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IN THE CIRCUIT COURT FOR THE TWENTIETH JUDICIAL CIRCUIT

ST. CLAIR COUNTY, ILLINOIS

FRANCES E. KEMNER, et al., Plaintiffs,	)	
vs.	)	No. 80-L-970
MONSANTO COMPANY, et al., Defendants.	)	

Before the HONORABLE RICHARD P. GOLDENHERSH, Judge

REPORT OF PROCEEDINGS

JURY TRIAL

April 24, 1984

APPEARANCES:

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

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

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

DONNA F. BREWER, CSR
Official Court Reporter

I N D E X

E X H I B I T S

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

* * * * * * *

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

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

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

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

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

THE COURT: Absolutely.

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

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

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

MR. CARR: No, I just got it.

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

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

MR. ALBERT SCHOENBECK: It's 66 pages.

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

I would say at least a week.

THE COURT: Do you want to confer?

MR. ALBERT SCHOENBECK: Yes.

(A short recess was taken.)

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

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

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

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

MR. HEINEMAN: I think that's right.

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

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

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

THE COURT: Any problem with that, gentlemen?

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

MR. CARR: That's correct.

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

MR. CARR: Yes.

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

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

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.

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

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

MR. HEINEMAN: Fine.

THE COURT: Okay. Let's go in.

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

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

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

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

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?

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

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

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

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

A. I am.

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

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

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

and make sure I read it accurately. It's noted there on page 43. "A case control study is usually less costly than a cohort study in terms of both time and resources and is therefore frequently undertaken as a first step to determine whether or not an association exists between the suspected cause and effect or to select between several hypotheses that may explain the observed characteristics of the disease. Cohort studies may then be undertaken to gain added confidence in the existence of a relationship and to measure more accurately its strength." Did I read that accurately, Doctor?

A. You did.

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

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

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

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

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

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

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

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

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

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

A. That's right.

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

A. That's right.

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

A. That's right.

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

A. An association is what scientists call for sure.

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

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

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

A. That's right.

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

A. That's right.

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

A. That's right.

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

A. That's right.

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

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

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.

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

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

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

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

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

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

A. That's right.

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

A. That's right.

Q. And he found none.

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

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

A. .02.

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

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

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

Q. In this particular disease.

A. That's right.

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

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

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

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

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

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

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

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

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

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

Q. He even listed traffic accidents.

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

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

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

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

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

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

A. No, I have satisfied my curiosity.

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

A. That's right.

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

A. That's right.

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

A. That's right.

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

A. (No response.)

Q. Yes? 1,971 workers?

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

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

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

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

A. Yes.

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

A. That's right.

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

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

Q. I know.

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

Q. My question is --

A. Which case control studies?

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

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

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

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

A. Among other things.

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

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

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

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

A. That's right.

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

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

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

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

A. No.

Q. -- than these studies do.

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

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

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

you are trying to do that.

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

A. And what they cannot find.

Q. Exactly.

A. And one of the things that many of them state is that they cannot make a statement about cancer itself. Pazderova says that. She can't make any conclusions on cancer. Others say given the short latency times they can't make final conclusions. Riihimaki says given the absence of information on dosage I can't make conclusions. They are very careful to limit what they can say. And that is what is being omitted in our discussion right here.

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

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

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

Q. So, it's not inconsistent?

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

Q. So, it's not inconsistent?

A. They are different questions. They are different answers.

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

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

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

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

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

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

A. That's right.

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

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

Q. You think it's narrower than that?

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

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

A. Well, since --

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

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

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

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

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

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

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

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

A. They were under contract to the Air Force.

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

A. Yes, by the Department of Defense.

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

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

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

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

Q. But Dr. John Moore --

A. You can determine that by asking them.

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

A. Such as it was, yes.

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

A. Yes.

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

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

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

A. That's right.

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

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

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

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

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

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

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

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

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

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

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

MR. HEINEMAN: I thought she had answered it.

MR. CARR: No, she was --

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

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

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

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

A. That's right.

Q. Isn't there?

A. But --

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

A. I am supposed to.

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

A. I do.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Q. Right.

A. -- if you read it carefully.

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

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

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

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

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

Q. That's right.

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

THE COURT: Fine. Is this a convenient point?

MR. HEINEMAN: Yes, it is.

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

(A short recess was taken.)

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

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

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

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

Q. All right. So, they talked to familiy members, did they not?

A. Yes, they did.

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

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

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

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

in articles in Nature magazine.

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

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

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

A. I do.

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

A. You did.

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

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

of the concerns which we have been talking about.

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

A. You did.

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

have caused cancer?

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

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

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

Q. I am --

A. I misinterpreted your question.

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

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

A. Molds and --

Q. Molds?

A. Right.

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

A. MCPA, 2,4,5-T and 2,4-D and related compounds. That's right.

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

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

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

could confound the results reached by Hardell.

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

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

powerful promoter of dioxin.

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

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

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

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

Q. You don't --

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

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

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

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

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

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

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

MR. HEINEMAN: No. 50, your Honor.

THE COURT: Thank you.

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

A. Yes, I do.

Q. And what is that opinion?

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

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

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

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

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

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

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

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

A. Yes, I think there is some evidence.

Q. All right. And what is that?

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

Q. All right.

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

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

the 1984?

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

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

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

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

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

A. I believe it is.

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

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

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

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

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

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

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

A. I do.

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

A. I do.

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

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

MR. HEINEMAN: Certainly.

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

A. That's right.

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

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

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

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

Q. Okay.

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

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

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

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

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

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

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

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

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

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

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

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

A. Yes.

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

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

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

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

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

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

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

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

A. So far, that's right.

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

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

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

Q. So, it's your --

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

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

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

Q. Okay.

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

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

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

be used in a statistical sense. But --

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

MR. CARR: The lady said --

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

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

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

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

A. And I stated yes.

Q. You said yes, based upon melanomas.

A. That's right.

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

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

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

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

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

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

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

Q. What the author says.

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

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

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

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

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

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

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

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

A. I will try again.

Q. Yes.

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

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

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

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

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

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

Q. All right.

A. There is no statistics for one.

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

A. That's true.

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

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

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

(At this time, Court recessed for lunch.)

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

demonstrates that --

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

MR. HEINEMAN: It isn't marked.

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

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

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

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

A. That's right.

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

A. Seventeen thousand four hundred.

Q. Now, what does that mean when --

A. Excuse me. That is melanoma only.

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

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

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

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

A. That's right.

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

THE COURT: Naturally.

MR. HEINEMAN: Was that Murphy's Law?

THE COURT: I think so.

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

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

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

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

THE COURT: Right.

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

A. Yes.

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

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

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

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

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

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

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

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

A. That's right.

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

A. Right.

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

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

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

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

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

MR. HEINEMAN: Q. What do they say?

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

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

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

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

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

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

Q. So that --

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

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

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

Q. I have just asked you about that.

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

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

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

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

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

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

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

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

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

THE COURT: Go ahead.

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

A. That's right.

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

A. You did.

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

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

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

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

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

is that right?

A. That's right.

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

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

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

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

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

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

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

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

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

A. That's right.

Q. You are familiar with the studies. You have read them before. They are being published -- each of the studies we have talked about is published between 1980 and 1983. I think that's right.

A. '77 through '83, yes.

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

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

Q. No.

A. I am not going to do that.

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

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

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

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

Q. Let me --

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

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

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

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

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

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

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

A. That's right.

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

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

That is --

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

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

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

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

Q. In this particular test.

A. But the individual causes were not tested statistically.

Q. In this particular test.

A. In this particular paper.

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

A. I don't seem to have that.

MR. CARR: No. 63.

THE WITNESS: I have got it.

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

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

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

THE COURT: Mr. Heineman?

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

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

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

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

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

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

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

A. They talk about some of them, yes.

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

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

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

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

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

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

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

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

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

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

it in the abstract at the beginning.

A. Yes.

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

A. Right.

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

A. Right.

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

A. You did, yes.

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

A. No.

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

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

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

A. That is a very small group.

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

A. That's right.

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

A. Yes.

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

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

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

A. That's right.

Q. And they are both lung cancer.

A. That's right.

Q. And again they talked about the skin conditions which

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

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

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

A. That's right.

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

A. That's right.

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

A. I think it is the same one.

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

A. That's right.

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

A. That's right. For deaths.

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

A. That's right.

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

A. Wait.

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

A. Yes.

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

A. That's right.

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

found two.

A. That's right.

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

A. That's right.

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

A. Skin cancer is not listed.

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

A. It may, yes.

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

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

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

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

Q. Same population.

A. It's not a different study.

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

A. Yes.

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

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

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

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

Q. All right.

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

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

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

MR. HEINEMAN: Are you objecting --

MR. CARR: I am objecting.

MR. HEINEMAN: -- to my doing this?

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

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

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

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

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

MR. CARR: Then turn it the other way.

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

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

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

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

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

THE WITNESS: I have not.

MR. CARR: Please --

THE WITNESS: Excuse me.

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

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

MR. HEINEMAN: May we approach the bench?

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

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

THE COURT: Of course you may. Sure.

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

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

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

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

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

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

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

MR. HEINEMAN: All right.

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

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

MR. HEINEMAN: All right.

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

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

(A short recess was taken.)

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

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

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

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

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

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

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

THE COURT: Thank you, Doctor.

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

A. That's my opinion.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A. They would be one cause.

Q. That might be one.

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

Q. All right.

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

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

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

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

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

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

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

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

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

A. That's correct.

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

A. That's right.

Q. Whatever it might be.

A. That's right.

Q. So whatever conclusions these papers reach or whatever

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

A. That's correct.

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

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

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

A. That's right.

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

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

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

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

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

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

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

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

Q. Okay. He looks for all types --

A. And puts them all together.

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

A. I think that's right.

Q. Okay.

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

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

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

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

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

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

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

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

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

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

Q. All right.

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

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

A. That's right.

Q. And he finds seven observed --

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

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

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

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

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

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

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

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

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

MR. HEINEMAN: I will be happy to.

Q. Dr. Silbergeld, Dr. Thiess here reports the expected deaths --

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

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

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

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

(The following proceedings were held at the

bench out of the hearing of the jury.)

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

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

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

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

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

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

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

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

MR. CARR: On relevant points.

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

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

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

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

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

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

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

MR. CARR: Yes, indeed.

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

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

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

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

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

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

THE COURT: I don't think you are.

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

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

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

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

MR. CARR: Yes, your Honor.

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

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

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

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

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

MR. HEINEMAN: What difference does it make?

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

MR. HEINEMAN: So what?

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

jargon.

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

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

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

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

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

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

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

THE COURT: Of course.

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

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

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

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

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

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

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

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

THE COURT: Sure, go ahead.

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

A. That's right.

Q. Without differentiating between cardiovascular diseases.

A. That's right.

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

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

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

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

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

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

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

MR. CARR: That's exactly right.

MR. HEINEMAN: As to that last remark.

THE COURT: Yes. The remark --

MR. HEINEMAN: You mean the which it does?

THE COURT: Which it does, yes.

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

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

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

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

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

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

A. No.

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

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

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

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

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

Q. So, the answer to that is yes?

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

Q. Well, you can --

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

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

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

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

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

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

A. If these cardiovascular diseases were all

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

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

A. No, I do not.

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

A. I don't know of any evidence.

Q. How about bone cancer, Doctor?

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

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

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

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

Q. All right. How about hematopoietic?

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

Q. Would you define hematopoietic cancers?

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

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

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

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

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

A. That is exactly what we have been doing.

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

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

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

Q. Despite its other infirmities?

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

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

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

Q. Tell me what that weakness is.

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

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

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

understand what has happened.

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

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

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

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

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

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

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

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

those other kinds of deaths could occur as well?

A. No.

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

A. I wouldn't do that.

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

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

Q. So that overall --

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

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

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

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

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

Q. But, again --

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

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

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

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

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

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

A. That's right.

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

A. No, not at all.

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

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

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

A. That's right.

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

A. That's correct.

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

THE COURT: Sure.

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

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

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

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

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

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

A. I do.

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

A. Of course.

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

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

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

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

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

A. That's right.

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

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

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

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

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

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

A. And I answered that question.

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

viruses.

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

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

A. To a very great extent you can.

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

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

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

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

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

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

A. To a certain extent they can.

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

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

immune system.

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

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

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

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

Q. Specifically?

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

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

A. Yes.

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

A. That's very true.

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

are made.

A. That's right.

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

A. That's true.

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

A. Age can affect the immune system.

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

A. It is.

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

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

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

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

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

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

during which the thymus gland is active.

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

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

Q. What period of time is that?

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

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

A. That's right.

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

a humoral function.

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

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

A. No, that's not quite right.

Q. Okay. Not quite right.

A. It's much more complicated than that.

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

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

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

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

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

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

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

Q. All right. Now, you have cells in the immune system that are called -- that have the portion on the end of their name of phages, do you not, P-H-A-G-E-S?

A. Yes, they are macrophages.

Q. Macrophages?

A. Uh huh.

Q. Okay. Now, what are those cells do to an invading organism?

A. Those cells mainly engulf or surround an invading body and then, what is called, phagocytize or really chew it up and destroy it. They have really strong enzymes inside them which are capable of breaking down a large number of substances or failing that, they merely immobilize an agent and then direct it to excretion.

Q. And when they immobilize an agent, then something else comes along and takes that agent out to be excreted from the body.

A. Well, the macrophage itself may be secreted into the bile system. And then the whole entity, the macrophage which has engulfed this foreign substance, broken down and excreted.

Q. All right. In fact, there are a whole lot of things that can go on in one's life that can affect the immune

system including stress.

A. Yes.

Q. As a matter of fact, I think there have been studies that have been demonstrated that immunological data can be affected by stress.

A. Certain types can, yes.

Q. Now, those changes that are produced by stress are normally transient in nature, are they not?

A. Depending on the nature of the stress, yes.

Q. If the stress goes away, the immune disfunction goes away.

A. In most cases.

Q. So, that -- is there any evidence that human beings can be affected by stress and, therefore, have their immune functions affected?

A. Yes, there is.

Q. So that is it possible that merely going in and having a test, if you are afraid of a test, could impose sufficient stress to affect the immune system?

A. Probably not. Now, I suppose if you thought about it for months in a kind of state of morbid fear, that is possible. But I -- there have been studies, of course -- this is a concern in any clinical test that the reactions of the patient to the test may influence the results. Immediate

stress reactions or transient stress reactions do not significantly compromise immune function. In addition, there are biochemical challenge studies in which the cells are taken out and then looked at for their ability to respond to immunologically active substances in a test tube. The cells have been taken from a person, but the test is done in a test tube. Therefore, whether the person is still feeling stressed or unhappy or upset doesn't matter any more. The cells are outside him or her. And those tests are relatively free of that kind of problem. And that is one reason why those kinds of challenge tests are so widely used in clinical immunology now to get around those problems of base line testing, if you will.

Q. So, you can take an in vitro study, which would be the cells removed --

A. It's not really an in vitro study. What has happened to the person has happened in vivo, in the person. They were exposed to the chemical or they had the under nutrition state or whatever happened to them has happened. You have taken the cells from them at the time they are actively in whatever has happened to them. You do the test in the test tube. But it's not exactly in vitro. In vitro is a word which more correctly describes if I took some white cells from you, I put them in a test tube; I added dioxin to the test tube and

then I did some tests. I would call that an in vitro test.

Q. All right. So the test may be that --

A. The test is independent of host factors. Let's put it that way.

Q. And an in vitro test is independent of hose factors?

A. An in vitro test would also be relatively independent of host factors. But I would not call this an in vitro test.

Q. Doctor, can the mere taking of aspirin or birth control pills affect the immune system response?

A. It may affect certain aspects of it. But those are fairly well characterized.

Q. So that if someone might be taking some sort of a drug at the time the test was made, but didn't report it, nobody would have any way of knowing that those results had been adversely affected by that drug?

A. No. Unless the effects were highly characteristic.

Q. Unless they could easily be seen, a characteristic of only that drug and nothing else.

A. That's right. For instance, I think, if someone were taking immunosuppressive therapy for transplant, those effects would be so devastating that suspicion would be immediately raised that either this person was in a very parlous state from disease or exposure or they were taking this kind of drug.

Q. And indeed the taking in of -- we mentioned birth control pills, estrogen, progesterone; the hormones of that type do affect the immune system, do they not?

A. They may, though the studies that I am aware of which have looked at women who have been taking birth control pills chronically, which is how women take birth control pills, show that the immune system does adjust after chronic medication.

Q. What are prostaglandins?

A. Prostaglandins are chemicals secreted by a number of cells which appear to mediate how membranes of cells and other functions in the cells respond. They inhibit a number of enzymes. They activate certain receptors. They are very powerful messengers in the body.

Q. Are they associated in any way with the menstrual cycle in women?

A. I don't think all prostaglandins are. Some may be.

Q. Some may be? So that --

A. I am not sure of that.

Q. So, is it possible that an immune function test could be affected in some way by the stage in a woman's menstrual sycle in which it's taken?

A. I don't think to any significant extent. Particularly not the challenge studies.

Q. Now, what do you mean by a significant extent? That's one of the things I want to get into is what constitutes a significant change in the immune function.

A. Well, there are several answers to that question. One answer is that at the level of looking at numbers that come out of clinical immune function tests, there is usually established a range of normal. We are not now looking at single numbers and comparing the way we were with the mortality and morbidity studies. But there is a range of values, enzyme activities, hormone levels, cell counts which have been found in people who as far as we know haven't been exposed or damaged by illness or had any other kind of unusual event. So, that is set as a normal range. So, when I say that I don't think the menstrual cycle affects the prostaglandin levels significantly, I mean there may be effects, but they are within that normal range. And there are statistical tests to determine whether something is outside that normal range. But there may be other --

Q. That normal range can be -- is determined in each laboratory, isn't it?

A. Well --

Q. So, if a lab --

A. No, wait. To a limited extent. There is a normal range which the American College of Clinical Chemistry publishes

in its papers and its journals for almost every clinical test. Now, it's true that every laboratory should establish its own normal range. But if a laboratory is doing measurements of, let's say, of porphyrins or prostaglandins and it takes six controls and it finds levels way up here and the published -- all the published articles and the literature indicate the normal range is down here, it's not good scientific practice to say these are my controls and those are the ones I am going to use because that's my laboratory. Good clinical and scientific practice would say, now, wait a minute. Something may be going on in my laboratory which indicates a problem in analytic chemistry or some other parameter. Maybe I haven't chosen my controls very well. So, it's not entirely true to say that every laboratory establishes it's own controls.

Q. But generally, I mean, unless the controls are totally out of wack -- generally a lab establishes its own controls, doesn't it?

A. Every laboratory should establish it's own control group if only to validate that it can conduct the test adequately.

Q. So that if the results are off a few digits or something off of what that control group in that lab says are the normal limits for that period of time, that wouldn't necessarily be abnormal in this general group of normals that

you described previously that this American group determines, would it?

A. Well, it may or may not. There are other definitions of significant difference which I was about to start when you asked me another question. One is to look at all the two groups and rank them. And if all members of one group, let's say the exposed group, have levels of whatever factor you are measuring which are consistently above the other group, that would -- that can be statistically tested by something called the Wilcoxon test. And that can be a very clear indicator that something is going on. And it would so be cited and referred to in the medical and scientific literature.

Q. You mean if something were detected in the control group? You mean something in an individual test might be higher?

A. No. What I meant was you may have this range established of so-called normals. But then if you ran a group of people who were exposed to something and you ran a control group at the same time and every single person in your exposed group was higher than the people in the control group, even if they all were within that range of normal, that kind of finding would alert most scientists that something is going on in this group.

Q. Even though they are totally within what that

laboratory determines may be normal ranges at that period of time?

A. That's right.

Q. But that wouldn't be an abnormal finding, would it?

A. It would be statistically abnormal, yes.

Q. But it may not be clinically abnormal.

A. Well, clinically abnormal is another question. Now, you get into the issue of what do these tests mean in clinical terms. And that's beyond my competence not being a clinician. I can only speak to the biochemistry and statistics of the test.

Q. All right. We did discuss a moment ago, did we not, Doctor, that taking therapeutic amounts of aspirin can affect immune function levels?

A. Can affect certain specific aspects of immune functions, that's right.

Q. So, if you have a headache and you take enough aspirin to help your headache, which is what I assume therapeutic amounts means, that it may affect some aspect of the immune system.

A. It may.

MR. HEINEMAN: I have gone past your time, Judge. Do you want to --

THE COURT: That's okay. You can go a little more.

MR. HEINEMAN: It's a good place for me if that's all right with you.

THE COURT: Oh, all right. Gentlemen, could I see you up at the bench for a second?

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

THE COURT: Ladies and gentlemen, we have come to a convenient point in the testimony at which we can adjourn for the day. So, we will. Besides the normal admonishments at any break, I advise you, since this is an overnight break, that you are not to -- you are to avoid watching, listening, or reading anything either about this case in particular or the subject matter in general in either the print or electronic media. I want to thank you for your attention and cooperation during the course of this trial today. Court is adjourned until 9:30 tomorrow morning.

(At this time, Court adjourned to 9:30 A.M. on April 25, 1984.)

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IN THE CIRCUIT COURT FOR THE TWENTIETH JUDICIAL CIRCUIT

ST. CLAIR COUNTY, ILLINOIS

I, DONNA F. BREWER, an Official Court Reporter for the Circuit Court of St. Clair County, Twentieth Judicial Circuit of Illinois, do hereby certify that I reported in shorthand the proceedings had on the hearing in the above entitled cause; that I thereafter caused the foregoing to be transcribed into typewriting, which I hereby certify to be a true and accurate transcript of the proceedings had before the Honorable Richard P. Goldenhersh, Judge of said Court.

Donna F. Brewer
Official Court Reporter

Dated this 30th day
of April, 1984.

IN THE CIRCUIT COURT FOR THE TWENTIETH JUDICIAL CIRCUIT

ST. CLAIR COUNTY, ILLINOIS

I, RICHARD P. GOLDENHERSH, Circuit Judge in and for the Twentieth Judicial Circuit of the State of Illinois, and the sole presiding Judge in the aforesaid cause on the 24th day of April, 1984, do hereby certify that I have examined the aforesaid transcript of the proceedings and further certify that the same is a true and correct transcript of said proceedings had in said cause.

DATED: This 1st day of May, 1984.

CIRCUIT JUDGE