. They were under contract to the Air Force.

12 Q. Right. You had -- I know that it was paid for,
13 financed by the government, wasn't it?

14 A. Yes, by the Department of Defense.

15 Q. But there was a whole slew of scientists that were
16 consulting on this. They had a science panel, didn't they,
17 on this study?

18 A. Yes, they did. The science panel, however, did not
19 pass on the final report. They were involved at varying stages
20 in giving advice to a varying extent.

21 Q. So, there was John Doull, the toxicologist we talked
22 about from the University of Kansas Medical Center?

23 A. Yes, but, Mr. Heineman, this is in no way a scientific
24 peer review panel. They weren't asked to perform that function.

1 Q. But Dr. John Moore --

2 A. You can determine that by asking them.

3 Q. Wasn't Dr. John Moore, Deputy Director of the
4 National Toxicology Program, chairman of this science panel?

5 A. Such as it was, yes.

6 Q. Dr. Alan Poland whose works you have cited here --

7 A. Yes.

8 Q. -- was on that panel. As well as Dr. Irving Selikoff.

9 A. They had a very eminent panel. Unfortunately, they
10 didn't use them.

11 Q. Again, Doctor, let's look at page 18, Table 20, where
12 it says, "Cites specific malignant neoplasm mortality." Again,
13 for bone, connective tissue, skin and breast cancer they
14 found none.

15 A. That's right.

16 Q. Correct. And in the comparison group they found one.

17 A. That's right. That undoubtedly reflects again
18 the small group and the relative youth of the population.

19 Q. Now, you say it's a small group. Wasn't this a
20 study of 1,269 people?

21 A. Yes, but once again to go over --

22 Q. Or 1,247, I'm sorry.

23 A. To go over this ground once more, Mr. Heineman, when
24 you are dealing with a rare disease, to turn up -- you need

1 a very large population to see any cases of a rare disease.
2 We talked about porphyria having an incidence of one in a
3 hundred thousand. So, you see, you wouldn't expect to see
4 a porphyria in this case.

5 Q. So, in a group of 68 people you wouldn't expect
6 to see any soft tissue sarcoma?

7 A. Not unless there was an absolutely extraordinary
8 toxic or other type of intervention. Nor would you expect
9 to see porphyria in a group that size. It is indeed the
10 diagnosis of such rare findings in small groups that leads one
11 to conclude on a scientific basis that something indeed has
12 happened to that population. It's important to note again
13 here --

14 Q. Doctor, has anybody diagnosed soft tissue sarcoma
15 on any of these plaintiffs?

16 MR. CARR: Your Honor, could the witness be allowed
17 to answer the question before counsel asks another one?

18 MR. HEINEMAN: I thought she had answered it.

19 MR. CARR: No, she was --

20 THE COURT: Go ahead and answer the question, please.

21 THE WITNESS: It was just once again I wanted to
22 point out if you look in the comparison group which is much
23 larger than the study group, only one soft tissue sarcoma
24 was found. That again tells us that we are dealing with a very

1 rare disease. That is why when you are studying rare diseases,
2 you go to the disease first. You do the case control method.
3 That is outlined elegantly by MacMahon's text book that you
4 have cited here as an authority.

5 MR. HEINEMAN: Q. Now, Doctor, in this it is the
6 contention, isn't it, that in those people that served in
7 Vietnam and were allegedly exposed to Agent Orange that there
8 was a toxic intervention?

9 A. That's right.

10 Q. Isn't there?

11 A. But --

12 Q. As I understand it, Doctor, you indeed are testifying
13 in that litigation as well, aren't you?

14 A. I am supposed to.

15 Q. And so that you believe, don't you, that there was
16 a toxic intervention in that instance as well, do you not?

17 A. I do.

18 Q. And so that if you are not going to find it in
19 1,247 people because it is too rare, why do you think you are
20 going to find it in 68?

21 A. You haven't asked me whether I expected to find soft
22 tissue sarcoma in the 68 people who are at issue in this
23 case, Mr. Heineman. Secondly, in answer to your other question
24 related to these people and the million people who served in

1 Vietnam for our country, there are two points at issue.
2 One is -- you know, when we went through many of these
3 tables I tried to point out that you could have a ten/fifty
4 fold increase in a rate of a very rare disease, and if your
5 population isn't big enough, you won't be able to detect it
6 statistically. So, you can indeed have a very big thing
7 happen. But unless you look at enough cases, enough people,
8 you won't see it.

9 Secondly, which is very relevant to this case and
10 also presumably to Sturgeon, because of the nature of how
11 chemicals cause cancer and the nature of soft tissue sarcomas,
12 you have to have time elapse between the exposure and the
13 onset of the disease, certainly of death. This is a
14 mortality study. So, I wouldn't expect to find in the Agent
15 Orange exposed group many cases of mortal; that is, fatal
16 cancer, yet occurring; nor would I expect to find in a
17 group of people exposed in this country either in the Missouri
18 sites where we talked about the CDC study or in Sturgeon
19 people who have been exposed for ten years or less to find
20 many incidents of fatal soft tissue sarcoma. But that does
21 not change my opinion about the incidence of an intervention
22 of a toxic exposure.

23 Q. If there were exposures where we had a human study
24 where they had been able to observe that group for ten,

1 fifteen, twenty years, would you expect these cancers to turn
2 up?

3 A. That I would and that is why I think the Hardell
4 studies are indeed revealing something of scientific importance.
5 Because that is exactly the right design, using the right
6 kinds of people, exposed for sufficient amounts of time with
7 very good clinical diagnosis through the Swedish Medical
8 System, and that is why I think that is an appropriate study
9 for answering this particular question.

10 Q. So that, Dr. Silbergeld, if -- take the Ott study
11 which is the Dow group, 204 people. And in the Ott study
12 they studied the people who had been exposed less than ten
13 years prior or from ten to fourteen years and from fifteen
14 to nineteen years and over twenty years. And we looked at
15 that study before, Doctor, for total malignant neoplasms,
16 total cancers. In the less than ten years, they found none.
17 In the ten to fourteen years, they found none. In the
18 fifteen to nineteen years, they found none. And in the twenty
19 plus years, they found one with .9 expected in Table 5.
20 Now, wouldn't you expect over that period of time that those
21 cancers would show up?

22 A. Depends on the number of people who wound up in those
23 categories. They started out with only 204. And they then
24 broke them down further and further based on job history.

1 And the numbers, although not specified, must be becoming
2 considerably smaller. In addition, as has been noted by
3 critics of this study, some of the people may have been exposed
4 for as short as one month. And where they fall in these
5 differing age groups, that is time since the first exposure,
6 is not clear.

7 Q. Are you talking about this particular study when
8 you say as little as one month?

9 A. That's right. It says on page 48, "Worked for one
10 or more months."

11 Q. So, that would fall in the less than one year
12 category, wouldn't it?

13 A. No, not on Table 5. It would not.

14 Q. So, they might have had an exposure of just one month,
15 but that exposure may have occurred ten years or twenty
16 years before.

17 A. Or three years or two years before. It is not -- what
18 they didn't do which they should have done is to take Table 4
19 and Table 5 and tell us exactly what is going on. Table 4
20 is the length of exposure, how long were the people exposed.
21 Table 5 is how long has it been since they were first exposed.
22 So we could figure out who was falling where and also give us
23 an idea of numbers. Because they are not giving us any idea
24 of the numbers in these groups.

1 Q. Would it be your opinion -- now, these are 204 people
2 that worked in a 2,4,5-T manufacturing process, correct?

3 A. Yes, but not all of them worked for ten years or
4 longer --

5 Q. Right.

6 A. -- if you read it carefully.

7 Q. Now, is it your opinion, therefore, that if one
8 were exposed to 2,4,5-T contaminated with dioxin on a daily
9 basis for one month or less, you wouldn't expect that to cause
10 any cancer?

11 A. No, that's not what I said. I said that in a small
12 group of people under those exposure conditions -- and Dr. Ott
13 doesn't tell us how many people he used for his analysis --
14 I don't know whether I would be able to pick up a statistical
15 increase in the rate of cancer. In toxicologic terms, I
16 would expect an increased risk of cancer. And I would expect,
17 just given the information you have proposed, that indeed
18 there was toxic exposure. But the ability to pick it up by
19 relatively weak epidemiologic method of small cohort assessment,
20 I wouldn't be at all hopeful that I could do that. And I
21 am not surprised by the results of Ott's study.

22 Q. So that all that Dr. Ott did was to take the 204
23 people that had been exposed in the 2,4,5-T production
24 contaminated with 2,3,7,8 TCDD and had taken the people that

1 were actually exposed -- some were less than a month and
2 some were exposed for much longer periods of time -- and in
3 that group he finds one case of cancer. And that is in
4 somebody who has been exposed for over twenty years or whose
5 exposure, excuse me, occurred at least twenty years before.

6 A. That is the only cancer death that he finds. That's
7 right.

8 Q. That's right.

9 MR. HEINEMAN: We are at an hour, Judge, if you would
10 like to take a break.

11 THE COURT: Fine. Is this a convenient point?

12 MR. HEINEMAN: Yes, it is.

13 THE COURT: Fine. Ladies and gentlemen, we will
14 take a short break in the testimony at this time. Since
15 it's been such a long weekend, you may have forgotten.
16 So, I will admonish you again. You are not to discuss this
17 matter among yourselves or with anyone outside the jury panel
18 or as yet form any opinions or conclusions about the matters
19 on trial. Court will be in recess.

20 (A short recess was taken.)

21 MR. HEINEMAN: Q. Now, Doctor, I would like to
22 discuss with you in a little more detail these two Hardell
23 studies that we have had reference to here, the case control
24 studies. Let me hand you first what has been marked as

1 Defendant's Exhibit No. 71 which I think you have already
2 seen which is the '79 Hardell study on soft tissue sarcoma.

3 Now, Doctor, as I understand it from the discussion
4 they have on methods and materials, they acquired their
5 exposure information by questioning family members of the
6 decedents either through questionnaire or telephone contact,
7 is that correct?

8 A. No, also to employers and, yes, persons and industries.

9 Q. All right. So, they talked to family members,
10 did they not?

11 A. Yes, they did.

12 Q. And they also talked to some employers to get
13 information about certain people, is that correct?

14 A. About all the people whose next of kin had stated
15 they were employed in certain industries.

16 Q. All right. Have you read the discussion of this
17 article written by Dr. Alastair Hay in which he describes the
18 fact this study has been criticized because of the fact that
19 just had two people questioned been wrong about their
20 recollection of the exposure, that the six-fold increase
21 found by the study would have disappeared, would have been
22 wiped out. Do you remember that statement?

23 A. I don't recall that statement. I know Dr. Hay did
24 describe -- it did discuss this study and has discussed it

1 in articles in Nature magazine.

2 Q. All right. I have here a book. It's an edition of --
3 a collection of articles called Chlorinated Dioxins and
4 Related Compounds. And it contains one of these papers
5 by Dr. Hay discussing this subject. Are you familiar with
6 that paper?

7 A. I am not sure. I have read parts of this book. I
8 am not sure if I have read this paper. I have read a number
9 of papers by Dr. Hay.

10 Q. Do you consider the writings of Dr. Hay to be
11 authoritative?

12 A. I do.

13 Q. You do? Let me direct your attention to page 597
14 in the last paragraph in the cancer section. Here we are,
15 right here. Where he discusses this Hardell study. And he
16 said as follows -- see if I read this correctly, would you,
17 please? "The type of study conducted by Hardell and Sandstram
18 is recognized to be subject to many confounding factors. The
19 authors attempted to eliminate many of these in their study.
20 A problem remains, however, over the identification of
21 herbicide users. This was done by use of a questionnaire.
22 A slight error in recall by just two subjects in the study would
23 remove the six-fold risk factor for soft tissue sarcomas."
24 Did I read that correctly, Doctor?

1 A. You did.

2 Q. All right. Indeed, Doctor, isn't it a fact that
3 this particular study has been criticized in Sweden as well?
4 Do you know that because of this problem in the exposure
5 information?

6 A. Well, first off, I am not certain I agree with
7 Dr. Hay's last sentence here where he says, "A slight error
8 by just two subjects would remove the six-fold risk factor."
9 I am not certain what he is referring to in terms of a slight
10 error in recall. And I would have to check through the
11 statistics to see what impact it would have if he is suggesting
12 that if one removed two cases from the so-called exposed
13 group. Second, of course, all case control studies, as is
14 pointed out here, as was pointed out by MacMahon's text
15 and we have discussed, are, if they are studies of people who
16 are dead, based always on the accuracy of the information
17 you can get about someone who is not around to answer questions
18 directly. It's one reason why Hardell did another study in
19 which he attempted to use more sources of information about
20 his cases. I am sure there has been comment in Sweden as
21 there has been in the United States, England, Australia,
22 New Zealand, all other countries where 2,4,5-T and dioxin
23 have been an issue of toxicologic concern. Dr. Hardell
24 appeared before the E.P.A. expert committee and discussed many

1 of the concerns which we have been talking about.

2 Q. Let me also direct your attention to The Chemical
3 Scythe which is by Dr. Alastair Hay which we have previously
4 referred to and page 178 in the marked paragraph. And if
5 you would, let me read that to you as well. This is again
6 Dr. Hay discussing the Swedish reaction. "Hardell's findings
7 have been accepted by the Swedish medical authorities but
8 with some reservations. According to one of the authorities'
9 reviewers, Professor Sune Larsson of Staten's Naturvardverk, ~~Pack,~~
10 the main reservation concerns the accuracy of reporting
11 exposure to herbicide. The herbicide 2,4,5-T has also been
12 a subject of heated debate in Sweden and, therefore, much
13 in the public eye. For this reason, Larsson has some doubts
14 that Hardell obtained unbiased information when assessing
15 herbicide exposure. And Larsson points out that had Hardell's
16 information been wrong on just two of his 27 subjects, 2,4,5-T
17 could not have been implicated as the cause of the soft
18 tissue sarcomas." Did I read that accurately?

19 A. You did.

20 Q. You mentioned a moment ago the 1981 Eriksson, Hardell
21 study which we have also previously identified as Exhibit
22 No. 72. Now, in this particular case, Doctor, wasn't
23 there a confounding factor that the people that were being
24 studied were exposed to a number of other things that could

1 have caused cancer?

2 A. That's true for all studies of TCDD. Because, as
3 we talked about a long time ago, I think with the exception
4 of those of us who are working with TCDD in laboratories,
5 there really are no cases where people are exposed solely
6 to TCDD. That goes for all the studies we have talked about
7 in this testimony.

8 Q. And so you would agree with that portion of this
9 very Eriksson, Hardell study in 1981 that exposure to chemical
10 pesticides other than phenoxy acids -- now, what are they
11 referring to there? The phenoxy acids, that's the 2,4,5-T,
12 right?

13 A. Now, wait. Were you talking about confounding
14 variables outside of chemicals in which TCDD would be expected
15 to occur as a contaminant?

16 Q. I am --

17 A. I misinterpreted your question.

18 Q. All right. I am talking about the confounding factors
19 that Dr. Hardell and Eriksson referred to in their 1981 study
20 on page 32 where they state as follows: "Exposure" -- this
21 is in the first column. "Exposure to chemical pesticides
22 other than phenoxy acids may be judged risk factors for the
23 morbidity under study, and might exert a confounding effect,
24 since the individuals using phenoxy acids were often also in

1 contact with other agents used to combat weeds, insects, or
2 fungi." Fungi would be toadstools and that sort of thing,
3 I guess. Isn't that right?

4 A. Molds and --

5 Q. Molds?

6 A. Right.

7 Q. Now, the phenoxy acids that are being referred to would
8 be the 2,4,5-T.

9 A. MCPA, 2,4,5-T and 2,4-D and related compounds.

10 That's right.

11 Q. And so they are saying these same people on which this
12 study was made, this 1981 study, were also exposed to other
13 things besides the 2,4,5-T or the other phenoxy acids which
14 these authors believe could exert a confounding effect on the
15 results.

16 A. That's true of every human study. That's right, of
17 any single substance.

18 Q. So, they say and I think you used the term before
19 of co-variation. Thus a co-variation in exposure tends to
20 prevail, which means that the effect of the simultaneous or
21 consecutive exposures to different pesticides cannot be
22 definitely evaluated in all respects. The same applies to
23 carrier agents and possible contaminants. So, you would agree,
24 as I think you just have, that the presence of other materials

1 could confound the results reached by Hardell.

2 A. They would only confound them if you were trying to
3 say that one chemical or one set of chemicals was solely
4 responsible for the increase in soft tissue sarcomas. You
5 will note that the authors don't make that claim. They
6 entitle their paper, "Exposure to Chemical Substances." They
7 have tried to elicit information on the chlorinated phenols
8 and phenoxy acids. But obviously, even if the people weren't
9 involved in agriculture or forestry, through living in
10 industrial society, we are all exposed to a number of chemicals,
11 many of which have been identified as carcinogens.

12 What is important in understanding the relative role
13 of one factor is to study large numbers of people to attempt
14 to get different patterns of exposure but still see the same
15 effect. But in the case of a chemical like TCDD, and it's
16 documented effect is a very powerful promoter, it probably
17 is true that the co-variation, that is the fact that a person
18 is exposed to one substance like lindane, for example, which
19 is mutagenic, and then to dioxin which is a very powerful
20 promoter may be a much worse circumstance for that person's
21 health than being exposed to lindane or dioxin alone. And
22 that, of course, holds true for all of us in this country.
23 We are also exposed to mutagens you have pointed out when
24 we discussed the paper by Bruce Ames and then to a very

1 powerful promoter of dioxin.

2 Q. Doctor, so that what this author is pointing out is
3 that his findings with respect to whether or not TCDD causes
4 soft tissue sarcomas in this case control study may well be
5 confounded by the fact that the people as to whom the study
6 was conducted were exposed to other materials?

7 A. Dr. Hardell has stated many times that his studies
8 cannot be used to identify one single chemical as the sole
9 factor in causing an increase.

10 Q. All right. Doctor, let me hand you what has been
11 previously marked as Defendant Monsanto's Exhibit 50 which is
12 the paper done by the American Medical Association on Agent
13 Orange and dioxin which we have referred to previously in your
14 testimony, and referring you specifically to page 28 and the
15 top paragraph in which the American Medical Association states
16 as follows: "Although 2,4,5-T and 2,4-D pesticides have been
17 used for over 30 years --"

18 A. I don't accept this as an authoritative source on
19 dioxin.

20 Q. You don't --

21 A. No. I believe we had a discussion of this the last
22 time.

23 Q. I didn't think we did, Doctor. I thought we used it
24 the last time. You disagreed with the result as I recall.

1 But you didn't deny it was authoritative the last time.

2 A. I think it is an opinion by the committee of the A.M.A.
3 and it is not an authoritative scientific paper on the subject
4 of dioxin toxicology.

5 Q. So, you would not accept this opinion by the American
6 Medical Association as authoritative?

7 A. No, I don't consider it a scientific document. I
8 believe that is consistent with my evaluation of it earlier.

9 THE COURT: What number was that, Mr. Heineman?

10 MR. HEINEMAN: No. 50, your Honor.

11 THE COURT: Thank you.

12 MR. HEINEMAN: Q. Doctor, do you have an opinion
13 as to whether or not dioxin causes liver cancer?

14 A. Yes, I do.

15 Q. And what is that opinion?

16 A. My scientific opinion based on the evidence to date
17 is that in animals dioxin is a very potent cause of liver
18 cancer. But I am not aware of human evidence one way or the
19 other to indicate a role for dioxin exposure in liver cancer
20 in humans.

21 Q. So, you are not aware of any evidence that dioxin
22 causes liver cancer in humans?

23 A. That's correct. I am not aware of any evidence in
24 humans.

1 Q. How about bladder cancer, Doctor? Do you think that
2 dioxin causes bladder cancer in human beings?

3 A. I am not aware of any evidence to suggest an increase
4 in the risk or incidence of bladder cancer after exposures to
5 TCDD.

6 Q. Thank you. So, hence, you don't have an opinion
7 that it causes bladder cancer in humans, is that right?

8 A. My answer is that I don't know of any evidence to show
9 an increased rate or risk of bladder cancer in humans after
10 dioxin exposure.

11 Q. How about skin cancer, Doctor? Do you believe that
12 there is any evidence to demonstrate that dioxin causes skin
13 cancer in human beings?

14 A. Yes, I think there is some evidence.

15 Q. All right. And what is that?

16 A. There is evidence from the Seveso study, from the
17 Binghamton state office building and from the morbidity,
18 that is the sickness study done by the Air Force of these
19 same Ranch Hand people we were talking about of an increased
20 rate of melanomas in exposed people.

21 Q. All right.

22 A. Now, I am referring only to evidence I am aware of
23 on melanoma, not of other types of skin cancer.

24 Q. Now, the Ranch Hand study you are referring to was

1 the 1984?

2 A. That's right. January, 1984, I believe.

3 Q. Ranch Hand study. And indeed that is a yes.

4 A. That is a yes. There is great increase in the rate
5 of melanomas.

6 (Defendant Monsanto's Exhibit No. 76 was marked
7 for identification.)

8 MR. HEINEMAN: Q. Doctor, let me hand you what has
9 been marked as Defendant Exhibit Monsanto No. 76 and ask you
10 to identify that. Is that the Ranch Hand 1984 study you
11 just referred to?

12 A. I believe it is.

13 Q. All right. Let me direct your attention to --

14 MR. CARR: Counsel, would you first establish that
15 the witness accepts it as authoritative?

16 MR. HEINEMAN: I'm sorry. I thought she just said
17 that she relied on it.

18 MR. CARR: You asked her, "Is that Ranch Hand II,"
19 and I think she said it was. That's not --

20 THE COURT: I think you have to explicitly talk about
21 it's being authoritative in her view. Would you please refer
22 to that foundation?

23 MR. HEINEMAN: I'm sorry, your Honor. I thought that
24 she had already said she based her opinion on that study.

1 Q. Dr. Silbergeld, do you consider the Ranch Hand
2 '84 study to be authoritative?

3 A. I do.

4 Q. Do you consider the Ranch Hand '83 study to be
5 authoritative?

6 A. I do.

7 Q. Okay. Now, if I could direct your attention to --

8 MR. CARR: May I have a copy, please?

9 MR. HEINEMAN: Certainly.

10 Q. I direct your attention to page X-4 in which
11 they have a table of verified malignant skin cancers. Now,
12 I believe you testified a moment ago that the Ranch Hand '84
13 study showed a great increase in melanomas, correct?

14 A. That's right.

15 Q. And if you look at this table, Doctor, under
16 melanomas, you find that in the comparison group there is a
17 total of two melanomas found, correct?

18 A. In the total of all the comparison groups. There is
19 a very large problem with what the Air Force did with reconstructing
20 comparison groups after the fact.

21 Q. So, in the total of all the comparison groups --

22 A. Right. The only way -- but that's not correct. The
23 only way to read that other side of this table, Mr. Heineman,
24 is to look at each column separately.

1 Q. Okay.

2 A. Column O which is the original control group they
3 set up, and then S where they did some re-arranging, and
4 then the replacement group which was yet another constructed
5 control group. And you can't really add them up because they
6 were all designed differently for reasons that have not been
7 clearly explained by the Air Force.

8 Q. All right. Now, if you take the original column in
9 the original comparison group, they found one melanoma?

10 A. That's right. My comment was based, however, on
11 both malignant and non-malignant skin cancers. As you know,
12 this document is not paginated in the index, so I can't find
13 the table. If you give me time, I can for the non-malignant --

14 Q. I guess I misunderstood you. I thought you were
15 talking about skin cancers.

16 A. I did. But non-malignant as well as malignant. And
17 that is where there is an increase in skin cancers.

18 Q. Now, in the malignant skin cancers, tell me what a
19 non-malignant skin cancer is. Is that like a mole?

20 A. No. Though it may be associated with a mole. It's
21 a type of proliferation of cells which is thought to be
22 controlable and localized to the site where it occurs. There
23 is, of course, considerable concern among people who deal
24 with cancer that what are called benign or non-malignant tumors

1 may be an indication that malignant tumors will follow. As
2 I am sure many people will know who have had friends or even
3 themselves operated on for benign tumors, they are usually
4 warned by their physicians' surgeons to be very aware of any
5 other change in their body which might herald the onset of a
6 malignant tumor. So, there is thought to be a connection,
7 biological connection between what are called benign or
8 non-malignant tumors and malignant tumors. That's why
9 putting the two together makes a certain amount of sense
10 particularly in this young group relatively soon after
11 exposure; that's the Vietnam veterans.

12 Q. So, you have put together in the Vietnam veterans
13 both the malignant skin tumors, melanomas, and the non-malignant
14 tumors?

15 A. That's right. Even though there is what looks like
16 a great increase here, three melanomas in the Ranch Handers
17 and only one in any one of the comparison groups, that is
18 obviously still very small numbers. Even if you put all the
19 skin cancers together, there are 35 in the Ranch Handers and
20 only 15 in the highest of the control groups and 5 in the
21 lowest of the control groups, I would still be, particularly
22 in this early stage of the exposure, although it looks as
23 though there is an increase in the rate of skin cancer, even
24 malignant here -- and one might even argue it's a two to seven fold

1 increase which is remarkably similar to what Hardell proposes,
2 interestingly enough -- I think we still have to see what is
3 going to happen with this population. But this is certainly
4 highly consistent with Hardell in that in all the control
5 groups there is an increase in the Ranch Handers of these
6 types of cancers. And when you add in the non-malignant ones,
7 that increase is even greater.

8 Q. So that -- I believe you said that you were talking
9 before only about melanomas in terms of your opinion here.

10 A. Yes.

11 Q. And so if we look at the melanomas --

12 A. But if you want to put in the others, you will see
13 that the situation gets even more shifted towards a great
14 increase in the Ranch Hand exposed group as compared to the
15 controls if you throw in basal cells and the others as well.

16 Q. If I understand it from what you just told the jury,
17 Doctor, your opinion is based only on the melanomas.

18 A. That's primarily because I think this study is a
19 study in progress although I do think it's authoritative. My
20 opinion is directed towards the melanomas for several reasons.
21 One as I mentioned, there is evidence from other exposure
22 incidents. There is a case of melanoma in the people exposed
23 at Binghamton. And there are two cases, I believe, of
24 melanomas in people in Seveso. In addition, there are

1 melanomas in persons exposed to dibenzo-furans in Taiwan
2 which is a structurally very similar chemical. And moreover,
3 based on the localization of dioxin receptors, getting back
4 to the mechanism of action of this substance, there is a
5 reason to suggest that there would be an association with
6 melanoma. I do not mean to exclude that there would be
7 other skin cancers that might be elevated as well.

8 Q. I see. So, that when you suggested previously that
9 your opinion was based solely on melanomas, that is not quite
10 accurate; that you base your opinion on other things as well?

11 A. No. My opinion was focused primarily on melanomas
12 as among the skin cancers because of the other evidence. But
13 I didn't mean to suggest that other types of skin cancer could
14 not also occur.

15 Q. And the other evidence was that in the Binghamtom
16 situation, they found one melanoma there.

17 A. So far, that's right.

18 Q. That's right. And didn't you tell this jury last
19 week that the finding of one cancer is never statistically
20 significant?

21 A. I was not citing Binghamtom or even this table as I
22 have tried to make very clear that any of these data were
23 statistically significant. That wasn't the question you asked
24 me. What I responded to was that there is evidence for these

1 types of cancer occurring in people exposed to these classes
2 of chemicals.

3 Q. So, it's your --

4 A. There is no -- there has been insufficient examination
5 of any exposed group to develop any statistical basis. You
6 were asking me if I thought there was any association between
7 exposure to TCDD and a series of types of cancers. And I
8 stated I thought there was some reason to associate TCDD
9 exposure with skin cancer.

10 Q. So, your opinion would be that the findings in the
11 Ranch Hand 1984 study are not statistically significant with
12 respect to melanoma?

13 A. I don't think they are. The Ranch Hand people,
14 scientists, state they are, but I am not sure they are.

15 Q. Okay.

16 A. Mr. Heineman, you are putting no on your exhibit.
17 That's not exactly what I have been saying. That is your
18 opinion, not mine.

19 Q. Well, you just told us that the finding of the Ranch
20 Hand study with respect to melanomas, which is what your
21 opinion is based on, is that that is not statistically
22 significant.

23 A. I stated earlier that there have been no studies of
24 skin cancer and TCDD which provide any information which can

1 be used in a statistical sense. But --

2 Q. Is that, Doctor, what the studies are for?

3 MR. CARR: The lady said --

4 THE WITNESS: No, Mr. Heineman. They are not.

5 MR. HEINEMAN: Q. I mean the whole purpose of an
6 epidemiologic study is to determine statistical significance,
7 isn't it, to see whether the occurrence of these things is
8 greater than chance?

9 A. That's not the question I have been talking about
10 here, Mr. Heineman. I will try once again. You asked me
11 whether there was any association between dioxin exposure and
12 certain types of cancers. I said -- that's what I heard. If
13 you were asking me another question, perhaps we should start
14 over again.

15 Q. My question to you, Doctor, was whether or not you
16 had opinion that dioxin causes skin cancer in human beings.

17 A. And I stated yes.

18 Q. You said yes, based upon melanomas.

19 A. That's right.

20 Q. All right. Now, are we to understand that -- I am
21 confused, Doctor. You are not saying, I take it then, that
22 there isn't -- or are you saying there is no epidemiological
23 evidence to establish a statistical significance in human
24 beings?

1 A. What I am saying is that this particular topic, this
2 type of cancer, has been only rarely looked at. And it is
3 my opinion that there is insufficient evidence to state
4 that there is a statistical association.

5 Now, the authors of the Ranch Hand study, if you
6 look at the top of X-4, state that there is a statistically
7 increased -- statistically significant increased rate of
8 skin cancers in the exposed groups. So, you shouldn't put
9 no there by your criteria. It is a statistically significant
10 increase in the opinion of the U.S. Air Force.

11 Q. But didn't you just tell me it --

12 A. I am not certain. Because I think this is a study
13 in progress. The same comments I made about the May study
14 and some others.

15 Q. So, you think this ought to be a yes?

16 A. If you are just writing down what this document --

17 Q. What the author says.

18 A. -- which is your exhibit, is stating, then it is a yes.
19 Now, when you were asking me, which I interpreted to be a
20 question as to is there any evidence for associating dioxin
21 exposure with skin cancer, then as a scientist, I review
22 all of the documentation that I know of. Some of that
23 documentation, like the Binghamton study and like the Seveso
24 study, are actually case reports. Now, that's a type of

1 medical literature we haven't talked about. A case report
2 is really just a description of a case. It has no statistical
3 dimension whatsoever. That's not why it's written up. That's
4 not why it is discussed. A case report is when a physician
5 or scientist sees something interesting happening in a case,
6 one person, and says to himself or herself, "This is really
7 interesting. I should communicate it. Maybe epidemiologists
8 or other people will go out and find out how often this occurs,
9 but I am going to describe it." That's what has been done
10 with the Seveso cases and with the Binghamton case. So, they
11 don't have a statistical dimension. They are not embedded
12 in statistics.

13 Q. It's just as though it's something that may be
14 purely anecdotal in nature. It is just that somebody says,
15 "I found X."

16 A. It's not quite anecdotal. I mean there is clinical
17 findings and evidence presented. It's not as if someone off
18 the street says, "I have a melanoma. And I am going to report
19 it in the St. Louis Post Dispatch." That's not a case report.
20 It's more scientific than that. It is a thorough diagnosis
21 and a description in as complete a terms as anyone can make
22 of all the circumstances surrounding that case. And the reason
23 why physicians make case reports is to produce in other people's
24 minds the thought that maybe this is worthwhile to study on a

1 more systematic basis. Maybe there is something going on here
2 and we ought to look for these associations. But those are
3 again totally different kinds of studies.

4 Q. So that it's your understanding or your opinion
5 that the finding of one melanoma in Binghamton or two at Seveso
6 are not statistically significant because they are not greater
7 than mere chance?

8 A. No, that's not what I have been saying, Mr. Heineman.
9 I will try and say it again. Those have been what are called
10 case reports. There has been no attempt to determine what
11 the statistical incidence of melanoma would be expected to be
12 in the Binghamton group of people who were immediately in there
13 after the fire. That is one of the people who is this case.
14 Or one of the people living in Zone A in Seveso which is
15 where these melanomas have been described. No one has tried
16 to do that. Once again, you are trying to take one kind of
17 study and turn it into another one and then asking me why it
18 doesn't fulfill the criteria of the other kind of study.

19 Q. Doctor, I am just trying to understand what you are
20 telling us here.

21 A. I will try again.

22 Q. Yes.

23 A. What it is is when a physician or a scientist sees
24 something interesting, what you do -- you really shut your

1 eyes to the rest of the world and say, "This is really
2 interesting. Here is a baby with five arms. Now, I don't
3 know anything about how this baby was created. I don't know
4 what drugs the mother might have been taking, what kind of
5 hereditary illness might be in this family, but I think this
6 is fascinating and I am going to write it up. And maybe my
7 colleagues who have seen a lot more births, say in a big
8 metropolitan hospital as compared to me out in the country
9 or whatever, maybe they have seen some other things like this
10 and we can get together." This is really how diseases are
11 first described. The first case of A.I.D.S. was described this
12 way as a case report. That is the progress of clinical
13 medicine. Doctors describe something interesting. Then
14 other people, other doctors, epidemiologists, others attempt
15 to amass the kinds of numbers which allow you to do the
16 statistics we have been talking about. But it usually starts
17 with case reports. And it is usually the case that doctors
18 and scientists will say and will refer to case reports in
19 trying to understand what might be going on. But we don't
20 put it in the same category as a cohort study or a case
21 reference study. It's part of the evidence, but a distinct
22 part, but a very important part.

23 Q. But there are no conclusions that you can draw from
24 it?

1 A. There are no epidemiologic conclusions, that's right,
2 because they are not epidemiologic studies.

3 Q. So that you cannot look at the Binghamton study
4 and say that that one finding is statistically significant,
5 because there hasn't been any determination of that.

6 A. It would be totally inappropriate to even use the
7 word "statistical" in any case study. Because by its very
8 name a case study is one case.

9 Q. All right.

10 A. There is no statistics for one.

11 Q. And that would be -- the same would be true with
12 respect to the Seveso incident?

13 A. That's true.

14 THE COURT: Have you come to a point where we can
15 stop for lunch?

16 MR. HEINEMAN: Oh, sure. Thanks for reminding me.

17 THE COURT: Ladies and gentlemen, it is time to break
18 for lunch. We will resume at 1:30. The admonishments which
19 I have given you previously apply to this break. Court is in recess.

20 (At this time, Court recessed for lunch.)

21 MR. HEINEMAN: Q. Dr. Silbergeld, let me hand you
22 what we have previously been looking at here, this Cancer
23 Statistics of the American Cancer Society for 1983 directing
24 your attention to Page 10 on the portion on skin. That

1 demonstrates that --

2 MR. CARR: What was that exhibit number, counsel?

3 MR. HEINEMAN: It isn't marked.

4 MR. CARR: Could you mark it, please, if you are
5 going to ask questions about it and see that it's identified
6 properly?

7 MR. HEINEMAN: Well, I would be delighted to, Mr.
8 Carr.

9 (Defendant Monsanto's Exhibit No. 77 was marked
10 for identification.)

11 MR. HEINEMAN: Q. Dr. Silbergeld, I hand you
12 what has been marked as Defendant Monsanto's Exhibit 77 which
13 is the Cancer Statistics book we have had prior reference to
14 in your testimony. And on page 10, the American Cancer
15 Society for 1983 publishes statistics with respect to the
16 amount of new skin cancer cases in the United States in both
17 males and females, does it not?

18 A. That's right.

19 Q. And what is the total figure for both males and
20 females of skin cancers for 1983?

21 A. Seventeen thousand four hundred.

22 Q. Now, what does that mean when --

23 A. Excuse me. That is melanoma only.

24 Q. What does that mean when they publish -- is that what

1 they anticipate or how are those figures reported? Do you know?

2 A. Those are the new cases they expect to occur in the
3 twelve-month period for the entire U.S. population.

4 Q. Based upon what they have observed in prior years?

5 A. That's right.

6 Q. Okay. I would like to look at the studies on skin
7 cancer or the studies we have been looking at with respect to
8 their application to skin cancer. And the first that I would
9 like you to look at would be the Axelson study which I think
10 you have before you. It's always at the bottom of the pile.

11 THE COURT: Naturally.

12 MR. HEINEMAN: Was that Murphy's Law?

13 THE COURT: I think so.

14 MR. HEINEMAN: What you are looking for is always
15 at the bottom of the pile.

16 THE COURT: That's one of the many applications we
17 have.

18 MR. CARR: That is if you start at the top of the pile.

19 MR. HEINEMAN: The jelly on the bread always falls
20 on the carpet.

21 THE COURT: Right.

22 MR. HEINEMAN: Q. In the Axelson study, Doctor,
23 there was a cohort of 348 individuals, was there not, according
24 to the abstract on the first page?

1 A. Yes.

2 Q. And this is the case, you may recall, in which in
3 Table 4 when Dr. Axelson lists the cancer sites among these
4 railroad workers that they are apparently listed in Latin
5 under the -- those that are exposed to phenoxy acids. Are
6 you able to interpret those words to see whether or not they
7 found any skin cancers in that group?

8 A. No, as I told you before, Mr. Heineman, I am not
9 an expert in the pathologic names of cancers. We went through
10 this table before.

11 Q. All right. So, I will put a question mark down
12 for Axelson.

13 A. I think it should be noted that the question is in
14 your mind, not in the paper. It may well be that there are
15 skin cancers listed here.

16 Q. Well, there isn't any question in my mind, Doctor,
17 that there isn't any skin cancers listed here. But I am
18 just -- because if you look at the terms that are used --
19 Tumor cerebri would lead you to believe that there was -- they
20 are talking about a brain tumor. Leukaemia would be certainly
21 not skin. Prostatae would lead one to believe it was prostate
22 cancer. Hodgkin would lead one to believe that was Hodgkin's
23 Disease and not skin cancer. Recti would lead one to believe
24 there was cancer of the rectum. Now, the Hypernephroma would

1 lead one to believe that would have something to do with the
2 kidney. But the two that are ventriculi, those are the two
3 I am not entirely sure of. Have you ever heard of that term
4 in relation to any skin cancer?

5 A. As I said, I don't know the Latin names, if these
6 are Latin, for any type of cancer. I take your explanation.

7 Q. Now, if we could look at the Ott study. Now, this is
8 the study of the 204 persons who had been exposed to 2,4,5-T
9 manufacture at the Dow plant. And on the third page of the
10 report, Dr. Ott, you will recall, reports that he found only
11 one malignancy in one of the people, one death from malignancy
12 in one of the people and that was a lung cancer in a gentleman
13 that smoked two packs a day of cigarettes, is that correct?

14 A. That's right.

15 Q. So, if there was only one cancer observed and that
16 was the lung cancer death, obviously, in the Ott study, he
17 did not observe any deaths from skin cancer.

18 A. Right.

19 Q. Now, if we look at the Zack, Suskind study published
20 in the Journal of Occupational Medicine we find in Table 1 on
21 page 13 that these authors report the finding of one skin
22 cancer death and expected 0.15 which they say is statistically
23 insignificant, is that correct?

24 A. No, that's not what they say.

1 MR. CARR: Is this 62 that you are referring to,
2 counsel?

3 MR. HEINEMAN: Whatever the number is, Mr. Carr.

4 THE WITNESS: Yes, it is. That is not what they say.

5 MR. HEINEMAN: Q. What do they say?

6 A. If you read the footnote to the table, Mr. Heineman,
7 they say there are less than five observed deaths. They didn't
8 do a statistical test.

9 Q. I see. Okay. So, there were so few that they did not
10 do -- or maybe that isn't so few. The fact that there were
11 less than five they did not do a statistical analysis as to
12 whether it was significant or not.

13 A. That's right. And what this points out to is as we
14 have gone over extensively already today is when you are
15 dealing -- you have to look at the expected rate of a disease
16 in order to determine whether indeed you are actually going
17 to be able to see it in a small number of people. And if you
18 go back to these statistics here, Mr. Heineman, in this book
19 by the American Cancer Society, you will see if you look,
20 it cites specific cancers that skin cancers are not among the
21 most frequent cancers in the population. Now, they are, of
22 course, more frequent than the soft tissue sarcomas that we
23 were talking about earlier. But still the same comments that
24 I have been trying to make all along about soft tissue sarcomas

1 do have a relevance here again that you are dealing with a
2 cancer which is relatively infrequent so much so that as
3 Zack and Suskind point out that they would only have expected
4 to find .15 cases, much less than one in the number of people,
5 only 121, that they were available to study. So, once again
6 you have to ask yourself the question, as I tried to ask earlier,
7 is this a study which could have found an increase; or
8 conversely, what an epidemiologist would ask is, given what
9 we expect to find, given the number of people we have got to
10 study, which as you pointed out you can't do much about, what
11 kind of an increase would have to occur in order for us to do
12 a test, a mathematical test of significance. Now, what
13 Zack and Suskind said was that unless they had five deaths,
14 they weren't going to bother doing any statistics. I think
15 there is a lot of justification for doing that. There are
16 some statistical tests you could do nevertheless.

17 At any rate, taking their standards for when they
18 are going to start looking, you would have had to have an increase
19 of about fifty-fold to get five deaths in 121 exposed people.
20 I think we have to keep those things in mind all along in this
21 discussion in order to decide whether these papers really are
22 on the point of answering your exhibit which you are setting
23 up in a very rigid way of was there or was there not skin
24 cancer. Because the question that is not being asked and can't

1 be answered, therefore, by your exhibit is, could we see any
2 skin cancers. What kind of exposure, what kind of impact
3 would have to be going on here for us to see skin cancers?

4 Q. So that --

5 A. And you can get that answer from this book.

6 Q. Your explanation, as I understand it -- I am just
7 trying to understand you -- is that if the group of people you
8 have to study is of a sufficient size, sometimes that study
9 will be able to demonstrate whether or not there is any
10 statistical significance to the findings. But if the group
11 is sufficiently small, it's impossible to tell.

12 A. That's right. And that's why most epidemiologists
13 when they are looking at once again a relatively infrequent
14 thing use the case referent, case control method. I am not
15 faulting the cohort method of looking at the entire health
16 picture of exposed people in these occupational studies done
17 by Monsanto, Dow and others. What I am suggesting is that
18 the utility and value of these studies begins to evaporate
19 the finer and finer you try to cut them. And you are taking
20 out of here now not all causes of death, not all malignant
21 neoplasms, but you are going through one after another -- maybe
22 you are going to go through them all. Each one of these cite
23 specific cancers with no reference to what you might possibly
24 find based on this.

1 Q. I have just asked you about that.

2 A. And I have told you what that means to me. And that
3 means that most of the rest of this, which I guess you are going
4 to go through now for the rest of the day, is not going to be
5 on point to answering that question. I can tell you that
6 now.

7 Q. Doctor, each of these studies that we have examined,
8 we have been through the various types of cancer that we have
9 been through at this point --

10 A. And I have raised objections to using them in a
11 scientific sense, scientific objections, to using them to
12 answer the kind of yes/no question you are trying to throw
13 at me.

14 Q. But indeed, Doctor, in each of these studies, haven't
15 we talked about all the malignant neoplasms that we found?

16 A. That was, I think, the last scientifically relevant
17 examination we did of these papers, Mr. Heineman.

18 Q. Then we went through one by one each of the types --

19 MR. CARR: Your Honor, I object to this. We are not really
20 getting anywhere. If counsel could ask a question, the witness
21 could respond. I think we could move along. And I might object
22 to counsel and the witness arguing back and forth here.

23 MR. HEINEMAN: Your Honor, I am cross examining the
24 witness about her statements she has just made. And I am going

1 through this test with her. I think it's a proper cross
2 examination.

3 THE COURT: Go ahead.

4 MR. HEINEMAN: Q. Doctor, we did go through in the
5 very first instance all of the malignant neoplasms, did we
6 not?

7 A. That's right.

8 Q. And at that time, didn't we talk about specific
9 neoplasms, cite specific items and we said we would go back
10 to those?

11 A. You did.

12 Q. All right. And didn't you as well point out to me
13 that there were certain of these where there were positive
14 findings when we went through the malignant neoplasms as a
15 whole?

16 A. I don't recall what context you are referring to.

17 Q. Well, what I am trying to go through, Doctor, is
18 each of these types of cancer, whether it be lung cancer,
19 skin cancer, whatever --

20 A. I am aware that is what you are doing, yes.

21 Q. And then we are going to talk about the lymphatic
22 system and we are going to talk about some other things as
23 well. But what I am asking you is, these findings in this
24 particular case -- they found one skin cancer in this group,

1 is that right?

2 A. That's right.

3 Q. And you told the jury earlier, did you not, that at
4 no time would one finding of one cancer be statistically
5 significant?

6 A. Mr. Heineman, I don't know how to answer these
7 questions other than I have been trying to do all day, which is
8 that I think you are significantly misusing the design of these
9 studies to try to get me to make an unscientific yes/no answer.
10 These studies were not by their very design capable of giving
11 a yes/no answer as you go through every single ICD classification
12 of tumors. Now, we can do that for every single one of these
13 tumors in every single one of these papers. I can tell you
14 ahead of time that that is going to be my answer.

15 Q. Now, Doctor, we have talked about the two different
16 kinds of studies that are available. And we have talked about
17 the fact that there are case control studies, have we not, and
18 there are cohort studies? Correct?

19 A. And we have also talked about when you use one and
20 why you can't use one to challenge or support the findings
21 of the other, which is what this exercise appears to be.

22 Q. Now, Doctor, what is the validity, if any, of a
23 cohort study then? Are they useful at all in the scientific
24 community? Why are so many of them published?

1 A. We went through this once before. I will try and go
2 through it again. A cohort study is very useful when it's
3 well designed and all factors are accounted for. And it is
4 particularly useful either when it is carried out over time
5 in a prospective design with complete follow-up, that is you
6 get all the people you had at the beginning all the way
7 through time to the end. And it is also useful when the
8 disease you are studying or the diseases you find could possibly
9 occur in the size of the population you are studying. That
10 is described very elegantly in Dr. MacMahon's text book.

11 It is not that one is an invalid study and the other
12 is valid. Their validity, their interpretability and their
13 use depends entirely on what is being asked and the power of
14 the study to answer the question. And power has a great deal
15 to do with, first, the size of the group being studied and,
16 second, the frequency, the expected frequency or occurrence of
17 the disease is being noted.

18 That's why you find over and over again in the cohort
19 studies the authors themselves say the study was too small
20 to provide any conclusive evidence. And I am not going to
21 change their conclusion and say, "No, it didn't provide
22 conclusive evidence," or, "Yes, it did." Because I respect
23 what they are saying to us which is you must not misuse these
24 studies.

1 Q. Doctor, the people that are writing these studies --
2 you have read a lot of these studies. You are familiar with
3 the ones we have talked about. Isn't that correct?

4 A. That's right.

5 Q. You are familiar with the studies. You have read
6 them before. They are being published -- each of the studies
7 we have talked about is published between 1980 and 1983.

8 I think that's right.

9 A. '77 through '83, yes.

10 Q. All right. Each of these studies is published by
11 its author for the purpose of telling the scientific
12 community something.

13 A. Yes, but not everything. For instance, in this very
14 study in the first sentence under the discussion section says,
15 "Because the study cohort was small and only 32 deaths were
16 observed, the results cannot be considered conclusive." Now,
17 you are trying to get me to change Dr. Zack and Dr. Suskind's
18 very statement and suggest that it is conclusive.

19 Q. No.

20 A. I am not going to do that.

21 Q. I am not asking you to tell us it is conclusive.

22 A. Well, that's what you are asking me when you want me
23 to give a yes/no answer in terms of statistical significance.
24 Because statistical significance is a conclusion.

1 Q. I am just asking you whether or not the author found
2 any statistical significance to the respective finding made in
3 the study.

4 A. And I have replied numerous times that that was not
5 the author's intent. And the authors have numerous times
6 stated explicitly that they could not do so given the size of
7 their study. That is not the same thing as saying that a
8 study is statistically insignificant. Perhaps that is the
9 root of our misunderstanding.

10 Q. Let me --

11 A. Excuse me. There is a very great difference in science
12 between a study which cannot answer a question and a study which
13 gives a yes or no answer. And to say something is
14 inconclusive is not the same thing as saying it is statistically
15 insignificant. Perhaps that is where we have been misunderstanding
16 each other.

17 Q. All I am trying to ask you, Doctor, is whether or not
18 these studies demonstrate that the particular authors found
19 statistical significance or insignificance to the findings that
20 were made in the study.

21 A. My answer will be that the author didn't ask that
22 question. And that will now be the answer I will give. I
23 think I understand your question.

24 Q. Doctor, in each of these instances there has been a

1 statement made in here as to whether or not it was statistically
2 significant.

3 A. In this paper, Mr. Heineman, there is no such
4 statement. If you will look again, as I said a long time ago,
5 at the bottom of Table 1, there is no such statement that
6 says not statistically significant. What it indicates is
7 just what I have been trying to say that the study was too
8 small. There are less than the minimum observed incidents
9 for the authors to put statistical significance. There is
10 nothing there that says P greater than .05. That is what
11 scientists put when something is statistically insignificant.
12 They indicate they have done a statistical test and it failed.
13 What this indicates, arrow up, which means qualitative increase,
14 but then less than five observed deaths means that Dr. Zack
15 and Suskind did not test for statistical significance. It
16 is not the same thing. So, the answer to your question is
17 they did not look for it.

18 Q. They did not determine statistical significance in
19 this case?

20 A. That's right.

21 Q. All right. What is the finding with respect to all
22 causes of death at the top of Table 1?

23 A. It is statistically significant. And it is
24 significantly less than expected at the P less than 0.15.

1 That is --

2 Q. So, what they found is that from all causes of death
3 that the deaths observed were significantly less than those
4 expected?

5 A. That includes automobile accidents, suicides, fires,
6 everything that happened to this group. That's right.

7 Q. Does it not include the causes of death reported on?

8 A. It includes all causes of death. But that doesn't
9 mean that each and every cause has been statistically tested.
10 I don't want to leave that implication behind this. A test
11 of the overall number of deaths and a finding of significance
12 or insignificance, that was done. And that is what that footnote
13 indicates.

14 Q. In this particular test.

15 A. But the individual causes were not tested statistically.

16 Q. In this particular test.

17 A. In this particular paper.

18 Q. In this particular paper. All right. Now, let us
19 look at the Edling and Granstam study of 1980, the Causes of
20 Death Among Lumberjacks.

21 A. I don't seem to have that.

22 MR. CARR: No. 63.

23 THE WITNESS: I have got it.

24 MR. HEINEMAN: Q. Now, in this particular study,

1 Doctor, indeed did the authors not look at the statistical
2 significance of the particular types of diseases that they
3 studied?

4 MR. CARR: Your Honor, may I object to this? The
5 witness has already stated that this particular study doesn't
6 establish anything because it doesn't establish what they are
7 exposed to, if anything. We have gone over this. This is
8 repetition of that which we went over last week. And I would
9 object to the repetition on this particular study because we
10 have gone into it. The witness has said already her view
11 of this particular study. It's repetition.

12 THE COURT: Mr. Heineman?

13 MR. HEINEMAN: Your Honor, I think it is proper
14 cross examination. We are going through this study with
15 respect to skin cancer on this occasion. And I would like to
16 ask the witness about that.

17 THE COURT: Confine to just that one particular
18 matter and you may proceed.

19 MR. HEINEMAN: Q. Indeed, Doctor, here was there
20 any finding with respect to skin cancer in terms of the Edling
21 and Granstam study?

22 A. I don't know. They don't talk about skin cancer.
23 They only pull out two types of cancers to look at specifically.
24 I can't answer the question.

1 Q. Doctor, you say they only looked at two. Let me
2 direct your attention to the second page of the exhibit,
3 second column.

4 A. Yes. They do mention digestive system and cancer
5 of the prostate as well and lung cancer, but they don't
6 discuss whether there were any skin cancers.

7 Q. Now, they talk about the cancers that they discovered
8 in the group, do they not?

9 A. They talk about some of them, yes.

10 Q. All right. Can you tell from the paper that there
11 were cancers discovered which they did not talk about? Or
12 would it be fair to assume that they discussed the cancers
13 that they found?

14 A. Well, I don't know. One would have to look at the --
15 I wouldn't assume anything, Mr. Heineman. They talk about
16 a total of 75 cancers discovered in this group of lumberjacks
17 whose relevance to this case is unclear to me. Now, of that
18 75, they then discuss more specifically -- they don't tell
19 how many cases of digestive system or prostate cancer they
20 found unless you see it. I don't. They see four deaths from
21 lung cancer. They see seven cases of kidney cancer, I think,
22 and eleven cases of lymphatic and hematopoietic system cancer.
23 That leaves a lot of cancers that they are not discussing.
24 I don't know what they are. I don't see anything in here. As

1 I told you, I have never read this paper because I didn't
2 think it had anything to do with TCDD or 2,4,5-T. But I don't
3 see anything in my examination right here with you that accounts
4 for most of the cancers listed here. So, there may well have
5 been some skin cancers.

6 Q. They do tell us though in terms of total cancer
7 deaths, do they not, that there were fewer deaths from cancer
8 than expected?

9 A. That has no relevance at all to the rate of any
10 specific site of cancer.

11 Q. All right. Does it have any relevance to the ability
12 to make a determination as to whether exposure to a material
13 would cause -- would increase the risk of cancer in general?

14 A. This paper has no relevance to that subject as I
15 have stated before. It has some relevance to the occupation
16 of lumberjacks.

17 Q. But in your view it has no relevance to whether or
18 not these particular people could have been exposed to 2,3,7,8
19 TCDD, is that right? That is not determined?

20 A. That is in no way established in this paper.

21 Q. All right. Now, if you will -- Doctor, let's look
22 at the Cook study where there were 61 males involved in a
23 1964 chloracne incident where they found that 49 developed
24 the chloracne skin condition, correct? I think you will find

1 it in the abstract at the beginning.

2 A. Yes.

3 Q. All right. And on page 531 Dr. Cook tells us that
4 there were a total of three malignant neoplasms found.

5 A. Right.

6 Q. And he found one adenocarcinoma, one fibrosarcoma
7 and one glioma.

8 A. Right.

9 Q. Now, we previously talked about the fibrosarcoma might
10 perhaps probably be a soft tissue sarcoma, did we not?

11 A. You did, yes.

12 Q. Okay, I did. All right. Do you see of any of the
13 cancers reported a skin cancer report?

14 A. No.

15 Q. All right. He does discuss whether or not the total
16 number of cancers found were statistically significant on that
17 same page, does he not?

18 A. That's right. And as I discussed earlier, I thought
19 the size of the study made that statistical test highly
20 suspect.

21 Q. And I understand that because of the group is only
22 51 people and there were 49 chloracne cases that that is a
23 small group.

24 A. That is a very small group.

1 Q. Now, Doctor, if we turn to the Pazderova study, there
2 is a statement in here -- there is no statement, I think you
3 will agree with me, with respect to the locations in which
4 cancers were found to be the cause of death of any skin
5 cancer.

6 A. That's right.

7 Q. They do -- or the authors do report here what they
8 found in terms of skin lesions. And they said that the one
9 thing they found was that 95 percent of the patients had
10 chloracne of different severity, correct?

11 A. Yes.

12 Q. But there was no report by these authors of the
13 presence of any skin cancer.

14 A. I think as I indicated to you when we studied -- talked
15 about this paper before, it's not clear to me that there was
16 an ascertainment of cancer morbidity. This paper is mostly
17 on porphyria and neurotoxicity. There is no mention of it
18 in the paper, but it is not clear that it was looked for.

19 Q. We do have two cases of cancer mortality reported,
20 do we not?

21 A. That's right.

22 Q. And they are both lung cancer.

23 A. That's right.

24 Q. And again they talked about the skin conditions which

1 were observed as well as the neurological and the other that
2 you have referred to. And on page 9 on the second column,
3 right above the term "Discussion" they say that chloracne,
4 which in the beginning of the illness was the most constant
5 sign of intoxication, has healed in one-fifth of the patients;
6 one-half of the patients has only isolated cysts and comedones.
7 So, they examine from a morbidity standpoint the skin of the
8 members of this study, did they not?

9 A. They examined the skin from the standpoint of finding
10 chloracne. Whether that would be sufficient to find all
11 forms of skin cancer, I do not know. That is a question of
12 clinical diagnosis.

13 Q. All right. But in any event, they did report the
14 chloracne lesions that they found. That was the only skin
15 lesion that they reported and they reported no skin cancers.

16 A. That's right.

17 Q. We go to the May study which was a study of some
18 79 workers with chloracne, some ten years following the Coalite
19 incident in England. And as we recall, May found no cancers
20 of any kind, did he?

21 A. That's right.

22 Q. And we go to the Thiess study which is the -- some 74
23 people were followed up from the GASF incident that you described.
24 Is that the incident where the rabbit cage situation occurred?

1 A. I think it is the same one.

2 Q. All right. And among -- in the tables there, there
3 are a few tables where they list various types of stomach
4 cancer -- pardon me, various types of cancer which they looked
5 for or found.

6 A. That's right.

7 Q. All right. And none of those cite specific
8 designations recites skin cancer, is that correct?

9 A. That's right. For deaths.

10 Q. Right. This was after all a mortality study.

11 A. That's right.

12 Q. Right. And if we look at the Bond, Ott study and
13 Table 5 on page 322 --

14 A. Wait.

15 Q. Oh, I'm sorry. Under the malignant neoplasms there
16 is a specific mention of skin cancer, malignant neoplasms of
17 the skin, correct?

18 A. Yes.

19 Q. And under the exposed group in the trichlorophenol
20 cohort, they found none; whereas in the control group they
21 found one.

22 A. That's right.

23 Q. Right. And in the 2,4,5-T exposed cohort in the
24 exposed group they found none and in the control group they

1 found two.

2 A. That's right.

3 Q. Now, if I could direct your attention, please, to
4 the Riihimaki study, Table 3 lists localization of malignant
5 tumours found among deceased 2,4-D and 2,4,5-T applicators,
6 and expected values, with a ten-year latency period, correct?

7 A. That's right.

8 Q. And there is no finding listed there as I see it
9 for skin cancer.

10 A. Skin cancer is not listed.

11 Q. Right. And in the table designation they say that
12 these are the sites at which malignant tumors are found.
13 So, does that indicate to you that they did not find any skin
14 cancers?

15 A. It may, yes.

16 Q. And in the Ranch Hand II study, if I can direct your
17 attention to Table 20 on page 18 that we looked at before
18 in connection with the connective tissue, you will see the
19 same table cites specific malignant neoplasm mortality; that
20 for skin cancer they find no deaths in the Ranch Hand group.

21 A. Mr. Heineman, if you are going to enter Ranch Hand
22 twice, I think that is a strange way to construct this exhibit.
23 You have Ranch Hand as the first entry there. This is the
24 same study.

1 Q. Well, now, didn't you tell me that the Ranch Hand '84
2 was a different study from Ranch Hand II?

3 A. No, it's not a different study. One is morbidity;
4 one is mortality, but it's the same population.

5 Q. Same population.

6 A. It's not a different study.

7 Q. Well, in this case, aren't we talking about the fact
8 there was no death caused by skin cancer in the mortality
9 study?

10 A. Yes.

11 Q. So, wouldn't you agree with me that in the Ranch Hand II
12 study they found no deaths caused by skin cancer?

13 A. It's your exhibit. I wouldn't construct this exhibit
14 like that at all. I wouldn't take two parts of the same
15 population and set one against the other, but --

16 Q. Well, the authors have written two separate
17 documents to report these results, haven't they?

18 A. That's true. That is frequently true in science.

19 Q. All right.

20 A. But it is possible when one has the benefit of having
21 them both to consider them as parts of the same study.

22 MR. CARR: Your Honor, this document was not marked
23 as an exhibit. Apparently, counsel is, of course, exhibiting
24 it to the jury nonetheless. The counsel is writing numerous

1 things on this exhibit to which the witness is not agreeing,
2 as a matter of fact, is protesting and saying that it's not
3 significant and not relevant to the issues in this case.
4 I don't know why counsel is writing these things on this
5 piece of paper where the witness is not agreeing to them. And
6 I would ask that counsel state the purpose of this exercise
7 in creating something that the witness is saying
8 is not relevant to the questions being asked. It seems to me
9 it's a complete waste of time what we are doing here.

10 MR. HEINEMAN: Are you objecting --

11 MR. CARR: I am objecting.

12 MR. HEINEMAN: -- to my doing this?

13 MR. CARR: I am objecting to your creating an
14 exhibit if in fact it is not an exhibit. An exhibit has to be
15 agreed to. The entry of the items of the exhibit has to be
16 agreed to by a witness. The witness on the stand right now is
17 not agreeing to your entries, is not agreeing that what you are
18 putting there is correct or that it is relevant or has
19 statistical significance or anything else.

20 MR. HEINEMAN: Do you deny that there might some
21 day in this case be another witness to come along --

22 MR. CARR: If you have a witness to support that,
23 show it to the jury when you have the witness to support it.
24 But it's improper to show to the jury an exhibit that isn't

1 marked properly, that doesn't have an appropriate
2 foundation. To this date you have not made a foundation for
3 this exhibit.

4 MR. HEINEMAN: I have not offered the exhibit yet.

5 MR. CARR: Then turn it the other way.

6 MR. HEINEMAN: No. Now, Mr. Carr, you have shown
7 your exhibits --

8 MR. CARR: That isn't true. Anything that anybody
9 objected to as an exhibit the jury did not see it until the
10 Court said it's properly marked and properly entered in
11 evidence. How do I know six months from now you will have or
12 not have or two months from now or two weeks from now have
13 some witness to support this? You don't have it here and we
14 are just wasting our time.

15 MR. HEINEMAN: I will assure you that two weeks from
16 now I will not have a witness here.

17 MR. CARR: Your Honor, I object to any exhibit
18 that is not offered into evidence as being shown to the jury
19 is a waste of time.

20 MR. HEINEMAN: Your Honor, I have no choice but to
21 mark this thing as we go along. The witness has agreed with
22 me, on a limited basis I must admit --

23 THE WITNESS: I have not.

24 MR. CARR: Please --

1 THE WITNESS: Excuse me.

2 MR. HEINEMAN: The witness has agreed with me in
3 certain respects with respect to what I have written down
4 here. And my belief is that the witness has -- when I have
5 written down a no, the witness has agreed with me that the
6 says on its face no, even though the witness may not agree
7 with the study.

8 THE COURT: Well, Mr. Heineman, until this matter
9 is fully constructed, objections to it specifically for any
10 specific use have been made, argued and decided upon by this
11 Court. I am requesting that you turn it out of the jury's
12 view.

13 MR. HEINEMAN: May we approach the bench?

14 THE COURT: All of the matters that have been
15 distributed to the jury or shown to the jury up to this
16 point by Mr. Carr, as you noted, had been done either without
17 objection or after I have ruled on objections. And I think
18 that in this particular case, this matter should be turned
19 around.

20 MR. HEINEMAN: May we approach the bench on this,
21 your Honor?

22 THE COURT: Of course you may. Sure.

23 (The following proceedings were held at the
24 bench out of the hearing of the jury.)

1 MR. HEINEMAN: Your Honor, I am cross examining
2 this witness with respect to particular studies and with
3 respect to what the findings of those studies are. I am
4 writing down on this piece of paper what -- I interpret her
5 answers to questions to be based upon what I am eliciting
6 from her.

7 THE COURT: That is the part that is subject to a
8 lot of dispute. And that is one of the problems at this
9 point in time with exhibiting this to the jury. You have the
10 right to construct this. And I assume you are ultimately
11 going to use it for the basis of some questions of this
12 witness. And I don't think anyone is objecting to that, but
13 until we get to -- to your construction of it rather. But
14 just as I had ruled previously on matters xeroxed and
15 distributed to the jury, I think the logic and spirit and
16 intention of that ruling would very logically apply to a
17 situation such as this. So that I would suggest that you
18 turn it the opposite way so that you and the witness can see
19 it. But the jury at this point in time should not and should
20 not until we have gone through the same procedure as before
21 where it's a completed entity where you have had a position
22 where objections, if any, are to be made, can be made. They
23 have been argued and ruled upon and at which point in time,
24 assuming that the objections are overruled, then, of course,

1 it can be displayed and should be. But at this point in time,
2 I don't think it's proper or it should be. I think the logic
3 and the spirit of the ruling I made before on the xeroxed
4 duplications of documents should apply to this situation.

5 MR. HEINEMAN: Well, the Court -- I am representing
6 to the Court that I will indeed have a witness on who will
7 discuss these very points and substantiate the chart. You
8 are saying I cannot have the jury see this chart until that
9 occurs.

10 MR. CARR: Exactly right. That's my objection to it.

11 THE COURT: What I am ruling at this point is based
12 on what has been done with the studies and transposing to the
13 chart at this point in time, it should not be exhibited to the
14 jury. I am not saying when it can or should be. I am not
15 a mind reader. I am not a prophet. I am not about to say when
16 it should be. I am saying at some point in time after all of
17 these opportunities to have a completed entity, have objections
18 made, if any, and have them considered by the Court -- when
19 that point is reached, that's something else again. It has
20 not been reached at this point. My ruling is limited to saying
21 that at this point in time it should not be exhibited to the
22 jury.

23 MR. HEINEMAN: All right.

24 THE COURT: And I am not about to give an advisory

1 ruling on when I think it should be or when it will be proper
2 to even be argued as to when it should be. So, let's turn
3 it around.

4 MR. HEINEMAN: All right.

5 (The following proceedings were held in the
6 presence and hearing of the jury.)

7 THE COURT: Ladies and gentlemen, we will take a
8 short break at this time. The admonishments I made earlier
9 would apply to all during this point and during this break.
10 Court is in recess.

11 (A short recess was taken.)

12 MR. HEINEMAN: Q. Doctor, I would next like to
13 discuss with you the subject of lung cancer. And I know
14 that you will recall that in some of these or at least one of
15 these tests we have looked at we have seen some lung cancers
16 reported.

17 A. I don't have any scientific opinion that dioxin
18 exposure is associated with any increase in lung cancer, Mr.
19 Heineman.

20 MR. ALBERT SCHOENBECK: Excuse me. I didn't hear
21 what the witness said.

22 MR. HEINEMAN: Q. All right. Let me be sure I
23 have that down.

24 THE COURT: Could you repeat that for Mr. Schoenbeck?

1 MR. ALBERT SCHOENBECK: I didn't hear what you said.
2 I'm sorry.

3 THE WITNESS: I don't have a scientific opinion that
4 dioxin is associated with an increase in lung cancer.

5 THE COURT: Thank you, Doctor.

6 MR. HEINEMAN: Q. Thank you, Doctor. That takes
7 care of that. Doctor, do you believe that there isn't any
8 evidence to support an opinion that dioxin causes lung cancer
9 in humans?

10 A. That's my opinion.

11 Q. Why don't we discuss cardiovascular diseases then. Do
12 you have an opinion with respect to whether dioxin exposure
13 can cause or increase the risk of cardiovascular diseases in
14 humans?

15 A. Yes, I do. I think that dioxin exposure by increasing
16 circulating lipids significantly increases the risk of
17 cardiovascular disease. But my opinion is related to the
18 hyperlipidemia associated with dioxin exposure.

19 Q. Let me ask you this. Do you believe that as a result
20 of dioxin causing hyperlipidemia that that would then result
21 in cardiovascular disease in the persons in whom that
22 hyperlipidemia was caused?

23 A. It may result in certain types of cardiovascular
24 disease, yes.

1 Q. What do you mean by may result in it? Do you have
2 an opinion that if one's blood lipids are raised as a result
3 of exposure to dioxin that, therefore, one is going to -- I
4 don't know what word to use -- one is going to contract a
5 cardiovascular disease as a result of that or develop a
6 cardiovascular disease?

7 A. I believe that increased circulating lipids in the
8 blood increase the risk of certain types of heart disease.
9 Not being a clinical cardiologist, I wouldn't go any further
10 than that. But I do -- it is my understanding based on a
11 large amount of data in clinical and experimental cardiology
12 that increased circulating levels of lipids in the blood are
13 a risk factor for heart disease.

14 Q. But it is equally true, Doctor, that people that
15 have increased blood lipids do not necessarily develop
16 cardiovascular disease as a result.

17 A. I am not sure I understand your question. I can only
18 really repeat what I have said which is that hyperlipidemia
19 or the condition of having increased circulating levels of
20 lipids in the blood is recognized as a risk factor by the
21 American College of Cardiology and the National Heart, Lung
22 and Blood Institute of N.I.H. and others is a significant
23 risk of heart disease.

24 Q. Okay. So that one would not really think then that

1 if one were exposed to dioxin then necessarily the incidence
2 of cardiovascular disease would increase among those that were
3 exposed, is that right?

4 A. Given sufficient time, certain types of cardiovascular
5 disease might well be increased, yes.

6 Q. What would be the types in your understanding that
7 would be increased?

8 A. I think myocardial infarct would be increased.
9 Hypertension would be increased, certain types of hypertension,
10 those that are usually associated with hyperlipidemia; not
11 necessarily essential hypertension or hypertension related
12 to kidney disease. And there may be other types of clinical
13 heart disease. As I said, I am not an expert in clinical
14 cardiology, so I am not certain all the differential
15 diagnoses of heart disease which clinicians have indeed
16 associated with hyperlipidemia. But those would be the
17 ones that I would associate with dioxin exposure.

18 Q. All right. Why don't we look at some of these
19 studies, Doctor, and see if they demonstrated an increase in
20 cardiovascular diseases.

21 A. Well, it would be important to know if they are
22 looking at the general category of cardiovascular diseases
23 which might include a whole range of disease not associated
24 with hyperlipidemia or whether they are focused on those

1 which I have just stated it is my scientific opinion would
2 be associated with dioxin exposure. It's an entire category.
3 I don't know how papers will address that question or
4 whether one would expect to pick up the entire category of
5 cardiovascular disease from these papers.

6 Q. But if one were looking, for example, if one were
7 looking for mortality as a result of cardiovascular disease,
8 one might expect that myocardial infarctions or heart attacks
9 would fall into that group and cause such increased mortality,
10 wouldn't they?

11 A. They would be one cause.

12 Q. That might be one.

13 A. Now, I want to state I am not talking about the
14 general category of cardiovascular disease despite what you
15 are writing.

16 Q. All right.

17 A. So, if we are going to go through these papers for
18 the entire category of cardiovascular disease, I am not
19 going to be able to give you answers that are relevant. I
20 think you are switching what I am saying.

21 Q. All right. Tell me again then so I can be sure
22 which cardiovascular diseases that you believe might be
23 associated with hyperlipidemia.

24 A. As I said I am not an expert in clinical cardiology and

1 I cannot give you a complete or comprehensive list. But I do
2 know that it is the case that not all cardiovascular diseases
3 are associated with hyperlipidemia. And that's why I object
4 to using the general category of cardiovascular disease not
5 differentiated in these papers.

6 Q. Okay. So I take it you are familiar with these papers
7 and the manner in which they discuss cardiovascular disease?

8 A. Mr. Heineman, as I told you, I have read most of these
9 papers.

10 Q. So the answer to my question is, yes, you are familiar?

11 A. Yes. And I do not believe they are relevant to what
12 I have described to be what I consider in my scientific opinion
13 to be that spectrum of cardiovascular disease which is
14 relevantly associated with dioxin exposure.

15 Q. In other words, from your understanding of these
16 papers, they relate to cardiovascular diseases in general?

17 A. That's correct.

18 Q. Of the entire spectrum, whether that be high blood
19 pressure, arteriosclerosis or atherosclerosis, myocardial
20 infarction?

21 A. That's right.

22 Q. Whatever it might be.

23 A. That's right.

24 Q. So whatever conclusions these papers reach or whatever

1 they demonstrate, whatever they may demonstrate with respect
2 to the occurrence of these cardiovascular diseases in these
3 incidents, then that covers a broader spectrum than you are
4 talking about?

5 A. That's correct.

6 Q. Now, tell me again, please, because I am not sure I
7 understand, what is the spectrum that you believe may be
8 caused by hyperlipidemia?

9 A. Among others -- and once again I would preface my
10 answer by saying I am not a clinical cardiologist, so I
11 do not know all the different clinical categories of heart
12 disease. I would expect them to be those associated with
13 increased circulating levels of lipids or hyperlipidemia.
14 Among those I would include certain types of hypertension and
15 heart attack. There may, of course, be others.

16 Q. So that if, Doctor, these papers, one or more of
17 these papers were to demonstrate fewer than expected incidents
18 of cardiovascular diseases over the entire spectrum, it's
19 your belief that that would be irrelevant to your determination
20 with respect to the two types of cardiovascular diseases that
21 you know about?

22 A. That's right.

23 Q. I am just trying to get straight in my own mind what
24 you are saying here, Doctor. Let me just take an example,

1 Doctor, to make sure I understand you, all right? Just by
2 way of explanation, Doctor, look for a moment, if you would,
3 at the Cook study, which is the incident involving 61 males in
4 the 1964 chloracne incident. I think you will remember that
5 Cook states that there were a total of four deaths. One
6 of these deaths was due to cardiovascular disease. And 3.8
7 were expected. Now, why is it then that that would not be
8 relevant with respect to whether or not exposure to 2,3,7,8
9 contaminated material would have an effect on cardiovascular
10 disease?

11 A. I have already said, Mr. Heineman, that I don't
12 consider that in my scientific opinion to be the question.
13 Because I don't consider the general category of cardiovascular
14 disease to be increased in incidence by exposure to dioxin.
15 Dioxin is a very specific chemical. We have spent a lot of
16 time talking about that. It is my scientific opinion that it
17 doesn't enter the body like a bludgeon and attack systems in
18 a totally non-specific and unpredictable fashion. I think its
19 actions are very defined and follow certain biochemical and
20 biologic principles. And that's why in all of this I have tried
21 to make very specific what it is I am talking about. And when
22 these papers do not make it that specific, then I don't consider
23 that they have given answers relevant to what we are talking
24 about here. Because I am trying to limit this discussion of

1 cardiovascular disease despite your re-opening it back to the
2 general category which is what Dr. Cook reports here.

3 Q. So, Doctor -- which is what Dr. Cook reports here?

4 A. The general category of cardiovascular disease
5 which is non-differentiated.

6 Q. So, Dr. Cook looks for any type of cardiovascular
7 disease?

8 A. No, all types. That's quite different than looking
9 for any type.

10 Q. Okay. He looks for all types --

11 A. And puts them all together.

12 Q. -- of cardiovascular disease. All right. And he
13 finds one death and that death he attributes to -- well, I
14 am not sure he attributes that to be fair to him. He says,
15 "The case No. 4 of the four total deaths in the study died
16 in 1976, seven years after his retirement, of hypertensive
17 heart disease." Now, I don't know whether he is saying he
18 died of hypertensive heart disease or he retired because of
19 hypertensive heart disease. I think he means, because of
20 the comma after the retirement, that he died of hypertensive
21 heart disease.

22 A. I think that's right.

23 Q. Okay.

24 A. Now, what kind of hypertensive heart disease that is is

1 not further described, nor is there a relative risk estimate
2 made of hypertensive heart disease. But rather, the 3.8
3 he lists here as the expected is for all types of cardiovascular
4 disease.

5 Q. All right. So, we don't know how many one would
6 expect of hypertensive heart disease?

7 A. Nor do we know the type of hypertensive heart disease.
8 As I stated earlier, I do not -- it is not my opinion based
9 on the scientific evidence that dioxin exposure would be
10 associated with essential hypertension or with nephritis
11 associated hypertension. I don't think this paper can be
12 listed as answering the question.

13 Q. All right. So, if he is saying that the -- that he
14 had one cardiovascular death, which he is saying, and that
15 that was due to some sort of hypertension, that doesn't answer
16 the question that you have with respect to whether that
17 particular type of hypertension would be the kind that might
18 be associated with dioxin exposure?

19 A. It is not relevant to my scientific opinion which
20 I have tried to make very specific and limited in the area
21 of cardiovascular disease.

22 Q. Which is that dioxin causes blood lipids to go up.
23 And you are listing two types of cardiovascular incidents
24 which might be attributable to elevated blood lipids.

1 A. That's right. And there may be others which clinicians
2 have so associated.

3 Q. Now, I thought you said that one of those types
4 was hypertension.

5 A. That's right. But I also stated, I think three times --
6 I will state it again -- that there are several types of
7 hypertension. And I know of at least two other types of
8 hypertension that I would not expect to be associated with
9 dioxin exposure.

10 Q. All right.

11 A. It is unfortunately a complicated diagnosis as is
12 most disease in this country.

13 Q. All right. I think I am getting what you are saying
14 now. If you would look at the Thiess study, that might be
15 illustrative. Now, in Thiess if you look at Table II on
16 page 183, he links together all cardiovascular diseases,
17 doesn't he?

18 A. That's right.

19 Q. And he finds seven observed --

20 MR. CARR: Your Honor, I object to it unless the
21 witness has first said that it's relevant to something. She
22 has already said at least ten times in the last thirty minutes
23 that these studies aren't relevant because they are not
24 specific as to the kind of cardiovascular disease. And

1 Mr. Heineman persists in asking the question that the witness
2 has said the articles don't address. I would ask that he
3 first establish from the witness that the article addresses
4 the problem that she sees as the problem. If she says it
5 does address it, I think it would be proper for him to continue
6 cross examination. If she says it doesn't establish it, I
7 think he must first establish that it indeed does address it.
8 Otherwise, we will never finish with the cross examination.
9 And I object to this kind of cross examination.

10 MR. HEINEMAN: I am cross examining this witness.
11 I am trying to understand exactly what her position is.

12 THE COURT: I think she has stated her position.
13 I think the objection is well taken. It's sustained. Ask
14 the preparatory question, please.

15 MR. HEINEMAN: I don't understand what question I
16 am being asked to ask.

17 MR. CARR: I am objecting to the question you are
18 asking because the witness has said this article and others
19 are not specific as to the cause of these cardiovascular
20 deaths. And, therefore, the fact that deaths occur or don't
21 occur can't be answered by her insofar as it relates to
22 the subject of this lawsuit, that is TCDD. Did TCDD cause
23 this death or not? She says that this article doesn't
24 reveal it because it is not specific enough. And, therefore,

1 I object to your questioning the witness about things that
2 are irrelevant to this case. It may be a fine question, but
3 it's not relevant to what this jury is being asked to decide.

4 MR. HEINEMAN: Your Honor, I object to the
5 soliloquy. Mr. Carr --

6 THE COURT: Now, wait a second. I think it was in
7 response to your request to clarify what the objection was.
8 I think it was so clarified. I think you have the structure
9 within which to ask the question to establish relevancy, if
10 any, in the scientific opinion of this witness. And I think
11 that that is the proper question that should be asked at this
12 point in time in the cross examination.

13 MR. HEINEMAN: I will be happy to.

14 Q. Dr. Silbergeld, Dr. Thies here reports the
15 expected deaths --

16 MR. CARR: Your Honor, I object unless the -- counsel
17 has deliberately ignored what the Court has ruled --

18 MR. HEINEMAN: I am trying, your Honor --

19 MR. CARR: The objection was that he may not refer
20 to what it said until he has first established that it is
21 relevant.

22 THE COURT: Gentlemen, could you approach the bench,
23 please?

24 (The following proceedings were held at the

1 bench out of the hearing of the jury.)

2 THE COURT: What I am getting at is she has very
3 carefully and definitively structured areas of relevancy and
4 points of relevancy as to these things when they refer to
5 cardiovascular activity as a whole and other possible
6 ways in which they can refer to anything in the study about
7 cardiovascular activity.

8 And what the objection was aimed to and the basis
9 upon which I sustained it was that given the structure
10 that this witness has laid out in response to your questions,
11 you first have to establish as far as the particular study
12 the relevancy of it and not -- you know, what you are doing
13 is basically repeating findings which may or may not be
14 established to be relevant. And what she has structured her
15 responses about is the structure of the study per se, the
16 objective of the finding of the study and the way that the
17 structure has been -- the study has been structured in order
18 to accommodate the question that the study is designed to
19 answer and not -- in other words, you are putting the cart
20 before the horse. I think you have to establish the relevancy
21 within those confines before you start discussing the findings
22 of the study.

23 MR. HEINEMAN: Your Honor, she is not my witness.
24 She has expressed her opinions and I am cross examining her.

1 I am testing her opinions. Now, I don't believe that Mr.
2 Carr has the right -- he has the right to do anything he wants,
3 I suppose. But I think that I have the right to cross examine
4 this witness in order to test her opinions. Now, one of
5 the things I want her -- the Court just asked me to find
6 out whether or not she, in fact, is stating that this finding
7 is irrelevant and that is what I am trying to do.

8 THE COURT: Well, the way you started the question
9 did not indicate that you were. Because it started off as
10 a repetition of the original question which was objected to.
11 Perhaps if that is where you intend to go in your own mind,
12 perhaps what you need to do is just rephrase the question.
13 Because I think this preparatory question should be aimed at
14 the question of relevancy of this particular study.

15 MR. HEINEMAN: What I want to ask her is, is it
16 irrelevant that the finding of observed of seven is less
17 than --

18 MR. CARR: He wants to read what I am objecting to.
19 But before he can read what I am objecting to, he has to first
20 establish from the witness that it is relevant without
21 repeating it so the jury can hear it. What he is trying to
22 do is bring in front of the jury what this article says when
23 he may not do it on this point because it is not relevant.
24 You can have 30,000 causes of death and not one be relevant.

1 MR. HEINEMAN: This isn't direct examination. This
2 isn't my witness. I am cross examining her. I am entitled
3 to test her as to whether or not it's relevant.

4 MR. CARR: On relevant points.

5 MR. HEINEMAN: No, I am entitled to test her on her
6 opinion. She has offered the opinion that it's not relevant.
7 That isn't a legal question. She has offered the opinion --

8 THE COURT: No, no, no. You haven't gotten to
9 that point. You haven't asked her about the relevancy of
10 this test, either the objective or the structure or the
11 findings. You haven't gotten to that point. That's the
12 problem.

13 MR. CARR: You are getting the cart before the
14 horse.

15 THE COURT: That's the problem. After a
16 preparatory question concerning relevancy, the question you
17 just posed may very well be appropriate. But the point is
18 you have the right to cross examine and cross examination
19 is liberally construed. You don't have a right to question on
20 the things that are not relevant to the points of issue.
21 The relevancy is a threshold question. And I suggest you
22 rephrase it in terms of relevancy in this study per se.
23 The components upon which the relevancy can be judged in this
24 study and all the studies have been repeatedly delineated by

1 this witness on the point being examined, the structuring of
2 it, the adequacy of the findings, the completeness of the
3 findings, the comprehensiveness of them. There is more than
4 an adequate basis and indication where a preparatory question
5 is relevancy. Because even cross examination is bound by some
6 rules of relevancy and materiality.

7 MR. HEINEMAN: That's where you and I are passing
8 each other in the night, Judge. Because we are not talking
9 about the legal relevancy to the issues in the lawsuit.
10 This witness says that findings with respect to cardiovascular
11 disease are not relevant to her opinion with respect to
12 whether or not dioxin causes certain types of cardiovascular
13 disease. And that is what I want to test.

14 THE COURT: You have jumped about three steps.
15 Because any time she has made that assertion, she has done
16 it on the basis of a particular study, objective structure,
17 completeness, comprehensiveness and scope of conclusions.
18 You are jumping a couple steps is what I am saying. And
19 I think that is what Mr. Carr's objection is.

20 MR. CARR: Yes, indeed.

21 MR. HEINEMAN: What he is saying is if she says
22 this finding is not relevant to her conclusion that I can't
23 cross examine her on that.

24 MR. CARR: No, no. You can, but you can't read that

1 first. That is what you end up with. You have to first
2 establish --

3 MR. HEINEMAN: Why not? Why can't I read it first?

4 THE COURT: Again, you are jumping over preliminary
5 questions of examining this study as a whole and the study as
6 a study before you even get to findings. That's what I am
7 saying. This whole point of relevancy is based on matters
8 preparatory to the findings which you are going into first.
9 You are switching the cart and the horse. Now, what I am
10 telling you is to rephrase it in terms of the relevancy of the
11 study as the study, the components of the study.

12 MR. HEINEMAN: I am not catching you, Judge.

13 THE COURT: I don't think you are.

14 MR. HEINEMAN: I am not understanding what I am
15 being asked to do.

16 THE COURT: In other words, what this witness is saying
17 is there can be any numbers on there within a given category
18 within a given study. The relevancy of those numbers to anything
19 depends on the study, the nature of the study in particular,
20 the structure, your question to be answered, all of those
21 various matters, in other words, the relevancy.

22 And what I think Mr. Carr is objecting to is if
23 you want to cross examine on relevancy, you have to cross
24 examine on relevancy before you can cross examine on the

1 substance of what so far has not been established to be
2 relevant. Is that --

3 MR. CARR: Yes, your Honor.

4 THE COURT: I am taking liberties with it, but that
5 is basically what you are saying, I think.

6 MR. CARR: Yes, he is jumping the cart before he
7 has established the horse.

8 THE COURT: And after hearing argument from both of
9 you gentlemen, I agree with Mr. Carr's position and that is
10 what I am asking you to explore and establish.

11 MR. HEINEMAN: Can't I ask her if this is what the
12 figures say and then I can ask her is that relevant? And
13 if it's not, why not.

14 MR. CARR: She can read it without you saying what
15 it says.

16 MR. HEINEMAN: What difference does it make?

17 MR. CARR: The difference is you are getting it to
18 the jury.

19 MR. HEINEMAN: So what?

20 THE COURT: I think you are getting the cart before
21 the horse because the cart is the figures. In other words,
22 you have got to establish the relevancy of the substantive
23 matter and not introducing the substantive matter in order
24 to establish its relevancy to get away from the scientific

1 jargon.

2 MR. HEINEMAN: That would be absolutely right in
3 my view if we were talking about illegal relevancy in a
4 lawsuit. But that isn't the relevancy that she is talking
5 about.

6 THE COURT: We are -- the relevancy that she is
7 talking about within the context of the rules of evidence
8 translates into, for our situation, an evidentiary relevancy.
9 They happen to be coincided.

10 MR. CARR: What I am saying is you may not cross
11 examine on a point that is not important to this case.
12 You can read 10,000 articles if you want to about
13 cardiovascular disease and unless this witness can agree that
14 yes, those are caused by TCDD in her opinion or that the
15 articles are even capable of showing what TCDD caused, you
16 cannot get the substance of the article in until you first
17 establish --

18 MR. HEINEMAN: Can I ask her if it's capable of
19 causing it?

20 THE COURT: You lost me. Is what capable of causing
21 what?

22 MR. HEINEMAN: I am trying to work back through
23 this. If she tells me that this study is not capable of
24 demonstrating what her opinion is with respect to causation

1 on cardiovascular disease, am I entitled to find out why?

2 THE COURT: Of course.

3 MR. HEINEMAN: Can I get into testing her relevancy
4 by talking about these numbers?

5 THE COURT: Not yet. That's the whole point.

6 MR. HEINEMAN: But I can after I ask her whether
7 or not it's relevant.

8 THE COURT: You may be able to at some point. At
9 this point you cannot. That's what the objection has been
10 made to and that's what I sustained. Now again, unfortunately,
11 not being able to prophesy, I am not about to rule at which
12 point you can. But at this point, you cannot. The objection
13 is well taken.

14 MR. HEINEMAN: I have got to say for the record,
15 your Honor, I think the Court is restricting my scope of cross
16 examination. I think I am entitled to test this woman's
17 opinions. And I will abide by the Court's ruling obviously.

18 THE COURT: For the record, I am not and in no way
19 intend to restrict the scope of examination. I think that I
20 am confining your methodology approach and sequence of cross
21 examination to proper evidentiary rules. Okay.

22 (The following proceedings were held in the
23 presence and hearing of the jury.)

24 MR. HEINEMAN: Can I take a moment, your Honor?

1 THE COURT: Sure, go ahead.

2 MR. HEINEMAN: Q. Let's look at Table II on page 183
3 in which there is a general listing of cardiovascular diseases,
4 correct?

5 A. That's right.

6 Q. Without differentiating between cardiovascular
7 diseases.

8 A. That's right.

9 Q. Is a listing of observed versus expected occurrences
10 of cardiovascular disease relevant in your view to your opinion
11 with respect to whether dioxin can cause cardiovascular
12 disease?

13 A. I think I have already answered that question by
14 saying no. Unless the disease is more clearly described, it's
15 not relevant. Because my opinion, as I have stated before,
16 is related to specific cardiovascular diseases and not to the
17 general category of cardiovascular diseases. That's why I
18 said at the outset, Mr. Heineman, to the best of my recollection
19 of all of these papers, none of them are relevant because
20 none of them treat the specific cardiovascular diseases
21 in a way in which the reader can see those specific cardiovascular
22 diseases which would be likely on the basis of primarily
23 experimental evidence and clinical evidence of hyperlipidemia
24 to have an association with dioxin exposure. So, the answer is

1 no, I don't think this is relevant. Nor do I think this
2 body of literature before me is relevant.

3 Q. But, Doctor, if a study shows fewer observed than
4 expected in a population of cardiovascular disease, which
5 this one does --

6 MR. CARR: Now, your Honor, counsel did exactly
7 what he should not have done and he knows it. And I object --

8 MR. HEINEMAN: I am trying to test her theory here.
9 I thought this was exactly what the Court --

10 THE COURT: Objection is sustained as to that last
11 remark only.

12 MR. CARR: That's exactly right.

13 MR. HEINEMAN: As to that last remark.

14 THE COURT: Yes. The remark --

15 MR. HEINEMAN: You mean the which it does?

16 THE COURT: Which it does, yes.

17 MR. HEINEMAN: Would you read what I said before
18 the which it does, please?

19 (At this time, the Court Reporter read back
20 the following question: Q. But, Doctor, if a
21 study shows fewer observed than expected in a
22 population of cardiovascular disease --)

23 MR. HEINEMAN: Q. If a study shows fewer cardiovascular
24 diseases observed than expected in a population, why does that

1 not then demonstrate that as to that study their not finding
2 that whatever these people were exposed to is not associated
3 statistically with cardiovascular disease?

4 A. Let me see if I can explain. This is going to be
5 limited because I am going to try and do it with my hands.
6 Suppose in one population you have five cases of cardiovascular
7 disease. And in another population you have three. Now, you
8 would say this population does not have more cardiovascular
9 disease than this one obviously, three as opposed to five. But
10 suppose out of this five there was no cardiovascular disease
11 associated with hypertension. And in this population all
12 three were hypertensive heart disease. That's my point.
13 When you deal with a general category, it is not relevant to
14 what you are really concerned about specific subcategories
15 of disease. Now, I hope that is clear. And I just used
16 five and three because I wanted to use my two hands.

17 Q. Now, but just hypertension is not enough, is it, as
18 we just learned from the Cook study?

19 A. No.

20 Q. It's got to be a specific kind of hypertension in your
21 view.

22 A. I'm sorry, Mr. Heineman. I will do it again. In
23 five cases of total cardiovascular diseases in one population,
24 three in the other, this is not greater than that. In this

1 population, they are all artherosclerosis, and in this -- or
2 they are a mixture, but none of them are hyperlipidemia
3 associated hypertension, whereas in this population they all
4 are. Then the picture changes considerably. That's why when
5 you are dealing with, which is my scientific opinion with
6 cardiovascular disease, a certain range of cardiovascular
7 diseases, but not all of them, you have to specify what you
8 are looking at. And it is my scientific opinion that these
9 papers do not do that. And that is why I do not think they
10 are relevant to my scientific opinion about the specific
11 cardiovascular diseases which I think are associated with
12 dioxin exposure. Now, we can do this for every single one of
13 these papers.

14 Q. If on the other hand, one had the opinion that more
15 cardiovascular diseases could be caused by dioxin than just the
16 two types that you believe are caused, then indeed these might
17 become much more relevant, wouldn't they, in dealing with all
18 cardiovascular diseases?

19 A. If I thought dioxin caused suicide, then a finding of
20 suicide would be relevant. Absolutely.

21 Q. So, the answer to that is yes?

22 A. I can't answer that question, Mr. Heineman. It
23 doesn't make any sense to me scientifically.

24 Q. Well, you can --

1 A. I don't think that dioxin is associated with every
2 disease under the sun. And I tried to make that clear in
3 answering your questions today. So, if you are trying to
4 turn around and say if you thought dioxin was associated with
5 every disease under the sun, then wouldn't a look at all the
6 diseases under the sun be relevant, then, of course, it would
7 be. But I wouldn't engage in such a fruitless task.

8 Q. Because you don't believe anything other than a specific
9 type of hypertension and myocardial infarction, because of
10 their relationship to hyperlipidemia, might be affected by
11 dioxin exposure?

12 A. And possibly other cardiovascular diseases which are
13 also linked to hyperlipidemia, which as I stated to you, I
14 am not aware of not being a clinical cardiologist. I don't
15 mean to limit the universe to those types. Those are the
16 ones I know are linked to hyperlipidemia. There may be others.

17 Q. And among all the cardiovascular diseases discussed by these
18 papers, some of those others might appear.

19 A. They may or they may not. I have no way of knowing.

20 Q. And, therefore, if these others that you are not
21 specifying are included in these tests, in these studies,
22 then the findings of these papers might indeed be relevant,
23 wouldn't they?

24 A. If these cardiovascular diseases were all

1 hyperlipidemia associated diseases, of course. But the point
2 is that they are not so specified. But there is a range
3 of hypotheticals that would make all of these papers very
4 different.

5 Q. Let's look at three other types of cancers, Doctor.
6 One I am talking about first is -- I will lump the three of them
7 together -- would be myelomas, bone cancers and hematopoietic
8 cancers. Do you have an opinion as to whether exposure to
9 dioxin can cause myeloma in humans?

10 A. No, I do not.

11 Q. Is there any evidence that you are aware of that
12 exposure to dioxin causes myeloma in humans?

13 A. I don't know of any evidence.

14 Q. How about bone cancer, Doctor?

15 A. I don't know of any evidence in humans.

16 Q. So, you don't have an opinion as to whether or not
17 dioxin would have any relationship with bone cancer in
18 humans?

19 A. No, not unless -- no. Not unless there is some kind
20 of -- let me preface all of these by saying unless there is
21 some kind of association between these cancers that in my
22 scientific opinion are linked to dioxin exposure such as the
23 soft tissue sarcomas, unless there is some ideologic or clinical
24 reason to assume a connection between those. My opinion is

1 that there is no evidence. There may be information which
2 clinical oncologists hold to be true that those cancers are
3 somehow linked. And in that case I would assume the
4 statistically significant linkage with one of them might cause
5 an association with the other one. But I am unaware of such
6 linkage. So, my answer is that I don't have an opinion they
7 are caused.

8 Q. All right. How about hematopoietic?

9 A. Same answer. I don't have a scientific opinion that
10 they are associated with dioxin exposure.

11 Q. Would you define hematopoietic cancers?

12 A. I presume, again not being a clinical pathologist,
13 that those would be tumors in the blood forming organs of the
14 human body.

15 Q. Doctor, we have not seen -- let me start over again
16 with that. Is there any evidence to establish that dioxin
17 increases human mortality in general?

18 A. I think insofar as dioxin increases the rate of certain
19 types of cancer which can be fatal and insofar as dioxin
20 produces an incidence of porphyria which in some cases can
21 lead to fatality, though the linkage between porphyria and
22 death is not clear even in the inherited diseases, and insofar
23 as dioxin can cause lethal birth defects and insofar as dioxin
24 can cause an increased risk of those cardiovascular diseases

1 we have been talking about, then yes, I think dioxin can cause
2 an increase in mortality. However, I want to preface this once
3 again that if we take the lump figure known as mortality from
4 all causes which is maybe done in these studies. We won't
5 be able to answer that question with that number. The way we
6 answer that question is the way in which we have been proceeding
7 which is to look at specific causes of death. Because just
8 once again you can have five people dead and if you don't look
9 at what those causes are, it doesn't help you understand whether
10 specific causes of death are increased, decreased or left
11 alone by a specific intervention, in this case, dioxin exposure.

12 Q. So, indeed in examining the tables in these studies,
13 you do need to look at the individual causes of death.

14 A. That is exactly what we have been doing.

15 Q. Including the individual types of cancer as well as
16 the total number of malignant neoplasms or the total number
17 of cancers. We need to look at all of those in order to
18 determine what the cause of death is in each instance.

19 A. That's right. But you also have to keep in mind as
20 we have been trying to do whether or not as you go down --
21 there are two sides to this. As you get more and more refined
22 in your diagnosis of the cause of death, particularly if that
23 cause becomes a rare cause of death normally, then you run
24 into the problems of the study being able to pick up an

1 increased rate of that cause of death. That's why, once again
2 I state, that when you are looking at relatively rare causes of
3 death, the case control or case reference study is the most
4 powerful technique.

5 Q. Despite its other infirmities?

6 A. That's right. Despite its other limitations. And
7 all epidemiologic studies certainly have limitations.

8 Q. Because the most that these studies will tell you is
9 associations, numerical associations.

10 A. No, that's not the weakness. The most any study,
11 whether it's a study that I can do with mice in a laboratory
12 or we do trying to find out what happened to dead Swedish
13 foresters, the most any study can do is build associations.
14 The weakness of epidemiology is more than that.

15 Q. Tell me what that weakness is.

16 MR. CARR: Your Honor, I think this is repetition.
17 The witness has said this probably 30 times in the last
18 several days she has been on the stand and I would object to
19 the repetition.

20 THE COURT: Overruled. I think it's in a different
21 context with the approach that's been taken.

22 THE WITNESS: I think the limitations of epidemiology
23 are that we are not conducting experiments. What we are
24 getting is what nature or life hands us. And we are trying to

1 understand what has happened.

2 Now, since no one is conducting an experiment with
3 dioxin or these phenoxia acetic acids or chlorophenols, then
4 you are dealing in all cases after the fact. What you have
5 got is that something happened. The plant exploded or there
6 was a leakage of chlorophenols inside BASF or at Sturgeon
7 or wherever. And you are dealing after the fact so you are
8 forced to reconstruct the exposure. That becomes very
9 difficult as we have seen. Nobody here has quantitative
10 numbers on exposure. We have got wide ranges and inferences.
11 But no one has written down, "We measured one microgram per
12 cubic meter TCDD in the air in Nitro, West Virginia, ten
13 minutes after that explosion. No one has that kind of
14 precision.

15 Worse than that or the other factor in epidemiology
16 is that we don't know everything else that happened to these
17 people before and after the particular exposure we are looking
18 at. Now, that goes for cohort studies, case control, anything.
19 We will never, ever know to complete satisfaction everything
20 what went on in that person's life. Suppose they went out
21 one day and ate five boxes of Duncan Hines pancake mix and
22 they got the ones that had the very highest levels of
23 ethylene dibromide. Now, on a quantitative basis, their risk
24 of cancer from that one episode, that one binge, might be much

1 higher than anything else they ever did in their life. They
2 didn't recall it. Nobody in their family saw them do it. We
3 will never know that they did it. The only way you get
4 around that nightmare of epidemiology of some hidden series
5 of events is through the use of numbers and by eliminating
6 the possibility that this kind of thing could have happened
7 in large numbers of people. That's the major problem of
8 epidemiology.

9 Q. And the more numbers you look at, the more sure you
10 can be.

11 A. The more numbers you look at, the more likely it is
12 that strange, bizarre things didn't happen to all the people.
13 That's all you can say.

14 Q. So, as I understand it, in connection with studies,
15 when you are looking at total number of deaths, that mortality
16 can be ascribed to a lot of different things which would
17 affect the numbers from which the calculations are made in
18 the study.

19 A. That's right. In many of these papers, they report
20 automobile accidents, suicides, house fires, every -- of course,
21 every single cause of death that they can find out.

22 Q. Doesn't the study have to take into account all the
23 kinds of death in order to draw any conclusions that would be --
24 that you could relate to a general population in which all

1 those other kinds of deaths could occur as well?

2 A. No.

3 Q. Let me ask you this, Doctor. Let's suppose that you
4 are studying an -- you are doing an epidemiological study on
5 a group. And that group has been exposed to 2,4,5-T in the
6 working environment. And you are looking at whether or not
7 that group has an increased rate of overall mortality as a
8 result of that. And you are going to compare that group
9 to a normal -- a control group, a normal group.

10 A. I wouldn't do that.

11 Q. You wouldn't compare it to a control group?

12 A. I wouldn't look at overall mortality for the reasons
13 we have been talking about.

14 Q. So that overall --

15 A. I think the reasons these papers report overall
16 mortality is really to account for everybody in the study.
17 When the Dow study is looking at 61 people and there are 14
18 of them who are dead, for purposes of appropriate scientific
19 completeness, they let you know how every single one of them
20 died. But the overall mortality rate is not what they are
21 interested in.

22 Q. But don't these people in these studies give a
23 standard mortality ratio or attribute a statistical significance
24 to those overall deaths?

1 A. The standard mortality ratio is for specific causes of
2 death. And it's based on materials like this, Mr. Heineman.
3 That is a misunderstanding of the term.

4 Q. All right. Well, let me take the standard mortality
5 ratio out of the question then. Don't some of these studies
6 make an attribution of statistical significance to the total
7 number of deaths?

8 A. They may or may not. But that is not relevant in
9 my opinion to the questions we are discussing in this case.
10 I don't consider it at all relevant to know how many people in
11 these groups committed suicide unless there is some reason
12 given or some explanation of the attendant psychiatric history.
13 Nor do I consider it relevant how many of them died in house
14 fires, hit by cars.

15 Q. But, again --

16 A. Whether the authors do it or not is not relevant to
17 my opinion.

18 Q. So, in your opinion, it's irrelevant and needn't have
19 been done in these studies if the author attributes a
20 statistical significance to the total number of deaths in an
21 exposed population as opposed to controls?

22 A. It adds nothing to the topic under discussion which
23 is whether or not dioxin exposure causes an increase in
24 mortality.

1 Q. All right. Now, let me get back again to the question
2 I was asking you before. If indeed you are taking an
3 exposed population and an unexposed population and you are
4 comparing their causes of death, because these unrelated
5 causes of death happen to everybody, automobile accidents,
6 falling out of a tree, getting hit by a bus, whatever, don't
7 you need to include those in your overall mortality so you
8 can see whether indeed the exposed group mortality is
9 different than the control mortality?

10 A. No, because that is not the question you are asking,
11 Mr. Heineman. I will try once again. What you are asking
12 is whether there is a change in mortality due to specific
13 causes.

14 Q. So, again, instead of looking at the overall deaths,
15 you have to look at the specific things that have caused
16 death.

17 A. That's right.

18 Q. And as I understand your testimony, that is not
19 described in these studies that we have been going through.

20 A. No, not at all.

21 Q. That's right, that's wrong. I take that back. Let
22 me start over again. In these studies, the examination of
23 overall mortality includes more than those specific causes of
24 death?

1 A. Yes, it does. Except for the case control studies
2 which start with the cause of death. They are not picking up
3 all the people in Sweden who died between the years of 1978 and
4 1982 and then going back to find out what was going on with
5 them. They are picking up people who died because of specific
6 causes.

7 Q. And then going back and asking questions of their --

8 A. That's right.

9 Q. -- spouses, of their employers in trying to determine
10 what common experiences they may or may not have had.

11 A. That's correct.

12 Q. Doctor, as I understand -- one moment. May we approach
13 the bench?

14 THE COURT: Sure.

15 (A discussion was held at the bench out of the
16 hearing of the jury and off the record.)

17 MR. HEINEMAN: Q. Would you like a glass of water?

18 A. I would. Thank you, Mr. Heineman.

19 Q. My pregnant partner over here is drinking up all my
20 water.

21 A. Tell her to be careful. It's not good for her.

22 Q. Doctor, you have the opinion, as I recall, that
23 exposure to 2,3,7,8 TCDD can affect the immune system, do you
24 not?

1 A. I do.

2 Q. All right. Now, are there other factors that can
3 affect the immune system as well as dioxin?

4 A. Of course.

5 Q. Okay. Would you enumerate some of those to the jury?

6 A. Other chemicals, viruses, bacteria, genetic
7 predispositions, nutrition, a range of factors.

8 Q. For example, if you had a virus or you had a cold
9 or you had some kind of illness that affected your immune
10 function and you had an immune function test at the time you
11 had that cold or virus, would that test result be abnormal?

12 A. It would depend on what was being measured. Because
13 it's not strictly speaking correct to say a cold affects the
14 immune system. A cold engages the immune system. The immune
15 system is what responds to a cold.

16 Q. There are certain types of viruses as I understand it
17 though which can adversely affect the immune system.

18 A. That's right.

19 Q. How do those viruses manifest themselves in the human
20 being?

21 A. There is a range of their manifestations. Some of
22 them may cause fevers, tiredness. Some of them may even cause
23 cancer.

24 Q. And those types of viruses may also affect the immune

1 system adversely so that it cannot fight them as well as it
2 would other viruses, is that right?

3 A. I am not sure I understand your question. Viruses
4 and other agents engage the immune system. Our immune system
5 is the body's defense against those substances. They don't
6 attack the immune system in the same way, for example, as
7 benzene depresses white cell count. That's what I would call
8 an attack on the immune system. To engage the immune system,
9 to involve it really in its proper life saving function which
10 is defending the body is slightly different. And depending
11 on the sensitivity and specificity of the test, one can
12 determine whether you are dealing with an exposure or condition
13 which is causing immunosuppression, that is decreased function
14 of the immune system, or whether you are dealing with a
15 condition in which the immune system is being attacked by
16 an immuno-reactive agent like a virus.

17 Q. All right. When I am discussing with you about an
18 adverse effect on the immune system, I am talking about the
19 former situation; not just where the immune system is reacting,
20 but where something has an adverse effect on the ability of
21 the immune system to function. And my question was, what
22 kind of things other than 2,3,7,8 can have that effect?

23 A. And I answered that question.

24 Q. And I thought one of those things you named was

1 viruses.

2 A. Well, I was thinking of the general proposition of
3 how is a person's immune system functioning. And one thing
4 which would reduce the functioning of the immune system is
5 that if it were engaged in dealing with an infection, then
6 its ability to handle another infection would be reduced.
7 That's why I included that in my answer. But it's not
8 quite exactly the same thing. And I think -- I am not trying
9 to split hairs, but the important thing is that when you go
10 out and test, you can make these distinctions.

11 Q. So, that you can determine in a test whether or not
12 an immune system is actually engaged in fighting something
13 off or whether it's being adversely affected in some way.

14 A. To a very great extent you can.

15 Q. Okay. Now, are these pretty ticklish tests?

16 A. I don't know. It depends who does them.

17 Q. I suppose it does. Do you know whether or not these
18 tests are subject to certain frailties, in other words, they
19 are very hard to do or very tricky to do or anything like
20 that?

21 A. I am not a clinical immunologist. I don't know. I
22 know that people do basic research in immunology quite
23 successfully, so I presume that they are doable. People repeat
24 each other's experiments. There are ten or twenty journals in

1 immunology. So, it's a big field. It can't be too intricate
2 or too impossible.

3 Q. All right. So that a person knowledgeable in doing
4 these kinds of tests can make determinations based upon
5 those test results of what is going on in the immune system
6 by reading those blood tests?

7 A. To a certain extent they can.

8 Q. What do you mean by to a certain extent? What does
9 that qualifier mean?

10 A. That qualifier means that, of course, we don't
11 understand everything about the immune system. For instance,
12 yesterday it was announced that we might have isolated the
13 virus associated with A.I.D.S. So, obviously, there are things
14 we don't know. People were testing, for example, the immune
15 system of people who had A.I.D.S. and they didn't know what
16 was going on until possibly just yesterday, a little bit before,
17 when it was announced yesterday. So, I don't mean to say that
18 one can read through a set of clinical tests and know absolutely
19 everything. But I do mean that one can read through those
20 tests and understand what part of the immune system is being
21 attacked, what kind of agent may be acting, that certain agents
22 indeed are acting or are not acting and what is going on in
23 the system as a system. Although, of course, we haven't
24 cured the common cold. So, we don't know everything about the

1 immune system.

2 Q. And one of the things that may be going on in that
3 immune system is that at the time of the test the person may
4 have the sniffles.

5 A. That kind of thing, as I tried to indicate to you,
6 can be differentiated from other types of effects on the
7 immune system. So, it's not the case that if you have some
8 kind of infectious disease or some kind of damage to the immune
9 system it messes up the test and you can't interpret them.
10 That is not true.

11 Q. You ought to be able to pick that out?

12 A. Depending on what is going on, yes, and what you
13 are looking for.

14 Q. Specifically?

15 A. Yes, these are specific tests, Mr. Heineman. I can't
16 make general statements about them.

17 Q. Now, there are indeed other things that can affect
18 the immune system test results, are there not, such as the
19 fact that someone may be on some sort of medication?

20 A. Yes.

21 Q. There are indeed medications that very severely
22 affect the ability of the body to fight off invading organisms.

23 A. That's very true.

24 Q. And some purposely so. For example, when transplants

1 are made.

2 A. That's right.

3 Q. Organ transplants. You very purposely depress the
4 immune system so that it won't reject the transplanted organ.

5 A. That's true.

6 Q. As a matter of fact, Doctor, age affects the immune
7 system, does it not?

8 A. Age can affect the immune system.

9 Q. And one aspect of it I want to discuss with you,
10 the thymus gland is an important gland in the immune function,
11 is it not?

12 A. It is.

13 Q. And the activity of the thymus gland occurs during a
14 certain segment of life, isn't that true?

15 A. Certain types of the activity of the thymus gland,
16 that's right. The thymus gland does not regress.

17 Q. So that, for example, animal studies on immune
18 functions are very frequently performed in neonatal animals,
19 are they not?

20 A. Only those studies that are looking at the
21 sensitivity of the neonatal period, Mr. Heineman.

22 Q. And that period during which the thymus gland is
23 active in a mouse or a rat?

24 A. It's a period of importance, but not the only period

1 during which the thymus gland is active.

2 Q. All right. Now, tell me about the other periods
3 during which the thymus gland is active.

4 A. Well, a major component of the immune system are
5 T-cells which are lymphocytes of thymic origin which is why
6 they are called T-cells. And they are conditioned in the
7 thymus throughout life. So, the thymus gland is contributing
8 some humoral biochemical factors which are important to the
9 function of T-cells throughout life. It is true that the
10 period of rapid differentiation and growth of the thymus
11 gland and of the maturation of the T-cells is in the human
12 in the late prenatal, early neonatal period. But it would
13 be --

14 Q. What period of time is that?

15 A. Approximately the last half of pregnancy, the first
16 six years of life approximately. But that's not to say that
17 after that time the thymus is devoid of influence on the
18 immune system. That is an important period, but not the
19 only period.

20 Q. So, the cell development of the immune system of
21 the thymus mediated portion of the immune system occurs within
22 the first six years of life.

23 A. That's right.

24 Q. After that time, the function of the thymus gland is

1 a humoral function.

2 A. That's right, a very important function.

3 Q. Now, the difference between a cell mediated function
4 and a humoral function has to do with -- in the humoral
5 function you are talking about fluids, materials biochemically
6 reacting or affecting the immune system as opposed to cells
7 which go out and engage the invading organism, are you not?

8 A. No, that's not quite right.

9 Q. Okay. Not quite right.

10 A. It's much more complicated than that.

11 Q. Now, in the cell mediated, you have cells, do you not,
12 that go out and engage the invading organism?

13 A. Yes, but the ability of those cells to deal with
14 invading organisms is highly dependent on humoral factors.
15 They have receptors on them for these hormones and substances
16 which is secreted by the thymus and the other glands as well as well
17 as by other cells. So, that's a very old-fashioned distinction
18 between humoral mediated immunity and cell mediated immunity.

19 Q. Well, I am just an old-fashioned kind of guy.

20 A. Well, it's a new-fashioned kind of system I am afraid.

21 Q. The humoral system is differentiated from the cell
22 system in that the humoral system is a biochemical arm, is it
23 not?

24 A. Well, Mr. Heineman, as a biochemically trained scientist,

1 I can't let that distinction go by. Cells are nothing more
2 than packages of biochemical reactions.

3 Q. All right. Now, you have cells in the immune system
4 that are called -- that have the portion on the end of their
5 name of phages, do you not, P-H-A-G-E-S?

6 A. Yes, they are macrophages.

7 Q. Macrophages?

8 A. Uh huh.

9 Q. Okay. Now, what are those cells do to an invading
10 organism?

11 A. Those cells mainly engulf or surround an invading
12 body and then, what is called, phagocytize or really chew it
13 up and destroy it. They have really strong enzymes inside
14 them which are capable of breaking down a large number of
15 substances or failing that, they merely immobilize an agent
16 and then direct it to excretion.

17 Q. And when they immobilize an agent, then something
18 else comes along and takes that agent out to be excreted from
19 the body.

20 A. Well, the macrophage itself may be secreted into the
21 bile system. And then the whole entity, the macrophage which
22 has engulfed this foreign substance, broken down and excreted.

23 Q. All right. In fact, there are a whole lot of
24 things that can go on in one's life that can affect the immune

1 system including stress.

2 A. Yes.

3 Q. As a matter of fact, I think there have been studies
4 that have been demonstrated that immunological data can be
5 affected by stress.

6 A. Certain types can, yes.

7 Q. Now, those changes that are produced by stress are
8 normally transient in nature, are they not?

9 A. Depending on the nature of the stress, yes.

10 Q. If the stress goes away, the immune disfunction goes
11 away.

12 A. In most cases.

13 Q. So, that -- is there any evidence that human beings
14 can be affected by stress and, therefore, have their immune
15 functions affected?

16 A. Yes, there is.

17 Q. So that is it possible that merely going in and having
18 a test, if you are afraid of a test, could impose sufficient
19 stress to affect the immune system?

20 A. Probably not. Now, I suppose if you thought about
21 it for months in a kind of state of morbid fear, that is
22 possible. But I -- there have been studies, of course -- this
23 is a concern in any clinical test that the reactions of the
24 patient to the test may influence the results. Immediate

1 stress reactions or transient stress reactions do not
2 significantly compromise immune function. In addition, there
3 are biochemical challenge studies in which the cells are
4 taken out and then looked at for their ability to respond
5 to immunologically active substances in a test tube. The
6 cells have been taken from a person, but the test is done in
7 a test tube. Therefore, whether the person is still feeling
8 stressed or unhappy or upset doesn't matter any more. The
9 cells are outside him or her. And those tests are relatively
10 free of that kind of problem. And that is one reason why
11 those kinds of challenge tests are so widely used in clinical
12 immunology now to get around those problems of base line testing,
13 if you will.

14 Q. So, you can take an in vitro study, which would be
15 the cells removed --

16 A. It's not really an in vitro study. What has happened
17 to the person has happened in vivo, in the person. They
18 were exposed to the chemical or they had the under nutrition
19 state or whatever happened to them has happened. You have
20 taken the cells from them at the time they are actively in
21 whatever has happened to them. You do the test in the test tube.
22 But it's not exactly in vitro. In vitro is a word which more
23 correctly describes if I took some white cells from you, I
24 put them in a test tube; I added dioxin to the test tube and

1 then I did some tests. I would call that an in vitro test.

2 Q. All right. So the test may be that --

3 A. The test is independent of host factors. Let's put
4 it that way.

5 Q. And an in vitro test is independent of those factors?

6 A. An in vitro test would also be relatively independent
7 of host factors. But I would not call this an in vitro test.

8 Q. Doctor, can the mere taking of aspirin or birth
9 control pills affect the immune system response?

10 A. It may affect certain aspects of it. But those are
11 fairly well characterized.

12 Q. So that if someone might be taking some sort of a
13 drug at the time the test was made, but didn't report it,
14 nobody would have any way of knowing that those results
15 had been adversely affected by that drug?

16 A. No. Unless the effects were highly characteristic.

17 Q. Unless they could easily be seen, a characteristic
18 of only that drug and nothing else.

19 A. That's right. For instance, I think, if someone were
20 taking immunosuppressive therapy for transplant, those effects
21 would be so devastating that suspicion would be immediately
22 raised that either this person was in a very parlous state
23 from disease or exposure or they were taking this kind of
24 drug.

1 Q. And indeed the taking in of -- we mentioned birth
2 control pills, estrogen, progesterone; the hormones of that
3 type do affect the immune system, do they not?

4 A. They may, though the studies that I am aware of
5 which have looked at women who have been taking birth control
6 pills chronically, which is how women take birth control pills,
7 show that the immune system does adjust after chronic
8 medication.

9 Q. What are prostaglandins?

10 A. Prostaglandins are chemicals secreted by a number of
11 cells which appear to mediate how membranes of cells and
12 other functions in the cells respond. They inhibit a number
13 of enzymes. They activate certain receptors. They are very
14 powerful messengers in the body.

15 Q. Are they associated in any way with the menstrual
16 cycle in women?

17 A. I don't think all prostaglandins are. Some may be.

18 Q. Some may be? So that --

19 A. I am not sure of that.

20 Q. So, is it possible that an immune function test
21 could be affected in some way by the stage in a woman's
22 menstrual cycle in which it's taken?

23 A. I don't think to any significant extent. Particularly
24 not the challenge studies.

1 Q. Now, what do you mean by a significant extent?
2 That's one of the things I want to get into is what constitutes
3 a significant change in the immune function.

4 A. Well, there are several answers to that question.
5 One answer is that at the level of looking at numbers that
6 come out of clinical immune function tests, there is usually
7 established a range of normal. We are not now looking at
8 single numbers and comparing the way we were with the mortality
9 and morbidity studies. But there is a range of values,
10 enzyme activities, hormone levels, cell counts which have been
11 found in people who as far as we know haven't been exposed or
12 damaged by illness or had any other kind of unusual event.
13 So, that is set as a normal range. So, when I say that I
14 don't think the menstrual cycle affects the prostaglandin
15 levels significantly, I mean there may be effects, but they
16 are within that normal range. And there are statistical
17 tests to determine whether something is outside that normal
18 range. But there may be other --

19 Q. That normal range can be -- is determined in each
20 laboratory, isn't it?

21 A. Well --

22 Q. So, if a lab --

23 A. No, wait. To a limited extent. There is a normal
24 range which the American College of Clinical Chemistry publishes

1 in its papers and its journals for almost every clinical
2 test. Now, it's true that every laboratory should establish
3 its own normal range. But if a laboratory is doing measurements
4 of, let's say, of porphyrins or prostaglandins and it takes
5 six controls and it finds levels way up here and the published
6 all the published articles and the literature indicate the
7 normal range is down here, it's not good scientific practice
8 to say these are my controls and those are the ones I am
9 going to use because that's my laboratory. Good clinical and
10 scientific practice would say, now, wait a minute. Something
11 may be going on in my laboratory which indicates a problem
12 in analytic chemistry or some other parameter. Maybe I
13 haven't chosen my controls very well. So, it's not entirely
14 true to say that every laboratory establishes it's own controls.

15 Q. But generally, I mean, unless the controls are
16 totally out of wack -- generally a lab establishes its own
17 controls, doesn't it?

18 A. Every laboratory should establish it's own control
19 group if only to validate that it can conduct the test
20 adequately.

21 Q. So that if the results are off a few digits or
22 something off of what that control group in that lab says
23 are the normal limits for that period of time, that wouldn't
24 necessarily be abnormal in this general group of normals that

1 you described previously that this American group determines,
2 would it?

3 A. Well, it may or may not. There are other definitions
4 of significant difference which I was about to start when you
5 asked me another question. One is to look at all the two
6 groups and rank them. And if all members of one group, let's
7 say the exposed group, have levels of whatever factor you
8 are measuring which are consistently above the other group,
9 that would -- that can be statistically tested by something
10 called the Wilcoxon test. And that can be a very clear
11 indicator that something is going on. And it would so be
12 cited and referred to in the medical and scientific literature.

13 Q. You mean if something were detected in the control
14 group? You mean something in an individual test might be
15 higher?

16 A. No. What I meant was you may have this range established
17 of so-called normals. But then if you ran a group of people
18 who were exposed to something and you ran a control group at
19 the same time and every single person in your exposed group
20 was higher than the people in the control group, even if they
21 all were within that range of normal, that kind of finding
22 would alert most scientists that something is going on in this
23 group.

24 Q. Even though they are totally within what that

1 laboratory determines may be normal ranges at that period of
2 time?

3 A. That's right.

4 Q. But that wouldn't be an abnormal finding, would it?

5 A. It would be statistically abnormal, yes.

6 Q. But it may not be clinically abnormal.

7 A. Well, clinically abnormal is another question. Now,
8 you get into the issue of what do these tests mean in clinical
9 terms. And that's beyond my competence not being a clinician.
10 I can only speak to the biochemistry and statistics of the
11 test.

12 Q. All right. We did discuss a moment ago, did we not,
13 Doctor, that taking therapeutic amounts of aspirin can affect
14 immune function levels?

15 A. Can affect certain specific aspects of immune functions,
16 that's right.

17 Q. So, if you have a headache and you take enough
18 aspirin to help your headache, which is what I assume
19 therapeutic amounts means, that it may affect some aspect of
20 the immune system.

21 A. It may.

22 MR. HEINEMAN: I have gone past your time, Judge.
23 Do you want to --

24 THE COURT: That's okay. You can go a little more.

1 MR. HEINEMAN: It's a good place for me if that's
2 all right with you.

3 THE COURT: Oh, all right. Gentlemen, could I see
4 you up at the bench for a second?

5 (A discussion was held at the bench out of the
6 hearing of the jury and off the record.)

7 THE COURT: Ladies and gentlemen, we have come to
8 a convenient point in the testimony at which we can adjourn
9 for the day. So, we will. Besides the normal admonishments
10 at any break, I advise you, since this is an overnight break,
11 that you are not to -- you are to avoid watching, listening,
12 or reading anything either about this case in particular or
13 the subject matter in general in either the print or electronic
14 media. I want to thank you for your attention and cooperation
15 during the course of this trial today. Court is adjourned
16 until 9:30 tomorrow morning.

17 (At this time, Court adjourned to 9:30 A.M. on
18 April 25, 1984.)

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1 IN THE CIRCUIT COURT FOR THE TWENTIETH JUDICIAL CIRCUIT

2 ST. CLAIR COUNTY, ILLINOIS

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7 I, RICHARD P. GOLDENHERSH, Circuit Judge in and for
8 the Twentieth Judicial Circuit of the State of Illinois, and
9 the sole presiding Judge in the aforesaid cause on the 24th
10 day of April, 1984, do hereby certify that I have examined the
11 aforesaid transcript of the proceedings and further certify
12 that the same is a true and correct transcript of said
13 proceedings had in said cause.

14 DATED: This 1st day of May, 1984.

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17 _____
18 CIRCUIT JUDGE
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