STATE OF MICHIGAN

IN THE CIRCUIT COURT FOR THE COUNTY OF HURON

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| ROGER A. HALEY and VALERIE J. HALEY, Husband and Wife; and DONALD L. HALEY and FLORENCE S. HALEY, Husband and Wife,<br><br>Plaintiffs,<br><br>-vs-<br><br>MICHIGAN SILO COMPANY, a Michigan Corporation, C & B SILO COMPANY, a Michigan Corporation; MONSANTO COMPANY, a Corporation; and CONCRETE SILO COMPANY, INCORPORATED, a Corporation, Jointly and Severally,<br><br>Defendants. | No. 77 002593 NP<br><br>VOLUME XXIV |

Excerpt of the proceedings had and testimony taken in the above-entitled matter on Tuesday, May 1, 1984, at 9:00 o'clock A.M., at the Huron County Courthouse, Bad Axe, Michigan, before the Honorable M. Richard Knoblock.

APPEARANCES:

MC GRAW & BORCHARD,
BY: PATRICK MC GRAW, Esq.,

and

JAMES N. WOODWORTH, Esq.,

and

CUBITT, CUBITT & TROWHILL,
BY: H. DALE CUBITT, Esq.,

Appearing on behalf of Plaintiffs.

CHAKLOS, JUNGERHELD & DELLA SANTINA,
BY: WILLIAM E. JUNGERHELD, Esq.,

and

ROBERT A. HAHN, Esq.,

and

JOSEPH F. NASSIF,

Appearing on behalf of Defendant Monsanto.

DAVIDSON, BREEN & DOUD,
BY: JOHN DAVIDSON, Esq.,

Appearing on behalf of Defendant C & B Silo.

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(Whereupon at 9:00 o'clock A.M., on Tuesday, May 1, 1984, the Hearing was reconvened.)

THE COURT: Bring in the Jury.

Doctor, resume the stand please. You're still under oath.

WILLIAM R. GAFFEY,

a witness herein, produced by and on behalf of the Defendants, having been previously duly sworn, testified further on his oath as follows:

THE COURT: Be seated.

Good morning, members of the Jury.

THE JURY: Good morning.

THE COURT: Mr. Jungerheld.

MR. JUNGERHELD: Thank you, Your Honor.

DIRECT EXAMINATION

BY MR. JUNGERHELD, CONTINUING:

Q. Dr. Gaffey, before we ended yesterday I had just asked you if you are a member of any professional societies in the field of epidemiology.

A. Yes. I'm a member of the Society for Epidemiologic Research.

Q. And could you tell us a little bit about that society?

A. It's a group of persons engaged in the practice of epidemiology and also publishes the only paper, journal, in the field. The American Journal of Epidemiology.

Q. Is that a peer reviewed journal?

A. Yes, it is. I'm an associate editor of that journal.

Q. And as an associate editor of that journal what do you do in connection with the journal?

A. On request of the editor I review selected papers that are presented for publication.

Q. And what do you review those papers for before they're permitted to be published in this journal?

A. For accuracy, internal consistency, for whether the author has examined and related his results to other results in the field, and whether the writing is clear enough to be

understandable.

These reviews, incidentally, are anonymous.

Q. And an anonymous review -- what is the advantage of an anonymous publishing in a review journal?

A. Essentially the reviewer can be as nasty as he wants without fear of degrading people with whom he may be professionally involved.

Q. And does the society also conduct meetings?

A. It conducts an annual meeting, yes.

Q. And are issues of interest to the epidemiologic field discussed at those meetings?

A. Yes, sir, they are, particularly three day meetings in which new research is presented in various areas. And the better of these are then reviewed and published in the American Journal of Epidemiology.

Q. Doctor, are you also a member of any other organizations?

A. Yes. I'm a member of the American Statistical Association; the Biometric Society; I'm a Fellow of the American Public Health Association; a member of the Institute for Mathematical Statistics; and a member of the British Royal Society of Health.

Q. When you say you're a Fellow of the American Public Health Association, what does that mean?

A. The American Public Health Association has two classes of membership. Regular membership and fellows who are elected

to fellowship on the basis of their accomplishments in the field.

Q. All right, sir.

Dr. Gaffey, have you also published in the Field of Epidemiology?

A. Yes, I have.

Q. And could you outline for the Jury please in what areas you have published? What studies, in other words.

A. I was the co-author of the first study that established that vinyl chloride was a major cause of liver cancer.

I have published, subsequently, studies of workers in the paints and coatings industry.

I'm a co-author of a study of gold miners, which has been accepted for publication but has not yet been published.

Excuse me. In addition I was co-author of a publication of a study of lead solder workers.

Q. With reference to the gold miner worker study, is that the one you referred to earlier when the gold was extracted from asbestos?

A. Yes, that is correct.

Q. Have you published any papers on the analysis of epidemiological data?

A. Yes. I have published one theoretical paper looking at some of the standard statistical calculations and I have another one in preparation.

Q. Dr. Gaffey, have you also reviewed and familiarized yourself with literature -- with other literature, not just your own you have published, but other literature within the field of epidemiology?

A. This is almost essential to keep up with the field to read the leading publications.

Q. Would this include work published in the field of epidemiology involving PCB?

A. Yes.

Q. Dr. Gaffey, is it within your expertise in the field of epidemiology to review the epidemiology publications that appear in the scientific literature regarding, in this case, PCB and to interpret their findings?

A. Very much so.

The federal government, in preparing various documents, evaluating the health effects of specific substances, has these reviews done by government epidemiologists. Actually, the process of reviewing a paper involves this because in order to draw conclusions of a paper to interpret a given topic I have to make sure the author himself has reviewed those topics.

And finally, one of the most recent publications on the Yusho incident was actually a review exactly this way of all the studies done on Yusho papers both in Japan and Taiwan.

Q. Was that in a standard scientific process in the epidemiological community?

A. Yes, indeed. The publication I talked about is in the American Journal of Industrial Medicine, first quarter of 1984.

Q. Incidentally, how many studies are there as they relate to PCB's

I'm talking epidemiology studies.

A. It depends on how one defines it. I was able to find 22 in the search of the literature.

Q. Incidentally, were you asked to undertake a task that resulted in doing exactly that by the American Chemical Society?

A. Yes, I was.

Q. Have you spoken to various scientific groups regarding this subject? This is the epidemiology of PCB's?

A. Yes. I have spoken to a meeting of the American Chemical Society symposium held by the University of Michigan and a symposium held by the EPA in Washington.

Q. And have the proceedings -- in other words your presentations on -- to these meeting in the field of epidemiology of PCB's been published?

A. The ones from the Michigan symposium and the EPA symposium, yes.

MR. JUNGERHELD: Your Honor, at this time I would tender Dr. Gaffey as an expert in the field of epidemiology.

THE COURT: Any objection?

MR. MC GRAW: Your Honor, as an epidemiologist in practical experience I think he has got some qualifications. But I think it -- we're stretching the expert standard here by taking an employee of Monsanto who's evidently biased and asking him to be declared an expert by the Court. I think we're going a little bit far by doing that at this point.

THE COURT: Evidently biased?

MR. MC GRAW: Well, he is an employee of Monsanto Corporation. Yet he is an agent speaking for the corporation and now they want to bring him in and make him an expert in this field for them. I just think that's stretching the rules a little bit.

THE COURT: It is? I don't think so. I'll overrule the objection. I find him qualified.

Do you have any objection, Mr. Davidson?

MR. DAVIDSON: No, Your Honor.

THE COURT: I find him qualified as an epidemiologist.

Q. (By Mr. Jungerheld, continuing.) Dr. Gaffey, I'm going to be asking you some questions that relate to your field of epidemiology and again it was yesterday that you explained that, but perhaps as a very short refresher would you explain to the Jury again what an epidemiologist is and what the

field of epidemiology is?

A. The field of epidemiology is the study of risks of general health in specifically defined populations.

For example, the risk of lung cancer in smokers. The risk of acute accident in coal miners. These are examples of risks of ill-health in particular populations, and that's the subject that epidemiologists study rather than the occurrence of individual illnesses in individual fields.

Q. Doctor, as an epidemiologist, tell me this: Do you have an opinion as an epidemiologist as to whether the Yusho incident that has been discussed previously in this Court and the Yu-Chen, that is the Taiwan incident, as an epidemiologist do you have an opinion as to whether or not those incidents were PCB?

MR. MC GRAW: Objection, Your Honor. I haven't heard any evidence about the Doctor's knowledge of Yusho or Yu-Chen.

MR. JUNGERHELD: Well, the next question was going to be if he has an opinion, what the basis of that opinion is.

THE COURT: Go ahead.

Q. Do you have an opinion, Dr. Gaffey?

A. Yes.

THE COURT: He wants to know the basis of the opinion.

Q. Would you explain to the Court and to the Jury the basis for your opinion about the Yusho and the Yu-Chen incidents?

A. I have read published accounts by the Japanese scientists who investigated the Yusho incident, some of whom followed the patients in that incident for a decade or more, and I have read a recent report by a Dr. Navhuho Konito (sic) and colleagues who looked also at Yu-Chen and made an evaluation of the role of PCB in both of those incidents.

Q. Have the Japanese and, indeed I guess others, published a substantial amount of scientific literature concerning Yusho and Yu-Chen?

A. Particularly Yusho, yes, the Japanese have published -- I don't know how many. I have read only the Englished publications.

Q. You mean the English translated publications?

A. The English translated publications. Some of the publications were published in Japanese and translated into English. Others were published initially in English by the Japanese scientists.

Q. Do you read Japanese?

A. No, I do not.

Q. So then you have read -- have you read then English versions of the Japanese studies as well as those published in English in the first place?

A. Yes.

Q. All right, sir.

And is it within the field then, as I think you have already testified, of epidemiology to review these scientific works for the purpose of forming epidemiological judgments as to such events such as Yusho and Yu-Chen?

A. Yes.

Q. Then I would ask you what is your opinion as it relates to the epidemiology of the Yusho and Yu-Chen events?

MR. MC GRAW: Excuse me, Your Honor. I still object on the foundation and the hearsay element of what the Doctor is going to testify to. I'm aware that these are epidemiological studies that he is going to be testifying about and if he's going to be taking these studies of Yusho and interpreting the health effects I don't think he's qualified to do that.

THE COURT: The medical --

MR. MC GRAW: The medical health effects and the effects on the people in Yusho and the specific chemicals involved.

MR. JUNGERHELD: Your Honor, I would suggest that we have already had ample testimony from Plaintiffs' experts on both Yusho and Yu-Chen. I recall Dr. -- well, Dr. Miester, Dr. Chase and Dr. Zimmerman all spoke to those very issues and -- well, with less background, I would offer, than Dr. Gaffey has.

So this is a recognized scientific principal, particularly as we're dealing narrowly here within the field of epidemiology, and it is a valid principal as he's indicated in the field of epidemiology to address studies from an epidemiological standpoint.

Now, I don't see any scientific problem with that whatsoever and certainly there's not any evidentuary problem in the way that this case is already proceeding.

MR. MC GRAW: Your Honor, I think the people that Mr. Jungerheld mentioned were M.D.'s and toxicologists who had the ability to comprehend this. Not to comment on the literature itself and pull out the health effects they feel are relevant without knowing the basis of these health effects and the basis of the literature and further taking all this hearsay evidence and trying to put it together in statistical form here which really will be misleading.

MR. JUNGERHELD: I don't think so, Your Honor.

THE COURT: I'll allow it over the objection.

MR. JUNGERHELD: Thank you.

Q. Dr. Gaffey, then could you tell us in your opinion or -- well, you have indicated you have an opinion as to Yusho and Yu-Chen from an epidemiological standpoint. Would you tell the Jury what is your opinion of Yusho and Yu-Chen from that standpoint? From your field of expertise as an expidemiologist?

A. The examinations of both the rice oil and the blood levels of the people in Yusho and Yu-Chen showed that there were essentially three groups of chemicals present. There were PCB's, there were polyquaterphenyls, call them PCF's, and polychlorinated dibenzofurans, PCDF's. No doubt the people in those incidences were sick.

Now, the later Japanese paper points out that there have been observations of Japanese PCB workers whose blood levels of PCB were higher than Yusho victims but showed no symptoms of Yusho disease. The authors point out that these highly exposed Japanese PCB workers had no PCF's and no PCDF's in their blood.

Furthermore, observations of the Yusho victims over a decade showed that over that time the PCB levels in their blood declined until they were approximately equal to the background level in the population but they still had PCF's and PCDF's in their blood and they were still sick. Japanese concluded from this, and in my opinion they are correct, that the active chemicals involved in the Yusho illness were not PCB's but either PCF's or PCDF's.

They did further animal experiments that convinced them that the PCF's were of little importance and that at least in animals the PCDF's were the active toxins.

Q. Dr. Gaffey, as an epidemiologist and with the background that you have put before the Jury here I want to ask you this,

this relates to some earlier testimony that occurred in the Plaintiffs' case: As an epidemiologist with the background relating to the epidemiologic consequences, if you will, of PCB's do you have an opinion as to whether the following conditions relate epidemiologically speaking from your standpoint to the PCB exposure, and that would be the following conditions: Depression, anxiety, decreased libido, impotence, tiredness, immune response, and enzyme induction?

A. I have opinions about several of these.

Let me, if I may explain --

Q. The next question would be, yes, what is your basis?

MR. MC GRAW: Excuse me, Counsel. Your Honor, now he's going to explain the medical terminology and he's going to go into some diagnosis that have been already, as Mr. Jungerheld said, brought out in this trial and I don't think he's got the expertise to do that.

MR. JUNGERHELD: Your Honor, Dr. Gaffey is offered only as an epidemiologist. We have had that testimony from toxicologists and they addressed this issue. We have had testimony from M.D.'s and they have addressed their field of expertise as it relates to this symptomatology of PCB. I would submit to the Court that this man is speaking from the standpoint of an epidemiologist, which I think has been shown by the foundation to be a field of expertise that has direct bearing on the human aspects of the

alleged PCB exposure.

THE COURT: I'll allow it over objection.

A. Most of what I'm going to say represents not my own opinion but a quotation from published papers.

MR. MC GRAW: Excuse me, Your Honor.

MR. JUNGERHELD: Well, we are interested in your own opinion as an epidemiologist. That is what you have been qualified as.

A. I'm looking at these papers and evaluating them and assessing what I think they tell me in terms of my opinion regarding these conditions.

Q. As an epidemiologist?

A. As an epidemiologist. I'm not concerned with the diagnosis that were made. I have no competence to evaluate a diagnosis. But what I have seen, and it is on this I base my opinion, are papers by Baker and colleagues and by Kreiss and colleagues, who inquired of people with varying levels of exposures to PCB's what their illness experience has been in various areas. These two investigators agreed that there was no difference between the high and low PCB exposed people in certainly the following matters: Number one, fatigue; two, fever; number three, heart disease, doctor visits, the use of prescription drugs, reproductive problems.

It seems -- in my opinion if these people had difficulty with their immune system it would mean to me they'd have more

colds, or illnesses, more conditions requiring medical attention.

MR. MC GRAW: Excuse me. Now he's going into the medical field and his opinion talking about the immune system and what it affects. He's an epidemiologist. You have let him go into the literature. Now he's going into the people and their symptomatology and what they exhibit and what they should exhibit in the immune responses. He's not a doctor.

MR. JUNGERHELD: He's not being offered as a physician.

MR. MC GRAW: Well, he's testifying as one. That's the whole thing, Your Honor.

MR. JUNGERHELD: If I may finish my response to the objection, Your Honor.

THE COURT: Go ahead.

MR. JUNGERHELD: I would remind the Court that in a rather lengthy background relating to the field of epidemiology we took some time to go through yesterday afternoon Dr. Gaffey has indicated working with the -- as a matter of fact he has indicated what an epidemiologist does is to study the health effects of people. I forget just exactly how the wording was. But nonetheless it is looking at the health impacts over a group of people. Now, the health impact, the health diagnosis, and these sorts of

things are indeed done by others but nonetheless an epidemiologist looks at these in terms of the representation, if you will, in a particular group of people and it is this field to which Dr. Gaffey is addressing himself.

MR. MC GRAW: Just a minute ago he was addressing the immune system and testifying as to what effects he would expect to see or what these people should have seen. Now, that's going beyond anything -- that's going into the medical field.

THE COURT: I don't think so. I'll overrule the objection.

Q. (By Mr. Jungerheld, continuing.) All right, Dr. Gaffey, would you continue with the -- you were explaining the literature you have indicated from the Kreiss study and the Baker study and you looked at a large variety of health effects and please continue with that answer.

A. Well, I was saying that there was no reported differences between the high and low PCB exposed groups in such things as doctor visits and use of prescription drugs. No difference in illnesses that might be thought of as measuring a problem with the immune system.

In addition to that Fishbein and colleagues, who looked at a group of heavily exposed capacitor workers, said at the end of their study there were remarkably few liver abnormalities in this group.

Q. Dr. Gaffey, again from the standpoint of an epidemiologist, do you have an opinion regarding whether or not, again I emphasize we are talking about the epidemiological aspects of this, do you have an opinion as to whether or not high blood pressure, heart disease, or elevated triglycerides relate to PCB exposure?

MR. MC GRAW: Your Honor, I'm just going to make the same objection as to his qualifications to address these issues.

MR. JUNGERHELD: I would make the same response. I'm limiting his testimony to the field of epidemiology.

THE COURT: You're asking whether or not exposure to PCB's has these health effects?

MR. JUNGERHELD: Is has been shown from the epidemiological standpoint.In other words it's a similar question, if not indeed an identical question to the prior questions that we have talked about here. As an epidemiologist does he have an opinion. Does he have an opinion as to whether in the epidemiological field as it relates to PCB's these particular conditions that have been mentioned earlier in this case relate to PCB exposure?

MR. MC GRAW: Just so I'm clear, Your Honor, he's testifying as to what he's pulling out of the literature? Not to what the causes or symptoms of these are? Just from his understanding from someone else's work?

THE COURT: That's correct.

MR. MC GRAW: Which is also hearsay.

THE COURT: I'll allow it.

Q. (By Mr. Jungerheld, continuing.) Do you recall the question, Dr. Gaffey?

A. Yes. I'd like to preface it by saying there are some generally accepted ground rules for going about examining epidemiology studies to determine whether or not they actually show cause and effect relationship.

Q. Would you outline those to the Court and Jury, please?

A. These are stated more or less by material. The most recent by Sir Richard Dow (sic), he is the man who discovered the link between smoke and lung cancer. Dow's criteria are you can deduce a cause and effect relationship in epidemiologic studies if, first of all, the studies are unbiased; if they are good studies; second, if the people who exposed have a higher incidence of the health effect than the people not exposed; second -- third, rather, if this is statistically significant; and fourth, if there's a dose response relationship, that is if the more exposure the more ill health; and finally, these findings must be repeatable in different studies conducted at different times.

So if we use these general guidelines to look, first of all, at heart disease, say, the evidence we have on heart disease is first of all from the Kreiss study where there was

no differnce in reported heart disease; second, from the several long term mortality studies, which were designed primarily to look at cancer but which also looked at other causes of death, none of them found any excessive heart disease; and last, I think most important of all, PCB's are widespread in the American environment, at least, and whether we like it or not we have an opportunity to observe what happened to American mortality over the last 10 or 15 years in a situation at which PCB's were more or less universal in the environment. One of the most startling things that happened is heart disease started to go down in the late 1960's and has from then until now decreased by about 25 percent. Stroke has gone down, I believe, by that much or more.

So we have, if you will, an epidemiology study of two million people with a widespread exposure to PCB's over a period of which heart disease went down rather substantially. As a matter of fact the decrease was so much that when it started Public Health statisticians thought something was wrong with the data and meetings were held to question what mistakes have we made that have lead us to basically believe that heart disease was decreasing, but in fact it was real.

As to the issue of hypertension we have somewhat a similar situation. That is we have a marked decrease in

hypertension in the general population and we have two epidemiology studies that looked at hypertension. One of them, the Kreiss study, found an association.

The second one by Dr. Alexander Smith and his colleagues found no significant association looking at a group of utility workers that were involved in the maintenance and repair of transformers that used PCB oils.

So again, in the case of hypertension we have a couple of contradictory epidemiology studies and we have general population data in which the mortality has gone down rather substantially over a period in which there was general exposure to PCB's.

On the matter of triglycerides there are some contradictory reports in the literature. The Kreiss study, for example, finds that there is no excess triglyceride level in five PCB exposures if you adjust for cholesterol level. In other words Kreiss says the increase that is seen in triglycerides comes from the fact that these are associated with cholesterol. And if you say what would be the situation if there were no differences in cholesterol levels, her conclusion, there is noise association with triglycerides.

Other studies have found the opposite. I think one of the issues here is whether PCB exposures lead to increased triglycerides or whether people with higher triglyceride levels absorb more PCB's. PCB's are absored selectively by

fat. Triglycerides are related to fat metabolism. I think there is a real question as to whether the PCB caused the increased triglycerides or whether the situation is in fact the reverse.

Q. Dr. Gaffey, the term statistically significant has come up earlier and I notice you just mentioned it a moment ago.

Would you explain to the Jury the concept of statistical significant as it relates to the field of epidemiology?

A. Well, I think -- yes. The way to start may be to remind you of the school principal who was against intelligence testing because he said every child in the class was either above or below average.

Similarly, when we go an epidemiology study, particularly the long term ones that I have been most involved with, we end up at the end of our study with a list of observed numbers of deaths from different causes, and then a list of expected numbers. Expected numbers are derived through fairly involved calculations essentially using the weights in general population. The observed values almost never equal the expected values. They're either higher, or lower.

For example, in a rare cause of death I find the expected number of deaths is one half and I cannot -- every result I find would be either below expected or above. Well, intuitively most of us realize if you have small numbers of deaths, observed deaths, there's kind of a random variation.

That is if I do a study I may find four deaths from a certain cause. If I do the same study over again I may have three deaths, or five deaths so the fact that an observed value differs from the expected value is not in itself very important. If it differs so much that the result is improbable, then we tend to believe it. So statistical significance is simply the -- it's the result of a reasoning that says we will pay attention to the difference between an observed and expected value if the difference is so great as to be improbable and our threshold, that is by -- at a usual convention, that if something has less than one chance in 20 of occurring by chance alone we conclude that it's real. So when we look at observedand expected values we conduct a statistical experimentation and try to determine the probability of that descrepancy occurring and if you see probability by .4, .5, by the usual standards these are not standards because the differences are quite likely to have occurred by chance alone. If you see a difference with associated probability of .04, one usually says this is significant because it's less than one in twenty. So statistical significance is the evaluation of the difference between what you see and what you expect to see and evaluation in terms of how rare this would be and the decision, if it's -- if the probability is below a certain amount a decision that -- projectionally we will accept this difference

as real. So generally speaking differences that are statistically significant by convention are accepted as real subject to other caveats. Differences that have a probability of greater than .05 are generally considered not statistically significant.

Q. Is the concept of statistically significant important in the field of epidemilogy?

A. Well, yes. Of course, because if one didn't pay attention to these probabilities then, for example, if I did a study looking at mortality in 10 cases of cancer I'd expect five of those would be -- more cancer would be acknowledged and five of the cancers would show less. If I didn't pay attention to statistical significance every epidemiology study, even of a population that had no problem would always show some excess, and it would be very easy to show that everything is a carcinogen. Much the same as writing your name is a cause of cancer. Without the technique for evaluating whether a difference is random or whether it's so unlikely you have to pay attention to it. So this concept is a way of distinguishing between the variations you see that maybe cause random background noise, and the variations that are important and should be evaluated, or suspected of being real.

Q. Dr. Gaffey, from your standpoint as an epidemiologist do you have an opinion as an epidemiologist as to whether

carcinogenicity in humans, I'm talking about, relates to PCB exposure?

A. The existing epidemiology studies provide no support for that.

Q. Could you give us the basis for you opinion in that regard?

A. There are -- well, first of all in order to study carcinogenicity one must do more than simply examine a population of living persons. Because the interval between an exposure and the occurrence of cancer could be as long as decades. A study of the relationship between anything, PCB's for example, and cancer has to start by identifying a population that was exposed to several decades ago, following them over a period long enough so if it were cancer it would have that time to develop, and looking at the mortality in that interval to see if there was any excess mortality.

There have been either three or four studies in the literature, depending on how you choose to look at it. There's a large study done by NIOSH. The authors are Brown and Jones. I think they have been mentioned.

There was an Italian study. The senior author was Bentazzi. There was an unpublished very small study of Monsanto workers. The authors were Zack and Musch. And there was a study by a Professor Anita Bahn, B-a-h-n, of chemical workers.

Now, the final -- the last study, that of Bahn, was never really published. It was announced in a brief note to

the New England Journal of Medicine in 1977, and according to the NIOSH criteria document on PCB's was withdrawn in 1977 because of some doubt as to whether the exposures were accurate, whether the group study had been accurately characterized as to exposure. It was never released. The author died a couple of years later, but the study has never been released yet.

Nevertheless, whether we consider three or four studies the thing that they have in common is that they don't agree with each other. In other words the final one of these guidelines for incurring carcinogenitity, the one that says the study should be repeatable, fails when we look at the studies we have. The excesses that occur in Brown and Jones occur in none of the other studies. The excesses, that occur in Bentazzi is found in none of the others. The excess that occurs in Zach and Musch is found in none of the others. The excess that occurs in Bahn is found in none of the others.

Let's look for a moment at the Brown and Jones study, because it's the largest of the group. It's a large group of people. The average length of follow-up was about 16 and a half years. Now, the Brown and Jones found an excess of liver cancer. It was not statistically significant but it's frequently mentioned and perhaps that's worth a little more attention.

If you look at the actual publication by Brown and Jones

you find that this excess of liver cancer does not obey one of the basic rules, that is it does not -- the excess does not get worse with increasing exposure. It gets less.

If you look at what is called latency, the interval from the beginning of exposure to the occurrence of the disease, again if it were occupational, the longer the latency the greater the excess. But in fact what happens in Brown and Jones is they look at three intervals after exposure. First 10 years, second 10 years, third 10 years. And that liver cancer excess is about six fold in the first 10 years. It's about two fold in the second 10 years. And there's a deficit -- it's less than expected in the third 10 years. So the numbers involved are very small, but if one looks at it it behaves just the opposite of what one would expect. If you look at it by duration of employment you find that all of the people who died from the liver cancer had less than five years of employment.

Now, this again violates the other rule. A little bit is bad, a lot should be worse, and here we have a situation which apparently a little bit is bad and a lot is good. What this means to me, this is not consistent with an occupational explanation.

The other excess that gets a good deal of attention in Brown and Jones, an excess of rectal cancer. And there again, epidemiologically, the pattern does not make sense as

far as relationship to occupation, for one thing. The excess is confined to one plant of the two that was studied. It's confined to women in that one plant. And the third thing is the plant that was studied is in a part of the United States in which the regional mortality rectal cancer is high. There are regional differences in mortality for most cancers.

MR. MC GRAW: Objection, Your Honor. Could we get the foundation for this testimony.

THE COURT: You mean for the regional difference?

MR. MC GRAW: For the regional difference. For all the papers he's citing and some of the cites and background levels. He's impeaching these papers and I'd like to know the foundation for where he's getting all this information to impeach these papers.

THE COURT: Well, it sounds like most of it is from internal, within the paper itself. But as to his background in the area, what is the basis of that information?

MR. JUNGERHELD: All right.

Q. Dr. Gaffey, would you tell the Court and the Jury what the basis is for your statement about a differing background around the United States? Background incidents of cancers of various types around the United States?

A. Yes. About 10 years ago the National Cancer Institute --

Q. Let me interrupt at this point.

Would you explain what the National Cancer Institute is?

A. All right. The National Cancer Institute is a government agency. It's part of the National Institute of Health which in turn is part of the Department of Health of Human Services.

Q. Are what you going to speak about then a publication of this agency of the United States government.

A. Yes, it is.

Q. All right.

A. This was a publication that resulted from calculations done by epidemiologists who worked for the National Cancer Institute using data provided by the National Census Bureau.

Q. Are you talking about the United States Census Bureau?

A. Yes, I am.

What the National Cancer Institute did was to identify -- for all the major cancers they calculated mortality rates by county for the United States. There was something like 3,000 such rates for each cause of cancer. They then adjusted these rates because there are differing age distributions in different counties and since cancer increases with increase in age if you saw a difference between two counties you might say we don't know whether this is a real difference or whether it's due to age differences. They

adjusted these rates for age using standard techniques so what they ended up with was a collection of rates which if they varied from county to county would be for reasons other than age. They did this for -- I forget how many, some 20 or 30 of the most important cancers and published this in a book of rates. But in addition they published some maps and the maps showed the position of each county with respects to the rates with color.

For example, the counties colored red rates in the top 10 percent in the United States counties. And which -- rates which were in the top 10 percent and were also statistically significantly high, so you could look at a given cause of death on one of these maps and the counties that were high in the sense I described are red. And there are regional groupings for different causes of death. For digestive cancer, particularly, cancer of the colon, and rectum, there is a stretch of red counties in the northeastern United States. This is the area in which Plant No. 2 of Brown and Jones is located. This is the reason why I said the background rate in the area of that plant was high.

Now, the study that was done by Brown and Jones --

Q. Let me interrupt a moment, Dr. Gaffey.

Would you give us the name of the government publication that set out the county by county rates?

A. The senior author was a Dr. Mason and it's called United

States Cancer Rates by County, 1955-1969.

This publication has recently been updated to 1979. However, the picture, at least as far as corresponding to the new one, have not been put out. Nevertheless, the National Cancer Institute has said with respect to the update that there are few major changes in the major causes of cancer. A few things have gone up. Lung cancer has gone up. Cancer of the uterus in women has gone down. Stomach cancer has gone down but there are no trends that warrant a trend early.

Q. And with reference then to the incidence of rectal cancer shown in the Brown and Jones study, are you relating that then to what is shown in this publication of the National Cancer Institute of the National Institute of Public Health of the United States government?

A. Yes. Because of technical reasons Brown and Jones had to compare what they observed to the United States first. If they compared the rates of the counties in which the plants were located it is clear that the excess in rectal cancer would have been smaller. Whether it would have disappeared or not I don't know. But there's no -- it's clear that calculation with that other standard would have reduced that excess.

I think that the finding in the other studies, because of their size, are simply not in my opinion as important

except for the fact, as I say, that the excess of Brown and Jones disappear in the other studies. Their excesses disappear when you look at Brown and Jones. So what we are seeing in this collection of studies is just about what you would see if you studied a group of people who had no excess risk. You would find, yes, indeed, every time you look at a population there would be some increase in cause of death, decrease in others. If you looked at three or four populations you would see different rates in population cropping up. Excesses, deficits. So what I see in these studies is what I what I would expect as an epidemiologist. If I studied a group of people that have nothing in particular on them. Excesses would pop up in some and deficits in others.

Q. Are you saying overall groups in all of these cancer studies --

A. Yes, I'm saying if I look at the studies that have been done of established human carcinogens, asbestos, vinyl chloride, nickel compounds, they are -- the studies are consistent. All asbestos studies show an excess of lung cancer. All vinyl chlorides show an excess of liver cancer. All nickel studies show an excess of nasal cancer. Here we don't have that consistency. The consistency that makes it convincing.

Q. Dr. Gaffey, as an epidemiologist do you have an opinion as to whether PCB's pose an unreasonable risk of harm to Mr. and Mrs. Haley in ingesting milk and meat that resulted in the

serum concentrations that have been testified to in this case?

A. The data -- most of the data that I have used or looked at in reviewing the literature dealt with occupationally exposed people whose blood levels were quite high, more often than not above a hundred parts per billion. In view of the fact that there are no ill effects other than chloracne in that group I -- in my opinion there can't be health effects in any individuals or groups with the exposures which is much lower than that. My argument is if nothing is found in people with high exposures then nothing could be found in people with low exposures. The argument if a lot of it is harmless, less of it would be harmless.

MR. JUNGERHELD: Your Honor, I believe that's all with this witness.

THE COURT: Mr. Davidson.

MR. DAVIDSON: No questions, Your Honor.

THE COURT: Mr. McGraw?

MR. MC GRAW: Thank you, Your Honor.

CROSS-EXAMINATION

BY MR. MC GRAW:

Q. Dr. Gaffey, my name is Pat Mc Graw. I think we have met before once in St. Louis and once at Michigan State.

Just going through your curriculum vitae did you obtain a Master's in between your B.A. and your Ph.D.?

A. No, I did not.

Q. Doctor, we got a definition of the word epidemiology. Does the word epidemic have anything to do with the origin of that word?

A. Yes. The first epidemiologists were people who studied epidemics, infectious diseases.

Q. Just had to do with infectious diseases?

A. Yes.

Q. Did it go on to systemic diseases?

A. Yes.

Q. Does it involve health and medicine?

A. I don't think I understand your question.

Q. Now, I guess what I'm getting at, as an epidemiologist are you required to get involved into the medicinal treatment of people or to their health effects and the underlying causes for their diseases?

A. No.

Q. Do you consider that important?

A. It depends on what diseases are involved and it depends on what kinds of exposures are involved.

Q. Okay. Let's take heart disease. Are there numerous causes for heart disease?

A. I believe so.

Q. Do the studies when they address heart disease, do they address the particular cause of the heart disease?

A. Sometimes, yes; sometimes, no.

Q. So if they didn't then would the study be any good in your mind?

A. Oh, yes.

Q. Oh, it would?

A. Yes, indeed.

Q. Why would that be?

I guess what I'm looking at, you got heart disease, you lumped your study into a general category of heart disease. But then there are different causes of heart disease. So now you're going to make a general statement based on all the heart disease without looking at the individual causes, which I think are important. Don't you?

A. That depends. We know, for example, that there are people who give certain kinds of answers on personality tests than people who give other kinds of answers. We have no idea what the cause and effect is but that difference is an epidemiological observation and it has value.

Q. Okay. As far as your studies go to show that one fact?

A. Yes.

Q. Do you have a degree in medicine?

A. No, I do not.

Q. Do you have a degree in public health?

A. No.

Q. Was that offered at the time you were in school?

A. Not in public health statistics, no.

Q. Okay. What kind of medical classes have you taken to assist you in your work?

I have taken classes in physiology and enzymology.

I've worked with physicians in the California Department of Public Health for about 10 years.

Q. What kind of physicians did you work with?

A. These were physicians with -- physicians were public physicians. Some of them with certification in pediatrics, some in general medicine, and some in preventative medicine.

Q. Did you ever take any anatomy classes?

A. No, I did not.

Q. Enzymology?

A. Yes.

Q. Infectious diseases?

A. No.

Q. Systemic diseases?

A. No.

Q. What about chemistry?

A. I have had courses in inorganic chemistry.

Q. What about organic?

A. No, I have not.

Q. Biochemistry?

A. No.

Q. Pharmacology?

A. No.

Q. You related in your deposition that you did a study at Monsanto involving workers exposed to PCB's?

A. If I did I was mistaken.

Q. Oh?

A. The study was done but not by me.

Q. Were you involved in that study at all?

A. I was involved in reviewing the text of the write-up.

Q. Did you ever visit any of those plants?

A. Yes.

Q. Which plant was involved?

A. That was the plant in East St. Louis.

Q. Did you come to any conclusions in that study?

A. I'm afraid -- I didn't do a study.

Q. Okay. You reviewed that study though?

A. Yes.

Q. Did it reveal anything significant?

A. No, it did not.

Q. Was it a good epidemiological study?

A. Yes. The sample size was small, which was beyond our control, but the study was good.

Q. Okay. Was it one of your criteria that you have a large number of people to sample?

A. As large as possible.

Q. Okay. Could you tell me what kind of people were involved

in that study?

A. They were people whose job histories indicated that they had worked in the unit in which PCB's were produced.

Q. For how long of a period of time?

A. I believe one year. That is one year or more.

Q. One year exposure?

A. Yes. That is one year of employment in the unit in which they were -- in which the material was produced.

Q. Okay. They all didn't have the same job then with touching it or sealing it? Some of these could have been truck drivers? Some of these could have been foremen?

A. They were hourly workers so they would not have been foremen.

Q. Okay.

A. They could not have been truck drivers because that would have been reflected in their job title. Since we're looking at exposures in that case before 1966 the people who did the study were limited to the records that were available by their work histories.

Q. What kind of records were available?

A. A typical work history record. Gives, as a man changes jobs, the date on which he entered the new job, the title of the job, and the location at which the work was performed.

Q. Okay. Were all these people the same race? Same sex?

A. They were all male. I don't know whether they were all the same race or not.

Q. Did you know at the time of your deposition?
A. Not that I can recall.
Q. Do you know the average daily exposure that these people were exposed to?
A. No, I do not.
Q. Do you know the degree of exposure?
A. No.
Q. Do you know the route of exposure?
A. I don't know the route of exposure, no.
Q. Okay. You think those would be important in doing a good epidemiological study?
A. If they could be determined they would be important.
Q. And if not you just forget them and do the study anyway?
A. The study has value. It may not -- you may not be able to quantify a relationship but if you find nothing the study has some value.
Q. To who?
A. To the workers mostly.
Q. You talked about vinyl chloride. What is the chemical composition of vinyl chloride?
A. I don't know.
Q. Is it similar to polychlorinated biphenyls?
A. No. It's a much simplier compound because of the molecule.
Q. What does the molecule look like?
A. I'm afraid I can't tell you right now.

Q. What does the molecule of PCB look like?

A. I can tell you in very general terms.

Q. That's fine. I'm just trying to see what the similarities between vinyl chloride and PCB's.

A. The PCB molecule is essentially a couple of benzine rings which are hexagons of carbon molecules attached together by a couple of oxygen atoms and to the periphery of that ring can be attached varying numbers of chlorine atoms. The number of atoms distinguishes between the biphenyl and the triphenyl and the quaterphenyl, and the position in which those atoms are attached determines to some extent the chemical properties of the substance.

Q. Okay. We were talking about the atoms. You're talking about the placement of the chlorines on the benzine rings?

A. That is correct.

Q. Vinyl chloride, that also has chlorine in it, does it not?

A. Yes.

Q. And does it also involve benzine rings?

A. No, it does not. But in addition vinyl chloride is a compound -- polychlorphenyl, or class of compound.

Q. Meaning what? When you refer to a class of compound how are you referrring to that?

A. Oh, of the molecular makeup I described there could be several variations on that I can picture, depending on the

number and placement of the chlorines. They would all be called PCB's. In the case of vinyl chloride there is a unique formula and that formula -- and that one only is vinyl chloride.

Q. Okay. Would a unique formula be something like Aroclor 1254 where you know the placement of the chlorines and the percent chlorination?

A. If I recall Aroclor 1254 is a compound defined only by the percent of chlorination so it is not a unique compound.

Q. Have you ever done any studies directly related to Aroclor 1254?

A. No.

Q. Do you know what the chemical involved in this case is?

A. It is one of the class of PCB's.

Q. Do you know which one?

A. I believe it's 1254.

Q. You testified you reviewed the literature with regard to PCB's. The literature reviewed, does that use consist of epidemiologic studies?

A. Yes.

Q. And those studies, did they summarize a lot of other studies to get effects?

A. A typical -- such study, particularly when they present their results, will refer and compare them to previous studies.

Q. Epidemiological or reviewed studies?

A. Sometimes both.
Q. When you reviewed this literature with regards to the health effects caused by PCB's or halogenated hydrocarbons, did you see any effects that related to the liver?
A. Yes.
Q. On the liver enzymes?
A. Yes.
Q. On the immune suppression system?
A. No.
Q. On dermatitis?
A. Yes.
Q. Carcinogenicity?
A. No.
Q. No studies on carcinogenicity?
A. You said studies that showed effects?
Q. Okay.
A. And no, I saw no such studies.
Q. Are you familiar with Rene Kimbrough?
A. Yes.
Q. Did her study show any effects?
A. She's never done an epidemiology study on PCB's.
Q. Did she do any studies with carcinogenicity?
A. If she did they were with animals, which is beyond my province.
Q. Okay. You don't know what she found even with regard to

animals?

A. Only what people have told me.

Q. Okay. Did any show effects in increased blood pressure?

A. Did any?

Q. Any studies you have looked at show an increase in blood pressure?

A. Yes.

Q. What about fetal toxic effects?

A. I'm aware of no studies that directly address this. But the study of Kreiss addressed it by asking the exposed people whether there was any problem.

Q. Okay. Reproductive effects?

A. The same answer. Kreiss addressed the issue by inquiry of the subjects which she studied.

Q. Arthritis?

A. Baker addressed that question. Again, by inquiry amongst the people that he studied.

Q. Stomach --

A. That was also true of the Baker study, yes.

Q. Early abortions?

A. Kreiss made inquiry in that area.

Q. Irregular menstrual cycles?

A. I'm not aware of any study.

Q. On those symptoms I just listed have you done an epidemiologic study on any of those individually?

A. I have not.

Q. Do you know how many PCB articles there are in the literature?

A. No.

Q. Do you have any idea?

A. If one includes animal work I imagine it must be several hundred.

Q. Do you know how many there are including halogenated hydrocarbons in general?

A. No, I don't.

Q. Could you venture a guess?

A. I'm afraid not because it's such a wide class of chemicals I have no idea.

Q. Would you agree there are thousands of articles on that?

A. There might be.

Q. How many did you review for today?

A. Twenty-two.

Q. Doctor, when you talked about a paper, or talks you gave, was one entitled, "The Epidemiology of PCB's," by William R. Gaffey, Monsanto Company, September, 1981?

A. That's correct.

Q. Was that the study you also, or talk, you gave at Michigan State University?

A. No. At the Michigan State University I looked at the study done after 1978 in somewhat more detail and reviewed those.

Q. Were those all industrial exposures?

A. No. They included the studies by Baker and Kreiss, which in the first case were mostly community people and the second case entirely community people.

Q. How were those community people exposed?

A. In Baker's case he looked at some people who used municipal sludge in their gardening. This sludge had an elevated level of PCB's. He had a second group, I think, who were, I believe relatives of PCB workers or families and third, he had a general community group.

In the case of Kreiss, he looked at people in the community which consumed fish that had unusually high levels of PCB's.

Q. And where was the location of that study?

A. It was in Trinana, Alabama.

Q. Where were they getting the fish from that they were consuming?

A. I can't tell you the name of the river but it was fish caught locally and consumed in a local river. I don't know the name.

Q. Was it near Anniston?

A. I have no idea.

Q. Does Monsanto have a plant in Anniston?

A. Yes.

Q. Doctor, are you familiar with the paper I have just mentioned?

A. Yes.

Q. Okay. I just wanted to ask you a few questions as I was going through it.

A. Sure.

Q. I wonder if you would answer those for me? How far back does the literature go in talking about effects of PCB's in humans?

A. I don't know. If you ask me about an epidemiology study, you know.

Q. Okay. Epidemiological?

A. I think the first -- let's see, there was a report by a Meigs, W. Lester Meigs, which was not strictly an epidemiological study but nevertheless ended up looking at risk. That was sometime before the Yusho incident. I believe it may have been in the '40's.

The rest of the epidemiology studies essentially followed the Yusho incident so they ran from about 1969 on up.

Q. Okay. When you did this paragraph on PCB's you entitled it, "The Epidemiology of PCB's," but I notice throughout the article you in your bibliography you refer to articles going back in the '30's?

A. Yes. If I'm not mistaken what I said at the beginning is that this is an example of the things that are not epidemiology, although they may be useful in guiding subsequent studies. I started it by saying I wanted to distinguish

between epidemiology and clinical reports such as, and it gave a couple of examples that found their way to my bibliography.

Q. You are aware of clinical reports that have been done on the effects of PCB's?

A. Oh, yes.

Q. When was the first clinical effect that you are aware of with regard to exposures to PCB's noted?

A. I believe there was one in the '30's, although it's a little bit hard to say. The substance referred to was halo wax. I know about that because it as an example --

Q. Halo wax is a halogenated hydrocarbon?

A. I'm afraid I know it only as halo wax because I didn't read the study after I found out that it was a clinical report.

Q. Did you cite that in your publications?

A. I cited the study as an example of something that was not an epidemiology study.

Q. But you didn't read that study before you put it in here?

A. Oh, I skipped through it and found it said things like a report of some people got sick. Well, that was sufficient to identify it as not being an epidemiology study.

Q. Why was that?

A. Because there was no attempt to look at the people who did not get sick which were similarly exposed.

Q. Did the article say anything about the people that did not get sick who were exposed?

A. No, it did not. It did not. This was a clinical description of people who got sick and so it was of no assistance to me in looking at matters of risk.

Q. So if you see a lot of articles which show exposure and some clinical signs or some injuries, unless they show a control group you don't consider it?

A. I think it might be a good reason to do an epidemiology study.

Q. Okay. If you were seeing the signs back in the '30's or '40's, you think that might be a good reason to start an epidemiological study?

A. If I saw them and if there were any epidemiologists around.

Q. Were there back then?

A. Not many.

Q. Do you know what kind of or types of effects were noticed in the literature in the '30's and '40's?

A. No, I do not.

Q. You also talked about in your studies that you did they fell into three categories. One was a relationship between exposure to PCB's and the resulting body burden of PCB's in serum or adipose tissue?

A. Yes.

Q. Then you talked about the relationship between the level of

exposure and the body burden. If those can't be verified the interpretation of the studies become difficult if not impossible?

A. That's correct.

Q. So in other words, what we need is some way to verify the body burden of PCB's with the exposure?

A. No. That was already verified by the studies that I reviewed.

Q. What? The body burden?

A. The studies that I reviewed showed that the greater the exposure the greater the body burden.

Now, if they had failed to show that I would have said, well, we're wasting our time in all these epidemiology studies because if I can't show that people who are occupationally involved in PCB's have a higher body burden there's no point in doing the study. But the material I reviewed showed in fact there was a relationship so it just justified going on and looking at these other studies.

Q. What kind of exposure is needed to get a body burden of, let's say, 10 ppm adipose tissue?

A. I have no idea.

Q. What about 50 parts per billion serum?

A. I don't know. Except the officiators in the Trianan1 population at the older ages had levels of around 60 parts per billion, if I recall correctly.

Q. In their serum?

A. In their serum.

Q. What about their adipose tissue?

A. No adipose tissues were made.

Q. Do you know what the Haleys' adipose levels are?

A. No, I do not.

Q. Do you know what their serum levels are?

A. I know Mr. Haleys' was 50 parts per million.

Q. Do you know Mrs?

A. No, I do not.

Q. You gave an opinion, Doctor, on whether they are at an increased risk based upon their serum levels and their fat levels and knowing what their body burden is. How could you give an opinion without knowing that?

A. I don't believe I gave an opinion based on their fat levels. And what I said, I did not know what Mrs. Haley's level was. I know that it was lower than that of her husband, but I don't know precisely what it was. So I'm dealing here with a situation in which the serum PCB levels are 50 parts per billion or less.

Q. Have you seen any documentation to that effect?

A. No.

Q. Did you take into consideration what they have in their adipose tissue?

A. No, I have not.

Q. Why don't you do that?

A. Because practically none of the epidemiology studies on which I base my opinions have measurements of adipose tissue.

Q. Okay. In your paper you talk about two epidemiology studies of accidental exposures were reported. You talked about Meigs who in 1954 described an outbreak of chloracne in a plant in which a process changed introduced an unspecified PCB compound into the work environment.

First of all what is an unspecified PCB compound?

A. I don't know. I believe I quoted Meigs.

Q. Okay. You said seven of fourteen exposed workers developed chloacne.

A. Yes.

Q. But liver function tests were normal in six of these with some borderline abnormalities in the seventh?

A. That's correct.

Q. What about the other seven workers?

A. I don't believe Meigs examined any except those who got chloracne.

Q. So you're saying seven out of the fourteen had -- or six of the fourteen had some normal liver function tests, the seventh was borderline abnormalities, and you're saying he didn't study the other seven if they didn't get chloracne?

A. He didn't report on the other seven.

Q. Do you consider that a good epidemiological study? He didn't look at the other seven? Reports on half having normal liver, and just ignoring the other half?

A. In my opinion the ones that got chloracne probably had a higher exposure than the ones that did not. I would rather that he looked at the whole group but I'm convinced that he looked at the group with the higher exposure. The 50 percent who had the higher exposure.

Q. Did you ever talk to Meigs?

A. No.

Q. Just looked at his paper?

A. That's all.

Q. And your conclusions are from his paper?

A. That's correct.

Q. And you don't know the PCB compound he is talking about?

A. No, I do not.

Q. You don't know for sure if the other six people then -- whether they had abnormal liver function or not?

A. No, I don't.

Q. You also said that in here, talking about the Yusho incident, they showed elevated serum triglyceride levels, lower serum cholesterol, and serious cases elevated SGOT and SGPT levels in serious cases?

A. I believe that's correct.

Q. Do you know what the SGOT and SGPT tests are for?

A. They test the induction of the various liver enzymes.

Q. Have you ever seen any epidemiological studies that tested these liver enzymes?

A. No.

Q. Do you know that PCB's do effect liver enzymes?

A. In certain cases, yes.

Q. Do you think that would be an element to look at when you do a study then to find the liver function?

A. Oh, yes.

Q. You also talked about the percentage of cancer deaths being 35.4 predictor in which the deaths occur and you qualified that by saying it wasn't useful for several reasons?

A. Yes.

Q. But at that time was there cause for concern, do you think, about the effects of PCB? Whether they did cause these effects?

A. My gosh, no. The cases -- the situation that you have described, all of these deaths were reported as of approximately 10 years after the PCB incident. There's no indication in the report which I read of when those deaths occurred. They may have occurred any time over that 10 year period and even if they had occurred at the end of that 10 year period that latent period is shorter than what most people would accept as being reasonable for suspecting PCB's as a cause of cancer.

Q. How long a latent period do you think we'd have to look at PCB's for a cause of cancer?

A. I'd say 15, 20 years.

Q. What is the latency period in other chemicals? Asbestos?

A. If I recall it's 15, 20 years. It's longer for some. Longer for mesothelioma. It's 30, 40 years. For the average latent period I'm talking about.

Q. Do you know whether it's been reported what the latency period is for PCB's?

A. Since they're not carcinogenic they have no latency period.

Q. That's in your opinion?

A. That's in my opinion. But that aside, I've never seen any reference to latency periods for PCB's.

Q. Have PCB's been declared carcinogenic in animals by any governmental agencies?

A. Yes.

Q. Does that lead you to conclude there might be a latency period?

A. In animals.

Q. In your paper you didn't say anything about PCB's not being a carcinogen in humans, but you did make the statement after you -- less than 10 years cannot be calculated on the death of those people. Then you went on to say that this may well be too short a period of cancers for exposure to show up.

Did you have an idea that PCB's were carcinogenic?

A. No. I said if they were then I'd expect a latent period similar to that of other carcinogens, so I would want more than 10 years.

Q. If PCB's are considered carcinogens for animals do we normally consider they are suspect for humans or should be treated as such?

A. Depends on the analytical evidence. And it also depends on what you mean by suspect. Certainly the international agency for research in cancer has classified PCB's as an animal carcinogen but considers the human evidence inadequate.

Q. Do they also say it's a suspect human carcinogen?

A. Yes. But I just defined what we mean by suspect carcinogen.

Q. Do you know what they mean when they talk about a carcinogenic risk?

A. Are you talking about --

Q. The one you have been talking about.

A. Yes, I believe I did.

Q. What is the definition they used?

A. I can't tell you right offhand.

Q. Maybe I can help you and you can tell me if it sounds familiar. The probability that exposure to the chemical will lead to cancer in humans?

A. That seems a reasonable definition. Certainly.

Q. Do you recognize the International Agency for Cancer as reliable?

A. In areas to which they have addressed themselves. Although, I have criticisms of some of their work.

Q. You don't think they're an agency -- you mean in the cancer area? I'm not talking about the other work that they do. I'm talking about the cancer aspect.

A. So am I.

Q. All right. So they are qualified in the cancer area?

A. No. I say I object to some of the work they have done in that area. Particularly with respect to PCB's.

Q. All right. Are you aware of when we talk about the relationship between PCB's in blood levels, are you aware of besides the Kreiss study any others?

A. There a number of Japanese studies of Japanese PCB workers that have measured blood levels. I can't recall offhand to what extent. They also measure air levels so as to get a comparison.

Q. Are you familiar with Dr. Humphrey's work in the State of Michigan?

A. Yes.

Q. Are you familiar with his work in the area of the silo farmers and fish eaters?

A. I'm familiar with his work on the fish eaters.

Q. You were at that seminar at Michigan State? The symposium on PCB's? Were you there when Dr. Humphrey gave his presentation?

A. I think I was.

Q. And relating the incidences of cancer, they found up to that point between the fish eaters and the silo farmers?

A. He didn't find any in the fish eaters.

Q. How about the silo farmers?

A. If I recall he said he found a small amount or at least he found a preliminary -- I don't recall any detail.

Q. You don't recall the numbers?

A. No, I don't. Because I would have expected this to be published and we don't -- you know, here we have something that had it been developed it would have been published.

Q. You never saw the published form of that then?

A. No, I have not.

Q. Have you looked for it?

A. Not recently, no.

Q. Does higher exposure to PCB's mean a higher body burden?

A. On the average I believe it does.

Q. We talked about the Haleys' fat levels here. I don't know if I told you exactly what they were. Do you know what kind of exposure they had been subjected to?

A. No, I don't. Except in the most general terms.

Q. Do you know how long their exposure was?

A. No, I do not.

Q. Do you know the dose they were getting?

A. No.

Q. Doctor, at the end of your paper you kind of summarized the PCB epidemiological studies other than mortality.

A. Yes.

Q. In the summary of findings you listed 17 studies, and they had all the studies listed, and then you had three areas of findings. Dermatologic; physiological; symptoms and illness; and others. Excuse me, four. What are the others?

A. If I recall -- let me see the symptoms and illness -- I think I classified and others a study that found altered pulmonary function levels which, if I'm not mistaken, I couldn't decide whether that was a symptom or an illness.

A. If there's a blank in there does that mean there wasn't anything looked at in that area?

A. That's correct.

Q. Okay. And out of these 17 studies here, how many out of the 17 found dermatologic findings?

A. Eight.

Q. How many found physiological parameters?

A. Ten.

Q. What about symptoms and illness?

A. Two.

Q. And others which you referred to as pulmonary functions, how many did they find?

A. One.

Q. And how many times was that looked at in there?

A. Once.

Q. How many studies did you list in the back of that booklet which showed the inconsistencies in the study of cancers in PCB exposed to populations of findings?

A. I believe in the earlier paper there was four.

Q. Is there an update to this?

A. No. Except one of them -- this one was withdrawn, you see.

Q. Do you know if that was because she died, or was it because of some other reason?

A. It was withdrawn approximately two years before she died and the NIOSH criteria document on PCB's states it was withdrawn because there were doubts about the accuracy of the classification of the exposed population.

Q. Who withdrew it? NIOSH or Bahn?

A. Bahn or her representative. I don't know which.

Q. Do you know what she died of?

A. She had a stroke.

Q. On these four studies here, how many were studied in the Bahn study?

A. There were 92.

Q. What were the findings?

A. An excess melanoma.

Q. What is a melanoma?

A. It's a type of skin cancer. Most skin cancers are not really serious. Melanomas is the type which is and can be

fatal.

Q. Are there any skin cancers, if you know?

A. I beg your pardon?

Q. Are there any skin cancers that are not serious?

A. You get them by suntan and the majority are treatable in a doctor's office and not lethal. Might consider the price of the suntan.

Q. What about the study by Zack and Musch? That was, as you said, Monsanto's employees?

A. That's right.

Q. How many people did they study?

A. Nine.

Q. And what were their findings?

A. The only excess was one of lung cancer. I forget on how many cases it was based but it was not statistically significant.

Q. What about Brown-Jones? How many did they study?

A. A large number. Two thousand five hundred sixty-seven.

Q. What kind of cancers did they find?

A. Liver and rectum.

Q. What about Bentazzi? How many she study?

A. I think it was a he, but anyhow it was 1,310 people.

Q. What kind of cancer did they find?

A. Digestive,hemaphic and hemaphoric, lukemia and lothorium. (sic)

Q. Do you agree with any of those studies and their findings?

A. Well, I agree with most of them.

Q. Okay.

A. Because they said further investigation is necessary. We don't think this means much.

Q. Okay.

THE COURT: At this hour, Mr. McGraw, we'll take our recess.

Members of the Jury, retire to the Jury Room. We will call for you in about 15 minutes.

(Whereupon at 10:30 o'clock A.M., a recess was taken.)

THE COURT: Mr. Mc Graw?

MR. MC GRAW: Thank you, Your Honor.

Q. (By Mr. Mc Graw, continuing:) Doctor, when we left off we were talking -- we had just left Bentazzi's study you had reviewed.

I wanted to ask you, have you ever heard of a publication from the U.S. Department of Health and Human Services, Public Health Service, which was put on by the National Toxicology Program at Research Triangle called Carcinogens?

A. No, I have not.

Q. Maybe I can show you the book and you might recognize it?

A. Not offhand, I'm afraid.

Q. The participants for that were the Department of Health and Human Services, National Toxicology Program, Centers for Disease Control, Consumers Product Safety Commission, Environmental Protection Agency, Food and Drug Administration, National Institutes of Health, National Cancer Institute, National Institutes of Health, National Institutes of Environmental Health Sciences, National Institutes of Health, National Library of Medicine, Department of Labor, Occupational Safety and Health Administration.

Do those seem like an impressive list of people that would have some knowledge in this area?

A. Extremely so.

Q. Do you think that booklet may be something you would want to

consult when you are looking at carcinogenic data?

A. My recollection is that the National Center for Toxicological Research confines itself to animal investigations.

Q. So what you are saying is there is no inclusion of humans mentioned in this booklet?

A. I don't know, but on the face of it I would have said that since it occurred at the locality of the NCTR, I would have expected it to be concerned with animal work.

Q. Do you have anything to do with estimating risk reduction as an epidemiologist?

A. No.

Q. Do you know whether EPA has included PCB's on its list of carcinogens?

A. It has been ordered to ban PCB's because of the passage of the Toxic Substancs Control Act.

Q. Which states what?

A. It states that PCB's are carcinogens.

Q. Does that contradict what you said earlier that you don't think PCB's are carcinogens?

A. Yes.

Q. Do you have an opinion now whether they are carcinogens or not?

A. They are not.

Q. They are not?

A. (Witness nods head.)

Q. You disagree with all those agencies?
A. Yes. That is, I disagree with what you have implied to be the position of those agencies. I don't know what their position actually is.
Q. Okay. What kind of people are involved in those agencies? Are they medical doctors, toxicologists?
A. It's impossible to give a simple answer.
Q. They cover a broad range of spectrums?
A. If you included NIOSH, they included epidemiologists.
Q. Is NIOSH the only one that includes epidemiologists?
A. No: NIEHS -- well, I take that back. EPA may have had some epidemiologists -- what is the date of that conference please?
Q. December, 1981.
A. They may have had an epidemiologist or two at the time of that.
Q. Do you know what those epidemiologists had to say about PCB's and carcinogenicity?
A. No, I do not.
Q. Doctor, you said that the Japanese scientists concluded in the -- I suppose we're talking about Yusho when you are talking about Japanese scientists, rather than the Taiwanise incident.
A. The reference that I made to the 1984 paper, the Japanese scientists looked at data from both Yusho and from the

Taiwan incident.

Q. And, in your opinion, they concluded that PCDF's were the active toxin?

A. That is correct.

Q. How are PCDF's manufactured?

A. First of all, I don't believe they are. I believe they're contaminants, but I don't know how they're produced.

Q. Are they contaminants of PCB's?

A. They have been of some PCB's.

Q. Of Aroclors?

A. I don't know.

Q. Cantaclors?

A. Yes.

Q. Do you know the percentage of chlorine that was involved in the Yusho incident?

A. No, I do not.

Q. Did these studies that the Japanese scientists reported on, did they look at the blood serum?

A. Yes.

Q. And that was in parts per billion?

A. That is my recollection.

Q. Well, how was blood serum normally reported?

A. Parts per billion.

Q. Did they look at the adipose tissue?

A. If they did, I have no recollection of it.

Q. Your opinion is based on -- you said that the blood serum levels had declined as far as PCB's went?

A. Yes.

Q. But PCDF's were still present?

A. They had also declined but were still present.

Q. Are PCDF's lipophilic as are PCB's?

A. I believe they are.

Q. So they also would be in the fat then?

A. I would expect so.

Q. Do you think, if they were measuring this decrease in PCB blood levels, that they should also look and see if there's a decrease in the PCB blood -- or, excuse me, tissue levels?

A. Probably would be a good idea.

Q. Which do you consider more reliable or do you have --

A. I have no opinion on that. I think that would be a medical matter.

Q. You also talked about three different studies, one was heart disease.

What study was that?

A. First there was the Kreiss study in which she queried people about presence of heart disease. But in the long-term mortality studies that were primarily interested in cancer, the very nature of the study requires you to get information on all causes of death.

So the data published in those studies, although the

authors may choose to talk about cancer, involves calculating observed and expected mortality from heart disease as well. And these studies then constitute additional evidence.

Q. Okay. What was the other -- was the other study Smith or was that hypertension?

A. The other study with respect to --

Q. Heart disease.

A. Kreiss is the only I remember other than the mortality studies.

Q. I think what you have referred to, and I have down, is the second, is the study that you said withtwo million people talking about --

A. I'm sorry, you're right. I referred to it as a study. It's in fact national statistics for the United States.

Q. And what is that?

A. Mortality is routinely calculated for most of the causes of death for the United States population including heart disease and some of its major subdivisions such as hypertension.

Q. And you indicated with the widespread use of PCB's and that heart disease had gone down?

A. Yes.

Q. Does that lead you to think that PCB's are beneficial for heart disease; that anybody with a heart disease should drink

a gallon of PCB's and --

A. No. For one thing it would be a formidable accident, but --

Q. A formidable accident?

A. Laxative.

Q. Laxative. Okay.

PCB's act as a laxative, too? I haven't read that one.

A. It's actually hearsay. I have no firsthand evidence.

No, I think the significance of that drop in cardiovascular disease is that there is certainly no widespread problem from the widespread PCB distribution other than the one that you suggested as a potential one.

Q. I haven't suggested that one yet.

The studies in hypertension, you said they were contradictory at this time?

A. Yes.

Q. Are there studies that show that hypertension are produced or aggravated by PCB's?

A. Yes, there is one study, not -- I'm sorry, I take that back. There is a study which says that hypertension is associated with PCB's, but this was a study in which the population was exposed not only to PCB's but to DDT, and that is the only study that shows this association.

Q. Do PCB's have a synergistic effect, meaning the PCB's and DDT's are they going to interact with each other?

A. I wasn't suggesting a synergistic effect, I was suggesting

that DDT could be the causative agent. I don't know whether there is any syngerism involved with PCB's and any other substance.

Q. Can you rule out the PCB's as a causative agent in any of these studies entirely?

A. Are you talking about as a cause of hypertension?

Q. As a cause of hypertension, heart disease, triglycerides?

A. Proving a negative is difficult, but certainly if I came to these studies with no advance opinions about PCB's, I would find no reason in the studies to say that they had anything to do with any of these conditions.

Q. Where did you get your advanced opinions regarding PCB's?

A. Many of them came from animal work, some came from the Yusho incident.

Q. You have looked at a lot of animal work then?

A. No, no, I haven't. But people who have done these studies have referred to animal work as the material that generated their suspicions.

Q. Do they extrapolate these animal studies into human studies?

A. No. What they say is this is what was found in animals, let's look and see if we find this in humans.

Q. Do they relate the direct effects like if an animal does one thing, is a human going to do the same thing?

A. Some people have conducted investigations based on that assumption.

Q. Are they reliable?

A. The investigations are reliable. The assumptions I think are frequently shaky.

Q. Say, if you have a rat that is ingesting PCB's or being dosed with PCB's, can you extrapolate that to a human?

A. I have opinions, I'm not an expert.

Q. Well, let me --

A. And I would say it depends, it depends. I've been told that, for example, a rat's liver is quite an unusual organ compared with the human liver. I would suspect -- I personally would be suspicious of extrapolations based on the liver. There are other areas in which I might not be.

Q. What about taking a rat study and taking the rat that is this big, making it weigh a hundred pounds.

Would you extrapolate to that?

A. Oh, I think that is a very useful exercise because that tells me what the consequences of my assumption would be in terms of human beings.

Q. So you'd extrapolate and then you'd know what the effect on a hundred pound rat is and you'd know the effect on humans?

A. I'd be surprised if 600 pounds -- you see, all the evidence we have is certainly with respect to carcinogenicity, that human beings appear to be relatively cancer proof.

Q. Cancer proof?

A. Cancer proof. The extrapolations that you are talking about, I think the question is --

Q. They stay in the realm of the animal world?

A. I certainly wouldn't want to pass any regulations based on that extrapolation.

Q. Based upon a hundred pound rat?

A. But I might find it very informative in terms of what I can think or believe about a human being.

Q. Do you know sometimes that there are ants that carry a hundred times their weight?

A. Yes.

Q. Do you know any humans that can carry a hundred times their weight?

A. No.

Q. Doctor, have we had an increase of cancer over the past 30 or 40 years?

A. Yes and no.

Q. Well, I will let you explain that.

A. There's been a spectacular increase in lung cancer and slight decrease in the totality of cancers other than lung.

Q. What is the slight decrease?

A. I'm guessing, because I'm remembering graphs that I have seen, but if you talk about the last 40 years, I would guess it's been three or four, five percent, something like that.

Q. So every other -- just lung cancer is the only one that has

increased and every other type of cancer has decreased?

A. No, because within that totality of other cancers, some specific ones, like stomach cancer, have gone down, others --

Q. There's been an increase in colon-rectal cancer.

A. I thought it had gone down, but, I'm not sure. I know that some cancers, like cancer of the pancreas, have gone up.

Q. Cancers of the liver?

A. They're about constant. No, they're actually slightly decreasing. Malignant myeloma has gone up. That's one of that lymphatic cancer group, although the National Cancer Institute speculates that there may be a change of diagnosis and that may in fact be a reason why some of the other rare cancers have gone down, that there's been a shifting of --

Q. So some of those others might go up and this one might go down?

A. There is speculation. I'm not aware that there is any evidence one way or the other.

Q. How many types of cancer are there?

A. That's very difficult to answer because if we say that lung cancer is one type of cancer, an expert will tell you that there are several different cell types within that. And so I know that a pathologist would deny that there were -- was such a type as lung cancer. And so --

Q. Let's talk, you and I, let's talk generally. We don't know about B cells and T cells in the lung. Let's just talk about the different organs.

How many different organ cancers are there?

A. I would have to guess because my knowledge is pretty much limited to the causes which are common enough so that rates are published, and there would be about 10 or 15 of those, I would say.

Q. What kind of cancers have PCB's been associated with?

A. None.

Q. None? No studies have dealt with cancer?

A. There have been several studies of cancer in people exposed to PCB's. I know of none of them that has come to a conclusion that PCB's have caused any of the cancers that they have looked at.

Q. So unless there is a direct -- one paper comes out and says PCB's cause this cancer, you aren't going to believe any of those papers yet?

A. That is not true. Because if I had seen four papers, all of which had shown an excess of the same type of cancer, even though the authors individually might not have said anything, I would have been convinced by the accumulation of evidence, and I would be willing in a situation like that to say for all practical purposes this causes cancer even though each of the four authors individually wasn't able to reach that

conclusion.

Q. Are those four cancer studies that you listed in the back of your papers as the only ones that you know of?

A. Yes.

Q. So what we need is three more studies on each one of those and that would give you four studies for each melanoma, four studies for a lung cancer?

A. In that case I would be overwhelmed.

Q. When you were talking about the background levels, and I referred to the U.S. cancer rates by county in the background rate for those plants, and I forget where they are --

A. They were on the border of New York and Connecticut, in that general area, as I recall.

Q. Would you have to look at the background rates for those counties and then compare it to the study Brown - Jones did?

A. What I would actually do is get the best estimate I could of the counties in which the employees worked. That would probably be a small group of counties surrounding the plant.

I would then, in an ideal situation, aggregate the rates for those counties and use them -- and use that as my basis for comparison.

Q. What counties did those employees work in at those two individual plants?

A. I don't know because that wasn't given in the report. It

would probably only be available by looking at plant records.

Q. So when they did that study, they used a U.S. background rate of cancer?

A. Yes, that's correct.

Q. And you are saying that had they used the counties it would have been lower?

A. Yes.

Q. But you don'tknow which counties?

A. I know that the counties will be within that group that have an above average rate. I don't know --

Q. Every county will be in that area?

A. No, I can't guarantee that. But that factory is in the center of a group of counties that are high. I can't guarantee that some workers may not commute from outside that area.

Q. Was one plant in Massachusetts?

A. I think it was.

Q. Instead of Connecticut?

A. I think the other one -- the one I'm thinking about, I believe, was in upper New York State.

Q. One is in New York and one is in Massachusetts?

A. One was in New York, I know, because that was the one that was in the high area.

Q. The other one might have been in the low area?

A. It might have been, yes.

Q. So then that's your opinion of -- that study might change then depending on the cancer rates in that county?

A. Well, except that the one that might have been in the low area didn't have an excess compared with the United States. It might have changed, yes.

Q. Doctor, have you ever testified for or on behalf of Monsanto before?

A. Yes.

Q. When was that?

A. Approximately four months ago.

Q. And what did that involve?

A. It involved testimony as to what records Monsanto had or had not received in connection with another lawsuit.

Q. What substance did it involve?

A. It didn't involve a substance, it involved a plant, and an assortment of substances made in that plant.

Q. What was the suit about? Did it involve PCB's?

A. No.

Q. What was your testimony in that regard?

A. I testified that we had not received raw data from a consultant regarding physical examinations that he had made on some of our employees.

Q. What were these examinations being made for?

A. In connection with litigation. These employees were litigants and some of those had previously been studied because

we wanted to evaluate possible long-term effects of some of their exposures at that plant.

Q. What were they being exposed to at that time?

A. Dioxin.

Q. Where is that plant?

A. West Virginia.

Q. Is that still in trial right now?

A. Yes.

Q. Did you testify in a trial or in a deposition?

A. It was testimony before a magistrate appointed by the judge to settle this particular issue of what records we had or had not received.

Q. Okay. Did you testify any other times for or on behalf of Monsanto?

A. I have given depositions.

Q. In what kind of cases? Let's start, if you can do it chronologically, for us, starting with the beginning, the first time you testified for Monsanto and work your way forward.

A. It would have been approximately two or three years ago in connection with a suit in Beaumont, Texas, involving plaintiffs who alleged their lukemia was caused by benzine from one of a number of defendants, including Monsanto.

Q. Does benzine cause lukemia?

A. In doses large enough to cause clinical illness it's generally

agreed that it does. In smaller doses there doesn't appear to be any evidence.

I take that back, the evidence is equivocable.

Q. Did that have to do with a playground?

A. Not that I know of.

The second deposition, I believe it was about, again, year and a half, two years ago. It was in connection with an EPA suit in which Monsanto was a defendant. It regarded -- it concerned PCB's present in Waukegan Harbor.

Q. What was your testimony in that case?

A. I was asked to -- I'm trying to remember. I was asked to review data that had been obtained by FDA on PCB levels of fish, and to look at the time trends in those PCB levels.

As I recall, the data showed a steady decrease in the PCB levels and that for most exposures of fish at the time of the most recent measurement, those levels were below the FDA limits.

This is my recollection, although I may not be precise.

Q. What were your opinions called for in that case?

A. Whether or not there was a clear and present danger of PCB's in that situation.

Q. And I take it you testified on behalf of Monsanto that it wasn't?

A. I testified that the situation was getting better and that by FDA's own ground rules there was no problem.

Q. So the answer would be yes?

A. Yes.

Q. In the benzine case, what was your opinion asked for there?

A. As to the -- again, my best recollection is as to the sequence of events -- in other words, what was involved in the benzine exposures measured in the literature that caused lukemia. And the data that were involved were -- there were studies in Turkey and Italy of people in the shoe and leather trades, and the benzine levels that were measured there appeared to be about 10 to 20 times as high as any of the exposures alleged by the plaintiffs in the case.

Q. And your testimony went to the effect that there would be no effect by Monsanto's benzine on these people?

A. That there were no data to that effect, that the existing data were not relevant to the levels that were at issue in the case.

Q. What other deposition or testimony had you given?

A. In connection with litigation over a spill from a tank car in Sturgeon, Missouri, a case in which Monsanto was co-defendant with several other companies: the railroad, the manufacturer of the tank car, and so on.

Q. Did this involve PCB's?

A. No.

Q. What did that involve?

A. It involved one of the chlorophenyls. I forget which one.

Q. Was it a chlorinated hydrocarbon?

A. Yes.

Q. What was your testimony in that case?

A. That I had not worked at Monsanto at the time of the incident and that I had never conducted any studies of litigants or of the area in which the spill occurred.

Q. So why did they have you testify then?

A. I wasn't allowed to ask.

Q. You didn't testify, oh. You didn't testify?

A. I gave a deposition. This was a deposition.

Q. Oh, your deposition was just -- you didn't know anything?

A. That's right.

Q. Going back to benzine, do you know how PCB's or the aroclors are made?

A. No, I don't.

Q. Do you know if benzine is part of that process?

A. I don't know.

Q. Did that cover all your litigation experience with Monsanto?

A. Except the deposition that you took.

Q. Okay. And that was a short one?

A. Yes.

Q. The one at Waukegon, was that the outboard marine?

A. Yes.

Q. How long have you been employed by Monsanto as of today?

A. Four years and seven months.
Q. I take it you are on a salary and you receive some fringe benefits as a part of your compensation?
A. That's correct.
Q. Do you have a pension plan with Monsanto?
A. Yes.
Q. Is that contingent upon any factors?
A. No.
Q. How long do you have to work for Monsanto before your pension is vested?
A. I think about four more months.
Q. Are you going to retire then or are you going to keep working?
A. I can't afford to retire.

You didn't ask about the amount of my pension, only the fact that I might have one.

Q. Do you want me to ask about the amount of your pension?
A. No, I don't. I don't want to think about it.
Q. Are there incentive plans or bonuses at Monsanto for extraordinary work, if you write a paper or you are published or --
A. No -- wait, I'm sorry, yes, there are.
Q. What are those for?
A. They're available for people at a lower level then me. The kind of activities you describe would be one reason. A

computer programmer who worked after hours for a long period of time on a special project would get one.

Q. Are you being paid to testify here today?

A. Not in addition to my regular salary.

Q. They're paying your salary, though, for your testimony today?

A. Yes.

Q. Were you subpoenaed here today?

A. No.

Q. Were you asked to come?

A. Yes.

Q. Are you paid for your travel and expenses?

A. Yes.

Q. Did you prepare for this testimony today in any way? Did you meet with any attorneys?

A. Yes.

Q. And who did you meet with?

A. Mr. Jungerheld.

Q. Was that up here in Bad Axe?

A. No, it was in Saginaw.

Q. When was that?

A. Saturday and very briefly on Sunday.

Q. So you've been up here since Saturday?

A. I've been up here in Bad Axe since Sunday.

Q. And what, you came into Saginaw to prepare for your trial testimony?

A. Also because it was the easiest way to get here.
Q. Did you happen to get any daily copies that are being made here?
A. No.
Q. You didn't read any transcripts of anybody that's testified before you?
A. Oh, yes, I read Dr. Chase's transcript.
Q. Did that give you any information to help your testimony today?
A. No.
Q. Did you know Dr. Chase before?
A. I don't know him. I met him professionally at one meeting.
Q. Did he challenge you at a seminar as to your results on a paper?
A. He challenged some of them, yes.
Q. He testified that he didn't agree with any conclusions you came to, did he?
A. I have to disagree with that because obviously since I read his testimony I've been trying to remember what went on. And, as I recall, Dr. Chase opened his conference by expressing his pleasure that I didn't criticize his paper.

So there must have been one thing at least we agreed on which was that he had written a good paper. Much of the rest of what I said there couldn't be disagreed with because I was quoting the authors of the paper. The disagreement was

with them.

I think Dr. Chase disagreed with a few places in which I made interpretations.

Q. Did you read in his daily transcript where he said, "I didn't agree with anything that man said"?

A. Yes, I did. He specifically questioned my interpretation of one paper. I think it was one of Fishbein's, and my response was I would have to go back and check it.

And then I think he further questioned my interpretation of the carcinogenicity studies and again that is an area in which we disagree.

Q. Do you find him a qualified medical doctor, toxicologist?

A. Insofar as I'm capable of judging, yes.

Q. Are there any other daily transcripts you read in preparing for the testimony today?

A. No.

Q. What information were you given before you testified today?

A. I was given a brief review of the facts of the case.

Q. Why don't you tell me what your brief review of the case covered in the facts of the case.

A. That Mr. and Mrs. Haley bought a farm, a dairy farm.

Q. Do you know what year?

A. I was probably told but I don't remember.

That they had difficulties with their cows. That eventually they were required, if I'm not mistaken, to stop

using their silos and that eventually they left their farming business and that they believed their difficulties were due to PCB's in the paint that was used in the silo.

Q. Was this a written summary that you were given?

A. No, no.

Q. Did you review any written summaries of the trial?

A. I don't think so.

Q. Any other written documents --

A. Oh, wait a minute. In the copy of Dr. Chase's transcript that I got, there was a Mr. Gemmell appeared right afterwards and his -- I don't know whether I saw all of his or not, but it was there and I did read it.

Q. Was Mr. Jungerheld the only one you met with in order to prepare?

A. Yes.

Q. Did you ever meet with Dr. Hartung before?

A. No.

Q. Did you ever meet with Mr. Hahn?

A. I was introduced to him but had no contact with him about the case.

Q. What about Mr. Nassif?

A. Oh, I know Mr. Nassif.

Q. From Monsanto?

A. From Monsanto.

Q. Did you and he talk about this case and your testimony and

when you'd come up and --

A. We talked -- he was present during some of my conversations with Mr. Jungerheld. I don't recall that he participated.

Q. What about Dr. Harbison?

A. I met him for the first time this morning. That is, I've known him in past years. I met him for the first time in several years this morning.

Q. What was your contact with him before?

A. I think we met in connection -- I don't recall whether it was at the PCB symposium or in connection with some other similar activity.

Q. The symposium, referring to MSU?

A. I don't remember which one if, indeed, it was either.

Q. Did you talk to Lynn Willett?

A. I've never met him.

Q. Have you talked to him ever?

A. No.

Q. Had you ever heard of PCB's before coming to Monsanto?

A. I don't believe I have.

Q. Okay. So your first work with PCB's would have been '79 when you came to Monsanto?

A. Yes.

Q. I think I already asked you, you don't know how aroclors are made or manufactured or were manufactured?

A. No, I don't.

Q. I don't know if I asked you, was benzine a carcinogen?

A. You asked me and I said it's generally agreed, I think, that if benzine exposure is large enough to cause actual anemia and damage to the blood-forming organs, then it frequently can progress to lukemia.

The evidence below that for a long, low level exposure to benzine, is extremely equivocable.

Q. Have you ever heard of Cumar?

A. Yes.

Q. In what regards?

A. Dr. Chase mentioned it in his transcript.

Q. Are PCB's in Cumar, to your knowledge?

A. I don't know whether I got that from Dr. Chase's transcript or from the verbal summary of the case, but I understood that PCB's were incorporated into Cumar to confer some physical properties on it.

Q. Are PCB's used in paints or coatings, to your knowledge?

A. They are not now. I don't know if they ever were.

Q. Did you ever do a study on paint or coatings?

A. Yes.

Q. What kind of substances did you use in the study that you did on paints and coatings?

A. We didn't use substances, we identified people who had been employed in the manufacture of paints and coatings and classified them by whether they were exposed to pigments,

whether they were exposed to solvents, and then look at these sub groups, follow them up to see what their mortality picture was.

Q. Were the people that manufactured or mixed up this Cumar coating, which included solvents and aroclors, the part of that group?

A. I'm almost certain they were not because this was an industry-wide study but the member companies were generally the larger paint manufacturers. If they had been a subsidiary of some larger group, they might have been included, but to the best of my knowledge they were not.

Q. Are paints and coatings generally made up of such things as a solvent and the aroclors and other chemicals like that?

A. When we looked at the problems of dividing these people by their exposure, we talked to industrial hygienists and PCB's never came up.

We divided these people generally into the solvent exposures, I believe liquid pigment, solid pigment. Things like PCB's never entered it nor were they mentioned by our industrial hygienist.

Q. Was benzine mentioned?

A. No, except -- wait, we were not able -- we considered the possibility that some of the solvents that were used could have been benzine, could have contained them, but we weren't able from the job histories to identify whether -- what the

solvents were.

We identified people who had solvent exposure, but we weren't able to subdivide it into what kind of solvents they had.

Q. Is benzine a solvent?

A. It certainly could be used. There must be some things that are soluble in benzine such as some of the pigments.

Q. When you did that study, did you find any excess mortalities or cancers?

A. I would have to review the study because it's been several years since I've looked at it. I think we found a few areas in which we advised extra study. I can't recall now what they are.

Q. Did you look at colon and liver cancers?

A. Yes, yes.

Q. Rectal cancer?

A. We certainly looked at them because the study group was fairly large. We looked at all the major cancers. What I can't recall is the pattern that we saw.

Q. In the PCB's that are involved in this case, did you ever look at the cause of the contamination as to the Haleys?

A. No.

Q. Are you doing any studies or reports at the present time with regard to people that have been contaminated by silos --

A. No.

Q. -- containing PBC's?

A. No.

Q. Are you aware of any such studies?

A. Possibly the Humphrey one you mentioned, but that's the only one I'm aware of.

Q. Were you ever provided with any medical records on the Haleys that showed what their levels were?

A. No.

Q. The only thing you were provided with then was the one 50 part per million -- or billion, excuse me, of serum level of Roger, and you just assumed Valerie was lower than that?

A. I had been told what both of their values were. I remembered Mr. Haley's, not Mrs. Haley's.

Q. And Mr. Haley's was 50 parts per billion?

A. That is my recollection.

Q. And those values, had they declined at all to your knowledge?

A. I can't recall.

Q. Do you know when those serum samples were taken?

A. No.

Q. Do you know when the fat samples were taken?

A. No.

Q. Would that be an important point for you to utilize in doing an epidemiological study, to know what the fat samples were, what the blood samples were when taken?

A. The epidemiology studies that I have looked at, there have been very, very few of them that have looked at fat samples. The ones that have looked at blood samples are contradictory as to what happens to them in short periods of time. Some go down, some do not.

Q. What about over the long term?

A. They tend to go down, although there, again, some people dispute this.

Q. So there are studies, both sides?

A. Yes.

Q. Which studies do you rely on then in forming your opinions? The recent Japanese study?

A. The recent Japanese study shows what it shows about the people in Yusho.

My opinion is that the reason for the contradictions in the study, I think, may be because some of the PCB's that are being talked about are higher chlorinated and some are lower chlorinated. I think there is some reason to believe that these are excreted in different ways.

Q. Does it matter if it's a higher chlorinated or a lower chlorinated aroclor?

A. It matters in the sense that the lower chlorinated ones in the bloodstream, I think, may decrease more rapidly.

In terms of effects, again, I would have to refresh my memory, but I think the studies are contradictory. Some

people allege differential effects depending on the level of chlorination.

Q. What is the importance of doing this serum sampling on these people. Why do they study the serum samples or serum levels on these people?

A. In order to get an estimate of the body burden of PCB's.

Q. And what does that show them?

A. In a negative sense, if anything -- if there are no PCB's, then you can hardly allege any effects of PCB's.

Q. Right. So if there are PCB's, then you can look for effects of PCB's?

A. Of course.

Q. Do you know what the level of chlorination of PCB's in the Haleys are?

A. No, I do not.

Q. It's been testified to that they have 1254 in their fat and serum samples.

Is that a higher chlorinated aroclor?

A. I'm not sure that that's a meaningful question. I think the 54 means that there was a 54 percent chlorination on the average. But these can be mixtures with PCB's at both higher and lower chlorination levels.

So the fact that one sees the number 54, doesn't mean that there were or were not any higher chlorinations.

Q. Are you aware that the higher chlorinated aroclors tend to

remain in the body fat?

A. I'm aware of studies that have concluded that, yes.

Q. Has Monsanto concluded that?

A. I'm not aware of Monsanto's opinion as a company.

Q. Do you know Monsanto's studies in this area?

A. No.

Q. Have you looked at any of Monsanto's studies in regards to toxicity of aroclors?

A. No.

Q. Do you think that would be a good place to start looking if you wanted to find out about the toxicity of aroclors in determining the risk of somebody?

A. I think it would be a good place for a toxicologist to start, if he wanted to look at the picture in animals.

Q. What about humans?

A. I wouldn't want to generalize that kind of thing from an animal to a human. I would want to look at humans.

Q. Okay. So what you have really done in your work is take articles, a selected few, and put together some sort of statistical analysis and come up with a level which you -- well, you haven't come up with a level because you didn't know what the Haleys were, but you came up with something to make an opinion on the increased risk to the Haleys?

A. Well, I haven't looked at a selected few. I've looked at all the studies that the literature contains to the best

of my knowledge on human data.

And, if I recall, none of my summaries were statistical, they were narrative summaries. But, yes, I did reach conclusions.

Q. And your opinions are that whatever levels the Haleys have, they don't have an increased risk?

A. I know something about the levels that they have, but the plain fact is that in the literature there have, to the best of my knowledge, simply not been any levels, blood levels associated with risk.

The Japanese studies have found values up to 300,000 parts per million in people and their only clinical illness has been chloracne.

Q. What about the studies with the fat levels, where the PCB's accumulated in the fat, such as the fat in the brain, around the liver?

A. I don't think I understand your question.

Q. Okay. You said that you haven't seen any effect with people who have high parts per billion in the serum.

What about people with high parts per million in the fat samples, in the areas of their body that contain those fatty areas where the lipophilic PCB's are attracted to?

A. There are very few epidemiology studies that have taken fat samples. The ones that have, have reported no -- there's been no more adverse effect there then there has been with

the blood levels. But the number of studies is very small. I don't think I found more than two in the literature, possibly three.

Q. Looking at a general picture now, if we look at the silo families that have been exposed to PCB's.

Are you aware that there has been more than the Haleys that have been exposed to PCB's through silo contamination?

A. Yes, I am.

Q. Do you consider that an epidemic, something that you might want to consider as an epidemic and look into as an epidemiologist?

A. I think it would be an extremely useful and interesting study.

Q. So the Haleys aren't just one poisoned family, they're part of an epidemic that should be studied and would be useful?

A. It remains to be seen whether there is an epidemic. There have been many studies of people with exposures to PCB's. I think this would be another opportunity to do a study of a low level exposure to PCB's.

Q. Sort of a human experiment unintentionally caused?

A. All epidemiology studies are on human experiments unintentionally caused.

Q. Doctor, are you aware of an animal study that showed some metabolites in PCB's that attached to the lung?

A. No, I'm not.

MR. MC GRAW: I have no more questions, Your Honor. Thank you, Doctor.

THE COURT: Redirect, Mr. Jungerheld?

MR. JUNGERHELD: Your Honor, I don't believe so.

THE COURT: Mr. Davidson?

MR. DAVIDSON: No, Your Honor. Thank you.

THE COURT: You may step down.

MR. JUNGERHELD: Your Honor, we'll call Dr. Raymond Harbison.

RAYMOND D. HARBISON,

a witness herein, produced by and on behalf of the Defendants, having been first duly sworn, testified on his oath as follows:

DIRECT EXAMINATION

BY MR. JUNGERHELD:

Q. Dr. Harbison, would you give us your full name, please, sir?

A. My name is Raymond D. Harbison.

Q. And, first off, what is your professional address?

A. My professional address is University of Arkansas for Medical Sciences at 4301 West Markum in Little Rock, Arkansas.

Q. And what is your home address?