IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

THE CITY OF BLOOMINGTON, INDIANA; THE UTILITIES SERVICE BOARD OF BLOOMINGTON, INDIANA; and MONROE COUNTY, INDIANA, Plaintiffs,	)	
vs.	)	Civ No. IP 83-9-C
WESTINGHOUSE ELECTRIC CORPORATION, a Pennsylvania corporation; and MONSANTO COMPANY, a Delaware corporation, Defendants.	)	

The deposition of WILLIAM R. GAFFEY, called for examination by the Plaintiffs, pursuant to notice and pursuant to the provisions of the Federal Rules of Civil Procedure of the United States District Courts, pertaining to the taking of depositions for the purpose of discovery, taken before Arnold N. Goldstine, a Notary Public and Certified Shorthand Reporter within and for the County of Cook and State of Illinois, at the Park Terrace Airport Hilton, St. Louis, Missouri, on September 4, 1987, at the hour of nine o'clock a.m.

WATER_PCB-00044417

APPEARANCES:

Mr. Joseph V. Karaganis and
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-and-

Mr. Geoffrey M. Grodner
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appeared on behalf of the Plaintiffs;

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appeared on behalf of Defendant
Monsanto Company.

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I N D E X

WITNESS:

WILLIAM R. GAFFEY

Direct Examination by

Mr. Karaganis: 4

E X H I B I T S

BLOOMINGTON DEPOSITION NOS.

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MR. KARAGANIS: Would you swear the witness.

(Witness sworn.)

WILLIAM R. GAFFEY

having been first duly sworn,

was examined and testified as follows:

DIRECT EXAMINATION

BY MR. KARAGANIS:

Q. Let the record show that this is the deposition of Dr. William Gaffey, who has been identified as a Monsanto witness.

Would you state your full name, please?

A. William R. Gaffey.

Q. Where do you reside, sir?

A. At 11269 Pine Side Drive, in St. Louis.

Q. By whom are you employed?

A. The Monsanto Company.

Q. At what location?

A. At their St. Louis offices.

Q. Are you employed in a particular department?

A. Yes. I am employed in the department of medical and health services.

Q. And what is your position in that department?

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A. I am epidemiology director.

Q. And how many professionals are on your staff?

A. There are four professionals on my staff.

Q. Four epidemiologists?

A. No, three are epidemiologists and one is a computer analyst.

Q. And with respect to the three epidemiologists, does that include you or that is in addition to you?

A. That is in addition to me.

Q. So there are four epidemiologists in the department, is that right?

A. That is correct.

Q. Then who do you report to?

A. I report to Dr. George Rausch, medical director of Monsanto.

Q. In the medical department, what would you classify, you are epidemiology, is that a division or is that a section or how do they treat it?

A. I believe it is called a section, but it is one of the major subdivisions of that department.

Q. What other subdivisions are there?

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A. Occupational medicine, toxicology, industrial hygiene and quality assurance.

Q. What is the difference between occupational medicine and industrial hygiene?

A. Occupational medicine is a branch of medicine concerned with illnesses that may be occupational. Industrial hygiene is concerned with measurements of contaminants in the workplace and other such possible risks to health.

Q. Is industrial hygiene simply then a department that monitors or measures or does it set standards with respect to health risks?

A. I believe it has on occasion set internal standards for substances for which no national standards exist.

Q. Okay.

So that of the two departments, it is the industrial hygiene department that sets the standard or am I mixing the two?

A. I'm not sure that they do this on their own responsibility. I really don't know.

Q. Okay.

Who is head of the occupational medicine section?

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A. Dr. Hubert Bonfili. That's B-o-n-f-i-l-i.

Q. And who is in charge of toxicology?

A. Dr. Frederick Joe Johansen, that's J-o-h-a-n-s-e-n.

Q. How about industrial hygiene?

A. Mr. John Lenshaw. L-e-n-s-h-a-w.

Q. Quality assurance?

A. Mr. Arthur Uellner. That's U-e-l-l-n-e-r.

Q. Dr. Gaffey, by way of functions within the department, what is the difference between the role of the toxicology department and the epidemiology department?

A. Toxicologists are concerned with the specific metabolism of various possible toxins, most particularly in animals. Epidemiology is concerned with the measurement of ill health in humans.

Q. Toxicologists are trying to identify toxins which may have an adverse effect in humans, are they not?

A. Yes.

Q. Okay.

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How do they go about it in their profession?

A. In general terms, they are most likely to look at the results of animal data. I can't be more specific than that.

Q. Would it be fair to say that toxicologists in setting levels of exposure for humans, use animals to experiment on, to subject to doses of a potential toxin, then use the results of those animal studies to extrapolate a health standard for humans?

A. I'm not aware that toxicologists set limit standards.

Q. Do they recommend health standards?

A. I don't know.

Q. Doctor, would it be fair to say that toxicologists do develop data from which to calculate what is called the no observed adverse effect level?

A. I believe that concept is used by toxicologists.

Q. Is that no observed adverse effect level then used by toxicologists or others to set a term called an acceptable daily intake, ADI?

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A. I don't know.

Q. Have you ever heard the term ADI?

A. I believe I have. Yes.

Q. What is done with the work that toxicologists do at Monsanto? In other words, what do they engage in the toxicological analysis for?

A. Usually to investigate the possible toxic effects of chemicals or substances that are proposed for manufacture.

Q. All right.

So if there is a chemical that's proposed for manufacture, it is run through the toxicology department to try and identify whether it represents a health risk; is that right?

A. I believe that's correct.

Q. All right.

That is a health risk to humans, isn't that right?

A. The toxicologists make that extrapolation.

Q. All right.

So Monsanto use the toxicology department to investigate the toxicological or toxic risk of

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proposed chemicals that are being proposed for manufacture, is that right?

A. That is correct.

Q. All right.

And they use the results of the toxicological experiments in the toxicology department toe stablish whether a chemical represents a human health hazard; is that correct?

A. In one way or another. Yes

Q. Would it be fair to say that the toxicology department does not subject humans to exposure of the proposed chemical?

A. That is correct.

Q. And why is that?

A. Aside from the question of ethics, the toxicologists do not consider themselves normally as being concerned with human exposures.

Q. They are using the animal data or somebody is using the animal data, Monsanto is using the animal test data to make determinations as to whether or not a proposed chemical represents a toxic risk to man, are they not?

A. For chemicals for which there is no exposure in existence, yes.

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Q. All right.

And it is then on the basis of those animal studies that Monsanto will represent to the government or otherwise that this chemical either represents a toxic risk or there is an acceptable level at which point it is not a toxic risk; is that right?

A. That is correct.

Q. That's for humans, is it not?

A. Yes.

Q. The presentation Monsanto makes to the government based on these animal studies for human risk is based on animal studies, is it not?

A. Yes.

Q. And is this true of all chemicals Monsanto proposes to manufacture?

A. No.

Q. All right.

What chemicals have to go through this toxicological review?

A. I don't know specifically, but in general it would be chemicals that had not already been subject to that review by the government.

Q. All right.

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So would it be fair to say that any chemical Monsanto proposes to manufacture has to go through an animal toxicological review to assess potential health risk to humans and that toxicological review has to be done either by the government or by Monsanto?

A. That is certainly the current situation.

Q. So would it be fair to say that for all chemicals proposed to be manufactured by Monsanto, the health risk to humans is assessed by doing animal studies?

A. No.

Q. All right.

Which chemicals are not, do not fall within that category?

A. Those which were initiated by other companies and for which the toxicology had been previously completed.

Q. By the toxicology, you mean the animal toxicology?

A. Yes.

Q. So in that situation we have now for any chemical Monsanto proposes to manufacture, any chemical, it falls within one of three categories.

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The human health risk is assessed by animal studies either: A, done by Monsanto; B, by the government; or, C, animal studies done by the person who has originally gotten the approval to manufacture the chemical?

A. Yes.

Q. In all three of those categories, the health risk to humans is evaluated by animal studies, is it not?

A. Yes.

Q. Now, Dr. Gaffey, how many chemicals does Monsanto manufacture that fall within this category of doing a human health risk analysis based on animal studies?

A. I don't know.

Q. Roughly, 10, 100, 1,000?

A. I don't have the slightest idea.

My concern is with looking at the health of people with various occupational exposures and I have no idea of what the inventory of chemicals is that Monsanto can or might manufacture.

Q. Monsanto is a chemical company, is it not?

A. That is correct.

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Q. It manufactures pesticides?

A. Yes.

Q. Herbicides?

A. It manufactures herbicides which normally would be a specific type of pesticide.

Q. All right.

Does it manufacture industrial chemicals?

A. Yes.

Q. Would it be fair to say based on your best recollection, that the total number of industrial chemicals and pesticides, herbicides would number in the hundreds?

A. I believe that's possible.

Q. And does Monsanto also manufacture drugs, therapeudic drugs?

A. They may. I'm not sure.

Q. And all of the chemicals that Monsanto manufactures from the standpoint of evaluating their human health risk, have gone through one of those three routes of animal testing for health risk analysis, isn't that correct?

A. Yes.

Q. Would it be fair to say that those chemicals that Monsanto manufactures --

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Well, would you describe or are you familiar with the toxicological methodologies or tests that toxicologists use in their animal studies to determine or to develop the database for assessing human health risk?

A. No, I'm not.

Q. You don't feel you are qualified to do so?

A. No, I am not.

Q. You feel yourself qualified to address the validity or the quality of the extrapolation of animal data to human data?

A. No, because that is primarily a social, societal question, not a scientific one.

Q. So it is a matter of society's judgment whether the animal data can be used to protect man's health as opposed to a scientific judgment, is that correct?

A. Yes.

Q. As these various chemicals are being proposed for manufacture, are they subjected to epidemiologic studies to determine whether or not they are safe for man?

A. That is impossible, since there is no

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human exposure at the time they are proposed.

Q. All right.

So basically it is true that for every chemical that is now proposed for manufacture, the toxicological risks to man are evaluated on the basis of animal studies; is that right?

A. That is correct.

Q. How many toxicologist are in the toxicology department at Monsanto?

A. I believe some four or five, but I'm not certain.

Q. Does Monsanto do its own toxicological experiments or are they farmed out under contract?

A. They do both, I believe.

Q. Now, in your department -- strike that.

What does your department do, the epidemiology department?

A. The epidemiology section carries out studies of the health of portions of the workforce, defined either by their exposure to certain substances or by their having been employed in certain plants.

Q. So you study Monsanto workers; is that right?

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A. That is correct.

Q. Now, what is the database used to set occupational exposure standards for workers in Monsanto plants?

Is that based on animal toxicology or is it based on something else?

A. I don't know. Because none of what I do is concerned with that.

Q. All right.

So your epidemiology studies are not used to set exposure levels for occupational health and safety in Monsanto plants, is that correct?

A. They have not been so used to date.

Q. What is the basis then of setting those exposure levels, animal studies?

A. I don't know.

Q. Would it be fair to say, then, that your epidemiologic work and the work of your section has not been used either to by definition establish human health safety standards for chemicals proposed to be manufactured, nor for health safety levels for workers in Monsanto plants?

A. I believe you are asking me two

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questions.

Q. Okay.

A. The first question, it is true that epidemiology studies are not used to establish safety levels for chemicals to which there has been no human exposure.

Q. All right.

A. Epidemiology work has been used to establish workplace standards in situations in which the epidemiology studies have shown no effects of exposure.

Q. I am asking you on your epidemiology studies, whether your epidemiology studies have been used by Monsanto or others to establish workplace standards for human health occupational safety?

A. No.

Q. And do you know what types of studies have been used to establish human health occupational safety for Monsanto workers?

A. No.

MR. FRUEHWALD: Third time he has said that, Joe.

MR. KARAGANIS: Okay.

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Q. Doctor, in examining your curriculum vitae, would you mark this as 519.

(The document above-referred to was marked Bloomington Deposition Exhibit 519 for identification.)

Dr. Gaffey, I show you what has been marked as Bloomington Deposition Exhibit 519, which purports to be a curriculum vitae for yourself.

Did you prepare that document?

A. Yes, I did.

Q. When did you prepare it?

A. I would have to look at the complete list of publications in order to tell you. This was prepared late last year, to the best of my recollection.

Q. Now, Dr. Gaffey, with regard to your educational background, and this may be part of the development of the science. Is there a degree program for epidemiology?

A. There is now.

Q. At the various universities?

A. Yes.

Q. Is that a degree program that is

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typically part of the schools of medicine or the schools of public health?

A. Usually in the schools of public health.

Q. Your degrees are not in epidemiology, isn't that correct?

A. That is correct.

Q. And looking at your professional positions that you have held, would it be fair to say that your background is in the area of mathematical statistics or biostatistics?

A. No. My education is, but most of my employment history and my publications are not.

Q. What is the difference between biostatistics and epidemiology?

A. Biostatistics is the general field of statistics applied to topics in biology.

Epidemiology is the specifics study of the health effects of humans, related to various circumstances in their life and exposure.

Q. Let me ask you, Doctor, going back to your point on the chemicals, chemicals proposed to be manufactured.

In the absence of epidemiologic data, do you consider it prudent public health policy to

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set safety standards for human health risk in the absence of epidemiologic data on the basis of animal data?

A. There is not a matter of science. It is a matter of social policy about which I have no expertise.

Q. Do you have an opinion as a layman?

A. I have a general opinion. Yes.

Q. What is that?

A. That such decisions tend to concentrate on risk and pay little or no attention to benefit.

Q. So from that standpoint, are you in favor of setting human health standards for proposed chemicals on the basis of animal studies or against such a process?

A. I am in favor of it.

Q. So would it be fair to say as a layman in the absence of epidemiologic data, you would set human health standards on the basis of animal studies?

A. Yes.

Now, Doctor, look at your vitae and your publications. They are arranged in order of chronology, are they not?

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A. That's correct.

Q. I am looking at page 2 of your vitae, the first study there is not a human epidemiology study, is it?

A. You are talking of the first in my list of publications?

Q. Yes.

A. No, it is not.

Q. And that would also be true of the second one?

A. That is true.

Q. And the third?

A. Yes.

Q. And the fourth?

A. Yes.

Q. And is the sixth, the educational qualification of statisticians, does that relate to epidemiology?

A. No, it does not.

Q. The next one, the mineral taste in water.

A. It deals with human effects, but is more like a clinical trail than it is an epidemiology study.

Q. What is the difference between a clinical

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trail and an epidemiology study?

A. In a clinical trail, the experimenter decides which people are exposed and which are not. In an epidemiology study, the determination is made by the circumstances under which the observation are made.

Q. Would it be fair to say that in an epidemiology study, the researcher is not in control of who becomes part of the exposed population?

A. That is true.

Q. The measure of body fat and related factors in normal adults, was that an epidemiology study?

A. Yes.

Q. What was that a study of?

A. It was a study of a sample of the population of the county in which the California State Health Department is located, in which a number of lifestyle factors were measured for everyone in the sample. Including, in this case, body fat and related physiological measurements.

Q. The next study with respect to children, is that an epidemiology study?

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A. Yes.

Q. Water bacteriology study, is that epidemiology?

A. No, it is not.

Q. The next study on the effects of ions on quality and action tendency ratings, is that epidemiology?

A. No.

Q. The next one, evaluation ratings of mineral taste in water, is that epidemiology?

A. No.

Q. Familial aggregation of blood pressure?

A. Yes.

Q. Current challenges to health statistics?

A. No.

Q. Possible manifestations of worsening environmental pollution?

A. Yes.

Q. Epidemiologic studies in industry?

A. It is a review of the principles of such studies. It is not itself an epidemiology study.

Q. How about mortality studies of workers in the vinyl chloride industry, the Tabershaw article, is that an epidemiologic study?

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A. Yes.

Q. The next one with respect to lead workers?

A. Yes.

Q. How about the paper on sulfur oxides?

A. Yes.

Q. And the study of sheet metal workers for NIOSH?

A. Yes.

Q. Critique of the standardized mortality ratio?

A. It is a mathematical analysis of a commonly used epidemiologic measurement.

Q. What is the standardized mortality ratio?

A. The standardized mortality ratio is the ratio of the number of deaths from a particular cause observed in a cohort mortality study to the number that would have been expected if this group had had the same mortality experience as a control group, as a matched, chosen control group.

Q. Okay.

Would it be fair to say that it is the ratio or this is used to compare the number of deaths observed with the number of deaths

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expected; is that right?

A. That is correct.

Q. Do you believe in the efficacy and the appropriate use -- I am sorry. Strike that.

Do you believe that it is appropriate to use the standardized mortality ratio as a measure of health risk?

A. Yes.

Q. The next article relating to overview of occupational method epidemiology.

A. That is again not itself a study. It is a review of study designs usable in epidemiology.

Q. All right.

Next study was an epidemiologic study, the paint and coatings manufacturing industry?

A. Yes.

Q. And the next study was what, that wasn't epidemiology, was it?

A. No, it was not.

Q. The study with Zack, was that epidemiology?

A. Yes.

Q. And then we have the epidemiology of pcb's?

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A. That was a review of epidemiology studies.

Q. Okay.

You didn't do a study of the epidemiology of pcb's, you reviewed other people's work, is that right?

A. That is correct.

Q. And would that be true of the next study, recent epidemiologic studies of pcb's?

A. Yes.

Q. And the next document, use of epidemiology in risk assessment?

A. It is a discussion of the possible use of epidemiology in risk assessment, but is not itself an epidemiology study.

Q. When you say risk assessment, would it be fair to say that the term risk assessment or as it is used contemporaneously tends to focus on cancer risk?

A. No.

Q. The formaldehyde study, was that an epidemiology study?

A. Yes.

Q. And the last study listed?

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A. No.

It was a study, it was an exposition of the methods used to try and reconstruct historical exposures in the preceding study.

Q. Now, how is the term -- is there a standard terminology used when one does an epidemiologic study -- strike that.

When one does an epidemiologic study, does one look for specific end points as a starting point in the study?

Are you looking for specific symptoms or diseases?

A. Sometimes yes, sometimes no.

Q. In the formaldehyde epidemiologic work you have done, has that been one study or has it been a number of different studies?

A. It was one study.

Q. Okay.

What work facilities were involved?

A. I do not --

I am not able to give you the names of those work facilities, but there were approximately ten of them.

Q. And were they Monsanto plants?

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A. Some of them were.

Q. Who did you do the work for?

A. The study was jointly done by an industry group called the Formaldehyde Institute and the National Cancer Institute.

Q. Did you do those studies while on Monsanto's payroll?

A. The studies were done by a joint committee of NCI and industry epidemiologists, of whom I was one.

Q. Your participation was funded by Monsanto, would that be fair?

A. Yes.

Q. Were you looking for specific end points or specific diseases in the studies of the formaldehyde industry?

A. No. It was a study of general mortality.

Q. Okay.

When you say a study of general mortality, is it correct that a mortality study looks at death certificates to categorize the cause of death?

A. That is correct.

Q. And are death certificates in the absence

WATER_PCB-00044445

of an autopsy prone to inaccuracies with respect to the diagnosis of the cause of death?

A. It varies with cause.

Q. How about cancer?

A. Studies have shown the errors to be minimal for cancer.

Q. So if a treating physician says this man or woman died of cancer, and he says that on the death certificate, you are pretty sure it was cancer; is that right?

A. That's correct.

Q. Are you sure of the organ etiology of the cancer?

A. Not always.

Q. There is the potential for error there, is there not?

A. The accuracy is not perfect.

Q. Did you conclude from the basis of your epidemiologic studies of the formaldehyde industry, that there was a human health cancer risk posed by exposure to formaldehyde?

A. No.

Q. Is formaldehyde considered a probable human carcinogen by federal regulatory agencies?

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A. No.

Q. It is not.

So it is not regulated as a probable human carcinogen, is that right?

A. I believe it is regulated currently as an irritant.

Q. So that your finding was consistent then with the regulatory posture of the agencies; is that right?

A. It was consistent with the regulatory posture of the agencies and with some ten to fifteen previous studies.

Q. With respect to mortality studies of the workers employed at the Nitro, West Virginia plant, what chemical exposure were you looking at there?

A. Which study are you referring to?

Q. The Zack and Gaffey study.

A. The study was a combination of a cohort mortality study of the whole plant, without regard to exposure, plus a study of deaths divided up by their exposure to 245 T.

Q. Did you find that your study of the Nitro plant determined that there was an increased risk

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of cancer to the workers from 245 T?

A. It was not possible to make that determination because the study wasn't designed to find that.

Q. I am sorry. I thought you said that was one of its goals?

A. I said that it was to study the -- among the deaths, those people who had died after exposure to 245 T and those who did not.

It was designed to look at the difference in the mortality patterns between those two groups.

It was not possible with that design to determine whether the cancer mortality was in fact in excess in the 245 T group.

Q. When you say, in fact in excess, what do you mean by in fact in excess, is that a term of art in the profession?

A. What I mean is that it was impossible to determine whether the risk of death from any cancer in the 245 T group was greater or less than that of the general population.

Q. When the term is used, whether the death rate was in excess, that typically means in excess

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of what would have been expected in the general population, is that correct?

A. That's correct.

Q. And why was that in the particular study, why were you unable to make that determination?

A. Because we did not partition the entire cohort according to whether or not it was exposed to 245 T.

Q. Meaning you didn't know whether your control group was exposed as well?

A. The question isn't answerable as you have asked it.

Q. Okay. Excuse my ignorance.

What is it that you didn't do in layman's terms that you should have done or would have done had you wanted to make that determination?

A. If we had been able to, we would have taken all the people who worked at the plant and divided them up into those who were exposed to 245 T and those who were not, and done, in effect, two separate studies, one in each group.

Q. All right.

A. What we did instead was to do that, confining ourselves to the minority of the people

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who had died.

Q. I am sorry.

To the minority of the people who had died. What do you mean?

A. Of the people study, a minority of them had died.

Q. Right.

A. We were able to classify the people who died by whether or not they had been exposed to 245 T.

We then looked at the causes of death in the exposed deaths and the unexposed deaths, to see if the distribution of causes was significantly different between the two groups.

Q. And did you find any significance?

A. No, we did not.

Q. But you did a statistical analysis to see whether there was a significance?

A. Yes.

Q. Again, as a layman, who has always found statistics to rank above economics in terms of difficulty.

If you did a statistical analysis to try and determine whether or not the deaths that you

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looked at represented an increased risk of cancer from 245 T, is it because there was no significance or was it because you didn't set up the study guidelines the right way?

A. Between those two alternatives, obviously, because there was no statistical significance.

Q. But if you were looking for statistical significance, you are indicating that you might have set up the study differently?

A. I don't believe I said that.

Q. How about the paint and coatings manufacturing industry. Did you find -- I am sorry, strike that.

You did a mortality study of paint and coatings manufacturing industry.

Were you looking at exposure to a particular chemical?

A. No, we were not.

Q. Was this a study done for workers in a Monsanto facility?

A. No, it was not.

Q. But it was done while you were working for Monsanto?

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A. No.

Q. I am sorry. When did you come to Monsanto?

A. I came to Monsanto in July of 1979. The study that you are discussing was in progress at the time and was completed without me.

Q. All right.

Your name is on the paper reporting the results of the study.

A. Yes.

Q. Did you write the paper?

A. I designed the study. I designed the data collection and analysis systems, and had an opportunity to review the final report and approve it.

Q. The mortality study of lead workers, for whom did you do that?

A. For the international lead, zinc research organization.

Q. And are the vinyl chloride workers, for whom did you do that?

A. For the Manufacturing Chemists Association.

Q. On the vinyl chloride study, did you find

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excess mortalities from vinyl chloride exposure?

A. Yes.

Q. How many plants did you study?

A. I am vague on the details, but I believe we studied some twenty plants.

Q. Now, had there been other studies of the vinyl chloride industry with respect to epidemiology and mortality?

A. None up to that time.

Q. And have there been subsequent studies?

A. Yes.

Q. Has every study of the vinyl chloride industry found excess cancer deaths from exposure to vinyl chloride?

A. Yes.

Q. By excess, do you mean statistically significant excess cancer deaths?

A. Yes.

Q. And what does the term statistical significance mean from the standpoint of excess cancer deaths?

A. It means that there is an observed excess whose probability is small, where small means below a generally accepted threshold.

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Q. Probability is small from other causes, you mean?

A. No.

I mean that given that the only factor operating is chance, one can set a threshold and say by chance alone, we would expect an excess above this amount to occur with a probability of .05 or .02, or any number that you choose.

Q. What is the threshold typically used by epidemiologists in their field?

A. .035.

Q. And if the survey or epidemiological study is determined to demonstrate statistically significant excess deaths, is that represented by the symbol P, is less than .035?

A. That is generally true.

Q. From a standpoint of cancer epidemiology, you then have done the vinyl chloride study.

Did the lead worker study address cancer mortality?

A. Yes.

Q. Did you find any excess cancers due to lead exposure?

A. No.

WATER_PCB-00044454

Q. Did you find any other causes of death that were excess as a result of lead exposure?

A. I believe that we may have found an excess mortality from hypertension, but I don't recall that it was statistically significant.

Q. And there is vinyl chloride. There is lead, the paint and coatings was -- I am sorry.

What was the substance in the paint and coatings study?

A. It was a mortality study of people employed in the manufacture of paints and coatings.

Q. Was there a specific chemical that you looked for in terms of exposure to a specific chemical?

A. No.

Q. Did you find any excess, statistically significant excess deaths?

A. My recollection is that there was an apparent excess in subgroups with certain exposures, and that these excess were further investigated later by the other investigators.

Q. What substances?

A. I believe solvents, but I'm not sure.

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Q. And the study at Nitro was what substance again?

A. That was a study of everyone in the plant who was alive and a study of those deceased persons who were exposed to 245 T.

Q. 245 T.

I don't want to go back over this again, but because of the study design, you did not make or were unable to make a determination as to whether or not there were excess deaths due to 245 T?

A. No. That is not true.

Q. Okay.

That's what I want to get clear.

A. We were able to establish that the pattern of mortality by cause in those people who had had exposure with 245 T was no different from among those who had not had exposure to 245 T.

Q. Would you consider that then an affirmative -- I don't know how to put this properly -- an affirmative negative finding that 245 T does not cause excess deaths?

A. Yes.

Q. If we were to look at epidemiology from a

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layman's standpoint, would it be fair to say that studies can fall within three categories: An affirmative finding of statistically significant excess deaths caused by exposure; a finding or a study result which does not allow one to make any conclusions as to positive or negative, in other words, whether there are excess deaths or not; and then, third, a result in which the study results allow you to make a conclusion, an affirmative conclusion, that the substance is not a cause of excess deaths?

A. I believe that is true. But it is my opinion and not one of the generally accepted principles of epidemiology.

Q. So would it be fair to say that there is a middle ground of study results which one cannot say on the basis of results of the studies that the substance is a cause of excess deaths or isn't a cause of excess deaths?

A. That is correct.

Q. And from the standpoint of your field, then, would it be fair to say that you would argue or I shouldn't say argue, but would you posit that such studies cannot be used to prove the existence

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of cancer risk from a given substance, but neither can they be used to demonstrate the nonexistence of a cancer risk from such a substance?

A. No, that is not true.

Q. I am now speaking of the middle ground studies.

A. I understand that, I believe, what you are saying.

Q. So you are saying that if you come up with equivocal studies or studies that don't produce affirmative negative results, that those studies are still evidence of noncarcinogenic risk, is that right?

A. Those studies are evidence of whether or not there is a carcinogenic risk.

Q. Is that also true of studies that show excess cancer deaths, but deaths that do not rise to a level of statistical significance, are those studies, can they be used as, quote-unquote, evidence that there is a cancer risk?

A. Under certain circumstances, I believe they can.

Q. So the fact that the excess cancer deaths don't rise to the level of statistical

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significance doesn't destroy the utility of the studies in terms of assessing whether or not there is a cancer risk, is that right?

A. It need not do so.

Q. Have you ever done an epidemiologic study, yourself now as opposed to a literature review, of exposure to a chemical and end points short of death?

A. No.

Q. So you have never looked at the epidemiology of exposure to a chemical and reproductive effects, for example?

A. I beg your pardon. I have done one such study.

Q. On reproduction?

A. Yes.

Q. What was that?

A. It was a study of the reproductive histories of workers with a specific chemical exposure at one of our plants.

Q. What plant was that and what chemical?

A. The chemical was DMAC, I am sorry that I don't know the precise chemical description. The plant was our plant in Decatur, Alabama.

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Q. When was that done?

A. I believe that was done approximately two years ago.

Q. Again is the same terminology used -- strike that.

What terminology is used to address whether or not a chemical presents a reproductive risk?

Mortality studies talk about excess deaths. What do you talk about in reproduction studies?

A. There are several measures, some of which deal with mortality of the fetus, either immediately before or immediately after birth. Others of which deal with such things as congenital malformations.

Q. Okay.

So you are looking at whether the fetus is either still born or born, or dies shortly after birth, and you are look at physical defects in the baby, is that right?

A. That is correct.

Q. All right.

I just want the get my terminology

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straight.

Would you categorize those effects as essentially reproductive effects?

A. No.

Q. What would you categorize them as?

A. They are part of the spectrum of reproductive effects.

Q. All right.

Are there any other measures that you use?

A. Yes. There is one other measure that could be used.

Q. What is that?

A. Infertility.

Q. Okay.

Did you look at infertility in the Decatur, Alabama study?

A. Yes.

Q. Did you look at all three, physical defects, infertility and mortality of fetuses?

A. Yes.

Q. And this was of exposed population to DMAC versus a nonexposed population?

A. Yes.

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Q. And how do you express the effects?

Do you talk about excess fetus mortality or excess physical defects or excess infertility?

A. We didn't talk about excess measures of anything.

We calculated measures of those three variables and looked at them in two populations, the exposed population and the control population.

Q. Did you find that there were more of those effects in the exposed population?

A. No.

Q. So was the result a finding that the DMAC, exposure to the DMAC, did not cause adverse reproductive effects?

A. That is correct.

Q. Other than the DMAC study, have you ever participated in any other reproductive or birth defect studies?

A. No.

Q. How did you in that particular study or in reproductive studies generally or birth defect studies -- how do you go about getting the evidence of whether or not there is mortality of the fetuses? Is that from death certificates or

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employee interviews or what?

A. In this case, it was from employee interviews done before any thought was even given to doing any kind of study.

Q. So the employees were interviewed for another purpose?

A. That is correct.

Q. What purpose was that?

A. Routine physical examination and medical history form.

Q. Okay.

Then you went back to those forms to identify whether or not there had been fetus mortality?

A. That is correct.

Q. Okay.

How about from the standpoint of physical defects, was that also from the employee form?

A. Yes.

Q. So you didn't make an examination of hospital records or the children themselves, you relied on the employee?

A. That's correct.

Q. And with respect to infertility, was that

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the same source of information?

A. Yes.

Q. So what you had essentially is layman saying whether or not their children had physical malformations or defects or whether they or their spouses were infertile; is that right?

A. That's correct.

Q. You have had no medical measurement of those conditions, is that correct?

A. We had self-reporting by people who did not know that there would be a study some years in the future.

Q. But who were not medical people in terms of identifying what the nature of the physical defects might be?

A. That is correct.

Q. And were not medically trained in determining whether or not they or their spouse were infertile?

A. That is true.

Q. So that the absence of reporting of birth defects -- I am sorry.

Would it be fair to say that infertility or subtle birth defects could theoretically have

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been overreported or underreported?

A. That is true in every study of everything that has ever been done.

Q. And this problem of overreporting or underreporting, would it be fair to say is enhanced or exacerbated when nonmedically trained personnel are making the medical evaluation?

A. I believe that is a fair statement.

But the question really is whether that under or overreporting was equally likely to have occurred in the control and the exposed groups.

Q. So that both groups may have been subject to significant error; is that right?

A. There is no reason to believe that there was any basis for differential bias between the two groups.

Q. You feel that the parallel potential for error cancels out the error or cancels out the risk of the error affecting the results of the study?

A. On the basis of the data that I saw, yes, I believe that.

Q. Have you ever done any epidemiologic studies with respect to birth weight or

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neurological adverse effects on children?

A. No.

Q. Dr. Gaffey, it says in Exhibit 18, Bloomington Deposition Exhibit 18, in the supplemental response, Monsanto's supplemental response to plaintiffs' interrogatory as to expert witnesses, that you are going to testify as to reporting results, epidemiologic and other studies on humans exposed to various types of pcb's.

What other studies, apart from epidemiologic studies, what other studies are you going to testify to?

A. There are studies of human exposure, which are in fact not epidemiology studies, on which I also propose to testify.

Q. Which studies are the human exposure but not epidemiology studies?

A. In my paper, I classified studies into those which evaluated the relationship between presence of pcb's and exposure, on the one hand, and epidemiology studies on the other.

In that publication I have listed the studies that have addressed the issue of exposure. And I have so stated that those were not

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epidemiology studies because there was no health outcome involved.

Q. They didn't study health effects?

A. That is correct.

Q. So that these would be studies of exposure as related to the body burden of pcb's?

A. Typically they looked at blood or serum levels of pcb's related to levels or estimated levels of pbc's in the environment.

Q. But they did not look at trying to relate those levels to health effects; is that right?

A. That is correct.

Q. It is the studies that you list in your paper that are the ones you are referring to as nonepidemiology studies?

A. That is correct.

Q. Let's see if we can gather in one place all of the papers that you have done on pcb's. Would you mark this as 520.

(The document above-referred to was marked Bloomington Deposition Exhibit 520 for identification.)

I direct your attention to what has been marked as Bloomington Deposition Exhibit 520. A

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paper entitled, "Recent epidemiologic studies of pcb's," by William R. Gaffey.

Can you identify that paper?

A. Yes.

This is the paper that I wrote and which was published under this title, I believe.

Q. Published by whom?

A. I believe this was published as part of the proceedings of an EPA symposium, and I believe it is listed in my curriculum vitae of -- it is the fourth item from the end of my list of publications.

Q. This is, "'Recent epidemiologic studies of pcb's,' Advances in Exposure, Health and Environmental Effects Studies: pcb's"?

A. That's correct.

Q. Was this a paper submitted or done under contract to EPA?

A. No. It was a paper prepared and read at an EPA symposium.

Q. When was that done, 1983?

A. I believe the symposium was done in 1981. Late 1981.

Q. Who was at that symposium?

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A. I believe that the symposium was devoted exclusively to pcb's and that the attendees consisted of those who were interested, plus speakers who had done various pieces of research in pcb's.

Q. Do you recall who those were?

A. I recall who some of the epidemiologists were who were in attendance, I don't recall whether they published or whether they spoke.

Q. Who were they?

A. One of them was a Dr. Clase. I forget his first name.

Q. Where was he from?

A. He was from New York. I don't remember what educational institution.

One was Dr. Alexander Blair Smith from the Center for Disease Control. Another I believe was a doctor Alf Fischbein from Mt. Siani Medical School in New York.

Q. Okay.

A. I don't recall the names, if any, of other people who might have been there.

Q. Now, the paper, the epidemiology of pcb's in humans and environmental hazards, is that a

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different paper?

A. Yes.

(The document above-referred to was marked Bloomington Deposition Exhibit 521 for identification.)

Q. Doctor, I show you what has been marked as Bloomington Deposition Exhibit 521, entitled, "The epidemiology of pcb's," by William R Gaffey.

Do you know what that paper is?

A. Yes. This is a paper that I gave at a symposium at Michigan State University.

Q. Excuse me a minute. May I look at that?

A. Yes.

Q. This purports to be chapter 20, I am sorry, this meaning Bloomington Deposition Exhibit 521, purports to be chapter 20 of a book entitled, "PCB - human environmental hazards."

A. Yes.

Q. So is Bloomington Deposition Exhibit 521 the chapter in the book shown as the fifth item from the bottom of your vita?

A. That is correct.

Q. Are there any other published reports by you on the epidemiology of pcb's?

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A. No.

Q. I have a marked up version which I prefer not to mark as an exhibit, but did you put together a paper which was then submitted to EPA by Ecology and Environment called, "The epidemiology of pcb's," September 15, 1981?

A. No.

I believe that this may be identical to the epidemiology of pcb's that you just referred to.

Q. Meaning the paper that was in the book?

A. I believe so.

Q. Do you recall Ecology and Environment putting together a document submitted to EPA entitled, "The epidemiology of pcb's," by William Gaffey, a Monsanto publication?

A. No, I don't.

Q. Directing your attention to a document by Ecology and Environment entitled, "Summary of the health effects of pcb's," dated November 1981, prepared for the Chemical Manufacturers Association by Ecology and Environment, they list as the first document, "The epidemiology of pcb's," by William Gaffey, a Monsanto publication.

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A. Yes.

Q. Are you familiar with Ecology and Environment assembling this overview and then including your paper within the documents?

A. I don't recall anything about that.

Q. So you were not asked by Ecology and Environment whether you approved their use of the document or whether you had changed your views?

A. I don't recall that I was asked.

Q. But the paper that they did use, which I will show you a copy of, which is, "The epidemiology of pcb's," by William R Gaffey, September 15, 1981, and I will give you a chance to look at it; is that the same as your book chapter?

A. I believe it is. Without reading it all the way through, in all major respects it appears to be the same document.

Q. All right.

We can come back to it.

Doctor, other than your book chapter, that publication is listed as a 1983 publication?

A. That is correct.

Q. The paper is dated 1981.

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A. Yes.

Q. What was the occasion for writing the paper?

A. The paper was written as the result of a request from the American Chemical Society, to make a presentation to their annual meeting, which I believe was the 1980 meeting in New York.

They were interested in having a brief example of the application of epidemiology to hydrocarbons, and I close pcb's. And having made that decision became aware that there was a literature considerably beyond what I had thought of including in my brief presentation to them.

Having made no literature search, I then compiled the paper, "The epidemiology of pcb's," a small portion of which I gave in the American Chemical Society meeting.

Q. Now, by the time you wrote this paper, you were employed as manager of epidemiology by Monsanto, were you not?

A. That's correct.

Q. Were you aware at the time you wrote the paper that the issue of the toxicity of pcb's was a matter that was being litigated and was a matter

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of controversy between Monsanto and regulatory agencies and Monsanto and private litigation?

A. I was aware that Monsanto had manufactured pcb's. I believe I was aware that issues existed about environmental levels and I was aware of no more than that.

Q. Doctor, have you reviewed, either critically or otherwise, the animal studies on pcb's?

A. No, I have not.

Q. So with respect to this, the question of pcb's and their toxicity to animals, would it be fair to say that you are not either by training or by actual examination capable of rendering an opinion as to the validity of those studies?

A. That is correct.

Q. Nor are you capable of rendering an opinion as to whether those studies do or do not show an adverse effect, the animal studies?

A. No, I am not qualified.

Q. Have you done any other internal studies of pcb's, internal research, reviews, et cetera, for Monsanto, other than the ones we have discussed?

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A. I have done no internal studies of pcb's. I have critiqued specific studies.

Q. Of pcb's?

A. Of pcb's.

Q. And did you do so in writing?

A. Yes.

Q. And where are those critiques?

A. I assume that they are in, if they still exist, are in the files of the individuals to whom I wrote them. Although, they may possibly also be in my past correspondence files.

Q. To whom did you write the critiques?

A. I believe that I wrote some of them to Dr. John Craddock and some to Dr. George Levinskas.

Q. And which studies did you critique?

A. The original NIOSH study by Brown and Jones, the subsequent update by Brown of that same study. The original study by Bertazzi and his colleagues. B-e-r-t-a-z-z-i. And the update of that study. And the study by Gustavsson and his colleagues.

And I believe I also wrote a critique of a study by Emmet, who I believe is on the faculty.

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at Johns Hopkins.

MR. KARAGANIS: While we are on the record, Mr. Fruehwald, is it your understanding that you are not under an obligation to produce these documents to us?

MR. FRUEHWALD: Yes.

MR. KARAGANIS: On what theory?

MR. FRUEHWALD: I am not - let's don't go through the argument.

MR. KARAGANIS: We have now come across specific documents relating to the health effects of pcb's an I think we have asked for these things dozens of times.

MR. FRUEHWALD: We have stated our position over and over again about what we think on this issue.

MR. KARAGANIS: What about these documents? Why were these documents not produced? Simply calmly asking why these documents were not produced.

MR. FRUEHWALD: First of all, I didn't know about them until recently. I don't know, maybe they will be. This is one that I hadn't considered before recently discovering the

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existence of these documents. So I will have to consider that.

BY MR. KARAGANIS:

Q. When did you write these documents?

A. It would have been over the last three years, in all probability.

Q. Apart from the published documents that we have described, Doctor, are you saying there are three documents, three separate -- four separate documents that you have prepared internally within Monsanto?

A. I believe that's correct.

Q. One is a written critique of the Brown and Jones studies?

A. Yes.

Q. One is a written critique of the Bertazzi studies?

A. There were two separate critiques. One of the original study and one of the update.

Q. And the next is a critique of the Gustavsson study?

A. There was one document I believe which contained brief critiques of both the Gustavsson and Emmet studies.

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Q. Now, in doing these studies, did you prepare any notes or memoranda other than the written critiques?

A. No.

Q. Did you have occasion to have any of your other epidemiologists or staff people review the critiques and provide an analysis?

A. No.

Q. And these were written to Mr. Craddock you said?

A. To the best of my recollection, the recipients were Dr. Craddock and Dr. Levinskas, but I don't recall which documents went to which persons.

Q. They asked you to prepare these or you just did this as part of your normal effort?

A. They asked me what I thought of these papers.

Q. Dr. Gaffey, do you maintain a working file on pcb's?

A. Yes.

Q. And is that maintained in your personal office?

A. I have files in my personal office.

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There may be additional files in the general epidemiology files.

Q. On pcb's?

A. Yes.

Q. You maintain an index of those files?

A. No.

Q. How do you know where the pcb files are?

A. I have them in a couple of folders in my credenza.

Q. All right.

How about in the general office, how does the general office know where their pcb files are?

A. There would be, in all probability, a file folder that said pcb's on it.

Q. But no index is maintained of where that file folder is located or the fact that there is such a file folder?

A. Not that I am aware of.

Q. Dr. Gaffey, have you ever been asked by anyone in Monsanto to produce the contents of your files or the departmental files on pcb's?

A. I can't recall. It is possible that we have had people come down and examine our file, but I don't recall for sure whether that happened.

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Q. Would that be true of your personal files as well?

A. Oh, yes.

Q. In the course of the last four years, have you had occasion to dispose of or destroy any documents relating to pcb's?

A. No.

Except that our retention policy on correspondence is I believe one year, and although I have tried to retain my own correspondence beyond that date, I cannot guarantee that some of the older correspondence might not have been destroyed, together with whatever it contained on pcb's.

Q. Did your counsel give you any guidance or did any company official give you any guidance about maintaining pcb's files after litigation had been filed?

A. We received instruction with respect to several substances to maintain the files and not to have them -- not to allow them to be disturbed or destroyed. I believe we received such instruction with respect to pcb's, as well as other substances.

WATER_PCB-00044480

Q. All right.

So that correspondence files then should not have been destroyed, isn't that correct?

A. The correspondence that I am talking about is a regular correspondence file. I don't recall that I made copies to go into our pcb files. If I did, those items are still there.

Q. If you didn't, then you had documents relating to pcb's that weren't sent to the special pcb file, they were destroyed, is that right?

A. I would have to look and see.

Q. Is there a possibility that they were destroyed?

A. There is a possibility that my copies were destroyed, if old correspondence were destroyed.

I cannot now remember whether I have kept correspondence for more than four years.

Q. For more than four years?

A. You mentioned the period of four years. I can't remember whether I have such correspondence, because for a period of time it was policy to destroy them.

Q. Doctor, this litigation against Monsanto

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was filed in 1981.

To the best of your recollection, have you destroyed any documents, any papers of any kind related to pcb's since 1981?

A. No.

Q. You have retained all those documents, is that right?

A. Yes.

Q. Do you know of anybody else who has disposed of or destroyed pcb documents since 1981?

A. No.

Q. Doctor, to your knowledge, were documents, your documents relating to pcb's or your department's documents relating to pcb's, taken to any other location by other officers or employees of Monsanto?

Were they physically removed from your working area?

A. I don't recall that they were.

However, if they were, they would have been labeled by whoever had taken them, so that by inspecting the files as they now exist, one would be able to tell whether they had in fact been looked at and microfilmed.

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Q. And then returned?

A. And then returned.

Q. Doctor, what other division or section within the medical department maintain pcb records?

A. I don't know.

Q. Does toxicology maintain pcb records?

A. I don't know whether they do or not.

Q. Who would know?

A. I assume that the current chief of toxicology would know.

Q. Doctor, let's see if we can get the subject of pcb's and what you have written about pcb's. I am now talking about whether it is a memo, a note to yourself, whatever.

You came to Monsanto in 1979?

A. That's correct.

Q. Let's go chronologically since 1979 and to the best of your recollection tell us what you have written about pcb's in any form, published, nonpublished?

A. The first thing that I wrote about pcb's was the review called the epidemiology of pcb's. I don't now recall what happened to the earlier

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drafts of that paper, if in fact it existed.

It is my custom to write material out by hand and have it typed, and if the typing is satisfactory, to destroy the original writing. And since do not now have any of that, I assume that is what I did.

Q. You did that, you wrote the paper in 1981?

A. That would have been in late 1980, to the best of my recollection.

Q. All right.

A. In late 1981, I wrote a paper called recent epidemiology of pcb's, which was a detailed examination of a subset of the papers reviewed in the earlier one.

Q. All right.

A. The comments about handwritten notes being typed that I made in connection with the first paper also apply to the second one.

Q. Are you still in possession of those notes?

A. No, I am not.

Q. So you destroyed those notes?

A. As was my custom, I hand wrote them, gave

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them to the secretary for typing, and when the typing was satisfactory, destroyed the hand notes.

Q. Was this before or after you were advised not to destroy any papers with respect to pcb's?

A. I assume it was before. But I am not certain. I assume that if it had been -- if I had been advised before that date that I then would have retained these papers.

Q. Let's go on in the chronology.

What papers, if any, published or otherwise, notes, memos, did you do with respect to pcb's?

A. The reviews that I described of the papers by Brown and Jones, Brown, Bertazzi, Gustavsson, Emmet, these reviews were embodied in memoranda which I had sent, and to the best of my recollection there were no other memoranda other than the ones embodying those critiques.

Q. Did you prepare the critiques first and then put them in the memorandum?

A. Yes.

Q. Did you do that in handwritten form?

A. Yes.

Q. Did you retain the handwritten copies?

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A. No, I did not.

Q. This was done when, critiques?

A. Those reviews were written between 1983 and '84. I guess, and '86.

Q. Which was the '86?

A. The most recent one would have been the comment on the studies of Gustavsson and Emmet, I believe.

Q. The Brown and Jones critique had to be done recently as well because of the second Brown update, isn't that right?

A. The second Brown update has not yet been published.

Q. Did you critique it?

A. Yes.

Q. So when did you have it available to critique?

A. About five or six months ago, I believe.

Q. So that was in '86 or '87 as well, then, isn't that correct?

A. That's correct.

Q. And the second Bertazzi update is an '86 document, is it not?

A. Yes.

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Q. So you would have had to do the Bertazzi memo in '86, isn't that right, or '87?

A. Late '86 or early '87.

Q. Again did you have handwritten notes in in the preparation of that?

A. I always write out by hand what I want to have typed up.

Q. All right.

And with regard to those handwritten notes, do you still have those in your possession?

A. No, I do not.

Q. Was that before or after you were instructed about document destruction relating to pcb's?

A. It was after.

Q. And yet you destroyed them anyway?

A. I didn't consider it a document. And it duplicated what had been typed.

Q. Did you ever go through drafts, do you ever change things, Doctor?

A. I do.

Q. Did you change them back on your original handwritten notes or do you change them on the typewritten draft?

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A. Almost always in my handwritten notes.

Q. So you go back and make the changes on your handwritten notes; is that right?

A. That is correct.

Q. So what your handwritten notes said may differ in terms of what they initially said from what is in the final typewritten draft, isn't that right?

A. That's possible.

Q. Were your draft memoranda on these subjects submitted to anyone for review prior to the finalization?

A. No.

Q. How about the chapter on the recent evidence of pcb's and the chapter or the title paper the epidemiology of pcb's?

A. Oh no, no.

Q. Any other writings, notes or otherwise, with respect to pcb's?

A. No.

Q. Did you receive any communications, written or otherwise, with respect to pcb's? Let's go back over the last six years.

A. I don't believe so, other than possibly

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telephone communication asking my opinions on particular papers.

Q. Did you receive any notes, memoranda, letters of any kind critiquing your papers or reviewing your papers or making any comments about your papers?

A. No. Not outside of what had appeared in other publications. No communications directly to me.

Q. Have your papers been critiqued in other publications?

A. Yes.

Q. Where?

A. I can't remember precisely, but soon after the presentation of my second paper on recent studies of pcb's, there was a critique by Dr. Fischbein. It appeared I believe in one of the periodic newsletters that turns up with news on occupational and toxicological issues.

Q. Any other written comments or critiques?

A. Not that I am aware of.

Q. Doctor, have you had occasion to testify either in administrative hearings, depositions or trials with respect to pcb's?

WATER_PCB-00044489

A. Yes.

Q. Where and when?

I am sorry. Before you answer that question. Is it correct that you have completely and fully described all the written documents that you are aware of, written papers either to or by you with respect to pcb's over the last six years?

A. Yes, to the best of my recollection.

Q. What else do you have in your pcb files?

A. Copies of reprints.

Q. Do you have copies of any other documents prepared by Monsanto employees or consultants with respect to pcb's?

A. No.

Q. To your knowledge has anybody else within Monsanto prepared any documents with regard to pcb's and health effects or pcb's generally that you are aware of?

A. Not that I am aware of.

Q. If there were any such documents, where would they be located?

A. In all probability, Dr. Craddock would have those either in his files or some place a available to him.

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Q. Do you know whether Craddock maintains his own pcb files?

A. No, I don't know.

Q. Okay.

Who else in the medical department is responsible for dealing with pcb's currently within Monsanto?

A. I don't know.

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Q. Have you had any conversations with other medical department personnel about the health effects or risks of pcb's?

A. No.

Q. In the time that you have been there since 1981, you have not had meetings or conversations with other medical department personnel concerning the health risks represented by pcb's; is that correct?

A. That is correct.

Q. How about nonmedical personnel of Monsanto. Have you had meetings with other personnel of Monsanto regarding the health effects of pcb's?

A. Yes.

Q. Who are those personnel and when did you

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have such meetings?

A. Dr. George Levinskas, formerly director of toxicology for Monsanto.

I seem to remember talking to him about some issues regarding the epidemiology of pcb's. This may have been the conversation as a result of which I wrote the critiques of the Gustavsson and Emmet papers that I have described.

Q. When you say former, at the time you had the conversation, was he an employee of Monsanto?

A. Yes, he was.

Q. Is he still an employee of Monsanto?

A. He is now a consultant.

Q. Did you prepare any written memorandum or recording of that conversation?

A. No. My only response to it was -- if my recollection is correct, my only response to it was the memorandum which contained the brief critiques of the two papers I mentioned.

Q. Did Levinskas send you any documents?

A. Not that I recall.

Q. When was the meeting with Levinskas?

A. I am not sure, but it must have been sometime early in 1986.

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Q. Was he a consultant or an employee at that time?

A. I believe he was an employee at that time.

Q. And he still consults for the medical department, does he?

A. He has never consulted for the medical department.

Q. Okay.

For whom has he consulted within Monsanto?

A. For the department of medicine and environmental health and for the toxicology group, which is a subset of it.

Q. Okay.

Is that different than the medical department?

A. When you say medical department, you must -- I assume you mean either occupational medicine or the department of medicine and environmental health. The latter is the group for which Dr. Levinskas consulted.

Q. What is the overall group called?

A. The department of medicine and

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environment -- pardon me. The department of medical and health services at the moment, its name changed.

Q. I forgot about reorganization within the company. Department of medical and?

A. Health services.

Q. All right.

Then within that department, there is the epidemiology department?

A. That's correct.

Q. The occupational medicine department?

A. Yes.

Q. Toxicology department?

A. Yes.

Q. Industrial hygiene department?

A. Yes.

Q. Quality assurance department, right?

A. Yes.

Q. That's it, right?

A. There is an information group which I think is now organized separately. It was formerly part of industrial hygiene. It is called information services. I had forgotten that when I listed these earlier.

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Q. That's called a department, too?

A. I don't know what formal designation is used for all of these. We usually called my unit a section.

Q. Now, Levinskas would be consulting for medical and health services?

A. He would be a consultant to that major departmental organization, probably in the area of toxicology, since that was his expertise when he was here.

Q. Okay.

Doctor, do you know how pcb files are maintained by the rest of the medical department, the big medical department?

A. No, I do not.

Q. How are files maintained generally through Monsanto Corporation? In other words, is there a central filing system or index?

A. I don't know what Monsanto does.

To the best of my knowledge, there is no central index for my files which are maintained independently within epidemiology.

Q. But how about epidemiology's files?

A. I am not aware that we have any files

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outside of my particular unit.

Q. And your unit's files are not maintained on any kind of index or directory?

A. There aren't that many of them. We have files filed alphabetically by plant. We have a limited number of files alphabetically by substance.

Q. You have obviously some files by substance for pcb's?

A. Yes.

Q. Do you know how the other sections within the medical department maintain their files?

A. No, I don't.

Q. Now, we were getting into before we went back and worked on the documents, we were getting into your testimony at either deposition, administrative hearings or trials or any other purpose. You were going to relate chronologically what you have done.

A. I provided testimony at a trial involving a manufacture named Haley in the town of Bad Ax, Michigan.

Q. All right.

A. I provided a deposition in connection

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with litigation over clean up of pcb's in Waukegan harbor. And I provided a deposition in connection with one other pcb case, I believe the plaintiff's name was Scott, but I am not certain.

Q. Where was that?

A. I believe that was in Texas.

Q. Are you scheduled to testify in the Scott case in Texas?

A. Not to the best of my knowledge. I have not been told so.

Q. And are those deposition transcripts, copies of those transcripts in your possession, or trial transcripts, either one?

A. I believe that the Scott one is. The others are not.

Q. Did you keep copies of the deposition transcript on the Waukegan case in your files?

A. No.

Q. Did you ever give copies of that Haley trial transcript to anybody else?

A. No.

Q. To your knowledge does the legal department of Monsanto maintain copies of your testimony?

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A. I believe they do, but I don't know.

Q. Who is the Monsanto attorney who is your liaison with respect to pcb's?

A. I believe it has been Mr. Thomas Bistline. That's B-i-s-t-l-i-n-e.

Q. He is located in St. Louis?

A. That's correct.

Q. And is he the one who advised you not to destroy documents relating to pcb's?

A. I believe that was in the form of a memorandum, but I don't recall who signed it.

Q. Do you have that memorandum in your possession?

A. I doubt it.

Q. Have you written any documents for Mr. Bistline?

A. Not that I recall.

Q. For any other Monsanto attorney?

A. I don't believe that I have.

Q. Do you know whether anybody else in the overall medical department or within the department of epidemiology has written any documents for Monsanto attorneys with regard to pcb's?

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A. I know that nobody in the epidemiology department has. I don't know about the rest of the medical department.

Q. What documents did you review for preparation for your deposition here today?

A. I reviewed again my two papers on the epidemiology of pcb's. I looked at a recent study of Bloomington by a group whose senior author was a doctor Stehr-Green. S-t-e-h-r-G-r-e-e-n.

Q. Is that a short paper on blood levels?

A. No. It was a paper in which the authors attempted to identify what they characterized as a high risk group in the town of Bloomington and then within that group looked at blood levels.

MR. KARAGANIS: Mike, maybe you can tell me, is this the New England Journal of Medicine update?

MR. FRUEHWALD: No. I don't know if it is the New England Journal of Medicine or not.

MR. KARAGANIS: This is with the State of Indiana?

MR. FRUEHWALD: I have some copies here. One of them -- these are my marked up copies. But one ever them is the publication is in the Archives of

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Environmental Health.

MR. KARAGANIS: Let me just look at the title. I won't look at your marks. This is Gregory Steel?

MR. FRUEHWALD: Yes. Gregory Steel and Stehr-Green. The typed up report on exposure of health assessment with Greg Steel.

A. In addition, I looked once again at the Gustavsson study.

BY MR. KARAGANIS:

Q. Did you go back to your memoranda with respect to the critiques of these earlier studies, the Brown?

A. No. I did not.

Q. What else did you look at?

A. I looked at two publications by Jacobson and the group of other authors on the relationship between pcb exposure and health measurements on young children.

Q. Which documents were those?

A. I forget the exact publications. One of them was a 1984 publication, one was a 1985. And I can't remember the precise citations on them.

Q. If you ou have got them here, I would

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like to have them identified for the record.

MR. FRUEHWALD: These are the once Bill gave me as having been looked at recently. One of them is called, "Prenatal exposure to an environmental toxin," published in the Developmental Psychology Volume 20, page 523, 1984.

Another one was in called, "The effect of interuterine pcb exposure on visual recognition memory," published in Child Development, Volume 56, page 853, 985.

I believe this paper was maybe one among the Mary Moses list.

MR. KARAGANIS: Both out of the University of Maryland?

MR. FRUEHWALD: No, Wayne State University. Greta Fein from the University of Maryland is a coauthor.

BY MR. KARAGANIS:

Q. Doctor, did you give Mr. Fruehwald a set of documents that you had examined?

A. I gave him the Jacobson studies.

I believe I gave him or made sure that he already had my two papers on the epidemiology of pcb's. He showed me the Gustavsson study, which I

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had a copy of already.

Q. Did you give him anything else?

A. No.

I beg your pardon. Yes. I gave him the most recent copy that I had of the Brown update, of the NIOSH mortality study.

Q. When did you give him these documents?

A. I guess two days ago.

Q. Here in St. Louis?

A. Yes.

Q. Had he given you the Stehr-Green Bloomington study to examine?

A. Yes.

Q. When did you first examine that study?

A. It is approximately two weeks ago.

Q. When were you first contacted about testimony in this case?

A. It would have been approximately three or four weeks ago.

Q. So you haven't done any work on this case or any analysis on this case until within the last three or four weeks; is that right?

A. Strictly speaking, I haven't done any analysis on the case. I have done analysis on pcb

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papers and literature and the Stehr-Green paper.

Q. In the last three or four weeks?

A. In the last three or four weeks. I have looked at the Stehr-Green paper and refreshed my recollection of some of the ones that I had reviewed earlier.

Q. Doctor, why don't you tell us what you expect to testify to with regard to epidemiological and other studies on humans exposed to various types of pcb's?

A. I expect to say, first, that it has generally been established that people who are exposed to high levels of environmental pcb's have detectable increased levels of blood and serum pcb's.

Second, numerous cross-sectional studies of health effects have shown no effect other than dermatitis, which has sometimes been described as chloracne and sometimes as dermatitis. That is, the so-called Yusho incident, by the statement of Japanese investigators who have concerned themselves with it, is not so much a pcb incident as an incident of exposure to dibenzofurans.

And finally, that the existing mortality

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studies of cancer in pcb workers show no indication of an excess. I beg your pardon, show no indication of an excess associated with pcb exposure.

Q. Have you written your opinions down anywhere?

A. No, I have not.

Q. Okay.

Let's start with the paper entitled, "The epidemiology of pcb's," which I believe you said you looked -- maybe you didn't.

Would you describe the structure of your paper called, "The epidemiology of pcb's," and what you looked at?

A. I began by saying that I was not going to look at antidotal, clinical accounts. That I was going to confine myself to an evaluation of the risk of ill health.

And I began, as I recall, by looking at those studies that investigated the relationship between occupational or environmental exposure to pcb's and blood levels.

Then having disposed of that, disposed of it means that I agreed that the literature showed

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that indeed there was a relationship between blood levels of pcb's and exposure. I then went on to look at the studies that had examined various kinds of symtomology.

I looked at, I believe, first, examination of the various kinds of metabolic alterations that were looked at. Some of these were liver metabolism. Others were lipid metabolism. Then I looked at dermatological findings. Then I believe I looked at other signs and symptoms, and finally at carcinogenicity.

And in each case I went back to the original listing of studies that I had obtained from the literature and identified those studies that addressed the particular points that I was considering in each of those sections.

Q. All right.

A. So the same study may have turned up more than once, if it addressed more than one of these particular issues.

Q. Okay.

Let's start with the environmental levels in blood and body burdens.

A. Yes.

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Q. All right.

You have your reprint in front of you. We may be dealing with different pages, but let's see if we can move forward.

A. Very good.

Q. You indicate that there are two studies of the relationship of pcb's, pcb exposure by ingestion and blood levels; is that right?

A. I don't recall what I said. Yes. I beg your pardon. Yes, that is correct.

Q. Is that still true?

In other words, that to your knowledge there are only two studies that show ingestion of pcb's and blood levels?

A. Yes.

Q. Now, you then talk about studies that have compared blood pcb's and exposure to atmospheric pcb's; is that right?

A. No. These are blood levels and exposure defined by occupation, with the exception of two community studies. I don't believe that there was any specification of the route of exposure.

Q. I am sorry. I am relying on the second paragraph of the paper that says, in the section

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it says a number of studies of blood pcb's and exposure to atmospheric pcb's have been made.

A. I believe this may be a change, then, because that is not what I intended. I think if you will look at the paragraph there.

Q. All right.

Obviously what you have pointed had out is a change between the September 15, 1981 epidemiology of pcb, Monsanto document 4416, and the published version, which is in chapter 20.

A. Chapter 20. I was not aware of the change, but the latter is the document that I have been relying on.

Q. With respect to that change, do you recall who made that change and why?

A. No. But it was probably me, because it was obvious that atmospheric exposures to pcb's could not have been the only route of exposure for any of the people that were studied here.

Q. So these would be, beyond ingestion you said there are two studies for ingestion.

A. That's right.

Q. Beyond ingestion, there are other studies that measure exposure to various environmental

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concentration of pcb's and body burdens, is that right?

A. Yes.

Q. You think you have defined that of those studies there are three kinds?

A. That's correct.

Q. What do you mean by type A? When you describe type A, what was type A?

A. A study which compared people who had been exposed with another group that had not been exposed.

Q. All right.

Q. Then what was type B?

A. Type B was a comparison of the same people during exposure to pcb's and after the exposure ceased.

Q. Type C?

A. Within those people who had exposure, a typical comparison looked at people with short exposures versus people with long exposures, although they may have been subdivided into more than two groups.

Q. The Baker study that you referred to here is a type A study, is that right?

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A. That's correct.

Q. Now, the Baker study was a study of Bloomington, was it not?

A. That's correct.

Q. And I believe you found that the Baker study did not show higher levels of pcb's -- higher levels of pcb in the blood, higher pcb levels in the blood in association with higher levels of exposure, is that right?

A. I believe it did show it. The results were not quite consistent because within the population, three groups were looked at. One was a group of occupationally exposed people; second was a group of people who used or said they used a municipal sludge which had allegedly a high level of pcb's; and, the third group was people who were in neither of these categories.

Q. The third group was the so-called control group, is that right?

A. The control group.

Q. Didn't you find that the middle group which had been exposed to pcb's had slightly lower levels?

A. Yes.

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Q. Than the controls?

A. Yes.

Q. Now, with respect to the exposure studies, isn't a fact that the Baker study, the results of the Baker study showed that people exposed to pcb sludge had lower blood level pcb's than the control population?

A. That's true.

Q. And you treat that as an anomaly, do you not?

A. No. Because in that same study there was a group of people with occupational exposure who had the highest values of the three groups.

Q. I am talking now about the people in the community who, according to the study, had said, alleged that they had been exposed to pcb's. They were compared to a control group, were they not?

A. No.

The study looked at three groups of people in the community. And some of them said they had occupational exposures. Some said they were exposed to sludge and some said they had no exposures at all.

And in that group the highest group was

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the occupational people, the lowest group was the sludge. So there was not a uniform gradient with presumed exposure.

Q. All right.

So that then is inconsistent with the proposition that the greater the pcb exposure, the higher the blood levels, isn't that correct?

A. No. Because the highest group of people, the people with the highest exposure, had the highest pcb levels.

Q. And the people with the middle exposure had the lowest pcb levels, is that correct?

A. Yes. So the trend does not agree precisely with what one would expect as a gradient.

Q. As a matter of fact, you describe it as and anomaly in your paper, do you not?

A. Yes.

Q. So the Bloomington study has at least one anomalous result that is inconsistent with your proposition that blood levels and pcb exposure correlate, is that right?

A. Yes.

Q. The fact that there is one anomalous

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study result doesn't necessarily mean that your conclusion is in error, does it?

A. No.

Q. The fact that there are individual studies that are inconsistent with an overall conclusion by an expert doesn't mean that there are not other pieces of evidence that support the conclusion; isn't that right?

A. Generally speaking, that's correct.

Q. Would it be fair to say that experts when they evaluate epidemiologic evidence may find pieces of evidence that are contrary or inconsistent with their conclusion, but may find that other evidence outweighs that inconsistency in their opinion, is that right?

A. That is generally true, yes.

Q. As a matter of fact, in the instance of the Baker study, based on your examination of other data, you would conclude that the anomaly with respect to the middle group is just that, an anomaly, and doesn't affect your overall conclusion, is that right?

A. That's correct.

Q. Now you say that as to the type B

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studies, now these are the studies that say that there is a decrease in exposure.

Are you familiar with any more type B studies other than the ones you have listed?

A. No, I am not.

Q. Now, of those studies which relate to exposing a population and then removing the exposure, there were four studies, were there not?

A. That's correct.

Q. Now, those four studies, two showed that when you removed pcb's, there was a decrease in blood concentration, and then there were two studies that showed that there wasn't a decrease, isn't that right?

A. That's right.

Q. So, based on these two studies -- I am sorry, these four studies, what do you conclude when you say you remove pcb's, exposure of pcb's, will there be a decrease or will there not be a decrease?

A. I believe they will be a decrease.

Q. Therefore, the two studies, the Hasegawa, H-a-s-e-g-a-w-a, and the Ouw, O-u-w, you reject the findings with respect to that proposition, do

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you not?

A. For two reasons.

Q. Just answer my question first.

A. Yes.

Q. All right.

And for what reasons do you reject, for what reasons?

A. In the case of the Japanese study, the reexamination was very soon after the exposure. In the case of the Ouw study, Ouw and his colleagues both say that the decrease was accomplished partly by recommending safety precautions, such as gloves and other protection, which they do not believe the workforce used consistently.

So there is some question as to whether or not there really was a meaningful decrease in exposure in the Ouw study.

Q. What you are saying is that while you may decrease one source, these people may have been coming into contamination or exposed to contamination from another source?

A. Or they may not have done the things that were recommended as a technique for reducing

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exposure.

Q. So, basically would it be fair to say that on the second group of studies, this group of studies that study pcb blood levels after removal of source of exposure, though two studies say there was reduction, and two studies say there wasn't reduction, you reject the two studies that say there was no reduction for the reasons you have given?

A. That's correct.

Q. And you are concluding that the two studies that do find reduction are the ones to be accepted for purposes of your analysis, is that right?

A. That's correct.

Q. Let's turn to the C type studies.

The C type studies are comparisons of groups with different durations of exposure, is that right?

A. That's correct.

Q. Now, this would be to say, look, if you were exposed for X number of years or X number of months, what your blood level is, versus exposure for Y number of years or Y number of months; is

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that right?

A. That's correct.

Q. And was it found that there was a correlation between length of exposure and pcb blood levels?

A. In general, yes.

Q. Now, you say in your paper that the results are not very consistent?

A. No, they are not. Three yes's and two no's. The study that is worth looking at in that one is Bomgardner. I tend to give his study less weight because it shows no relationship between pcb levels and age. That is probably the most strongly related factor that's been found in other studies.

Q. In what way?

A. Pcb levels go up with age.

And if you do an analysis in which you look at the effect of age jointly with other factors, age is the most important determinant of pcb levels.

Q. So would it be fair to say that, again, though you have some studies that show a positive correlation between the duration of exposure and

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pcb blood levels, and other studies which show a negative correlation; that on the basis of your analysis of the weight of the evidence, you conclude that there is a relationship between length of exposure, duration of exposure and pcb blood level?

A. It would be more correct to say that some studies showed a positive relationship and some did not.

Q. Right.

A. Not that they showed a negative relationship.

Q. All right.

A. But, yes, on the basis of the data, I have concluded that in my opinion pcb levels are related to level of exposure, all other things being equal.

Q. So it is fair to say that you have weighed the different evidentiary value of the various studies and chosen to use some evidentiary basis of those studies to support your conclusion and to reject others?

A. That's correct.

Q. And that's part of the normal scientific

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process, is it not?

A. Yes.

Q. And if there might be another scientist who might say that there is no relationship between pcb blood level and duration of exposure and that scientist were to rely on Bomgardner and Hasegawa, while you might disagree with that scientist, that scientist might have a different evaluation of the weight of the evidence, is that right?

A. That's quite true.

Q. That is a matter of scientific dispute, is it not?

A. Yes.

Q. Now, what is the significance may I ask of pcb blood levels, pcb exposure and health effects, in your opinion?

In other words, you have got a whole section in here that says that in your opinion there is a positive relationship between duration and blood levels, positive relationship between exposure levels and blood levels. What does this mean with respect to health effects?

A. Are you asking me now what is the

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relationship between pcb blood levels and health?

Q. Well, what is the purpose of this section in the report; I take it it is related to human health.

A. The purpose of this section is to deal with the issue that if there were no relationship between exposure and body burden, there would then be no meaning to the subsequent studies.

Q. All right.

A. Having found a relationship, I then conclude that there is meaning to the subsequent studies.

Q. So that if another scientist were to say of that, the data is equivocal or the data with respect to the relationship of exposure and blood levels is contrary, that that would cast doubt on the validity of the epidemiologic studies, is that right?

A. Yes.

Q. So you have to reach the conclusion that there is this relationship in order to go to the next step; is that right?

A. That is correct.

Q. Now, let's turn to the epidemiologic

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studies of pcb's and health.

Before we do, this duration of exposure group of studies with the three yes's and two no's, you indicated that the lack of consistency in these studies may be due to what you call confounding effects of age and sex.

A. Yes.

Q. What do you mean by confounding effects?

A. That we know that, all other things being equal, blood pcb levels increase with increasing age. We know all other things being equal that blood pcb levels are higher in men than in women.

So, if you were to look at duration and if it turned out that all the short-termers were young and all the long-termers were old, you wouldn't know whether the difference you saw was in fact due to the duration of exposure or whether it was due to the age, which we call a confounding factor.

Q. You are not able by looking at the data and the report to make any adjustments, is that right?

A. That is correct.

Q. So this is a hypothesis on your part as

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to what may be the explanation for the inconsistency, is that correct?

A. That's correct.

Q. And it is not a proven hypothesis, it is a hypothesis to suggest one possible reason for the inconsistency, is that right?

A. That is right.

Q. Would it be fair to say from a scientific standpoint that another hypothesis might be that, indeed, there is a inconsistency in results, a legitimate inconsistency; that there is not a relationship between pcb blood levels and duration or amount of pcb exposure?

A. Yes.

Q. Do you know of any scientists who have taken that position?

A. No.

Q. Now, you have a group of reports in here as to pcb, epidemiologic studies of pcb and health. You say excluding the mortality studies, there are eighteen studies.

Do you know of any more than the eighteen?

A. Yes. There are the two subsequent

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studies by the Jacobson's, which relate to health of young children. And I guess that is about all. I am sorry, no. There is also the study by Emmet at Johns Hopkins.

Q. That study is what?

A. It is a combination of studies of exposure, because he looks at an exposed group and an unexposed group, and looks at their levels of pcb. And also a study of health effects.

Q. Okay.

What kind of health effects was he looking at?

A. I believe he was looking at various types of symptoms that he elicited in response either to a physical examination or to a questionnaire.

Q. Now, of these seventeen studies, I am sorry, the eighteen studies, plus the ones you have just mentioned, you list in table 4, in fact, studies which have dealt with dermatological findings and the other studies that dealt with physiological parameters and then which ones dealt with symptoms and illness.

A. Yes.

Q. So let's see if we can, independent of

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the dermatological findings for the moment, let's look at physiologic parameters.

What physiologic parameters were being measured?

A. Various liver enzymes, which reflect liver function. Various concentrations of different types of fat in the blood, such as cholesterol and triglycerides. And measurements such as red blood count, white blood count and blood pressure.

Q. All right.

Then what health effects were discussed?

A. The health effects covered a rather large spectrum. They typically dealt with illnesses and reproductive problems. I have listed in some detail the particular things that were covered by the various studies. But, essentially, they covered reported illnesses, reported disabilities, infertility, birth defects.

Q. Where are the studies related to birth defects and infertility?

A. I would -- if you will give me a moment.

Q. Sure.

A. In the section entitled symptoms, illness

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and other conditions. In the first paragraph, the last sentence describes a study by Kreiss et al, and they looked at prevalence of various conditions, which included use of medication, use of medical care, history of heart disease, and percentage of pregnancies ending in miscarriage, stillbirth, or infant death.

Q. All right.

So, would it be fair to say that the only study that you mention in your paper, the only study that you analyze in your paper that dealt with reproductive effects or birth defects or birth abnormalities was the Kreiss paper?

A. I believe that is the case.

Q. And if we look at medical effects, the Baker paper simply interviewed people to see whether they complained of weight loss, anorexia, fatigue, headache, eye irritation, shortness of breath, et cetera?

A. That is correct.

Q. The Chase study, when you say no evidence of organ toxicity, what did Chase look at, what do you recall?

A. He gave people a physical examination and

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then took blood samples from which he analyzed things like liver enzyme values and pcb levels. The sentence, the expression no evidence of organ toxicity is a quote from Chase.

Q. That's based on liver enzymes and --

A. And a physical examination which he conducted, he or somebody under his direction conducted.

Q. So, of all these studies of the health effects -- I shouldn't say all these studies, eight studies dealt with health effects, is that right?

A. I would have to look at -- these are studies of health effects other than the physiological parameters and the dermatology?

Q. Yes.

A. Right.

Q. By that you mean whether people became ill?

A. Yes.

Q. So there were eight studies dealing with illness; isn't that right?

A. Yes.

Q. And only one of those studies that you

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looked at dealt with reproductive or developmental toxicity or birth defects; isn't that right?

A. That is correct.

Q. Now, the one study, let's turn to the cancer studies. Would it be fair to say that your analysis of the cancer studies, that there were basically four studies that you looked at?

A. That is correct.

Q. And the first of those was the Bahn, B-a-h-n?

A. That is correct.

Q. Now, the Bahn study, did that find a level of cancer of concern with respect to pcb exposure?

A. It found a level of one particular type of cancer, which is malignant melanoma.

Q. Did it find that there was a --

A. It found there was an excess.

Q. An excess which in their opinion represented a health concern in terms of cancer and pcb's?

A. That is correct.

Q. So of the four, one found that pcb's represented a human health cancer risk, but you

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point out that that study was withdrawn; is that right?

A. That is correct.

Q. So the evidence that you have got left, you have got three studies left, is that right?

Did you just disregard the Bahn study?

A. The conclusion aren't altered if you choose to believe the Bahn study. It doesn't make any difference.

Q. Now, the Zack and Musch study -- and I know you coauthored something with Zack. Has Zack been a consultant to Monsanto?

A. She was at that time an employee of Monsanto.

Q. Okay.

And what is her full name?

A. Judith Zack.

Q. Where is she now?

A. If she is still alive, she is in a small town in Michigan outside of Ann Arbor.

Q. Before we go on to the Zack study, would you define what you mean by cross-sectional studies?

A. A cross-sectional study is one which

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identifies a group of individuals and for each of them looks at a measure of the presence of some possible causative factor, and a measure of the presence of some health outcome.

In other words, it is a study in which you take a group of people and however things come out they come out. You look at the distribution of the exposed -- the potential exposure and a distribution of the outcome.

Q. Now, with regard to the Zack and Musch study, was Musch also an employee of Monsanto?

A. He was a summer employee, I believe in the summer of 1978, but that was before I came to Monsanto, so I am not certain.

Q. Okay.

So we have got the Bahn study, which showed a statistically significant relationship between pcb exposure and malignant melanoma. But you indicated before that was withdraw, and even if it wasn't withdrawn, it wouldn't change your conclusion; is that right?

A. That's correct.

Q. You have got the Zack and Musch study done by Monsanto employees, which says that there

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were no deaths from cancer of the liver, but there was an excess in respiratory cancer, is that correct?

A. That's correct.

Q. We indicated before that from an epidemiologic standpoint, the fact that there is not a statistically significant excess doesn't negate the value of a study. In other words, if there are excess deaths, that may be some evidence that you rely upon to reach a conclusion; isn't that right?

A. Yes.

Q. Even in the absence of statistical significance; isn't that right?

A. Yes.

Q. Now, do you find that the Zack and Musch study is positive evidence that pcb exposure does not cause or does not present a cancer risk to humans?

A. Yes. I consider it so, in connection with other studies that -- considered together with other studies that have been done.

Q. Now, the Zack and Musch study, were there things in the Zack and Musch study that may have

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affected the utility of that study from the standpoint of drawing an epidemiologic conclusion?

A. Yes.

Q. What were the factors that might have affected the utility of that study?

A. The first is that there was an excess of lung cancer throughout the whole plant, in which the study was done, and throughout the county in which the plant was located.

Q. An excess of lung cancer over what?

A. Over the national average.

Q. All right.

When we talk about what is expected, do we use the national average for what is expected?

A. People have sometimes used national averages and sometimes state or local rates. In the particular case in point we used national rates.

Q. Okay.

That was done in '82. Did you supervise that study?

A. No. It was reported in '82. It was done before I came to Monsanto.

Q. All right.

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So excess of lung cancer in the county is one problem.

A. Actually, the other problem is the small size of the study.

Q. What is the problem with the small size of the study?

A. It means that one's estimates of the risk involved are relatively imprecise, subject to a large potential random variation.

Q. So they are subject to a large potential for error, are they not, because of the size of the sample?

A. That is correct.

Q. What was the pcb concentration study by Bahn, do you remember? I am sorry, the type of pcb, not concentration.

A. I don't recall.

Q. What about Zack and Musch?

A. I don't recall specifically, but it was whatever type Monsanto was manufacturing at that time. That mix I believe changed over time, but I am not sure.

Q. Okay.

Let's go to the Brown and Jones study.

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Did the Brown and Jones study conclude that pcb's did not cause or did not pose a cancer risk to humans?

A. No.

Q. Is there any evidence in the Brown and Jones studies of pcb's posing any cancer risk to humans? I am talking now about the 1981 study.

A. No. There is equivocal evidence that they do not. But it is not very strong.

Q. So, from that study, it is one -- you can't use it as evidence that it doesn't cause cancer, but you can't use it as evidence that it does cause cancer; is that right?

A. Relying on my earlier statement that statistically -- that statistical significance is not crucial for drawing a conclusion, the weight of the evidence in the Brown and Jones study is slightly against pcb's as a human carcinogen.

Q. In your opinion?

A. In my opinion.

Q. You recognize that other scientists of qualification in their field might have different opinions, is that right?

A. Yes. But Brown and Jones are not two of

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them, because they did an update on the study as a result of the ambiguity.

Q. What was the ambiguity in the study?

A. That the number of deaths was small.

Q. You mean the number of death certificates them looked at?

A. No. The number of deaths that were stated on a death certificate to be due to liver cancer were small.

MR. KARAGANIS: Okay. Let's take a break for lunch.

MR. FRUEHWALD: Okay.

(Whereupon a recess was taken to one o'clock p.m. of the same day.)

WATER_PCB-00044533

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

THE CITY OF BLOOMINGTON, INDIANA; THE UTILITIES SERVICE BOARD OF BLOOMINGTON, INDIANA; and MONROE COUNTY, INDIANA, Plaintiffs,	)	
vs.	)	Civ No. IP 83-9-C
WESTINGHOUSE ELECTRIC CORPORATION, a Pennsylvania corporation; and MONSANTO COMPANY, a Delaware corporation, Defendants.	)	

The continued deposition of WILLIAM R. GAFFEY, called for examination by the Plaintiffs, pursuant to notice and pursuant to the provisions of the Federal Rules of Civil Procedure of the United States District Courts, pertaining to the taking of depositions for the purpose of discovery, taken before Arnold N. Goldstine, a Notary Public and Certified Shorthand Reporter within and for the County of Cook and State of Illinois, at the Park Terrace Airport Hilton, St. Louis, Missouri, on September 4, 1987, at the hour of one o'clock p.m.

WATER_PCB-00044534

APPEARANCES:

Mr. Joseph V. Karaganis and
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-and-

Mr. Geoffrey M. Grodner
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Mr. Michael R. Fruehwald
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appeared on behalf of Defendant
Monsanto Company.

WATER_PCB-00044535

WILLIAM R. GAFFEY

having been previously duly sworn,

was examined and testified as follows:

DIRECT EXAMINATION

BY MR. KARAGANIS:

Q. Now, Doctor, you said gave a copy of the Brown update to Mr. Fruehwald, is that correct?

A. That's correct.

MR. KARAGANIS: Would you, Mike, can I see that, please?

MR. FRUEHWALD: Yes. That I think is the same paper as what we gave to you earlier. But I was asking him for one that was not all marked up. And this was the final format, and that appears to be it.

MR. KARAGANIS: So has there been a change in the text?

MR. FRUEHWALD: I have not had time to compare them. I don't know. I just asked Bill for the version he thought was the one that was being published, and that's what he gave me.

MR. KARAGANIS: Would you mark this as 522.

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(The document above-referred to was marked Bloomington Deposition Exhibit No. 522 for identification.)

Q. Directing your attention to what has been marked as Bloomington Deposition Exhibit 522, entitled, "Mortality of workers exposed to polychlorinated biphenyls - an update," by David P. Brown, M.P.H., is this the update of the Brown et al study that you referred to, Brown and Jones study that you referred to in your paper, "The epidemiology of pcb's"?

A. It is the update of the study that's referred to there by Brown and Jones.

Q. Now, let's go back to the original Brown study.

Would it be fair to say that the original Brown study reported that there were more deaths from cancer of the rectum and more deaths from cancer of the liver than were expected?

A. Yes.

Q. And what population did they compare?

A. They compared that to the United States population.

Q. But they determined that the liver cancer

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was not statistically significant, is that right, the difference in liver cancer?

A. That is correct.

Q. Now, what kind of pcb's were study there?

A. I don't recall.

Q. These were capacitors, were they not?

A. The people who were studied were capacitor makers, yes.

Q. And the plants used 1254, 1242 and 1016, did they not?

A. I don't recall.

Q. From the standpoint of the epidemiology of pcb's as it relates to cancer risks, your opinions wouldn't be any difference whether it was 1242, 1016, 1254 or 1260; is that right?

A. That's right. Because my opinions are based on the outcome rather than on these supposed exposures.

Q. Now, in the first Brown study, the authors did note that the excess in liver cancer is noteworthy because it is consistent with toxicology data observed in laboratory animals exposed to pcb's where effects have been noted in the liver. That observation was made?

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A. Yes.

Q. Can you recall which studies they were referring to?

A. No. I don't recall, though I am aware that studies existed.

Q. Which showed that there was a cancer risk in animals, in pcb's?

A. There was an excess of liver lesions, whether they are cancer or not is something that the toxicologists are competent to pronounce on.

Q. You can't?

A. I can't.

Q. As a matter of fact, while there were a small number of death certificates due to cancer, the authors conclude that the slight excess for liver cancer and sclerosis of the liver, consistent with previously reported findings on experimental animals exposed to pcb, suggest that there may be and association between these causes of deaths and occupational exposure to pcb's; i.e., Aroclor 1254 and 1242. Do they not?

A. That's what they say.

Q. Do you disagree with that statement?

A. Yes.

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Q. So you disagree with the authors of the Brown and Jones report?

A. I disagree with some of their conclusions.

Q. Now, Brown and Jones, what were the original concerns about the Brown and Jones, the fact of the latency period and the small number of death certificates, is that right?

A. No. The main concern is that the -- although the number of death certificates were small, the greatest excess was in the people with the shortest employment and with the shortest interval from exposure to diagnosis.

Q. I am now referring, let's turn to 522, if I may.

MR. FRUEHWALD: That is the new study.

MR. KARAGANIS: Yes. I just want to compare it with the copy I have.

Q. Regard regarding the May, 1987, Bloomington Exhibit 522, do you know why there is a difference --

Let's go back. In Exhibit 522, the authors state that a statistically significant excess in deaths from cancer of the liver and

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biliary passages were observed, do they not?

A. Do they say that or do they say that was in women?

Q. I am sorry.

They say a statistically significant excess of deaths was observed in the disease category that includes cancer of the liver, primary and unspecified gall bladder and biliary tract, 5 observed versus 1.9 expected. P less than 0.05.

MR. FRUEHWALD: Less referring to the update, Bill, as opposed to the '81.

A. I am sorry, okay. I am sorry, that could well be.

BY MR. KARAGANIS:

Q. So that while they didn't find it statistically significant in the database that they had in the earlier study, they did find it statistically significant for liver cancer in the later study, did they not?

A. Yes.

MR. FRUEHWALD: Is that liver cancer or liver and biliary cancer?

A. It was liver and biliary cancer.

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BY MR. KARAGANIS:

Q. Did you peer review the Brown update?

A. No.

Q. Did you undertake any review of it?

A. I read it and reviewed it and commented on it internally at Monsanto in the documents that I have mentioned.

Q. Did you comments on it to Dr. Brown?

A. No.

Q. I am going to show the draft that we received from Mr. Rosiello of Barnes & Thornburg on August the 14th, which is a January 1986 draft, and ask you whether you have seen that before?

A. Yes. I have seen January 1986 draft.

Q. Do you know whose handwriting is on that draft?

A. Excuse me. Do you mean on the front page?

Q. On the front page or anywhere else in the draft.

A. I don't recognize the -- no, I don't. That is not my handwriting. And I don't know whose it is.

Q. All right.

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Now, with respect to the updated review, Exhibit 522, is it not correct that the authors conclude, or I should say Dr. Brown, or Mr. Brown concludes, quote:

"The update of this study provides limited information indicating that occupational exposure to pcb's may be associated with an excess risk of mortality from cancer of the liver, gall bladder and biliary tract."

Is that correct?

A. That's what he says, yes.

Q. Do you disagree with that statement?

A. Yes.

Q. So, let me just see if I have got this right.

The Bahn study, the authors concluded that there was a risk of melanomas from pcb, and although the study was withdrawn, you say even if it wasn't withdrawn, it supports your conclusion that pcb's do not represent a cancer risk, is that correct?

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A. That is correct.

Q. And the Zack and Musch study was done by Monsanto employees and contained only a group of 89 workers; is that right?

A. That is correct.

Q. And in the Brown and Jones study, you would agree that Brown and Jones indicate that there is a risk, that the evidence indicates a risk of cancer from pcb's, is that correct?

A. No. They said that the evidence indicated a risk.

Q. Yes.

A. Yes.

Q. That the authors concluded that the evidence indicated a risk, isn't that right?

A. That is correct.

Q. All right.

So that at least as to Bahn and Brown and Jones, the authors of the studies that you have evaluated indicate that pcb's represent a cancer risk to humans; isn't that right?

A. That's what they say.

Q. And why do you disagree with them?

A. Essentially because the International

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Agency for Research on Cancer has produced a set of criteria, which one should use as a basis for judging carcinogenicity in epidemiology studies.

And one of those criteria is, first, that there should be a dose response relationship. If a little bit is bad, a lot is worse.

The second is that the finding should be repeatable consistently in different studies. Now, if we apply those criteria to the studies here.

Q. Are those the only two criteria?

A. There are many others, but those are the ones that I thought were relevant.

Q. Okay.

So dose response and repeatability?

A. Dose response relationship, and that the findings should be observable in many independent studies, in different independent studies.

Q. All right.

A. The one interesting thing about the four studies, Bahn, Zack and Musch, Brown and Jones and Bertazzi, is that they are not consistent.

Q. They are not consistent in what sense?

A. The melanoma that Bahn found is lacking,

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there is no mention of melanoma in any of the other studies.

Q. All right.

A. It is not just that there isn't a statistically significant excess, it is missing, it is not there. The lung cancers that Zack and Brown find are missing in the other studies. The liver and rectum cancer is missing in the other studies.

Q. The liver and rectum studies that --

A. That Brown and Jones found. Because the typical mortality study looks at multiple causes of death. The probability that there will be at least one statistically significant result in a study that looks at ten or fifteen or twenty or thirty different causes of death, the probability is overwhelming that there will be at least one statistically significant excess. And if I did not see an excess in a study, I would be suspicious of it.

Q. A statistically significant excess?

A. Depends on the size of the study. I would expect that any large study that did, looked at fifteen or twenty cancers, the probability

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would be high that there would be one statistically significant excess at least.

Q. All right.

A. So what I would expect to see, if I did a series of independent studies of a population with no excess risk, is that I would see sporadic excess from different causes that had no connection between them from one study to the next.

That's exactly what I see here. With one more exception or one more addition. Which is, that in the Brown and Jones studies, the gradient, the dose response relationship is the reverse of what one expects in an occupational study.

Brown -- the reason I don't agree with the conclusion of Brown, and Brown and Jones, is particularly in the update, Brown looks at the dose response relationship, finds that it is the opposite of what it ought to be, and in his text says it is uninformative.

He does this with several other analyses, such as analyses of women who are the group in which the excess is greatest.

And the net result is that nowhere in the

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text of Brown's paper can one find any suggestion that the dose response relationship is in the opposite direction to what should be expected. Only way you can find that out is by looking at the tables.

Q. So you find that the Brown and Jones study, including the update, even though the authors indicate that there is a risk of cancer from pcb's, you disagree with that?

A. Yes, I do.

Q. And you base that on comparing the Brown and Jones and Zack studies and Bahn, if that was included with the IARC criteria, is that right?

A. That is correct.

Q. What about Bertazzi?

A. The Bertazzi study is really not consistent for the same reason, but has a couple of other major defects that would make one suspect the legitimacy of what happens in the study.

For one thing, Bertazzi did no analysis by -- to determine whether there was a dose response relationship. He did no analysis by duration of employment.

What is more important is that in

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Bertazzi's study, about three-quarters of his cohort was female. And if you look at the expected mortality that Bertazzi expected to get, done by the kinds of calculations that are conventionally done in epidemiology. If that study were done in the United States, the only way you could get an expected mortality that low would be if the average age of the workforce was below the age of twenty.

This means to me that not only that the average age must have been below twenty, but must have stayed below twenty for the twenty years of follow-up.

The only way in which one could account for this would be to hypothesize that, A, that the mortality rate for Italian women is spectacularly low, or that the public figures against which Bertazzi made his comparisons were not very valid.

Therefore, I suspect the Bertazzi study because his expected values are much too low. They are so low that you could not have done a study in the United States and gotten expected values as low as Bertazzi got.

Q. With respect to the control population?

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A. That is correct.

Q. Nevertheless, Bertazzi found a statistically significant increase in cancer among females, did he not?

A. Yes.

Q. With respect to lymphatic and hematopoietic cancer?

A. Yes.

Although, in fact, the excess was specifically in Hodgkin's disease -- well, in Hodgkin's disease, he had one nephrosarcoma, I believe, but he had three Hodgkin's. None of which incidentally turned up in his males.

Q. Well, he had a statistically significant increase in males in digestive cancer, did he not?

A. Yes, but a a different cancer site. A differ etiology.

Q. What do you mean a different etiology?

A. The orgins of the cancer is different. And one of the ways you can tell this is by looking at what happens to the cancer rate by age.

You find that cancer rates for digestive cancer have an entirely different age pattern from the cancers rates for leukemia.

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And so you lack the consistency that IARC says you ought to have before you can draw this conclusion. You see, if you don't believe --

Q. Before you can draw the conclusion that?

A. That pcb's are a human carcinogen on the basis of the evidence of this study.

Q. On the basis of human data, is that right?

A. Yes.

Q. Now, did Bertazzi say anything in his studies, either the original study or the update, with respect to indications as to whether pcb's were a carcinogen, human carcinogen?

A. It seems to me that he said they might be.

Q. All right.

You disagree with that?

A. Certainly. Unless he can explain the apparent anomaly in his study, it seems to me that the validity of the study as evidence of any kind is suspect.

Q. You are saying basically that the validity of the four studies, you disagree with Bertazzi, you disagree with Brown and Jones, Bahn

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you disagree with or it's been withdrawn, and Zack. Did they conclude that there was a statistically significant increase in cancer?

A. They did not find a statistical increase in cancer, but I believe you misstated my position.

Q. All right.

A. I disagree with the way that Bertazzi did his study. I have no difficulty with the way in which Brown and Jones did their study. I disagree with their interpretation, which I consider to be blatantly biased.

Q. All right.

You consider Brown and Jones to be blatantly biased.

And Bertazzi indicated there may be a risk of cancer from pcb's, is that right?

A. If Bertazzi's study were valid, his interpretations would be to my mind reasonable.

Q. All right.

A. I have no problem with his interpretations from the data that he got. My difficulty is with the data that he got.

Q. Given, if the data were valid, you would

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conclude that there was a risk of cancer from pcb's?

A. I would conclude that there was a suspicion. Because again we don't have any analysis by latency.

Q. All right.

A. We don't have the consistency between men and women.

Q. But if the data were valid, the evidence, if one were to weigh the evidence on both sides of the issue, the evidence from Bertazzi, if the data were valid, would tilt towards carcinogenicity from pcb's, is that right?

A. I think it would tilt a little bit toward carcinogenicity, yes.

Q. Brown and Jones you don't have anything in disagreement with their data, you disagree with their interpretation, is that right?

A. That's right.

Q. And their interpretation tilts towards carcinogenicity of pcb's, is that right?

A. That's correct.

Q. Other than yourself, do you know of any other authors or experts in the field who conclude

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that on the basis of the epidemiologic evidence, that pcb's are not a carcinogen?

A. I think that Brown and Smith, two with distinguished names, wrote a book on pcb's, the same Brown who did this study. And their conclusions about pcb's are certainly rather tentative.

If I am not mistaken, they say something like there is no indication of carcinogenicity as yet, and we must study the issue further.

Q. I am not asking whether there is evidence yet that they are a carcinogen. I am asking you, let's go back a step.

Is it your testimony that you intend to present to the jury that in your opinion there is sufficient evidence on which to conclude from human data that pcb's are definitely not a carcinogen?

A. No.

What I propose to say is that the human data are exactly what one would expect to find in a population in which there was no excess risk.

Q. But you are not prepared to professionally state that on the basis of the

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evidence that is in to date, the human data is that is in to date, you are not prepared to testify, are you, that in your opinion pcb's are definitely not a carcinogen?

A. I couldn't testify to that, no matter how much epidemiology evidence I had, because no matter how much there is, the possibility always exists that there is some small carcinogenic effect that was missed.

Q. Now, would it be a fair statement to say that from the deficiencies you have noted in the Bertazzi and Brown and Jones and Bahn studies and, indeed, the Zack study as well, that as far as you are concerned, we have not had multiple, competent epidemiologic studies of pcb's at this point?

A. That is not true.

I think the Brown and Jones study, let me back up a little bit. I want to distinguish between the design of the study and the interpretations that are made of the studies.

Q. All right.

A. I think there were two competent studies. One is the Zack and Musch and one is the Brown and Jones studies.

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The Zack and Musch study suffers from the weakness of having an extremely small sample size. But in terms of study design, there is nothing wrong with the design of either of those studies as far as I can make out.

Q. You indicated and I think quite candidly earlier that the Zack study's deficit is that there is a large potential for error, given the small sample size?

A. A random error, which is not the same as a design error.

Q. I am talking about an error in terms of whether or not it reports a cancer incidence, not a design error?

A. But that is a well designed study whose only fault is its small sample size.

Q. I am not quarreling with the design of the study.

I am simply saying because of the small sample size there is a potential for missing cancer, is there not?

A. Yes, there is.

Q. All right.

A. That's also true in any study that one

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could name.

Q. All right.

Because of the sample size?

A. You asked earlier about a formaldehyde study in which we had a sample of 28,000 people. It's been alleged that this study, although it didn't find anything, could have missed a small effect. And the answer is yes, it could.

Q. All right.

We are not dealing with 28,000 people in these studies, are we?

A. No.

Q. With respect to the Zack study we are talk about 89 people, are we not?

A. That's true.

Q. Now, you mentioned policy before, public policy versus science.

Doctor, we are in a situation in which we have, you are referencing four epidemiologic studies of pcb's.

I am going to ask you now, and I will ask you again with the jury, are you telling the jury in this case that the four pcb epidemiology studies that you reviewed affirmatively

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demonstrate that there is no cancer risk to humans from pcb's?

A. I believe that they demonstrate with a high probability that the risk, if it exists at all, is minor.

Q. So that what you are saying in your opinion is that there may be a risk, but it is minor?

A. I am saying that in my opinion there is not a major risk. There may be a minor risk or there may be zero risk.

Q. You don't know whether there is a zero risk or a minor risk, is that right?

A. No, I do not.

Q. All right.

So in your opinion there may be a cancer risk, the degree of cancer risk you interpret to be minor, but there may be a cancer risk from pcb's?

A. The evidence cannot rule that possibility out.

Q. All right.

Now, are you are you familiar with the development of risk levels for suspected

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carcinogens, acceptable risk levels?

A. Yes.

Q. From the data, from the epidemiologic data, if one were to accept that pcb's represent a minor cancer risk, how would one develop a concentration of pcb's which would represent say a cancer risk of one in a million?

A. I don't have the slightest idea.

Q. Okay.

Would it be fair to say that you can't do that from the epidemiologic data available?

A. You can't do it from anything that is a available.

Q. You disagree with the use, development of cancer risk exposure levels from animal data, is that right?

A. No. I disagree with the pretense that they are scientific.

Q. You consider them to be nonscientific?

A. I consider them to be political and not necessarily legitimate, but certainly not scientific.

Q. You are familiar with the fact that EPA uses them?

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A. I am, indeed, and I am familiar with the fact that EPA says the same thing that I do.

Q. That they are not scientific?

A. That they are not scientific. They are public-policy issues.

Q. All right.

As public-policy issues, what are public-policy issues, the degree of risk that is to be accepted, or how you estimate the concentration that represents that risk?

A. Both.

Q. So you are saying that development of the unit risk factor approach of EPA is considered a public policy or political decision, is that right?

A. The way in which they have arrived at that is also a -- yes. And the way in which they arrived at it is also a public-policy issue.

Q. As opposed to a scientific process?

A. Yes.

Q. All right.

Now, are you familiar with the fact that EPA does use arithmetic calculations to derive concentration levels that they say translate into

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a risk of one in a million or one in a hundred thousand or one in two million?

A. Yes.

Q. And are you familiar with the fact that such a unit risk factor has been developed for pcb's?

A. I am aware that it probably has been developed. Yes.

Q. Could such a risk factor, can that metholology be applied to the epidemiologic data you have got?

A. In general, no.

Q. Let me ask you, in Bertazzi or in any of these others, are you able to reconstruct with any quantitative accuracy the dose, the exposure levels that these people have historically over twenty and thirty years?

A. Not that I am aware of.

Q. So that you really don't have a dose, you are just saying that these people were exposed and you have an effect, is that right?

A. I think we can do a little better than that in the sense that we can identify -- we can say, for example, that pcb levels in some

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situation were high enough to cause dermatitis.

Q. All right.

A. But, in general, we cannot quantify that exposure in terms of parts per million or anything of that kind.

Q. All right.

So what we are basically looking at is the fact that there was some qualitative exposure to pcb's, and we know are observing the results; is that right?

A. Yes. We know a little more than that. We know that in the occupationally exposed populations, the evidence we have suggests that the exposure levels were from 10 to 100 times or more the levels that are present in the general population.

But that is a general statement and we cannot classify individual people who were exposed by the level that they were apparently or you think they were exposed to.

Q. Indeed, you have some people within the study groups of exposed population that may have been exposed to no more than the general population, is that right?

WATER_PCB-00044562

A. I can't rule out that possibility.

Q. As a matter of fact, in Baker, one of the criticisms of the Baker study, was that the so-called people who used the sludge had lower blood levels than the general population, isn't that right?

A. However, we were talking about occupational studies and the Baker study is a study of the general population.

Q. But they didn't necessarily -- what I am saying to you is that there may be blood levels in some of the exposed workers in the Brown study?

A. That's possible.

Q. That are less than the general population or equal to, isn't that right?

A. And there may be levels that are 10 or 100 times as much.

Q. Right.

But the fact is that some of those workers in the group in the Brown study or the Bertazzi study may have had blood levels equal to the general population?

A. It is possible.

Q. And exposed to levels equal to the

WATER_PCB-00044563

general population?

A. Unlikely, but possible.

Q. Would it be fair to say that your conclusion on cancer from the epidemiology studies are then these four studies, Bertazzi and update, Brown and Jones an update, Zack and Bahn?

A. Yes.

Q. All right.

Did the Gustavsson study add anything to your analysis?

A. No. Because the latent period was too short.

Q. Did Emmet have, well, the Emmet study didn't deal with cancer, did it?

A. No, it did not.

Q. Do you recall what kind of pcb's were exposed -- the workers in the Bertazzi study?

A. No, I don't.

Q. From the standpoint of cancer effects, based on the analysis of epidemiology, I believe your earlier expressed opinion is that there is really no difference in cancer effect to be observed from whether it is 1242, 1016, 1254 or 1260, is that right?

WATER_PCB-00044564

A. I believe what I said was that in doing the kinds of mortality studies that we have done, our question is whether there is an excess mortality. And the specific kind of exposure has never been looked at.

Q. All right.

It has been looked at in the sense that it has identified what the chemical was, isn't that right?

A. That may well be.

Q. But it was not of relevance in your analysis, is that correct?

A. Nor to the best of my knowledge in anybody else's.

Q. All right.

I am just trying to establish that.

You didn't say, gee, this is important because it is a particular compound of pcb, you just said pcb's versus health effects, is that right?

A. That is correct.

Q. Did you have anything to do with the development of the Monsanto material safety data sheet?

WATER_PCB-00044565

A. No.

Q. Who does for pcb's?

A. Material safety data sheets go through a rather elaborate process, by which they are circulated to those people who may have something to contribute or to criticize.

And I am trying to remember the person who manages that process. I believe that it is Dr. Michael Stevens, who is one of the toxicologists at Monsanto.

Q. Would you mark there as 523.

(The document above-referred to was marked Bloomington Deposition Exhibit No. 523 for identification.)

Dr. Gaffey, directing your attention to what has been marked as Bloomington Deposition Exhibit 523, Monsanto material safety data, page 1 of 6, and there are six pages in this exhibit.

With respect to health effects, did you have any hand in developing the information used in the health effects summary on page 3?

A. I don't believe that I did.

Q. Now, it says in the health effects summary that:

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"The consistent finding in animal studies with pcb's is that they produce liver injury following prolonged and repeated exposure by any route, if the exposure is of sufficient degree and duration.

Liver injury is produced first, and by exposures that are less than those reported to cause cancer in rodents. Therefore, exposure by all routes should be kept sufficiently low to prevent liver injury."

Again, I don't mean to be facetious. Would it be fair to say that that warning in that first paragraph is directed at humans and not rodents?

A. I would assume so.

Q. So that, therefore, it would be fair to say that concern here is that humans might suffer liver injury and are to avoid exposure by all

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routes?

A. I think this might better be asked of the people responsible for the sheets.

However, I think that one of the plain reasons for the paragraph is to avoid liability. Rather than to talk about facts such as whether or not there is human injury or not.

Q. This is not to warn people about health effects?

A. I am sure it is. But whether the health effects are perceived by Monsanto as real or whether they are mandated by law, I don't know.

Q. Well, is it common to put in health effects warnings that are mandated by law even though, to avoid liability?

A. I don't know.

Q. Can you say whether this statement about liver injury is produced first and by exposures that are less than those reported to cause cancer in rodents is accurate from a health standpoint?

A. I don't know.

Q. And do you agree or disagree with the statement that, therefore, exposure by all routes should be kept sufficiently low to prevent liver

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injury?

A. Well, since I don't know about the first statement, I have no opinion about the second one.

Q. Do you know from epidemiologic studies what level is necessary, what the level of exposure must be to prevent liver jury in humans?

A. I am aware of no epidemiology studies that have found liver injury in humans. So I don't know what the exposure level necessary would be.

Q. All right.

Do you believe that there is an exposure level necessary?

A. I have no idea.

Q. All right.

So you can't say on the basis of your epidemiologic studies what concentration of pcb's is sufficient to protect humans from liver injury?

A. I know that whatever level causes liver injury is higher than the highest level that we have every seen in an occupational study, because there are no liver injuries reported.

Q. Well, there are liver cancers reported?

A. Not in excess.

WATER_PCB-00044569

Q. Yes, there are. The Brown study showed them in excess.

A. No. The Brown study showed that the longer you worked, the less liver cancer you had.

Q. Okay.

The Brown study reported excess liver cancer, did he it not?

MR. FRUEHWALD: Let me interpose here.

If we are going to be short cutting these things, it is liver and biliary. There is a list of what they actually are in the update. It is plainly biliary and not liver. So you are shortcutting what the study really says.

I would appreciate it, if you are going to ask questions based upon Brown, that you quote Brown accurately and use the data, rather than some kind of shorthand version of it.

BY MR. KARAGANIS:

Q. Doctor, can you set a staff level for workers; for example, if you go back to the skin and respiratory protection, does NIOSH and --

MR. FRUEHWALD: Is that a portion of it?

MR. KARAGANIS: Yes, page 2, occupational control procedures, airborne exposure limits.

WATER_PCB-00044570

That's set by OSHA and what is ACGIH?

A. American conference of government and industrial hygienists.

Q. Okay.

Are those exposure levels set off of epidemiology studies?

A. Typically no.

Q. What are they set off of?

A. I believe they are generally based on either animal studies or clinical reports, plus some judgmental factors.

Q. All right.

But they are not based on epidemiology studies to your knowledge, isn't that right?

A. Not to the best of my knowledge.

Q. Isn't it typical to set exposure limits by taking an animal study and finding an observed adverse effect or a level of no observed adverse effect, and then apply a safety factor to it, to come up with an exposure level?

A. I don't know.

Q. You just don't know.

But you know they are not done with epidemiology studies?

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A. That is correct.

Q. Do you know whether OSHA considers pcb's to be a carcinogen?

A. I don't know.

Q. Do you know whether the National Institute for Occupational Health and Safety considers pcb's to be a carcinogen?

A. I don't know.

Q. Exhibit 523 says, quote:

"Numerous epidemiologic studies of humans, both occupationally exposed and nonworker environmentally exposed populations, have not demonstrated any statistically significant causal relationship between pcb's exposure and chronic human ilnesses, such as cancer or neurological or cardiovascular effects."

Doctor, with respect to cancer, for epidemiologic studies, there are only the studies

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that you have mentioned; isn't that right?

A. That's correct.

Q. And the statement in here that they have not demonstrated, you agree that Brown and Jones agree that there is a statistically significant relationship, isn't that right?

A. The question here is not what the authors say, it is what the studies in fact demonstrated.

The Brown and Jones study demonstrates that the longer you work, the less liver cancer you have.

Q. And that's your interpretation of it and they have a different interpretation, isn't that right?

A. They have interpreted to the contrary. They have shown that relationship and called it uninformative.

Q. All right.

That is a different interpretation of the data than yours, is it not?

A. It sure is.

Q. You would rely on your interpretation on evaluating Brown and Jones and these other studies according to the IARC criteria, isn't that right?

WATER_PCB-00044573

A. I would rely on my judgment and that of any competent epidemiologist who would --

Q. Following the IARC criteria, isn't that right?

A. Yes.

Q. Who made the interpretation that is in this paragraph 2 of their safety data sheet?

A. I don't know. But I would certainly endorse the interpretation. I don't recall that I was consulted, but I certainly agree with the answers, with the statement there.

Q. Now --

MR. FRUEHWALD: I think you have got a page on your exhibit which you don't want to have on there.

MR. KARAGANIS: Yes. Thank you.

Q. Doctor, to leave cancer for the moment. Let's go to birth and teratogenic effects.

I believe you indicated before that only the Kreiss study in 1981, of the studies you reviewed at the time you wrote your paper, Exhibit 521, that only the Kreiss study dealt with birth defects, is that right?

A. That is correct.

WATER_PCB-00044574

Q. So, I take it that the Kreiss study, the two Jacobson studies and the Emmet study are the only epidemiologic evidence you have with respect to birth defects or teratology?

A. Oh, the Emmet study as far as I know doesn't deal with birth defects and teratology, but there is one other study that I didn't mention which is a study by a man named Taylor of General Electric Corporation.

I can't at the moment remember where it was published, but it was published I believe in 1986. So the totality of studies in addition to Kreiss is the two Jacobson studies and the study by Taylor.

Q. Are you relying on the Taylor study for your opinions?

A. Yes.

Q. You have reviewed that?

A. Yes.

Q. Do you have it here?

A. No. I don't have it here.

Q. What is the title of the paper?

Do you have it, Mike?

MR. FRUEHWALD: I don't have it. It is on

WATER_PCB-00044575

Moses' list.

MR. KARAGANIS: Okay.

MR. FRUEHWALD: Number 38, on the Exhibit 502.

(A short recess was taken.)

BY MR. KARAGANIS:

Q. Doctor, with respect to birth defects, or reproductive effects, tell me where in the Kreiss study, Kreiss discusses the findings with respect to birth defects or reproductive effects from pcb exposure?

A. I don't have a copy of the paper with me. But if you let me look at it, I think I can probably find it.

Q. I do. Here, absolutely.

MR. FRUEHWALD: It is not, of course, the same paper cited in his article.

A. That's true.

MR. KARAGANIS: I am sorry.

A. That is correct.

Q. I am sorry. That is a different study?

A. Explains my difficulty in finding it.

Q. All right.

I should have turned you to the right one.

WATER_PCB-00044576

A. Okay.

Q. The paper you have referred to is entitled, "Association of blood pressure and polychlorinated biphenyl level"?

A. That is the paper.

Q. Okay.

A. The first paragraph under health effects.

Q. Okay.

Now, what was the Kreiss study, the epidemiologic study she did?

A. Well, to begin with, it wasn't a study of pcb's. It was a study of DDT.

Q. All right.

A. And in the process, apparently the fact that there was a pcb exposure became apparent, and the publication that you have there is an analysis of those results.

They looked at people who eat fish from a nearby river in which the fish, at least, contained relatively high levels of pcb's.

They established that the levels of pcb's in the population they observed was significantly affected by the amount of fish that they eat, and then in that population, they looked at a number

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of variables related to health, including the ones that are mentioned in the first paragraph under health effects.

Q. Okay.

Now, how many people were in the study, do you recall?

A. No. I know there were several hundred, but I don't recall how many.

Q. With respect to the focus of the study, independent of its emphasis on DDT, the focus of this particular paper is the association of pcb and blood pressure levels rather than birth defects, isn't it?

A. That is correct.

Q. All right.

A. And that in itself was something that the authors didn't start out to look for, but which turned up in the study.

Q. There is really not a discussion or an analysis in this paper with respect to birth defects, reproductive effects, fertility, is there?

A. No, there is not.

Q. Nor an analysis, is there?

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A. No analysis is detailed. That is true.

Q. And that wouldn't be in the same category, would it, as the Jacobson and Taylor papers which focused on birth or reproductive effects?

A. That's correct.

Q. Now, turning to the Jacobson papers, do you have the ones that he gave you? Can we mark them?

MR. FRUEHWALD: These are my copies. You are taking all my copies and marking them.

(Discussion had off the record.)

MR. KARAGANIS: I have a copy of the second Jacobson, I don't have a copy of the first with me. We won't mark them, we will use them.

MR. FRUEHWALD: I just would like to have them. I need to read these things, too. You can take them and mark them. I just want to get some copies back quickly, then.

MR. KARAGANIS: Let's mark it as 524.

(The document above-referred to was marked Bloomington Deposition Exhibit No. 524 for identification.)

And do you have the other one?

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MR. FRUEHWALD: This is stapled together.

BY MR. KARAGANIS:

Q. Directing your attention to what has been marked as Bloomington Deposition Exhibit 524, which is a copy of two articles. The first by Jacobson is entitled, "Prenatal exposure to an environmental toxin: A test of the multiple effects model."

And the second article entitled, "The effect of intrauterine pcb exposure on visual recognition memory," by Jacobson et al. Both of which are in Bloomington Deposition Exhibit 524.

Are these the two Jacobson articles you referred to?

A. Yes, they are.

Q. All right.

And what, if anything, do the authors -- why don't you describe the studies?

A. They are two different studies.

In both of them, the authors attempted to classify mothers of infants by their degree of exposure to pcb's, measured in various ways.

And in both cases they then attempted to look at various abnormalities in the infants and

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attempted to show a relationship between the extent of those abnormalities and the estimated level of pcb exposure in the mothers.

Otherwise, the two papers are quite different. The earlier paper, which is the first one in the pile, attempted to assess the relationship between pcb's and these various abnormalities in the presence of a number of confounding effects.

You will recall that we said other things such as age and fish consumption and so on, sex, would modify the actual levels of pcb's.

I have two problems with this paper. The first is that in trying to estimate the effect of pcb's on the various subsequent abnormalities, the authors did two things. One, they used an estimates of pcb's based on the mother's statement as to her amount of consumption of fish. And from there they reconstructed an estimated level of pcb's in the mother.

They state in the paper that their estimated level is not associated with age. Which we know from the Kreiss study to be the most important component, the most important factor

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associated with pcb levels.

So, the estimate that Jacobson and his colleagues used based on fish consumption is suspect, because it is an estimate that doesn't behave the way we know pcb's should behave.

That aside, the authors then attempted to adjust for the many other factors that could affect things like childhood behavior and pcb levels, and they did it using a technique which is not correct.

It is a technique which incidentally they corrected in their 1985 paper. The 1984 paper, therefore, suffers from two problems. One, a definition of pcb's, which is suspect, because it does not behave the way we know such estimates should behave. And, second, an analytic technique which is arithmetically incorrect. Pardon me, I mean statistically incorrect.

I am sure they did their arithmetic correctly. But they used a technique which is provably erroneous.

Q. What was the technique, what specific technique are you talking about that they used?

A. In technical terms, they identified the

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covariables, took the regression of the outcome variable and the covariables, and then used the deviation from regression as a dependent variable in a subsequent regression procedure.

I know, I wish there were a simpler way to describe it.

Q. Sounds okay to me.

A. The best way to put it, perhaps, is to say that what they should have done was to construct a single equation in which all of these variables entered in.

What they did was they took some of them and constructed one equation, and then got a second equation to fit the part that wasn't explained by the first equation.

The results are not the same as if one used a straightforward multiple regression, which is a conventional technique.

Q. Okay.

A. And in their second paper they corrected that, and used what I regard as an appropriate multiple regression technique.

They also abandoned for analytical purposes their earlier estimate of pcb levels and

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actually used the observed pcb levels in the blood, in the umbilical cord of the infant. They found a relationship between that level and various subtle behavioral effects measured by certain tests of infant behavior.

Q. You disagree with their conclusion?

A. I think that they should have qualified it, because one of the things they did not do is to take into account social class.

If you read the paper it looks as if they did. They give a table in which they dutifully show the exposed group and the unexposed group and show that on the average these two groups did not differ, except trivially, in average social class.

But their analysis is based on analysis within the exposed group, where the social class would have varied, and a lot of other things would have varied.

What they did not do in their analysis was to show that they were measuring social class. They actually looked at social class. I am not sure how this entered into their predictions.

If I had to criticize their conclusions, I would say that I think they tended to

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overinterpret the data, to reach a firmness of conclusion that I wouldn't have accepted, unless I had seen this repeated in another study, again using the IARC criteria.

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Q. Is the IARC criteria applicable to noncarcinogenic epidemiologic studies?

A. Most epidemiologists would say that it is applicable to any chronic condition.

Q. IARC don't apply then to other epidemiologic studies?

A. They mentioned it only in connection with carcinogenicity, because that's their business.

Q. With respect to the two Jacobson studies, the authors conclude that pcb's produce an adverse health effect in infants, do they not?

A. They conclude that in their first study and then take it back in their next.

Q. They take it back, that they don't?

A. They said, if I can find the place where they say, it causes behavioral problems, but it doesn't cause any other problems.

Q. You don't consider behavioral problems to be an adverse health effect?

A. I am simply pointing out that they

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claimed one sort of health effect in their first paper, and then took it back in their second.

Q. Would you show me where that is?

A. I think I can do that. I'll have to look more carefully.

Q. Take your time.

A. No, I am sorry, I am mistaken. They refer to their earlier study as if it were a fact. I take it back, I remembered wrong.

Q. Now, where are you referring to, that you have corrected yourself?

A. I am looking at --

MR. FRUEHWALD: There is the page number up there.

A. Page 854. The first paragraph on the page.

BY MR. KARAGANIS:

Q. Now, are you familiar with the Allen, Barzetti and Carstons rhesus monkey studies?

A. No, I am not.

Q. Are you familiar with the Tilsen mice studies?

A. No.

Q. You do know that the authors of the

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Jacobson studies found that the adverse effects that they noted in human infants were similar to adverse effects that had been noted in animals, is that right?

A. That's what they say, yes.

Q. Do you find that where you have of a consistency in result between animal studies and the human studies, that that strengthens the evidentiary support for adverse effect?

A. If such a consistency exists, yes.

Q. You haven't been able to determine that, have you?

A. They haven't established that the consistency exists with respect to the physical characteristics.

Q. For the humans?

A. That's correct.

Q. As far as you are concerned, you don't find their evidence to support their conclusion, is that right?

A. That's right. I don't know that their conclusion are false, but I don't believe their evidence supports it.

Q. Would you agree that the evidence

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supports a finding -- if you were to tip the scales, and on one side was that the evidence tended to lead to the conclusion that there were adverse health effects found in the Jacobson study from the data, and on other side of the scale that there weren't. Would your opinion be that the evidence weighed more heavily on the side of adverse health effects?

A. No, not on the basis of the evidence here.

Q. In either study?

A. In either study.

Q. So you disagree with Sandra Jacobson Greta Fein, Joseph Jacobson Pamela Schwartz and Jeffrey Dowler?

A. Yes, I do.

Q. You disagree with Brown and Jones?

A. Yes, I do.

Q. And Berzati?

A. You mean Bertazzi.

Q. Bertazzi.

A. Yes. And with the EPA.

Q. And with EPA.

A. Okay.

WATER_PCB-00044588

Q. Now, would it be fair to say that the Jacobson studies are the only two studies that you are aware of that measure neurobehavioral effects, attempt to measure neurobehavioral effects from pcb exposure?

A. That is true.

Q. Now, let's turn to Mr. Taylor, the GE study.

What is it that you conclude from reading the Taylor study?

A. Taylor looked at employed women, actually he looked at the babies born to employed women and classified them by whether their mothers had been in jobs with relatively high exposure to pcb's versus in jobs not involving exposure to pcb's.

And he compared particularly the birth weight and the length of gestation in these babies and found out, first of all, that there were small differences in both these factors. But when he adjusted for one of them, the other disappeared.

And I believe that what happened was that when he adjusted for birth weight, the difference in gestational age disappeared. I don't remember.

The differences, however, were something

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like, in gestational age the average difference, I think the average difference was something like six days.

In birth weight, the average difference was something like 100 or 150 grams. Which means five or six ounces. But these two were dependent.

So that you were not looking at a -- you were not looking at a difference in both of them. You were looking at a difference in one of them, which created a difference in the other one.

Q. Okay.

Was he saying that pcb's caused an effect?

A. He was saying this was associated with an effect. I think, it may be real. One of the complications, which I got in talking to Taylor, was that the low exposure women at GE seemed to have heavier babies than the general population. How relevant that is, I don't know. But it is one of the complications.

Q. Certainly the Taylor study can't be used to support a conclusion that pcb's do not cause adverse reproductive effects; isn't that right?

A. That is correct.

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Q. So on the basis of the available data, the only available data with respect to pcb's and reproductive effects, the only available human epidemiological data I should say, that is indicative of adverse effects one way or another, are the Jacobson studies, isn't that right?

A. Yes. That's right.

Q. And as we have agreed before, they conclude that there are adverse effects, and you disagree with the findings?

A. That is correct.

Q. What is it that you have done with respect to Bloomington data?

A. I have examined the study by Stehr-Green, that is all.

Q. And for what purpose?

A. To see whether I thought the experimental design was good, and the conclusion were reasonable.

Q. And what are the conclusions?

A. The conclusions are -- may I back up a little.

The results of the study are that the group studied which of these people had higher pcb

WATER_PCB-00044591

levels than the general population. Their conclusion was that the population of Bloomington had a higher pcb level than the general population.

In no case were any of their differences statistically significant, and --

Q. I guess I am confused.

You said they concluded that one group had a higher blood level than the general population of Bloomington?

A. No. They took a group of people who lived near some toxic waste dumps. The group -- they then studied this group. The group that they studied was the result of a multiple selection process, as a result of which they had something less than a 42 percent response rate.

These were people who were selected because their activities indicated they were highly exposed.

Within that group, they looked at people with particular high exposure activities, and a random sample of the rest of the group, and found the difference between the two not statistically significant.

WATER_PCB-00044592

Q. Difference in blood levels?

A. Difference in average blood levels, not statistically significant. From there they concluded that the population of Bloomington had a higher level than the general population. That conclusion isn't legitimate.

If they had done their original study correctly, their conclusion would have been illegitimate. They didn't do their original study correctly, because they got such a small response rate.

So, I don't really know to what extent the study, the people they looked, at were selective. But I do know that no matter what the selection was, the values they found did not differ statistically significantly between the people they called highly exposed and the people they said were a random sample from their study group.

So, what they did was to select people with high exposures and then find that the results were not stastistically significantly different from what they would have expected.

On the basis of this nonstatistically

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significant difference, they recommended the whole city be studied in a comprehensive way.

Well, if they had found a statistically significant difference, I am inclined to think they would have made the same recommendation. Which means to me that the recommendation that Bloomington be studied is independent of the study results.

In other words, they would have been more honest had they not done the study, simply issued a pronouncement saying study the whole town.

Q. I won't mark it, but would you pull out the study?

MR. FRUEHWALD: Yes. And what?

MR. KARAGANIS: Show me where they make their conclusion and then their recommendation.

A. Okay.

MR. FRUEHWALD: All right. This is my marked-up copy here.

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MR. KARAGANIS: I am not going to --

MR. FRUEHWALD: I am not sure I want to. Let's see what we can find here.

A. Okay.

Conclusions.

WATER_PCB-00044594

The population in this geographic area appears to have generally higher average human serum pcb levels compared to previously characterized populations in other areas of the United States.

BY MR. KARAGANIS:

Q. All right.

A. Exposures in this general community and other similar situations require further evaluation, perhaps, and a comparison of a representative population-based sample from Bloomington, Indiana to a truly nationally representative population sample.

So what they have done is they have made a statement that the population in this geographic area has a higher level, which is not justified by what they did.

Q. It is not justified by the data?

A. No.

Because they didn't look at any kind of a random sample of the population of this area.

Q. What you are saying is they looked -- the population sample was biased?

A. Yes.

WATER_PCB-00044595

I say that they deliberately intended to bias it; and, furthermore, that they weren't even successful. So, I don't really know what happens in that population that they examined.

Q. All right.

A. They set themselves the task of looking at people who were among the most highly exposed in the area. They were unsuccessful because of the response rate.

We don't know how successful they were because of the low response rate. And on the strength of that, they have generalized to the whole community.

Q. Do you have any information as to whether or not the people in Bloomington -- I am sorry.

Would you agree that this sample demonstrated a higher pcb concentration in their blood serum than the population generally in the United States?

A. Yes.

Q. You just don't like their sampling as being representative?

A. Give me the rest of the United States and I will show you a sample with even higher levels

WATER_PCB-00044596

than Bloomington, if I can select whoever I want.

Q. You are saying they selected a biased sample and you can select a biased sample?

A. That's right.

The fact that there is an excess doesn't impress me.

MR. FRUEHWALD: I think maybe we are using the term bias here in a pejorative sense. This is what they expressly said they were going to do is select that type of sample.

A. There was nothing underhanded about what they did. They were perfectly aboveboard in what they said they were going to do.

The other complication of the study is that they weren't able to do very well that one thing that they said they were going to do.

BY MR. KARAGANIS:

Q. Now, Doctor, directing your attention to 520, is that it?

A. I don't know. What is it?

Q. 520 is the chapter on pcb's.

MR. FRUEHWALD: 520 is the recent epidemiologic studies.

MR. KARAGANIS: That is the symposium paper,

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520.

A. That is one of them. This is recent epidemiologic studies of pcb's.

Q. Is that different than your updated studies or is that the same thing? You have only done two papers, one was this chapter and one was the updated studies, right?

A. That's right. And this one is what you have called the updated studies, yes.

Q. This is the one you gave at the EPA seminar?

A. That is correct.

Q. And is there anything in here that is different than your 1981 paper?

A. Yes.

Strictly speaking, there is a difference in that in the tables that I listed here, in addition to talking about what the studies found, there is a notation for whether or not they had adjusted their findings for other variables that might be confounders.

So you will see that in tables 1, 2 and 3, I listed tables -- I listed studies, and in the extreme righthand column I have indicated yes, no,

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for each study to indicate whether the findings were adjusted for other variables, such as age and race and sex.

Q. Doctor, would it be fair to say that you are not aware of any study in the Bloomington area with respect to pcb's and cancer?

A. That is correct.

Q. Would it be fair to say that you are not aware of any study in the Bloomington area with respect to pcb's and birth defects?

A. That is correct.

Q. Would it be fair to say you are not aware of any study in the Bloomington area with respect to pcb's and developmental toxicity in infants or in young children?

A. That's correct.

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Q. Would it be fair to say that you are not aware of any study in the Bloomington area with respect to pcb's and their effect on fertility?

A. That is correct.

Q. So that when you make opinions with respect to public health risk in Bloomington, you have to rely on the studies we have referred to earlier, is that right?

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MR. FRUEHWALD: Let's me object. He has expressed no opinion on the public health risk in Bloomington. He has not been offered for that purpose and has expressed none.

MR. KARAGANIS: Okay.

Q. Let me ask you something.

Do you have any opinion as to whether or not pcb's and pcb exposure in the Bloomington area represent a health risk to the residents of Bloomington?

A. I have, yes. I do have opinions.

Q. What is that opinion?

A. The opinion is that there is no health risk to this population associated with their exposure to pcb's, whatever that exposure may be.

Q. You don't know what the exposures are?

A. No, I don't.

Q. All right.

You say there is no health risk from the standpoint of cancer?

A. No health risk from the standpoint of cancer.

Q. You agreed before that based on your analysis of the evidence, you could not disregard

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the facts that there might be a slight cancer risk from pcb's; isn't that right?

A. That is correct.

Q. All right.

Now, if they are exposed to pcb's, is there a threshold level for cancer?

A. I don't know.

Q. All right.

Is it not a fact that EPA and a number of scientist believe that there is not a threshold level for cancer?

A. That's true.

Q. So would it be fair to say that if they are exposed to pcb's and if pcb's do represent a cancer risk of some magnitude, that there is a risk however small it may be?

A. There ae lots of if's, but if pcb's are a carcinogen, then I can't rule out the possibility that there may not be a threshold.

Q. All right.

So if pcb's are a carcinogen, and if the population of Bloomington is exposed to pcb's, is there a cancer risk?

A. There might be a cancer risk if your

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assumptions are true.

Q. All right.

And the only basis for which to say my assumptions aren't true are your epidemiologic analyses; isn't that right?

A. The only basis to oppose it is the evidence.

Q. Is your epidemiologic analyses, is that right?

A. Not -- my epidemiologic analysis proceed mostly by quoting the people who did the studies.

So, yes, it is my analysis. But, most of my analysis is simply a recitation of the conclusions of the people who did the studies.

Q. We agreed, you disagreed with the conclusion of Brown and Jones?

A. Yes.

Q. You disagreed with Bertazzi?

A. Yes.

Q. So there what your really saying is that you agree with Zack?

A. No. I am saying that I looked at twenty-two studies and I agree with approximately twenty of them.

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Q. Four cancer studies. My question is limited to cancer.

A. In that case, I have four cancer studies and I see nothing in them except what I would see in similar studies done in a completely unexposed population.

Q. I am saying to you, you indicated before that on the basis of those four studies, you could not rule out a slight risk of cancer, isn't that right?

A. That's true. That would be true in any studies of anything, anywhere.

Q. You are not testifying here today that pcb's on the basis of only four studies you have examined do not pose a risk of cancer; isn't that right?

A. I am saying that the available evidence tells me that if there is any risk of cancer, it is so small that it could not be discovered by the aggregate of the studies that have been done.

Q. You have indicated in your paper the recent studies of pcb's, that the power of the studies maybe is relatively low; isn't that right?

A. The power of each of the individual

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studies may be relatively low. But we also agreed that achieving statistical significance is not necessary in order to draw a conclusion.

What we have got here is a situation in which we have four studies, and in those four studies, some common cause, such as lung cancer, for example, had been high, never mind statistically significant, high, I would have considered this suspicious evidence as to carcinogenicity.

We don't have anything even approaching that in these studies.

Q. I want to get this straight from a layman's standpoint.

Are you saying that it is your opinion that on the basis of these four studies, or on the basis of any other information you have, that your opinion is clearly that pcb's do not represent a cancer risk to man?

A. I would say they do not represent a detectable cancer risk.

Q. You are saying these studies provide sufficient information to say that pcb's cancer risk can be detected?

WATER_PCB-00044604

A. Of course not.

Q. Doctor, I am going to ask you to hypothesize that the population in Bloomington is exposed to some level of pcb's. Your opinion is independent of the level of pcb exposure with respect to carcinogenicity, isn't it?

A. Yes.

Q. Now, I ask you to hypothesize that the population is exposed to a level of pcb's. Is it your statement that that population has no risk of cancer from those pcb's?

A. If the level of exposure is no greater than that of the occupationally exposed populations that have been studied by groups like NIOSH, then if there is an excess, it would be too small to be detected.

Q. I am asking you is it then your opinion that there is no risk of cancer?

A. There is no risk of cancer.

Q. None whatsoever?

A. None whatsoever.

Q. Okay.

You are basing that simply on these four studies?

WATER_PCB-00044605

A. Yes.

Q. Okay.

And with respect to that, you are not including any analysis of the animal studies either?

A. I am not including the animal studies.

Q. Doctor, have you been asked to give any opinions as to reproductive hazards to the population in Bloomington if they are exposed to pcb's?

A. I have not been asked, no.

Q. Do you have an opinion?

A. Yes.

Q. And what is that opinion?

A. That, again, if the level of exposure is no higher than what is seen in an occupationally exposed population, I would see no danger of any reproductive problems in this population.

Q. By reproductive problems, I am talking about neurological problems of infants, fertility and low birth weight or any birth problems.

A. Yes. I would agree. I agree, that is my definition also.

Q. Yet we agreed that with respect to

WATER_PCB-00044606

neurological problems with respect to babies, the only studies we had were the Jacobson studies, isn't that right?

A. That's right.

MR. FRUEHWALD: Are you talking about neurological problems or are you talking about what the Jacobson's measured?

MR. KARAGANIS: Neurological problems.

A. The Jacobson's draw some inferences about neurological problems. What they actually measured was the baby's ability to stare at one target and then change his view and look at another target. Neither they nor I are aware of what, if anything, this measures in terms of neurological problems.

Q. Doctor, let me get this straight.

The only two studies we know about that purport to measure neurological problems in babies were done by the Jacobson's, isn't that right?

A. That's correct.

Q. And they conclude on the basis of those studies, the four authors of those studies conclude that there are neurological problems, is that right?

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A. That's their conclusion.

Q. And is there anybody else in the world that you know of who stands with you and says the Jacobson's are wrong?

A. Not that I know of offhand.

Q. Now, the women in the Jacobson studies were not occupationally exposed, were they?

A. Not as far as I know.

Q. These were people who eat fish, isn't that right?

A. That's correct.

Q. So that this was not a population that suffered major occupational exposures; this was environmental exposure, since that right?

A. That is true.

Q. Doctor, you have mentioned, you referred previously to the IARC criteria for epidemiological analysis.

Are you familiar with the IARC criteria for probable human carcinogens?

A. Not really. Except indirectly by hearsay.

Q. You would accept the IARC criteria for epidemiologic analysis. Do you except the IARC

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criteria for probable human carcinogens?

A. Sure.

Q. Directing your attention to Bloomington Deposition Exhibit 516, which is the IARC monbgraph on the evaluation of carcinogenic risk of chemicals to humans.

I direct your attention to category 2, which is, and I quote, "The following 61 chemicals, group of chemicals, or industrial processes are probably carcinogenic to humans."

A. Yes.

Q. I direct your attention to category 2 B on the next page;

A. 2 B, yes.

Q. Okay.

You see polychlorinated byphenyls there?

A. Yes.

Q. I take it you disagree with that conclusion of IARC?

A. What is the definition of 2 B?

Q. Probable human carcinogens.

A. No. I think it has to be more of a definition. That is a label for the category. That's not the definition.

WATER_PCB-00044609

Q. It is a conclusion, is it not, that they are probable human carcinogens?

A. No. That is a label for a category and what I would like to have is the definition that gets a study into that category.

Q. All right.

Here, let me have the exhibit.

MR. FRUEHWALD: Insufficient. You can find it. Insufficient human and sufficient animal, I think is what it is.

BY MR. KARAGANIS:

Q. Direct your attention to the definition for group 2.

A. Sufficient data in animals and inadequate date in humans. Yes.

Now, the other thing that you have to ask IARC is do they ever recognize such a thing as no data in humans or data indicating no carcinogenicity. They call that inadequate evidence.

Q. Yes.

A. So, the category 2 B can cover as I understand it animal data and almost anything in the way of human studies. What IARC calls

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inadequate human data covers what most other people would call also negative studies.

Q. Now, do you consider all four of the studies you have described negative studies?

A. No, I considered the totality of the evidence negative.

Q. Do you consider any one of the studies negative?

A. I can't call them negative or positive, because the term has no meaning until you look at the totality of the evidence.

If these were, for example, studies of vinyl chloride. I would have found excesses in liver cancer in every one of the studies.

Q. That's one of the 23 chemicals for which there is human epidemiologic data confirming that they are a carcinogen, is that right?

A. I believe that to be true, whether or not it is in the IARC list.

Q. Now, with respect to that, Doctor, wouldn't it be correct that there are many chemicals for which there is inadequate human epidemiologic data, which public health policy says should be protected as a risk against cancer?

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A. I don't know about policy. I know about science. There are many chemicals for which there is no data or data that I would call inadequate regarding their carcinogenicity.

Q. For that would you rely on animal data?

MR. FRUEHWALD: For what?

MR. KARAGANIS: For protection of the public health.

A. That I don't know. It would depend on the cost and the benefits of the various actions that were contemplated. I really don't know.

That is a matter again, it is a matter of societal drives rather than science. And most of my energies have gone into trying to separate the two rather than to confuse them.

Q. I see.

From the standpoint of the human data and the animal data, you are saying that you don't rely on any one study, but you rely on the cumulative weight of the studies as evidence, is that correct, with respect to the human data?

A. That's correct.

Q. So it is kind of a weight of the evidence approach, is that right?

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A. Yes.

Q. And that is an accepted scientific approach, even though some authors may disagree with you?

A. Yes.

Q. You look at the total weight of the evidence, is that right?

A. I do. And that kind of thing is commonly done.

Q. Have you ever developed a no adverse effect level or acceptable daily intake level for humans through epidemiology?

A. No.

Q. I think you indicated before that is normally not done with epidemiologic studies, is that correct?

A. That's correct.

Q. Based on IARC, would you recommend protecting the public against pcb's as a human risk carcinogen, as a probable human carcinogen?

MR. FRUEHWALD: Based upon what?

MR. KARAGANIS: Based on IARC's categorization of pcb's as a probable human carcinogen. If you had the public health responsibility of deciding

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whether to protect the public or not from pcb's.

MR. FRUEHWALD: I am going to object to the question, in the sense that is totally irrelevant what Dr. Gaffey would do in a position that he doesn't hold, and is therefore irrelevant. He is not an expert in this, doesn't purport to be. This is an irrelevant question.

MR. KARAGANIS: It is a central question in this case.

MR. FRUEHWALD: Not for this witness. Somebody else may answer that question.

MR. KARAGANIS: I want to know what this witness has to say about it.

MR. FRUEHWALD: If he has an opinion, he can give it, for whatever it is worth.

A. I think to a certain extent we may be playing with words. Because it's been pointed out before to IARC in connection with other things like formaldehyde, that their label probable human carcinogen, and the term probable human carcinogen that is used are two different things.

The IARC label is a category label. You are using the term probable human carcinogen in the sense that most of us would think of it, as

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something that more likely than not is a human carcinogen.

I do not believe that is true of pcb's and I believe that we are introducing some confusion here by using the term probable human carcinogen in two different places with two different senses.

Q. Do you know that EPA also uses the term probable human carcinogen?

A. I do.

Q. And do you say that that is some strange variant of the word probable?

A. Yes.

Q. They are not saying it is more likely than not to be a carcinogen?

A. No, they are not saying that.

What they are saying is something that I don't quite understand about their societal duty to be conservative.

Q. They are saying it is a probable human carcinogen to support the need to protect the public against that?

A. I don't know what they have in mind.

But I know that one of the things they do

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net have in mind is questions like is it or is it net mere probable. Their concern is a much different one, which is essentially a social concern with what their actions ought to be.

And about this I have I have no knowledge, and it certainly has nothing to do with science.

Q. Do you know of EPA using what is called the weight of the evidence approach?

A. I have heard them do that. Yes.

Q. Don't they use a weight of the evidence approach to determine whether or not a substance is more likely than not a probable human carcinogen?

A. Often they do.

Q. Have they done with so with pcb's?

A. I don't know.

Q. Doctor, assuming you had the public health responsibility of deciding whether the public needed protection against pcb's, with respect to the IARC classification of pcb's as a probable human carcinogen, would you seek to protect the public against pcb's as a possible carcinogen?

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MR. FRUEHWALD: Wait a minute.

You went from a possible carcinogen to an IARC probable carcinogen.

A. Which he already said is a confusing terminology.

What was your question? You switched in the middle of it.

MR. KARAGANIS: I am going to go back.

Q. I ask you to hypothesize that you are in charge of public health in Bloomington. Would you seek to protect the public against a cancer risk from pcb's knowing that IARC has classified them as a probable human carcinogen, that EPA has classified them as a probable human carcinogen?

A. The short answer is no.

If I had nothing better to do, I might think about it. But if I look at the possible hazard to a population, using something like Bruce Aims' method of assessing carcinogenic problems, I would think beer would be a much more serious problem than pcb's. There would be a couple of orders of magnitudes more serious. Drinking water would be worse than pcb's. Again --

Q. Why drinking water?

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A. Because if you look at the kinds of evidence we have in animals, plus the ubiquity of the organic contaminants in drinking water, you come to the conclusion that a lot more people are at risk from drinking water than from --

Q. Let me ask you something.

Do we have epidemiologic evidence that the contaminants of drinking water cause cancer?

A. No.

Q. Do we have animal data that the contaminants of drinking water creates cancer in animals?

A. I believe it is, yes.

Q. Is it proper to use that animal data to reach a conclusion that the contaminates in drinking water pose a risk of cancer in humans?

MR. FRUEHWALD: Let me object.

You asked him to assume in this line of questioning, that these types of elements would be used. That's what he was doing.

MR. KARAGANIS: He mentioned the Aims test and drinking water. I didn't ask him that.

A. I didn't say anything about the Aims test.

WATER_PCB-00044618

I said Bruce Aims' methods of ranking carcinogens, in which he finds as I said beer is a spectacular --

Q. You mentioned drinking water.

A. And drinking water.

Q. I am asking you with respect to drinking water, do you have any knowledge that there is human epidemiologic evidence that drinking water causes cancer?

A. Not any good evidence. No.

Q. All right.

Now, there is evidence from animal studies that constituents of drinking water produce cancer in animals, isn't there?

A. I believe so.

Q. All right.

Is it proper from a public health perspective to recognize that the animal data presents evidence of a risk in humans?

A. I think that is a reason to study human exposures. I don't think it is a reason to take action.

Q. Okay.

So from the standpoint of protecting the

WATER_PCB-00044619

human populace, you wouldn't protect the populace against the current elements in drinking water, is that right?

A. I wouldn't protect them from a nonexistent danger. I would try to find out whether the danger was real.

Q. If the danger was real, after they had consumed the water, what would you do then, say don't drink any more water?

A. Yes.

See, they have been drinking the water for decades already. All they got to do is look.

Q. So --

A. Again, I think you are possibly the victim of some confusion in terms. Because the great majority of things about which we argue pro and con on carcinogenicity are things to which we already have exposure.

When one asks for human data, one is not saying let's go out and kill some people and look at what they die from. We are saying these people are living or dying right new. Let's look at what happens to them and document it.

So when I talk about wanting to verify an

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allegation about drinking water by doing studies, I am not talking about letting people drink water until they dye. I am saying people have been drinking the water. It is now time to study them.

Q. And you wouldn't take prophylactic action until you had done such studies; is that right?

A. That's right.

Q. Okay.

Prophylactic, I mean public health prevention action?

A. From a scientific point of view, I would not. People with --

Q. Let me just get this straight.

Are you familiar with the fact that EPA based on animal studies, based on animal data alone, on a conclusion that the human epidemiologic data is insufficient, has concluded that there are a number of substances which represent probable human carcinogens for which the public is entitled to protection?

A. I am aware of their conclusion,

Q. You disagree with that, is that right?

A. Yes.

Q. Would it be fair to say that you have no

WATER_PCB-00044621

knowledge of the specifics of the exposure situation in Bloomington?

A. That's correct.

Q. Or what the potential for exposure is?

A. That's correct, yes.

Q. Is it your intention prior to trial to develop opinions with respect to the risk posed by pcb's, human health risks posed by pcb's to the Bloomington population?

A. No.

Q. Pcb's are an industrial chemical, aren't they?

A. What do you mean by industrial chemical?

Q. They are used in industry.

A. Yes.

Q. Okay.

From a prudent public health standpoint, is it a smart idea to pour pcb's down sewers?

A. Not now it isn't.

Q. In your opinion, based on what you know, would it be a good idea to pour pcb's down sewers?

A. Not now it wouldn't.

Q. Based, if you had a vial of pcb's and there weren't any laws on the books, would you

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consider it a good idea to pour pcb's down sewers?

A. No. Any more than would I consider it a good idea to popur kerosene down a sewer.

Q. Any industrial chemical or any chemical, is that right?

A. Any chemical.

Q. Would it be fair to say that assuming no laws were on the books, would you consider it a good idea to dump pcb's or any chemical in a landfill that was subjected to fractured limestone geology and sink holes?

A. I don't know. I don't know.

Q. Assuming that you were in charge of disposal practices for a company.

MR. FRUEHWALD: Let met object to this line of questioning.

This witness is not being offered for expert testimony on this and no grounds has been laid floor any expertise. This is pure argumentation over things that are not within this expert's competence.

MR. KARAGANIS: Not at all.

This witness is being asked, from what I gather from his testimony, that the pcb's that

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were placed in the Bloomington area are innocuous.

MR. FRUEHWALD: You have asked him questions about that, but that's not what he has been offered for. That is not what the interrogatory answer said.

You are going well beyond it, Joe, and you are geing even further beyond it now.

MR. KARAGANIS: You made your objection.

MR. FRUEHWALD: This man's expertise is what it is.

MR. KARAGANIS: You made your objection.

Q. Would you dump any chemical into a landfill that had sink holes and was based on fractured geology?

A. I probably would not if I thought that the chemical was likely to be a problem, and if I thought it was likely to spread.

Q. Okay.

New, let's direct your attention, if you knew what you know today, and there are no laws on the books about peb's, would you dump pcb's in a landfill that had fractured geology and sink holes?

A. On the basis of what I know from the

WATER_PCB-00044624

epidemiology studies?

Q. On the basis of what you know from anything.

A. I wouldn't bother. It wouldn't worry me particularly in terms of a health effect.

Q. Okay.

Let me see if I have got this straight from the summary. With respect to pcb's being a probable human carcinogen, you disagree with EPA, right?

A. That's right.

Q. You disagree with NIOSH?

A. If they have so called it, yes.

Q. You disagree with IARC?

A. No. Because we have a difference in terminology here.

I agree that there is animal evidence and that the human evidence does not show anything. That puts it in IARC category 2 B. I don't think that the label for IARC category 2 B is descriptive. But the chemical does belong rightly in category 2 B.

Q. But you disagree with the descriptive label?

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A. That's right.

Q. Okay.

They describe it as a probable human carcinogen in that label, do they not?

A. They can do what they want, sure.

Q. You disagree with IARC in that respect, is that right?

A. That's right. So does their former director.

Q. You disagree with the cancer assessment group of EPA, that pcb's are a probable human carcinogen?

A. Yes, I do.

Q. Have you read Dr. Goodman's deposition?

A. No, I have not.

Q. Have you read any other depositions given by any of the plaintiffs' witnesses in this case?

A. No.

Q. Do you intend to read their depositions?

A. I see no need to.

Q. Have you read Dr. Hendricks' deposition, I take it that is included in your statement that you hadn't read any depositions in this case, is that right?

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A. That's right.

Q. Do you know Dr. Hendricks, Andrew Hendricks?

A. No.

Q. Do you know Dr. Joseph Rodricks?

A. No.

Q. Do you know Dr. Dawn Goodman?

A. No.

Q. Do you know Dr. Marion Moses?

A. We never met.

Q. Do you know that she has expertise in the field of epidemiologic analysis?

A. That's what she says.

Q. Now, would it be fair to say that neither Dr. Goodman nor you have degrees in epidemiology per say?

MR. FRUEHWALD: You mean Dr. Moses?

MR. KARAGANIS: I am sorry.

Q. Dr. Moses or you have degrees in epidemiology?

A. Yes, but one should add that at the time I got my degree I couldn't get a degree in epidemiology without being an MD.

Q. All right.

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So because of whatever the limitations were, you didn't get it?

A. Nevertheless, it is a fact that I do not have a degree in epidemiology.

Q. I am not quarreling with that. I am not challenging your expertise in terms of testifying with respect to epidemiologic evidence. But I just wanted to find out what the specifics are.

MR. FRUEHWALD: It is clear on the resume, Joe. The only reason you brought it up was for that reason.

BY MR. KARAGANIS:

Q. Do you agree with the following statement or do you agree with the proposition that carcinogenic activity in rodents is generally accepted by the scientific community as an indicator that a chemical poses a carcinogenic risk to humans?

A. Not as a generality. No.

Q. You do not agree that. Why is that?

A. Well, simply because there are people who don't agree with that.

Q. I am talking about you --

A. You are saying?

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Q. Do you agree?

A. Do I agree. No, not as a generality.

Q. What is the basis for your disagreement?

A. Because metabolism in animals and humans are quite different. If, for example, you look at a mouse and if you make what most scientists think is a reasonable assumption that the risk of cancer is proportional to the number of cells, then a man has about three times -- three thousand times as many cells as a mouse.

And so if generalization were appropriate, we should all die of cancer before we are twenty years of age. Obviously, the generalization simply is not straightforward. If it is to be made at all, it has to be qualified in some serious way.

Q. Who is the ex-president of IARC who doesn't agree with IARC's classification?

A. John Ligginson.

Q. Where is he located?

A. I believe he is at Georgetown University, I believe.

Q. Do you consider lead a carcinogen?

A. No.

WATER_PCB-00044629

Q. Are there others who consider lead a carcinogen?

A. I don't know.

Q. Well, you did a study on lead, an occupational expesure to lead, did you not?

A. Yes.

Q. Do you know whether there are people who consider lead a careinogen?

A. No, I don't know. What I do know is what we found. What we found is that it is not a carcinogen.

Q. I am asking you whether there are others whe --

A. I said I don't know.

MR. FRUEHWALD: Three times.

MR. KARAGANIS: Okay.

Q. Doctor, with respect to your chapter or your update on recent epidemiologic studies of pcb's.

A. Yes.

Q. Was that followed by a discussion among the participants in the seminar?

A. Yes. I believe it was.

Q. Did the seminar sponsors essentially note

WATER_PCB-00044630

your comments and the comments of others?

A. I don't recall whether they did or not. I believe that the sessions were recorded, so I believe that those comments did get down. What happened to them I don't know.

Q. Let's take about a five minute break.

(Whereupon a short recess was had.)

Dr. Gaffey, these are clean up questions.

Is everything that you have stated on your curriculum vitae true and accurate to the best of your knowledge?

A. Yes, it is.

Q. To your knowledge, has Monsanto retained any outside consultants who have prepared any reports or memos or letters or other documents relating to the health effects of pcb's?

A. To the best of my knowledge, they did not.

Q. Do you know of any epidemiologic studies that have tried to examine the role of pcb's as a promoter or co-carcinogen, do you know what that term is?

A. I am familiar with the term. I am not aware of any pcb studies that have tried to

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investigate that.

Q. Any epidemiologic studies?

A. Any epidemiologic studies of human beings.

Q. Would it be fair to say that you have no human information whatsoever with respect to the potential of pcb's as a co-carcinogen?

A. Neither for nor against.

Q. All right.

So my statement is correct, is it?

A. Your statement is correct.

Q. What do you intend to read or review for purposes of your upcoming trial testimony beyond the testimony you have given today?

A. Nothing beyond a further review probably of the papers we have mentioned that were published after I had completed my review.

Q. You mean the papers that you testified to today?

A. Yes.

Q. Those are the papers like the Bertazzi update?

A. The Bertazzi and Brown update. The Taylor paper and the two Jacobson papers.

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Q. You have already read those, given your opinions on them?

A. Yes, I have.

Q. And you have already given it on the Bertazzi and Brown updates, you have already done written critiques, have you not?

A. Yes, I have.

Q. Do you intend to consult with any other witnesses or experts, I am sorry, anybody else with respect to your opinions in this case?

A. No.

Q. Other than counsel?

A. No.

Q. Are you intending to prepare another draft or a redraft of your report or an updated draft of your report?

A. I haven't considered doing that, no.

Q. Have you consulted about your opinions in this case, other than your attorney, with any other witnesses or any other experts in any field?

A. No.

Q. Has Dr. Harbison, for example, consulted with you about his opinions in this case?

A. No, he has not.

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Q. Apart from your normal salary with Monsanto, are you being paid separately for your testimony in this case?

A. No.

Q. Have you done any epidemiologic reviews other than your statements on pcb's, and I think you said you did a review of a compound for reproductive effects that you hadn't written up, on another compound. I believe it was --

A. I mentioned doing a study of DMAC.

Q. Right.

A. That was not a review. That was a study, an actual study of an individual set of data.

Would you repeat that question?

Q. I will withdraw the question.

Other than the DMAC was that?

A. Yes.

Q. Have you done any epidemiologic reviews of -- I am sorry, epidemiologic work on other substances other than that reported in your vita?

A. Yes.

Q. What has that been?

A. At various times, I have done studies which did not result in published reports. Before

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coming to Monsanto, there was one industry-wide study of the aluminun industry. One study of lead chloride producers, a study of a general chemical company, and a study of petroleum refinery workers.

Q. What opinion have yeu given in the Scott case with respect te pcb's?

A. I am summarized the work that I did and gave essentially the opinions that I gave here about the consensus of the epidemiology data regarding health effects.

Q. Were any of the opinions that you have gave in the Scott case different than the opinions you have given here?

A. No.

Q. Did you give any opinions in the Scott case in addition to the ones you have given here?

A. Net that I can remember.

Q. What opiniens did yeu give in the Waukegan ease?

A. What I had intended to give were the same opiniens that I have given here in terms of summarizing the existing literature. I can't remember whether I was actually able to give that

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information or not, because I don't think that the deposition proceeded that far.

I am a little hazy on precisely what happened, but it seems to me that I wasn't asked very many questions, and the deposition terminated very quickly.

Q. Had you been given the opportunity to proceed, would you have given the same opinions in the Waukegan case?

A. Yes, I would have.

Q. Basically that pcb's do not represent a human health hazard, isn't that right?

A. That is correct.

Q. Are you familiar with any other published warnings or labels similar to the material safety data sheet for pcb's?

A. No, I'm not. I don't normally see material safety data sheets.

Q. Other than the papers that are post your paper on the epidemiology of pcb's, other than the papers that yeu have testified here today about, have there been any other papers or literature that you have reviewed for purposes of your opinion?

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A. No.

Q. To your knowledge, are you aware of any other studies other than the ones that you have testified here today about that are relevant to the opinions you have given in this case?

A. No, I'm not.

Q. That would be true with respect to any of the epidemiological conclusions you have reached?

A. That is correct.

Q. Doctor, is it a fair statement to say that unless there is epidemiologic human data to demonstrate adverse health effects or adverse health risks to humans, that from a scientific standpoint it is your opinion that absent such data, chemicals should not be regulated?

A. I think you are confusing two things. Absent such data, I do not believe scientifically that there is a cause-and-effect relationship.

Q. All right.

A. I am unable to pass on the societal considerations that lead to regulation.

Q. Or to prevention of exposure?

A. Or to prevention of exposure.

Q. So that is a judgment as to whether or

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not, if there is risk based on animal data, whether society should protect against such risk is a societal judgment, not a scientific judgment?

A. That's my opinion, yes.

Q. Are you aware of any work that Harbison, Dr. Harbison, has done for Monsanto?

A. I am aware that he testified for Monsanto in the pcb case at Bad Ax. I don't know what his testimony was, but I know that he was there.

Q. Any other work that Harbison did for Monsanto that you are aware of?

A. Not that I am aware of.

Q. Prior to his testimony at the Bad Ax case, had you met Dr. Harbison before?

A. I don't believe so.

Q. Have you ever had occasion to review the Industrial Bio-Test data?

A. No.

Q. Are you aware of it?

A. I am aware that -- I am aware the company exists and I am aware they did work for Monsanto, but I have never had an opportunity to look at their data.

Q. Have you had occasion to discuss your

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testimony or your opinions with Dr. Kaley?

A. No.

Back up. Dr. Kaley knows my opinions because he has seen the two documents that I produced. But I have never had any discussion with him about them.

Q. How do you know Dr. Kaley has seen those documents?

A. I don't know that he has seen them. But I think I have probably sent them to Dr. Craddock. I deduce that they went to Dr. Kaley.

Q. Does Dr. Kaley work for Dr. Craddock?

A. I believe he does.

Q. In what capacity?

A. I think he manages the data files in connection with several litigation activities, one of which is pcb's.

Q. What data files are you talking about?

A. Files of reprints.

Q. What else is in those files?

A. I don't know.

Q. Are they kept under Dr. Kaley's control?

A. I think so.

Q. And is that in the overall medical

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section or department of whatever you called it?

A. No. That is part of something called the environmental policy staff. One subset of that is the department of medical and health services, another subset is a group of several people which include Dr. Craddock.

Q. What is that department called?

A. It is not. It is a collection of people who are called regulatory directors. Dr. Craddock works for one of them, a Dr. William McCarville.

Q. Let's see if we have got this straight. The department of medical and health services reports to?

A. Dr. Harold -- Mr. Harold Corbett.

Q. Okay.

A. Two t's.

Q. Dr. Roush is the head of the medical health center?

A. Dr. Roush reports to a Mr. Singer, who reports to a Mr. Corbett.

Q. Okay.

Where does Mr. Craddock come into that?

A. Among the other people reporting to Mr. Corbett, are several regulatory directors, one of

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whom is Dr. McCarville. Dr. Craddock reports to Dr. McCarville.

Q. What is Dr. McCarville's title?

A. Beats the hell out of me.

Q. That's an honest answer.

A. It might be an appropriate title, but it is not one that he probably has. He is one of the regulatory directors but, I don't know his precise title.

Q. Regulatory directors of what?

Are there a bunch of regulatory directors of something?

A. We have, one of them is concerned with regulatory matters, one of them is concerned particularly with air regulations, with water regulations, and there may be some others, I don't remember.

Q. Okay.

And Dr. McCarville reports to Corbett. Craddock reports to McCarville?

A. Yes.

Q. Where does Kaley come into this?

A. I think he reports to Craddock. If he does, it will involving drawing fewer lines, but I

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think it is the truth.

Q. Who is in charge of the environmental policy staff?

A. Mr. Corbett.

Q. Okay.

Who does he report to?

A. Probably to the president of the company, but I am not sure.

Q. Who is the president now?

A. Mr. Earl, who is also, it is Harbison. It is an odd coincidence.

Q. Is that Harbison?

A. I think it is Harbison. Yes.

Q. Has Dr. Kaley discussed his testimony with you?

A. No. I was not aware that he had testified.

Q. Or that he is planning on testifying?

A. Or that he is planning on testifying.

Q. On Kaley, where does he maintain the case files on various pieces of litigation?

A. I don't know. I know where his office is, but I don't know physically where his files are located.

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Q. But he does maintain files on various matters that are in litigation, including pcb's?

A. I believe, I know he maintains files on pcb's. I believe he may maintain other files, but I am not sure.

Q. How many files on pcb's?

A. I don't know.

Q. And his responsibility is to supervise the data with respect to --

A. I believe that is the case. That he manages input and retrieval from a file, I think. I am not sure, because he is not in my unit and I see him rarely.

Q. Input and retrieval of data regarding pcb's?

A. I believe so.

Q. When were Kaley's files created?

A. I have no idea.

Q. Do you know if anybody else in the company maintains files regarding pcb's?

A. No.

Q. Does Mr. Bistline maintain files regarding peb's?

A. Bistline, I have no idea.

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Q. Doctor, are you aware of anybody in the course of your travels, either inside the company or outside the company, who has expressed an opinion contrary to yours on pcb's?

A. I haven't talked to any such people. I am aware that EPA doesn't agree with them.

Q. Who in EPA?

A. I don't know.

Q. But the agency has expressed disagreement, is that right?

A. The law that established TSCA has made pcb a carcinogen by act of Congress. EPA can't possibly disagree.

Q. You are saying Congress has made a judgment?

A. Yes, Congress. Pcb's are a carcinogen by act of Congress.

Q. So that what you are saying is that as a matter of law, in your opinion --

A. They may not say that pcb is not a carcinogen.

Q. As a matter of law, we are required to treat pcb's as a carcinogen, is that right?

A. I don't know. But the fact that pcb's

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were said to be a carcinogen, was one of justifications for passing the TSCA law.

Q. Do you know of anybody in Monsanto Company who has expressed an opinion that they agree with EPA, that pcb's are a carcinogen?

A. I am not aware of anybody. No.

MR. KARAGANIS: Doctor, I am going to leave this deposition open.

We need to discuss with Mr. Fruehwald the disclosure of various documents to which you have referred today. And after I have examined those documents, I may wish to continue this deposition to question you about those documents. But other than that, I have no further questions.

MR. FRUEHWALD: All right.

I don't necessarily accept that we are going to need to resume, but that can be, of course, considered after we have further discussions. I have no questions today.

MR. KARAGANIS: Thank you.

A. You are welcome.

DEPOSITION CONCLUDED

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IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

THE CITY OF BLOOMINGTON, INDIANA; THE UTILITIES SERVICE BOARD OF BLOOMINGTON, INDIANA; and MONROE COUNTY, INDIANA,

Plaintiffs,

vs.

WESTINGHOUSE ELECTRIC CORPORATION, a Pennsylvania corporation; and MONSANTO COMPANY, a Delaware corporation,

Defendants.

Civ No. IP 83-9-C

I hereby certify that I have read the foregoing transcript of my deposition given at the time and place aforesaid, consisting of Pages 1 through 229, inclusive, and I do again subscribe and make oath that the same is a true, correct and complete transcript of my deposition so given as aforesaid, as it now appears.

_____
WILLIAM R. GAFFEY

SUBSCRIBED AND SWORN TO
before me this_____day
of_____, 198___.

_____
NOTARY PUBLIC

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UNITED STATES OF AMERICA)
NORTHERN DISTRICT OF ILLINOIS)
EASTERN DIVISION) SS:
STATE OF ILLINOIS)
COUNTY OF C O O K)

I, Arnold N. Goldstine, a notary public and Certified Shorthand Reporter in and for the County of Cook and State of Illinois, do hereby certify that the aforesaid deponent was by me first duly sworn to testify the whole truth, and that the foregoing deposition was recorded stenographically me and was reduced to typewriting by computer-aided transcription under my personal direction and supervision; and, that the said deposition constitutes a true and accurate record of the testimony given by said deponent.

I further certify that the reading and signing of said deposition was not waived by the deponent or counsel.

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I further certify that we I am not a relative or employee or attorney or counsel of any of the parties, or a relative or employee of such attorney or counsel, or financially interested directly or indirectly in this action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Chicago, Illinois, this 21st day of September A.D. 1987.

Notary Public/Certified Shorthand Reporter

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