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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
-vs-	)	No. 78 C 1004
	)	
OUTBOARD MARINE CORPORATION and MONSANTO COMPANY,	)	
	)	
Defendants.	)	

The deposition of Harold E. B. Humphrey, called by the Defendant Monsanto Company for examination, pursuant to agreement and pursuant to the Rules of Civil Procedure for the United States District Courts pertaining to the taking of depositions, taken before Jean Korinko Sweeney, R.P.R., a Notary Public in and for the County of Cook, State of Illinois, and a Certified Shorthand Reporter of said state, at the U. S. Attorney's Office, 219 South Dearborn Street, 15th Floor Conference Room, Chicago, Illinois, 60604, on the 12th day of August, A.D. 1981, commencing at 10:00 o'clock a.m.

Thea L. Urban
Certified Shorthand Reporter
134 South La Salle Street
Chicago, Illinois 60602

11-5V28.0/070

PRESENT:

MR. JAMES P. WHITE,
(Assistant United States Attorney
United States Attorney's Office
219 South Dearborn Street, 15th Floor
Chicago, Illinois 60604),

appeared on behalf of the United States of America;

MS. ROSEANN OLIVER and MS. CAROL DORGE,
(Phelan, Pope & John, Ltd.,
30 North LaSalle Street,
Chicago, Illinois 60602),

appeared on behalf of Outboard Marine Corporation;

MR. BRUCE A. FEATHERSTONE,
(Kirkland & Ellis,
200 East Randolph Drive
Chicago, Illinois 60601),

appeared on behalf of Monsanto Company.

* * * * * * *

I N D E X

WITNESS:	PAGE
HAROLD E. B. HUMPHREY	
Direct Examination by Mr. Featherstone	4
Direct Examination (Resumed) by Mr. Featherstone	74
Direct Examination (Resumed) by Mr. Featherstone	213
Direct Examination (Resumed) by Mr. Featherstone	308
Direct Examination by Miss Oliver	328

* * * * *

E X H I B I T S

Humphrey Deposition Exhibit No.	
1	5
2	5
3	13
4	34
5	74
6	282
7	282
8	383

* * * * *

MR. FEATHERSTONE: Would you swear the witness in, please.

(Whereupon, the witness was duly sworn.)

HAROLD E. B. HUMPHREY,

called as a witness by the Defendant Monsanto company for examination, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. FEATHERSTONE:

Q Are you Dr. Harold E. B. Humphrey?

A Yes, I am.

Q What is your title presently with the State of Michigan?

A Environmental Epidemiologist, scientific liaison coordinator for the Division of Environmental Epidemiology, Bureau of Disease Control and Laboratory Services, Michigan Department of Public Health.

MR. FEATHERSTONE: Would you mark this as Exhibit 1.

(Said document was marked Humphrey Deposition Exhibit No. 1 for identification as of 8/12/81, JKS.)

BY MR. FEATHERSTONE:

Q Dr. Humphrey, I have had marked as Exhibit 1 to your deposition a five-page document that purports to be your curriculum vitae. Is that what it is?

A Yes.

MR. FEATHERSTONE: Would you mark this as Exhibit 2.

(Said document was marked Humphrey Deposition Exhibit No. 2 for identification as of 8/12/81, JKS.)

BY MR. FEATHERSTONE:

Q Dr. Humphrey, I have had marked as Deposition Exhibit No. 2 to your deposition a document that bears the title, "Evaluation of Changes of the Level of Polychlorinated Biphenyls (PCB) in Human Tissue." The author of the report is listed as yourself. Were you the author of the report?

A I was the director for that project, and the principal author of the report, yes.

Q Doctor, looking at Exhibit 1, which is your curriculum vitae, and looking under Professional Publications, which is on Page 4, the only document or professional publications of yours that I see on that list that relate to PCBs is what I have now marked as Exhibit 2, is that correct?

A That is correct.

Q For purposes of the balance of your testimony, and the balance of my examination of you, would you understand me if I used the phrase 1976 report to be referring to what is now Exhibit 2?

A That would be satisfactory.

Q Doctor, would you look, please, at Page 3 of your curriculum vitae, Exhibit 1. It is headed Professional Presentations. Do you see where I am?

A Yes.

Q I notice that the last and the third to the last entry in that list -- Are those speeches that you gave?

A Yes. The content of that page represents talks or invited or accepted at professional or other types of forums.

Q The third to the last entry is entitled, "Evaluation of Polychlorinated Biphenyls in Humans Exposed to Contaminated Fish." That was a speech?

A That was a speech.

Q Did you prepare a draft of the speech?

A I am trying to find the specific one here. You say third from the last?

Q Third from the end, Page 3.

A I have an updated one here.

This one here, the 19th Annual Meeting of the Society of Toxicology?

Q Yes.

A Yes. This is a talk, and the content of the talk is basically this document. (Indicating.)

Q This document you have pointed to, Exhibit 2, the 1976 report?

A That is correct.

Q In giving that speech did you speak from a written draft?

A No, I didn't. Generally when I prepare talks of this nature I have chosen to speak extemporaneously, and I make notes and talk from slides. The composition of the slides would be

two by two slides of some of the charts and graphs in this report, which is Exhibit 2.

Q If I understand you correctly, you did not prepare anything new, so to speak, for this speech that you gave in Washington, D.C.?

A That is correct.

Q I notice that you have a different curriculum vitae than what I have introduced and marked as Exhibit 1.

Let's go off the record.

(Discussion had off the record.)

MR. FEATHERSTONE: We will substitute this as Exhibit 1.

For the record, we have substituted as Deposition Exhibit 1 a more current curriculum vitae which Dr. Humphrey had before him when he was answering my earlier questions.

BY MR. FEATHERSTONE:

Q Doctor, so that we don't have to go through each one of these presentations one by one, would you take a minute here and on Exhibit 1 put an X in the left-hand margin next to those presentations which relate to PCBs.

A This one has not happened yet. (Indicating.)

Q Would you please read into the record which one you are talking about.

A Epidemiologic Studies of Humans Exposed to Chemical Contaminants, International Symposium on Environmental Pollution, Miami 1981, is scheduled for, I believe, November, 1981.

Q It will relate to PCBs?

A Yes. Not exclusively, but it will relate to PCBs.

Q Why don't you mark that one as well. Those would be the ones then.

A At the Symposium, that was exclusively PBBs.

Q Okay. When you made that statement, you were referring --

A I was referring to the last entry, a symposium at Rockefeller University in 1981, which was held in June of 1981.

Q You have marked with an X, five presentations which either have or will relate to PCBs?

A That is correct.

Q Now, I have already asked you about the first one. The remaining four -- Strike that.

Let me ask you about the three that you have given, and put aside for a minute the one that will be given in Miami later this year. The three that you have given, did you prepare any draft, written draft for the presentation?

A The answer in all cases was no -- is no.

Q I take it then you spoke extemporaneously from the slides as you did in response to my questions about the earlier presentation.

A That is correct.

Q Have any of these presentations been summarized in any of the professional literature that you are familiar with?

A I am not aware that they have, no.

Q Were there any proceedings of these symposiums or meetings that would contain either a transcript of your remarks or some kind of summary of your remarks that were circulated to the participants or others?

A With respect to these that we have Xed, no.

Q In other words, there is no written record

of anything you said at any of those meetings?

A No. The written record with respect to those would be this (indicating).

Q And this is?

A An exhibit.

Q Exhibit 2.

A Exhibit 2.

Q Doctor, on Exhibit 1 you have a listing that is noted invited participations. What are these?

A That pertains to meetings or work-related conferences where I have been invited to give a comment or make a presentation or participate. For example -- Can I give an example?

Q Certainly.

A From this.

The American Association of University of Women, program panel speaker in 1978. This association, one of their local branches, was establishing a panel to discuss PBBs, polybrominated biphenyls. I was invited to speak there. That is typical of what these listings indicate.

Q To the extent that you made any remarks in your presentations that are listed here, any

remarks on PCBs, I take it they were also based on your findings that are now in Exhibit 2 of your deposition?

A That would be correct.

Q I take it that likewise you didn't prepare any written materials?

A That would be correct.

Q Doctor, we have been advised by the United States Government that you will, "Testify as to the bio-accumulation of PCBs in humans who eat Lake Michigan fish."

This was a letter from Jim Hynes, Assistant U.S. Attorney to the defense lawyers in this case describing the testimony you will give at trial in this litigation.

Have you been advised by Mr. White or Mr. Hynes, or anybody else in the U.S. Attorney's office that you will testify "to the bio-accumulation of PCBs in humans who eat Lake Michigan fish"?

A Yes.

Q Have you been advised by Mr. White or Mr. Hynes or anyone else in the U.S. Attorney's office that you will give testimony on any other subject

other than that?

A No.

Q Doctor, to the extent that you have done work relating to the bio-accumulation of PCBs in humans who eat Lake Michigan fish, I take it the only written report on that work is Humphrey Exhibit 2?

A That would be correct.

MR. FEATHERSTONE: Would you mark this, please.

(Said document was marked Humphrey Deposition Exhibit No. 3 for identification as of 8/12/81, JKS.)

BY MR. FEATHERSTONE:

Q Dr. Humphrey, I have had marked as Exhibit 3 to your deposition a multi-page document that is entitled, "Evaluation of Humans Exposed to Water-Borne Chemicals in the Great Lakes." What is that document?

A That is a document which encompasses the protocol for a research grant which has been awarded by the EPA to conduct a study of the same title.

Q Have you begun work on this project?

A Yes.

Q Have you written any reports as a result of the work you have done on the project?

A Yes, with this qualification; not a formal report such as Exhibit 2, which is a final, complete compilation, but the project is a three-year project. At each annual renewal there is a progress report to the contract officer. We have renewed two times now. I don't personally consider those reports on the project, as they are more operational progress so far as meeting, fulfilling the scope of work that is intended, as opposed to detailed data analysis.

Q These progress reports, how long are they in terms of pages?

A Five pages.

Q Do they in short set forth the progress you have made, the actions you have taken toward meeting the goals of the project?

A Yes, they do.

Q Is there any data set forth in these reports?

A Yes, there is.

Q Are there any conclusions that are set forth?

A No, there are not.

Q Who is the project officer involved in the work that you are doing on Humphrey Exhibit 3? In other words, who do you send the reports to?

A Dr. Michael Mullin.

Q Who is he?

A He is a research chemist at the EPA Large Lakes Research Laboratory at Grosse Ile, Michigan. He has been designated as the project officer for this project.

Q Have you sent these progress reports to anyone else at USEPA?

A No.

Q Do you --

A Could I -- The progress reports that we are referring to are a part of the re-application package, and it is sent to the Grants and Contracts Branch of the EPA as well, simultaneously with being sent to the project officer.

Q Is the re-application package more than just the progress report?

A Yes, it is.

Q What else is in a re-application package?

A Budget, continuing budget for the upcoming

year, a narrative statement for the anticipated work to be accomplished in the upcoming year; other assurances; listings of personnel on the project and so forth; and this progress report on work done to date. It's a standardized type package which are typical of renewal of grants, so far as the documents requested.

Q I apologize if I have asked you this question, but do you send progress reports to anyone else at USEPA other than Dr. Mullin?

A No, I do not.

Q Other than the administrators to whom you send the re-application package, do you send materials relating to your project, and the one I am referring to is the one you summarized in Exhibit 3, to anyone else in the Federal Government?

A No, I don't.

Q Does Mr. Mullin receive any reports other than the progress report from you, or anybody involved in this project?

A I don't understand what you mean by that question.

He is the project officer, and I am the

project director. If he requests something, verbally or in writing, I send it to him. If he requests anything to do with this project, it goes to him through me.

Q So you are the link, in essence, between Dr. Mullin on the project?

A Yes.

Q Have you sent Dr. Mullin any of your data?

A Yes, we have.

Q Has Dr. Mullin asked you to express any conclusions, final or tentative, on what your data shows?

A No, he has not.

Q Has anyone asked you to do that?

A No.

Q Are you in a position now to draw any conclusions from your data, or your project?

A No, I am not.

Q When is this project supposed to be completed?

A A year and a half from now.

Q That is the end of the year, 1982?

A Yes.

Q Doctor, the trial in this litigation is now set for March 1, 1982. Are you going to be in a position on that date, or during the trial which may last two months after that date, to draw any conclusions based on any of the work that you have done in this new project summarized in Exhibit 3?

A It's possible that I will by that date, yes.

Q When do you anticipate being in a position to make any type of conclusion or render any opinions as a result of the work that you have done in this project that is Exhibit 3?

A I would expect within the next six months that a definitive report would be prepared on part of the scope of work that is included in that project.

Q You chose your words very carefully and said, "on part of the scope of work that is included in the project."

A Yes.

Q Which part?

A The scope of work -- I don't know exactly where you'd find it in there.

Q Well, can you describe it for me generally?

A Yes, if I can do that I will.

The concept of this project is to return to the cohort of people that were the subjects of the study, the 1976 study, Exhibit 2.

The concept there being to revisit this cohort, obtain blood samples, retest them, because of the five-year span that will have occurred between when they were initially studied and current.

The other part of this research project is to enroll an additional number of people. In other words, to enlarge the cohort above and beyond the original group. To also enroll comparison people from the communities, and to in a similar way study their blood level and determine their rates of consumption, et cetera.

In addition, the expanded portion of the study is intended to do some medical evaluations of the subjects, exposed and comparison. Medical evaluations being defined as certain types of physical measurements, height, weight, skin conditions. A detailed medical history. Then some specific medical tests, such as evaluation of blood for certain enzymes, evaluation of vital lung

capacity, evaluation of blood pressure.

So the project basically has two major divisions. Return to the original cohort; and continue the study with an expanded group of people in more detail.

I would anticipate that our return to the original cohort, the first part that I have spoken of, has basically been completed. The laboratory tests are nearly completed. I would anticipate that we would be able to prepare a report on that aspect within the next six months.

A report on the larger aspect of the grant would come at the end of the grant period.

Q In other words, year end 1982.

A That is correct.

Q You are speaking about this second part of the project, if you will, the new people that you will enroll in the project.

A Um-hum.

Q You have to answer audibly.

A Yes.

Q I take it you have people working for you on this project?

A I do.

Q Have any of the people working for you drafted any memoranda expressing any opinions or conclusions about the data that you have gathered with respect to the 1976 cohort, five years later?

A No, not that I am aware of.

Q By the way, Exhibit 3, which I believe you have identified as the document summarizing the project proposal --

A That is correct.

Q -- were there changes made to the project you proposed?

A No. This is the original application for the project which was intended to be a three-year project.

Q Exhibit 3 then will tell me what it is that you are doing?

A That is correct.

Q Doctor, have you given any testimony at any trials on PCBs?

A No, I have not.

Q Have you given any testimony in any hearings about PCBs?

A No, I have not.

Q Do you have in your files the progress report or other written communications that you have had with Dr. Mullin regarding this project, Exhibit 3?

A Yes, I do.

Q Do you have any objection to providing them to me and presumably Miss Oliver?

MR. WHITE: Certainly Miss Oliver.

BY THE WITNESS:

A No. My only qualification would be --

MR. WHITE: Go ahead and say it.

BY THE WITNESS:

A If it's all right with Dr. Mullin. Our files are not closed in the sense that --

BY MR. FEATHERSTONE:

Q But you have communications, written communications from Dr. Mullin about this project, Exhibit 3?

A Yes.

Q Obviously there are written communications from you in addition to the progress reports you send to Dr. Mullin.

A That is true.

Q They are in your office in East Lansing?

A In Lansing, that is correct.

MR. FEATHERSTONE: Mr. White, we would like those materials. Any problem with that?

MR. WHITE: I don't know. I haven't seen them. I passed over them because of I don't think they are relevant. But I will be happy to take a look at them and provide them to you, if they are relevant.

MR. FEATHERSTONE: Well, is Dr. Humphrey going to be asked at trial for any opinions or conclusions based on the new project, Exhibit 3?

MR. WHITE: Bruce, I am not going to resolve the question on the record with you with respect to -- If you want to take Dr. Humphrey's deposition, go ahead, but you are not going to take mine.

MR. FEATHERSTONE: I don't want to waste any time. If you are not going to ask him that, maybe I won't ask him that. You haven't made a determination, or you are not willing to make a statement on the record?

MR. WHITE: I am not willing to make a statement on the record, because I haven't made a determination

at this particular point in time.

BY MR. FEATHERSTONE:

Q Dr. Humphrey, have you done any work on PCBs other than what is summarized in Exhibit 2 to your deposition, or what is proposed and is now ongoing and is summarized in Exhibit 3 to your deposition?

A Yes, I have.

Q Would you describe that work for us.

A As my curriculum vitae shows, I am responsible for the administration of a number of projects for the State Health Department, and one of the other major projects is an investigation of polybrominated biphenyl exposure.

Q PBBs?

A Correct. As a part of that investigation, we have analyzed human blood samples for PCBs as well as PBBs. So that in that kind of a context my answer to you is yes. Although that obviously is not a specific PCB project, we are generating PCB residue data.

Also as a part of that study, we are evaluating farms that have silos that were coated

with a PCB material. Again, the subjects, their blood is being evaluated for PCBs.

In addition, we have also assessed the levels of chemical contaminants in breast milk of women in Michigan. Among the contaminants evaluated by the survey was PCBs. So that we have data on PCB values in the human breast milk.

I believe that encompasses the other areas where the topic PCB might be included in the activities.

I might add one more item, if I could, and that is occasionally as a routine matter we receive requests from physicians to evaluate specimens submitted to us for PCB and/or other chemicals, and that is done. Again, that is not a specific project, but that is data which we do generate, which the laboratory does the analysis.

Q When you say evaluate specimens, what type of specimens are you talking about?

A Generally these are blood specimens. Occasionally there are adipose specimens, or other type of surgically obtained specimens.

Q In the work that you have done or been

involved in that involves the analysis of human blood samples for PCBs as well as PBBs, did you identify any health problems of any of those individuals that you could attribute to PCBs?

A No, not exclusively.

Q In the work that you have done, looking at individuals who live on farms with silos coated with PCB material -- Is t :t correct?

A That is correct

Q --you have taken blood specimens from those individuals?

A That is correct.

Q Did you take anything other than blood specimens?

A We asked them questions with respect to the medical background, medical history, interviews. But specimens, no. Blood was the specimen that we received.

Q In the work that you have done with these people who live on farms, did you identify any health problems that you say or can say are the result of exposure to PCBs?

A I can't answer that question with a simple

yes or no at this time. The reason is that is an ongoing investigation, in that the data is in the process of being analyzed. We have not reached a conclusion on that question.

Q Have you reached any conclusions at this time?

A What do you mean by -- Could you expand on that a little bit?

Q Certainly. You say it is an ongoing project, and that data is still being analyzed. How many years has this project been ongoing?

A Pardon?

Q For how many years has this project been ongoing?

A With respect to the silo people, I think this is the third year.

Q Have you reached any tentative conclusions about the exposure of PCBs to these individuals?

A Yes. We have some information which we would consider tentative conclusions.

Q What are the tentative conclusions?

A One is that they have distinctly elevated blood level of PCB above and beyond that of other

farmers.

Q Any other conclusions?

A Another is that certain types of diseases appear to be occurring more frequently in this group. But there are qualifications on what those results mean at this time, which is why I said we have not drawn conclusions yet.

Q Any other tentative conclusions?

A Those would be the two basic areas; blood residue levels and occurrence of disease.

Q Which diseases?

A There is a variety of diseases which would include cancer. Without the list in front of me, I cannot accurately tell you exactly. But hepatitis, liver-type diseases, cancers, among a variety of other things, are being investigated by that project.

Q Well, I think maybe you and I missed a beat here on this last question.

You stated that it was your tentative conclusion that certain types of diseases appear to be more regular in people that live on farms with silos coated with the PCB material. I want

to know what those diseases are.

A Cancer was one.

Q Any others that you can remember right now?

A No, I can't right now without consulting my notes on it.

Q You carefully phrased a previous answer and said certain types of diseases appear to be more regular. I take it you have not run a statistical correlation?

A That is correct.

Q Is that correct?

A That is correct.

Q So at this time I take it you would be unwilling to express a conclusion, a medical conclusion, that the PCB exposure to these individuals has caused cancer in these individuals?

A At this time, at this hour I cannot do that.

Q When are you going to be in a position to render an opinion on that?

A I am not sure that I can answer that question directly.

Q When is the project supposed to be completed?

A Twenty years.

Q Twenty years from today?

A Twenty years from its inception. This is a part of this long-term evaluation of humans exposed to polybrominated biphenyls. That project began in 1976, with the intent it would be a long-term study, defined as ten or more years. While no ending date has been established, studies of this type would be expected to go from 15 to 20 years.

Q So what you are telling me it may be several years before you can express any type of an opinion.

A Yes, that is what I am telling you.

Q These farm people that we have been talking about, were they also exposed to PBBs?

A Some of them were, and some of them were not.

Q And that is a complicating factor, obviously.

A Yes.

Q You testified that you have been involved in some work that has concerned analysis of female

breast milk for chemical residues.

A That is correct.

Q I take it you found some PCBs in some of these breast milk samples?

A That is correct.

Q Have you been able to attribute any health problems in any of these women, or any of their offspring, to the presence of PCBs in the breast milk?

A I don't know, because it was not the intent of the survey. The intent of the survey that I referred to was merely to analyze the presence of the chemical. It was not a survey intended to evaluate health or the health of offspring.

Q What you are telling me is the sole purpose of the survey was to gather residue data?

A Correct.

Q So you can't point to any health problems and say that is attributable to PCBs in the female breast milk?

A From that survey I cannot do that.

Q Do you have any plans to take a look at that data and see whether you can draw any conclusions?

Plans in the next six to eight months, for instance?

A No.

Q You testify that as a routine matter you and people you have worked with evaluate specimens submitted by other doctors. I take it in the State of Michigan?

A Not exclusively the State of Michigan, but generally yes, the State of Michigan.

Q These are generally blood specimens?

A That is correct.

Q From this work are there any health problems in humans that you can point to and say they are attributable to the PCBs that you found in these blood specimens?

A Specifically I cannot do that.

However, I'd like to qualify that statement. Many of the specimens that are submitted under that program are from physicians who are treating a patient for some kind of a health condition, and they are curious as to whether or not PCB might be a complicating factor. And we therefore provide the testing and report the value. So I don't know but what those specimens

may in fact indicate a correlation between PCB and health. But I can't state, because I am not treating those patients, what that might be. And the intent of that testing is not a study to try and answer that question, it is a service.

Q Let's go to your 1976 report.

Off the record.

(Discussion had off the record.)

BY MR. FEATHERSTONE:

Q Dr. Humphrey, the title of your 1976 report is, "Evaluation of Changes of the Level of Polychlorinated Biphenyls (PCBs) in Human Tissue." Doctor, I have read through this report, and frankly I didn't see anything that related to the levels of PCBs in human tissue. Am I right?

A You are wrong.

Q Okay. Where is it?

A Blood is considered a human tissue.

Q Ah-hah. I take it nowhere in this report do you discuss the levels of PCBs in what is known as adipose tissue? Or is blood considered adipose tissue as well?

A No. There is no reference in the report

to adipose tissue.

Q Doctor, would you look at Finding No. 7 in your Summary of Findings. It reads:

"As a group the exposed participants had no health problems or medical conditions that could be correlated with PCB blood levels, exposure to Lake Michigan fish, or known symptoms of PCB poisoning."

Have you changed that conclusion or finding in any way since 1976?

MR. WHITE: We do not have that No. 7.

MR. FEATHERSTONE: What is the problem?

MR. WHITE: Off the record.

(Discussion had off the re

MR. FEATHERSTONE: Would you mark this as Exhibit 4.

(Said document was marked Humphrey Deposition Exhibit No. 4 for identification as of 8/12/81, JKS.)

BY MR. FEATHERSTONE:

Q Dr. Humphrey, I have marked as Exhibit 4 to your deposition another version of your 1976

report which you have identified to me as a final report. And we will get to that in a second.

So the record is clear, the reason for concern with respect to the last question and answer was that I happen to be working off what I believe Dr. Humphrey will identify in a minute as an earlier draft of his final report, and Dr. Humphrey was responding from a final draft of the final report.

In any event, Dr. Humphrey, let me show you Exhibit 4. Is that the final draft of your 1976 report?

A Yes, I believe it is.

Q Doctor, I am going to show you Exhibit 2, which you earlier identified as your 1976 report, and ask you what it is.

A The previously described document that you referred to appears to me to be a draft of the final report. The major difference between it and the final report being in the Summary of Findings.

Q So Exhibit 2 is a draft?

A Correct.

Q Other than the difference you have pointed

out in the Summary of Findings, is there any other differences that you can identify right now between Exhibit 2, the draft, and Exhibit 4, the final report?

A None that I discern.

Q Doctor, would you keep in front of you Exhibit 2 and Exhibit 4.

Off the record for a second.

(Discussion had off the record.)

BY MR. FEATHERSTONE:

Q Are you ready, Doctor?

A Yes.

Q A preliminary matter. Exhibit 2, did you participate in the writing of that document as well?

A Yes, I did.

Q Would you turn to Exhibit 4, which you have identified as the final draft. Finding No. 12 in the Summary of Findings reads:

"No health problems or medical conditions could be correlated with PCB blood levels or exposure to Lake Michigan fish."

Have you changed that finding in any way since 1976?

A. Do you mean by the question has a new --

MR. WHITE: Do you understand the question, Doctor?

BY THE WITNESS:

A I'd like a further explanation on the question.

MR. FEATHERSTONE: All right.

MR. WHITE: Would you rephrase the question.

BY MR. FEATHERSTONE:

Q The finding that is stated in Finding No. 12 in the Summary of Findings, have you since the time that you issued this final report re-evaluated that data and in any way changed that finding?

A The data has not been re-evaluated.

Q So Finding No. 12 remains your opinion today as to what your study showed in 1976?

A Finding No. 12 refers to one point in time, and that was at the time of the study. With respect to the correlation of health problems as defined by the study, there are caveats in the study with respect to health problems.

Q Doctor, let me --

A And it is stated in the paragraph that

follows, and is stated throughout the report, and I can refer to those points.

Q Doctor, let me try it again. Finding No. 12 is a finding, is it not?

A It's a Summary of Findings, a summarization.

Q Of your findings?

A Of a finding.

Q And Finding No. 12 is based on your analysis of the data you gathered in the 1976 study.

A Correct.

Q Now, Finding No. 12, which is a summarization of your findings, have you re-evaluated the data?

A No, we have not.

Q Have you in any way changed your opinion as to what your data showed with respect to Finding No. 12 in 1976?

A No, I have not changed my opinion with respect to what is stated in No. 12, referring to that point in time.

Q That point in time being 1976?

A 1974, when the data was actually gathered

from the people, yes, the 1976 report.

Q I take it, Doctor, you don't have any information that leads you to believe that those people suffered any health problems or medical conditions since 1974 that you could correlate to PCBs?

A Your question is too broad.

Q Well, let me try to narrow it.

A Okay.

Q Finding No. 12, your finding of no health problems in the people you studied in 1973 to 1975.

A I don't agree with that.

Q That could be correlated to PCBs.

Do you agree with that?

A Listen.

Q Doctor, I will start over again. Your 1976 study reflects the work you did on data you gathered between 1973 and 1975, is that correct?

A That is correct.

Q You took that data, including data pertaining to health conditions of these people and analyzed it, is that correct?

A Not fully. I am having trouble with the words you are using.

Q Which words are causing you trouble, Doctor?

A Health conditions.

Q It is certainly not your testimony that you didn't gather any data concerning the health conditions of these individuals which you studied.

A Well, is your definition of health conditions the same as mine?

Q It is the same as yours as shown in your report, your 1976 report.

A Okay. My report indicates that we asked historic health questions, questions about the health history, and we asked the participants whether or not they had experienced a listing of specific symptoms or conditions, diseases. But that does not constitute a health evaluation of those individuals. That is why I am having trouble with your words.

Q Let me start over again, and I will keep trying to make it so that you can understand it and respond to it, Doctor.

This 1976 study, as you have testified concerned data that was gathered in 1973 to 1975, correct?

A Correct.

Q Some of the data you gathered concerned a list of symptoms from the Yusho incident in Japan.

A Correct.

Q I take it at the time that you made a decision to gather data from these fish eaters with respect to the Yusho symptoms you did this because you thought the Yusho symptoms were attributable to PCB exposure, is that correct?

A Could be attributable.

Q I take it that the list of conditions, health conditions that you found in your 1976 study was pretty much a complete list of the conditions that you then thought could be attributable PCB exposure.

A I don't agree with that.

Q What, did you leave some out?

A You are suggesting that the list we used would answer the question.

What I am trying to tell you is that list was not intended to fully answer the question of whether or not these people could be or were suffering from PCB exposure. The listing was used as an indicator. It was used to provide us with a sense of magnitude of the problem. But it was not intended or designed to fully answer the question regarding whether these people were suffering medically from a certain chemical exposure. That list would be inadequate to do that.

Q Well, Doctor, in 1973 when you developed the list of medical conditions that you wanted your people to go out and talk to the study group about -- I take it some care went into the development of that list.

A Yes.

Q I take it the idea was to see if you could correlate certain health conditions or certain health problems with exposure to PCBs by eating Lake Michigan fish.

A Um-hum.

Q Is the answer yes?

A Yes. Yes, correlate at that point in time.

Q Now, for the list of conditions or health problems that you used, you turned to the Yusho incident in Japan, is that correct?

A That is correct.

Q Is the reason you did that because at that time it was thought that the Yusho health problems were attributable to PCB exposure?

A That is correct.

Q Did you turn to the Yusho incident for your list of health problems because at that time Yusho was thought to be the only incident in which people had been exposed to PCBs through their diet?

A I believe that would be consistent, yes.

Q I take it you did some reading on the Yusho incident back then.

A Yes.

Q If I am not mistaken, you came up with about 17 health problems that you wanted your people to specifically ask the Michigan fish eaters about, is that correct?

A We selected a list of 17. Whatever the -- 18.

Q You participated in the selection of the 18 medical conditions.

A I did, and others, yes.

Q Were these 18 health problems that you inquired about the principal health conditions reported in the literature in the early 1970s, describing the Yusho incident?

A It includes the principal ones that we reported.

Q Did you leave any principal health conditions off your list?

A We may have left some health conditions off the list, yes.

Q I am asking about the principal health problems of the Yusho victims. Did you leave any of those off the list?

A No. Let me qualify that. Yes, we did.

Q Let me make sure I understand it. You are testifying that you left off your list of health problems that you wanted your people to ask about, some of the principal health problems suffered by the Yusho victims?

A Yes.

Q Which ones did you leave off?

A It appears in examining the list here that the ones that we omitted pertained to reproduction and to children born of exposed mothers.

Q Why did you leave those off the list?

A We left them off the list because the primary aim of that study was to deal with adults. We were interested in people who were catching and eating fish, and as we enrolled our people, we found that the age group was, I believe the mean age was 45.

Q Forty-six.

A Forty-six. And there were not a number of small children involved. So that the list was tailored to address the symptoms and conditions that would pertain to adults.

Q So with respect --

A It's a matter of selecting in order to interview.

Q So with respect to adults then, the list of 18 health problems that you inquired about include the principal health problems of adult Yusho victims?

A Yes, I would agree with that, as reported

in the literature at that time.

Q We will get to that qualification later.

All right. Let's go to Finding No. 12. As a result of analyzing the information you got from your study group about these 18 health problems, one of the conclusions you reach was Finding No. 12, is that correct?

A Finding No. 12 is stated as it appears.

Q Well, that doesn't answer my question, Doctor.

A It is one of the conclusions stated for the study, considering the limitations of the study to fully document item No. 12.

Q Let me try it again. Finding No. 12 is a finding and a conclusion you reached on the basis of the medical information, the medical data you gathered in your study, is that correct?

A That is correct.

Q Now, with respect to the medical data --

A That were collected.

Q -- that you collected --

A Yes.

Q -- in the period of time 1973 to 1975,

have you changed your mind in any way about what that data showed?

A No.

Q In other words, --

A I have not.

Q Doctor, would you look at Finding No. 10 on Exhibit 4. It reads:

"Higher PCB levels were associated with those reporting a substantial history of consuming Lake Michigan fish suggesting a net accumulation of PCB in such persons over the years."

Have you changed that conclusion in any way since 1976?

A No, I have not. Except your statement pertains to blood levels.

Q Didn't I include blood?

A You omitted the word blood.

Q Okay.

A It has not changed.

Q You testified earlier that the mean age of your group that you studied was 46 years old, is that correct?

A Yes.

Q I take it in identifying the people that you wanted to interview and study you sought out those people who you thought had consumed and would consume large quantities of Lake Michigan fish.

A Yes.

Q The mean age, Doctor, of 46 suggests to me that a number of the people that you studied in this 1973 to 1976 period had a long history of consumption of Lake Michigan fish. Is that what you found?

A No. Some did and some did not. There wa a range.

Q Okay. Let's take that for a second.

A And I believe there is a table in there. We grouped them by ranges.

Q Could you identify that table, Doctor.

A Yes.

Q Referring to Exhibit 4.

A Referring to Exhibit 4, Page 43, Table 15 shows four ranges of years reported having eaten fish, and also shows the number of people in those

various time ranges.

Q If I read Table 15 correctly, Doctor, it shows that in your study group 43 individuals had a history of consuming Lake Michigan fish for ten or more years.

A That is correct.

Q I take it that Finding No. 12 applies to those people with this long period of consumption, Finding 12.

A Finding No. 12 pertains to the entire study group, and it would include these 43 people.

Q Looking again at Table 15, I take it that ten or more years working backwards from 1973 would give us a consumption period of at least 1963 to 1973 for these people, is that correct?

A That would be approximately correct.

Q Are you aware that there are many people who have estimated that PCBs have been present in Lake Michigan fish since at least the early 1960s?

A I am aware of that.

Q Is it your best scientific judgment that these people were consuming Lake Michigan fish with PCB residues during that period 1963 to 1973?

A It's my judgment that they reported they had been consuming fish during that period of time you just named. I would therefore assume if those fish contained PCB residues, that indeed would be the case. But I can't state that in fact they had been.

Q No. But is it your scientific judgment that if they had in fact been eating what they said they were eating during the period of time 1963 to 1973, that is, eating Lake Michigan fish, that they were consuming PCBs during that period of time as well?

A Yes. To some extent it's undefined.

Q Doctor, would you take a look at Exhibit 2, which is one of the drafts of the final report, Exhibit 4, and take a look at what is Paragraph 7 of Exhibit 2. Do you see that?

A Item 7?

MR. WHITE: The Summary of Findings?

BY MR. FEATHERSTONE:

Q Yes. Finding No. 7 in the Summary of Findings.

A Yes.

Q It reads:

"As a group the exposed participants had no health problems or medical conditions that could be correlated with PCB blood levels, exposure to Lake Michigan fish, or known symptoms of PCB poisoning."

Did I read that correctly, Doctor?

A You read that correctly.

Q Does that finding, Finding No. 7 in Exhibit 2, is that in any way different from Finding 12 in Exhibit 4?

A No, it is not.

Q Other than there are some additional words.

A Yes. With the caveat that I have placed on that that I have stated before.

Q Just so that I am clear, Finding No. 7 in Exhibit 2 is not intended to convey any different opinion than Finding 12 of Exhibit 4, is that correct?

A You are correct.

Q Doctor, would you turn in Exhibit 4, the final report, to the Introductory Remarks, and look

at the paragraph entitled Conclusion. The second sentence of that paragraph reads: "The dose received is insufficient to produce a detectable acute effect on human health." Do you see that?

A I see it.

Q Is that sentence meant to express any different opinion than was expressed in Finding 12 of the Summary of Findings?

A Yes.

Q How so?

A If you will couple that sentence with the one which follows, it is a more thorough explanation of the meaning of No. 12. It's part of the concept, the caveat which I have been trying to place on summary 12.

Q Let's take the sentence, the second sentence of the conclusion for a second again. "The dose received is insufficient to produce a detectable acute effect on human health."

When you use the phrase "dose," are you referring to the total dose?

A We are referring to the dose as measured by the study, which would be for a defined period

of time in the study, basically the two year span of the study. It does not refer to overall dose, lifetime dose.

Q But if I understand what you just stated, the phrase "the dose" means the total dose over that two-year period that you measured.

A That would be correct.

Q Doctor, does that sentence, the second sentence of the Conclusion apply equally to people who at the time of your study had a long history of consumption of Lake Michigan fish?

A It would apply to everybody who was in the study. So it would include that group, yes.

Q So for those people who had consumed Lake Michigan fish for the ten or more years prior to the time of your study, the dose over the ten or more year period of time was, "insufficient to produce a detectable acute effect on human health."

A I can't state that for sure.

Q With respect --

A I don't agree.

Q With respect to the health problems that

you looked for, that is true, isn't it?

A With respect to the point in time at which we made the measurements, the measurement being defined as that listing of health, and the dose that we measured for any of the people including the group you are referring to, that would then be true.

Q Well, you are not testifying --

A It does not infer history. It infers, we took a person at a point in time, measured his dose, we asked him these questions. That's what that statement pertains to.

Q Well, Doctor, can you infer from the absence of any health problems that you could detect in these people with a history of consumption of Lake Michigan fish of ten or more years that the total dose that they had received up to the time of your study had been insufficient to produce a detectable acute effect on human health?

A I would agree with that.

Q And the phrase "insufficient to produce a detectable acute effect on human health" means no health problems, as far as you could determine,

is that correct?

A That would be correct.

Q The next sentence in your Conclusion reads:

"It has not been determined whether long-term exposure to PCB contaminated fish will result in a continuing accumulation of PCBs . . . "

Let's stop there.

Have you changed that conclusion in any way since you wrote your final report?

A At this time I am more confident that the answer to that is going to be yes, that it will.

Q Is your new answer based on a re-evaluation of the data that you obtained from 1973 to 1975?

A No.

Q So let's take that first. The data that you obtained from 1973 to 1975 I take it leaves in doubt whether "long-term exposure to PCB contaminated fish will result in a continuing accumulation of PCBs."

A The statement is intended to convey that we cannot, with certainty, say that was what was happening. The data indicate that that may be happening. Two years is not sufficient span of

time to fully answer that question. Therefore, the caveat in the sentence.

Q And therefore the conclusion that you couldn't tell.

A In scientific certainty, we didn't, we couldn't tell with this data base for sure.

Q This data base being 1973 to 1975 data?

A That is correct.

Q I take it your 1973 to 1975 data base also did not permit you to determine how rapidly PCBs might accumulate in the body if they in fact do accumulate in the body.

A That would be correct.

Q Have you done any work since this 1976 study that permits you to determine how rapidly PCBs accumulate in the body?

A I have work that is in progress which is the grant that we have referred to as Exhibit --

Q Three.

A Three, which is intended to address that question.

Q Have you reached any conclusion on the basis of that work?

A I have not reached any conclusions on the basis of that work at this date.

Q Just so that I am careful in all of this. To you the words conclusions and opinions don't have any different meaning, do they?

A No. I distinguish between the two.

Q Okay. Do you have any opinions --

A Yes, I have an opinion.

Q -- as to the rate --

Well, let me get the question out, first.

A Okay.

Q It's hard to have an opinion to a question that hasn't been posed.

Do you have any opinion as to the rate of accumulation of PCBs in the human body based on any work that you have done?

A As to the rate, no, I do not have an opinion as to the rate.

Q Doctor, from the results of your 1976 study, it's true, isn't it, that you could not find any health problems that any of the people you studied would suffer in the future if they kept eating Lake Michigan fish in large quantities?

A Would you say that again.

MR. FEATHERSTONE: Would you read it back, please.

(The record was read as requested.)

BY THE WITNESS:

A You are asking me to predict the future.

BY MR. FEATHERSTONE:

Q No. I am asking you to answer the question.

MR. WHITE: If you can answer the question.

BY THE WITNESS:

A I can't answer that question as stated.

BY MR. FEATHERSTONE:

Q What is the problem with the question as stated?

A As I understand the question, you are asking me if our data that we collected at one point in time is going to predict an outcome in the future.

Q The question doesn't ask that at all, Doctor. The question asked whether you could, from your data, point to any problem that these people were going to have in the future if they kept eating

Lake Michigan fish. Health problems.

MR. WHITE: He answered the question.

MR. FEATHERSTONE: No, he didn't.

BY MR. FEATHERSTONE:

Q Doctor, from your 1976 study, could you point to any health problem that these people eating Lake Michigan fish would suffer if they continued to eat fish, Lake Michigan fish in the future?

MR. WHITE: If you can't answer, Doctor, say so.

BY THE WITNESS:

A I can't answer that question, I am sorry.

BY MR. FEATHERSTONE:

Q Doctor, state for me the health problems that you identified in 1976 that people eating Lake Michigan fish would suffer if they ate Lake Michigan fish in large quantities after 1976.

A It's included in the list. Some of those kinds of health problems are included in the list in Table 15.

MR. WHITE: No, no.

BY THE WITNESS:

A On Page 45, 45, yes.

BY MR. FEATHERSTONE:

Q Doctor, are you testifying that if the people you studied in 1976 continue to eat Lake Michigan fish in large quanities after 1976, that they would suffer one of these 18 medical conditions or medical problems you list in Table 15?

A The question uses the word "would." I can't answer that.

Q In other words, you can't say it will happen.

A I can't predict the future.

Q It was nothing in your study that would allow you to say that those people would in fact have health problems in the future.

A I don't know of any study that would tell what will happen in the future.

Q Doctor, from your 1976 study it's true, isn't it, that you could not identify a risk of any health problems if the people you studied kept eating Lake Michigan fish in large quantities after 1976?

A Did you use the word --

MR. WHITE: Read the question back, please.

(The record was read as requested.)

BY THE WITNESS:

A I don't agree with that.

BY MR. FEATHERSTONE:

Q What health problems did they run the risk of suffering if they kept eating Lake Michigan fish?

A The health problems that they would run the risk of suffering is included in the list which is Table 16, Page 45, Exhibit 4. But that is not an all-inclusive list.

Q Doctor, what data did you gather in your 1976 study that you can point to and say that shows that there is a risk that these people will suffer or may suffer health problems in the future?

A The answer to that question is Table 16. The yes responses indicate that there were people who reported certain kinds of medical conditions or problems that could be associated with PCB exposure, and that list is not all-inclusive.

Q Well, Doctor, let's for once and for all dispose of your "not all-inclusive." The fact is you didn't study anything more than these 18 health problems.

A At that point in time we inquired about those 18 health problems, that is correct.

Q So you don't know anything about health problem No. 19 and thereafter, is that correct?

A That is correct. This data does not reflect that.

Q Well, Doctor, I took a look at your Table 16 and some of the other information you have in there, and one of the things I found rather interesting was that for at least 11 of the health conditions that you asked about the people who responded yes had lower -- had higher PCB levels than the people who responded no. How do you explain that?

A For 11 of the conditions the people who said yes, I have this condition, had higher PCB --

Q I am sorry. Strike that. It's the other way around.

MR. WHITE: Why don't you rephrase the

question?

BY MR. FEATHERSTONE:

Q Doctor, I took a look at Table 16 and some of your supporting data, and from that found that the people responding yes to 11 of the health conditions you asked about had lower PCB levels than the people who responded no. How do you explain that?

A I explain it on the basis that that is what they reported, and that this listing of conditions obviously occurs in those with and without exposure to fish.

Q Did that help you in your conclusion in any way about whether the consumption of fish results in a risk of those 11 health problems?

A It doesn't help, in that it complicates estimate of that risk.

Q It complicates it because it doesn't correlate to it, isn't that right?

A It complicates it because it is not clearcut.

Q Well, answer my question. It doesn't correlate to it either, does it?

A Doesn't correlate to -- The yesses and noes don't correlate to?

Q The consumption of fish.

A To the consumption of fish.

Q With PCBs.

A That is correct.

Q It's one of your jobs at the Michigan Department Department of Public Health to assess important health risks to the citizens of the State of Michigan?

A That's one of the functions of my work. Although, going through the mathematics of actually calculating these risk estimates is not a specific part of my job. I have other people on the staff that do that.

Q I didn't want to get into it that deeply. All I wanted to do is make sure in my own mind that one of your jobs is to look out for the health of the people of the State of Michigan.

A Yes.

Q That includes the people who eat Lake Michigan fish.

A Correct.

Q As a result of this 1976 report, did you make any recommendations to the Michigan Department of Public Health to do any followup work with these people?

A Yes.

Q What happened to that recommendation?

A The end product of that recommendation is the grant which we are now conducting.

Q That is Exhibit 3?

A Exhibit 3.

Q When did you quit collecting data or following these people who were the subject of your 1976 report?

A It would be 1975, I believe. I believe the last data collections were 1975.

Q When did you start following these people again in your project, which is summarized in Exhibit 3?

A That began in 1979.

Q So there was roughly a four-year period of time after you stopped following them for purposes of the first report and until you began following them again in your report or study which

is now Exhibit 3.

A That is correct.

Q In that four-year period of time, 1975 to 1979, did you learn of any health problems of the people you studied back in 1976 that you can attribute to PCBs?

A No.

Q I take it, Doctor, that if you had felt there was a serious risk of harm to these people from eating Lake Michigan fish, that you would have followed their health progress continuously since 1975.

A Not necessarily. I don't agree with that fully.

Q Just so that I am clear, if it had been your conclusion as a result of your 1976 study that these people eating Lake Michigan fish were running a serious risk of health problems, is it your testimony that you would not have followed them continuously since 1976?

A That is correct.

Q When I say "you," you understand that I am referring to yourself personally and the

people working with you?

A Well, your question is not thorough enough, because you are narrowing something to a specific set of words.

Q Well, I am asking you --

A You are making an inference in that question which I don't think accurately reflects the situation.

Q You mean my question about "you"?

A No. You are inferring that is the only thing we could do if we had serious concern.

Q Well, all right.

A There is a variety of actions.

Q You are talking about following these people, is that right? Is that what you are talking about?

MR. WHITE: You are talking about that.

MR. FEATHERSTONE: I want to make sure he is talking about it, too.

BY THE WITNESS:

A No. Your question as stated infers that if we had serious concern about this situation, we would be taking a singular action, following these

people. I am saying that's one of several options.

BY MR. FEATHERSTONE:

Q But you didn't do it?

A No, we did not follow the people between 19 -- when this study ceased and our current study resumed, that is correct.

Q Doctor, do you follow the literature concerning environmental exposure to PCBs?

A I try to, as best I can, yes.

Q Are you aware of any other published report concerning exposure to PCBs by consumption of fish with PCBs? I am talking about human exposure now.

A I am not aware of other investigations of that nature.

Q So insofar as you know, your 1976 report is the only report that discusses PCBs in humans as a result of consumption of fish?

A I believe -- I agree with that.

Q Do you have Exhibit 4 in front of you, Doctor?

A Yes.

Q Take a look at Page 1, which is entitled, Introduction. The first sentence of the second

paragraph reads: "The human health effects from PCB exposure, especially long-term low level exposure, are not clearly understood." Do you see that?

A I see that.

Q Long-term low level exposure as you use the words there, Doctor, would include exposure to PCBs through the consumption of fish with PCBs.

A That is correct.

Q The sentence which I have read to you, does that still state your opinion?

A Yes.

Q Doctor, later in that paragraph you refer to the Yusho incident. Is that correct?

A Correct.

Q The last sentence of that paragraph reads:

"Although reports on the toxic symptoms observed with Yusho have generally been accepted as attributable to PCB poisoning, the suspected existence of other toxic contaminants in Japanese PCB preparations has raised questions on the cause of some of these observed effects."

I take it that states your opinion of what the literature on Yusho showed as of 1976.

A Yes.

Q In that sentence you referred to "the suspected existence" of other toxic contaminants. Doctor, have you followed the literature on Yusho since 1976?

A Yes, I have.

Q Are you aware that the literature today has removed all doubt about "the suspected existence" of other contaminants in the Yusho oil?

A I am aware of that.

Q You are aware of a variety of other contaminants that have been identified as being present in that Yusho oil.

A I am aware of that.

Q In large quantities as well.

A Yes.

Q At the time that you did your 1976 report, which is Exhibit 4, I take it it was your assumption that the reported PCB levels in the Yusho incident were the cause of the reported health problems of the Yusho victims.

A No, I don't agree with that.

Q Well, Doctor, what did you mean in 1976 when you wrote the first part of that sentence, "Although reports on the toxic symptoms observed with Yusho have generally been accepted as attributable to PCB poisoning."

A That is why I hesitated on your question, "generally accepted." Which conveys not total certainty. I interpret your question as certainty.

Q But for purposes of the calculations that you do later on in your 1976 report, and which I will get to later, you assumed that the symptoms were caused by the PCBs.

A No, I did not. I postulated.

Q By that you mean if these symptoms were in fact caused by PCBs, they were caused by this level of ingestion of PCBs, is that correct?

A No. Almost. Not exactly.

If PCB causes certain symptoms -- If people who are exposed to PCBs are suffering these symptoms, they may be the result of that exposure. So the hypothesis then is that indeed that is a

fact, and you try to test it. There is a difference.

MR. FEATHERSTONE: Do you want to break for lunch now?

MR. WHITE: The day is yours.

(Whereupon, the deposition was recessed until 1:15 this date, August 12, 1981.)

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE UNITED STATES OF AMERICA,	)	
Plaintiff,	)	
-vs-	)	No. 78 C 1004
OUTBOARD MARINE CORPORATION and MONSANTO COMPANY,	)	
Defendants.	)	

The deposition of Harold E. B. Humphrey resumed pursuant to recess, at the U.S. Attorney's office, 219 South Dearborn Street, 15th Floor Conference Room, Chicago, Illinois 60604, on the 12th day of August, A.D. 1981, commencing at 1:15 p.m.

PRESENT:

MR. JAMES P. WHITE,

appeared on behalf of the United States of America;

MS. ROSEANN OLIVER and MS. CAROL DORGE,

appeared on behalf of Outboard Marine Corporation;

MR. BRUCE A FEATHERSTONE,

appeared on behalf of Monsanto Company.

MR. FEATHERSTONE: Would you mark this as Exhibit 5.

(Said document was marked Humphrey Deposition Exhibit No. 5 for identification as of 8/12/81, JKS.)

HAROLD E. B. HUMPHREY,

called as a witness herein, having been previously duly sworn, and having testified, was examined and testified further as follows:

DIRECT EXAMINATION (RESUMED)

BY MR. FEATHERSTONE:

Q Doctor, you have in front of you Exhibit 2 and Exhibit 4 to your deposition?

A Yes.

Q Would you look at the Conclusion portion of the Summary that appears at the beginning of each exhibit.

A Okay.

Q Looking first at Exhibit 2, the last sentence of the Conclusion. Would you read that, please, to yourself.

A Okay.

Q Doctor, am I right that that sentence does

not appear in the conclusion portion of the Summary that is in Exhibit 4?

A That is correct.

Q Why is that?

A I can't -- I have to try to recall. I can't give you an exact answer. I believe the revision of the summary is, between the draft and what's the final, constitute revisions that were suggested by my Department, the director or one of the officials of my Department. As best I can recall with respect to this conclusion referring to a limitation of eating of fish, they felt that was a decision to be made by Michigan, and didn't need to be included in this report. That is my reconstruction of why it was deleted in the report.

In fact, that's exactly what was done. The fish warning was continued, has been.

Q Well, the missing sentence we are talking about reads:

"The data also justify a continued recommendation that intake of Lake Michigan salmon and lake trout be limited to less than one meal per week or 24 pounds per year."

A Right.

Q So the data is more specific than data for -- Strike that.

The restriction that you referred to just a minute ago is more limited than just a restriction on the consumption of Lake Michigan fish. It's limited to particular species of Lake Michigan fish, isn't that right?

A Which one are we talking -- Are you talking about the one that is in existence?

Q No. I am talking about the recommendation that you set forth in the last sentence of the paragraph entitled Conclusion in Exhibit 2.

A That sentence refers to lake trout and salmon.

Q Okay.

A Yes, it does.

Q Is it your testimony that people senior to you in your Department decided to strike that sentence from the final report, or the final draft?

A I am saying that that sentence was stricken in the final draft. I frankly don't remember exactly who did it, but -- I am sure it was during the

revising and the draft review by the Department. These were --

Q When you say "the Department," what are you talking about?

A The Department of Public Health, Michigan.

Q So the decision to make that excision from the document was made by your Department?

A Yes. To my recollection that's the source of the removal of that sentence, yes.

Q Doctor, would you look at Page 3 of Exhibit 4. Do you have that in front of you?

A Yes.

Q Doctor, do you have any expertise in analytical chemistry?

A I have a familiarity with it, but that's not my -- it's not my discipline.

Q Well, part of this project, this 1976 project, was the development of an analytical technique for the measurement of PCBs in blood, is that correct?

A Yes.

Q Were you involved in that?

A Not directly, no. Under my supervision

was the man who heads up the analytical laboratory, and it was he and his laboratory colleagues who developed the technique, the analytical technique.

Q I take it you followed the progress that they made.

A Yes.

Q And you certainly reviewed the steps they took and the errors they made along the way.

A Certainly the steps they took. Are you implying they made errors?

Q No. Correct me if I am wrong, but the portion of this 1976 report describing the development of the analytical technique that is attached to the back of the report suggests that there was a trial and error process that went on in developing that technique.

A That is true.

Q And all I am asking is, you followed that development.

A Yes, I did. And what I am telling you, I was not a principal in doing that work; others were.

Q Have you followed developments in

analytical chemistry enough to be familiar with the general developments in the field?

A Yes.

Q And in particular the developments in the analytical ability to identify PCBs?

A Yes, in general.

Q Doctor, would you look to the bottom of Page 3. There is a sentence which reads:

"PCBs were first detected in Great Lakes fish in 1969 when substances interfering with the analysis of DDT in Coho salmon samples were determined to be PCB."

A That is true.

Q I take it that statement reflected your opinion and conclusion in 1976.

A It was a review of a piece of literature that addressed that. It's cited there as reference No. 3. That is the source of that.

Q Well, have you learned of anything since 1976 that leads you to believe that PCBs were detected in Great Lakes fish before 1969?

A Not specifically. But I don't really --

I have not really been following into the history background.

Q But insofar as you know, the first identification of PCBs in Great Lakes fish occurred in 1969?

A I would prefer to restate that. During the 1960s. I was citing a specific reference and established that date. I do not know precisely when the first PCB was discovered in Lake Michigan fish. I don't know the date of that. It could be looked up. I don't have it at hand.

Q But the earliest one you have at hand is 1969.

A That is certainly the one that I have at hand. That has been referenced, correct.

Q Doctor, would you agree that the analytical techniques for identifying PCBs in samples are tricky?

A Yes, I would.

Q If I read this description of the efforts that your group went through to develop an analytical technique for PCBs in blood, I take it you would agree that it's a very complex

thing.

A Yes, I would agree.

Q Doctor, would you turn to Page 12.

MR. WHITE: Exhibit 4?

BY MR. FEATHERSTONE:

Q Yes. Exhibit 4.

A Which is Table 3?

Q Yes.

Why is it that in the study that was conducted in 1974 and 1975 you did not use fish eaters located near South Haven?

A The answer to that lies in the same reason we did not use fish eaters located in Algonac.

Those two communities, the cohorts there, were subjects of an earlier -- were actually comparison subjects for an earlier study, which was investigating the contamination of fish with mercury, over in Lake St. Clair. Algonac was a community on that lake.

South Haven served as comparison with respect to being people who ate fish from an area that did not have mercury.

When this PCB study was initiated, we

were just wrapping up the mercury study, and so we included in 1973 the South Haven and Algonac people for comparison purposes. But we did not revisit them the following year because we had used them in the previous study, and we elected to go with the group from Manistee, Ludington and Traverse City, who had been recruited specifically for this. So it was an administrative decision.

Q If I have my geography correct, South Haven is the southernmost of the cities of Traverse City, Manistee, Ludington and South Haven.

A That is correct. There is a map in here on Page 9 that shows that.

Q In your report you also state that the type of species of fish consumed by fisherman in South Haven tend to be perch and chubs rather than lake trout and Coho salmon, am I right?

A As I recall, that statement is in there, yes.

Q Did the fact that people in the South Haven area catch and consume different types of Lake Michigan fish than people in Traverse City, Manistee and Ludington play any role in your

decision to drop South Haven from the study?

A Possibly, to a small effect, to a small amount.

As I stated a moment ago, they had originally been components of an earlier study, and we wanted to continue the study with people who had been recruited specifically.

We also felt that the information gained from the South Haven and Algonac people had sufficed to make the point we wished to make, as shown on Table 3, during 1973. Our election to go forward into 1974-75 with more intensive evaluations, as I reported in this study, we elected to go with the Ludington, Manistee and Traverse City people. And the fact that they were eating the predator species of fish more intensely than these particular South Haven people was also possibly a factor, because we were interested in following people who were consuming the predator species.

Q Is it fair to state, Doctor, that the bulk of your conclusions about PCB blood levels and changes in the PCB levels in the blood are

largely based on the data you obtained from fish eaters located in Traverse City, Manistee and Ludington?

A Well, what was the tail end, the tail end of his question?

MR. WHITE: Would you read the quetion again, please.

(The record was read as requested.)

BY THE WITNESS:

A Yes, I agree with that.

BY MR. FEATHERSTONE:

Q If I get the gist of your report, certainly one element that plays an important role in determining the exposure to an individual eating fish with PCB in it would be the species of fish consumed.

A Yes.

Q It is also your knowledge, Doctor, isn't it, that predator species of fish like trout and salmon tend to accumulate higher levels of PCB than fish like perch and chubs?

A I have seen that reported, yes, I agree.

Q Would you expect from that difference,

Doctor, to find that for a group of fish eaters consuming the same amount of fish, in terms of pounds, out of Lake Michigan, that fish eaters consuming perch and chubs would have lower levels of PCBs in their blood than fish eaters consuming trout and Coho salmon?

A I don't agree with it exactly how you have stated it.

Q Am I close?

A You are close.

Q Okay. What change would you make?

A You said something about would reflect -- Would you reread it, I will pick it out.

(The record was read as requested.)

BY THE WITNESS:

A Okay. The lower levels in their blood. I would agree with you that I would expect that they would have lower consumption doses of PCB. But I can't say for sure that they have lower levels in the blood.

BY MR. FEATHERSTONE:

Q When you say you can't say for sure, do

you mean you can't say one way or the other?

A I can't predict what the person's blood level will be unless, you know, all -- What I am trying to infer is the perch species have less PCB than the trout species. Therefore, if all you eat is perch, then I would say you **probably** are going to, pound for pound, going to receive less PCBs than you do if you eat lake trout. Most people blend. They are not exclusively one or the other. That confuses it. So then to extend that statement and say this guy's blood level will be correspondingly lower, I can't say that for sure.

Q Let me try a series of questions, and bear with me.

A Okay.

Q Assume, Doctor, that a group of fish eaters located around South Haven consume, vast majority, perch and chubs.

A Okay.

Q Assume for the other three cities, Traverse City, Manistee and Ludington, that the fish eaters in those areas consume, the vast

majority, trout and salmon, the predator species. Okay?

A Um-hum.

Q You have to answer audibly.

A Yes.

Q I take it you would expect to find under those assumptions, and assuming that the people in South Haven and the people in the other cities eat the same amount of fish, you would expect to find the PCB levels in the people in and around South Haven lower than the PCB levels in the blood of the people located in and around Traverse City, Manistee and Ludington.

A In your hypothetical case, yes, assuming all other things are equal.

Q By "other things -- "

A Occupation, for example.

Q -- you are referring to PCB exposure in other ways other than eating fish.

A Yes. Because you have capacitor company workers in South Haven. That could greatly influence their blood level.

Q Let me change the assumptions a little

bit.

Assume that the fish eaters in and around South Haven consume perch and chubs to the extent of 60 to 70 percent of their diet. The balance, mixture of fish, okay? You have to answer audibly, Doctor.

A Yes.

Q Assume that the fish eaters in the Traverse City, Manistee and Ludington area consume lake trout and salmon to 60 to 70 percent of their diet, of their fish diet, okay?

A Okay.

Q And assume the balance for those people a mixture of fish as well.

Further assume that the people in -- the fish eaters in South Haven consume the same poundage of fish, or roughly the same poundage of fish as the people in the Ludington, Manistee and Traverse City area, okay?

A Okay.

Q Under those assumptions would you expect to find the PCB levels in the blood of the people in South Haven lower than the PCB levels in the

blood of the people catching and eating fish in Traverse City, Manistee and Ludington?

A That's a long question.

Q Did you follow it?

A Yes.

Your hypothesis is that people in one community have 60 percent?

Q My hypothesis basically is, Doctor, that in one community people are eating, in the main, fish with a lower level of PCBs than fish eaters in another community.

A Okay.

Q The question is, again, that would you expect the people eating the perch and chubs in the main in South Haven to have lower PCB levels in their blood than fish eaters located in Traverse City, Manistee and Ludington?

A I would expect the contribution of PCBs in their blood to be less in the community where they are eating the fish with the lower amounts.

Q In my example in South Haven.

A Yes.

Q When you say contribution, you mean the

PCBs that are attributable to the ingestion of fish, or consumption of fish.

A Yes.

Q So if we assume that the PCB exposure is only through the consumption of fish, with that additional assumption you would expect to find the PCB levels in the blood of the people of South Haven lower than the PCB levels in the blood of the fish eaters in Manistee, Traverse City and Ludington?

A Under those assumptions in these hypothetical situations, yes, assuming one thing that hasn't been stated. And that is that these fish are all falling in the stated ranged of PCB contamination. Your assumptions have not covered --

Q When you say stated ranges, you mean the levels as shown in your 1976 report?

A The averages that are shown in the 1976 report. All those averages have ranges.

For example, we have seen lake trout that are not very highly contaminated, and we have seen lake trout that are highly contaminated. The same is true for the pan fish. Not every perch

obtained in South Haven is going to be at the median level of PCB. Some are higher, some are lower. Those are all ranges.

So one of the assumptions that must be placed in your hypothetical situation is that we are assuming these trends or these relationships on the basis that the fish are static, that they are at certain levels.

Q Well, wouldn't your answer be the same, Doctor, if we assumed that the PCB levels in the various species moved up and down, but maintained the same relative proportion?

A Yes.

Q So for instance, if we had declining PCB levels, but in perch the level, the new level, the new lower level was the same proportion to the new lower level for trout as existed in the older -- in the higher levels, your answers would be the same?

A Yes.

Q Doctor, would you look at Appendix A for a second, to your Exhibit 4. It's on Page 60.

A Yes.

MR. FEATHERSTONE: Off the record.

(Discussion had off the record.)

BY MR. FEATHERSTONE:

Q Appendix A sets out the PCB levels in the blood of the specimens you collected.

A Yes.

Q In doing the blood analysis for PCBs, I take it the analytical chemist was to determine total PCB levels, is that right?

A Yes, that is correct.

Q I notice that the total PCB levels are made up in each case of PCB 1254 and PCB 1260, is that right?

A That is correct.

Q Is it also accurate that wherever you use the word PCB, the acronym PCB in discussing your results and your data, you are referring to either PCB 1254 or PCB 1260?

A No. I am referring to total PCB.

Q Total PCB in the blood.

A Yes.

Q Which, since I am pretty sure I did my math correctly, was made up of either 1254 or 1260.

A The way you stated it, no.

Q All right.

A Do we need an explanation?

Q I think so.

MR. WHITE: Would you explain it.

BY THE WITNESS:

A As you stated and I agreed earlier, PCB analyses are tricky, from an analytical and chemical sense. PCB is a mixture. To imply our subjects had only 1254 and 1260 in their blood is wrong. The convention selected for determining PCB levels chose to measure total PCB as defined by adding the collection of mixture peaks under 1254 and under 1260. This ignores the detailed evaluation of other PCBs that might be present in the blood.

That is why I have trouble when you ask me to agree that 1254 and 1260 are the sole PCBs in the blood of these people.

BY MR. FEATHERSTONE:

Q I will rephrase the question.

A Our convention was total PCB as defined by measuring peaks, summating the peaks under

1254 and 1260.

Q Did your people look for PCB 1242 or PCB 1248 or any other PCB other than 1254 or 1260?

A No, they did not specifically.

Q Were they instructed not to look for those PCBs?

A No, they were not instructed not to look for the others.

Q Were they instructed to look only for PCB 1254 or 1260?

A No, they were not instructed only to look at 1254 or 1260.

Q So if one of your analytical chemists found 1242 or 1248, he could have reported it back to you.

A He could have done so.

Q Did any of them?

A They did not evaluate the data in that manner, so it wasn't done.

Q Who decided to look only for 1254 or 1260 -- strike that.

Who decided --

Would you read back his answer, please.

(The record was read as requested.)

BY MR. FEATHERSTONE:

Q When you say they did not evaluate the data in that manner, what do you mean by that?

A In the report is a section which discusses the analytical techniques, or the analytical work. The instructions to the chemical laboratory were to choose an analytical procedure. That was their specific instruction. Irrespective of any of the specific aroclore , our interest was to measure total PCBs.

As I tried to explain a few moments ago, there are several conventions by which you can arrive at the total. The convention that was chosen is described in here. It was primarily a combination of choosing a technique that was expeditious insofar as laboratory turn-around time and techniques that could be repeated and were accurate.

Q When you say accurate, I take it you do not mean to imply that your analytical chemists mis-identified which PCBs were in the blood?

A No, I do not mean to infer that they mis-identified.

What I do mean to infer is when you choose a convention that we are going to judge PCB on the measure of measuring all the collection of peaks defined as 1254, and all the collection of peaks identified as 1260, by choosing that convention, you necessarily ignore some of the precision that might pluck out the 1248 component or the other components. Because when you choose this convention, this array of peaks, some of those peaks are 1242 peaks, but you are not quantitating them as 1242.

Q Were you involved --

A We have a problem here, because this is a very complicated analytical procedure.

Q Well, were you involved in the decision to use the convention, as you used the term, of using PCB 1254 and PCB 1264 for the purposes of identifying the PCBs in the blood?

A Not specifically, because the assignment was given to the chemists, and they experiment with different techniques, and they came up with

a recommended technique, and I agreed that was the one to go with.

Q Was it your understanding from the technique that they recommended, that the reason they recommended using PCB 1254 and PCB 1260 as the convention for identifying the PCBs in the blood, was because the blood was made up, to the extent it had PCBs, they were PCBs 1254 and 1260?

A No. I think the real reason behind that was that 1254 is commonly reported in fish. If you are receiving an exposure from fish, you would naturally want to look for that. Or, to restate it, 1254 is apparently the more common PCB that is found in the fish. So that did establish a background as to a starting point.

Q Well, what I am driving at, Doctor, is you don't mean to suggest that if there had been significant quantities of PCB 1242 or 1248 in the blood that the analytical chemists would have chosen a convention for identifying the PCB that would have resulted in an improper identification of 1242 and 1248 as 1254 and 1260?

A No, I don't mean to infer that. I think --

the analytical technique workup was accomplished before the blood collections from the people were done. So that we -- I think you were inferring that we knew what would be in the blood, so we chose that technique.

Q Not at all, Doctor. What I am asking is -- Let me ask it this way, because I don't mean to, at this stage, anyway, cast any aspersions.

A Okay.

Q My question is simply this: I take it the fact that your Appendix A does not report levels of PCB 1242 and 1248 in the blood means that there were not significant quantities of those two PCBs in the blood that you took as specimens for analysis.

A I'd agree with that.

Q To take it one step further, I take it that since the levels of those particular PCBs, I am referring to 1242 and 1248, were not significant, it was not thought to be important from the point of view of evaluating -- or point of view of conducting this project to break out those PCBs if they were in fact in the blood.

A Yes, I agree with that.

Q Doctor, are you familiar with the reports that show that PCBs with five or fewer chlorine atoms in a molecule are metabolized by humans?

A Five or fewer?

Q Yes.

A Yes.

Q Are you aware that many people in the scientific community have expressed the opinion that PCBs with five or fewer chlorine atoms per molecule are relatively readily metabolized by humans?

A Could you rephrase the question. I am having trouble with your reference to humans.

Q Well, let me try it this way. Do you agree with this statement:

"The tissues from animals and man containing PCBs from environmental exposure have patterns resembling those of PCB mixtures with more than 50 percent chlorination."

Let's stop there. Do you understand that to mean generally the patterns are 1254 or above?

A Um-hum.

Q You have to say yes.

A Yes.

Q Continuing with the statement:

"This observation has led to the general belief that the less chlorinated components are more readily metabolized."

Do you agree with that statement?

A Yes, I do.

Q When that statement uses the phrase, "less chlorinated components," do you understand that to mean aroclor or PCB 1242 and 1248 and others that are lower?

A No, I don't necessarily, because these are mixtures. And PCB 1242 will have as a component of the mixture highly chlorinated forms.

Q But very few.

A Less, yes, a smaller quantity, a smaller percentage of the total. That in fact 1242 tends to be, the greater percentage is 40 percent chlorination.

Q Which are readily metabolized, is that right?

A And the lower the chlorination, and I don't know the cutoff point, the lower the chlorination,

the more readily these materials are metabolized. Earlier you stated something about a penta.

Q I didn't say anything about a penta. But let me go on to the next question.

A I interpreted one of your things, the question to refer to the five chlorine atoms, which would be penta.

MR. WHITE: Yes.

BY THE WITNESS:

A The point is yes, the lower chlorinated forms are more readily metabolized. The higher chlorinated forms are more readily stored. I can't tell you exactly what the cutoff point is.

BY MR. FEATHERSTONE:

Q Doctor, would you agree that the fact that the blood specimens which you found in this 1976 study had insignificant levels of PCB 1242 and 1248 suggests that those PCBs are metabolized?

A No, I don't agree with that.

Q How do you explain the absence, Doctor?

A They may not have been exposed to those PCBs.

Again, I have to repeat, though, because

the data in the report is reported as 1254 plus 1260 equalling total, does not infer that 1242 or 1248 or any other aroclor is absent. It merely infers that there was a convention selected for quantitating total PCB, and that method identified PCB present as 1254 and 1260 and summated them.

Q We continue to battle about this, Doctor. But the fact is that, as you admitted, that the convention was hopefully as accurate as you could get it.

A That's right. That is true.

Q I don't want to debate that point anymore.

Doctor, in your report you used the phrase body burden.

A Yes.

Q First of all, by the phrase body burden, you don't mean to suggest any health problems, do you?

A Body burden is a term that is used to express quantity of a contaminant in an organism.

Q Could you answer my question, please, Doctor.

MR. WHITE: Read back the question.

THE WITNESS: I am sorry.

(The record was read as requested.)

BY THE WITNESS:

A No.

BY MR. FEATHERSTONE:

Q Doctor, the PCB levels in the blood you measured, do those measurements permit you to determine the body burden of PCBs?

A No, not by themselves.

Q I take it by that you mean that you would need to know or take measurements of the PCB levels in adipose tissue, for instance?

A Yes. What I mean by that response was they can be used to estimate. But if you want to know precisely, you have to take other tissue specimens and test them, yes.

Q You did not do that, is that correct, in your 1976 study?

A I did not do what?

Q Test adipose tissue or these other specimens that you would have to take in order to

determine body burden?

A We did not test adipose. We did test a breast milk, and we were able to estimate body burdens on the basis of blood values, but we could not state the exact body burden.

Q Doctor, were you able to determine -- Strike that. We will get to that in a minute.

You stated that you took a sample of breast milk.

A Yes.

Q You took one, is that correct?

A That is correct.

Q Do you consider that a statistically significant sampling?

A No, I don't.

Q I take it you don't mean to suggest that you were able to estimate body burden by comparing the blood level of that women with the PCB levels in her milk.

A No, I do not.

Q Doctor, do you have any idea how high the PCB levels in human blood must be before that individual experiences some health problems?

A No, I don't, exactly. But I do have references from the literature which can give some approximations, and those are stated in the report.

Q Where are they? You are looking at Exhibit 4, first of all?

A I am looking at Exhibit 4 at Page 35, where, for example, in the third paragraph on Page 35 of Exhibit 4 we talk about maximum allowable ingestion. I am referencing Reference No. 8, which as I recall is an FDA document, yes, from the Federal Register. We talk there about estimates as to what are representative maximum allowable doses. As the paragraph continues, there are further discussions specific to your question.

Q Doctor, my question specifically is at what level of PCB in the blood will a human experience health problems?

A I can't answer that. I don't know.

Q Doctor, at what level of PCB in adipose tissue will a human experience health problems?

A I can't answer that, either. I don't know.

Q Doctor, would you please turn to Page 25

of Exhibit 4. At the end of the first full paragraph on Page 25 this sentence appears:

"It appears that an additional exposure through consumption of contaminated fish, even in small amounts, contributes to the existing body burden of PCB in humans."

Do you see that sentence?

A Yes, I do.

Q Doctor, I take it you were making that statement only on the basis of the PCB levels in the blood that you measured?

A That is correct.

Q You testified earlier that the PCB levels in the blood are at best an estimate of body burden.

A That is correct.

Q Doctor, would you turn to the Summary of Findings at the beginning, and keep your hand also on Page 25, so you can find that. Would you look at Finding No. 7.

A Okay.

Q It reads:

"The level of PCB found in the blood of participants did not change significantly from

year to year, nor did it diminish significantly when fish consumption was eliminated for up to nine months."

Have you changed that finding in any way since 1976?

A Yes, I believe we have.

Q Well, the change that you believe you have made, is that on the basis of a re-evaluation of the data?

A No.

Q So I take it any change that you would want to make to Finding No. 7 in Exhibit 4 is based on information you have obtained since 1976?

A Yes.

Q So let me take this as the first question. I take it Finding No. 7 still states your opinion as to what your data taken in the 1973 to 1975 period establishes?

A Yes, it does.

Q Now, the information that you have that leads you to believe that perhaps that is not an accurate statement on the whole, outside of your project -- First of all, is this a correct

interpretation of your answer?

A I am sorry.

Would you read what he just said back.

(The record was read as requested.)

BY MR. FEATHERSTONE:

Q I will start over again. You testified you have received some information since 1976 that leads you to believe that Finding No. 7 taken outside the confines of the 1976 report and study would lead you to change that finding, is that correct?

A Yes.

Q How would you like to change that finding?

A Okay. The finding No. 7 states: "did not change significantly from year to year." The data that I am thinking of is the data that is evolving out of the current investigation, which my opinion is going to show that there is a gradual increase over time.

This statement No. 7 infers that from year to year there is no change. Although there is a statement farther on that implies that there

is relationship between exposure and PCB levels -- No. 7 -- No. 7 states that there is no change from year to year. I believe the data we are accumulating is probably going to indicate that there is change over time. So that's why I answered your question in that manner.

Q I asked you earlier about whether you were ready to express any conclusions with respect to the data you are presently gathering in your present project for the Federal Government. Do you remember that?

A Yes. And I said no.

Q I take it you are unwilling to state a conclusion that your data shows PCB levels increase.

A At this time, sitting here this hour, no, I am not ready to state a conclusion. I was giving you my impression. I believe your question was framed, do you have any reason to believe that Item No. 7 is going to change. And I tried to indicate to you yes, I think it will.

Q Doctor, are you aware of -- I will get to that in a minute. Strike that.

First of all, in the context of your

1976 report and findings, how do you reconcile the Finding No. 7 in which you state, in essence, that the PCB levels in the blood of the fish eaters does not change from year to year with the statement on Page 25 that reads: "It appears that an additional exposure to consumption of contaminated fish, even in small amounts, contributes to the existing body burden of PCB in humans"?

A Item No. 7 is a summary of one of the hypotheses which we were trying to test. The hypothesis was that the PCB levels are going to change from year to year. Actually, that they are going to fall off on the off-season, when they are not eating fish.

That, in fact, was not borne out by the data. The data, though, however, does show a definite correlation between time of having been exposed to the Great Lakes fish and quantity of fish eaten with PCB levels.

Therefore, in the text, the statement, which is an opinion, that length of exposure or extent of exposure is going to contribute to body burdens, as measured by blood levels.

Q Well, Doctor, first of all, you are not suggesting that Finding No. 7 in Exhibit 4 is a hypothesis.

A No, I am not.

Q It is a finding.

A That is correct.

Q Now, turn to Page 26. Do you see in the middle of the page, beginning, "No annual variation..."

A Yes.

Q The first two sentences:

"No annual variation in PCB levels in humans could be demonstrated. The mean PCB values for the control and exposed groups did not appear to change markedly from year to year..."

A That is correct.

Q I take it that is a conclusion based on the data you gathered.

A And that's --

Q Am I right?

A Yes.

Q Now, I take it that also means that looking at the exposed participants, as you described them,

those are the fish eaters.

A Yes.

Q People that you studied who consumed large amounts of fish in 1973, in 1974 and 1975, had the same PCB levels in their blood, is that right?

A Their blood levels as groups were not statistically significantly different.

Q Which means that you didn't find statistically significant increase or decrease in those levels.

A That is correct.

Q Which further means that you could not conclude from your data that the PCB levels changed from year to year.

A One year to the next.

Q Right.

A We could not conclude there was a significant change from one year to the next.

Q Now, how do you reconcile that conclusion with your broader statement that additional exposure through consumption of contaminated fish, to use your words, even in small amounts, to use

your words, contributes to the existing body burden of PCBs in humans?

A All right. That takes into consideration the fact that the exposed group had higher levels than the intermediate or the comparison group, and it didn't matter which year you looked at. There was a consistent pattern that those who were labeled as exposed had higher levels than those labeled as having lesser exposure.

That also takes into consideration the fact that we found, when we looked at people who had no fish exposure versus those who had just a very small amount, that there was a significant difference in PCB levels, which is Table 9. And that takes into consideration the fact that when you look at the table that appears back here further, which is Table 15, where the people are arrayed by length of time of eating Great Lakes fish, there is a relationship with PCB. That is what contributes to the statement on Page 25 that you are referring to.

Q The statement on Page 25 where you say, "additional exposure through consumption of

contaminated fish, even in small amounts, contributes to the existing body burden. . ." I take it by "contributes to the existing body burden" you mean increases it?

A Yes.

Q Which means higher PCB levels.

A Yes.

Q But isn't it a fact that when you look at your data for the people who eat a lot of Great Lakes fish, what you found was that the additional consumption did not increase PCB levels in the blood, and that's why --

A I don't agree with that.

Q -- you make the statement that the mean PCB values for the control and exposed groups did not appear to change markedly from year to year.

A I don't agree with that.

Q Well, let me try it this way, Doctor. You will agree that the mean PCB levels in your exposed groups did not statistically change -- Strike that.

You will agree that the mean PCB levels in the blood of your exposed group did not change

in any statistically significant way from year to year during the years of your study.

A That is correct.

Q What that means is that any increase that there was during that period of time you could not attribute to consumption of Great Lakes fish, with any degree of confidence.

A No, I am not agreeing with that.

Q Well, Doctor, you run a statistical test to data in order to determine your level of confidence, don't you, that the results are explained by a particular variable, am I right?

A Yes.

Q In this case the particular variable is PCB, is that right?

A Yes.

Q The particular variable is the consumption of Great Lakes fish, isn't it?

A Yes.

Q The thing you are trying to explain are the PCB levels in the blood, isn't that right?

A Yes.

Q When you determine that the PCB levels

in the blood do not change in any statistically significant way --

A For the group.

Q -- for the group you are studying --

A Average for the group.

Q -- with an increased consumption of Great Lakes fish, where does that lead you?

A I don't agree with the last few words. Increased consumption implies that they increased their intake of fish to greater quantity, and there was no change. That is not what the data says.

Q What the data says is if you take one of your fish eaters --

A A single person.

Q No, no. Let's start over again. Let's take your group of exposed persons.

A Okay.

Q Those are the people who eat fish, Lake Michigan fish in large quantities, right?

A Yes.

Q Now, what you found was if you took that group and measured the PCB levels in the blood on year one, year 1973 or 1974, that PCB levels did

not change with the consumption in the following years of your study, is that right?

A That is where I am having trouble.

Q Yes?

A The consumption may have changed in the following years, and that's why I don't agree when you imply that the consumption was rising, but the blood levels weren't.

Q Go back to Finding No. 7. We will be here forever. I am going to get to the bottom of this.

Finding No. 7 reads: "The level of PCB found in the blood of participants . . ." Stop there. The word "participants," who are we talking about?

A The study group.

Q The exposed group?

A Participants I would interpret to mean everybody.

Q Including exposed group?

A Yes.

Q Which are the large consumers of Lake Michigan fish?

A Yes.

Q Yes?

A Yes.

Q Reading on: "The level of PCB found in the blood of participants did not change significantly. . ." Stop there. When you use the word "significantly," what did you mean?

A That implies that there could have been change, but it was not statistically significant.

Q In other words, you couldn't attribute any change in the PCB levels to the consumption of Great Lakes or Lake Michigan fish.

A That is not what that statement says. The statement says if you measure participants on one year, you measure the same participants the next year, it did not change significantly. That is what the statement says.

Q In other words, the additional consumption represented by consuming fish in the second year didn't increase the PCB levels in the blood in any measurable way.

A For the groups.

Q Am I right?

A Didn't produce a significant change the following year, I would agree.

MR. WHITE: Significant as opposed to measureable.

THE WITNESS: Yes.

BY MR. FEATHERSTONE:

Q When you use the term "significant," it means that you could not -- Strike that.

Is it fair to say that any change that you did observe in the PCB levels in the blood of the exposed group, any such change you could not attribute to one additional year of consumption of Lake Michigan fish.

MR. WHITE: You want the question read back?

THE WITNESS: Read the question back, please.

(The record was read as requested.)

BY THE WITNESS:

A I can't agree with that. I am sorry.

MR. FEATHERSTONE: Off the record.

(Discussion off the record.)

BY MR. FEATHERSTONE:

Q Doctor, let's look at Table 8.

A Okay.

Q Let's try it this way. Look in the part of the table that is headnoted, "Mean Total PCB

Value (PPM) 1973."

A Yes.

Q Look in the column for that year that relates to Exposed. Do you see that?

A Yes.

Q Those are the large consumers of Lake Michigan fish.

A Yes.

Q The mean PCB level in the blood of those individuals was .073 parts per million, is that correct?

A For the entire group averaged, yes.

Q Take a look at the table for 1974, right next to it.

A Yes.

Q Looking for the same group, the exposed group.

A Yes.

Q The mean total PCB value in parts per million for that group in 1974 was .075.

A Yes.

Q So the mean value increased from .073 to .075, is that correct?

A Yes, it did.

Q That is from 1973 to 1974.

A Which is a one-year span, yes.

Q During that additional one year, 1973 to 1974, these people were eating Lake Michigan fish, is that correct?

A Yes, they were.

Q Now, isn't it a fact that you could not attribute that increase from .073 to .075 to the one additional year consumption of Lake Michigan fish?

A I don't agree with that.

Q All right. Where in the report do you explain this increase?

A It's in the text on Page 26. But your question --

Q Page 26. Point it out to me, please. In fact, read it.

A "No annual variation in PCB levels in humans could be demonstrated. The mean PCB values for the control and exposed groups did not appear to change markedly from year to year. The exposed group included individuals . . . " so on and so forth.

Here is the sentence:

"Considering these individual variations in PCB exposure the similarity of the annual mean values strongly suggest that PCB levels in exposed persons as a group do not change significantly from year to year."

But I will not agree that there is no change.

Q Doctor, my question didn't ask whether .073 is different from .075. My question was that increase from .073 to .075 you could not attribute to the one additional year's worth of consumption of Lake Michigan fish.

A That's not the way you asked your question. The question was the negative side of that. That I could not attribute it to the PCB exposure. And that's what I couldn't agree with.

Q Well, doctor, let me try it again this way.

Your data shows a slight increase in the mean level of PCBs in the blood of the exposed group for 1973 to 1974, is that correct?

A I agree.

Q That slight increase you attempted to explain through statistical means, is that correct?

A Yes.

Q And you were unable to do so, is that correct?

A Well, we were able to do that, yes.

Q Well, you were unable to attribute that slight increase in the mean PCB levels to any particular variable, is that right?

A We were unable to establish the significance of that change to any variable.

Q Which means you were unable to point to a particular variable and say that the change in that variable caused the change in the mean PCB levels in the blood, isn't that right?

A No, that is not right.

Q Doctor, when you went into this project in 1973, did you expect to find that PCB levels in the blood would decrease as consumption of Lake Michigan fish decreased?

A No.

Q Did you expect to find a decrease in the PCB levels in the blood of individuals who had been

consuming Lake Michigan fish, and then stopped doing so for a period of time?

A Yes. We expected that might occur.

Q Did you expect to see a decrease in the PCB levels in the blood of fisherman who ate less fish or on a less regular basis?

A We had no expectations there. We didn't know.

Q Doctor, what is your explanation for your data which shows no decrease in the PCB levels in the blood when consumption of Lake Michigan fish is halted?

A The questionis what is my explanation for that?

Q Yes.

A My explanation is that the elimination of PCBs from the body, as expressed by blood levels, is very slow. Therefore, the blood level doesn't diminish.

Q You phrased that very carefully, does that suggest that there may be PCB elimination from the blood which you can't depict by looking only at PCB levels in the blood?

A No. That is intended to mean I don't know everything there is to know about PCB elimination.

Q So there might have been PCB elimination from the body, but you couldn't measure it in the blood, is that correct?

A That is correct.

Q So your failure to see any decrease in the PCB levels during this period of abstinence does not lead you to conclude that there was no excretion of PCBs from these humans?

A That is correct.

Q Doctor, do you follow reports on studies performed on workers' occupationally exposed to PCBs?

A I have seen reports on occupational exposures.

Q The question is, do you follow that body of literature?

A No.

Q So I take it you are unable to express any conclusions that you as a doctor would put any great degree of significance in on what the occupational data shows.

A All I can say is that I am aware of some of the occupational data. I am aware of some of the studies. I have opinions as to what some of it means. But am I expert in occupational medicine? No.

Q Well, do you consider yourself an expert on what the studies done in the occupational context with respect to PCBs show?

A As I stated, I am familiar with some of them. I don't know if I know the full body of literature in the area. But I am familiar with some of them, yes.

Q Are you aware that there have been a number of studies that have shown that if the PCB exposure in the occupational context is terminated, that PCB levels in the blood fall rather swiftly?

A Yes, I am aware of that.

Q And rather dramatically as well.

A I can't recall well enough if it's dramatic. But I will agree with you that the blood levels fall.

Q Well, you will also agree with me that

they fall significantly.

A Yes.

Q Are you aware that in these studies summarizing work done on workers exposed occupationally to PCBs, that when the PCB exposure is terminated the PCB levels in tissue fall?

A Yes.

Q And they fall significantly.

A I am not sure. I can't -- I am not sure if I can agree with your term "significantly."

Q Do you know by how much they fall, according to the literature?

A No, I can't quote that to you, no.

Q Well, can you tell me about it, if you can't quote it to me.

A My impression is that when exposure ceases there is a reduction of body burden. But I can't tell you exactly what that rate is.

Q Doctor, turn to Page 25 of your report, please. Exhibit 4. The beginning of the last paragraph reads: "A substantial exposure to contaminated fish makes a highly significant contribution to the PCB body burden. A comparison

of PCB blood values for exposed persons (those who consumed 24 or more pounds of Lake Michigan fish per year) in the four communities bordering the lake were compared to the blood values for the zero consumption controls."

Did you make any, or attempt to make any correlation with respect to subgroups of those who consumed 24 or more pounds of Lake Michigan fish per year?

A What do you mean by subgroups?

Q Did you make any attempt to compare the PCB levels of persons who eat 24 to 30 pounds of fish per year with those who eat say 50 to 80 pounds of fish per year?

A Specifically, no, we did not.

Q Why not?

A That was covered in the general scatter plots and tables which compared pound of fish consumed per year versus PCB values. I believe that comparison on small subgroups was not done on the advice of the statisticians, because the numbers were too small. The numbers of the subjects were too small to carry that out, to

segregate it in that way.

Q So I take it you don't know whether the PCB levels in the blood of those fish eaters who consumed 40 or more pounds of fish per year were greater than the mean PCB value or level in the blood of those who consumed 24 to 40 pounds of Lake Michigan fish per year?

A No. I know that. Figure 3 and 4 address that.

Q What pages?

A Page 23 and 24, as well as the corresponding tables on data which I believe are Tables 4, 5, and 6, where we have -- In Tables 4, 5, and 6, that would be Document 4, Page 18 through 22, the people are arrayed low to high, according to fish consumption, and their data for PCB blood values for the different times that were taken are arrayed there. So yes, the data is there. It can be picked out.

The way it was displayed was on Page 23 and 4 where we plotted pounds of fish consumed per year versus blood PCB, and then transformed that on Page 24 to a natural log plot, acknowledging

that at any given fish consumption amount you will have a large variation in blood levels. And the text talks about that.

Q Well, the difference in the blood levels between some group consuming 40 or more pounds of Lake Michigan fish per year, that blood level as compared to the blood level of persons consuming 24 to 40 pounds of fish per year, you said there was no statistical test run on that difference.

A That split was not made, that is correct.

Q Any split like that?

A No. The split that was chosen is as is shown here, and that was basically exposed people.

Q Which are 24 or more pounds of fish per year.

A Versus the unexposed people, which were either zero or zero to six pounds.

Q So is it fair to say that you cannot state whether the difference in the PCB levels in the blood of various groups above 24 pounds of fish consumed per year is attributable to the increase in fish consumption?

A Yes, I can say that.

Q How can you say that if no statistical test was run?

A It was. The fish consumption from 24 pounds up was correlated with the PCB levels in the blood, and there was a statistically significant correlation relationship between quantity eaten and blood level. And that's stated in the text.

Q Then you did in fact run a statistical test on it?

A Yes. But we did not segregate it as you described.

Q Doctor, in this 1976 study you gave the fish eaters logs in which to record how much fish they consumed.

A That is correct.

Q Did you find that any of the people you studied didn't regularly fill out their logs?

A Yes, we did.

Q Did you find that in order to complete the logs you had to go back and have them shake their memories as to when they consumed fish and when they did not, to make the entries?

A No. The logs were received as prepared. They weren't modified after they were turned in.

Q Well, in your data that you say shows that PCB levels in the blood did not decline in the period of abstinence, is it possible, Doctor, that these people who claimed that they were abstaining from eating Lake Michigan fish did in fact consume fish during that period?

A That is possible, yes.

Q Do you, Doctor, feel that happened in some cases?

A It may have, in some. My impression is that for the group as a whole who participated in that part, it did not happen. But I can't guarantee it.

Q But if it happened in individual circumstances, that would tend to throw off your data.

A Only if it happened in a sufficient number of circumstances would it have thrown off the statistics.

Q You can't tell me whether it did or did not happen in sufficient numbers or instances?

A No. I am telling you I doubt that it

happened in sufficient numbers.

Q We have no guarantee of that.

A I can't prove it.

Q Doctor, how do you explain an increase in the PCB levels in the blood during the period of abstinence from Lake Michigan fish?

A I explained that partially to the variation in levels seen when you sample more than once, that natural variation. Also, we don't fully understand the mechanism of the entry and removal of PCBs from the blood. So there may be other compound factors that could influence a blood level at any given moment.

Q So let me take Point No. 1. What you are suggesting is that because the method of analysis or measurement of PCB in the blood is so sensitive and tricky that there may be analytical variations.

A There is always some degree of analytical variations, yes. Our technique was selected to try to minimize that.

Q Doctor, turn to Page 31 of Exhibit 4.

A Okay.

Q The last sentence of the only complete paragraph on the page reads:

"Thus, an evaluation of the half-life of the concentration of PCBs in humans could not be made within an abstinence period of 90 to 278 days."

A I see that.

Q Now, the PCBs in humans that you are referring to there are the 1254 and 1260 PCBs that you measured in the blood, is that right?

A Correct. The total PCB is measured by our selected analytical convention.

Q That sentence does not deal with PCBs 1242 and 1248 specifically.

A Specifically it does not.

Q Doctor, what conclusion for human health do you make from your finding that, "An evaluation of the half-life of the concentration of PCBs in humans could not be made within an abstinence period of 90 to 278 days"?

A You are asking for what my opinion of what that means?

Q In terms of human health.

A In terms of human health, I don't know.

MR. FEATHERSTONE: Would you read back the question. I want to make sure I have it in the present tense.

(The record was read by the reporter as requested.)

BY MR. FEATHERSTONE:

Q You just testified that you simply don't know what that means for human health, is that correct?

A I said I cannot make a conclusion on what it means.

Q Do you have an opinion, within a reasonable degree of medical certainty, what that means for human health?

A For human health?

Q Right.

A I still don't know.

Q I take it you still don't know what that means for any person who consumes Lake Michigan fish with PCBs, in terms of human health?

A Would you put the whole -- The inability to evaluate the half-life, and I don't know what

that will mean for any person who consumes fish, is that the line we are still --

Q No. That doesn't matter. Just leave it where it is.

From your 1976 study did you reach any conclusion about the types of PCBs in human tissue other than blood? I am talking about the tissue of the people eating fish that you studied.

A The only type of specimen we tested other than blood was a breast milk.

Q What particular PCBs did you find in the breast milk?

A I believe the breast milk was tested by the same analytical convention as the blood, which would mean we evaluated the total PCB as quantity 1254 and 1260.

Q So you didn't find any PCB 1242 or 1248 in that sample of milk, breast milk.

A They were not specifically sought or quantitated.

Q So you didn't find any.

A Yes, that would be correct. We didn't find any.

Q Page 32, Doctor. Your study shows, doesn't it, that most of the PCBs in fish are concentrated in parts of the fish not eaten by humans?

A No, I don't agree with that.

Q Well, Doctor, how else do you explain the significant difference between the PCB levels in the portions of the fish consumed by humans in your study and the PCB levels in the fish swimming around in Lake Michigan?

A The PCB levels in fish consumed by our participants had been prepared and cooked for consumption. I acknowledge there is a difference in the PCB level of fish that entered their mouth as opposed to the level in the fish swimming. But I don't know. I don't know which. I don't know exactly why the difference in between. We speculate in the text as to several possibilities.

Q What you are saying is you don't know whether the reduction in the PCB levels in the edible portion of the fish were due to the trimming away of the fat or cooking of the fish?

A Yes.

Q But you would agree that the difference

you measured between the PCB levels in what humans eat and the PCB levels in the whole fish themselves are markedly different.

A Yes.

Q I ran some calculations on your data, Doctor, and I found that the PCB concentration of that portion of the fish actually consumed by the people in your study was about 15 to 20 percent of the total PCBs in the whole fish.

A You mean, your calculation, the cooked portion versus the original?

Q Yes.

A I haven't made that calculation myself, but it's definitely lower, yes.

Q Would you agree that the PCB levels in the cooked fish are roughly 15 to 20 percent of the PCB levels in the whole fish?

A Without going throught the mathematics, that seems approximately correct, yes.

Q Would you agree that insofar as assessing the consumption of Lake Michigan fish and its implications for PCB levels in humans that it's the edible portion of the fish that is important?

A From a human health perspective, definitely, yes. That's what the humans eat.

Q I take it you would also agree that the difference between the whole fish PCB data and -- Strike that.

Would you agree, Doctor, that the whole fish PCB data is not an accurate measure of PCBs, the level of PCBs consumed by humans?

A I'd like you to rephrase that question.

Q Certainly. Would you agree, Doctor, that whole fish PCB data is not an accurate measure of the PCB exposure to humans by eating fish?

A No, I wouldn't agree with that.

Q Why not?

A It can be an accurate measure. You have just given me a conversion factor. I don't agree with -- That factor could be accurate.

Q If I gave you whole fish PCB data, what conversion factor would you apply in order to determine the PCB levels or exposure to humans?

A I could use the one that you just said that you had done the calculation on. You took my data.

Q If you didn't use mine, what would you use?

A I would turn to data such as this. There are some published reports in the literature that give an estimate of reduction through cooking. I believe at least one of them is referenced here. So there are a variety of studies that have been done or show cooking or food preparation reduces it. And you could choose any one of those percentages and apply that to whole fish value and come up with a number that would be representative of what people might eat.

Q Have you seen any reports that give you an idea of how much actual cooking of the fish reduces PCB levels?

A Yes. I just mentioned some that are cited in my report. I know the -- Well, the answer to the question is yes, I have seen them.

Q By what factor or percentage does cooking reduce PCB levels in fish?

A Thirty percent comes into my mind immediately. I'd have to check the reference to give you an exact number.

As I recall, different cooking techniques had different percentages of reduction.

Q When we are talking about cooking, we are talking about something other than actual cutting away of the fat and the head and portions of the fish that are not eaten by humans.

A In those reports I believe it was strictly confined to taking equal quantities and cooking them in different ways.

Q So if you were given fillet data on a raw fish basis, you would have to reduce those PCB levels by some factor to come up with a PCB level for the cooked fish, is that correct?

A Yes.

Q The figure you have in the back of your head is you would reduce it to 30 percent of the raw fillet PCB level?

A I am not committing myself to that number. What I said was I would refer to those articles where that has been done and see what those percentages are. Thirty percent sounds familiar to me, but without checking the reference, I can't give you an exact number.

Q Which reference are you referring to?

A Mary Zabik is published on this. That might be the one I referred to.

Q Is that cited in your 1976 report?

A It should be, although I don't see it. When I discuss the fish, I did refer to something here -- No. 19, which one is that. Mary is not the lead author; Smith, Funk and Zabik. So there is an example.

Q Would you turn to Page 41 of your report, Doctor. I changed my mind. Would you turn to Page 35 of your report, first.

A Okay.

Q Would you read to yourself the balance of the paragraph on 35, the last paragraph on 35, and it runs over onto the top of Page 41. It begins, "The maximum allowable. . . "

A Okay.

Q Was one of your findings that people who eat large quantities of Lake Michigan fish are exposed to PCBs in doses greater than that recommended by the FDA, is that correct?

A Yes.

Q Do you mean in any way to state that if consumption at this level continued in the future, that these individuals would suffer health problems?

A We could not conclude that at this time.

Q Have you concluded it since?

A No. That is predicting the future. I can't do that.

Q All right. Still on Page 41. If you look to the middle of the paragraph that begins, "Lake Michigan fish consumption. . . "

A Okay.

Q There is a sentence that begins, "If the annual rate of PCB ingestion . . ." Do you see that?

A Yes.

MR. WHITE: "The average rate."

BY MR. FEATHERSTONE:

Q "If the average annual rate of PCB ingestion . . ." Would you read that sentence to the end of the paragraph to yourself, please.

A Yes.

Q The first assumption you make reads, "If the average annual rate of PCB ingestion from fish shown in Table 14 is continued over the years,..."

I take it that is one assumption on which the following calculations are made?

A Yes.

Q All right. Doctor, are you aware that PCB levels in Lake Michigan fish have declined since the time of your study in 1976?

A Yes, I am.

Q Are you aware that they have in many parts of Lake Michigan declined significantly?

A Yes.

Q I take it if you assume that the consumption habits of the people you studied remained relatively stable, in other words, they ate basical the same quantity of fish and the PCB levels declir I take it you would agree that their daily dos of PCB, annual dose of PCBs would decline as well?

A Yes.

Q If that is true, the time it would take to reach the total dose of either 200 milligrams or 500 milligrams or 2,000 milligrans, as you calculate in the following sentences, the time it would take to reach those total doses would extend as well?

A Yes.

Q In other words, it would take longer?

A Yes.

Q You make a second assumption, Doctor, and that reads as follows: ". . . if net accumulation occurs . . ." Am I correct, that is an assumption?

A Yes.

Q When you say net accumulation, I take it you mean if the body burden of PCBs increases with the duration of consumption of Lake Michigan fish?

A With time. The assumption means if indeed PCBs are stored, and they accumulate over time, regardless of the exposure, then, so on and so forth. In other words, the assumption is retention far exceeds elimination. So that you get a net annual increase.

Q When you speak in terms of net accumulation, Doctor, does it matter in your calculations as to how much of a net accumulation there is?

A We don't know how much. So I can't answer the question.

Q Well, does a very small net accumulation

have the same consequence as a large net accumulatic

A It could have.

Q You don't know?

A I don't know precisely.

Q Well, when you say you don't know precisel does that mean you don't know such that you could have an opinion within a fair degree of medical certainty?

A If I am an infant who has just received his first dose, small additional accumulation is going to be like one plus one equals two.

If I am an adult, say 50 years old, and I have had a dose over 50 years, and now I am at 50 years, and my small addition is 50 plus one, that is 51. Two versus 51 is quite different. That is why I can't tell you for certain if in any given year an additional dose, what that impact is going to be. We just don't know in this area exactly what would happen with each additional dose.

Q In other words, this phenomenon of net accumulation might not have any implications for human health.

A That is possible.

Q And that's regardless of whether you are speaking about adult or a child.

A That is true.

Q Doctor, the calculations you make in determining how long it would take to reach, let's take as an example the lowest total dose reported to produce an overt effect in humans in Yusho. Do you see that in the paragraph I referred you to, the paragraph on Page 41?

A Yes.

Q The sentence in particular I am referring to is, "The lowest total dose reported to produce an overt effect in humans (500 milligrams) would be reached in 10.7 years."

A Yes.

Q Do you see that?

A Yes, I see it.

Q That lowest total dose of 500 milligrams, that is based on the reported findings in Yusho as of 1976?

A That is correct, and probably comes from the reference that I cited in these two paragraphs

of discussion, which I believe was the Federal Register, the FDA, Reference 8.

Q It is your recollection that the FDA reference attributed the overt effects in Yusho, at that time, anyway, to PCBs?

A I believe that was the assumption at that time, yes.

Q I take it, Doctor, that with the recent work done on the Yusho incident you would agree that there is serious question as to whether PCBs have anything to do with Yusho poisoning symptoms?

A I wouldn't agree with your word "anything."

Q Well, would you agree with me that you could not, with the state of knowledge today, point to the Yusho symptoms and state that they were attributable to PCBs?

A No. You need another word in that sentence.

Q What is the other word I need, Doctor?

A Solely.

Q All right. Let's try it this way. Is it fair to say that it's your opinion that given the state of knowledge about the Yusho incident today

that you cannot point to the Yusho symptoms and state that they are solely attributable to PCBs?

A I would agree with that.

Q Is it also your opinion today, Doctor, that you cannot point to the Yusho symptoms and state that they were necessarily caused by the PCBs in the rice oil?

A No, I can't agree with that.

Q Well, Doctor, which symptoms demonstrated by the Yusho victims are attributable to PCBs?

A I can't state that for certain. I can't state for certain which ones are not.

Q How much of the effects shown by the Yusho victims are attributable to PCBs in the rice oil?

A I can't state that, either.

Q Now, we discussed earlier that you are now aware that it's been concluded that the Yusho oil had other chemicals in addition to PCBs?

A Yes.

Q Now, this lowest total dose of 500 milligrams, that, at the time you wrote this

report was assumed to be all PCBs, I take it it is now PCBs and something else.

A At the time of the report I believe that was the assumption, that PCBs was the major toxin involved.

Q Doctor, the total dose of 500 milligrams -- let's strike that.

Let's take the average total dose of 2,000 milligrams that caused -- that you say caused the effect in the Yusho victims. I take it today you cannot say that the 2,000 milligrams PCBs would cause the Yusho symptoms?

A I cannot state that, that's right.

Q Doctor, you had this sentence:

"An individual who habitually consumed large quantities of contaminated fish would reach these total dose levels sooner, 1.75 years and 4.3 years respectively, if the top range value is used."

A Yes.

Q I take it by that statement you mean that the lowest total dose of 500 milligrams would be reached in 1.75 or 4.3 years.

A Either that, or the 200 milligram -- Wait a minute. No, it would be the 500 milligrams.

Q Okay. That sentence that I just read to you, did you intend to mean in any way that after 1.75 years or 4.3 those individuals consuming Lake Michigan fish would suffer any overt health problems?

A No. These are calculations, and I cannot state when or exactly at what quantities something is going to happen.

Q Or if it's going to happen.

A I can't state for certain if it is going to happen.

Q Doctor, do you understand the concept of dose rate?

A Yes.

Q What does it mean to you?

A It's the rate at which a dose is received, generally given as frequency or time.

Q In your opinion is the dose rate an important factor in assessing the toxicity of a chemical?

A Yes, it can be.

Q You are aware, aren't you, Doctor, that there are certain chemicals that if you take a large dose may kill you?

A That is correct.

Q But if the same chemical is taken in a smaller dose over an extended period of time, it may have little, if any, effect.

A That is true, too, as well as the inverse.

Q Let's take the average total dose in Yusho, which you say was 2,000 milligrams. On Page 41, do you see that?

A I think 2,000 milligrams refers to the dose calculated to have been received by those who showed the symptoms in Yusho.

Q That is what I want to refer to.

A Okay. It may be -- Yes, I guess it's the average. Yes, you are right, I agree.

Q The average total dose of 2,000 milligrams, is it your understanding that that dose was taken over a period of approximately 50 to 60 days?

A I believe that is correct. We are referring to the Yusho incident and whatever the

exposure period was as reported in the literature. Yes, I would agree with that. That sounds familiar.

Q On the basis of your calculations you figured that it would take seventeen and a half years for someone eating -- or for one of your study group members eating Lake Michigan fish to reach the total dose, is that correct?

A That is the calculation that was made, yes.

Q In your medical judgment, is it a fact that the total dose of 2,000 milligrams spread over seventeen and a half years is significantly different from the same total dose spread over 50 to 60 days?

A Yes, I think that could be significantly different.

Q For instance, in the case of 2,000 milligrams over 50 to 60 days, there may well be symptoms, but the symptoms may not exist if the total dose went out over seventeen and a half years?

A That is possible, and the inverse is possible.

Q With respect to PCBs, which is the case?

A With respect to PCBs, my opinion is many small doses spread out over time have a greater potential for impact than a single dose.

Q Doctor, are you aware of any person anywhere in the world eating fish contaminated with PCBs over a long period of time who suffered any health problems that you can attribute to the PCBs in the fish?

THE WITNESS: Would you reread the question?

(The record was read as requested.)

BY THE WITNESS:

A No, I can't answer that in the affirmative. I am not aware.

BY MR. FEATHERSTONE:

Q When you say you can't answer in the affirmative, it means you don't know of any instance.

A I don't know, yes.

MR. FEATHERSTONE: We can take a break now.

(A recess was had.)

BY MR. FEATHERSTONE:

Q Will you turn to Page 44 of Exhibit 4.

A Okay.

Q In the second to the last paragraph, the middle of the paragraph, it reads:

"No health conditions or group of symptoms could be identified that were clearly related to PCB exposure. This implies that exposure to PCB from eating contaminated fish and the presence of PCB in exposed persons had not caused an observable acute effect in humans at the time of the study."

Does that remain your conclusion today?

A That statement as you have read stands.

Q Doctor, the next paragraph down, there are these two sentences:

"A significant number of exposed subjects or subjects with high PCB levels would be expected to report a given health condition if such a condition was a manifestation of the presence of PCBs in humans. The failure of this to occur suggests that there was no common illness related to PCB exposure or that PCB blood levels were not related to the appearance of any of the conditions investigated."

Does that remain your opinion today?

A With the caveat in the sentence you quoted above, yes. In other words, it refers to a point in time under the conditions of this study at that time.

Q As you testified earlier, you know of nothing that has happened to the individuals you studied in the period 1973 to 1975 that leads you today to believe there is anything wrong with those people with respect to their eating Lake Michigan fish.

A Well, that is the subject of the current investigation that we have under way, and I have stated that I have not reached a conclusion on that. So I can't answer that.

Q You stated, you just stated that you have not reached a conclusion with respect to your ongoing study, your present ongoing study. Do you have an opinion as to whether the people you studied in 1973 to 1975 had today suffered any health problems as a result of their eating Lake Michigan fish?

A I can't, I do not know that for a

certainty at this time.

Q So you don't have an opinion that there has been any problem?

A I have not formulated that opinion yet, because the data is not finished.

Q Doctor, you stated just before we took a break that it is your opinion that long-term consumption by individuals of PCBs is, I think, more dangerous than a short-term exposure, is that correct?

A Not with the word "is."

Q If I said may be more dangerous, would that restate your opinion?

A Then I would agree.

Would you like me to restate that opinion?

Q Okay. Why don't you restate it for me.

A What I inferred was that repeated doses over a long time could be of greater concern so far as eliciting a health impact than one dose.

Q Now, when you talk about dose, are you talking about the ingestion of PCBs by eating fish?

A Yes, that could constitute a dose, yes.

Q What experiences with human being exposure,

long-term exposure of PCBs, do you point to as a basis for that conclusion?

A I can't point to any specifically. That is in fact the topic of the study, is to try to generate that type of data.

Q You haven't yet seen any real world data that would substantiate that opinion of yours?

A In humans.

Q In humans, is that correct?

A Data for humans that would substantiate the opinion, that is correct.

Q Doctor, who is Howard Tanner?

A He is the Director of the Michigan Department of Natural Resources.

Q He is a state official in the State of Michigan, I take it?

A Yes.

Q Who is John Hess, do you know?

A I believe that name is Hesse, H-e-s-s-e.

Q That is correct.

A Who is he?

Q Yes.

A A former employee of Howard Tanner's,

currently an employee of the State Health Department in a coordinator's role.

Q John Hesse was employed by the Department of Natural Resources in February, 1979, is that right?

A Yes, that is correct.

Q At that time he was Chief of the Department of Natural Resources Office of Toxic Materials?

A Controls, Office of Toxic Materials Control.

Q Did you meet John Hesse from time to time when he was in that position?

A Yes.

Q Doctor, did you ever talk to John Hesse about the levels of PCBs in fish in Lake Michigan?

A Probably.

Q John Hesse made this statement in 1979, with respect to PCB levels in Lake Michigan fish. He said, "The PCB levels were 'down so far that we could hardly believe our eyes.' "

MR. WHITE: Is that reported someplace, Bruce, that you are referring to, that statement Mr. Hesse made?

MR. FEATHERSTONE: It is reported, yes.

BY MR. FEATHERSTONE:

Q Doctor, did you ever hear John Hesse make that statement, or a similar statement?

A No, I didn't hear him make that statement.

Q Are you aware that was his opinion in 1979?

A If you are reading from something that is printed, he must have made a statement. I can't attest to whether he would rest as to its accuracy. It's possible.

Q Does Mr. Hesse's statement in any way reflect your opinion as to the decline in PCBs in fish in the second half of the 1970s?

A He's reflecting that the levels of PCBs in fish have gone down. The statement that you have read puts some adjectives on it. I don't know if I'd add the same adjectives.

Q You understand the adjectives?

A I acknowledge that the PCB levels in fish have declined, yes. I am aware of that.

Q You of course know Governor Miliken?

A Yes.

Q Governor Miliken made this statement in November of 1978 with respect to PCB levels in Lake Michigan fish:

"According to initial findings compiled by the Department of Natural Resources, the PCB levels have been cut in half since 1975."

Do you agree with the substance of that statement?

A Cut in half? All right.

Q When you say "all right," you mean you agree with it?

A I am not going to argue percentages; fifty percent, forty percent, sixty percent. Where I rest my case is they had been reduced. Without looking at the array of fish data, I can't tell you if I agree exactly with a fifty percent cut.

Q But it's in that neighborhood.

A It's been cut, obviously, yes.

Q Doctor, for your information about the Yusho incident, have you relied on materials prepared by Japanese medical experts?

A I have seen reports originating from those who have been investigating the Yusho incident

in Japan. I have also seen reviews of these, and I have seen chapters in books which refer to them.

Q Would you look to Reference 7 in Exhibit 4.

A Yes, I see it.

Q There is an author by the name of Kuratsune, do you see that?

A Yes, et al.

Q Is Kuratsune someone you recognize as an expert in the Yusho investigation?

A Those authors, the combination of four Japanese authors, I have seen their names associated with Japanese investigations, yes.

Q I take it since you referenced one of Kuratsune's et al.'s publications, you relied upon it in your report, your Exhibit 4?

A Yes, I referred to it in some way. I can't recall exactly where.

Q The Yusho incident involved consumption by Japanese families of rice oil, is that right?

A That is my understanding, yes.

Q Is it your understanding that the rice oil was contaminated with the Japanese PCB known as Kanachlore 400?

A Yes.

Q Monsanto PCB was not involved.

A To my knowledge, no.

Q When you say "no," you mean no, it was not involved.

A No, it was not involved.

Q Are you aware that analytical chemists have determined that the organic chlorine content of the rice oil involved in the Yusho incident contained between 2,000 and 3,000 parts per million chlorine?

A I have no comment. You know, I don't recall the exact chlorine content.

Q When you say you don't recall the exact chlorine content, does 2,000 to 3,000 parts per million fall in the range or the estimate that you remember from your reading on Yusho?

A You said chlorine content, and you have given me a concentration. Do you mean the rice oil was contaminated at a level of two to 3,000 parts per million, or do you mean the composition of the PCB was --

Q No. What I am asking you is do you

remember or do you know that the rice oil was contaminated to the extent of two to 3,000 parts per million with chlorine. I haven't made reference yet to PCBs?

A I will acknowledge that.

Q As being a range.

A Yes.

Q Okay.

A Okay.

Q Are you, Doctor, aware that Mr. Kuratsune, on whom you relied in doing your 1976 report, has issued a very recent article in which he stated that of the two to 3,000 parts per million chlorine contamination, PCBs accounted for only 1,000 parts per million?

A I cannot confirm your exact number, but I acknowledge that other materials were present, and so of the total, PCBs was not the entire chemical present, yes.

Q Would you also acknowledge, Doctor, that other contaminants were present in the rice oil to insignificant quantities?

A I have read that, yes.

Q Have you read, Doctor, that the analytical chemists looking at the Yusho rice oil have found dibenzofurans in the rice oil?

A I am aware that is one of the contaminants that was detected, yes.

Q You know, don't you, Doctor, that dibenzofurans are considerably more toxic than PCBs?

A I am aware of that.

Q Would you agree with the Federal Food and Drug Administration that the toxicity of dibenzofurans is about 500 times the toxicity of PCBs?

A Is that a quote from the FDA?

Q It's reported in the 1979 Federal Register by the FDA.

A Then I would concur.

Q I take it given the very high toxicity of dibenzofurans for purposes of making a medical judgment about the cause of the Yusho symptoms, the presence of dibenzofurans is very important.

A Yes.

Q Now, perhaps you answered this earlier,

and I apoligize that I can't remember the answer, but have you followed the Yusho literature since 1976, to some extent?

A To some extent I have, yes.

Q Would you agree that the presence of dibenzofurans has greatly complicated the determination of the cause of the Yusho victims?

A Yes, it has complicated it. I do not know to what extent. It's definitely a complicating factor.

Q When you say you do not know to what extent, I take it you don't have an opinion as to the extent.

A You used the word "greatly." I don't know if I necessarily agree with "greatly." But I acknowledge and agree that it complicates the evaluation.

Q Doctor, are you aware that analytical chemists looking at the Yusho rice oil that was involved in this Yusho incident in Japan have found several very highly toxic isomers of dibenzofurans?

A I am less familiar with that detail,

but if you have seen that in the literature, then I would concur.

Q Doctor, do you know anything about dibenzofurans and by that I mean the particular isomers of dibenzofurans, which are more toxic, which are least toxic?

A I have a general knowledge of that, and of the fact that the isomers and the congeners of the chemicals, especially this family of chemicals, has an important role in toxicity, yes.

Q Doctor, do you know the toxicity of what is known as the 2 3 7 8 tetrachloro dibenzofuran?

A Yes.

Q Do you recognize that that is a very highly toxic dibenzofuran isomer?

A Yes.

Q Do you know of the toxicity of the 2 3 4 7 8 pentachloro dibenzofuran?

A I am less familiar with that.

Q When you say less familiar?

A Less familiar with the reputation of that isomer.

Q Well, Doctor, for purposes of the next

couple of questions assume that that isomer as well as the tetrachloro dibenzofuran earlier described to you were present in the Yusho rice oil. Okay?

A Okay.

Q I take it the presence of particularly highly toxic isomers of dibenzofurans would be very important in determining the cause of the Yusho symptoms.

A Yes, they would.

Q Doctor, would you agree that a dizenzofuran contamination of the rice oil of five parts per million would be significant in rendering a medical judgment as to the cause of the Yusho symptoms?

A Can you restate that. Is your question --

Q I will restate it. I don't want to answer yes or no, my question is this or that.

A Yes, okay.

Q In terms of rendering a medical judgment about the cause of the Yusho symptoms, I take it you would agree that a five part per million dibenzofuran contamination of the rice oil is significant?

A I don't know.

Q You don't know because you haven't done any work on dibenzofurans?

A Yes. Basically I can't say if that degree of contamination would -- what the impact would be. I can't say.

Q You would defer to other experts on that.

A Yes.

Q Doctor, are you aware that dibenzofurans were identified in the liver and adipose tissue of the Yusho victims?

A I don't recall that I have seen that. It follows that that could be the case, but I can't personally say I have seen the report. I do not recall.

Q Whether you have seen that or not?

A Yes.

Q You wouldn't be surprised to find dibenzofurans in the liver adipose tissue, assuming dibenzofurans were in the rice oil that was consumed?

A I would agree with that.

Q Doctor, are you aware that the Japanese analytical scientists have found polychlorinated

quaterphenyls in the Yusho rice oil?

A Yes. That is spelled q-u-a-r-t --

Q No. Q-u-a-t-e-r--p-h-e-n-y-l-s, also known as PCQs.

Do you recognize the acronym PCQs to stand for polychlorinated quaterphenyls?

A Yes.

Q Doctor, do you know to what extent the Yusho rice oil was contaminated by PCQs?

A No, I do not, but I am aware that it was another contaminant present.

Q If I told you that PCQs contamination of the Yusho rice oil was almost the same as PCB contamination of the rice oil, would that be significant in your determination of the cause of the Yusho medical symptoms?

A I don't know.

Q Is that because you don't know anything about the toxicity of PCQs?

A No. I can't answer your question because I don't know whether the two chemicals together are additive, synergistic or antagonistic. So I can't state to you an answer of what their contribution

is on either side of that ledger.

Q By that you mean you cannot yourself determine the significance of the presence of PCQs in the Yusho rice oil? Toxicological significance.

A That's basically correct, yes.

Q Doctor, you would agree that the presence of substantial quantities of PCQs further complicate the determination of the true cause for the Yusho symptoms?

A Yes, I would agree.

Q Doctor, do you agree with this statement:

"Uncertainty about the confounding of effects between PCBs and dibenzofurans makes it difficult to determine from the Yusho data exactly what effect exposure to only PCBs could have on humans."

THE WITNESS: Could you read that again?

(The record was read as requested.)

BY THE WITNESS:

A I'd prefer if you would state that a little differently.

BY MR. FEATHERSTONE:

Q Well, it's a quotation of the Food and Drug Administration. Would you agree with that quotation?

MR. WHITE: Do you understand the question?

Why don't you rephrase the question.

BY THE WITNESS:

A Yes. I don't care if it's a quote from the FDA. I am not sure if I agree with it as stated.

BY MR. FEATHERSTONE:

Q My question is whether you agree with the following statement, and it's a statement of the Food and Drug Administration.

"Uncertainty about the confounding of effects between PCBs and dibenzofurans makes it difficult to determine from the Yusho data exactly what effect exposure to only PCBs could have on humans."

A All right. I agree with that. I am sorry if I missed it. I didn't hear the Yusho part. The Yusho data. Yes, I agree.

Q Would you agree with this statement:

"A causal relationship between PCBs and cancer cannot be inferred by the Yusho incident because of the confounding introduced by the presence of dibenzofurans in the oil."

A I'd agree with that.

Q Doctor, would you agree with this statement of the Food and Drug Administration. It is a statement made after looking at the Yusho data, recent Yusho data.

"Because of the presence of toxic impurities other than PCBs in the rice oil, it is likely that amounts of PCBs greater than those reported in Yusho would be required to produce similar symptoms."

A Did you say the word "likely" was in there?

MR. WHITE: If you didn't hear it all, have her read it back, or restate it.

MR. FEATHERSTONE: Madam Court Reporter, why don't you read it back.

(The record was read as requested.)

BY THE WITNESS:

A I'd agree with that.

BY MR. FEATHERSTONE:

Q Doctor, are you aware that recent study of Yusho victims has shown that the PCB levels in their blood and tissues have declined to background levels?

A Yes, I am aware of that.

Q Are you aware that despite the decline of the blood levels and tissue levels to background levels, the symptoms persist, or some symptoms persist?

A Some symptoms, yes, I would agree with that.

Q What conclusion do you draw from that with respect to the cause of the Yusho symptoms?

A Well, I don't know what caused the Yusho symptoms. And that is where I will stop.

Q I take it you don't have an opinion, either?

A Sure I have an opinion.

Q Do you have an opinion within a fair degree of medical certainty?

A No.

Q If it's not within a reasonable degree

of medical certainty, I don't want it.

In the last couple of questions when I used the phrase "background level," did you understand that to mean the level of PCBs in the blood and tissues of people not exposed to the Yusho rice oil that was contaminated?

A That is the interpretation that I made of that, yes.

Q Doctor, the fact that the PCBs in the blood of the Yusho victims and in the tissues of the Yusho victims had declined to background levels, do you conclude from that evidence that the PCBs were metabolized and excreted?

A And/or? Can we put an and/or in there?

Q Yes.

A Metabolized and/or excreted?

Q Yes.

A Yes, then I would agree.

Q Is it your opinion that humans to some extent metabolize PCBs?

A Yes.

Q Doctor, do you agree with this statement:

"Valid human data should take precedence

over predictions arrived at by extrapolations from animal studies."

A Yes, I agree with that.

Q Doctor, do you agree with this statement:

"The fact remains that after more than 30 years of widespread environmental exposure to PCBs we had no documented cases of human injury or poisoning due to chronic trace exposure to this chemical."

A I'd agree.

Q Doctor, do you agree with this statement? This is a statement by Dr. Colby. Do you know who he is?

A Yes.

Q Who is he?

A Medical -- I can't give his whole title. He is with the FDA, medical consultant. At one point I think he was Deputy Chief of one of their bureaus.

Q Would you classify him as a top official with the Food and Drug Administration?

A I think so, yes.

Q Dr. Colby made this statement in 1980.

"I am unaware of any human sickness in the

United States that is related to the ingestion of PCBs."

Are you aware of any human sickness in the United States that is related to the ingestion of PCBs?

A I am thinking. Your question is, am I aware of?

MR. WHITE: Read the question.

(The record was read as requested.)

BY THE WITNESS:

A I guess to the best of my knowledge, no.

BY MR. FEATHERSTONE:

Q Doctor, you are aware that PCBs have until 1977, had been used in the United States since the early 1930s?

A Yes.

Q Have you learned of any reproductive problems for any individual who has eaten fish containing PCBs, that you can attribute to PCBs?

A No.

Q Have you learned of any either malfunction or damage for any person who has eaten fish containing

PCBs, that you can attribute to PCBs?

A No.

Q Have you learned of any person who has consumed, either in long-term or short-term, fish containing PCBs, and who has cancer that you can attribute to PCBs?

A No.

Q Have you learned of any hormonal problem for any person who has eaten fish containing PCBs on either a short-term or long-term basis, that you can attribute that problem to the ingestion of PCBs?

A No.

Q Doctor, have you learned of any weight or growth problem for any person who has eaten fish containing PCBs, and for whom you can attribute those problems to PCBs?

A No.

Q Doctor, have you learned of any thyroid condition for any person who has eaten fish containing PCBs, on either a short-term or long-term basis, and for which you can attribute that thyroid problem to PCB ingestion?

A No.

Q Doctor, have you learned of any death of any person who has eaten fish containing PCBs, on either a short-term or long-term basis, and for which you can attribute that death to PCBs?

A No.

Q Doctor, have you learned of any disease, sickness or disorder that can be attributed to any environmental exposure to PCBs?

A No.

Q Doctor, have you learned of any growth problems in any child who has been nurtured by a female who has eaten quantities of fish containing PCBs?

A No.

Q Doctor, are you aware of any child who has suffered any disease, sickness, or disorder that you can attribute to PCB exposure?

A No.

Q Doctor, do you agree with this statement?

"Human exposure to PCBs from air and water appears to be minimal."

A I have trouble with "minimal." Is there a basis of comparison?

Q Well, it's a statement of the Food and Drug Administration, Doctor. I can't help you. I didn't make it up.

A Okay. I will go along with that, not because it is from the FDA, but I --

Q But you agree with it?

A It's minimal.

Q Doctor, are you familiar with the work done exposing Rhesus monkeys to PCBs?

A Yes.

Q Are you familiar with the effect of the Rhesus monkeys of -- Strike that. I am sorry.

Are you familiar with the effects on the Rhesus monkeys from the feeding of PCBs in the diet?

A Yes.

Q Doctor, do you agree with this statement:

"Such effects as seen in the Rhesus monkeys have not been noted in humans exposed to environmental PCBs in food in the United States."

A Have not been --

MR. FEATHERSTONE: Why don't you read the question.

(The record was read as requested.)

BY THE WITNESS:

A I will agree with that.

BY MR. FEATHERSTONE:

Q Doctor, would you agree with this statement:

"It is not yet possible to make a direct comparison of the effects of PCBs from one kind of test animal to another or to humans."

A I'd agree with that.

Q Doctor, when, to your knowledge, were PCB residues first identified in human foods?

A I believe in the 1960s. I can't give you the exact date.

Q Doctor, would you agree that since that time, and up through today, that PCB residues in food have declined significantly? I am talking about human food.

A I am not familiar enough to make a statement. So I don't know.

Q If I told you that was a statement quotation of the Food and Drug Administration, would you have any reason to dispute it?

A No, I wouldn't. They run the market-basket surveys.

Q Doctor, would you agree with this statement:

"The amount of PCBs in fish that is required to produce overt toxic effects is unknown."

A I'd agree with that.

Q Doctor, what do you understand the phrase "overt toxic effects" to mean?

A Overt toxic effects would be those which can be measured or diagnosed.

Q To a layman, health problems?

A Health problems or test results which indicate abnormality.

Q Doctor, would you agree with this statement. This is another statement by Dr. Colby of the Food and Drug Administration.

"PCB is not a highly toxic compound."

A That's the full extent of the quote? Then I don't agree.

Q Doctor, are you by training an epidemiologist?

A No, not by training.

Q Are you an epidemiologist by anything?

A Yes.

Q By what?

A In-service experience and training. But I interpreted your first remark to mean --

Q Education.

A Education in epidemiology, and the response is no.

Q But your jobs have been in the area of epidemiology.

A Yes.

Q What is an epidemiologist?

A A person who studies the course of disease in human populations.

Q Is it fair to say that epidemiologists focus on human beings and their response to certain chemicals, for instance?

A Chemicals. Traditionally the field has been in communicable diseases. But in recent years it has expanded to non-communicable disease, which would be chemicals.

Q Doctor, as part of the work that you are doing now with respect to PCBs, which you summarized in Exhibit 3, you stated that you are measuring, I think you said, certain chemicals in the blood?

A Yes.

Q Does that include enzymes in the blood?

A Yes.

Q Are you doing anything to determine the effect of ingestion of PCBs through the consumption of Lake Michigan fish on a liver enzyme or series of enzymes known as the mixed function oxidase?

A Not specifically, no.

Q So I take it any of the data that you collect will not lead to any conclusions about the effect of PCB ingestion by eating fish on the mixed function oxidase, is that correct?

A Probably not specifically. I have to qualify that answer, because the enzyme tests which we are running, I don't know if there can be inferences drawn from them as to what it would mean to the mixed function oxidasis.

Q So what you are --

A In other words, I am saying people may look at the data, interpret it, and say an alteration here has a correlation with mixed function oxidasis.

Q Maybe I can shortcut it here.

I take it as a result of your work now you

don't anticipate, yourself, being in a position to render any opinions about the effect of PCB ingestion by humans on the mixed function oxidase enzyme.

A I would agree with that.

Q Doctor, let's go to Exhibit 4 for a second. You testified earlier that in your 1976 study you conducted interviews with people thought to be consumers of large quantities of Lake Michigan fish.

A Correct.

Q Before you conducted these interviews you had a list of 17 or 18 symptoms that were largely taken from the Yusho incident, is that correct?

A That is correct.

Q I remember seeing in your report that you conducted a medical history of these people by interview, so to speak.

A That's correct.

Q So I take it you spoke to these people about medical conditions more broadly than the 17 or 18 symptoms you were specifically looking for?

A Well, not very much more broadly. The medical history was in the context of the 17 to 18 health conditions. We were inquiring whether or not

they were suffering or had in the past suffered from any of these problems. In that context, that is a history.

In the broader context, did you take a full medical history of every medical event that has ever occurred on these people, then the answer to that is no.

Q Did you do anything more broadly than ask them about the 17 or 18 conditions that you selected out of the Yusho episode?

A At that time -- I don't have the questionnaire with me -- but I believe no.

Q Doctor, you wouldn't have any objection to providing us with the questionnaire used, would you?

A No. I am sorry I didn't bring it to show it to you today.

MR. FEATHERSTONE: Mr. White, I take it --

BY THE WITNESS:

A The reason I hesitate, there is probably a question in there, something about has there been any other unusual events. And that's probably what comes here under "Other," and I would probably have to consult the questionnaire to give an exact answer.

The point is we utilized this list of symptoms to try to determine whether these people had been experiencing or were experiencing certain kinds of medical problems. The intent was to be an indicator, as opposed to a thorough medical evaluation.

BY MR. FEATHERSTONE:

Q Were the medical histories, to the extent you got them, set down in something other than a questionnaire form?

A No.

Q Did anybody sit down and look at or look for data other than the 17 or 18 particular conditions that you were particularly concerned with?

A No. As I explained, this was a person-to-person interview by a non-medical person asking questions, soliciting responses from the participants.

Q Doctor, have you explored in any detail the literature discussing the effect on PCB ingestion or exposure on the mixed function oxidase enzyme in humans?

A No. I am more familiar with working with rats. But I am not --

MR. FEATHERSTONE: Would you repeat his answer, please.

(The record was read as requested.)

BY THE WITNESS:

A I am familiar with the work reported that has been done with rats and mice. To answer your question, in humans, no, I am not familiar with that.

BY MR. FEATHERSTONE:

Q Doctor, I want to ask you a few questions about liver enzymes that one might find in human blood. I take it this is something that you are looking at now in your ongoing study.

A We are looking at a selection of enzymes, yes.

Q Can you tell me which enzymes you are looking for?

A GTTP.

Q SGOT?

A SGPT.

Q Any others?

A At this time I don't believe we will be

looking at any others.

Q Why are you looking for those? Strike that.

Why are you measuring those liver enzymes in the human blood samples that you are gathering?

A We are interested in whether or not in the cohort we are studying there is a correlation between PCB levels and alterations in these enzyme levels.

Q By alterations, you mean up or down in terms of numbers?

A Either up or down. There are some reports in the literature where tentatively it looks like this might be an area to examine with respect to PCB exposure.

Q In other words, you are familiar with some reports in the literature that suggest that PCB exposure increases the liver enzymes in the blood?

A Certain liver enzymes, yes.

Q When you say certain liver enzymes, do you include SGOT, SGPT and GTTP?

A Yes.

Q I apologize to everybody here. I can't pronounce the formal names.

A I can't remember the formal names.

That is off the record.

Q Doctor, are you aware that none of these studies to which you refer have linked any human health problem with an increase in these three liver enzymes which we have mentioned?

A I'm aware that that conclusion has not been made, that is correct.

MS. OLIVER: Can I have the question back, please.

MR. FEATHERSTONE: Let's have the question and answer back again.

(The record was read as requested.)

BY MR. FEATHERSTONE:

Q When you say "that conclusion," you mean that nobody has linked any human health problems to any increase in these three liver enzymes?

A Yes, that's right.

Q In your ongoing study, Doctor, and when I say ongoing study, I mean the study you have going on right now, are you looking at plasma lipids at all?

A Yes.

Q Which ones are you looking at? By

looking at, measuring, I mean.

A We are interested in cholesterol.

Q Is that total cholesterol, or are they particular cholesterol items?

A Particular ones. The highs and the lows, you know. The differential of the types of cholesterols, triglycerides.

Q So you were looking at trigylcerides?

A I believe we will be. The cholesterols, yes. The triglycerides, that hasn't been settled.

Q Why are you looking at the high density cholesterols?

A There are reports in the literature associating high and low density cholesterol levels with certain types of diseases. We are interested if there is a correlation here of interest. Without looking at the literature, I can't give you a full explanation of it.

Q Just so I am clear, the literature you have seen has not linked any disease to PCB exposure, is that correct?

A That is correct.

Q What you are referring to is literature

that links a change in certain of these cholesterols with a disease, but the stimulants for increasing the cholesterol is not PCBs.

A It is not known.

Q Have you done any research into these studies done on workers exposed to PCBs with the purpose of determining what the effect, reported effect, has been on the workers' cholesterol levels in the blood?

A I am aware of some studies on workers exposed to PCBs, and some of the reports. I can't recall right now if the cholesterol was -- what the cholesterol association was with those reports. You know, without looking at them, I can't answer your question accurately.

Q I take it you have not yet formed any opinions about the relationship between PCB ingestion by eating fish with PCBs and either liver enzymes in the blood or cholesterols in the blood?

A No, I have not at this time.

Q Doctor, have you been provided with any materials by Mr. White or Mr. Hynes, U.S. Attorney's Office, USEPA, in connection with this litigation?

A I have been shown certain reports and documents with respect to the background of Waukegan, some other types of technical reports, yes.

Q Have you been shown -- Well, first of all, do you have that material here?

A No, I don't.

MR. FEATHERSTONE: I take it, Mr. White, you don't have that material readily available, do you?

MR. WHITE: No, I don't.

BY MR. FEATHERSTONE:

Q Have you been given any material showing PCB levels in fish in or about Waukegan Harbor, or the Illinois waters of Lake Michigan?

A I have received this from two sources. It seems like some of the materials that you showed me had fish levels, but I am receiving it also in Lansing as a part of my job, because these materials -- because they pertain to the contributary of Lake Michigan, are being sent to the Governors of the states, and it filters its way to me as, you know, background reference material. So I have been, you know, I am aware of some of the fish testing that's been going on here.

Q Have you been asked in connection with this litigation to render any opinion about any dangers from the PCBs in the bottom of Waukegan Harbor to any human being?

A No.

Q Do you have any idea whether you are going to be asked for such an opinion at trial in this litigation?

A I don't know.

Q A fair answer.

A Yes. I can't predict. I don't know what is going to happen at trial.

MR. FEATHERSTONE: Would you read back my second to the last question.

(The record was read as requested.)

BY MR. FEATHERSTONE:

Q Have you been asked in any context to render any opinion about any dangers or health problems from PCBs in Waukegan Harbor to any human being?

Let me have that question back again.

(The record was read as requested.)

BY MR. FEATHERSTONE:

Q All I meant to do is take out --

A Any context?

Q By any context I mean to delete the words "in this litigation" from my question two questions ago.

A No.

Q The reason for that is you said you got the information as a part of your normal course of business, and I just wondered whether anybody asked you for any opinion in that connection, as opposed to Mr. White or Mr. Hynes, or somebody.

A No. I am asked for opinions as a part of my state job. But it's not specific to the Waukegan, you know. In other words --

Q No, no. I am only asking for your opinions in connection with Waukegan Harbor.

A No, I have not been.

Q Have you been furnished with any information about the species of sport fish caught and consumed by Illinois fisherman?

A I can't remember specifically. I may have been. You know, I have seen some of the data with

respect to fish --

Q Let me rephrase the question.

A I am sorry, I can't remember accurately.

Q Let me rephrase the question this way. Do you have any information or knowledge about the fishing habits of Illinois sport fisherman?

A No, I don't, specifically.

Q Do you have --

A I do for Michigan, but not --

Q Not the State of Illinois.

A Not the State of Illinois.

Q You will admit, they may well be different.

A They could be. I may have seen data like that, but it's not at the forefront of my mind.

Q Do you have any information or knowledge about the sport fish species caught by Illinois sport fisherman?

A Yes. Again, this is again in the general context of Lake Michigan contaminants, and as routine fish monitoring over the years, either by the EPA or the states, or the State of Michigan, I have seen data pertaining to fish caught. Therefore, fisherman in Illinois catch and eat certain

types of fish, such as Michigan residents do.

Q What are the species of fish most frequently caught in Illinois waters of Lake Michigan?

A I don't know. I don't know specifically. What I am aware of is that again the lake trout, the Coho, the salmon, are caught, just as they are anywhere in the Great Lakes -- in Lake Michigan, but I can't tell you what the frequency of specifically which species is caught more than another for Illinois.

Q Do you know which species of fish are the principal commercial fish species in the Illinois waters of Lake Michigan?

A No, I don't specifically. I could take a guess at it, but I don't know.

Q Do you, Doctor, know anything about fishing habits in Waukegan Harbor itself?

A Not for sure. I am trying to find out.

Q You say you are trying to find out. What are you trying to do?

A I am going to run a study.

Q That brings us to the famous radio advertisement I heard. I almost signed up for that,

Doctor.

A No, I don't know specifically what the fishing habits are of people with respect to Waukegan Harbor. I have asked the Lake County health officials if they do, and I haven't gotten an answer yet.

Q Well, let me start at base one. The study that you say that you are trying to make on the fishing habits in Waukegan Harbor, is there something different from the ongoing study which you have which is summarized in Exhibit 3?

A No.

Q In other words, some of the people you are looking at are people in the Waukegan area?

A Some of the people that we plan on including in the study will include people outside of the State of Michigan, and very likely could include people from Waukegan Harbor, yes.

Q With the appropriate modifiers in your answer, I take it you have not gathered any information from anybody in the Waukegan area?

A That is correct.

Q When do you anticipate beginning that

process, if anyone from Waukegan is to be included in your study group?

A This would be an event that would begin to occur late in the second year of the project and in the third year of the project.

Q When is that?

A That would be starting this fall into the next full year.

Q So if I understand it correctly, your opinions and conclusions about any of the people in Waukegan Harbor area who you study won't be finalized until late next year?

A That is a reasonable assumption, yes.

Q In other words, not in time for the trial on March 1, 1982?

A I couldn't -- I don't know. If you read the grant -- Well, if you read the grant application which was distributed to you, which was created two years ago, the intent of that study has three major thrusts. One is return to the people who were in this 1976 study, re-evaluate them.

Number two was to increase the total number of people with appropriate controls who were

going to be studied.

Number three, to extend the study to other areas of interest in the Midwest.

That could include any number of places. The latter was intended and planned to be begun to be implemented in the third year of the study. We are adhering pretty much to that timetable.

We had the cohort expanded in Michigan, controls. We are about to embark on the consideration of other places where we might extend the study.

Q When you say you had contact with the Lake County Health Department, what did you ask them to do?

A I asked my employee who handles the field work and directs the field staff to call them up and see if there was linkage that we could have with them so far as whether or not they wanted to have the study done in their jurisdiction, and would they be willing to help us with the study.

Q Are you in any way looking for a cohort of sport fisherman who fish exclusively or primarily in Waukegan Harbor itself?

A I think this is one of the questions which needs to be resolved. Are there people who fish and eat fish exclusively from Waukegan Harbor.

Q In other words, you don't know the answer to that.

A I don't know the answer to that, no.

Q What efforts are you making in order to determine the answer to that?

A We have asked the local people to check around and try and find out, you know, whether or not this is the case.

Q Local people then being --

A I am sorry, local health department people there in Lake County.

Q Who have you been dealing with?

A I am sorry, I don't remember.

Q Doctor Nedved?

A Yes.

Q Anyone else?

A The man who is in charge of his environmental work. Like I said, these contacts have been made through my field coordinator who sets up the field-work for our project.

Q Is your field coordinator himself making any effort to obtain this information directly, or is he relying on Dr. Nedved and his crew to do it?

A No. We would, our team of people would be doing the data collection.

Q But in terms of -- My question relates to whether or not people exclusively or primarily fish in Waukegan Harbor. Okay. You said you were trying to get that kind of information.

A No.

MR. WHITE: That is not what he said.

MR. FEATHERSTONE: That is what my question was.

MR. WHITE: He said he hadn't made a determination as to whether or not.

MR. FEATHERSTONE: Whether or not what, Jim?

MR. WHITE: They can get those people who fish exclusively in Waukegan Harbor.

BY MR. FEATHERSTONE:

Q I thought the preliminary step was you were trying to determine whether there were any people who fish exclusively and primarily in Waukegan Harbor, and then after you had that

information you would try and determine whether or not you wanted them in your study.

A Essentially we are at the planning stage with respect to that site and some others. And in the planning stage protocol calls for -- you know, you have got to contact the local officials in charge. If they don't want you conducting research in their jurisdiction, then probably you don't conduct the study. That is generally never a problem.

Q Did you meet any resistance from Dr. Nedved or anybody from his office?

A No.

Q Did anybody at USEPA or the U.S. Attorney's office suggest Waukegan area as a place to possibly study?

A That site was named three years ago as a possible spot, as well as three or four in Wisconsin, and a couple on the Mississippi River.

Q You are looking at all of those sites today?

A I don't know which sites we are going to examine. Frankly, the criteria will be whether or not there are people who are exposed to the

environment in question. And if the answer is yes and, you know, we could carry out a study of recruiting these people and enrolling them, then we will make the attempt to do it.

If the answer is no, then we will choose other sites. We are frankly just at the preliminary stage on this, and you know, with the expansion of the study beyond the boundaries of the State of Michigan is just starting.

So I can't predict where we are going to go. We have been in contact with the folks mentioned in Illinois. I have been in contact with the epidemiologist in Wisconsin, the State Health Department there. At this time we are at the planning stages.

Q Doctor, let me ask you a couple of questions here, and then we will go home for the day.

I take it from the material you have been furnished and the materials you have read, you are aware that the U.S. Government claims there are PCBs in the bottom of Waukegan Harbor.

A Yes. I know that from the newspapers, too.

Q Doctor, you are aware that the government is asking for the dredging and removal of the PCBs from the bottom of Waukegan Harbor.

A I don't know the specifics of what they are asking, but yes, I have heard something about removing the PCBs from the harbor, yes.

Q Doctor, do you know of any harm that has been caused to anyone on account of the PCBs that are at the bottom of Waukegan Harbor?

A I can't answer that question. I don't know.

Q In other words, you don't know of any harm to anyone.

A I can't say whether there has or hasn't been.

Q Doctor, I am going to be persistent here for the last 20 minutes.

The question is, do you know of any harm that has been caused to anyone on account of the PCBs that are on the bottom of Waukegan Harbor?

A No, I don't.

Q During the period 1952 to present, do you know of any harm that has ever been caused to anyone

because of any PCBs on the bottom of Waukegan Harbor?

A No, I don't.

Q During the period 1952 to present, do you know of any harm that has been caused to anyone on account of the PCBs in the water of Waukegan Harbor?

A No, I don't.

Q Doctor, do you know anything about the uptake of PCBs by fish in Lake Michigan?

A In a general sense, yes.

Q Doctor, I want you to assume that the bottom of Waukegan Harbor is dredged, and the PCBs are removed, as the government wants. What effect will this have on the PCB levels in Lake Michigan fish?

A I can't say for sure. I don't know.

Q I want you to assume that the bottom of Waukegan Harbor is dredged and the PCBs are removed, as the government wants. What effect will this have on humans who eat Lake Michigan fish?

A I can't predict what effect that would have.

Q In other words, you don't know.

A I don't know for sure.

Q Do you know of any harm that has been caused to anyone from 1952 to present as a result of eating Lake Michigan fish caught in or near Waukegan Harbor?

A I do not specifically know.

Q Do you know of any generally?

You are shaking your head no?

A No.

Q Doctor, I want you to assume that the PCBs presently sitting on the bottom of Waukegan Harbor have no significant bearing on the PCB levels in the fish found just outside the harbor, or anywhere else in Lake Michigan.

I want you to assume that the dredging of Waukegan Harbor will not reduce the PCB levels in Lake Michigan fish to any significant degree.

In light of those assumptions, would you agree, Doctor, that the dredging of the harbor bottom and the disposal of PCBs elsewhere will have no consequence on the health of fisherman eating Lake Michigan fish?

A Given the two assumptions as you have

stated, I'd agree with that.

Q Doctor, are you aware that there is a gully known as the North Ditch on the Outboard Marine Property?

A I have heard of that, yes.

Q Are you aware that there are some allegations that there are PCBs in the North Ditch?

A I have heard of that, yes.

Q Are you aware that there are some allegations that some small quantities of the PCBs in the North Ditch move out into Lake Michigan?

A Yes.

Q Doctor, do you know of anyone who has ever been harmed by any PCBs from the North Ditch?

A No, I do not.

Q Do you know of anyone who will be harmed by any of the PCBs presently in the North Ditch if there is no dredging of the North Ditch?

A I can't answer that. I don't know.

Q Doctor, I want you to assume that the North Ditch is dredged or in some other way PCBs flowing into Lake Michigan from the North Ditch, or that are alleged to flow into Lake Michigan is stopped, okay?

A Okay.

Q What effect will any of that have on the levels of PCBs in Lake Michigan fish?

A I do not know for certain what effect that would have on the fish.

Q What effect will any of that have on the quantities of PCBs ingested by humans?

A I don't know that, either.

Q What effect will any of that have on the exposure of humans in Illinois, Waukegan Harbor, or anywhere else in the Great Lakes Basin to PCBs?

A I don't know precisely what effect it would have.

Q Do you know generally what effect it would have?

A Well, in a general sense if you reduce contamination going into the lake, one would expect you are reducing the contamination in the lake and fish therein, so you have a reduction. But your questions are do I know for sure what would happen. I don't.

So in general, if you remove the source of contaminants, you would expect reductions to

occur. But I don't know precisely if that indeed will happen.

Q Well, Doctor, do you know whether the PCBs in the North Ditch do in fact contaminate anything that humans come in contact with?

A If they reach, if the contaminants reach Lake Michigan and are absorbed into the food chain and into the fish, then the answer would be yes.

Q Do you know for a fact that the PCBs allegedly moving from the North Ditch and into Lake Michigan are in fact being absorbed -- taken out by the fish?

A I would expect it would be behaving like any contaminants entering the lake. That is entirely possible and probable.

Q Well, then, what effect has that process had on the PCB levels in Lake Michigan fish?

A I don't know precisely.

Q Doctor, I want you to assume that the North Ditch is dredged; and assume further that the dredging of the North Ditch will have no significant effect on the PCBs in Lake Michigan. I take it you would not expect any benefits to human

health from the dredging of the North Ditch?

A Given the two assumptions that you just stated?

Q That is correct.

A I would agree with that then.

Q I take it the reason you agree with that is because the dredging would not have any effect on the PCBs ingested by humans eating Lake Michigan fish?

A That was one of the assumptions that you stated, and if that's to be assumed in the hypothesis, then the answer is yes.

Q That was your inference from my assumption that the dredging of the North Ditch will have no significant effect on the level of PCBs in Lake Michigan fish, is that correct?

A In both the hypotheses --

Q Is that correct?

A Yes. Both your hypotheses for the harbor and the ditch, you gave two assumptions, given those, my response stands.

MR. FEATHERSTONE: Would you give me a second?

(A short recess was had.)

MR. FEATHERSTONE: I think this is as good a place as any to stop for the day.

(The deposition was recessed to August 13, 1981, at the hour of 10:30 a.m.)

Curriculum Vitae

Harold E. B. Humphrey, Ph.D.
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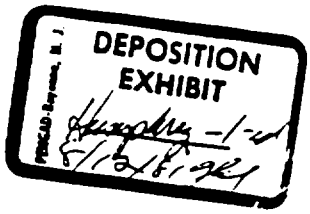


Personal:

Born August 5, 1940, Lansing, Michigan
Married, two children

Employment History:

Michigan Department of Public Health, Science Liaison Coordinator and Assistant Chief, Division of Environmental Epidemiology	Present
Michigan Department of Public Health, Assistant Chief, Division of Environmental Epidemiology & Director of Field Studies	1975-1978
Michigan Department of Public Health, Environmental Epidemiologist, Bureau of Community Health	1971-1
Michigan State University, Assistant Professor	1970-1971
Executive Office, Science Advisor, Council for Environmental Quality	1969-1970
Michigan State University, Assistant Professor	1968-1969

Education:

Michigan State University, Microbiology and Public Health	Ph.D.	1970
University of Michigan, Microbiology & Biochemistry	M.S.	1965
University of Michigan, Biology & General Science	B.S.	1962

Professional Affiliations:

American Society for Microbiology
American Association for the Advancement of Science
American Chemical Society, Division Environmental Chemistry
International Association for Great Lakes Research
Sigma Xi Honorary Society
American Public Health Association

Honors and Distinctions:

University of Michigan Regents Alumni Scholarship, 1958-62
American Society for Microbiology President's Fellowship, 1966
Elected to Sigma Xi Science Honorary Society, 1968
Selected as a U.S. representative to the NATO Workshop on Ecotoxicology, Surrey, England, 1977
Selected as U.S. representative to the International Joint Commission Science Advisory Board 1981
Cited in American Men and Women of Science and in Who's Who in Amercia
Founder and Director, Keimik Corporation, 1971-
Cited in the United Nations World Environment Center Guide to Specialists on Toxic Substances

Harold E. B. Humphrey, Ph.D.

Consultantships and Appointments:

Governor's Science & Technology Advisory Commission, 1976-
Governor's Nuclear Waste Disposal Taskforce, 1976-77
International Joint Commission Science Advisory Board, 1981-
International Joint Commission Health Effects Committee, 1975-
Michigan Environmental Review Board, 1974-
Chemicals and Health Center, Department of Public Health, 1978-
Interagency Clearinghouse for the Health Impact of Pollutants, 1973-78
Interagency Hazardous Waste Disposal Committee, 1973-78
Great Lakes Environmental Contaminants Survey Committee, 1973-80
Fish Contaminants Advisory Committee, 1981-
Liaison with Providence of Ontario - Fish Contaminants, 1980-
Liaison with Center for Disease Control - Chemical Problems, 1978-
American Public Health Association consultant on toxic substances, 1980-
Affiliate, Michigan State University Toxicology Center, 1981-
Adjunct faculty appointments Michigan State University, 1973-76
Research Review Committee, Michigan Department of Public Health, 1980-

Major Responsibilities:

Establish and maintain contact with the scientific community with respect to environmental and chemical contamination problems. Participate in problem definition and government policy development. Design and direct investigations which evaluate the human health impact of exposure to toxic substances. Participate in the administration of a division within a state government agency.

Director, Evaluation of Humans Exposed to Mercury Contaminated Fish. 1971-73, state funded.
Director, Evaluation of Changes of the Level of Polychlorinated Biphenyls in Human Tissues. 1973-75, FDA contract, $50,000.
Director, A Study of the Human Health Consequences of Polybrominated Biphenyl Contamination of Farms in Michigan. 1976-present, HEW contract $2.5 million to date.
Principle Investigator Director, Evaluation of Humans Exposed to Water Borne Chemicals in the Great Lakes. 1979-82, EPA Grant $1.05 million.
Project Officer, Iowa Comparison for the Study of Human PBB Exposure. 1977-present, $305,000 to date.

Special Training:

International Symposium on Livestock Wastes and Pollution Abatement, Ohio State University, 1971.
Water Pollution Control Fundamentals Course, Washington University, 1972.
Advanced Training Course on Pesticides and Public Health, EPA, Atlanta, Georgia, 1972.
Applied Statistics Training Course, National Center for Health Statistics Institute, Ann Arbor, Michigan, 1972.
Graduate business administration course work in law, marketing, management and organization.

Harold E.B. Humphrey, Ph.D.

Community Activities and Recreation:

Phi Sigma Kappa fraternity, Officer
U of M campus carnival parade committee Co-Chairman
Episcopal Church Youth Group Advisor
City of East Lansing Recreation Commission, Chairman

Great Lakes sailing, woodwork, auto mechanics and home decorating

References:

Jerry B. Hook, Ph.D., Center for Environmental Toxicology, Michigan State University, East Lansing, Michigan 48824, (517) 353-6469
Frank R. Bacon, Jr., Ph.D., Professor of Business Administration, Michigan State University, East Lansing, Michigan 48824, (517) 351-4357
Daniel E. Williams, M.D., Medical Consultant, Michigan Department of Public Health, Division of Environmental Epidemiology, 3500 North Logan, Lansing, Michigan 48933, (517) 373-2037
George C. Becking, Ph.D., Chief, Environmental Toxicology Division Health Protection Branch, Health and Welfare Canada, Ottawa, Ontario K1A062, (613) 992-5250
Alvin L. VanderKolk, M.S., Deputy Chief, Bureau of Environmental and Occupational Health, Michigan Department of Public Health, 3500 North Logan, Lansing, Michigan 48933, (517) 373-1410

Harold E. B. Humphrey, Ph.D.

Professional Publications:

"Liquid Purifying Process," U.S. patent #3,928,195 issued 1975, a new chemical method for separation of solids from liquid suspensions

"Environmental Quality in Michigan," a technical publication prepared for the Executive Office, State of Michigan, 1970

"Mercury Concentrations in Humans and Consumption of Fish Containing Methylmercury," Harold E. B. Humphrey, Heavy Metals in the Environment, International Symposium Proceedings in Progess in Water Technology 7, 33, 1974

"Polybrominated Biphenyls: An Agricultural Incident and Its Consequences, An Epidemiological Investigation of Human Exposure." H. Humphrey and N. Hayner. Trace Substances in Environmental Health. 9, 57-63, 1976

"Evaluation of Changes of the Level of Polychlorinated Biphenyls in Human Tissues," Final Project Report, 1976

"Polybrominated Biphenyl Exposure - Michigan." M. Budd, N. Hayner, H. Humphrey, J. Isbister, H. Price, M. Reizen, G. VanAmburg, K. Wilcox. Morbidity and Mortality Weekly Report. 27, 14, 115-116, 1978

"Breast Milk Monitoring to Measure Michigan's Contamination with Polybrominated Biphenyls." L. Brilliant, G. VanAmburg, J. Isbister, H. Humphrey, K. Wilcox, J. Eyster, A. Bloomer, H. Price. The Lancet 2, 8091, 643-646, 1978

"Cohort Study of Michigan Residents Exposed to Polybrominated Biphenyls: Epidemiological and Immunological Findings." P. Landrigan, K. Wilcox, J. Silva, H. Humphrey, C. Kauffman, C. Heath. Annals New York Academy of Science 320, 284-94, 1979

"Cohort Study of Michigan Residents Exposed to Polybrominated Biphenyls." H. Humphrey, Proceedings VII International Congress of Rural Medicine, September 17-21, 1978

"Lymphocyte Function in Humans Exposed to Polybrominated Biphenyls." J. Silva, C. Kauffman, D. Simon, P. Landrigan, H. Humphrey, C. Heath, K. Wilcox, R. Kaslow, A. Ringle, and K. Hoff. J. Reticuloendothelial Society 26, 341-47, 1979

Harold E. B. Humphrey, Ph.D.

Professional Presentations:

"Performance Characteristics of a Prototype Biodialyzer," 152nd National Meeting of the American Chemical Society, Chicago, Illinois 1962

"Dialysis Culture," 69th Annual Meeting American Society for Microbiology, Miami, Florida 1969

"Dialysis Aeration of Microbial Cultures," 69th Annual Meeting American Society for Microbiology, Miami, Florida 1969

"Ecology Factors and Human Health," University of Michigan School of Public Health Alumni Days keynote speaker, Ann Arbor, Michigan 1972

"Evaluation of Humans Exposed to Mercury Contaminated Fish," International Symposium on Heavy Metals in the Environment, Vanderbilt University 1973

"Polybrominated Biphenyls: An Agricultural Incident and Its Consequences, An Epidemiological Investigation of Human Exposure," 9th Annual Conference on Trace Substances, University of Missouri, 1976

"Mercury Studies in Michigan," 4th Invitational Symposium of the Interuniversity Consortium for Environmental Studies, University of North Carolina 1977

"Environmental Epidemiology; A Means of Addressing Environmental Problems," Society of Epidemiological Research, University of Iowa 1978

"Cohort Study of Michigan Residents Exposed to Polybrominated Biphenyls," VII International Congress of Rural Medicine, Salt Lake City, Utah 1978

"Health Status of Persons Exposed to Polybrominated Biphenyl," 18th Annual Meeting of the Society of Toxicology, New Orleans 1979

X "Evaluation of Polychlorinated Biphenyl in Humans Exposed to Contaminated Fish," 19th Annual Meeting of the Society of Toxicology, Washington, D.C. 1980

"The Epidemiology and Pharmacokinetics of PBB in Humans," Methods to Enhance the Excretion of PBB Workshop, Michigan State University 1980

X "Evaluation of Humans Exposed to Halogenated Biphenyls," Symposium on Ecological and Health Effects of Chlorinated Hydrocarbons, American Chemical Society, San Francisco 1980

X "Surveys of PCB Residues in Humans," Central States Association of Food & Drug Officials, Spring meeting, Grand Rapids 1981

X "Human Health Effect Evaluations - Toxicology's Bottom Line," Toxicology in Michigan Today Symposium, Michigan State University 1981

X "Epidemiologic Studies of Humans Exposed to Chemical Contaminants," International Symposium on Environmental Pollution, Miami 1981

"Epidemiologic Studies of Humans Exposed to Halogenated Bipnenyls", Symposium on Assessment of Health Effects at Chemical Disposal Sites. Rockefeller University, 1981.

Harold E. B. Humphrey, Ph.D.

Invited Participations:

Interuniversity Consortium for Environmental Studies, University North Carolina Chapel Hill 1972

Michigan United Conservation Clubs Directors Conference Panel on Spray Irrigation of Wastewater, Lansing, Michigan 1974

Michigan State Medical Society Presentation on Environmental Epidemiology 1974

Michigan State University Dairy Science Faculty Seminar speaker, East Lansing 1975

Wisconsin Food & Fishery Seminar on PCB, Sturgeon Bay, Wisconsin 1976

Northern Regional Public Health Conference speaker, Midland, Michigan 1976

Ingham County Republicans Open Forum speaker, Lansing, Michigan 1977

University of Michigan School of Public Health Seminar on PBB, Ann Arbor 1977

Michigan State University Department of Toxicology and Pharmacology lectures, 1978 1979

American Association of University Women, Program Panel speaker 1978

Michigan Sea Grant Coastal resource Program speaker, East Lansing 1979

Michigan State University Resource Ecology and Man lecture, East Lansing 1979

Governor's Conference on the Impact of Science and Technology on the Quality of Life in Michigan. Program moderator, Detroit, Michigan 1979

Great Lakes Basin Commission Workshop on the scientific basis for dealing with toxic substances in the Great Lakes speaker, Milwaukee, Wisconsin 1979

PIRGIM Seminar on Hazardous Substances speaker, Ann Arbor 1980

Great Lakes Basin Commission Conference on Research Needs panelist, Ann Arbor 1980

American College of Physicians Regional Conference speaker, Traverse City 1980

National Oceanic and Atmospheric Administration Great Lakes Pollution Monitoring Workshops, Traverse City 1980 and Ann Arbor 1981

International Joint Commission, workshop on the Compatibility of Great Lakes Basin Cancer Registries. Participant, Windsor, Ontario 1981

Michigan State University Symposium on Toxicology in Michigan Today. Speaker, East Lansing 1981

Central States Association of Food & Drug Officials Spring meeting. Speaker, Grand Rapids 1981

Rockefeller University Symposium on Evaluation of Chemical Disposal Sites. Speaker, New York City 1981

EVALUATION OF CHANGES OF THE LEVEL OF POLYCHLORINATED BIPHENYLS (PCB) IN HUMAN TISSUE

Final Report on FDA Contract 223-73-2206

Michigan Department of Public Health
Lansing, Michigan

Harold E. B. Humphrey, Ph.D.
Project Director
1-517-373-2037

DEPOSITION EXHIBIT
Humphrey 2nd
5/27/81 218

MICHIGAN DEPARTMENT OF PUBLIC HEALTH

DIVISION OF ENVIRONMENTAL EPIDEMIOLOGY

"EVALUATION OF HUMANS EXPOSED TO WATER BORNE CHEMICALS IN THE GREAT LAKES"

ENVIRONMENTAL PROTECTION AGENCY FUNDED RESEARCH GRANT

DEPOSITION EXHIBIT
Humphrey-3
8/13/81 GLS

Dr. Harold E. C. Humphrey
Project Director

EVALUATION OF CHANGES OF THE LEVEL OF POLYCHLORINATED BIPHENYLS (PCB) IN HUMAN TISSUE

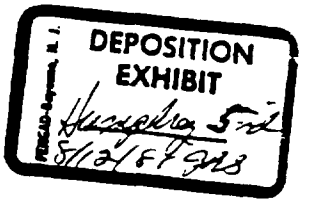
Final Report on FDA Contract 223-73-2209

Michigan Department of Public Health
Lansing, Michigan

Harold E. B. Humphrey, Ph.D.
Project Director

DEPOSITION EXHIBIT
Humphrey-4
8/13/81

PCB's in Great Lakes Fish



Prepared by: The Michigan Department of Public Health
Division of Environmental Epidemiology

The aquatic environment of the Great Lakes basin has long been a sink for chemical contamination as a result of terrestrial activities. Various chemical compounds, including PCB's and DDT, which degrade slowly and are lipophilic in nature, have been detected in most compartments of the lakes' environment. Annual testing of fish indicates that DDT levels are dropping at a rate faster than expected, however, unlike DDT, the PCB levels in the lake environment have only slowly declined since their initial detection in fish in the late 1960's. Because of their persistence in the environment, their bioaccumulation in fish, resulting in significant levels depending on species, size, and age, and continued deposition into the Great Lakes, the presence of PCB's in fish will continue for some time.

To consider the PCB problem an interagency committee was formed. Three questions regarding PCB contamination of fish were addressed:

1. What are the current levels of PCB's in fish?
2. What legal remedies are available for protection of the public?
3. What is the significance of PCB's from the human health perspective?

These topics were discussed as follows:

1. <u>What are the current levels of PCB's in fish?</u>

Since 1973, the Great Lakes Environmental Contaminants Survey (GLECS) has provided data on the levels of PCB's and other chemical contaminants, in various species of Great Lakes fish. Unfortunately, the most recent data from the survey is for 1977 and although laboratory tests of more recent fish collections are in progress, no complete report has, as yet, been released. The U.S. Fish and Wildlife Service (USFWS) also provided data on chemical contaminants in fish from 1972 to 1976. Applying trend-line analysis to this data, 1981 levels of PCB's would be approximately 7.4 ppm in coho and 8.7 ppm in lake trout, which are both above the current and proposed FDA guidelines for commercial sale of fish. Assuming the rate of decline in PCB levels remains constant, it would not be until 1986 for the PCB levels in coho and 1982 for the PCB levels in lake trout to drop below the

current 5 ppm FDA tolerance and not until 1992 for coho and 1984 for lake trout would PCB levels drop below the proposed FDA standard of 2 ppm.

2. What legal remedies are available for protection of the public?

For a number of years the Michigan Department of Public Health has published advisories concerning consumption of fish from Michigan waters including the Great Lakes. The public is informed of these advisories through media attention and the fishing guide provided to licensed fishermen. Unfortunately, the update and revision of these advisories are dependent upon fish monitoring reports which, as discussed above, have been unavailable in recent years. It is essential that this fish monitoring data be finalized and released and that support be provided to allow the GLECS monitoring program to continue at a reasonable pace.

Control of commercially available fish in Michigan is a responsibility of the Michigan Department of Agriculture (MDA) which historically enforces guidelines established by the FDA. Although the FDA has established a PCB tolerance for fish of 5 ppm, individual states are able to establish and enforce their own more stringent standards. Thus, the MDA can establish a standard by requesting enactment of a law or by proposing enforcement rules. The former process was accomplished for PBB in October 1977 for which a Michigan standard was established at a level lower than that set by FDA for commercial sale of red meats, poultry, whole milk, and feed.

The extent of protection provided by a lower standard is questionable in view of the fact that 1978 data from the U.S. Department of Commerce indicates that the annual per capita consumption of commercial fish and shellfish is only 13.4 pounds and that commercial catches of Great Lakes fish has been a declining enterprise over the past decade. However, in contrast, a 1974 study by the Michigan Department

of Public Health revealed that Michigan sport fishermen caught and consumed approximately 32 pounds of Great Lakes fish per year with some individuals exceeding 250 pounds per year. Thus, in terms of protection, it should be understood that although a lower Michigan standard for commercial sale of fish would provide some additional protection to the general public, it would not effect the hundreds of thousands of sport fishermen exposed to much greater amounts of PCB's.

3. What is the significance of PCB's from the human health perspective?

PCB's are a mixture of chlorinated biphenyls. Although this material has been in use for years and has consequently become a world-wide contaminant, the toxicology of the individual PCB congeners and their metabolites is still not fully understood.

The nature of this material, a mixture, complicates research as human exposure does not normally occur to pure compounds. Nevertheless, research over the past decade has indicated clearly that some PCB congeners are not biologically inert and are metabolized by the body into intermediate compounds which display a variety of toxicities in laboratory animals. Recent epidemiologic studies have also provided evidence of a correlation between PCB exposure and elevated blood pressure, diminished lung function, arthritis, and elevated levels of certain liver enzymes.

As our state of knowledge on PCB's advances, it has become clear that exposure to a mixture of compounds of this nature should be avoided where possible.

The FDA established the 5 ppm guideline based on information available at that time which consisted mainly of studies of short-term exposure accidents such as the Japanese Yusho incident. Based on these studies, it was determined that a 5 ppm guideline provided a sufficient margin of protection and that daily consumption of 5 ppm PCB's would prevent citizens from exceeding the 1 ug/kg/day maximum allowable dose believed tolerable for long-term exposure. However, data generated since that time has indicated that PCB exposure is a continuous phenomenon, that

PCB's may gradually accumulate in body tissues, and that the maximum daily dose for long-term exposure is exceeded by persons who regularly consume contaminated fish. Through human studies performed in Michigan, it has been shown that the "margin of safety" provided by the 5 ppm guideline is uncomfortably small and insufficient for certain population groups. Furthermore, various animal studies have shown PCB's to be animal carcinogens and, therefore, potential human carcinogens.

Calculations of the FDA risk assessment was performed using these animal data as human data sufficient for use in the mathematical extrapolation model (described below) were unavailable. There are several difficulties in extrapolating from animal data to humans. First of all and most importantly is the assumption that no metabolic or kinetic differences exist between the test animals and humans. Secondly, as only a limited number of animals are used in these studies, (usually no more than 100 per dose), large doses of the test substance are administered to increase the likelihood of eliciting a detectable toxic response. Unfortunately, human exposure levels to environmental contaminants seldom fall in this dose range but rather well below it thus necessitating the use of statistical extrapolation for determination of response. This is further complicated by the fact that there are an infinite number of paths the dose-response curve can follow as it approaches zero dose.

The FDA utilized the conservative linear single hit extrapolation model which of all the models is least likely to underestimate the risk. Due to several built-in conservative factors, this model was not designed to estimate actual risk but rather to estimate the upper bounds of risk.

Selection of appropriate animal data to use in the linear extrapolation model is difficult for PCB's as there are no toxicity studies performed with residues that actually occur in fish. Environmental transformation results i PCB residues in fish that are different in chemical composition than industri PCB products, the latter of which are used in laboratory studies. As residue for Aroclor 1254 most closely resemble the PCB residue in fish, most PCB toxi studies were performed with this product.

For the FDA risk assessment, two studies were selected, 1) the NCI bioa of Aroclor 1254 fed to male and female rats at 25, 50, or 100 ppm for 104-105 weeks and 2) a study by Kimbrough with female rats fed Aroclor 1260 for 21-22 months.

Based on these studies and the exposure data listed in Table 1, the upper confidence limits (99%) on lifetime risks for cancer are presented in Table 2. In addition to the 50th and 90th percentile eaters, the lifetime risks for consumers of sports-fish in Lake Michigan is also presented under the 90th percentile column. Risks were estimated for tolerances of 5,2,1 ppm, and no tolerance using both Kimbrough and NCI data. The NCI data was divided f her into risks for total malignancies for males plus females, liver carcinomas d adenomas for males plus females, and on hematopietic in males plus females. T risks for sports fishermen were calculated assuming no tolerance as they would be unrestricted by any tolerance.

Although the accuracy of these numbers to estimating actual risk is unkno the relative effects of exposure reduction can be seen from the data presented in Table 2. Assuming that risk is evenly distributed over a 70 year average lifetime, a tolerance of 5 ppm, 2 ppm, and 1 ppm would reduce cancer risk 8-10% 32-58%, and 55-61%, respectively, from the cancer risk involved with no toleran

Sports fishermen would have a 12-14 fold increased risk compared to the general population.

Conclusions:

It is the consensus of the committee that the logic behind the FDA's desire to reduce exposure to PCB through a more strict standard is sound. PCB's are a toxic mixture of chemicals which accumulate in human tissues. Their long-term human health effects are unknown, therefore, the possible consequences of this exposure are not fully known. For these reasons, attempts to reduce exposure above an unavoidable background are prudent.

Although commercial food guidelines do not restrict sport fishermen who catch, clean and cook fish on their own, this group tends to be more aware of the condition of the fish they seek and more knowledgeable of methods to reduce exposure through proper cooking and cleaning procedures. It is vital that these people be kept informed and up-to-date on the condition of the fish and advisories concerning consumption.

The current public health advisory which emphasizes reduced annual consumption of certain species and recommends that women in the reproductive phase of their lives and children avoid such fish is proper. This advisory should receive greater publicity and should be re-issued annually. Correspondingly, current surveillance data necessary to formulate the advisory should be available so that the information provided to the citizens of Michigan is as accurate as possible.

The question of setting a special state standard for PCB is one which involves social and econonic considerations. To choose a number and adopt it is the prerogative and responsibility of the legislature and executive branch.

Everyone is exposed to small amounts of PCB's in the air, water, and soil. These exposure routes are unavoidable and in most instances, uncontrollable. Consumption of contaminated fish, on the other hand, represents the greatest source of PCB exposure to the average citizen and is avoidable and controllable. A strict standard for PCB's in fish is a necessary and correct mechanism for reducing exposure and reducing the risk of potential human health effects.

Table 1 Intake of PCB's from Fish for Eaters of Species of Interest[1]

	Assuming[2] No Tolerance	Assuming Tolerance = 5 ppm	Assuming Tolerance = 2 ppm	Assuming Tolerance = 1 ppm
Intake at 50th percentile -				
µg per day	8.46	7.57	5.59	3.30
PPM of diet[3]	.0056	.0051	.0037	.0022
µg per kilogram of body weight	.12	.11	.08	.05
Intake at 90th percentile -				
µg per day	22.1	20.1	14.9	9.22
PPM of diet	.0147	.0135	.0099	.0061
µg per kilogram of body weight	.32	.29	.21	.13

1 Taken from FDA publication entitled, "An Assessment of Risk Associated with the Human Consumption of some species of Fish Contaminated with Polychlorinated Biphenyls (PCB's)

2 For assumed tolerances, PCB values exceeding the tolerance were eliminated

3 Assumed 1500 grams daily intake

Table 2 Upper Confidence Limits (99%) on Lifetime Risks of Cancer in Eaters of Fish Special of Interest[1]

Animal Studies on which risks are based	50th Percentile Eaters					90th Percentile Eaters				
	Assuming No Tolerance	Lake[3] Michigan USA	Assuming Tolerance = 5 ppm	Assuming Tolerance = 2 ppm	Assuming Tolerance = 1 ppm	Assuming No Tolerance	Lake[3] Michigan USA	Assuming Tolerance = 5 ppm	Assuming Tolerance = 2 ppm	Assuming Tolerance = 1 ppm
Kimbrough - Rats Liver Carcinoma	1.3[2]	18.4	1.2	0.8	0.5	3.4	41.4	3.1	2.3	1.4
NCI Bioassy - Total Malignancies for Male & Female	4.1	58.0	3.7	2.7	1.6	10.6	129.2	9.8	7.2	4.4
NCI Bioassay - Liver Carcinoma & Adenomas for Male & Female	0.9	12.75	0.9	0.6	0.4	2.5	30.5	2.3	1.7	1.0
NCI Bioassay Hematopietic for Male & Female	2.7	38.25	2.4	1.8	1.1	7.0	85.3	6.5	4.7	2.9

1 Taken from FDA publication cited in Table 1.

2 All risks are lifetime risks computed as rates per 100,000 of the population at risk.

3 Risk calculated for Lake Michigan sports-fish eaters who consume an average of 1.7 μg/kg/day PCB or 3.9 μg/kg/day at the 90th percentile. Risks in other areas having similar sports-fish consumption and PCB contamination are probably similar.

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REMARKS

A couple of weeks ago I mentioned a study of fish consumption and human PCB levels. This is a report of the study. The final report is to be completed "within a month".

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CHAPTER 21

POPULATION STUDIES OF PCBs IN MICHIGAN RESIDENTS

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INTRODUCTION

Between 1929 and 1977, about 1.4 billion pounds of polychlorinated biphenyls (PCBs) were produced in this country. Although U.S. production of the chemical has ceased, it is estimated that 750 million pounds are still in service (Miller, 1982). The rest has been exported, destroyed, buried, or lost to the environment. Acknowledgment that PCB is a worldwide pollutant serves as proof that past and potential future losses to the environment are not insignificant.

The Great Lakes present a unique situation for long lived contaminants which can bioaccumulate in living organisms. Our lakes act as reservoirs for atmospheric and terrestrial pollutants such as PCB. The relatively slow turnover and removal of contaminants plus biomagnification in the food chain make the aquatic environment of the Great Lakes a potential source for significant human exposure.

PCB has been shown to be toxic in animals, has a long half-life in mammals, and is present in our environment. Most humans are unavoidably exposed to small quantities of this chemical during their lives. It is not certain whether or not contact with additional sources constitutes an increase in exposure which will produce disease or degraded human health. It is of scientific and public interest to define whether such exposure in the Great Lakes basin has the potential for impact on the population using this resource.

At the Michigan Department of Public Health, we are conducting several cohort studies which examine the extent of

human exposure to chemical contaminants. We are attempting to define whether or not possible negative health effects have occurred or may appear as a result of such exposure. In this presentation, I will draw on data collected from our long-term polybrominated biphenyl (PBB) study of farmers from Michigan and Iowa (Landrigan et al., 1979), a long-term study of families exposed to farm products contaminated by PCB's from silos, the 1974 evaluation of Great Lakes fishermen (Humphrey, 1976), and our on-going study of persons who consume Great Lakes fish. Human specimens tested in these studies will demonstrate levels of exposure, and evaluation of interview and medical data collected from participants will document the occurrence of health events in these cohorts.

HUMAN EXPOSURE ASSESSMENT

Human breast milk has been reported to be a good predictor of exposure to fat soluble chemicals (Brilliant et al., 1978). The data shown in Table 1 indicate that PCBs are frequently found in women nationally and always found in women residing in Michigan. Monitoring of the general population indicates that most people receive a background exposure to this ubiquitous chemical contaminant. It is of interest to note that persons exposed to additional known sources of PCB receive significantly greater exposures. The consumption of contaminated fish from the Great Lakes or food from a farm with a PCB coated silo appear to significantly increase contaminant levels in breast milk.

The extent of PCB exposure can also be demonstrated by evaluation of serum specimens from population groups. The lower fat content of blood makes this a less sensitive specimen than breast milk for detecting small exposures to fat soluble chemicals. However, if exposure has been sufficient or long standing as in the case of PCB, circulating levels provide a convenient method for establishing exposure in cohorts. In addition, detection of PCB in blood gives an indication of the level at which the internal organs of the body are exposed to the circulating contaminant. Table 2 shows the range and median levels of PCB found in sera from the four cohorts which we have under evaluation. The data again demonstrate that PCB is commonly found in American citizens at low levels (Michigan and Iowa farmers with median values of between 5 and 6 ug/kg), and at significantly greater levels in persons who consume food which has been shown to be contaminated with PCBs (fish eaters and silo farm families with median values of 56 and 28 ug/kg, respectively). It can be concluded that consumption of Great Lakes fish represents a convenient and substantial way to increase human exposure to PCB.

TABLE 1

PCB in Mothers Milk

Study	Number of Women	PCB (Fat Basis) Concentration (mg/kg) Detectable (percent)	Median	Range
1975 National	1,038	69	--	--
1977-78 Serv. Testing	1,057	100	1.35	0.3 - 5.1
1976 Random Survey	95	100	0.82	0.1 - 3.3
1980-81 HDET Study	120	100	0.96[a]	0.2 - 3.0
1974 Fish Eater 12.73 kg/yr	1	--	4.0	--
Silo Daughter	1	--	13.0	--

[a]Mean

TABLE 2

PCB Levels Found in Humans

Group	Sample	Number of People	Range (ug/kg)	Median (ug/kg)
Iowa Farmers	Sera	803	5-50	5
Michigan Farmers	Sera	1,631	ND-57	6
Silo Farmers	Sera	149	5-300	28
Fish Eaters	Sera	90	25-366	56

ND = Detection limit of <5 ug/kg

Contaminants from environmental sources would be less of a problem if the chemical was quickly excreted from the body and did not accumulate in fat stores. However, for fat soluble chemicals, this is not the case. Because of its long half-life, many small exposures to PCB result in a gradual increase in body burden. The long-term study of over 4,000 Michigan farmers who have had no extraordinary exposure to sources of PCB has shown that serum PCB levels gradually rise with age (Kreiss et al., 1982). This indicates that unavoidable background exposure results in small but significant increases in human body burden over a lifetime. Additional sources of exposure will add to this background body burden, and such additions will also be retained for long periods of time.

EVALUATION OF PERSONS EATING GREAT LAKES FISH

In his talk earlier today, Dr. Swain indicated that cooked Great Lakes fish provide a significantly greater potential dose of PCB than that provided from water and atmospheric sources combined. Table 3 presents these estimates and shows that habitual fish consumption could provide a dose 4,300 times that estimated from background environmental sources.

Our interest in evaluating the significance of this source of human exposure to PCB led to our 1974 study of 178 persons who consume Great Lakes fish (Humphrey, 1976). This investigation showed that persons from four communities who ate greater than 10.91 kg of fish per year had serum PCB levels which were significantly greater than people from the same communities who rarely ate such fish (Table 4). The contrast in serum PCB levels between groups who never eat fish, rarely

TABLE 3

Comparison of Non-Occupational Sources of PCB Exposure

Estimated Human Exposure	Exposure Source
7.8 ug/yr	Ambient air at 1.9 ng/m^3 air level PCB
2.9 ug/yr	Drinking water at 4 ng/l raw water PCB
46.5 mg/yr	Cooked Lake Michigan fish at 0.4 to 5.4 ug/kg PCB

TABLE 4

Median Serum PCB Values for Persons From Michigan Communities in 1973

City	Median Serum PCB (ug/kg) Comparison (0-2.73 kg/yr)	Median Serum PCB (ug/kg) Exposed (>10.91 kg/yr)
Traverse City	13	41
Manistee	23	105
Ludington	15	62
South Haven	22	48

TABLE 5

Relationship Between Fish Consumption by Geographical Location and Human Serum PCB Levels

Source of Fish	Consumption (kg)	Number of People	Serum PCB (ug/kg) Range	Serum PCB (ug/kg) Mean	Serum PCB (ug/kg) Median
—	0	29	ND-41	17.3	15
Lake Michigan	0-2.73	39	ND-41	18.5	20
Lake Michigan	10.91-118	90	25-366	72.7	56
Lake St. Clair	5-66.8	15	ND-38	19.4	17

ND = Detection limit of <5 ug/kg

eat fish, eat more than 10.91 kg/yr of contaminated Lake Michigan fish, and eat uncontaminated fish from Lake St. Clair is shown in Table 5. The study documented a direct relationship between consumption of contaminated fish and elevated serum PCB

fish consumption. Consumption for the "exposed" group ranged from 10.91 kg/yr (an average of about one fish meal per week) to as much as 118 kg/yr. Human blood levels correspondingly ranged from the limit of detection (<5 ug/kg) to a high of 366 ug/kg. When the exposed group was sorted according to the length of time participants had actively been catching and eating Great Lakes fish, it was found that those who habitually ate fish over the longest period of time had greater serum PCB levels than those who had eaten fish for shorter periods (Table 6).

The 1974 study confirmed that contaminated Great Lakes fish are a source of exposure which contributes to elevated human PCB levels which are significantly greater than background. In addition, the absence of a reduction in PCB levels in the exposed group between fishing seasons when no fish were consumed, and the correlation between the number of years of fish consumption and PCB levels supports the contention that PCB exposure from this source, if sustained, may result in a continuing accumulation of PCB which is retained over time.

The evaluation of human exposure to Great Lakes fish is continuing through a follow-up study currently in progress. In addition to re-evaluation of the participants in the 1974 study, the current work has expanded the cohort to include over 600 persons from 12 communities who eat 10.91 or more kg of Lake Michigan fish per year. An equal number of persons who do not consume fish are being randomly selected and matched for

TABLE 6

Relationship Between Serum PCB Levels and Number of Years of Fish Consumption

Number of Years Fish Eaten	Number of People	Serum PCB (ug/kg)		
		Range	Mean	Median
1-3	9	ND-90	48.9	48
4-6	33	ND-164	56.1	45
7-17	9	15-261	79.8	61
≥ 20	41	12-366	87.1	64

ND = Detection limit of <5 ug/kg

comparison. This study when finished will provide data on human levels of PCB and 10 other contaminants, 1980-82 fish consumption patterns, regional differences in serum and cooked fish contaminant levels, and comparison to findings from the earlier study. Preliminary data from 1980 on part of the original 1974 cohort show that these people ate less fish in 1980 than they did in 1974 (Table 7). The decline in number of meals and pounds of fish eaten in combination with the general reduction in contaminant levels in Lake Michigan fish reported earlier in this conference appear to have contributed to a decline in serum PCB levels (median of 56 ug/kg in 1974 versus median of 48 ug/kg in 1980). Although these results are encouraging, it should be noted that the range of serum values remains similar to that observed in 1974; many individuals continue to eat large quantities of fish (up to 84 kg/yr in 1980), and the association between consumption of fish and significantly elevated serum PCB levels remains unchanged. Further analysis of the species of fish eaten is also necessary before the data in Table 7 can be confirmed as a real trend or artifact. This evaluation is underway.

EVALUATION OF PCB SILO FARM FAMILIES

Tables 1 and 2 show that persons from farms with silos coated on the interior with a sealant containing PCB are a second group who have received significant non-occupational exposure to PCB. We have had the opportunity to include some of these farm families in our long-term study of PBB exposure. Blood collected from 183 people (60 families) indicated a PCB concentration range nearly equal to that of the fish eater group

TABLE 7

Comparison of Fish Consumption and Serum PCB Levels, 1974 Versus 1980

Persons Consuming >10.91 kg of Fish/Yr	Median Values for Study Year	
	1974	1980
Number of Meals/Yr	60	39
Kilograms of Fish/Yr	14.55	9.55
Serum PCB (ug/kg)	56	48

and a median serum PCB value (28 ug/kg) which is nearly five times that expected in the general population. Farm family exposure to PCB occurred when the sealant peeled off the silo walls over the years and contaminated the silage eaten by the farm animals. Those families who regularly ate dairy products and beef directly from their own farm unknowingly consumed PCB contaminated food. Because of the relatively small number of farms involved, the domestic food supply for the general public is not believed to have been adversely affected. For the farm families, this situation represents a continuous daily exposure of long duration which contrasts with exposure from fish which is intermittent in nature. Contamination of farm food is presumed to have occurred over many years, possibly greater than twenty since some of the silos which were constructed in the 1940s and 1950s were still in use in the mid-1970s when these families were enrolled. A current survey by the Michigan Department of Agriculture is expected to identify all of the farms in Michigan which have silos contamined by PCBs. Evaluation of persons exposed in this manner is of interest because it provides the opportunity to learn more about the human impact of long-term exposure to PCBs.

HUMAN HEALTH IMPLICATIONS

The cohorts established in Michigan to study persons exposed to halogenated biphenyls constitute the largest such investigation in the country and provide an opportunity to investigate the meaning and significance of such exposure. Specimens from these cohorts have documented the extent of PCB exposure from potential sources of concern. Interview and medical record data which record actual human experiences have been evaluated in an attempt to determine whether or not there is a relationship between symptoms and diseases of toxicological importance and body burden. The difficulty in such an evaluation lies in quantifying subtle or delayed physiological changes in humans which would indicate the presence of a toxic reaction or disease attributable to exposure as predicted from animal experiments. Environmental exposures are seldom extensive enough to produce easily observable toxic effects. Yet, the long half-life of the halogenated biphenyls results in a continuing internal exposure, the outcome of which has not been fully defined in humans.

The medical histories of study participants were obtained by interview and screened for acute, neurological, dermatological, skeletal, and metabolic disorders or diseases characteristic of those presumed to be caused by chlorinated biphenyl exposure. Those exposed to Great Lakes fish did not in 1974 report health problems or medical conditions which could be

correlated with serum PCB levels or fish consumption. The type and frequency of various medical complaints were similar for exposed and comparison persons. Evaluation of data collected during the current investigation is incomplete at this time. Whether or not the lack of symptomatology is due to insufficient exposure, insufficient time since initiation of exposure, or the lack of sensitivity in detecting slowly emerging toxic effects is undecided at this time. Follow-up studies will help clarify this as time passes and diagnostic techniques improve. It should also be noted that this cohort study was not designed to seek out former fishermen who may no longer be up to the rigors of sport fishing because of medical problems or chronic illness. Instead, it was designed to assess exposure in those currently practicing sport fishing on the Great Lakes.

The silo farm family cohort provides an opportunity to evaluate the outcome of long-term continuous PCB exposure. Medical histories for farmers with PCB contaminated silos were reviewed and compared to those of Iowa farmers and Michigan farmers recently exposed to PBBs.

Comparison of reported symptoms (Table 8) showed that the PCB exposed silo farmers had a greater frequency of joint problems and numbness. To a lesser extent, this was also found among the PBB exposed farmers. These symptoms were found to have weak but positive correlation with serum PCB levels when adjusted for age. Such a correlation was not seen for PBB

TABLE 8

Percent Persons Reporting Health Symptoms

Symptom	Percent of Silo Farmers	Percent of Iowa Farmers	Percent of PBB Farmers
Tiredness	14	3	17
Headaches	10	3	10
Rashes	7	<1	4
Skin Problems	4	1	4
Numbness	19	5	10
Joint Problems	20	6	13
Nausea	5	3	11
Number of People	183	1,636	2,150

levels. Although the subjectivity of reported symptoms makes a firm conclusion difficult, the correlation with PCB exposure is interesting because central nervous system and connective tissue defects are possible outcomes of prolonged PCB exposure.

The occurrence of diseases which have been confirmed by medical records were also compared for the three cohorts and are shown in Table 9. Among the diseases evaluated, the 3.3 percent frequency of cancer in the silo farm family cohort was significantly greater than the occurrence of this disease in the other two farm groups and was greater than the 0.3 percent rate predicted by the national Surveillance, Epidemiology, and End Results Program (SEER) cancer morbidity rates. The cancers found in the silo group were located in a variety of sites and occurred more frequently in females, 6.1 percent than males 1.8 percent. This observation is interesting because PCB is considered to be a promoter (Nobuyuki, 1973), a carcinogen (Kimbrough, 1974, 1975, 1979), and is regarded as a human carcinogen (IARC, 1978). The silo families have possibly received a chronic repeated exposure from their diet on a regular basis for over twenty years. It has been speculated that prolonged exposure to a potential carcinogen with a long half-life could produce continuous target organ exposure which would result in tumor production. The occurrence of disease events in the silo farm group also serves an indication of health events which could possibly occur in fish eaters in the future. However, this data should be treated cautiously at this time. The PCB silo cohort is too small to provide appropriate statistical

TABLE 9

Percent Persons Reporting Disease Conditions

Symptom	Percent of Silo Farmers	Percent of Iowa Farmers	Percent of PBB Farmers
Heart	6	4	4
Hepatitis	1	1	1
Diabetes	3	1	2
Thyroid	2	1	2
Tumor (benign)	6	3	4
Cancer	3.3	0.8	0.4
Number of People	183	1,636	2,150

evaluation of events which are occurring and needs to be enlarged to properly evaluate the PCB/cancer hypothesis. The findings to date do demonstrate a lead which should be pursued with continued and expanded surveillance of persons exposed to PCB in this manner.

In conclusion, our cohort studies have provided data which demonstrates a clear relationship between environmental sources of PCB and increased human exposure. Consumption of contaminated fish or farm products results in elevated PCB levels in humans. No acute disease has been identified in exposed individuals, but the long-term outcome of this added body burden remains to be determined. The data generated to date provide viable leads which should be pursued. The cohorts which we have established in Michigan provide an excellent opportunity to continue evaluation of the significance of halogenated biphenyl exposure in humans.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE UNITED STATES OF AMERICA,	)	
Plaintiff,	)	
-vs-	)	No. 78 C 1004
OUTBOARD MARINE CORPORATION and MONSANTO COMPANY,	)	
Defendants.	)	

The continued deposition of Harold E. B. Humphrey, called by Monsanto Company, resumed pursuant to adjournment, on Thursday, August 13, 1981, at the hour of 10:30 a.m., at the United States Attorney's Office, 219 South Dearborn, 15th Floor Conference Room.

PRESENT:

MR. JAMES P. WHITE,

on behalf of the United States of America;

MS. ROSEANN OLIVER and MS. CAROL DORGE,

on behalf of Outboard Marine Corporation;

MR. BRUCE A. FEATHERSTONE,

on behalf of Monsanto Company.

HAROLD E. B. HUMPHREY,

called as a witness by Monsanto Company, having been previously duly sworn, was examined and testified as follows:

DIRECT EXAMINATION (RESUMED)

BY MR. FEATHERSTONE:

Q I want to ask you a few cleanup questions on the Yusho incident in Japan.

The Japanese medical reports on the Yusho incident you have seen, are those by and large epidemiological studies, the type of work that you do?

A Yes. I am not sure what you mean by "by and large." Yes, there has been an epidemiological study of people exposed in the Yusho.

What I am not sure on is in addition to or in connection with that there have been other ancillary studies, medical-type studies. But yes, there is a major epidemiological study of those people, and this is what it is commonly referred to as.

Q You made reference in Reference No. 7 of your report to an article authored by Kuratsune, in Japan.

A Yes, I did.

Q I take it from the title of that it's epidemiological work?

A Yes, I believe that's correct.

Q Is it your understanding that the work that he has been doing since then has also been in the vein of an epidemiological study?

A It's my understanding that the combination of authors cited in that reference have been conducting a continuing epidemiologic study of the Yusho people.

Q From your review of the literature pertaining to the Yusho incident, I take it you would agree that the report and the tentative conclusions reached by authors have been very fluid. In other words, they have been changing over the years.

A Yes, I think that is a correct perspective, yes.

Q So for instance, the analysis of the contaminants in the rice oil has changed over the years.

A I would prefer to restate that.

The detection of contaminants or the

ability to detect contaminants has changed over the years.

Q That's what my question was searching for. The contaminants reported in the rice oil changed over the years.

A That is my understanding, yes.

Q So have the medical opinions and conclusions that have been reached by the experts studying that situation.

A Well, what do you mean by that?

Q What I mean is that the possible causes of the Yusho poisoning have changed over the years, as the medical experts refine their opinion as to what exactly was in the Yusho rice oil, and in what quantities.

A I think I understand what you mean, but the way you have stated it, I still don't completely agree with you.

Q Tell me how much you agree with.

A You are addressing the question of the responsible agent, causative agent.

Q In other words, the chemical that is at fault.

A Is that what you are saying?

Q Yes.

A And in reply to that I would agree that over the years additional agents, chemical toxins, have been detected. What I don't know is what is the proportionate role of each of those chemical toxins as to being responsible for the observed effects.

Q In light of these changes that occurred in the last decade with respect to the observations made by experts about the Yusho incident, I take it in your medical judgment the more current reports are the more reliable, is that correct?

THE WITNESS: Would you read back what preceded the last sentence.

MR. FEATHERSTONE: Why don't you read the question.

(The record was read by the reporter as requested.)

BY THE WITNESS:

A No, I wouldn't agree with that entirely.

BY MR. FEATHERSTONE:

Q You would agree with it in some respects,

obviously.

A Well, I'd like to get at a little more exactly what you mean by the current reports are more reliable.

Q In terms of furnishing data, as to what was in the rice oil.

A Oh, as to what was in the rice oil?

Q Yes.

A Okay. I was interpreting your question more broadly.

Q I am going to get to the more broad questions.

A The people eight years ago, the effects that they observed were, I felt, accurate. But if you are distinguishing with respect to the content of contaminants in the rice oil, then I would agree that the most recent reports appear to have the most up-to-date analytical analysis of such contaminants, yes.

Q Do you also agree that the more recent report which discussed the possible role of the various contaminants in causing the effects noted in the Yusho victims are the more reliable reports?

A Again, I take it -- I can't agree with the way you have stated that question. What do you mean by "reliable"?

Q Well, Doctor, I will approach it this way. Early in the 1970s the common thought among medical experts in this country and in Japan was that the Yusho symptoms were caused by PCB exposure. Isn't that right?

A And that was a reliable report.

Q At that time.

A Yes.

Q Since that time, however, further analytical work has detected other contaminants in that rice oil.

A That is correct.

Q Including dibenzofurans and PCQs.

A I agree.

Q Indeed those other contaminants have been present in substantial quantities.

A That appears to be so.

Q In light of the detection of these other contaminants in the Yusho rice oil, there have been new reports that have been issued discussing the role of these contaminants in causing the Yusho

symptoms.

A Yes, there have.

Q My question is, Doctor, in your medical judgment would you put more reliability on the current state of the literature, current state of medical knowledge with respect to the Yusho incident than you would on reports that were issued in the early 1970s?

A Yes, I would.

Q I take it from your testimony today and yesterday, you yourself have reached no opinion, with a reasonable degree of medical certainty, as to the cause of the Yusho symptoms?

A I have not, that is correct.

Q I take it, in light of that, you would defer to the medical experts who have been following the Yusho incident more closely than you have?

A Well, yes. I would defer to people who are following it more closely.

But the question is -- I have an opinion. So that the question is, is it known what the various agents present in the rice oil have done, or what their contributions are.

Q And you have no idea.

A My feeling is that this is not known for sure, and therefore I don't know for sure.

Q Doctor, when you say you don't know for sure, you testified yesterday that you have no idea about the toxicological consequences of exposure to PCQs, for instance.

A That I have no idea?

Q That's right.

A Implying?

Q You haven't studied PCQs.

A But I have read about them.

Q Well, Doctor, I asked you just a minute ago whether you have an opinion, within a reasonable degree of medical certainty, as to the cause of the Yusho symptoms.

A And I replied I did not.

Q You did not. Okay.

Doctor, you have done some work with PBBs, is that correct?

A That is correct.

Q The work that you have done with PBBs has been in the nature of epidemiological work?

A That is correct.

Q From your work and findings with respect to PBB exposure to humans, have you drawn any opinions, with any reasonable degree of medical certainty, with respect to the effects of PCB exposure on humans?

A No, we have not.

Q Doctor, do you agree with this statement:

"There is no evidence of deleterious effects resulting from inhalation of PCBs from the air."

A No. I don't think I'd agree with that.

Q What evidence do you have that there is any health harm to humans from inhalation of PCBs in the air?

A There are reports in the literature where occupation workers have been studied. These are workers in occupations where PCBs were used, and there is some evidence that there may be an association between an occupation in which there was air contamination by PCBs, and various abnormalities as measured in followup studies of the people.

Q So your only evidence is in the occupational context?

A Yes, that is correct.

Q Have you in the course of your work followed the information pertaining to PCB levels in the atmosphere? I am talking about outside of the working environment.

A The general environmental atmosphere?

Q Yes.

A In a general sense, yes.

Q So if I use the phrase general environmental atmosphere, you understand that to exclude plants in which PCBs are used?

A I will.

Q Okay.

A That is our agreement, yes.

Q With respect to PCBs in the general environmental atmosphere, Doctor, do you agree with this statement:

"There is no evidence of deleterious effects resulting from inhalation of PCBs from the air."

A As quoted, I would agree.

Q Doctor, do you agree that that statement which I have read to you constitutes valid human data?

A Constitutes valid human data?

Q Yes.

A Would you please read the statement again.

Q "There is no evidence of deleterious effects from inhalation of PCBs from the air." This refers to human effects.

A I hear no reference to data.

Q So your statement is it's not valid human data?

A That is a statement that you quoted, but I hear no reference to data, to measurements. So no, that is not human data.

Q You do not consider --

A That is a conclusion or a statement. That is not data.

Q So if somebody were to tell you there is no evidence of something, you would consider that a statement, and not zero data.

A In my profession, generally if someone makes a statement such as that they have some kind of measurements that have been made to support the statement. That is the data. Such measurements are the data. If such measurements can't be produced to support the statement, then it is an opinion.

Q Let me ask you this. This statement:

"There is no evidence of deleterious effects resulting from inhalation of PCBs from the air."

Do you consider that a valid conclusion?

A No, I don't.

Q Or opinion?

A I consider it an opinion. Somebody must have said it, so it's an opinion.

Q Do you consider it a valid opinion, based on your knowledge of PCB levels in the general environmental atmosphere, and your knowledge of the absence of any health problems from those PCBs?

A I am having trouble with your word "valid." It is an opinion, it's someone's statement. You are asking me to judge --

MR. WHITE: If you can't answer the question, say so.

BY MR. FEATHERSTONE:

Q All I am asking you, in your medical judgment, to tell me whether it's right or wrong. It's a statement by the Food and Drug Administration, to the extent that makes any difference to you.

A No.

I can't say whether that is a correct -- a right or a wrong statement.

Q Doctor, would you pull out Exhibit No. 4.

A I have it in front of me.

Q All right. Look at Finding No. 12, please.

A I see it.

Q Would you read it, please, out loud.

A "No health problems or medical conditions could be correlated with PCB blood levels or exposure to Lake Michigan fish." Item No. 12.

Q As we discussed yesterday, that was one of the findings in your 1976 study.

A One of the stated summary conclusions, yes.

Q Do you consider that statement valid human data?

A No, I do not. That is --

Q Do you mean to suggest that statement is not valid?

A No, I do not. I don't mean to suggest it's not valid.

That statement as it appears is not data.

That is a conclusion. The data is here. (Indicating.)

Q The data shows no health problems?

A The data does not support a conclusion that there are health problems. If you examine the data, health problems are reported in this data. There are people in this study with health problems.

Q Yes. But not that you can attribute in any way to PCBs.

A Not that you can conclude was caused exclusively by PCBs, that is correct.

Q And not that you can, in your medical judgment, could attribute to PCBs.

A In my judgment the data is insufficient to support a conclusion that attributes the reported health problems exclusively to PCBs.

Q Doctor, can you say, with a reasonable degree of medical certainty, that any level of PCBs in human blood likely to result from eating fish with PCBs, poses any danger to human health?

A I can't answer that question as you have posed it.

Q Well, I will repeat it, because I stumbled in the middle.

Can you say, with a reasonable degree of medical certainty, that there is a level of PCBs in human blood that poses a danger to human health?

A And your question is asking a specific level in the blood, am I correct in my interpretation of your question?

MR. WHITE: If you can't answer --

BY MR. FEATHERSTONE:

Q The question asked for any level.

MR. WHITE: Tell him you can't answer it. Let him rephrase the question.

BY MR. FEATHERSTONE:

Q Any level, Doctor.

MR. WHITE: You want a level, Bruce, is that what you are looking for?

BY MR. FEATHERSTONE:

Q Can you answer the question, Doctor.

MR. WHITE: If you can't answer the question, tell him you can't answer. Let him rephrase it. We have been through this 18,000 times.

BY THE WITNESS:

A Could you rephrase the question again, please.

BY MR. FEATHERSTONE:

Q Can you say, with a reasonable degree of medical certainty, that there is any level of PCBs in human blood that poses any danger to human health?

A No, I cannot.

Q Can you say, with a reasonable degree of medical certainty, that there is any level of PCBs in human tissue or in the human body that poses any dangers to human health?

A I am sorry, I am having trouble with the way you are phrasing these questions.

"Dangers to human health," I think we are going to have to explore what we mean by that.

Q Doctor --

A The interpretation of those words.

Q Doctor, can you say, with a reasonable degree of medical certainty, that there is any level of PCBs in the human body that poses human health problems?

A Again, you are going to have to rephrase the question. What do you mean by "poses"?

Q You don't understand the word "poses," Doctor?

A I'd like to know what your understanding of the word "posed" is.

Q Doctor, why don't you tell me how you understand the word "posed."

MR. WHITE: Just tell him you can't answer the question. He will rephrase it.

BY THE WITNESS:

A Rephrase it.

BY MR. FEATHERSTONE:

Q Doctor, give me a definition of the word "poses."

A I prefer to hear your definition of the word "poses."

Q Answer the question.

MR. WHITE: You have got to answer his question, if you understand the question.

BY THE WITNESS:

A If something poses, my interpretation is that there is a reasonable belief that it is causing some event.

BY MR. FEATHERSTONE:

Q Or could cause some event?

A Something poses a risk. There is a

reasonable belief that some risk is involved, that some event could occur.

Q Okay. Let us use that definition. Can you say, with a reasonable degree of medical certainty, that any level of PCBs in the human body poses human health problems?

A I still can't answer the question, because we are going to have to deal with "human health problems." Do we mean by "human health problems" diagnoses? What do you mean by that?

Q You have never understood the phrase "human health problems"?

A I deal with the phrase "human health problems." I understand it thoroughly.

Q What do you understand the phrase "human health problems" to mean?

A "Human health problems" can range from diagnosed disease, the appearance of signs or symptoms of disease, the appearance of abnormalities in various diagnostic tests to detect disease, the appearance of other -- Anything that would be considered abnormal, be it a medical evaluation or a test that's indicative of disease.

Q When you say "indicative of disease," do you mean there is a reasonable likelihood that disease may follow?

A Or there is a connection between the measured event and some kind of a disease or health condition -- I am sorry. We are defining health condition. Disease or human condition.

Q Let's use that definition. With that definition, your definition of the word "pose" or "poses," can you say, with a reasonable degree of medical certainty, that any level of PCBs in the human body poses human health problems?

A Yes, there are. In the context that we are discussing the question, yes, there are.

Q Explain it.

A There are reports in the literature which have correlated human PCB levels with various types of, quote, "abnormalities" in some diagnostic tool. Abnormalities such as elevated enzyme levels, or elevated blood pressures, or elevated -- or decreased vital lung capacities, for example.

Q What is decreased vital lung capacity?

A That is a measurement of the assimilative

capacity of the respiratory system in comparison with what at any age, station in life this capacity should be.

Q You are aware, however, that those reports, those diagnostic changes that you just described, have not linked those changes to any sickness, illness or disease?

A Specific disease, illness, or condition, that is correct.

Q Or any general disease.

A But my definition --

Q Or any general disease.

MR. WHITE: You asked him a question with respect to his definition. If you want to ask another question, go ahead. But let him finish.

BY MR. FEATHERSTONE:

Q We are beyond that answer. Go ahead, answer, complete the answer. You have already answered now, but go ahead.

A I was just going to remark with respect to health conditions as defined.

Q When I asked you for a definition of human health problems, and correct me if I am wrong,

but I am certain the record will bear me out on this. When you defined the phrase "human health problems," you said any change in a diagnostic sense that could reasonably lead to disease. Am I right?

A I don't know what is on the record.

MR. FEATHERSTONE: Why don't you go back, Madam Court Reporter, and reread his definition to my question asking for a definition of human health problems.

(The record was read by the reporter as requested.)

BY THE WITNESS:

A What is your question?

BY MR. FEATHERSTONE:

Q Doctor, I want to arrive at a definition that means something to me as a lay person. And by way of background let me say this, and maybe you can help me arrive at something you and I can understand which will expedite the next three hours of questioning.

That is what I am searching for. Okay?

A Okay.

Q I realize in the literature there have been reports that PCB exposure effect changes in

the liver enzymes in the blood, correct?

A Correct.

Q I am also aware that those reports have not attributed those changes in the liver enzymes to any illness, disease, sickness or disorder. Okay?

A When you have -- Well, let's just take that point for a second.

Q All right.

A Liver disease, what is it? There is no singular, easy definition of what liver disease is. Liver disease can be as simple as abnormality of the enzymes within the liver. An abnormality in the levels or the function of these enzymes. That could constitute liver disease.

Q Therefore, under your definition, could constitute a human health problem.

A That is why I am having trouble with the question. Yes, it could. Now, generally --

Q Even though that person, as far as you or I could tell, would have no disease, sickness, or illness?

A No observable symptom, that is correct.

Q He could function as a normal human being.

A He could function as a normal human being, but would be diseased.

Q In a very technical sense.

A In a very real sense.

Q Well, if you gave that guy a medical examination, would you tell him he is diseased, or would you tell him he is healthy?

A On the basis of the example we are giving, you could not declare that person perfectly healthy.

Q Would you tell him he is diseased, that he is sick?

A It would depend on more than that singular test.

Q On that basis alone you wouldn't tell him he's diseased or sick.

A Probably would follow up with other inquiries.

Q On that basis alone you would not tell him he was sick or diseased.

A On that basis alone I could not tell him for sure what his sickness or disease is. One could speculate.

Q Okay. In your role as an epidemiologist in the Michigan Department of Public Health, are

you principally concerned with disease -- Strike that.

Would you consider an elevated liver enzyme level in the blood to be a human health problem?

A Yes.

Q Would it concern you, in the absence of anything else?

A Yes.

Q Would you consider it an illness?

A No.

Q Would you consider it a sickness?

A No.

Q Would you consider it a disease?

A It could be.

Q Does it necessarily have any physiological effect on the human?

A It could have, yes.

Q But it might not have?

A But it might not have.

Q Doctor, do you consider elevated liver enzyme levels -- And by the way, we are taking these as examples.

A I understand the discussion.

Q Do you consider elevated liver enzyme levels

in the blood to be a symptom or a diagnostic tool?

A A symptom -- a sign, elevated liver enzymes would be a diagnostic -- yes, they are a diagnostic tool. They are a sign. They would not be a symptom, because generally a symptom is associated with a dysfunction or a condition which is observed as abnormal.

Q So you wouldn't consider an elevated liver enzyme level in the blood to be by itself a dysfunction or abnormality?

A Yes, I would.

Q You consider it a dysfunction?

A It would be a dysfunction in that the production of that enzyme is different from the normal.

A symptom of an elevated enzyme could be jaundice. This is an observable effect. Something wrong in the liver. Your skin turns yellow.

Q Doctor, when you say something is a diagnostic aid, what are you trying to diagnose?

A Disease, illness, change in health conditions from the norm.

Q So in your terminology, if you found

elevated liver enzymes you would consider that a dignostic aid. To what end?

A It's a diagnostic aid which would help to measure the normalcy of that person's metabolic process as defined by liver function.

Q Do you have a term or a phrase, and this is again coming from a layman, for health problems that you can see in somebody, or dysfunction that you can see in somebody? In other words, a person can't operate as a normal human being, or they get diseased and die, or they can come down with a serious human disease.

What I am trying to do, Doctor, is distinguish that case from a case in which there is an elevated liver enzyme level which you say may or may not have any real consequence.

A The problem that we are having in the dialog is the fact that there can be abnormal signs, abnormal tests, but a conclusion of what that means, of what that is in terms of disease, can't be reached.

A disease is something which can be defined as a set of parameters with some consequences. A

health condition is an observable effect.

Q In other words, something that I could see?

A Yes. This is a condition right here. (Indicating.) You can see a shaking hand. Now, what is causing that? Now, you can run tests which would indicate that there is something wrong with the nerves of the arm. But the arm may not be shaky. So what you have is your test is a sign, a measurement, a tool to indicate abnormalities. But there often may be a gap between that information and the actual recognition of a disease or the definition of a condition. You can have --

Q Now, I want to -- let me. I understand where you are coming from, at least insofar as that is concerned.

I want to get to the more subtle distinctions. I want to address the difference between an elevated liver enzyme level in the blood which may not have any significance for the functioning of a human being, and those health problems, if you will, that have a significance for the functioning of the human being. Do you understand that difference?

Did I make that clear?

A I think you can have an elevated enzyme and you may or may not have a recognizable disease.

Q Or any disease that, as a practical matter, affects the functioning of the human being. Okay?

A Okay.

Q All right. Now, what phrase would you use that would apply to something that either does cause, or there is a very significant correlation with a serious human problem that affects the functioning of the human being?

A That's where we are going to have very grave difficulty. There is no firm line there. It is gray. That's really the crux of many of these arguments. You can't define that that closely.

Q Well, do you have any phrasing --

A You are asking, you know, what is jumping the gap between a series of signs or even symptoms, and the definition of an actual disease that is debilitating, and that is very hard to tell, and sometimes it takes 20 years to determine the answer.

For example, let me give you an example

of that.

Q All right.

A The high and low density lipoproteins. Various epidemiological studies have associated, correlated these with cancers.

Now, the fact that a person has a high amount of high density lipoprotein does not mean that he has diagnosed case -- does not mean that he has a case of cancer.

Q That doesn't mean he will, either.

A It doesn't mean he will, and it doesn't mean he won't. But these associations have been shown in studying population. That is where I am having trouble with what you are trying to ask. Because here it a sign, but I can't tell you for sure that that sign is going to result in a disease. But I also can't tell you that it will not.

Q Well, when you use the words, in your last sentence, when you used the word "sign," are you referring to something like elevated liver enzyme levels?

A In that case what I mean is an elevated level of high density lipoprotein.

Q Which you don't consider to be a disease, as such.

A As such, it is not.

Q Do you consider elevated liver enzymes to be a disease as such?

A As such, elevated liver enzymes are not a disease, no.

Q The mixed function oxidase, if you induce that, or stimulate that, do you consider that a sign or a disease?

A That is a sign. That is not itself a disease.

Q The distinction you are making between sign and disease is that with a sign you simply don't know, using your medical judgment, whether or not a disease will follow.

A That's correct.

Q Okay.

A That sign, that sign with other pieces of evidence can then lead to a definition of a disease. But that sign all by itself does not.

Q I take it that sign with other pieces of information might not lead to any disease as well.

A That is true. Diseases generally are defined as a combination of factors which have been defined over the years as constituting a certain kind of a disease.

Q Do you distinguish among sickness, illness, and disease?

A Yes.

Q How so?

A A person can be sick without having a defined disease. Disease, being as I referred to it before, has a defined set of signs, conditions, measurements, that have been defined as this disease, often with a causative agent being known, etiologic agent known, but not necessarily always.

A sickness is more a subjective situation. A person can be, can perceive themself as sick, and yet you are unable to define a disease in that individual.

Q Is sickness something more than a sign?

A Yes. Because a person can have a sign, such as abnormal liver enzyme level, and not have any self-perception of illness, and therefore not feel sick, not claim that they are sick.

A person with syphilis, you can measure the presence of the agent in the body, and at certain stages of that disease that individual has no idea they have that condition, they have that disease, and yet they do, and later it can manifest itself.

Q So that essentially the difference between sickness and disease is a subjective difference.

A The way I am trying to explain it here, yes.

Q What is the difference between disease and illness?

A I would put illness and sickness in the same class as --

Q Synonyms?

A Yes. As opposed to disease. A disease is something that is defined. I can go to a medical dictionary and I can find diseases listed.

Illnesses, sicknesses, are not defined.

Q Do you consider elevated liver enzyme levels in the blood to be a sickness?

A No, I do not. By themselves, I do not.

Q Do you consider a change in the level of

low density or high density lipoproteins in the blood to be a sickness?

A No, I do not.

Q Do you consider those to be signs?

A Yes, I do.

Q I take it you would consider any additional stimulation to the mixed function oxidase to be a sign and not a sickness or illness.

A I agree with that.

Q So there has to be something more than a sign to reach the stage of sickness or illness.

A There has to -- I don't agree with that.

Q Sorry.

A There has to be something more than a sign to conclude that there is a sickness or an illness. You said reach.

Q Okay.

A The person may reach that before someone can conclude it.

Q So if I used the words human disease, human illness, or human sickness, can we understand for the balance of this examination and your testimony that I am referring to something more than these

diagnostic signs that we have been talking about, the liver enzyme levels in the blood, the mixed function oxidase, the blood lipoproteins, and things of that nature?

A Okay.

Q All right?

A All right.

Q Let's try it again.

Doctor, can you say, with a reasonable degree of medical certainty, that any level of PCBs in the human body poses the danger of human disease, sickness, or illness?

A I can't answer it as you phrase it again.

Q What is the problem now?

A Well, now we are on "poses the danger."

Q You don't understand that?

A I understand it.

Q All right. Let me hear your definition of the phrase -- Is the difficult phrase "poses the danger"?

A Um-hum.

Q Yes?

A Yes, it is.

Q Tell me how you understand the phrase "poses the danger"?

A Poses the danger means does the item listed represent a risk of having the final consequence.

It's like walking across the street poses a danger of getting run over. I don't know if I will, and I usually don't, but I could.

Q Doctor, what I want to get away from is any risk, okay? I mean, any risk that you may not put any stock in in terms of medical judgment, but you can't rule out in the universe of things. Do you understand where I am coming from? Kind of?

A I think so. Why don't you ask the question that way.

Q What I am looking for is if I were to use the phrase "poses a reasonable medical danger of human disease," how would you understand that phrase?

A I would understand that to mean does the item listed have the potential of ending up in this medical disease.

Q How is that different from the other phrase? You have switched from "risk" to the word

"potential" now.

A Have the risk of causing -- Have the ability to cause this thing.

Let's take an example. An abnormal -- Well, say your question is, does an abnormal liver enzyme pose the danger of causing disease.

My feeling on that is yes, it does. Because I am not certain that it will, and I am not certain that it won't, and yet that abnormality has been associated with certain diseases. So therefore, it poses a danger.

But I don't think that is the kind of question -- I don't think that is the intent of your question. But is how I am interpreting --

MR. WHITE: You are absolutely right on that.

MR. FEATHERSTONE: You don't have the faintest idea.

BY MR. FEATHERSTONE:

Q Doctor, what I want to do is, I want your reasons, medical judgment. I want an opinion with a reasonable degree of medical certainty, okay.

Now, in your judgment, with a reasonable degree of medical certainty, does the elevation of

liver enzymes in the blood lead to human disease?

A My response to that is it can.

Q Let me ask this question. In your judgment, with a reasonable degree of medical certainty, does the elevation of liver enzyme levels in the blood caused by PCB exposure lead to human disease?

A And my answer would be the same as the last; yes, it could.

Q Can you say, with a reasonable degree of medical certainty, that it will?

A No, I cannot.

Q Let me ask the question this way. Doctor, can you say, with a reasonable degree of medical certainty, that any level of PCBs in the human body leads to human disease, sickness or illness?

A No, I cannot.

Q We talked at the tail end yesterday about the PCBs in Waukegan Harbor; do you remember that?

A Yes, I do.

Q You told me yesterday that you have reviewed to some extent materials pertaining to the situation in Waukegan Harbor.

A Yes, I have.

Q In your medical judgment, Doctor, is the risk of exposure to humans from the PCBs in the bottom of Waukegan Harbor, is the risk of exposure through the consumption of fish?

A Is there a risk?

Q Is the risk of exposure through the consumption of fish?

A Not exclusively.

Q Have you reviewed any of the data pertaining to the level of PCBs in the water of Waukegan Harbor?

A I have to the extent that I recognize that there are PCBs in the bottom sediments that have been measured in the water column and in fish.

Q Are you familiar --

A I can't quote you numbers, though.

Q You have seen the data?

A Yes, I have seen data on amounts.

Q Can you say, with a reasonable degree of medical certainty, that the PCB levels in the water of Waukegan Harbor lead to human disease, sickness, or illness?

A No, I can't say.

Q Have you reviewed any data pertaining to the level of PCBs in the atmosphere, or in the air, in the Waukegan Harbor area?

A I am aware of the -- Not specifically the Waukegan Harbor area, no. I am generally aware that there is PCB, measurable PCB, in the atmosphere.

Q But what you are telling me is you have no idea today, anyway, whether any of the PCBs in the atmosphere, or in the air generally, are in any way traceable to or due to the PCBs in Waukegan Harbor?

A That would be correct.

Q Doctor, do you agree that to the extent humans are exposed to PCBs in Waukegan Harbor, in any medically significant way it is through the consumption of fish that might pick up those PCBs?

A I don't know.

Q You don't have an opinion on that?

A I don't know what the various contributing factors would be, so I can't answer the question.

Q Doctor, in your 1976 study is it fair

to say that most of the fish eaters you studied who were large consumers of Lake Michigan fish consumed between 24 and 100 pounds of fish per year?

A That would be correct, basically. I think the top level was more than 100, but most of them, yes, would be in the range of 24 to 100 pounds. Yes, I agree.

Q If you had to pick out a significant range, would you pick out like a 24 to 100 pounds per year? Significant in the sense that most people, most heavy fish eaters are in that range?

A Yes. In our survey, most of the quote, "heavy fish eaters" were in that range.

Q Are you aware of any other survey that has demonstrated that there is a substantial number of fish eaters who consume more than 100 pounds of fish a year?

A I am not aware of any studies that have demonstrated that.

Q Doctor, I am going to ask you a series of questions which I am going to ask you to assume facts. The reason I am going to ask you to assume the facts is because I asked you yesterday, and

you hadn't any information on the facts. After each assumption I am going to ask you basically okay, so that I understand that you have followed the assumptions. All right?

A Okay.

Q Doctor, I want you to assume that one of the principal on-shore fishing spots in the Waukegan Harbor area is from the south side of Waukegan pier. Okay?

A All right.

Q Now, in April, 1981 there were fish caught near that pier. I want you to assume that the fish caught in April of 1981 are typical of the fish that are caught by fisherman fishing off that pier. Okay?

A All right.

Q And indeed, one of the reasons the Illinois Department of Conservation went out and caught those fish was to grab fish typical of the fish caught by people off that pier.

Now, the State of Illinois caught several species of fish and measured the fish for PCBs, okay?

A All right.

Q The data on the PCB levels generated was

for the raw fillet of fish. Okay?

A All right.

Q As you testified yesterday, the cooked fillet of fish will have a lower PCB level than the raw fillet of fish.

A That's been our experience, yes.

Q Now, I want to show you Muench Exhibit 1. It is a five-page document that sets forth the level of PCBs found in the fish that were caught south of Waukegan pier. Okay? I want you to review that data.

A May I ask for a point of clarification?

Q Certainly.

A South of Waukegan pier. Is that on the inside or the outside of the harbor?

Q Outside of the harbor.

A Outside of the harbor.

(Reading document.) I have looked at them.

Q And you have reviewed the PCB data shown in Muench Exhibit 1?

A Yes.

Q Doctor, I want you to assume that there are people fishing from this pier in Waukegan and catching

fish of this type and with these levels of PCBs. Okay?

A All right.

Q I want you to assume that these fisherman catch and consume anywhere from 24 to 100 pounds of fish a year.

A All right.

Q With those assumptions, can you say, with a reasonable degree of medical certainty, that long-term consumption of fish at the PCB levels shown in Muench Exhibit 1 leads to human disease, sickness, or illness?

A No, I cannot.

Q Now, Doctor, I want you to take the same assumptions, essentially the same assumptions, and using the same data shown in Muench Exhibit 1, and I want you to make several additional assumptions.

I want you to assume that the individuals who catch fish from Waukegan pier have a history of heavy consumption of Lake Michigan fish. In other words, let's assume that they have been catching and consuming Lake Michigan fish at the rate of 24 to 100 pounds of fish per year for 15

to 20 years prior today.

A All right.

Q Let's say that historically the fish that these fisherman caught and consumed for the 20 years prior to today had the PCB levels that you report in your 1976 study.

A All right.

Q With that history of consumption, and the other assumptions made, can you say, with a reasonable degree of medical certainty, that long-term consumption of fish at the PCB levels shown in Muench Exhibit 1 leads to human disease, sickness, or illness?

A No, I cannot.

Q Doctor, I want you to assume that there is fishing that goes on in the Illinois waters of Lake Michigan outside the harbor other than off the pier. I am talking now about fishing off of boats.

A Okay.

Q I want you to take a look at the PCB data reflected in Muench Exhibit 2 and Muench Exhibit 10.

For purposes of assisting you in this I

have paper-clipped the PCB data, but feel free to look through the entire document, if you want. Muench Exhibit 10, I have opened up to the page with the PCB data. Again, feel free to flip through the document.

A I am to assume on this exhibit here that these are all lake trout?

Q Yes, you are.

A Am I missing something in the title?

Q You are referring to Page --

A Okay. Here it is.

Q -- 2537 of Muench Exhibit 10. It is a lake trout report.

A Yes.

Q You are to assume it is lake trout data.

A Okay. I have looked at these two reports.

Q You have looked at Muench Exhibit 2 and Muench Exhibit 10?

A Yes, I have.

Q Doctor, I want you to assume that the lake trout PCB data that you just reviewed -- strike that.

I want you to assume that the lake trout

PCB data that you just reviewed in Muench Exhibits 2 and 10 are representative of the levels of PCBs in lake trout caught and consumed by Illinois sport fisherman. Okay?

A All right.

Q I want you to assume that these sport fisherman eat Lake Michigan fish in the same quantities that you found in your 1976 study. In other words, 24 to 100 pounds of fish per year. Is that okay?

A All right.

Q I want you to assume long-term consumption of lake trout, Lake Michigan fish.

A All right.

Q Can you say, with a reasonable degree of medical certainty, that long-term consumption of fish with the PCB levels shown in Muench Exhibits 2 and 10 lead to human disease, sickness, or illness?

A No, I cannot.

Q I want you to take all of the assumptions that we have just made about the lake trout, and add a couple of more.

I want you to assume that there are sport fisherman who have a history of heavy consumption of

Lake Michigan fish. Okay?

A All right.

Q Let's assume that these Illinois sport fisherman have been consuming Lake Michigan fish for the past 20 years at the rate of 24 to 100 pounds of fish per year, okay?

A All right.

Q Now, with that history and the other assumptions, can you say, with a reasonable degree of medical certainty, that long-term consumption of lake trout at the PCB levels shown in Muench Exhibit 2 and 10 leads to human disease, sickness, or illness for these sport fisherman?

A I cannot say that, no.

Q Doctor, I want you to assume that the yellow perch -- strike that. Let me back up for a second.

Doctor, I am still on lake trout. Okay?

A All right.

Q I want you to assume there are sport fisherman who have a heavy consumption, a history of heavy consumption of Lake Michigan fish. Okay?

A Okay.

Q They have been consuming fish at the rate of 24 to 100 pounds per year for the past 20 years. Okay?

A All right.

Q I want you to assume that the PCB levels in the fish they caught and consumed in that 20 year period of time prior to today was at the PCB levels shown in your 1976 report.

A All right.

Q With that history of consumption, and those assumptions, can you say, with a reasonable degree of medical certainty, that long-term consumption of fish with the PCB levels shown in Muench Exhibit 2 and 10 leads to human disease, illness, or sickness?

A No, I cannot.

Q I want to turn to yellow perch. I want you to assume that the yellow perch accounts for 80 percent of the catch of Illinois sport fisherman.

A All right.

Q I want you to assume that the PCB levels in the fillet of yellow perch presently run between .159 parts per million and .415 parts per million.

A All right.

Q Let me show you Muench Exhibits 7 and 14. The first page of Muench 14 summarized the PCB data, and I have opened up Muench Exhibit 7 to the page that summarizes the PCB data in yellow perch. You are, of course, free to look through the entire report, if you wish.

A (Examining document.) Okay, I have taken a look at these.

Q You have taken a look at Muench Exhibits 7 and 14?

A Yes.

Q I want you to assume that the PCB levels in the perch that are shown in Exhibits 7 and 14 are representative of the PCB levels in the yellow perch in the Illinois waters of Lake Michigan.

A All right.

Q I want you to assume that these yellow perch are caught and consumed by Illinois sport fisherman.

A All right.

Q I want you to assume that Illinois sport fisherman eat 24 to 100 pounds of Lake Michigan fish a year.

A All right.

Q With these assumptions, can you say, with a reasonable degree of medical certainty, that long-term consumption of fish at the PCB levels shown in Muench Exhibits 7 and 14 lead to human disease, illness, or sickness?

A No, I cannot.

Q Doctor, I want you to assume that there are Illinois sports fisherman catching the yellow perch at the PCB levels shown in Muench Exhibits 7 and 14 who have a history of heavy consumption of Lake Michigan fish.

A All right.

Q I want you to assume that these Illinois sport fisherman have been consuming Lake Michigan fish in large quantities for the past at least 20 years.

A All right.

Q I want you to assume further that throughout the entire period of this past heavy consumption they have been eating Lake Michigan fish at the rate of 24 to 100 pounds a year.

A All right.

Q I want you to assume that the Lake Michigan fish they have consumed in the past 20 years have been at the PCB levels that you show in your 1976 report.

A All right.

Q With this history of consumption, and with the other assumptions that I have made, can you say, with a reasonable degree of medical certainty, that consumption, long-term consumption of perch at the PCB levels shown in Exhibits 7 and 14 leads to human disease, sickness, or illness?

A No, I cannot.

Q I want to turn to the bloater chub.

A All right.

Q I want you to assume that the bloater chub pulled from the Illinois waters of Lake Michigan and gutted have PCB levels between .2 and 3 parts per million.

A All right.

Q By the way, do you under the term "gutted" with respect to the bloater chub?

A Yes. Entrails are missing but the heads are still there.

Q I want you to assume that bloater chubs with the PCB levels that I just described are regularly caught and consumed by Illinois fisherman.

A All right.

Q I want you to assume that there are Illinois fisherman who eat between 24 and 100 pounds of Lake Michigan fish a year.

A All right.

Q Can you say, with a reasonable degree of medical certainty, that long-term consumption of bloater chubs with the PCB levels in the neighborhood of .2 to 3 parts per million leads to any human disease, illness, or sickness?

A No, I cannot.

Q I want you to add some further assumptions to the ones we just made.

A All right.

Q I want you to assume that there are fisherman catching and eating these bloater chubs who have a history of very substantial consumption of Lake Michigan fish.

A All right.

Q I want you to assume that there are Illinois

sport fisherman who have been eating substantial quantities of Lake Michigan fish for 20 or more years.

A All right.

Q And that for this 20 or more year period of time they have been eating 24 to 100 pounds of fish per year.

A All right.

Q Can you say, with a reasonable degree of medical certainty, that consumption of chubs -- strike that.

With those assumptions, and the history of fish consumption that I have described, can you say, with a reasonable degree of medical certainty, that long-term consumption of bloater chubs at the .2 to 3 parts per million level, or in that area, leads to any human disease, sickness, or illness for these sport fisherman?

A No, I cannot.

Q Can you say, with a reasonable degree of medical certainty, that consumption of chubs, and I am talking about long-term consumption of chubs, at .2 to 3 parts per million concentration of PCBs or greater, cause any disease, or sickness,

or illness to any Illinois sport fisherman?

A No, I cannot.

Q Doctor, I want to take again for a moment the Illinois sport fisherman who has a 20 or more year history of heavy consumption of Lake Michigan fish. All right?

A All right.

Q The assumptions again are that for this 20 or more year period of time they have consumed between 24 and 100 pounds of fish annually.

A All right.

Q I want you to assume that for that 20 or more year period of time that the PCB levels in the fish they caught and ate were roughly the PCB levels shown in your 1976 report.

A All right.

Q With that history of consumption, can you say, with a reasonable degree of medical certainty, that long-term consumption of bloater chubs at PCB levels of anywhere between .2 and 3 parts per million, or in that area, lead to any human disease, illness, or sickness for those sport fisherman?

A No, I cannot.

Q Doctor, I'd like to show you Muench Exhibit 8, which is a report authored by the Illinois Department of Conservation, and its title, "Bloater Chub Assessment in Illinois Waters of Lake Michigan, 1980." I want you to look in particular at Page 15, and at the top of Page 15, because it's there that the State of Illinois sets out the results of its testing of bloater chubs for PCBs. Feel free, of course, to look through any of the portion of the document. But I thought I'd open it up. It is the first full paragraph at the top of the page.

A (Examining document.) Okay.

Q Do you see the passage in there that sets forth the PCB residue level in the bloater chub?

A Yes. It's the one that reads 0.11 and PCB 1254 0.49 parts per million.

Q That's right.

A I see that.

Q When you are finished with that report, let me know.

A (Reading document.) Okay.

Q I also want to show you Muench Exhibit 4, which sets forth the results of some testing by the

Illinois Department of Conservation for PCB levels in bloater chubs.

A I have looked at it.

Q I also want to hand you Muench Exhibit 5, and this is the real Muench Exhibit 5 this time. That sets forth some PCB residue data for bloater chubs pulled from Illinois waters of Lake Michigan in 1980. The data is summarized on Page 2 of the document, but it is a three-page document.

A Okay. I have looked at it.

Q I take it by that you mean you have reviewed the PCB data shown in these exhibits for the bloater chubs?

A Yes, I looked at the values.

Q Can you say, with a reasonable degree of medical certainty, that long-term consumption of bloater chubs at the PCB levels shown in Muench Exhibits 4, 5, and 8 leads to any human disease, sickness, or illness for any sport fisherman?

A No, I cannot.

Q Doctor, I want to turn to the Coho salmon. I want you to take a look at the PCB data for Coho salmon pulled from the Illinois waters of Lake

Michigan that are summarized in Muench Exhibits 6 and 15.

A I have looked at these.

Q Doctor, I want you to assume that the PCB data for the Coho salmon described in Muench Exhibit 6 and 15 are representative of the PCB levels in Coho salmon caught and consumed by Illinois sport fisherman.

A You want me to assume that?

Q Yes.

A Yes.

Q Do you know of anything contrary?

A No. I just want to clarify this was an assumption.

Q Well, my question is, do you know of any contrary information from the Illinois waters of Lake Michigan?

A No, I don't.

Q That is why I am having you assume this.

A All right.

Q I want you to assume that there are Illinois sport fisherman who catch and eat in the range of 24 to 100 pounds of Lake Michigan fish a year.

A All right.

Q Can you say, with a reasonable degree of medical certainty, that long-term consumption of Coho salmon at the PCB levels shown in Muench Exhibits 6 and 15, or in that area, leads to any human disease, sickness, or illness for these sport fisherman?

A No, I cannot.

Q I want to add several other assumptions. I want you to assume there are Illinois sport fisherman who have a long history of heavy consumption of Lake Michigan fish.

A All right.

Q I want you to assume that for at least 20 years these sport fisherman have consumed Lake Michigan fish at 24 to 100 pounds per year.

A All right.

Q I want you to assume further that the PCB levels in these fish caught and consumed for that 20-year period of time were at roughly the PCB levels shown in your 1976 report.

A All right.

Q With this history of consumption and these

assumptions, can you say, with a reasonable degree of medical certainty, that long-term consumption of Coho salmon at the PCB levels shown in Muench Exhibits 6 and 15 lead to any human disease, sickness or illness for these sport fisherman?

A No, I cannot.

Q Can you say, with the same assumptions, and within a reasonable degree of medical certainty, that consumption of Coho salmon with the PCBs at the levels shown in Muench Exhibit 6 and 15 leads to any human disease, illness, or sickness for any sports fisherman?

A No, I cannot.

Q Doctor, I have over here, and I have put in a pile on the table, all the PCB data that I have shown you; and that are Muench Exhibits 1,2, 4, 5, 6, 7, 8, 10, 14 and 15. If you want to review any of these exhibits or documents for the purposes of responding to any of my next questions, let me know, I will make them available to you. Okay?

A All right.

Q What I am relying on is you remember

roughly the PCB levels that you just reviewed, is that correct?

A Yes.

Q You will agree that we have reviewed PCB data for various species of trout, chub, perch, and salmon.

A Correct.

Q I want you to assume that these are the four principal species of fish caught and consumed by Illinois fisherman and by Illinois residents.

A All right.

Q When I say "caught," I mean caught out of Lake Michigan.

A All right.

Q I want you to assume that the PCB levels shown in Exhibits 1, 2, 4, 5, 6, 7, 8, 10, 14 and 15 of the Muench deposition are approximately the PCB levels today found in fish fillets of the fish caught in the Illinois waters of Lake Michigan.

A All right.

Q I want you to assume there are fisherman who eat anywhere from 24 to 100 pounds of Lake Michigan fish each year.

A All right.

Q Is there any mixture of these various species of fish, the trout, chub, perch, and salmon, in the diet of these fisherman that you can say, with a reasonable degree of medical certainty, leads to any human disease, sickness, or illness for these sport fisherman?

A No, I cannot.

Q I want you to add a few additional assumptions to the ones we just made.

I want you to assume that there are Illinois sport fisherman who have a long history of heavy consumption of Lake Michigan fish.

A All right.

Q I want you to assume that these sport fisherman have been consuming Lake Michigan fish for the past 20 or more years.

A All right.

Q I want you to assume that for this period of time, 20 or more years, they have been consuming Lake Michigan fish at the rate of 24 to 100 pounds of Lake Michigan fish a year.

A All right.

Q I want you to assume that for that 20 or more year period of time that the fish they have caught and eaten have had PCBs at the levels reported in your 1976 report.

A All right.

Q Is there any mixture of any of the species that we have reviewed, the chub, perch, trout or salmon, any mixture in the diet of these fisherman, that you can say, with a reasonable degree of medical certainty, leads to any human disease, sickness or illness for these sport fisherman if the fish is consumed on a long-term basis?

A No, I cannot.

Q When I have used the word or the phrase "mixture of these species," do you understand me to mean any proportion of the species of fish that we have reviewed in any proportion of the diet?

A That is my interpretation.

Q That is what I intended to mean.

A All right.

Q I want you to consider all of the fish PCB data that I have shown you in the Muench exhibits. Is there any quantity of Lake Michigan

fish that if consumed on a long-term basis, and at the PCB levels shown in the Muench exhibits that I have just shown you, that you can say, with a reasonable degree of medical certainty, leads to any human disease, illness, or sickness for any sport fisherman?

A No, I cannot. Actually, that should be that no, I don't know what quantity.

Q I want you to again consider the PCB data shown in the Muench exhibits that I have put in front of you.

A All right.

Q I want you to assume that there are Illinois sport fisherman who have a 20 or more year history of heavy consumption of Lake Michigan fish.

A All right.

Q I want you to assume that for that 20-year period of time these Illinois sport fisherman have consumed 24 to 100 pounds of Lake Michigan fish a year.

A All right.

Q And for that 20 or more year period of time, I want you to assume that they have caught

and consumed Lake Michigan fish with PCB levels at approximately the levels you show in your 1976 report.

A All right.

Q With that history of consumption, and with those assumptions, is there any quantity of Lake Michigan fish that if consumed on a long-term basis in the future you can say, with a reasonable degree of medical certainty, leads to any human disease, sickness, or illness for any of these sport fisherman?

A No, I cannot.

Q I want to turn for a minute, Doctor, to the concept of dose of PCBs.

A All right.

Q Am I right that an annual PCB dose to a fisherman eating Lake Michigan fish with PCBs in it is calculated by taking the PCB levels in the fish consumed and multiplying that by the pounds of fish eaten?

A Yes. But generally, it's also expressed in terms of his body mass.

Q In other words, if we took the weight of

our fisherman and put it into kilograms, you would take the PCB levels in the edible fish, multiply it by the pounds of fish consumed in the year, and express that figure on the basis of a per-kilogram of weight?

A Yes. The common terminology is in that term.

Q So that we understand each other, let's take that definition for dose.

A All right.

Q With that definition of dose, I want you to consider the PCB data that I have shown you in the Muench exhibits, okay?

A All right.

Q Can you tell us, with a reasonable degree of medical certainty, the annual dose of PCB that leads to any human disease, sickness, or illness for any sport fisherman consuming Lake Michigan fish on a long-term basis?

A No, I cannot.

Q I want you to take our group of Illinois sport fisherman who have a long history of heavy consumption of Lake Michigan fish.

A All right.

Q Again, the assumptions are that this group of Illinois sport fisherman have a history of heavy consumption dating back at least 20 years. Okay?

A All right.

Q I want you to assume for that 20-year period of time they have consumed Lake Michigan fish at the rate of 24 to 100 pounds a year.

A All right.

Q I want you to assume that the Lake Michigan fish that they have caught and consumed in that 20 or more year period of time contained the PCB levels that you show in your 1976 report.

A All right.

Q With that history of consumption, and the assumptions that I have given you, can you tell us, with a reasonable degree of medical certainty, the annual dose of PCB that leads to any human disease, illness or sickness for any of these sport fisherman, assuming long-term consumption of Lake Michigan fish in the future?

A No, I cannot.

Q I take it that what may be important in your medical judgment to human health, and I am speaking now about consumption of Lake Michigan fish --

A Okay.

Q -- is the total amount of PCBs consumed and accumulated in the body.

A Yes.

Q And that's where you have been coming from for the last two days.

A Yes.

Q So if it's the total amount of PCBs consumed and that have accumulated in the body, I take it that it doesn't matter how much fish is consumed, necessarily.

A All right.

Q For instance, you could have a large consumption of a number of fish with very low levels of PCBs and a much smaller consumption of certain fish with much higher levels of PCBs, and each of these individuals are exposed to the same dose of PCBs.

A That is correct.

Q In your medical judgment, do you see any differences in the way those individuals obtain their doses of PCBs?

A Do I see any?

Q Yes. In the terms of human health.

A Would you restate the question, so I understand exactly what you are asking.

Q Certainly.

I want to take two individuals, okay?

A All right.

Q They are both sport fisherman, all right?

A Hypothetical individuals, okay.

Q I want to assume that one eats Lake Michigan fish at the rate of 25 pounds per year, okay?

A All right.

Q I want you to assume that the other eats Lake Michigan fish at a rate of ten pounds per year.

A All right.

Q I assume from our prior discussion that if the PCB levels in the fish consumed by the individual who eats ten pounds a year is sufficiently higher than the PCB levels in the fish consumed by

the person who eats 25 pounds of fish per year, these individuals may have the same PCB dose, is that correct?

A Yes. I am with you.

Q In your medical judgment, does it matter, from your appraisal of human disease, sickness, or illness, whether that PCB dose is in the form of 25 pounds of fish per year, or ten pounds of fish per year?

A I don't know --

Q Okay.

A -- for sure.

Q You said "for sure." Do you have an opinion, within a reasonable degree of medical certainty?

A No, I don't know. I can't tell you whether those are equal.

Q So, if I understand you, it may well be possible that the individual who consumes the ten pounds of fish per year, and who consumes fish at higher than average PCB levels, may be better off medically than the other fellow?

A He could be.

MR. FEATHERSTONE: Would you mark this 6 and 7.

(Said documents were marked Humphrey Deposition Exhibits 6 and 7 for identification, as of 8/13/81, JKS.)

BY MR. FEATHERSTONE:

Q Dr. Humphrey, I have had marked as Exhibit 6 to your deposition a two-page document bearing the numbers US 7198 and 7199. Those are numbers given by my law firm, so that we can retrieve the document. The document was produced by the United States Government in the litigation. It is entitled, "Analysis of Waukegan Harbor Fish for PCB Residues" and its purported author, anyway, is G. D. Veith.

I have had marked as Exhibit 7 to your deposition a three-page document bearing the number US 22442, US 22443 and US 22444. The document is a letter from Sandra Gardebring to Michael Conlin of the Illinois Department of Conservation, and it attaches a document dated June 18, 1981, "Subject: New PCB data on fish from Waukegan."

I hand that to you and ask you to look at both of them.

A (Examining document.)

Q What might help your consideration of these exhibits, Doctor, is I want to ask you about the PCB data in the documents.

A Okay. I have looked at these.

Q Doctor, the PCB levels in the fish reported in Humphrey Exhibit 6 and 7 are whole fish PCB data, is that correct?

A I believe that's what was stated. I'm sorry, I don't recall.

Q For instance, Humphrey Exhibit 6 --

A There it is. Yes, I see it. In both cases, it is stated.

Q If humans were to eat these fish, or fish with PCB levels similar to the PCB levels reported in Exhibits 6 and 7 to your deposition, I take it the PCB levels actually consumed would be less than what is reported in these exhibits?

A That is possible.

Q Well, it's more than just possible, isn't it? Assuming that the fish are trimmed and cooked.

A If you assume that, then probably -- Yes, I would expect that they would be lower.

Q As we discussed yesterday, you would expect that the PCB levels in the edible fish would be substantially lower than what is reported for the whole fish.

A Yes.

Q Doctor, I want you to assume that there are fish in Waukegan Harbor that have PCB levels as shown in Exhibits 6 and 7 to your deposition, on a whole fish basis.

A All right.

Q When I say that, you understand me to mean this area.

A All right.

Q At these levels.

A Yes, range.

Q Range, right.

I want you to assume that those fish in Waukegan Harbor with these relatively high PCB levels on the whole fish basis are a small part of the sport fishery.

A All right.

Q In the Waukegan Harbor area. Okay?

A By that you mean proportionate?

Q That is correct.

A All right.

Q I mean proportioned both in terms of number of sport fish and poundage of sport fish.

A All right.

Q I take it if this assumption were demonstrated to be true, that this would have a significant impact on your evaluation of the PCB data shown in Exhibit 6 and 7 with respect to the meaning of this PCB data for human health?

A I am not -- Could you state the question in one line, so I can follow it?

Q I don't know if I can state it in one line, but I will try and restate it to make it clear.

A All right.

Q My assumption is, and the assumption I want you to accept for the time being, is that the fish in Waukegan Harbor that have PCB levels in the range shown in Humphrey Exhibit 6 and 7 --

A All right.

Q -- form a small part of the total sport fishery in the Waukegan Harbor area.

A All right.

Q And as I stated to you earlier, I mean both in terms of number of sport fish and poundage of sport fish in the Waukegan Harbor area.

A Yes.

Q I want you to assume that I can prove that assumption, and say it's demonstrated.

A All right.

Q I take it you would agree that the smaller the portion of sport fishery in the Waukegan Harbor area accounted for by fish in Waukegan Harbor with high PCB levels, the less the impact of those sport fish if caught and consumed on human health.

A I don't know. I can't say what that impact would be, so therefore I can't agree with your question.

Q Well, I am not asking you to tell me precisely what the impact would be. First of all, I am asking for your reasonable medical judgment, based on the work you have done with people who eat Lake Michigan fish, and the research work you have done and the literature you have read. Based on all of that, in your judgment is it better

that these fish with high levels of PCB comprise a smaller part of the sport fishery than if they comprised a larger part of the available sport fishery?

A I would agree with that. It would be better if they comprised a smaller amount, than if they comprised a larger amount of the fishery.

Q When you say it would be better, I take it you are speaking from the point of view of human health.

A Yes, in the general sense of human health and the context of receiving a dose of a chemical.

Q In this case, a dose of PCBs.

A Yes.

Q Let us take a sport fisherman who consumes 24 to 100 pounds of Lake Michigan fish a year.

A All right.

Q If these fish with high PCB levels, and I'm speaking about the fish that are set out in Humphrey Exhibits 6 and 7, or similar fish --

A All right.

Q -- account for only a small portion of this total consumption, you would agree, wouldn't

you, that these fish with high PCB levels may well pose no problems for human health.

A No, I would not agree with that.

Q Well, do you have an opinion, within a reasonable degree of medical certainty, about whether a sport fisherman consuming 24 to 100 pounds of Lake Michigan fish a year -- That is assumption one, okay?

A Okay.

Q Who catches and eats fish shown in Exhibits 6 and 7 as a small part of that total consumption. That is assumption number two. Okay?

A All right.

Q Do you have an opinion, within a reasonable degree of medical certainty, whether that small consumption of fish with high PCB levels, as set forth in Exhibits 6 and 7, lead to any human disease, sickness, or illness?

A I don't know if it would.

Q So you can't say that it would?

A No, I can't say that it would, that is correct.

Q Can you say, with a reasonable degree of

medical certainty, that this small consumption by this fisherman of fish with the PCB levels shown in Exhibit 6 and 7 to your deposition, leads to any human health problems?

A I don't know.

MR. FEATHERSTONE: Would you read the last question and answer.

(The record was read by the reporter as requested.)

BY MR. FEATHERSTONE:

Q I want you to assume that the total annual dose of PCBs by the consumption of Lake Michigan fish to certain fisherman is low.

A All right.

Q I want you to assume that fish with the PCB levels shown in Exhibit 6 and 7 account for a very high percentage of that total dose.

A All right.

Q Can you say, with a reasonable degree of medical certainty, that consumption of fish with the PCB levels shown in Exhibits 6 and 7 leads of any human disease, illness, or sickness for these sport fisherman?

A No, I cannot.

Q The same assumptions, Doctor.

A All right.

Q Can you say, with a reasonable degree of medical certainty, that long-term consumption of fish with PCB levels shown in Exhibit 6 and 7, and at the proportion that I have asked you to assume, leads to any human health problem for these sport fisherman?

A No, I cannot say.

Q In fact, it may well be that this consumption of fish at the PCB levels shown in Exhibits 6 and 7 may have no effect on human health?

A That is possible.

Q I want to take my Illinois sport fisherman who has a long history of heavy consumption of Lake Michigan fish.

A All right.

Q To review those assumptions, I want you to assume that these sport fisherman have a history of eating 24 to 100 pounds of fish annually for a period of 20 or more years prior to today.

A All right.

Q I want you to assume that a small portion of their fish diet is made up of fish with the PCB

levels shown in Exhibit 6 and 7.

A A small portion of their diet?

Q A small portion.

A All right.

Q Can you say, with a reasonable degree of medical certainty, that long-term consumption of these fish at the PCB levels shown in Exhibits 6 and 7, at the proportion that I have just asked you to assume, leads to any human disease, sickness, or illness for these individuals?

A No, I cannot.

Q With this history of consumption that I have asked you to assume, can you say, with any reasonable degree of medical certainty, that any consumption of fish with the PCB levels shown in Exhibits 6 and 7 leads to any human health problems or conditions?

A Can I say with certainty that this will lead to problems and conditions?

Q Can you say with a reasonable degree of medical certainty?

A No, I cannot.

Q Doctor, would your answers to these questions

change if I added the assumption that for the 20-year period prior to today these Illinois sport fisherman had been consuming 24 to 100 pounds of fish per year, and the fish were at the PCB levels shown in your 1976 report?

A My response would be the same.

Q Doctor, I want you to again take the group of Illinois sports fisherman who consumed 24 to 100 pounds of sport fish, or Lake Michigan fish a year. Okay?

A All right.

Q I want you to assume long-term consumption.

A All right.

Q Can you say, with a reasonable degree of medical certainty, at what level of the diet fish with the PCB levels shown in Exhibits 6 and 7 to your deposition lead to any human disease, sickness or illness?

A No, I cannot.

Q With those same assumptions, can you say, with a reasonable degree of medical certainty, at what portion of the diet consumption of Lake Michigan fish with PCB levels shown in Exhibit 6 and 7 lead to any human health problems or conditions for these fisherman?

A No, I cannot.

Q In the last two questions, or the last several questions, I have used the word diet. Have you understood me to mean the fish portion of the diet?

A I understood you to mean the fish portion of the diet, yes.

Q That portion of the 24 to 100 pounds of fish consumed in the annual diet that I asked you to assume?

A Yes, that is my understanding.

Q I want you to assume that there exists a group of Illinois sport fisherman who eat Lake Michigan fish on a long-term basis in large quantities.

A All right.

Q I want you to assume that this group, that the members of this group have consumed Lake Michigan fish for 20 years or a longer period of time prior to today.

A All right.

Q I want you to assume that during that period of time they have consumed fish annually at the rate of 24 to 100 pounds per year.

A All right.

Q I want you to assume that the PCB levels in the fish that they have consumed for the 20 or more year period of time are at the PCB levels shown in your 1976 report, or thereabouts.

A All right.

Q I want you to assume future long-term consumption by these fisherman.

A All right.

Q Can you say, with a reasonable degree of medical certainty, at what level of the fish diet that fish with the PCB levels shown in Exhibits 6 and 7 leads to any human disease, illness, or sickness for these sport fisherman?

A No, I cannot.

Q Making the same assumptions, can you say, with a reasonable degree of medical certainty, at what level of the fish diet consumption of fish with the PCB levels shown in Exhibits 6 and 7 leads to any human health problem or condition --

A No, I cannot.

Q -- for these sport fisherman?

A No, I cannot.

Q I want you to assume that there exists a group of sport fisherman who individually consume less than 24 pounds of fish per year.

A All right.

Q I am talking about Lake Michigan fish. Okay?

A All right.

Q Let's assume that for these sport fisherman the consumption of Lake Michigan fish at the PCB levels shown in Exhibits 6 and 7 constitute a small part of the fish diet.

A All right.

Q Let's assume long-term consumption in the future.

A All right.

Q Can you say, with a reasonable degree of medical certainty, that consumption by these individuals of fish at the PCB levels shown in Exhibits 6 and 7 leads to any human disease, sickness, or illness for these people?

A No, I cannot.

Q Making the same assumptions, can you say, with a reasonable degree of medical certainty, that consumption of fish with the PCB levels shown in Exhibits 6 and 7 leads to any human health problem or condition for these individuals?

A No, I cannot.

Q Doctor, I want to add to these assumptions the assumption that these sport fisherman have a

long-term history of fish consumption.

A All right.

Q Let's assume that in the past these individuals have consumed large quantities of fish.

A All right.

Q But that today they have cut down on their consumption of fish.

A All right.

Q Let's assume for the 20 year period before today these sport fisherman consumed 24 to 100 pounds of fish a year.

A All right.

Q Let's assume that the Lake Michigan fish they consumed at the rate of 24 to 100 pounds a year contained PCBs at the levels shown in your 1976 report.

A All right.

Q Let's assume long-term consumption of Lake Michigan fish in the future.

A All right.

Q With these assumptions, can you say, with a reasonable degree of medical certainty, that consumption of fish at the PCB levels shown in Exhibits 6 and 7 lead to any human disease, sickness or

illness for these individuals?

A No, I cannot.

Q With the same assumptions, can you say, with a reasonable degree of medical certainty, that consumption of Lake Michigan fish with the PCB levels shown in Exhibits 6 and 7 leads to any human health problem or condition?

A No, I cannot.

Q Can you say, with any reasonable degree of medical certainty, that any long-term consumption by these individuals of fish at the PCB levels shown in Exhibits 6 and 7 leads to any human disease, illness, sickness, condition or problem?

A No, I cannot.

Q Dr. Humphrey, are you in a position today to render any opinion, with a reasonable degree of medical certainty, as to the human health implications of the PCBs at the bottom of Waukegan Harbor?

A Yes.

Q Are you in any position today to render an opinion, with a reasonable degree of medical certainty, as to whether the PCBs at the bottom of Waukegan Harbor lead to any human disease, illness, or sickness?

A No.

Q Are you in any position today, Dr. Humphrey, to render an opinion, with a reasonable degree of medical certainty, as to whether the PCBs at the bottom of Waukegan Harbor will cause any human problem or condition?

A What was the beginning of your question?

MR. FEATHERSTONE: Would you read it back, please.

(The record was read by the reporter as requested.)

BY THE WITNESS:

A No, I am not.

BY MR. FEATHERSTONE:

Q Before you can render any opinion, with a reasonable degree of medical certainty, about whether the PCBs in Waukegan Harbors lead to any human health disease, illness, or sickness, or condition from any means of exposure, what other information do you need?

First of all, I take it the list is rather lengthy?

A Yes.

Q Can you give me a list of the types of

information you need?

A Well, that would take a considerable amount of time and thought for me to give you a definitive list that would fully answer that question.

Q In other words, you are not prepared to do that now?

A I am not prepared to do that right now, no.

Q Well, with that explanation and since I obviously can't hold you to a definitive list, can you give me a listing of the some of the types of information you would need? I take it you at least would know that much, without having sat down and thought it through.

A Yes. But I'd like to state that your question is one for which there is no certain answer. Therefore, in order to answer your question fully, or to come to an answer to your question, would involve research that doesn't presently -- data for which doesn't presently exist fully.

Q When you say in answer to my question, you are referring to the question that I asked you to list the information you would need in order to

render an opinion, with a reasonable degree of medical certainty, as to whether the PCBs in the bottom of Waukegan Harbor lead to any human health disease, illness, sickness, or condition by whatever means of exposure?

A That is correct.

What I am telling you, to answer that question we would have to -- we would be involved in a research question, and that as each piece of data gathering that is done is assimilated and evaluated, this may then lead to other things that would be needed. That is why I can't give you a definitive list, because I don't know fully what the impact of the PCBs in the harbor or anywhere, to any degree of exposure, are going to do.

So that I could give you a list right now, and it could be modified tomorrow, as further information came in. The list might be modified again and again. Because there is no certainty as to what will lead to the answer. I can sketch for you kinds of research projects that might elucidate this. But I think you are asking me for a list of things that if we had the answers to this list,

we would then know, and I am telling you I can't give you this list for sure.

Q My question was a little bit different. Yo emphasized the words "then we would know." I take it you meant then we would know whether the PCBs at the bottom of Waukegan Harbor would lead to or may lead to any human health disease, sickness, illness, or condition.

A That's right.

Q My question is not whether you would know, but whether you could state an opinion, with a reasonable degree of medical certainty. And I take it you still need to do more research to answer that question.

A Yes.

Q Doctor, do you see any way in God's green earth you can do all that research and accumulate all that knowledge before the trial in March of 1982?

A I would doubt it.

Q Doctor, I'd like to put in front of you --

A Can we break for 30 seconds?

Q Sure.

(A short recess was had.)

BY MR. FEATHERSTONE:

Q Doctor, I'd like to hand you once again Exhibits 6 and 7 to your deposition. These show the PCB data for certain fish taken from Waukegan Harbor.

A Yes.

Q Are you reasonably familiar with the acute toxicity data for PCBs?

A Yes, I am.

Q Is it your understanding that on an acute basis PCBs are not very toxic?

A Yes, I'd agree with that.

Q Can you say, with a reasonable degree of medical certainty, that an isolated catch or consumption of fish with the PCB levels shown in Exhibits 6 and 7 lead to any human health disease, illness, or sickness, for any sport fisherman?

A No, I cannot.

Q Doctor, I asked you some questions yesterday about the dredging of Waukegan Harbor and the North Ditch. Do you remember that, generally?

A Yes, I recall that line.

Q I want to ask you some more questions about

that. Okay?

A All right.

Q I want you to assume that Waukegan Harbor is dredged, as the government wishes, and that the PCBs at the bottom of Waukegan Harbor are removed.

A All right.

Q I want you to assume further that fish, or that the number of fish with PCB levels as reported in Exhibits 6 and 7 to your deposition is reduced as result of the dredging.

A All right.

Q I want you to assume that before the dredging the fish with PCB levels as those shown in Exhibits 6 and 7 made up only a small portion, very small portion, of the sport fishery in the Waukegan Harbor area and the Illinois waters of Lake Michigan.

A All right.

Q I want you to assume again that before the dredging the fish with PCB levels of those reported in Exhibit 6 and 7 were or made up only a small portion of the total amount by pounds and numbers of sport fish caught and consumed each year by Illinois sport fisherman.

A All right.

Q In Lake Michigan. Okay?

A Okay.

Q Can you say, with a reasonable degree of medical certainty, that the dredging of Waukegan Harbor will in any way reduce the incidence of human disease, sickness or illness -- strike that.

Do you have my assumptions in mind?

A I believe I do, yes.

MR. WHITE: Would you like it read back?

BY THE WITNESS:

A Can we summarize them?

BY MR. FEATHERSTONE:

Q No.

Jean, would you read the assumptions back.

(The record was read by the reporter as requested.)

MR. FEATHERSTONE: Show on the record that you read the assumptions.

BY MR. FEATHERSTONE:

Q Can you say, with a reasonable degree of medical certainty, that the dredging of Waukegan Harbor will improve human health as a consequence

of the removal of PCBs at the bottom of Waukegan Harbor?

A No, I cannot.

Q In your medical judgment, is it possible that the dredging of Waukegan Harbor will in fact have no benefit for human health?

THE WITNESS: Would you read that back.

BY MR. FEATHERSTONE:

Q I will strike it, and let me pose another question.

A All right.

Q In your medical judgment, is it possible that the dredging of Waukegan Harbor will in no way improve human health as a result of the removal of PCBs from the bottom of Waukegan Harbor?

A I don't agree with that.

MR. FEATHERSTONE: Would you read back two questions ago to me.

(The record was read by the reporter as requested.)

BY MR. FEATHERSTONE:

Q Is it possible, in your medical judgment, that the dredging of Waukegan Harbor, and the removal

of the PCBs will have or will yield no detectable improvement in human health as a result of the removal of those PCBs?

A I can't agree with that.

Q But you can't state that it will, either, can you?

A That's right, I can't.

Q With the state of your knowledge, you can't render an opinion, with a reasonable degree of medical certainty, either way?

A On what will happen?

Q That's right.

A Is that your question?

Q That's right.

A No, I cannot.

Q So that I am clear, we are talking about what will happen for human health as a result of the dredging.

A That's correct.

MR. FEATHERSTONE: Let's take a lunch break.

(Whereupon, the deposition was recessed until 2:30 p.m., August 13, 1981.)

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE UNITED STATES OF AMERICA,	)	
Plaintiff,	)	
-vs-	)	No. 78 C 1004
OUTBOARD MARINE CORPORATION and MONSANTO COMPANY,	)	
Defendants.	)	

The deposition of HAROLD E. B. HUMPREY, called by Monsanto Company, resumed pursuant to recess, on Thursday, August 13, 1981, at the United States Attorney's Office, 219 South Dearborn Street, Chicago, Illinois, 15th Floor Conference Room, at the hour of 2:30 p.m.

PRESENT:

MR. JAMES P. WHITE,

on behalf of the United States of America;

MS. ROSEANN OLIVER and MS. CAROL DORGE,

on behalf of Outboard Marine Corporation;

MR. BRUCE A. FEATHERSTONE,

appeared on behalf of Monsanto Company.

HAROLD E. B. HUMPHREY,

called as a witness by the Monsanto Company, having been previously duly sworn, was examined and testified further as follows:

DIRECT EXAMINATION (RESUMED)

BY MR. FEATHERSTONE:

Q Dr. Humphrey, I have asked you for opinions with a reasonable degree of medical certainty on what might be the human health consequences to people eating fish pulled from Lake Michigan, the Illinois waters of Lake Michigan and Waukegan Harbor, and you have expressed your opinions.

Is it more difficult for you to determine the health consequences to offspring or babies being nursed by mothers who have eaten Lake Michigan fish with PCBs than it is indeed to determine the health consequences to the mothers themselves?

A No, I would not say it was more difficult. I'd say both issues are of equal precedence, equal difficulty.

Q Does the fact that to the extent there is any exposure to the baby to PCBs, does the fact that that exposure comes from the fish through the mother introduce another complicating factor in your

determination?

A Yes, it does.

Q You understand that I am referring to for instance the nursing of babies with mothers' milk.

A Okay. Yes, I agree, that is one part of that issue.

Q The other part I take it is whether there is any movement of PCBs across the placenta.

A That would be another, yes.

Q I take it in that circumstance, the latter circumstance, that whole mechanism of exposure to the fetus is very complicated?

A Yes.

Q In your medical judgment, with a reasonable degree of medical certainty, has it been determined what the significance, if any, to the health of the baby from the movement of PCBs across the placenta?

A Is that the end of the question?

Q I think so.

A Okay. Will be or --

Read back the question.

Q I tried to do the best I could.

(The record was read by the reporter as requested.)

BY THE WITNESS:

A Will be? What that effect will be?

BY MR. FEATHERSTONE:

Q Yes.

A That is the question?

Q Yes.

A I don't know. But it is another complicating factor in understanding what the human health impact might be.

Q And in your medical judgment, as far as you know, the question is still unresolved?

A That's right.

Q Doctor, do you agree with this quotation:

"The relevance of the observations in the monkey studies to human infants nursing on mother's milk containing PCB residues, due to maternal exposure to PCBs largely from environmental sources, is not known."

A Yes, I agree with that.

Q Doctor, yesterday I asked you whether you are generally familiar with the work done by Dr. Allen and Dr. Barsotti on the Rhesus monkeys?

A Yes, you did, and I replied yes.

Q You are aware, are you not, that the maternal monkeys that were nursing the offspring were themselves diseased?

A Could you clarify that? What do you mean, diseased?

Q They were sick, or ill, or had shown toxic effects, external toxic effects.

A Yes, all right. Yes.

Q Would you agree that the nursing female monkeys exhibited very serious health symptoms?

A I would agree that those monkeys were reported to have suffered health symptoms. I'd rather not place a judgment on the severity, in that I am not an expert in primate medicine.

Q Do you agree with this quotation with respect to the Rhesus monkey studies:

"Additionally, the maternal monkeys were toxic and hence toxicity effects in the offspring monkeys may not be purely due to the relatively low levels of PCBs received through monkey milk."

A What is your question, do I agree with that?

Q Yes.

A Tentatively, I agree with that. But I do have to qualify. Now, these sentences and paragraphs that you have been quoting to me, often should be looked at in terms of what preceded and what comes after. So that a sentence as it is spoken, or that paragraph as you cited sounds reasonable. But for me to render a complete judgment on its quality, I would need to see the entire page or the topic that is under discussion where that is told.

Q Do you agree, Doctor, that the fact that the maternal monkeys themselves were toxic may well be an important complicating factor in determining the significance of the PCB residues found in the nursing monkey's milk?

A Could be. We'd have to get into a discussion of what we are meaning by the mothers were toxic, what that all means, and so forth. But I will acknowledge that, yes. A mother monkey which was visibly ill, that yes, that could have an impact on what the offspring -- result in the offspring is.

Q From the PCBs in the monkey milk.

A The illness of the mother, adult mother,

could have many impacts, yes. That could complicate --

Q The determination of the significance of the PCBs in the mother's milk,

A Which would complicate the results in the infant.

What I am thinking of, perhaps the illness of the mother was in milk quantity. This would have an impact on the offspring, which has nothing to do with a chemical being present. That is what I mean by yes, it could be a complicating factor.

Q From your review of the Rhesus monkey studies of Drs. Allen and Barsotti and colleagues, did you reach the opinion that the toxicity effect in the offspring monkeys may not be purely due to the relatively low levels of PCBs received through monkey milk?

A No, I did not reach that conclusion.

Q Did you reach any conclusion?

A Not of that nature, no.

In other words, without having sat here at this deposition and read all of these papers over so that it's fresh in my memory. I have seen his work, I have seen the publications therefrom.

I am relatively familiar with them. My impression is that he was reporting certain types of effects in adults and in offsprings of those adults, and that is --

Q You were talking about the monkeys?

A I am talking about monkeys.

Q Yes.

A And that his conclusions were that these effects were attributable to the dosages of the chemicals that he had provided.

Q To the adults.

A To the adults.

And that his point was that the toxicity was passed on from mother to offspring.

Q But it's your recollection that he did not attribute that passing along of the toxicity necessarily to PCBs in the milk of the nursing mother?

A Not exclusively. As I recall, it was a matter of the offspring of the dosed adult received the toxicity. This could have been in utero, it could have been from feeding. A number of factors. But no, not the milk exclusively. That was one component of it. That is my recollection.

Q What I am interested in, Doctor, is your opinion as to the cause of the toxicity in the offspring of the Rhesus monkeys who were exposed to PCBs. From your review of the literature with respect to that, did you form an opinion with a reasonable degree of medical certainty, as to the cause of the health symptoms or health problems in the offspring monkeys?

A Again, for the record, I have not reviewed these documents in the last day or two, so I am working from recollection, and therefore I can't critique them, because my opinion is, would be, really my best opinion would be based on a critique of those papers.

My impression, recollection, is that the way the experiments were designed, that the effects on the offspring were caused by the PCB dosing of the adult mother was a plausible explanation for the results seen in the report. How valid that is would require a critique of work, and I am not prepared to do that at this time.

Q At this time you are not prepared to offer an opinion, with a reasonable degree of medical

certainty, about the effects or about the cause of the effects in the offspring?

A That is correct.

Q Do you have --

A I have to rely in that answer on, you know, it was a published article, therefore manuscripts received peer review. So I am assuming from that system that there has been some review of this to see that it is proper. On that basis.

But for me to give you, render you a critique of that, which would be my best opinion, I would have to review the papers, and I am not prepared to do that right now.

Q Doctor, have you learned of any health problem to any child nursed on mother's milk containing PCBs?

A No, I have not.

Q Can you say, with a reasonable degree of medical certainty, at what level or range of levels of PCBs in the mother's milk lead to disease, sickness, or illness in the offspring?

A No, I cannot. However, I do have an opinion.

Q But it's not one within a reasonable degree of medical certainty?

A That is correct.

Q Can you say, with a reasonable degree of medical certainty, what level of PCBs in the mother's milk leads to any health problems or conditions in the offspring nursed by the milk?

A No, I cannot.

We are talking humans here, I assume.

Q That is correct.

A Okay. That was my assumption.

Q And for the last several questions it's been your assumption?

A Yes.

Q I am sorry. If you have any questions like that, please feel free to ask me.

What do you consider to be the important literature that you would rely on in assessing the medical significance of PCBs in the mother's milk?

In other words, I am trying to get a list from you of the work that's been done that you think is significant and ought to be considered.

A Well, I --

Q I am talking again about assessing the

medical significance to human babies.

A Well, I have done this, or I have been one of several people who have done this. We have approached this issue in Michigan in February of this year, and the State Health Department took a position with respect to PCBs, the presence of PCBs in mother's milk. I can't quote the literature that was cited or used, but I have seen much of it, and I could provide such a list, if that was important.

I don't know exactly what you are driving at. You know, I can't sit here and out of recollection give you chapter and verse of what may be as many as 50 to 100 articles that would be germane. There have been national surveys of mother's milk, there have been a variety of work that has been done with respect to trying to assess that.

Q I take it the surveys you are talking about are surveys which seek to detect the levels of PCBs in the mother's milk.

A That is correct.

Q Are you aware of any study or survey made in the medical community to determine the medical

significance of the PCBs in the mother's milk? Again, I am talking about humans.

A No, I am not aware of any document that does that, that accomplishes that.

Q You are aware, aren't you, that there have been reports that some of the babies of the Yusho victims showed symptoms?

A Yes.

Q Can you describe those symptoms for me?

A As I recall, items such as babies' weight was light at birth; there was extraordinary pigmentation of the skin; problems with the eyes and eyelids. Those are predominant things that come to my mind at the moment. There were some others. This has been discussed in some of the literature we have been discussing, or literature that is available on Yusho.

Q On the literature you have reviewed with respect to the symptoms exhibited by the babies of the Yusho victims, have you reached an opinion, with a reasonable degree of medical certainty, as to whether the PCBs in the rice oil that was consumed by the maternal mother caused the problems?

A No, I do not have a clearcut opinion as to whether PCB or the other contaminants which have been identified were the sole or in combination or some interaction thereafter the cause of these effects.

In other words, the presence of other toxic chemicals in addition to PCB in that mixture have complicated that conclusion.

Q I take it that you took a position where you can't offer an opinion, with a reasonable degree of medical certainty, as to whether PCBs themselves caused the problem.

A That's correct.

Q Doctor, I have shown you earlier today a number of Muench deposition exhibits showing PCB levels in fish caught in the Illinois waters of Lake Michigan and in the vicinity of Waukegan Harbor.

A Yes.

Q Do you remember those exhibits, generally?

A Yes, I do, generally.

Q I want to ask you a couple of questions making reference to those exhibits in a general way, and if you want to look at those exhibits for any reason, please say so. They are right here. I will

pull out whichever one you want. Okay?

A All right.

Q I want you to assume that the data, PCB data that you have seen in the Muench deposition exhibits are representative of the PCB levels found in Lake Michigan fish and the Illinois waters of Lake Michigan, okay?

A All right.

Q I want you to assume that a mother who has just given birth has consumed large quantities of Lake Michigan fish for ten to fifteen years before today. Okay?

A All right.

Q And she was consuming at the rate of 24 to 100 pounds of Lake Michigan fish a year. Okay?

A Okay.

Q The PCB levels in the fish she caught and consumed were at the levels reported in your 1976 study. Okay?

A All right.

Q Now, assume that today she is catching, consuming 24 to 100 pounds of Lake Michigan fish with the PCB levels shown in the Muench exhibits.

A Yes, all right.

Q Can you say, with a reasonable degree of medical certainty, that a baby nursed by that mother will experience any disease, sickness, or illness as a result of the PCBs ingested by the mother?

A No, I cannot.

Q Can you say, with a reasonable degree of medical certainty, that that nursing baby will experience any health condition or problem as a result of being nursed by that mother?

A No, I cannot.

Q Doctor, yesterday I asked you some questions about the analytical technique your group developed to identify PCBs in the blood specimens you collected in 1973 to 1975.

A Yes.

Q At that time you and I agreed that the identification of PCBs in the blood is a tricky process.

A Yes.

Q I may have asked you this, I can't now remember it. But when I was reviewing the six or

seven page portion of your 1976 report that describes the efforts that were made to develop an analytical technique for PCBs in the blood, I came away certainly with the impression that it was a very complicated process. Is that right, was it?

A Certainly to the layman it's complicated. There is no doubt that analyzing a mixture is a complicated process. But I don't want to leave you with the impression that to a comptent biochemist, analytical chemist, that this was an insurmountable problem. Complicated, but one of the daily complications an analytical chemist faces.

Q How long a time period did it take to develop the analytical techniques that you finally selected to use in identifying PCBs in the blood?

A I believe the development of the analytical technique that was adopted for this study took place over roughly a six-month period. But I want to qualify this. They did not invent the procedure that we used. Instead, what the development, and what I mean by development, what occurred in the project was acceptable methodologies for determining PCBs, were examined for application to this

purpose, specifically for being sure that the specimens that we were testing, blood, would be able to be evaluated as expeditiously and accurately as possible. So that was the development. It really was an improvement of the existing body of analytical knowledge for these chemicals at that time.

Q If I understand you, what was involved was taking equipment that was in existence, and some methodologies that were in existence, and modifying them so you could apply it to the detection and measurement of PCBs in blood.

A Essentially that is right, and looking at the different options, to choose the one that appeared to be best to use for further study. Remembering that we are talking about 1973-74.

Q I am sorry. What is the significance of that?

A Well, I am just putting the time clock back. We know much more about the analytical chemistry of these chemicals today, 1981, than we did in 1973-'74.

The reason I made that comment is to

make sure that the perspective is that back at that time,recalling it was in the late 1960s when PCBs were able to be elucidated out of the whole pesticide mixes that were being observed. So we are talking like the methodology for these blood specimens being developed approximately four to five years after the methology to separate PCBs had been perfected.

Q I take it from what you just said then that you would agree what is important is having a top perspective on the state of the analytical art, if you will, when these methodologies for detecting and measuring PCBs were developed?

A That is correct. That should be acknowledged. That is correct.

Q I take it you would agree with me that the state of the analytical art in 1966, 1967 and '68 when PCBs were first being detected in environmental samples was not as developed as it was in 1973-74 when you and your group developed the analytical capabilities to measure PCBs in blood?

A That is a correct impression.

Q Would you agree that there was a considerable advancement in the state of the art for

detecting PCBs in samples from, say, 1967-68 until 1973?

A I have to qualify my answer again. I am not an analytical chemist, so therefore I am not a good historian of the rate of progress in analytical chemistry during that period. Therefore, I have to give you my general impression.

My general impression is that yes, strides had been made almost every year, certainly every two years in this whole area, and apparently continue to be made. So that in that context, in generalities, I would say yes, definitely has improved, had improved during that time span.

Q From what you know about the analytical methodologies for PCBs, I take it there is a lot of fine tuning that has to go on insofar as taking an analytical method that is developed for one type of sample and trying to make that same analytical method apply to another, different type of sample?

A That may be necessary.

Q For instance, the detection of PCBs in water samples may be significantly different in terms of methodology from the detection of PCBs in air

samples.

A I don't know about the word "significantly." But it definitely could be different, yes.

Q Since it took you and your group a good six months to develop the methodology for measuring and detecting PCBs in blood, I take it you wouldn't find it scientifically unreasonable to learn that it took people back in 1967 or 1968 a year or two to develop analytical methodology for PCBs in water samples, air samples, and tissue samples.

A That undoubtedly could be the case. Again, I am not a historian of those events.

Q But you wouldn't find that a scientifically unreasonable length of time, a couple of years, back in the late 1960s, with what we knew about analytical methodologies.

A I really can't comment on that.

MR. FEATHERSTONE: I have no further questions.

MR. WHITE: Do you want to start? Keep going?

THE WITNESS: We are sitting here; I guess we might as well.

DIRECT EXAMINATION

BY MS. OLIVER:

Q Dr. Humphrey, when did you first start your investigation of PCBs?

A The study which is in Exhibit No. 4.

MR. WHITE: Four?

THE WITNESS: Four.

It was started in 1973.

BY MS. OLIVER:

Q Had you done any work involved in PCBs or connected to PCBs before your study which is reported in 1976?

A No, I had not.

Q About how much of your time in the last eight years since 1973 would you say you have been involved in studies of PCBs?

A All right. The study, which is Exhibit 4, of PCBs, began in 1973 and concluded in 1975, so far as the active field work and so forth. By the time the data was compiled and statistically analyzed, and the report prepared, that takes us up to the report date, which is, as I recall, 19 -- well, let's say 1976.

Since that time, until 1979, I had no specific investigations under my direction with regard to PCBs. In 1979 I prepared and was successfully awarded a grant to do a follow-up study on PCBs. That work is continuing to date.

In the interim between the two studies, the 1976 study, Exhibit 4, and the grant I am speaking of, I was of course involved in various PCB issues that were coming up, such as fish contamination. I sit on committees as a part of my job representing the State Health Department on committees that review the fish contaminant problem in the State and so forth. So that I have kept up on the issue of PCBs.

Also, the issue of PCBs has arisen in our major study in Michigan on the polybrominated biphenyl investigation, which was begun in 1976 and is running concurrently. So the specific studies are as I cited, but the interest and activity on the topic has been continuous.

Q Would you say that from 1973 to 1976 when you published your report that the study of PCBs in human blood was the major study in your department,

or under your supervision?

A I answer that yes and no. When this study was initiated, we were tailing off a study of investigating mercury contamination, so there was some overlap. When this study of, and I am referring to Document 4, Exhibit 4, was being completed, the PBB study was underway. So there was overlap. So yes, there was a period of time when this was the sole thing that was occupying my time, but it was of relatively short duration.

Q Is the new study, that I think is the grant application as identified as Exhibit No. 3, occupying the majority of your time presently?

A No. At this time I am responsible for three major studies which are underway.

Q What are the other two studies?

A The one is the grant that we just referred to. The other is the long-term study of human exposure to polybrominated biphenyls. The third is a cohort of people in Iowa, which we are using as comparison purposes to that, the polybrominated biphenyl study.

Q Is the polybrominated study a funded

study?

A Yes. It is funded by HEW, which is called - It's a health and human services agency. The funding comes from a variety of federal departments.

Q Does HEW also fund the study of the cohort of people in Iowa?

A No. The money for that is State of Michigan money.

Q Am I correct that the money to fund your project comes from in the state or from the federal government?

A That is correct.

Q What is your operating budget for your projects for the year 1981?

A Collectively?

Q Yes.

A Roughly speaking, say $800,000.

Q How much of that is from HEW or the EPA?

A EPA and HEW, it's $300 and some thousand dollars for both accounts.

Q So the balance would be from the State of Michigan?

A From the State, that is right.

Q What was the grant from the US EPA, the amount of the grant for your studies, Exhibit No. 3?

A The projected three-year funding for it was $1,000,000, $1.1 million, or something. Very close to that.

Q I notice on your curriculum vitae, Exhibit No. 1, that you are the founder and director of a corporation called Kelmik Corporation?

A That is correct.

Q What type of business is that?

A That's a patent holding company, and it was formed when a colleague of mine and I invented a liquid purifying process and had it patented. This company was formed to market that process. This was done roughly at the conclusion of my doctoral work, when I was associated with the University.

Q What type of uses does this patent have?

A Basically, it is a solids-liquid separation process. It has application in various industrial wastes, such as heavy metal plating waste, which are slurries of solids and liquids. The point being to remove the solid, and that clarifies the liquid portion for re-use, recycling.

Q You are not involved in the manufacture of these?

A No. My involvement is minimal at this time. I am co-inventor, and I am an officer of the company. But I have no other involvement. In other words, I am an officer, on the Board of Directors of this.

Q I guess my question was, does the corporation manufacture this thing?

A No. It has sold the rights to the patent to other outfits and we collect royalties.

Q Dr. Humphrey, what is blood titer, t-i-t-e-r, test?

A A blood titer generally refers to the level of a chemical in the blood. It's commonly used in the field of immunology, to measure the presence of antibodies. In other words, you take a blood sample, and by certain types of immunological tests you can measure the concentration of antibodies in that blood, as challenged by antigen that they would react to. It is a concentration measurement, basically.

Q Are you doing any of those types of tests or studies presently?

A What, immunology tests?

Q Blood titer.

A As I have just defined it, no.

Q Have you had conversations with Dr. Kimbrough?

A Yes.

Q Do you know Dr. Kimbrough, personally?

A Yes, I do.

Q Could you give me an approximation over the last number of years how many times you have met with Dr. Kimbrough concerning your work?

A All right. My acquaintance with Dr. Kimbrough begins with the PBB problem in Michigan, which began in 1974. She works, is employed by the Center for Disease Control, and they have assisted us with our PBB project all along. Obviously the questions about PBBs are toxicology and human exposure in medicine. Dr. Kimbrough has been a consultant to our project in that sense. I have probably met with her or spoken to her or seen her at meetings ten to twenty times.

Q Have you had conversations or discussions with Dr. Kimbrough about your PCB studies?

A I probably have, but frankly my conversations with her have really been focused on the PBB.

But undoubtedly her knowledge of what I have done before on PCBs, we may have talked about it. But I have not consulted her specifically with respect to PCBs. In fact, the study, which is Exhibit 4, was essentially completed before I ever became acquainted with her.

Q Have you sent her any of the data that you collected for your study, No. 4, Exhibit No. 4?

A I may have, and it would have been in the context of to provide background for our PBB work. I am sure that she has seen this Exhibit No. 4, because I am certain it's been circulated fairly widely within the federal agencies.

Q Have you discussed with Dr. Kimbrough the new study that is being done presently, Exhibit No. 3?

A Yes. I can't recall specifically, but undoubtedly we have talked about it, again because of my involvement with her with respect to PBB and our desire in the new study to look into some of the measurement parameters that we might make on humans, to try to determine if there is a cause-effect relationship. I probably had conversations with her about that. I have not invited her specifically

to consult on it. But again, because we are acquainted and do talk as colleagues, I am sure the topic has come up.

Q Do you recall any recommendations she may have made concerning the new study?

A They would be in the area of tests that we would do on human subjects to try to measure whether or not there has been any impact on human physiology. I am thinking of, and I can't remember which, but I know she is very interested in lipoproteins, the high-low density cholesterol issues. I probably had asked her if there were some other tests that might be useful. Colleagues of hers have suggested some of the enzyme tests we are doing, so yes. But I can't be too much more specific than that.

Q With respect to your new project that is underway, have you communicated in writing with Dr. Kimbrough or other colleagues concerning what types of things should be included, or might be included?

A Again, I am being vague because I am trying to recall. I may have, but I have often accomplished these aims by face-to-face, verbal, and my taking notes. Again, I see people from time

to time for one reason or another, and I know the topic has come up. I can't tell you specifically if I wrote her a letter and she sent me a response. It's entirely possible.

Q If you have correspondence from Dr. Kimbrough or any other scientist concerning your project under way, would you have that in one location in your office?

A Probably not, but I'd have to check my correspondence file to see.

Q Do you have a general correspondence file for all of your work?

A Yes. But that's generally not where I keep papers like that.

Q Well, I would like you to look and see if you can find any correspondence from Dr. Kimbrough, or, as you mentioned, other colleagues of yours, relating to suggestions or comments they may have made.

A Okay.

Q With respect to your new study.

A Yes, I can search my file to see if I can find that, and again I will remind you that I think

a lot of this has come through telephone or personal conversation.

Q Have you had conversations or discussions with Gilman Veith concerning PCB-related problems?

A No, I have not. I know who he is, but I do not recall speaking to him about our projects or about this, no.

Q Have you ever read any of his publications or articles relating to PCBs?

A Yes, I have, from time to time. As I recall, they pertain more to fish, fish contaminant levels. So in following that line, yes, I have seen them from time to time, but not as a habit, no.

Q Have you had conversations with Wayland Swain?

A Yes, I have.

Q Who is Dr. Swain?

A Dr. Swain is the Director of the Large Lake Research Laboratory of the EPA, which is located at Grosse Ile, which is the administrative unit through which our grant project, the current Exhibit 3 grant project is administered.

Q Have you had your discussion or communications

witn Dr. Swain relating to your new grant project?

A We have had numerous verbal conversations. I often go down there for an afternoon and we talk about things. Often -- I should say periodically, because the project officer, Dr. Mullen, is also located in that office. So for either administrative work or intellectual scientific work, we often communicate.

Q Has Dr. Swain made suggestions or recommendations?

A Yes, he has.

Q What were his suggestions or recommendations?

A I can't precisely tell you. He was one of the people that approached me going on three years ago about would we be interested in resuming our 1976 study. We have talked on numerous occasions about what we might -- what such a project might involve. The evolution of that is the final document which is that application which states basically in generalities what is going to be done.

Q Am I correct, Dr. Humphrey, that the suggestion to undertake a new study was from Dr. Swain of the US EPA?

A Well, it is a combination of events. We had been desirous, "we" meaning myself, my colleagues and our department, had been desirous of following this 1976 study up. But at the time we were deeply involved in the PBB problem, and frankly I had to put that idea on a shelf.

In late 1978-1979, I was approached by the Large Lake Research people at Grosse Ile, which would have been Nelson, Thomas, and Wayland Swain about that prospect. So we picked it up from there.

Q What was their **stated** interest in your new project?

A I frankly don't know. Their approach to me was that they also were interested in following up on my previous work. They are involved in developing models to try and understand what is the state of pollutants in the Great Lakes. Their feeling was one of the compartments of that model was the human. And that they had contracts out that were evaluating air, water, fish, and other compartments. They were interested in getting, obtaining data on the human component of their big model. That is why they were approaching me.

That was the introduction I was given.

Q Have you reviewed these types of models in the past?

A Such as referred to, that they are doing?

Q Right.

A No, I am not an ecological modeller.

Q You worked with Dr. Swain and Dr. Mullen in preparing the protocol for your study?

A No, no, I did not. I prepared the protocol for the study, but I have had dialogs with them. But it was not a joint project. They never set pen to paper, nor did they direct me what to do. We talked about the scope of this thing, and I was asked why don't you submit an application, and I took it from there.

Q Since that time in late 1978 or early 1979 you have had communications with them about the on-going work, I take it?

A Yes, that is correct. Both administrative book work as well as scientific communications.

Q Would the grant file that you keep contain communications with the US EPA concerning the grant?

A It should, yes.

Q Would it contain the scientific exchange as well as, you know, funding questions and responses?

A Yes. I would expect it would. That is where you expect to put those pieces of information.

Q I would like to see the entire grant file that you have to date on this new project.

A All right. I guess that is all right.

MR. WHITE: Yes.

BY THE WITNESS:

A I don't know what is going to entail to copy it.

Q With respect to this new project, I think you testified yesterday, and correct me if I am wrong, that you have collected the data from the subjects or the cohort from your 1976 study?

A That is correct.

Q You are in the process of analyzing the blood specimens taken from those same people?

A That is correct.

Q With the analysis of those blood samples, that phase will be completed, that phase of the project will be completed?

A Yes, with the exception of then we will complete the data analysis, the statistical analysis of the data. But yes.

Q Do you know how many people from the first study or from the 1976 study are included in the second study?

A Yes, I do. I will try to recall as best I can. It's not 100 percent. One hundred percent of the 1976 cohort are accounted for. Some had died, some have moved away, some don't want to participate, and so forth. My guess, without checking my records to give you an exact number, is 75 percent of them are in the study today.

Q Is the questionnaire interviewing procedure followed in this new project the same as was done back in 1973-'74?

A Yes, and no. Yes, in that we -- by returning to the 1976 cohort and trying to duplicate that previous communication, so that we will have direct comparison.

Now, in addition, these people are going to become part of this larger expanded cohort, and for the larger expanded cohort additional or slightly

different questions are being used. So that our 1976 cohort will end up being interviewed twice, if you will, or with both instruments.

Q Am I correct that part of this new interview procedure will involve questions relating to the presence or absence of the 18 symptoms that appeared on the first questionnaire?

A Yes, I believe they do, yes.

Q Are there additional symptoms added to the new list?

A I can provide you with the questionnaire, and that will answer the question precisely. I don't think so. But the added questionnaire is going to get into some other areas. So there would be some overlap on that. Also, we will be going into a clinical phase, where we will be asking more detailed questions with respect to certain kinds of medical or health condition parameters. So I don't know if you construe those as additional to the 18 original questions or not. Obviously, currently, we will be gathering additional medical or health condition-type information, yes.

Q Can you give me an idea, and I know, I

don't want you to try and think of what those parameters are, but the types of medical parameters or conditions that you are following up on in this project that were not included in the last one?

A Yes. I gave a partial list yesterday. I will try to repeat that.

In the period of time since 1974 additional research has been done in the world with respect to PCBs, or more appropriate the polyhalogenated biphenyls, and some of these research reports give leads as to things that might be investigated, such as vital lung capacity, blood pressure, certain types of liver function enzymes, certain types -- measurement of certain types of lipids in the blood, and so forth. To the extent that it's feasible and practicable, we have been trying to incorporate those kinds of things into our ongoing study. We may not be able to do everything, because of certain limitations. But the philosophy is we are going to try to incorporate those leads, incorporate techniques to gather data on those topics which we consider to be leads from what has been in the published literature.

Q So am I correct that what you intend to do

is to bring these people in or have somebody go out to their home and not only ask questions and take a blood speciment for purposes of identifying PCB residues, but also identifying liver enzymes in the blood and taking blood pressure and testing lung capacity?

A That is correct. That is the right impression.

Q In the 1976 study, did you compile any information concerning the occupations of the people in the study?

A Yes, as I recall we did ask that.

Q Was any use made of that information in terms of your reports?

A As I recall it does not appear in the report, which strikes me as meaning it was -- we felt it was insignificant. And in that context I mean the enrollees, the participants in that study were not occupied in occupations which were of concern to us.

Q If we could stay with your new project for a minute. The second to the last page, I guess, is a, "Proposed Project Workscope Schedule."

A That is correct. Written in 1979.

Q Are you still on line, time-wise?

A No.

Q Are you behind schedule?

A Yes.

Q What do the broken lines indicate on this chart?

A Uncertainties about the starting date and the tailing off dates. For instance, Cohort Expansion, B. Field. A dashed line at the beginning and dashed into the third year. We weren't certain when the field work would actually commence. That depended on several variables; contacting all of our previous cohort and arranging to do that, getting the documents prepared and so forth. At the end, as you move over to the third year period, we weren't sure how long it would take to complete our work. So I would just say they represent time line uncertainty.

Q With respect to Cohort Expansion, you mean the new people added to the group, not the followup to the people in the 1976 study, correct?

A That is correct. You can see on there

that the 1976 study, which is defined on this document as 1974, in fact is a work unit by itself. Cohort Expansion there on this document refers to recruiting new people above and beyond that.

Q The field work for that has not begun yet?

A No. The field work for that has been ongoing for over a year now. The first phase of that Cohort Expansion has occurred in Michigan. Additional shoreline communities, additional people in those communities have been recruited, and the comparison persons from those communities have been selected.

Q What has not been done is to go beyond the Michigan communities to the other areas of interest that you mentioned yesterday?

A That is correct. It would be the third phase of the cohort involvement.

Q The field work on that aspect of it has not begun.

A That is correct, insofar as actively recruiting people.

Q Right.

In several places on this schedule there

are black dots appearing. What do those indicate?

A Those are indications of when we estimated in 1979 reports would be ready, would be prepared and ready.

Q For the 1974 PCB study followup part of the project, first part, there is an indication that a report would be ready in September of 1980 and April of 1981. Have either of those two reports been done?

A There is a report prepared at the anniversary of each year of the project. We have just gone through the second anniversary. In other words, the first year is concluded, and when we re-up the grant for continuation funding, a report is prepared. We discussed this yesterday. This function has just completed in the second year. The anniversary being September, a report was prepared there. So there are two reports that have been prepared. They are considered progress reports in respect to grant renewal.

Q Do those progress reports cover each of the four different areas?

A Yes, they do. The dots beyond those

would represent final reports on certain phases of the project. If you focus on the 1974 phase, you see there is a dot out there in April of 1981. Okay. We nave missed that date, but this, what I referred to yesterday, I would expect in the next six months that that report should be drafted.

Q Doctor, do you know of anyone in the United States who has accumulated as much data on PCBs in humans as you have on the basis of your 1976 report, and that you will gather on the basis of your new project?

A No, I don't know of any more extensive studies than ours; nor am I aware of studies that pertain to PCB exposure from fish.

I do know, and it's in the literature, and it's been published in books and what-not, certain types of studies of smaller groups; capacity company workers, people in Indiana who are exposed to sewage, sludge, and so forth. You may be familiar with some of this literature. But I don't regard -- Those were not as extensive as these studies. So my answer is no.

Q You wouldn't disagree that your work,

your study in 1976, and your present study will probably accumulate the greatest body of data on PCBs in humans, on humans from exposure to fish?

A That's possible, and I have been told that that is probable.

Q Yesterday you testified that you hadn't testified at any hearings or trials or given any -- Well, strike that.

Let me ask you this. Have you given any depositions in any cases or matters relating to PCBs?

A No, I have not.

Q Yesterday, in response to some of Mr. Featherstone's questions regarding whether you could say certain things or whether you knew certain things your response was you couldn't say for sure or precisely. Do you remember using those words?

A Yes.

Q When you said, "for sure," or "precisely," would you agree that what you meant and what we could understand you to have meant would be that you couldn't say with any degree, or with a reasonable

degree of medical certainty?

A Yes. And let me explain. That's one of the problems that we probably run into in trying to have a dialog like this. If you ask me a question, I am scientist, and if I don't have data which precisely gives me an answer to that question, then I can't reply with certainty, from my perspective.

However, I can, even on the basis of partial data, have a hunch, an opinion, a feeling.

But I interpret most direct questions as: Give me a precise answer. So that's why my responses, as they were. That's why when asked with a high degree of medical certainty, and to me that is a qualifier, and that says: All right, if you answer yes, you should have some reference data to back it up.

Q The questions referred to a reasonable degree of medical certainty. That is what you understood it to mean?

A To me, reasonable degree of medical certainty would mean that I have a reasonable amount of information to back up that opinion, thought, statement, comment, or whatever.

Q In your 1976 study or report, am I correct that you made no attempt to determine what other sources of PCBs may have been involved in reaching the readings that you gathered?

A No, that is not entirely correct.

Our emphasis and the selection of our exposed subjects was on the basis of their fish consumption. But we did inquire as to other possible PCB exposures.

In the questionnaire, there was reference to occupations, or to other chemical exposures. So that we attempted, through the interview, to weed out other obvious exposures to PCBs, such as working in an occupation where they knew they were exposed to it.

Q Other than working in an occupation and exposure to fish with PCB levels, there are no other, in your opinion, significant exposures to humans from PCBs, are there?

A There is one other, at least in my opinion, to my knowledge, and that would be with respect to living on farms which have the silos coated with material that contain PCBs.

Q Any others?

A We have covered fish, silos, occupation, direct occupation, obvious occupation. There are some others, but they would be more anecdotal. I am thinking of the study in Indiana with respect to sewage sludge, but I do not believe that is significant.

So I believe those three, silos, occupation and fish constitute the major possible exposures.

Q In doing your study in 1976 and your present one, those three areas are the ones that you are inquiring into to find exposures?

A Yes. We are inquiring, trying to determine if there are other obvious exposures.

Q Am I correct, Doctor, that the blood transfers or transports chemicals not only coming into the body, but going out of the body?

A That is correct.

Q There is no way to tell in taking a blood specimen what is happening to that material or chemical in the blood that you are measuring, is there?

A Essentially that is correct. In other

words, a measurement of the quantity of a chemical in the blood gives you just that, a concentration of that chemical in the blood. It does not tell you whether it is on its way into the body tissue or on its way out. All it does is give you a reading in the blood.

But I must qualify that. Based on other work, both that we have done and that is reported elsewhere, we have a little more knowledge on what might be going on than just a singular blood reading would give you.

For example, with our PBB work, we have evaluated human tissues and breast milk and so forth, as well as blood, simultaneously, from the same subject. So that we have learned what some of the proportions are. And in our PBB work, we have been able to establish certain ratios between blood, breast milk, and adipose. We have had sufficient evidence from this to understand what the range of those ratios, and what those ratios generally are.

Q Have you done that with PCBs?

A No. We have not specificially done that

with PCBs. But we can infer certain generalities from the other work. We have not done it precisely with PCBs.

Q From the other work that was done on PBBs, could you make those determinations or make those comparisons to PCBs with a reasonable degree of medical certainty?

A Yes, I believe we can.

Q Is part of your new project to study tissues, other than blood?

A No, it is not.

Q Would you consider adding that aspect to your study?

A We have, and it is. But that concept is present only on a voluntary basis.

In other words, the study is designed on the basis of we will collect blood specimens. If the opportunity arises that one of the subjects becomes pregnant and is willing to provide certain tissues, be it breast milk, placenta, cord blood, or what. Or if one of the subjects is going in for elective surgery, and is willing to donate certain tissues, then we will collect them and

test them.

But the protocol does not state that we will do this. And there are obvious reasons for tnat, because this is a human study.

I might add as an amendment, it would be very desirable to get all of those tissues. But in doing a study of this nature it is not practical.

Q You testified earlier today, Dr. Humphrey, that in order to give an opinion with a reasonable degree of medical certainty, concerning whether the PCBs at the bottom of Waukegan Harbor will lead to disease, sickness or illness in humans, you would have to do research.

A That is correct.

Q You said you couldn't give a whole list of things that would need to be included in that research.

What I would like you to tell me is approximately, or estimate for me what length of that research project in your opinion would need to be in order to have an opinion?

A Well, as I qualified this morning when I tried to respond to the question, the basic problem that that question poses is my interpretation of your question is what will PCBs do to humans. We have to

answer that before I can tell you what PCBs in a certain location is going to do.

Precisely what PCBs will do to humans is not known. I can't tell you when it will be known. It could be a matter -- And one of the essential questions about what PCBs could do to humans lies in the issue of long-term or chronic exposure. The only way to address that is probably to do a long-term study. Therefore, in answer to your question, I can't clearly define at this point in time, in its entirety, what would need to be done, and I can't tell you how long it would take to do it, either.

Q What would you define as a long-term study? In the medical community, what is a long-term study?

A Generally a long-term study is regarded as the length of a generation, and that would be approximately 20 years.

For example, our long-term PBB study in Michigan is designed to be a 15 to 20 year study. It's in its fifth year.

Q Would I be correct in saying that in your best medical judgment that a long-term study of

approximately 20 years is the type of study that needs to be done in order to determine what effects PCBs will have on humans?

A If you will remove the word "is" and replace it with "might be," I would agree with you.

Basically, a long-term study might be what is necessary to fully answer the question. Because I can't tell you that that indeed will. We may discover some information tomorrow or next year that will answer the question.

Q My question is, based on what you know now, as you are sitting here today, is that your best judgment that a long-term study --

A May be.

Q -- may be what is --

A -- necessary in order to fully answer the question, yes. I would agree to that.

Q You testified yesterday that one of the projects you are involved with with PCBs is analyzing specimens that other doctors sent you from patients.

A That is correct.

Q About how many specimens do you get a month?

A I can't answer you precisely. My guess

would be ten.

I might also add, parenthetically, that this service to physicians is something that was born out of the PBB problem, when there were many questions and many people desiring information. There were times when we had as many as 100 specimens a month coming in, or more.

But with respect solely to PCBs, it is generally in the context of a physician treating a patient, who the physician has reasonable belief that the patient may have had undue exposure to PCBs, and he is interested in what the person's PCB blood level is, or on occasion an adipose, or whatever.

Q Your Department will analyze the specimen using the technology that you have come up with?

A That is correct.

Q And send the specimen back with the results.

A That is correct.

Q Do you have any follow-up contact with these doctors or their patients?

A No, we do not. It's not a specific project. It is, as I said yesterday, it is a service-type

operation.

Now, we retain the data in the sense of what the levels were, but we have no further follow-up specifically with respect to this.

Q What information do you get along with the request?

A It will vary from none to a full diagnostic chart on the patient. It depends on the doctor who participates.

Q Have you used the data that you have come up with in doing these analyses in connection with any of your studies of PCBs?

A No. Charts, graphs, figures, conclusions with respect to the study is generated by the data on the participants who are identified and defined in that study.

The data that is gathered on the service-type of analysis goes into our general body of knowledge, but is not specifically incorporated.

For example, from time to time we do get workers that have been working in incinerators or capacitors, or what not. We are building a file on all the incinerator workers we have tested. We

have that kind of information. But no specific reports, and those are not a component of these studies.

Q With respect to the 1976 report, Exhibit No. 4, the blood specimen samples that you took showed a wide range of variation, is that right?

A Yes.

Q In order to make your correlations or attempt to make some statistical significance from the data you used means.

A Yes, we did.

Q Did you consider using the actual data itself to make correlations?

A Yes, we did. I believe this is exemplified in figures 3 and 4 of the report.

Q What do those figures show?

A Figure 3 is a correlation of PCB levels in human blood with fish consumption.

Q Those are the actual data?

A Yes. Actual readings on individuals plotted against their reported poundage per year of fish eaten.

The feeling of the statisticians were

that they needed -- in order to make proper correlations and do the statistical tests, they needed to transform that data.

Figure 4, then, is a replot of the same data, but here the natural log values of PCB values have been used.

In the text there is a little bit of explanation as to why that was done. I am not a statistician, but we have at the Department and at the service of our project people who are experts in statistics. So I rely on them to determine what needs to be done with a body of data to best analyze it. And so that's what this final report represents.

Q So, as I understand you, you didn't do the statistical work or determine how these statistical correlations could be made, if they could be made. You relied on a statistician in your Department or at the University.

A In our Department. That's basically correct.

Q Who was the statistician?

A I don't recall right now. It's no secret. There are one of several people who we commonly work

with. I don't know which one. Actually, it's a collective type of thing. So I can't answer you precisely, except that can be obtained.

Q I didn't understand the difference between figure 3 and figure 4, and what the natural log means in terms of the data or the correlations. Would you explain that to me.

A Well, I can try to, but I might better refer you to the text on probably Page 17, which carries over into Page 25. In the text on Page 17, the paragraph which occupies the center of the page, is a statement there which talks about using the natural log transformation, and it's asterisked. The note at the bottom of the page talks about a log transformation is used when variance increases as values increase.

Now, this is statistical jargon. Again, I have to defer to a statistician to clearly explain that to you. But the essence is, if you line up all of your people who have say ten pounds of fish consumption, you get a range, a scattering of their blood levels. Then you line up the people who have 20 pounds of reported consumption, and you line up

all of the blood values for them. The scatter is even wider. What this note is saying is when that occurs, that the best way to handle the data is to make log transformations. I will have to rest my comments with that, because the area of statistics is a whole mathemathical endeavor, an art, if you will, or a science form, and there are many different ways to deal with data in assessing its significance. There are different possibilities chosen. Sometimes you try two or three before you hit one that really works with the data at hand. I would have to defer to the experts for that.

Q In making or attempting to make correlations with the data, the problem that you found that you had with the variances among the specimens caused you and your statisticans some problems on how to arrange and how to interpret the data.

A Yes.

Q You relied basically on your statisticians in your department to arrange the data in a manner that could be presented in this report.

A Yes, that is correct.

Q On Page 17, the first full paragraph,

the first sentence reads:

"There was a highly significant correlation between the reported quantity of Lake Michigan fish consumed and the concentration of PCB in the blood of participants in the study."

Do you see that sentence?

A Yes, I do.

Q Is this statement, that there was a highly significant correlation, based on the data appearing in figures 3 and 4, and the interpretation of that data from there?

A Yes. Actually, it is based on the data values which appear in table 4, 5, 6 and 7. Those data values are arrayed in figure 3; but the actual data itself is contained in those tables that I just cited. So those are the figures, the numbers that are used.

Q What I am trying to understand, though, is that the data that is the basis for the statement appears initially in figure 4, and then was rearranged in some way by the statistician in tables 4, 5, 6, and 7?

A No. I don't think that is an entirely accurate interpretation.

The blood values -- The data on the individuals is provided in tables 4, 5, 6 and 7. Those are the numbers, the figures, the actual data points. One way to display those is shown in figure 3. Another way to display those is shown in figure 4. But those data points, that data values, are put in a computer and various statistical tests run on them, irrespective of how you chart them in those two figures.

It is on that basis of applying the various types of mathematical statistical tests that the summary statement "highly significant correlation" comes from. There are specific mathematical tests that are run to determine significance. It doesn't matter on how you plot. It is dependent upon the actual data values themselves.

Q Does figure 3 and figure 4 only include the data on the 1973 study?

A That's possible, yes. I believe in the text we refer to a plot of the levels of PCBs in blood versus pound of fish consumed for this group.

In the preceding sentence we talk about 117 participants who reported eating fish in 1973. So I say that that would be correct.

As I recall, it wasn't deemed necessary to display figures and report every correlation we made or every plot of data. Figures 3 and 4 are exemplary.

But table 8, for example, the mean values and so forth, is based on data collected on the two different years.

Q You mentioned yesterday, I think, that your conclusion section on Exhibit No. 4, if you look at that for a minute.

A Summary of Findings?

Q The conclusion.

A Okay.

MR. WHITE: No. 7?

MR. FEATHERSTONE: Fine. No, at the bottom of page vii.

BY MS. OLIVER:

Q The third sentence of that conclusion that begins, "It has not been determined. . . "

A Yes.

Q You were asked some questions about that sentence, that conclusion, yesterday. I think you testified that you were confident, I think you said, that long-term exposure to PCB contaminated fish will result in continuing accumulation of PCBs. Do you recall that testimony?

A Not precisely as you have stated it.

Q Well, let me ask you this then. Has your conclusion that appears -- Does this conclusion that appears in your 1976 report, is that still your conclusion today?

A Does that still stand?

Q Yes.

A Yes, it does.

MS. OLIVER: Let's take a couple of minutes.

(A short recess was had.)

MS. OLIVER: Back on the record.

BY MS. OLIVER:

Q Dr. Humphrey, yesterday I think you expressed an opinion that based on the new data on your new study you felt that long-term exposure to PCB contaminated fish would prove to show a continuing accumulation of PCBs. Is that a correct

statement?

A I believe I agree with you there, yes. That was an opinion.

Q Is it an opinion based on partial data that you have looked at?

A That's right.

Q It is an opinion that you couldn't say could be given with a reasonable degree of medical certainty?

A As I sit here right now, I would hesitate to put that much strength on it. In another week or two I may be able to. I am talking about data which is under analysis right now.

Q What data specifically have you seen that leads you to that opinion?

A Okay. Now we are talking -- Let me just clarify, if I may. We are talking about accumulation. The question of whether or not PCBs accumulate in people.

Q That's right.

A Now, at the time this 1976 report was written, we had the data which is contained in the report, which is basically a two-year study. At

that time two vital questions remained with respect to this statement that you have called my attention to in the conclusion. One was we didn't know what long-term exposure would -- what would happen after long-term exposure. We still don't know that today.

The other was a question of whether or not PCBs were slowly accumulating in human tissues, blood, people.

At the time of this report we didn't have enough information over a multi-year span to tell.

Today, as I sit here, we have had another five years time go by, and we have gone back and re-evaluated many of these original members of the cohort. We are now analyzing the current testing of their blood with the past testing.

It is my opinion that this is showing an upward trend. But I cannot render that opinion with the certainty that you ask until that data analysis is complete, and I have a report.

Q Have you done or asked your statisticians to do any statistical analysis of the upward trend that you see to determine whether there is a significant upward trend, or whether it could be

due to chance?

A Yes, we are doing that.

Q That has not been done yet?

A That is in process.

Q You haven't received any tentative conclusions or opinions on that aspect?

A I haven't as of this moment, no. I may have it tomorrow when I get back. It's in process, it's under way.

Q We will have it when you come back to Chicago.

With respect to the second part of that conclusion in your 1976 report, which reads:

". . . or eventually produce identifiable health effects in humans."

Do you have an opinion today, based on the new data that you have accumulated, whether long-term exposure to PCB-contaminated fish will result in identifiable health effects in humans?

A I do not know at this time.

Q You don't have even any tentative opinions on that aspect?

A No, I don't.

Q You mentioned earlier today that you did have some opinions that you could state with a reasonable degree of certainty relating to PCBs. Do you remember?

A I don't remember what they were, but if I said it, it's on the record.

MR. FEATHERSTONE: Read the question back, please.

(The record was read by the reporter as requested.)

BY THE WITNESS:

A I thought you were giving me a list of opinions that I had rendered. I am sorry. On the topic of PCBs do I have some opinions: Yes.

BY MS. OLIVER:

Q That you consider to be within a reasonable degree of medical certainty?

A Yes.

Q Could you tell me what those opinions are?

A All right. I believe that there is a growing body of evidence that is showing that PCB is definitely a toxic chemical. That it has a variety of measurable impacts on biochemical processes,

physiological processes of animals.

There is also a growing body of information which shows that some of these effects are found in humans. I have referred to some of these in my testimony from time to time; correlation of vital lung capacity with PCB; blood pressure, elevation of certain enzymes, and so forth.

Also, there is increasing evidence that the halogenated biphenyls, of which PCB is one, are animal carcinogens.

There is evidence that specifically for PCB that it is an animal carcinogen.

Therefore, we must consider that it may be a human carcinogen, although this has not been definitely demonstrated.

That general body of knowledge, which is in the medical and scientific literature, which is growing daily, therefore leads me to have the opinion that this PCB is a toxic chemical, and that it is to be considered very seriously, because we don't fully understand what this toxic chemical does to humans. We can't state with certainty what the critical doses are, or what the chemical will do in

terms of impacting human health, as defined as causing sickness, illness or disease.

As I referenced a moment ago, we do have some indications that PCB can cause some abnormalities with respect to certain physiologic activities in people, but we have not been able yet to make the link between what those alterations mean with respect to illness and disease.

But because of the evidence that I have been talking about for the last few minutes in the laboratory and in animals, it is my opinion that PCBs should therefore be avoided, if possible. Exposure to PCBs should be avoided, if possible. And that in fact the basic premise of public health protection today is when you are faced with exposure to toxic chemicals that are believed to be toxic, or have the potential to be toxic to humans, in all cases attempt to reduce exposure.

So my opinion is that there is a growing body of evidence which leads us to believe that PCB has the potential to cause problems with humans, and that therefore exposure to this chemical should be minimized wherever, and if possible.

Q Dr. Humphrey, if I can attempt to summarize your testimony a few minutes ago here, it's your opinion that PCBs are a toxic chemical?

A Yes.

Q And although there is no data to support the conclusion that they cause harm or health effects in humans, in your opinion there is a possibility that they cause those effects in humans, is that correct?

A I am not going to agree with exactly how you summarized that.

I could state that there is reasonable uncertainty as to what PCBs will do to humans, as defined as any alteration of normalcy leading all the way to an identifiable disease.

In the presence of that degree of uncertainty, and the fact that this is a toxic chemical as shown by a variety of laboratory and animal tests, we then exercise as scientists a great deal of interest and caution with respect to this kind of a chemical, especially because it has been shown to accumulate and store in the tissues of animals, which would include humans. And with

those parameters then, we have a great deal of concern then as to what this means, even though we do not have data which clearly has defined that there is a disease.

Q Isn't it true that there isn't even data which has clearly shown a relationship, significant relationship between a sign or a symptom of a disease or a health condition and PCBs?

A Well, that is what I was having trouble with your summary a moment ago. And as we discussed this morning, an alteration in an enzyme level is a sign. That is not a disease. So we do have evidence, we do have data that there are some impacts between -- there are correlations between quantity of PCB in a human, and certain physiologic signs.

Q Doctor, correct me if I am wrong, but aren't those correlations not been shown to be direct correlations attributable to PCBs? There have just been findings of PCBs and elevated blood pressure or elevated liver functions.

A Yes, that is what I am referring to.

Q Okay. So there is no data supporting

a conclusion that PCBs leads to elevated liver functions or these other signs.

A That is correct. And I correct myself if I gave the impression that that was a conclusion. I meant there is an association, a body of information that is beginning to show these associations.

But that is correct. The final conclusion that PCB is solely responsible for these things, no. That is the uncertainty part. We don't know that for certain.

Q Would it be fair to say then that your opinion that PCB is a toxic chemical and caution should be exercised, is based not on data supporting conclusions showing the relationship between PCBs and human health conditions or effects, but on associations which have been found in studies?

A All right, yes.

Q How do you define "association"?

A This would be situations where a variable is shown to correlate with the presence or quantity of PCB. The variable being defined as a blood pressure, or an enzyme level, or whatever you choose.

Q But in associations, the variable is not

shown to be significantly correlated with the symptom or sign.

A I'd have to check the references on the specific citations to see what degree of significance was attributed. I can't comment on how significant. Just that the correlations were reported.

Q These correlations do not show a causal relationship, however.

A What do you mean by "causal"?

Q That the sign or condition is attributable to the variable.

A No, they do not.

Q When we are talking about association, that is what we mean by that.

A Yes, okay.

Q If I can refer to the 1976 study again. As I recall from reading it there were some specimens taken from persons who were fasting at certain times and non-fasting at other times, for the purpose of determining whether mobilization of lipids causes a release of PCBs with the resultant increase in blood levels.

Do you recall that being part of the study?

A Yes.

Q Could you explain to me what that was intended to show?

A The purpose of that exercise was to select which kind of blood specimen would be suitable for giving us an accurate reading of PCB in the blood of the participants. PCB is lipophilic. Therefore, the question was, well, if you had some of your people in fasting state, and some of your people had just eaten, those two situations impact the quantity of lipids in the bloodstream, and would this then impact the readings you get.

In other words, did we need to instruct all of our participants to be fasting when we took the blood. So that exercise was to investigate whether or not there was a significant difference. The result was that there was not.

Q What part of the study involved this exercise?

A There was a preliminary investigation. In fact, it may have been a part of another -- I'd have to reread the text where we referred to that. Either this was preliminary on these subjects, or

it was blood fasting and non-fasting blood taken from our other study group and evaluated for the presence of PCBs. I believe that is commented upon in the text, and I can't right now cite exactly what case. But I recall reading it. It's probably under the section about laboratory. Is it important, or do you want to --

Q We will go on. No reason to look for it now.

A Okay.

Q If you would look again at the Conclusion part of the report, Exhibit No. 4. The first sentence reads:

"Consumption of Lake Michigan fish causes the appearance of PCBs in the blood of humans."

A Yes.

Q What did you mean by the statement, "the appearance of PCBs"?

A Well, basically that. That if you eat fish, PCBs appear in the blood of the humans.

Q Is there any question in doing your analysis of whether you in fact were finding PCBs?

A What do you mean by that?

Q Whether there were interferences by other substances or chemicals.

A No. We are fairly confident that the analytical work that was done in fact was showing us the presence of polychlorinated biphenyls. I am confident. Yes, there is always a possibility of a certain degree of laboratory error that is inherent in analytical work. But no, I am confident that the analytical work reflects truly what was in the blood by that technique.

Q The reason I mention this sentence is because in looking at Exhibit No. 2, which is the earlier draft of your report, the Conclusion listed there, that sentence does not appear. If you want to look --

A Actually, the difference between the two conclusions is that the one in Exhibit 4 is a watered-down version of the sentence that appears in Exhibit 2.

Q Okay. I will accept that.

A As I told you yesterday, the internal review -- the difference between these two drafts, the Michigan Department of Public Health reviewed

the Summary and Conclusions, and some modifications that was desired for clarification purposes.

Q Before it was actually put out as a document by the Michigan Department of Public Health it underwent some revisions?

A Yes.

Q Doctor, are you familiar with the FDA no effect safety range for PCB exposure?

A Yes, I am generally aware of what you mean by that.

Q No effect safety range is within the 150 to 300 milligram per day exposure, is that correct?

A I am not sure. Do you have a reference to it, either in my report, or in one of the --

Q Does that sound familiar at all?

A Yes, it does.

MS. OLIVER: Let's mark this as another exhibit.

(Said document was marked Humphrey Deposition Exhibit No. 8, for identification, as of 8/12/81, JKS.)

BY MS. OLIVER:

Q Dr. Humphrey, if you would look at what we have marked as Exhibit 8. If you can identify that as a paper prepared by you.

The underlinings, for the record, were not on the original copy.

MR. WHITE: The underlinings were put on this by --

MS. OLIVER: By me, I believe.

BY THE WITNESS:

A I see it, and I don't recall its preparation.

BY MS. OLIVER:

Q Do you recall presenting a paper to the State of Wisconsin Public Health on PCBs, August 28th-29, 1975?

A I commented at that, and I do not recall presenting a paper. That is why -- I don't recall submitting a paper for that.

Q Well, if you would look at this, and tell me whether you have any reason to believe that that was not prepared by you for purposes of presentation at that Public Hearing.

A I am not sure what the source of this

document is. I think it may be a transcript as opposed to something directly prepared by me.

Q By reviewing this document, does it refresh your recollection as to whether in fact you made the comments which appear there?

A This appears to be a description of the Exhibit 4 study. Apparently it was in 1975. So this would be when that study was in progress. I see a description of the survey design and collection procedures and so forth, and some preliminary data.

MR. WHITE: If you want to review it before you answer the question, review it in its entirety.

BY THE WITNESS:

A I guess without reading it, I have little else to say about this document.

BY MS. OLIVER:

Q Let me refer you then to Page 9 of the document, the middle paragraph, the last sentence that begins, "Thus, PCB exposure from eating Great Lakes fish. . ." Do you see that?

A Yes.

Q Would you read that to yourself for a

minute.

A All right, I have read it.

Q Does that refresh your recollection as to a conclusion or opinion you gave concerning your 1976 test or study?

A No. I really don't have any comment on this until I have reviewed this entire document, except to say the date on this precedes the preparation of our final report.

Q There is a reference in this document to that very fact.

Well, from reviewing the sentence on Page 9 of this report, of this document, from your final report, is it your testimony that that conclusion or opinion expressed on Page 9 is incorrect?

A I would have to -- I cannot answer that until I have checked and seen where the 150 to 300 milligrams per day FDA No Effect Safety Range reference comes from.

Q For the record, let me read the sentence. It reads:

"Thus PCB exposure from eating fresh Great Lakes fish, although difficult to calculate

exactly, may be regarded as relatively low, with the majority of the exposed group falling within the 150 - 300 MG./DAY FDA No Effect Safety Range.

So you can't tell me right now whether that statement was a correct statement or not?

A I cannot. The reason I cannot is those numbers are different than the safety limit that is referenced in my Exhibit No. 4 report. So without researching where that might have come from, I can't respond.

Q Dr. Humphrey, have you been asked to examine or conduct blood burden examinations on individuals from the Waukegan Harbor area?

A Have I been asked? Have we been asked to?

Q Yes.

A No.

Q Other than the projected part of your new study to include perhaps people from the Waukegan Harbor area, you have no other plans to conduct blood burden examinations on persons in the Waukegan Harbor area?

A No. The extent of my or our project interest in Waukegan is merely that it's one of a number of possible candidates for expansion of the cohort. As I testified yesterday, with respect to that, we have had some contact with the Lake County people to determine working relationships, feasibilities, whether or not this could be done. There have been some references to individuals that we might contact, but no one has specifically asked would you test the blood of these people. We have had, you know, a few individuals, names of individuals identified to us, "If you conduct a study, here are some people that eat a lot of fish," or something like that, which is typical of our general field procedures, that we will have people identified to us that are alleged or suspected to be consuming fish in the community.

Q What other areas are being considered as possible locations?

A Several of your areas in the State of Wisconsin.

Q Do you recall specifically where?

A Sheboygan, Wisconsin, and I believe it's

Fox River is another. Two or three places where there is belief that there has been PCB contamination. They tend to be more localized contamination problems, as opposed to the big lake as a whole.

Q You mentioned a possible site down the Mississippi.

A That was mentioned at one time. I believe it was because there was some belief that some people eating catfish were exposed to dioxins. I have heard nothing more about that since. At this time it is not under active consideration, mostly because of spatial arrangements.

Q Do you have an idea today as to whether in fact your study will include Waukegan Harbor fisherman?

A I think that it probably will, yes.

Q How big a group would you anticipate you would need in your study?

A I am not sure what would be necessary. We have been consulting with our statisticians about this concept of how many people can we add on and still use, for example, the comparison persons we are developing in Michigan. If you add very many

people in a community outside of Michigan, then you are also going to have to include a comparison group in that locale. We are trying to determine what those numbers are. That has not been settled as of this moment. So I don't know. My guess would be 20 to 50 exposed people.

Q With no control group from that area?

A I am not sure if I would need to have a control group at those numbers or not.

Q And the second study that you are doing right now where you have gone back and measured people in the first cohort, have you measured controlled persons from that study?

A Yes.

Q Have you had any indication of the trend of PCB levels in their blood?

A This will be -- This is in process. This will be the subject of the report that we have referenced several times, to be upcoming sometime in the next six months.

Q You don't have any knowledge today what --

A I don't at this time. The reason I don't is the laboratory testing of the blood specimen is

done in a blind fashion. That is just finishing up, and so some is -- I don't know what has been done and what hasn't. It is going right in the computer. So we are in the process of evaluating.

MS. OLIVER: Off the record.

(Discussion had off the record.)

MS. OLIVER: Back on the record.

We are, by agreement, going to recess the deposition right now, and we will resume either here or in East Lansing.

MR. WHITE: Lansing.

MS. OLIVER: Lansing, upon agreement of a convenient date and time.

MR. WHITE: Fine.

(Whereupon, the deposition was continued sine die.)

STATE OF ILLINOIS)
) SS:
COUNTY OF C O O K)

I, Jean Korinko Sweeney, a notary public within and for the County of Cook, State of Illinois, and a Certified Shorthand Reporter of said state, do hereby certify:

That previous to the commence of the examination of the witness, DR. HAROLD E. B. HUMPHREY, he was first duly sworn to testify the whole truth concerning the matters herein;

That the foregoing deposition transcript was reported stenographically by me, was thereafter reduced to typewriting under my personal direction, and constitutes a true record of the testimony given and the proceedings had;

That the deposition was taken before me at the time and place specified;

That the said deposition was adjourned sine die;

That I am not a relative or employee or attorney or counsel, nor a relative or employee of such attorney or counsel for any of the parties hereto; nor interested directly or indirected in

the outcome of this action.

IN WITNESS WHEREOF, I do hereunto set my hand and affix my seal of office at Chicago, Illinois. this 7th day of August, 1981.

Notary Public,
Cook County, Illinois.

My commission expires 4/16/84.

C.S.R. Certificate #84-413.

Analysis of Waukegan Harbor
Fish for PCB Residues
G.D. Veith

Samples were collected by CRL and shipped to EPA-ERL Duluth, Minnesota Details of collection procedures are with CRL staff.

The whole fish composite samples were homogenized while frozen and aliquots of tissue homogenate were weighed, mixed with anhydrous Na_2SO_4 and placed in all-glass Soxhlet extractor thimbles. The samples were extracted for 8 hours using a 1:1 mixture of hexane were concentrated to 20 ml. A 2 ml aliquot were pipetted into tarred weighing pan for gravimetric lipid determination. The remaining 10 ml was placed on a 20 gm Florsil column and eluted with 250 ml hexane. The eluant was adjusted to an appropriate volume for GC analysis.

The samples were initially analyzed by packed-column GC. The packed-column analysis were conducted on a Hewlett-Packard 5730-A gas chomatograph fitted with an auto sampler, a Ni^{63} electron capture detector, and a Hewlett-Packard lab automation data system. The column was 1.5%/1.95% SP-2250/SP-2401 coated on 100/120 mesh Supelcoport. Approximately 40 ml/min of 5% methane in argon was used as a carrier in the 2m x 2.3mm column. The temperature was programed with a 4 min hold at 160°C, and 2°C/min increase to 200°C followed by a 16 min hold at 200°C. The inlet and detector temperatures were 250°C and 300°C, respectively.

The PCB mixture in the fish extracts produced packed-column chomatograms with approximately 16 major peaks. A computer program was prepared which measured the areas of 8 of the major peaks and calculated a mean concentration for the 8 peaks compared to Aroclor standards. The total PCB concentrations are based on standards prepared from Aroclor 1242 and 1248.

DEPOSITION EXHIBIT
Humphrey-Lee
5/12/87

US 0007198

Concentrations of PCB in Waukegan Harbor Fish

CRL Identification	Species	Weight(gm[a])	Lipid(%)	Total PCBs (mg/gm)[b] as 1242:1248 (1:1 mixture)
LB-21-501	Carp	14 lbs	24.2 28.4[c]	38.5 37.3[c]
LB-21-502	Carp	8 lbs.	14.0	18.4
LB-21-503	Largemouth Bass	97.5	2.92	18.9
LB-21-504	White Sucker	132	5.96	26.8
LB-21-505	Carp	459(2)	13.3	8.2
LB-21-506	alewife (see CRL log)	26	3.82	7.0
LB-21-507	Brown Bullhead	543(4)	3.24	8.3

a. Total of fish or composite sample of fish ( ) indicates numbers of fish in sample. Sample weights for LB-21-501 and 502 expressed as pounds.

b. Standards prepared as Arclor 1242 and Arclor 1248 mixtures.

c. Replicate analyses on this sample.

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION V
230 SOUTH DEARBORN ST
CHICAGO, ILLINOIS 60604

REPLY TO ATTENTION OF:
5E

JUL 9 1981

Mr. Michael Conlin
Director
Division of Fish and Wildlife
Illinois Department of Conservation
600 N. Grand Avenue West
Springfield, Illinois 62706

Dear Mr. Conlin:

The enclosed memorandum of June 18, 1981, contains two new analyses of whole fish from Waukegan Harbor, 162.9 ppm for a white crappie and 20.2 ppm for a yellow perch. These fish were collected by your staff on September 26, 1980. We will continue to provide fish results as we receive them.

Sincerely yours,

Sandra S. Gardebring
Director, Enforcement Division

Enclosure

cc: Michael P. Mauzy, Director
Illinois Environmental Protection Agency

Bruce Muench
Illinois Department of Conservation

Frank Beal, Director
Illinois Institute of Natural Resources

John VanVranken, Esquire
Assistant Attorney General

Mayor Bill Morris
City of Waukegan

Steven R. Potsic, Executive Director
Lake County Health Department

Lloyd R. Claiborne, Regional Director
Federal Food and Drug Administration

Ralph Pickard, Acting Technical Secretary
Indiana Stream Pollution Control Board

DEPOSITION EXHIBIT
Humphrey-7
8/13/81

US 22442

James Schink, Esquire
Kirkland and Ellis

John E. Ball, Director
Cook County Department of Public Health

Byron J. Francis, Acting Director
Illinois Department of Public Health

Richard Phelan, Esquire
Phelan, Pope and John

James T. Hynes
Assistant U.S. Attorney

Hugh B. Thomas
Outboard Marine Corporation

Andrew Damon, Deputy Secretary
Wisconsin Department of Natural Resources

Howard Tanner
Michigan Department of Natural Resources

Theodore Ervin
Acting Director
Michigan Department of Public Health

Roy Upham
Illinois Department of Public Health

Lawrence Kamer
Lake Michigan Federation

Thomas Nedved
Lake County Health Department

Victor White
Port Authority
City of Waukegan

George Masters
FDA

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION V

TE. 18 June 1981

:i. New PCB data on fish from Waukegan

OM: Jim Clark, Coordinator, JRC
Great Lakes Fish Monitoring Program

TO: Howard Zar, Enforcement Division

:B concentrations in Fish Samples from Waukegan Harbor, Illinois

:ollected 9/26/80 by Illinois Department of Conservation, Bruce Muench
:ollection site: Slip #1
:ollection method: gillnet

he fish samples were frozen by the IDOC and delivered to the USEPA CRL for
naiysis. A chain of custody log was maintained and is in CRL possession.
ne fish samples were analyzed as part of the Great Lakes Fish Monitoring
rogram by contractor personnel utilizing CRL equipment and procedures.
il samples were whole fish ground into a homogenate for contaminant extraction
nd analysis. Sample data represent composites of whole fish if more than one
ish was included in the sample.

ie results of analysis for PCBs are as follows:

RL #	Species	#Fish	Weights	% Lipids	Total PCB ug/g (ppm)
F00S46	Rainbow Trout	1	200g (0.44 lbs)	5.1	2.0
F00S48	Carp	1	1400g (3.09 lbs)	4.8	131.0
F00S49	Largemouth Bass	1	500g (1.10 lbs)	12.0	187.4
F00S50	White Crappie	1	(210 mm length, no weight recorded)	11.1	162.9
F00S45	Yellow Perch	1	(180mm length, no weight recorded)	8.2	20.2
00S51	Yellow Perch	5	composite 75g (0.16 lbs) 60g (0.13 lbs) 50g (0.11 lbs) 50g (0.11 lbs) 75g (0.16 lbs)	5.8	34.0

:w fish contaminant data from the previous collection, one coho salmon still
:ing analyzed. More than 85% of the PCB quantified in all samples was as
oclor 1248.

: J. Braun, 5AHS
E. DiDomenico, 5EWHME
P. Redmon, 5EP
C. Ross, 5SCRL
C. Steiner, 5SCRL
G. Vanderlaan, 5AHS

FORM 1320-6 (REV 3-76)

US 22444

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE UNITED STATES OF AMERICA, Plaintiff,	)	
-vs-	)	No. 78 C 1004
OUTBOARD MARINE CORPORATION and MONSANTO COMPANY, Defendants.	)	

The deposition of Harold E. E. Humphrey, called by the Defendant Monsanto Company for examination, pursuant to agreement and pursuant to the Rules of Civil Procedure for the United States District Courts pertaining to the taking of depositions, taken before Barbara A. Bostrom, R.P.R., a Notary Public in and for the County of Ingham, State of Michigan, and a Certified Shorthand Reporter of said state, at the U. S. Attorney's Office, 3500 North Logan Street, Lansing, Michigan, 48900, on the 2nd day of October, A.D. 1981, commencing at 10:00 o'clock a.m.

ENFORCEMENT SENSITIVE

PRESENT:

MR. JAMES P. WHITE,
(Assistant United States Attorney
United States Attorney's Office
219 South Dearborn Street, 15th Floor
Chicago, Illinois 60604),

appeared on behalf of the United States of America;

MS. ROSEANN OLIVER,
(Phelan, Pope & Joh, Ltd.,
30 North LaSalle Street,
Chicago, Illinois 60602),

appeared on behalf of Outboard Marine Corporation;

MR. BRUCE A. FEATHERSTONE,
(Kirkland & Ellis,
200 East Randolph Drive
Chicago, Illinois 60601),

appeared on behalf of Monsanto Company.

****

October 2, 1981

Lansing, Michigan

PROCEEDINGS

Ms. OLIVER: Would you swear the Witness in please.

HAROLD E. B. HUMPHREY

Being first duly sworn in by the Court Reporter, was examined and testified under oath as follows:

DIRECT EXAMINATION

By Ms. ROSEANN OLIVER

Ms. OLIVER: Let the Record show this is the resumed Deposition of Dr. Harold E.B. Humphrey which began in Chicago on August 12 of 1981 and was recessed on August 13, 1981, and continued to this date.

Q (BY Ms. OLIVER) Dr. Humphrey, do you understand that you are still under oath?

A I do.

Q Have you had an opportunity to read the transcript of the first two days of your Deposition?

A Yes, I've had the opportunity to scan them, uh-huh.

Q So, you are familiar with your previous testimony, if I refer to that, you and I will understand each other probably?

A Yeah, I hope so.

MR. WHITE: Roseann, if I could just take a moment for a couple of housekeeping matters.

Ms. OLIVER: Sure.

MR. WHITE: On the Record, pursuant to an earlier question in the Deposition of Dr. Humphrey back on August 12 and 13, there was a question posed to him with respect to hearing testimony. And, Dr. Humphrey after that Deposition has reviewed his files with respect to Exhibit 8, and we have today a transcript of Exhibit 8 with respect to Dr. Humphrey's testimony at that Wisconsin public hearing. Also, Dr. Humphrey's indicated to me that Exhibit No. 5 to his Deposition, which is titled PCB's In Great Lakes Fish prepared by the Michigan Department of Public Health Division of Environmental Epidemiology, was a draft. And, that a final document with respect to that topic is in the process of being typed this day, October 1st, 1981. And, we will provide that to you when it becomes final or when it is typed and ready for publication. That's all I have.

Ms. OLIVER: Go off the Record a minute.

(WHEREUPON, THIS MATTER WENT OFF THE RECORD.)

Back in session

MR. WHITE: Also, with respect to your request for documents in Dr. Humphrey's files, back on August 12 and 13, through my own inadvertence, there were a number of documents that were not included in the package that

was sent to you as of September 21st and we have those documents for you today. And, I tender a copy to you as I have to Mr. Featherstone earlier this morning.

Q (BY Ms. OLIVER) Dr. Humphrey, since the recess of your Deposition, back in August have you done any further work with respect into your testimony in this litigation?

A Yes, I have. In that references in the testimony to our on going study of people who consume Great Lakes fish has continued and that would be the nature of the work.

Q We will get to the on going study in a little bit. But, have you done anything else except continue with the present project that is underway?

MR. WHITE: With respect to PCB?

Ms.OLIVER: Sure.

THE WITNESS: Well, with respect to the nature of my job here with the State Health Department -- off the Record.

(WHEREUPON, THIS MATTER WENT OFF THE RECORD.)

(BACK IN SESSION)

THE WITNESS: The question of PCB's is a topic which is continuous in the state of Michigan because of the Great Lakes. The document that Mr. White referred to as being a draft has been under revision for example. The question of selling fish at the weirs, in the river mouth in

Michigan has come up. I have been involved in discussion about those.

Q (BY Ms. OLIVER) Have you reviewed any literature on PCB's or the effects of PCB's on human health?

A Since we last talked?

Q Since we last talked.

A Not specifically, no.

Q Have you discussed possible effects or any effects of PCB's on human health with anyone?

A External of our own work group here at the Department, no.

Q And within your own working group would it be fair to say that your discussion involves the on going projects that you have?

A That would be correct.

Q Are you aware of any other persons in the United States right now who are doing studies of the effects of PCB's on human health besides yourself?

A I believe the group at Mount Sinai School of Medicine in New York have been. Urben Silikoff has done so in the past and may very easily be continuing some studies on PCB's relative to worker exposure. I haven't spoken to them in recent months, so I can't be precise on that. That would be the only ones that comes to mind instantly.

Q Are you familiar with Dr. Silikoff's findings and conclusions?

A I have seen work reported in the Academy of New York or the New York Academy of Sciences which addresses their study of

capacity or co-workers.

Q Did they reach conclusions or have opinions?

A Do they?

Q Yes.

A In that, I believe they do.

Q Okay, do you recall what those opinions or conclusions are?

A My answer will be inprecise in that I don't have the report before me. As I recall, their conclusion was in the context of not finding overt health problems in the workers, but it did report some association between workers that were exposed and I believe vital lung capacity measurements. There may have been some other things but that in my recollection were two things that stood out.

Q Do you remember, are those studies still on going?

A I don't know.

Q Do you know if anyone else or any other group which is presently conducting studies of PCB effects on human health?

A I am not aware of any no.

Q Okay, that's if there were such studies you would be interested in looking at them in relation to what you are doing?

A Yes. Oh, I believe there is a group at the University of Minnesota and I can't recall right this second who's heading that up. Who is looking at it. I believe it's a study of statistics, health statistics relative to exposure to the Great Lakes. That's the only other thing that I can think of

at the moment.

Q Okay, have you reviewed any findings or data from that study?

A No, I have not. Recall is beginning to come. There is another group, at the University of Michigan, who have a study going which started at the same time that our fish eater study began. The emphasis of their investigation is the offspring of mothers that have been exposed to fish and when I say offspring, it's the developmental aspects.

Q Okay, and do you know who's in charge of that program or who is working on that program?

A That would be Greta Fein and Pam Swartz.

MR. FEATHERSTONE: Greta is the first name?

THE WITNESS: Greta is the first name.

MR. FEATHERSTONE: Fein?

THE WITNESS: I believe it.

Q (BY Ms. OLIVER) And what was the second name, Doctor?

A Pam Swartz.

Q Okay, has that data been published?

A The University of Michigan's School of Public Health, no it has not to my knowledge.

Q Have you seen data from that study?

A I have not seen data from that study in a year, and prior to that I saw some preliminary pieces of information, but it dealt

with cohort selection, testing processes and things.

Q I take it that study has not concluded, that offspring of --

A That's correct.

Q Of mothers who consume PCB have been a health problem?

A That's correct, my understanding is that it will be a relatively long study because one of their hypothesis involves following a child to age seven.

Q Okay.

A To see if changes occur.

Q Now, that study began you said when your study began, back in 1973?

A That's correct.

Q So, it should be --

A We are roughly the same. No, no, I'm sorry, 1979.

Q Okay.

A 1979.

Q You are talking about your second study?

A Yes.

Q So, that study is two years old, approximately?

A Yes.

MR. FEATHERSTONE: Are they looking at physical development or behavioral development?

THE WITNESS: My understanding is behavioral development is their interest.

MR. FEATHERSTONE: Okay.

Q (BY Ms. OLIVER) Okay, have we exhausted your recollection of other studies?

A I believe so.

Q Okay. Now, in referring to Dr. Silikoff's study you mentioned he had or found no overt health problems?

A I might add that the principle author in that study is a colleague of Silikoff's, named Fishbein, Al Fishbein.

Q Okay. You have made the distinction in your testimony up to this point between subtle effects, chronic effects and overt effects. Do you recall using those terms, Doctor?

A Yes, I do.

Q Okay, could you tell me how you define an overt health effect?

A The context I used with respect to that would be where a person has visible signs or symptoms of toxicity. For example, Chloraecne, that would be an overt sign of toxicity.

Q Okay, there are other examples that you can give me of overt signs or overt problems?

A Well, to continue that, these would be things which would or could be readily observed. Changes in behavior or physiologic functions that a diagnostic test would show as abnormal. Generally, that context is one where there is a disease state or an illness state and a person perceives he is ill, or a diagnostic conclusion can be reached concerning disease or illness, as opposed to the other two kinds of problems.

Q What is the chronic problem?

A. Chronic problem can be one which began, it can be diagnosed as a disease or an illness and preceived. Generally, it continues for a long length of time, as opposed to a problem that would be of short duration. Arthritis for example is considered to be a chronic problem, a chronic disease. The common cold is not. It's over and done with in a short period of time.

Q. Okay --

MR. FEATHERSTONE: Is a chronic health problem also one that is overt in your definition?

THE WITNESS: Yes, a chronic health problem could be overt in that arthritis for example you can make certain types of measurements which are observable and continual to the conclusions that this person has arthritis. Arthritis goes on for years and is chronic.

Q. (BY Ms. OLIVER) Where would cancer fit in to those two categories?

A. That is considered a chronic or a long-term type disease.

Q. Now, when you say that --

A. Now, I must add once the cancer has been diagnosed, then it may show overt signs and symptoms, but cancer is regarded as in the category of diseases that are delayed in appearing or chronic in nature. People can live with a type of cancer for many years for example.

Q. What about subtle health problems, what are those?

A. These would be in the context in which we use that word, in

discussions or writings, these would be problems that fall, problems, signs, symptoms, conditions, that are not obvious.

Q Such as what?

A And here we get into the area of one out of ten liver function tests for example be abnormal. This fall shorts of meeting the criteria to define a disease state, but it is an abnormal test result. It could be relating to a subtle change, a change that is going on in the body which has not yet manifested itself in a way that you can pinpoint that there is something wrong. I guess that is the best example I can give.

Q Well, would decreased lung capacity be what you would call a subtle health effect or condition?

A Yes, I believe it could. The context here is there can be a variety of reasons why a person's lung capacity is diminished. One of which could be toxic chemical exposure and yet the diminution of lung capacity itself, does not debilitate the person or it may not debilitate the person, but it is a change and it can be a change by digress so it's a subtle change that is occurring.

Q Well, I take it that the data has been accumulated to date on PBC effects in humans, doesn't support a finding of any chronic health problems.

A At this time, that is correct.

Q And the data we are talking about is not only your data but all of the data from the other researchers or doctors who have

studied the problem?

A I believe that would be correct, yes.

Q And I guess I could likewise say that the data to date doesn't support a finding that PCB's has caused any subtle health problems or health conditions.

A That I can't agree with as stated, no.

Q What data is there that supports a finding or conclusion that PCB has caused subtle changes in humans?

A We are understanding, we are talking about humans through this whole dialogue?

Q That's right.

A Okay. In my previous testimony I pointed to various investigations which have been recorded. Such as for example, the Treana, Alabama investigation, where there was an association between people with PCB levels above normal, and elevated blood pressure measurements. That's an association.

Q Right, I am talking about data that supports a finding that PCB causes subtle changes.

A Well, that association would be interpreted to mean that PCB is the causative agent.

Q It could be, Doctor, but it has not been so determined, isn't that right?

A Conclusively, it has not been determined.

Q Well, isn't --

A There is --

Q Isn't the reason that it is only characterized as a mean that there is not data to support a conclusion of a causative relationship between PCB and for example elevated blood pressure?

A I will agree with that.

Q So, to get back to my original question on subtle effects, subtle health effects, you would agree with my statement that there is no data to support a conclusion or a finding that PCB has caused subtle health changes in humans?

A I will agree with that.

Q Now, with that in mind, I can ask you several other questions along those same lines. You testified earlier that you had some opinions concerning the effect of PCB's on human health?

A I did.

Q Okay. Do you have an opinion that PCB's caused subtle changes in human health?

A No, I don't.

Q Do you have an opinion that PCB's caused chronic health problems in humans?

A No, I don't.

Q And I take it your opinion -- strike that -- I take it you don't have an opinion that PCB's cause overt health problems in humans?

A Could you read the --

Q Let me strike the question. Okay, it came out in the

negative, I guess. Do you have an opinion Doctor that PCB's cause overt health problems in humans?

A. No, I don't.

Q. We have covered overt problems, chronic problems and subtle problems or conditions. Are there any other health conditions or categories of health conditions which you are aware of besides those three sort of categories?

A. We didn't address acute.

Q. Okay.

A. But I think we covered it in the context of the dialogue.

Q. Do you have an opinion that PCB's cause acute health problems?

A. Yes, I do.

Q. Okay. And, what is your opinion?

A. My opinion would be that they can cause acute problems and this has been demonstrated in reports on occupational exposures.

Q. And let's define what you mean by acute.

A. Acute is where there is an illness state supported by diagnostic signs or visible symptoms such as Chloracene for example, which would show a medical problem which is a result within a reasonable length of time. Result in the sense that after exposure ceases they go away.

Q. If we are talking in terms of exposure to humans through consumption of fish from Lake Michigan, we are not speaking of acute exposure, am I correct?

A. We could be, in that when you eat a fish and if the fish

contains a contaminant you've been exposed and there would be the opportunity for -- that would be an acute exposure. If you eat fish for a year, or five years or ten years, that's chronic exposure.

Q Do you have an opinion that an acute exposure to PCB's from consumption of fish causes health problems in humans?

A No, I don't.

Q Am I correct, in there is no data that you are aware of to support such an opinion?

A I am not aware of any.

Q And the data you are aware of with respect to acute exposure to PCB's through occupational work has concluded that at the end of the exposure or when the exposure ceases, the symptoms of the overt health problems clear up, so to speak?

A Yes, or at least diminish. For example, I can't recall right now how fast Chloraecne disappears, but basically the context is one removed from the source of exposure, many of the things that we are defining an acute disease state or can be an acute illness resolved or diminished or greatly reduced.

Q You state somewhere in your first report, your 1976 report, that your study was intended to determine the sense of magnitude of the problem of PCB exposure through fish consumption. Have you reached a conclusion or an opinion concerning the magnitude of the problem?

A Yes, I have.

Q And what is your conclusion?

A. Given in the context you have just stated, the thrust of the study that was reported in 1976 was to obtain data on human beings, exposed to the fish. That data being essentially the quantity of contaminants present. PCB, being the primary focus. That study accomplished that goal in that it looked at a sufficient number of people who had a variety of degrees of exposure to the fish and demonstrated in an association between the activity of eating the fish, and PCB levels in their body as defined as PCB levels in their bloodstream.

Q Okay, well I guess what I am asking, I don't think I got an answer but maybe I'm not asking it clearly enough. I'm referring to the quote, " magnitude of the problem." Magnitude to me Doctor means some quantification or some way to define the problem that you are dealing with or the magnitude of the problem, I guess. Have you been able to do that?

A. Yes, my previous answer addresses things like magnitude, measurement, quantification, when the study began we didn't know if there was PCB in people. As a result of eating the fish. The study showed that. We didn't know what the range of values might be in people who consumed fish. The study showed that. We didn't know the geographic location of people who might show PCB levels from eating fish. The previous study showed that to the extent that it went to several cities and several locations and so on and so forth. And, therefore,

that demonstrates a magnitude of the problem that wasn't previously well understood.

Q Okay. Has your understanding of the magnitude of the problem, you could use that term as you used it in your report, in your activity previously, changed since the day you accumulated in 1976?

A I am not sure if it is changed or not. Certainly, PCB continued to be found in Great Lakes' fish. People continued to consume those fish. One would infer therefore that there is the opportunity for continuing significance of exposure.

Q Well, if you assume, I'm sorry --

A The quantity of PCB in people's body, has that change is the subject of the study that we are doing currently.

Q Okay.

A And I don't have data yet to provide to you to answer that question.

Q Okay, would you agree that if you assumed that the PCB levels in fish in Lake Michigan and Great Lakes, is declining and, therefore, the doses that people who are consuring those fish are decreasing, would you agree that the magnitude of the problem may be decreasing?

A May be decreasing, yes, I agree with that.

Q And you would expect that to be true assuming the other factors I asked you to assume?

A Confined exclusively to the factors you've stated, yes, but

you left one factor out.

Q Which factor is that?

A The question of whether or not there is a net accumulation of PCB in the human body from repeated exposures.

Q Okay.

A That would change the answer.

Q Your first study did not conclude that there was that accumulation of PCB's from long-term consumption of fish did it?

A No, the first study showed evidence that could lead to that conclusion.

Q Okay, you would know data to support that conclusion?

A We did have data to support that conclusion.

Q And which data are talking about?

A One, is a table.

Q Do you want to refer to Exhibit No. 4 which is your report, your final report?

A Page 27, Table 8 of that report shows that the demeaning PCB value for the groups did increase from 1973 to 1974.

Q Okay.

A Also, and more importantly, to this question would be Table No. 15. On page 43, which shows subjects in the study arrayed by a length of time, that they claimed to have been consuming fish from the lake and the Table demonstrates a correlation between blood levels of PCB, and length of time in

years that they have been consuming fish.

Q Okay, if we go back a minute to Table 8, in the mean PCB values that increased from 1973 to 1974, in the groups, although there is an increase noted there, you are not able to find that increase to be statistically significant, am I correct?

A. That is correct.

Q Okay, so, that data does not support a finding that PCB levels increased from year to year, or with continued consumption of fish?

A. We maybe having trouble with the word finding then.

Q Okay, I am talking about --

A. I consider this data a finding, we found a mean in 1973, we found a mean in 1974.

Q Well, in your opinion, without a statistical significance attached to that data, in your medical judgment is that data sufficient to support a valid conclusion or finding or reliable conclusion or finding that PCB's increase in the blood level of persons from year to year with continued consumption?

A. Table 8?

Q Table 8.

A. Does not.

Okay. Let's leave aside for a minute Table 15.

A. All right.

Q Is there any other data that you are aware of which supports a reliable finding or conclusion that there is a net

accumulation of fact from PCB consumption of fish over years?

A In humans?

Q In humans.

A No.

Q Now, we get to Table 15 and you are talking about a correlation of PCB level with number of years fish consumption. Your data there shows that people who reported more years of eating fish from Lake Michigan had higher mean PCB levels in their blood, is that correct?

A Correct.

Q Were there any attempts made in this study to determine whether there were any other levels or -- strike that -- any other sources for PCB findings in blood?

A Yes, there were.

Q Okay, and what were those?

A The nature of the questionnaire, involved inquiry into types of occupation, and questions about other kinds of chemical exposure that a person could respond to.

Q Okay. The 1976 report doesn't discuss the findings or the questionnaire concerning occupational exposure?

A No, I don't believe it did.

Q Okay. Did you perform a statistical analysis of the data, the mean PCB rates or levels shown in Table 15?

A Yes.

Q Between subject groups or among the subject groups?

A Yes.

Q When I refer to subject groups, I am referring not only to each of the groups listed here, for example, one to three, four to six, seven to nine, or ten or more, I am referring to within each of those categories.

A No.

Q Okay, so statistically statistical analysis was done for these groups but these subgroups were not or the groups were not broken down into subgroups?

A Could you explain a little more what you mean there, I am not sure.

Q Sure. Okay, I think you testified that you did a statistical analysis to determine the significance of the mean PCB levels among the four groups listed on this Table 15?

A Among or between?

Q Well, among four, between two.

A Yes.

Q Okay. You understand I mean between each of the groups?

A That's where I want to make sure we understand each other. The question group one through three was their mean PCB level tested for significance compared to ten or more years, yes, that was done.

Q Okay, was the one to three group tested against the four to six group?

A Yes, uh-huh.

Q Okay, and the one to three group was tested against seven to nine group too, I take it?

A I believe these were done, yes.

Q And what I am asking is whether the ten or more years group was broken down into subgroups for purposes of statistical analysis?

A I don't understand.

Q Well, you have people who consumed fish for ten or more years, some of them consumed fish for ten years, some consumed for twenty years.

A I'm sorry?

Q Some consumed fish for fifteen years?

A No, they were lumped.

Q Okay. So you have one group of ten or more years?

A Correct.

Q What did the analysis show with respect to these PCB mean figures or mean PCB figures?

A There were adequate numbers of people in the four to six range and in the ten or more range, 35 subjects, and 43 subjects respectively to provide us a sufficient number of data points to make statistical analysis and there was the mean values for those two groups are significantly different. The meaning that the difference is due to more than just chance.

Q Okay. Well, you were talking about there were enough subjects in the four to six and ten or more groups, were there not

enough subjects in the other two groups?

A There were not.

Q So, you didn't make any statistical comparison with those groups because there weren't enough people in those groups?

A Yes, we did, but there were insufficient numbers of people to reach a conclusion.

Q Okay.

A You have to have a minimum amount of data in order to do it.

Q To have a statistically significant conclusion you have to have enough people in your sample group to be able to do your statistical analysis, right?

A Correct.

Q So, you were able to do that with your four to six group and your ten or more group but not the two smaller groups?

A That's correct.

Q So, what you are saying is if I understand it, your statistical relationship on which you base your conclusions or your opinion, that there is an increase in PCB's in blood level with continued consumption of fish, is based on the two groups in your 1976 study in the four to six year consumption group, and the ten or more year consumption group?

A That's correct.

Q Is there any other data that you are aware of anywhere that supports that opinion?

A No, I'm not aware of other data.

Q Now, you mentioned earlier in your testimony that PCB's metabolize and/or excrete to some extent or are metabolized and/or excreted to some extent, do you recall that?

A Yes.

Q Would you explain to me what you mean by metabolize?

A Well, in the context, PCB's being metabolized means that the compound is broken down or changed in some way by the physiologic and chemical processes of the body.

Q And does that metabolism or metabolizing significant of any adverse health effects?

A It could.

Q Okay, are you aware of any data which supports the conclusion or a finding that that is the case?

A In humans?

Q In humans.

A No.

Q And I take it then that you don't have an opinion that it does cause adverse health problems in humans?

A That it does?

Q That it does.

A No, I don't.

Q Now, would you explain to me what excretion of PCB's means?

A This would be the process by which a chemical leaves the body.

Q And I take it that -- strike that -- do you have an understanding or is there an understanding in the medical field of how PCB's

enter the blood stream of humans?

A Yes.

Q And how is that?

A Well, this is not precisely known or fully understood. It's believed that if a chemical such as PCB is ingested, it goes through the digestive tract, is acted upon by various digestive enzymes, so forth, this allows presents the chemical either in the original form or in some altered metabolized form to be absorbed through the walls of the intestine and into the blood stream.

Q Okay.

A And then there are a variety of other types of changes that go on within the body once it's in the blood stream.

Q What are those exchanges?

A Chemicals will cross various blood tissue barriers. The blood brain barrier, the blood adipose barrier. In other words, if a chemical is in the blood stream, it's by definition made available to every tissue of the body. Some of those tissues, passages from the blood stream into the tissue more readily occurs. It's dependent on a variety of things. Permeability, the nature of the chemical, solubilities and so forth. PCB has been shown in animal studies to prefer to be centrally located in the fat tissue that have lipids in it.

Q Has that been confirmed in humans to your knowledge?

A Oh yes, I believe it has.

Q And how has that been confirmed?

A In those occasions where we have had or where there have been opportunities to look at various human tissues, such as breast milk, adipose tissue, various tissues of organs, the level of PCB is accordingly higher in a tissue. Generally, in direct proportion with the quantity of fat or lipid that is associated with that tissue.

Q Are there other exchanges between blood and other parts of the body that you haven't referred me to?

A There is the oxygen, the circulation within the liver and the bile. Association with bile, intracapatic in circulation is often mentioned. These chemicals are believed to circulate and return through the bile to the intestine only to be reabsorbed again. And, it's that, that is one of the theories as to why PCB's as one of a number of kinds of chemicals are excreted only very slowly.

Q Okay.

A Because they are continually reabsorbed.

Q What data is there concerning the excretion of PCB's from the body?

A Oh, I believe there are reports in the literature with respect to the presence of PCB in bile, feces, probably urine.

Q Okay, do you specifically recall seeing reports indicating PCB's in urine samples?

A I have to answer that in a general sense. I can't cite

specific reports. It's my feeling that these kinds of measurements have been made.

Q Is it your opinion that PCB's are excreted slowly?

A That is my opinion.

Q And what is that opinion based on?

A It's based on a combination of animal studies where excretion rates have been studies, and various reports would show that, which would discuss or get into this area.

Q Okay, well what animal studies support that opinion?

A Well, there have been a variety of animal studies, the studies with primates, studies with rats and mice.

Q Are the levels of excretion found in primates and rats and mice valid for making a medical judgment on the excretion rates of PCB's in humans?

A To the extent that a certain kind of information such as that can be extrapolated, yes, but precisely, no.

Q Are you saying that you would rely in making a medical judgment on the findings in these animal studies?

A Exclusively?

Q Let's start exclusively, yes.

A No.

Q Okay, well then my next question is what other data supports your opinion?

A Data on tests from humans.

Q Okay, which tests are we talking about?

A. And from a number of animal studies.

Q. If we put aside the animal studies for a minute.

A. Okay.

Q. And we assume that you would not rely on animal studies alone to extrapolate excretion rates from animals, to excretion rates from humans, right?

A. Uh-huh.

Q. Okay, what other data have you seen or reviewed or been told about or done yourself, gathered yourself, to support your opinion that PCB's are excreted slowly from humans?

A. Do you want me to cite references?

Q. Well, if you can.

A. Well, I am sorry, I'm not prepared to do that.

Q. Well, generally.

A. Well, that's what we are talking about, and you are asking me to be percise.

Q. Well, no, I am asking, what I am asking Doctor, let me clarify this so we don't misunderstand each other. You mentioned that your opinion is based upon animal studies, and other things, other studies or other literature, and I am saying put aside for a moment animal studies. What other things form the basis for your opinion and if you can tell me specifically or precisely, names and authors or whatever, and I'm asking for general information.

A. Okay, what I am telling you is there is an enlarged body of

information of science and medicine on toxic chemicals, PCB specifically, and related compounds such as PBB's. And, taken in its entirety some of these studies are with animals, some of them are human studies, it is the general determination from this material and I believe generally accepted that PCB's have certain characteristics and one characteristic is that they store in the fat tissues of the body and that they are slowly excreted. Now, this opinion, this conclusion, this general feeling on PCB's,is that then comes from many sources of which there are some data on tests of humans and specimens.

Q Okay. Well, my question Doctor is what tests generally, specifically, anyway are there on humans with respect to this question of excretion rates?

A. It's the third time you've asked that question. I guess we are not transmitting something. I don't understand.

Q Okay, well let's go on to something else.

A. I have something -- well, okay.

MR. FEATHERSTONE: Would it help to go off the Record to see if you guys couldn't get to it faster and then go back on the Record? Let's go off the Record.

(WHEREUPON, THIS MATTER WENT OFF THE RECORD.)

9BACK ON THE RECORD)

Q (BY MS. OLIVER) Doctor, I've asked you a series of questions about excretion rates, PCB's in humans and you gave me your opinion and stated that your opinion was based on animal, certain animal studies that had been done and other studies that you are not prepared right now to reference me to, is that correct?

A That's correct.

Q Okay. Your opinion then is based as you sit here today and as you have given it to me is based on your general experience or knowledge in the field and that any specific references or studies or data, am I correct?

A Yes.

MR. WHITE: That you can recall at this point.

THE WITNESS: That I can recall, yes.

Q (BY MS. OLIVER) Okay. Have you or well -- strike that -- has your group in Michigan State or Michigan Health Department done any work in trying to determine what the excretion rate of PCB's from humans is?

A Yes, we have.

Q And is that currently underway in your project?

A No, it is not.

Q Okay, is that related to your PBB work?

A Yes.

Q. Okay, in one part of your PBB work was to determine data on excretion rates, am I correct?

A. Yes, part of the work is to address that problem.

Q. Okay. Your main focus in that study, obviously, is PBB?

A. That's correct.

Q. But one of the other things you are measuring or maybe measuring is PCB?

A. That's correct.

Q. Excretion rates?

A. That's correct.

Q. Have you reached any conclusion or opinions based on that data?

A. About what?

Q. About PCB excretion rates?

A. We have observations.

Q. Well. . .

A. Yes, I think we have conclusions.

Q. Okay, is your data completed?

A. No.

Q. And, what is the status of that data collection?

A. The status of the data collection is that now over a period of five years we have had the opportunity to make a number of measurements on individuals. These have been primarily blood measurements but we have an occasion to get various types of body tissue and on some occasions more than one. Well, this is still on going, and to do a good statistical analysis more data

is required to have sufficient data points. There is the impression from the data that is coming in is that the material is staying in the body.

Q Okay.

A That it is only very slowly leaving.

Q Okay, when you say the impression, you are not referring to a medical opinion, am I correct?

A That's correct because when you ask medical opinion or scientific conclusions, that says to me that the data has to have passed certain criteria to be considered significant. And, this isn't always possible and yet observing the data can give you an impression, an opinion, and even allow you to reach a conclusion but a conclusion that doesn't have the defense of having been statistically validated.

Q Would the impression be sufficient for you to make a medical judgment?

A Probably not in this kind of a case, no.

Q So, the impression that you have reached to date from your PBB work on excretion from the body of PCB's and among other things, you would not rely on in your medical judgment?

A No, I can't agree with that.

Q The impression would not be sufficient, sufficiently valid or sufficiently tested for you to make medical judgments based on that data?

A Well --

Q Would you agree with that?

A. All right.

Q Okay. Now, in your recent work with PCB levels in the blood in humans, have you confirmed a variation in PCB levels at any given time in taking a blood sample?

A Yes, we have confirmed that there is a variation.

Q So, when we talk about variations we are talking about taking a blood sample from a person and finding a PCB level and then going back to that person next day or the next month or the next week and having an entirely lower, or higher PCB level?

A. Yes.

Q Okay. How do you explain that variation?

A. I can't thoroughly explain it. There are several factors that probably account. One is and I believe this to be a small contributing part, laboratory error. You repeat a test a number of times and you do not always get the same number. The other would be the phyiologic state of a person at the time of the sampling.

Q How does that affect the level that you are finding?

A We are not sure exactly. You have to understand we do not fully understand the dynamics of these kinds of chemicals within the body. We don't fully understand why or how or when or what causes PCB to come out of the fat stores and into the blood stream for example. Or, to go back in again. This is a body of knowledge that is emerging but I believe it is

accepted that this is not at this time still fully understood. So, that and there are other factors, with human subjects, you sample them at different times and you may not get the same reading and this could be caused by something as simple as say they were undergoing stress that day and that was causing a process to go on within the body. So, there are a variety of mitigating factors which cause variations and levels from time to time. Some of these you can try to test for and others are just the consequence of the nature of the study.

Q Do the variations that you have found starting in 1973 in which you have confirmed are sort of a fact of life in this type of testing, affect at all in your opinion the reliability of your data?

A No, I don't think so.

Q And why not?

A Well, first of all, we are dealing with human subjects and human study. And, therefore, by definition this is not an experiment. And, therefore, you can't control so many variables, life style variables and so forth. Therefore, it is generally accepted in human studies that you are going to have a higher degree of variations than you would in other types of studies because you can't control many things that may influence say the level of the chemical in the blood. So, that within the context of human studies then the facts that

there is a variability which would perhaps be unacceptable and they want to find a controlled experiment is by necessity acceptable to human study. Therefore, conclusions made on the human study are still considered valid even though there is variation and I might finally add there are types of statistical tests, mathematical evaluations that can be used on the data to try to reduce the variation to get at the relationships between two variables.

Q Okay, and in fact in your 1976 study you used the mean PCB levels to do that, right?

A That was one thing that we used, yes.

Q Okay, and by using the mean you could come up with what you considered reliable results and conclusions and findings?

A Yes.

Q Okay, I'm going to take a minute to look at the study. I have a couple of questions on it.

A This is the 1976?

Q In 1976.

A Okay. Can we take a five minute recess?

MS. OLIVER: Sure.

(WHEREUPON, THIS MATTER WAS IN RECESS AT 11:00 A.M.)

(BACK IN SESSION AT 11:10 A.M.)

Q (BY MS. OLIVER) Okay. Dr. Humphrey, if you would look a minute at Exhibit No. 4, your 1976 report, page number two, the

introduction about a third of the way down that long paragraph, there is a sentence that begins, "And the accumulation and storage of a chemical would theoretically make it available," do you see that sentence?

A Yes, I do.

Q If you would read it to yourself a minute.

A Yes, I've read it.

Q In that sentence you were speaking generally of chemicals and their effects in the body, am I correct?

A Yes.

Q You are not referring to PCE's there?

A Only in the context that they fit into the whole general discussion.

Q When you say in that sentence that under appropriate conditions recirculation within the body could occur, what appropriate conditions are you referring to?

A Probably thinking of the intracapatic circulation for example, where material goes into the bile, goes into the intestines, reabsorbed and comes back.

Q Would that type of recirculation be an on going process or is that something that occurs at certain times and not at other times?

A No, it's an on going process, the context of the sentence, you know, appropriate conditions is meant to point toward body processes which are going on and may contribute to this but

aren't fully defined yet. That's the whole point is theoretically we need to understand this, hypothetically something could occur.

Q Okay, this sentence is a hypothetical situation?

A Yes, I believe that's the spirit of it.

Q Okay, and you did no study or cumulated no data showing that after continuous or repeated exposure -- strike that -- showing that there can be continuous or repeated exposure of target organs long after the original dose has ceased?

A Do we have data that addresses that? Yes, yes we do.

Q PCB data?

A Yes.

Q Okay, and what data is that?

A That would be data in this report that refers to blood levels of PCB at two separate times of sampling.

Q Two separate times, when?

A Yeah, for example, it was Table 8 that showed that the people sampled in 1973 have certain levels and then in 1974 they were sampled and tested again and they had similar levels.

Q Okay.

A This supports the concept of continuous circulation. In other words, this PCB, apparently, was continually in the blood at relatively the same level.

Q Okay, but you are referring in this sentence to after the original doses cease, did the original doses with respect to

people in Table 8.

A No.

Q Okay.

A But there are other parts of the report where that was tested. Just a minute, I will find it. It's exemplified on pages 81 and 82 where data is shown where people did abstain from consuming fish for a period of time, and the conclusion of examining that data is that their PCB levels did not go away or drop off markedly, so that that's further supporting data to the concept of being continuous. There, we would consider their dose for the season, stopped, three didn't eat fish for a long time, so it was a break from exposure to fish.

Q Okay, does that data that you just referred me to support this conclusion in a reliable manner in your medical judgment?

A Would you state the conclusions that we are talking about?

Q Well, the conclusion that there could be continuous or repeated exposure of target organs long after the original dose has ceased.

A The data that I have referred to supports that.

Q Okay, in your medical judgment is data sufficiently significant or adequate for you to base a medical opinion on?

A Not in its entirety, no. Can I amplify on that?

Q Sure.

A The data addresses the question, provides information relative to that statement. The data is not sufficient to close the

case on the question, if you will. How do you define long after? Six months enough? Is it one year?

Q I don't know.

A Well, that's the point I am making. This sheds some light on it, it doesn't fully answer the question.

Q Okay, does it answer the question in your medical judgment?

A Not fully, no.

Q Well, when you say not fully what does that mean?

A Well, that reply means no, it does not supply complete answers.

Q Okay, did you do any or -- strike that -- did you make a determination from your 1976 study of an accumulation of a critical level of PCB's?

A No.

Q So, when you refer to say the rest of that sentence, to multiple low doses are received and accumulated to a critical level you are again speaking of a hypothetical?

A Yes, the whole spirit of that paragraph is a discussion of hypothetical situations.

Q Okay, we talked a little bit at the Deposition in August about the attempt that was made in your 1976 study to determine between fasting and non-fasting persons.

A Yes.

Q And the purpose of that was to determine if mobilization of the fatty tissue causes a release of PCB's into the blood and would increase PCB levels, is that correct?

A. Not entirely.

Q. Okay, well tell me what it attempted to show?

A. Our primary interest was to determine whether there was a preferred sampling of blood that should be used for the study. That being that you can sample a person either at any time of the day or you can sample their blood after fasting for twelve hours. This will make a difference in the amount of lipid in the blood stream. So, our interest here was we wanted to get, we wanted to find out if blood taken at different times, say from fasting people or people who were not were going to be significantly different and so the purpose was to evaluate that effect and our conclusion is that it didn't impact to a significant degree the quantification of PCB in the blood.

Q. Okay, the fact that there was no real difference in the amounts of PCB's in people's blood taken at different times of the day, does that fact lead you to any opinion concerning the rules of PCB's?

A. No, it doesn't.

Q. Does it give you any type of impression or indication?

A. The only indication or impression it gives me is that by virtue of the testimony we did, there did not appear to be a difference in blood stream PCB loads, whether it was a fasting condition or a non-fasting condition.

Q. And, that fasting versus non-fasting procedure was not

attempted or was not meant to determine whether PCB's were being released from the body into the blood stream.

A No, that was not the intent.

Q It was just for purposes of how to get the sample, the best sample you could?

A Selection of the best, yes.

Q Was any work done in that study to determine if PCB's were being released from the body, or into the body?

A No, it was not the thrust of the study.

Q You assumed that the PCB levels you were measuring were being taken in through consumption of fish, that being taken out from the body into the blood and then elsewhere?

A We were measuring the circulating PCB's in the blood stream, or the PCB's circulating in the blood stream, that's the measurement we made.

Q You made no --

A We also measured intake, we tried to determine fish consumption and so forth. We did not deliverately try to test all of the possible excretion mechanisms but we referred earlier this morning to the generally accepted body of knowledge which states that it is slowly excreted.

Q Has that body of knowledge remained the same since 1976?

A I believe that the generally accepted characteristic of PCB is remaining in the body for long periods is consistent today as it was then.

Q In your new study have you attempted to measure PCB's in urine?

A. No, we have not.

Q Have you attempted to measure an output of PCB's in any way?

A. No, we have not.

Q In your opinion would that be informative or valuable in giving you information?

A That would be useful information, yes it would.

Q Okay, do you not do it because the mechanics of it would be too difficult?

A. No, it's the primary nature of the current study is to measure exposure, to assess quantities in the humans that are under investigation as opposed to a study of it being designed to address the question of PCB half life or PCB excretion. It's a matter of convenience. If you want to collect a large number of people to do certain things you go one way. If you want to take a discreet subject group and intensely study them and collect many many specimens, that's a different kind of thing. We are doing the first one, the one where we are studying the large group of people to try to find out the relationship to substantiate and confirm earlier impressions on the relationships between PCB's, fish contamination, and human contamination. We may in the future, take a subject group of highly exposed people for example, and study them, with respect to your quesiton.

Q Okay.

A But we are not at this time.

Q Well, to make a determination of the effects of PCB's in health of humans, from exposure to fish, don't you consider it necessary to also measure not only what's coming in through fish consumption, but what's going out?

A No. Useful yes, necessary no.

Q Well, can you determine what the health effects of PCB's are on humans without knowing the mechanics of PCB's leaving the human body, as well as entering?

A Yes, I believe you can.

Q Okay. Well, explain to me why the mechanism of PCB excretion is not necessary?

A Well, your question was can we study the potential health impact or health effects of exposure without studying excretion and my reply was, yes you can.

Q Well, you can study anything.

A Excretion is a nice additional piece of information to have and it is useful as I said earlier but what you want to establish is dose response and if you can establish a dose has been received or that there is a dose in the blood stream and there are measured responses to that, in the human, or the animal, human physiology, biochemistry or something, you can establish then an affect without ever understanding whether the stuff is coming out the other end and being excreted, so that's where I am coming from.

Q When you are dealing with long term exposure?

A Uh-huh.

Q For example, from consumption of lake fish or Lake Michigan fish over several years?

A Yes.

Q Doesn't the process of what is remaining in the body or being excreted become more important in determining the effects of that long term exposure to the body?

A Yes, it's useful, it's important, more important is debatable. The question here in my mind is what are the circulating le ls of this chemical because the targets, if you will, for action by this chemical are bated by the blood stream, so that the chemical being present in the blood stream it is circulating to wherever or if ever there is a target so that to me is the most important aspect.

Q Have your studies determined a circulatin aspect of PCB's?

A Yes they have.

Q Okay, and when you talk about the circulating aspects, what do you mean?

A I mean the concentration of PCB found in the blood stream.

Q Okay, you mean the measurement?

A The measurement.

Q And what's that?

A The quanification of PCB in the blood stream.

Q Well, that doesn't address the issue of how it circulates or

where it circulates from the blood into the body, a

A Well, it's if it is in the blood stream, it's where goes in the body. I don't think that's the intent question now.

Q Well, if we are talking about the effect of PCB's in blood, we are talking about its effect in the body?

A Uh-huh.

Q And it goes from the blood elsewhere in the body, I

A Yes.

Q Okay, your study has measured PCB levels in the b

A Yes.

Q Okay, what I'm asking you is have your studies determ the process of recirculation or circulation from the other parts of the body, of the body?

A And my reply to you is yes wherever there is a capill the body there is blood and there is distribution.

Q You stated earlier that the mechanics of recircu are not precisely understood?

A I think we are not agreeing on some definitions here.

Q Okay, why don't we use your definition then.

A Okay.

Q And I will understand yours.

A You want me to define them?

Q Uh-huh.

A Okay, blood distributes.

Q Uh-huh.

A Everywhere in the body. You know, it's officially accepted the body is and all tissues are bathed an well known and defined and it is not as well under does the chemical leave the blood stream and go som either to be deposited in a tissue or to be deposit lymphatic system. The dynamics of what triggers th exchange from blood to some other place, like a tis organ --

Q Can I interrupt and request a question there? of this dynamic interreaction between blood and the parts of the body.

A Okay.

Q Now, in determining the health impact or health effec in the blood level of humans, on other parts of the bo would you have to know something about this dynamic re am I right?

A Yes.

Q Okay, and that is why, that's why I asked you the ques earlier that that is not known.

A I don't mean to leave you with the impression that ther total ignorance on this.

Q I understand.

A It is not fully understood, but there is knowledge on th from animal studies.

Q And it's not understood in a manner or any way on which you or your colleagues could make reasonable medical judgments?

A No, I don't agree with that.

Q Okay, well what is known upon which you could make medical judgments?

A Well, from human tissue testing and from animal studies there is good evidence that PCB distributes to various organs. Primarily, in proportion to the fat content of the organs, so that therefore, obviously an exchange has occurred. It's gone from the blood, it's gone into tissues, organs, fat, the fact that what we don't fully understand is what triggers that exchange or what triggers the reverse of it. Blood appears to be an equilibrium situation.

Q Which means what?

A It stays fairly constant and the other parts can change but the blood level stays constant.

Q Well, that's not what you found in your study.

A I am not defining that very well. I don't think you understand what I am trying to say.

Q Well, what I'm asking right now is if you say blood levels are at an equilibrium or blood levels reach an equilibrium level and stay the same pretty much, how does that square with your findings that PCB levels went all over the ball park on the same people?

A Well, this is the area that is not well understood. There

obviously, if you sample a person, several times you sample that person, and you get variations that means that there are different quantities of the chemical in a blood stream at any given moment. What I am trying to tell you is that in general I think it is understood that there is an interchanging going on, but, specifically it's not well understood why or when the interchange is occurring. So, but at various moments you can have greater quantities in the blood stream than in others, but the blood tends to be an equilibrium, meaning you have got things moving in and out of storage or you might have a spite and excretion rate that is temporary or something like this, this is not well understood.

Q So, the interchange or the exchange between blood levels and other body tissues or organs is not well understood?

A. I agree.

Q Okay, and you would also agree that the effect on human health of that interchange is also not well understood?

A All right, I will agree with that.

Q You mentioned earlier in your testimony in August that one of the goals or intents of your studies is to estimate the risk of PCB's to human health.

A. Yes.

Q. Is that fair?

A. Yes.

Q Have you been able to estimate the risk?

A To a degree yes.

Q Well, when you talk about estimating a risk to human health, how generally as an epidemiologist would you do that?

A It's a combination of characteristics of the element, nature and degree of exposure and those are the primary things or factors. If you have a toxic substance that being defined as you have a basis to reasonably conclude this thing can have a biologic impact, laboratory tests, invitro type tests, analysis and so forth, a toxic substance if you then have exposure to this you have created a risk. There are assumptions, but as to toxic substances and an object, a person, an animal, exposed creates risk. The greater the exposure or the more toxic the chemical the higher the risk, so to that degree, yes, we have accomplished that end.

Q Okay, so there are variables?

A Yes, there are.

Q Based on the dosage of a chemical?

A Yes.

Q What other variables are there?

A There is the dosage, the magnitude of exposure, there is the nature of the exposure, repeated versus one massive dose, duration of exposure, once, twice, ten, twenty years. Those are three factors that come to mind.

Q Okay, when you attempt to estimate risk do you quantify it?

A Yes this can be attempted.

Q Okay, and how do you quantify it?

A Well, there are two ways of quantifying risk. One is to use mathematical models to predict risk where you plug in knowns and where you don't have information you use assumptions and come up with a number, if you will.

Q I recall --

A As a risk estimate.

Q Excuse me, I recall that you were not familiar with models, is that correct?

A That is not my day to day business, true, that's correct. I am familiar with them but I don't work with them on a day to day basis.

MR. FEATHERSTONE: You don't construct them?

THE WITNESS: I don't construct them, that's correct.

Q (BY MS. OLIVER) You don't prepare models in your estimation of risk?

A No, I don't, I rely on other people to do that. The other way would be to count events and that can range from dead bodies to cases of some kind of a defined disease to frequency of medical condition or problems, to the appearance and frequency of diagnostic indicators, all of those things would contribute to another way of assessing risk.

Q And, I take it that you go down the scale from dead bodies to

diagnostic science, that affects the degree of the risk?

A. No, I can't agree with that as just that at this time I stated no.

Q. Well, if you have a toxic chemical and you relate it to causing fifty dead bodies or fifty deaths, then the risk you assess to that toxic chemical would be higher would it not than to a toxic chemical which you do not relate to death, but which you relate to a high blood pressure or elevated blood pressure?

A. No, not necessarily.

Q. Okay, why not?

A. You are giving -- you know, two kinds of examples and we can, of course, expand on that. One is an example of an acute risk. The cehmical, the exposure occurs and then a very dramatic event happens, death. And an end point has been reached and you could define it and this is your typical dose response curve. If you will, you built a number of animals with increasing the amount, but then there is another kind of situation where the dose is received and no event is recorded for perhaps a long period of time and then an event does occur and we will say for example is cancer which leads to death. Where I don't agree with what your question is, both kinds can be of equal risk to the human.

Q. Well, let me restate it. If we assume that what we are talking about is not an acute exposure leading to an event like death.

A. Uh-huh.

Q. Immediate event, we are talking about a chronic or long term exposure.

A. Yes.

Q. Such as consuming Lake Michigan fish and with a toxic chemical which is consumed or ingested over a long period of time you have a relationship or you find a causative relationship between that chemical, that consumption, and death, cancer?

A. Chronic disease.

Q. Chronic disease, so on overt problems subtle, overt or chronic disease.

A. Okay.

Q. And you have another toxic chemical over a long period of time which is ingested or consumed and what you find is an association with some subtle effects such as vital lung capacity diminishment, would you estimate the risk of those two toxic chemicals equally?

A. I guess my reply to you would be perhaps.

Q. Okay, and what would that depend on?

A. We are covering a number of the factors, another factor would be evidence showing potential for one of the two chemicals to cause an event. I am thinking of toxicity tests or animal tests which indicate that this chemical is highly or has biological activity it has a potential for doing something.. In the example you have given, chemical one had a greater

number of check marks in the columns of things happening, chemical two did not have yet very many check marks, perhaps say diminution of vital lung capacity and yet chemical number two could have on a basis of toxicity potential to do this, to do more pronounced effects.

Q Well, on the --

A That would be a you know, another consideration as to whether the two would weigh equally.

Q On the basis of potential, would you, if you were asked to give your opinion as to the quantification of the risk of those two toxic chemicals, would you rate them equally?

A I could, yes.

Q Okay, have you been able to quantify the risk of PCB's from consumption of Lake Michigan fish to human health problems?

A No, we have not.

Q I take it you would want more data and information to be able to do that?

A That's correct. I should add there is data and can be put into a model and risk quantified that way if you will through mathematical quantification and in fact the FDA rountinely does this in setting standards for example. But, I interpreted your question to be more direct towards results of studies and things.

Q Right.

A Yeah, okay.

Q You and your work have not quantified the risk of PCB's?

A No, we have not.

Q Are you aware, putting aside the FDA for a moment of anybody who has?

A No.

Q Do you foresee being able to do that?

A I can't say for sure, I don't know.

Q What factors would you need to be able to make a determination that you don't have now?

A Well, frankly, there have not been sufficient studies to generate an adequate amount of information on humans exposed in the matter that we are talking here, to fish to provide enough data to do that. Now, as time goes on, if such studies are accomplished, if such data can be generated then perhaps yes this could be done. That's my hesitation. It depends on more data, but I don't mean an endless supply of data that goes forever. You know, at some point, I think a sufficient length of time and nature of study is done should reach a point where it should be clarified, that has not happened yet.

Q You spoke earlier of some studies being done that had a duration of ten years or so. Is that the type of study that you think would be necessary?

A I believe that that is evolving, the state of knowledge is evolving that question. It's going to be that kind of a study that is going to fully answer the question with regard

to PCB's.

Q. Dr. Humphrey, have you been given any information concerning the out take of PCB's from fish in Waukegon harbor?

A. No, let me ask, out take?

Q. Out take, I mean accumulation.

A. In where?

Q. In fish, from PCB's in Waukegon harbor.

A. I have seen tests on fish, yes.

Q. Okay.

A. If that is what you mean, I have seen that.

Q. Have you been given any information on the movement of PCB's from the sediment in Waukegon harbor?

MR. SMITH: Yes you have.

THE WITNESS: I guess I have, yeah.

Q. (BY MS. CLIVER) Do you recall that information today?

A. It's part of the general background material. It addresses sediment loadings and water columns and quantities and as I recall some engineering study or something like that, addressing that question.

Q. I take it you looked at that information for purposes of background and not really relying on it for any of your opinions or conclusions?

A. That's correct, you know, it's one more component in about 19 years of background information on PCB's.

Q. Would it be fair to say, Dr. Humphrey, that your work with

PCB's has led you to believe that more work needs to be done and that PCB consumption should be avoided if possible?

A. Yes.

Q. That's a fair conclusion of where you are at, I take it?

A. Yes.

Q. How do you define the term, if possible?

MR. FEATHERSTONE: I'm sorry, the term you wanted a definition, you want the definition for a phrase if possible?

MS. OLIVER: If possible.

MR. FEATHERSTONE: Okay.

THE WITNESS: This refers to people who have some control over what they do, and therefore, they can exercise judgment. Restraint or one thing or another, so in the context that we are speaking here to avoid exposure, if possible. For instance, you may clean your fish in a different way than you might normally because in doing that you have taken away some of the available contaminent, you have to the extent possible reduced your risk of exposure by eating that fish. That the government can pass laws, that prevents food going into the consumers. That's another way. So, that's what the if possible is. If you don't have any control over being born into a world that perhaps has something in the air, you have no control over that.

Q. (BY MS. OLIVER) The government in this litigation has

suggested a remedy of dredging the Waukegon harbor and removing PCB's from the sediments of the harbor at a cost varying from 29 to 89 million dollars. Do you have any -- strike that -- do you have a medical judgment that the risk from PCB's in the sediments of Waukegon harbor should be reduced by that type of remedy?

MR. WHITE: I think I'm going to object to the question based upon the competence of the Witness to answer the question.

MS. OLIVER: Can you answer it Doctor?

MR. WHITE: If he can answer it.

THE WITNESS: I would like to rephrase it, I can't answer it.

MR. WHITE: Do you understand the question Doctor?

THE WITNESS: No, I don't.

Q. (BY MS. OLIVER) Okay, in your medical judgment is the removal of PCB's from the sediment in Waukegon harbor necessary in terms of human health?

MR. WHITE: Same objection applies to that and also, of course, as to the form of the question. Answer if you can, if you understand the question.

THE WITNESS: Well, you know, I understand the question and my answer is yes.

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[illegible] MS. OLIVER: Okay, have you considered in answering your question the inability to quantify the risk of PCB's?

A. I'm sorry, inability to what?

[illegible]

[illegible]

[illegible] opinion better than [illegible] million [illegible] cost of anywhere from [illegible] 29 [illegible] dollars?

MR. WHITE: Objection.

THE [illegible] I want to --

MR. WHITE: Based upon the incompetency of the Witness to answer the question.

MS. OLIVER: Well, Sir, I am not sure I understand your objection. Are you saying that he is not competent to testify as to whether there is a risk benefit trade in the Waukegan harbor situation?

MR. WHITE: I think the form of the question asked for cost benefit analysis. I don't think the Witness is capable of answering the question with respect to cost benefit analysis or whether or not the remedy is in fact the remedy that should be applied one way or the other. He has testified during the course of his testimony here this morning and defined, if possible exposure, with respect to that, what with respect to PCB's, and he says exposure to PCB's should be avoided, if possible, and Roseann asked him to define, if possible. Now, we are getting into an area with

respect to what is the appropriate remedy for Waukegon harbor to reduce that exposure, if possible. He's not competent to answer that question.

MS. OLIVER: But for I'm asking him based on medical judgment which he is --

MR. WHITE: Well, that, you know, that distinction thrown in there is a distinction without a difference with respect to him, that doesn't make the question anymore valid medical judgment.

Q. (BY MS. OLIVER) Okay, you objected. Do you remember my question Dr. Humphrey?

A. No, I guess I would have to have it read back.

MR. WHITE: And we are not going to terminate this Deposition and having to ask you to answer the question if in fact you can understand it and give the answer to the question.

THE WITNESS: I can't, I can't say.

Q. (BY MS. OLIVER) Okay.

A. I don't know.

Q. Doctor, in your work with Michigan Department of Public Health, have you done cost benefit analysis?

A. I am familiar with the term. I am familiar with the process. I don't routinely do them, but you can't work in the area that I am without that coming up.

Q. Okay, do you consider yourself competent to give an opinion concerning the benefit to human health from the removal of PCB's from the Waukegon harbor at a cost of from 20 to 49 million dollars, if we assume that that is the project that is going to done.

MR. WHITE: I have a standing objection to this question and that is the competence of the Witness to answer the question.

THE WITNESS: I have. I can't answer that question.

Q. (BY MS. OLIVER) Before you go on, let me clarify. I thought my question Doctor was whether you can give an opinion on that type of analysis and Mr. White's objection was that you are not competent to give that opinion, is that your answer?

A. Your question boils down to my providing an opinion on a value, a dollar value, and I can't do that. There are too many unknowns in this. In the nature of the question for me to tell you a direct response.

Q. Well, are you saying that the cost benefit analysis is not as simple as just there are PCB's there and they should be removed?

A. It's more complicated.

Q. At any cost?

A. I would acknowledge it as more complicated than that, yes.

Q. It depends on a determination of what is the risk to the

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THE EIGHTH JUDICIAL CIRCUIT
IN MACOMB COUNTY, MICHIGAN

humans from those PCB's in the harbor, correct?

A. Risk, exposure, toxicity.

Q. Right, dependent on all of those things?

A. Conditions, biological conditions to humans. Now, or in the future, it goes on, it's very complicated, yes.

Q. And based on the work you have done to date in the fact that you are not yet able to quanitfy the risk of PCB's from long term consumption or ingestion of PCB's, you don't believe you can make that type of analysis with respect to Waukegon harbo am I correct?

A. That's correct.

Q. Okay if I could just have a few minutes. I think I'm about done. Let's take a recess.

(WHEREUPON, THIS MATTER WAS IN RECESS.)

(BACK IN SESSION)

Q. (BY MS. OLIVER) When later we were together Dr. Humphrey yo told us that the present study on PCB's is being done right now?

A. Yes.

Q. Okay, and part of it, the first part of it goes back to the original cohort of persons that were tested back in 1973 and 1974 was near completion and analysis of their data was being done, is that right?

A. That's correct.

Q Since your August Deposition have you been given any data on that first phase of the project?

A Data analysis is still in process.

Q So, you have not been given any opinions or conclusions or findings based on that data?

A That's correct, nor have I drawn any yet.

Q We also discussed that at your last Deposition the fact that you were trying to locate some persons in the Waukegon harbor area to include in the cohort of persons to be studied.

A That's correct.

Q And you said at the time that you didn't have much success up to that point.

A We were just starting at that point.

Q Have you done anymore in that regard?

A Yes, our field worker has been to Waukegon harbor, they have located some individuals. They are in the process of developing a cohort there.

Q Okay.

A Some personal contacts have been made I believe and some blood samples have been drawn. I don't believe that they have arrived in Lansing yet.

Q Okay. Do you have -- can you give any indication of how these people were picked?

A As I indicated it last August we contacted the local health authorities in Lake County Health Department.

Q. Dr. Nedved?

A. Nedved was mentioned and some of these people and they have been assisting us on the aspects of identifying potential candidates.

Q. Okay.

A. From their knowledge of the territory and so forth.

Q. Has Dr. Nedved provided you with the names of persons whom you contacted and taken samples from?

A. That's correct.

Q. Okay, how big is this group presently?

A. At the present time I believe we are attempting to make contact with about 20 people.

Q. Okay, blood samples have been taken from how many?

A. Oh five or six so far.

Q. Okay.

A. And I don't know exactly how large the cohort will develop, this is something that is under consideration right now.

Q. Okay, what were the criteria for choosing these people?

A. We, of course, are trying to find the criteria is whether or not to eat Great Lakes' fish. Now, where we are specifically interested in is areas where there is known contamination, such as a particular river or a harbor as in the case of Waukegon, whether or not there are people who narrowing the definition also or in addition, or exclusively consume fish from that particular body of water.

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THE ELIZABETH JUDICIAL CIRCUIT
IN AND FOR ST. JOSEPH, MICHIGAN

Q. Okay, and have you made that determination with these 20 people?

A. That's what the field process is doing, so I don't know at this point what the status of that is.

Q. With the five people that have already been sampled, do you know what category or subject group they fall into?

A. I don't, for sure, but I suspect they probably are people that have been identified as currently or historically having eaten fish out of the harbor. You know, that's how our first priority is to try to locate people of that nature.

Q. Have you been given enough information on the characteristics of the harbor or the physical outlay of the harbor to ask these people questions about where the harbor that they have consumed their fish or caught their fish or obtained their fish from?

A. Yes, and that's one of the reasons that the background material that we have referenced which has maps as I recall has been sent up to the field office. So that the field workers can familiarize themselves, our first cut very likely will be to define people in terms of have you caught fish from the harbor. We may then go into a more precise definition of where in the harbor if blood levels or anything indicates that we should really try to be more precise, you go with this in degrees, as you go.

Q. So right now your concern is to find people who will represent

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THE 16TH JUDICIAL CIRCUIT
IN AND FOR MONROE COUNTY, MICHIGAN

to you that they have eaten fish from the harbor and then work from that?

A. Correct.

Q. The way you work from that is to determine, take blood samples from them, determine whether there is a difference in their levels with respect to other peoples' levels?

A. Basically, that's correct.

Q. Okay.

A. Taking into consideration that to my knowledge nobody has ever sampled the blood and tested for PCB of people that eat fish out of that harbor, so, that's one of the things that we are going to attempt to do.

Q. Okay.

A. And in the spirit of the research contract agreement we will undoubtedly be developing several cohorts in Wisconsin, and in Illinois at Waukegon which will address and which will develop a group of people irrespective of whether we can identify people that eat fish right out of the harbor, we will still undoubtedly develope cohorts of people who are catching fish out in that territory.

Q. How long do you think this phase of the study will take, finding these people and sampling them and then determining whether you should do more with Waukegon harbor fish eaters?

A. Well, this phase of the study is, you know, scheduled basically for the next 12 to 15 months. I can't remember exactly the

anniversaries but, you know, it's the third year of activities of the project. We are actively involved with Waukegon, elements of it. So, we are moving forward. I would expect within a month, we probably will have collected our first round of blood and hopefully perhaps they will be through the laboratory. I will not commit myself to that, that that is exactly when it is going to happen because there are many on going things. But, we are on the schedule that we are active in the area now and undoubtedly will begin to start activities in Wisconsin also.

Q. Has the United States asked you to expedite this phase of the new cohort group?

A. No.

MR. FEATHERSTONE: Objection, they don't want to generate any bad information.

Q. (BY MS. OLIVER) How many blood samples do you plan to take from each person in this cohort from Waukegon harbor?

A. At this time the intent is one sample.

Q. Okay, and then you would compare those levels with levels of other Great Lakes fish eaters?

A. Yes, as well as with comparison people.

Q. Okay, because of the variations and PCB levels found in blood, do you think it would be important to take more than one sample?

A. Not necessarily. If you take into consideration at least the

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THIRTIETH JUDICIAL CIRCUIT
INGHAM COUNTY, MICHIGAN

initial purpose is to screen one sample, at a given point in time will suffice to screen a person for whether or not they have had exposure.

Q. Okay.

A. Do you want to define more precisely what the circulation, the levels are, the norm samples we need?

Q. To make any reliable comparisons between levels of people who eat fish from Waukegon harbor and levels of people who eat from say Lake Michigan, Traverse City, would you consider important to make, to take more than one sample from the Waukegon cohort?

A. No, I think it would be more important to have a sufficient number of people in the cohort. Who fall into those categories for comparison. The advise I am getting from the statisticians is a sufficient number of individuals is going to be more important to making the comparison than say multiple tests from what any different individual or group has.

Q. What does your statistician say is the minimum number of persons in the cohort from which to make any comparisons?

A. I can't remember exactly but I think it may be in some of the papers that I've provided. I can look that up. 20 comes to my mind, but it may vary, you know, if the difference between the two groups is astronomical for example, well then you probably are not going to need as many people as if the difference between the two groups is small. So, again, it's

something that probably our findings will tend to guide us but as, you know, there is a rule of thumb, we felt in order to make some comparisons we needed a minimum number of people in each of the locations outside of Michigan. And, as I recall, I think it is probably 20 exposed people and 20 controls, but I may stand corrected, I have to consult my notes.

Q. Do you have any data today to support a reliable conclusion that PCB levels with people who eat like Waukegon harbor fish are significantly higher than people who eat Lake Michigan fish from other areas?

A. No.

Q. So, you don't know what your -- you don't, you haven't gone into this project with a predilection in either direction?

A. No, I don't.

Q. Okay, let me ask you about Exhibit No. 8, which was marked at the end of the August 13 Deposition. Okay, I show you what was marked as Exhibit No. 8 which was a paper.

A. Okay.

Q. That appeared to be given by you for the state of Wisconsin public hearings on PCB's in 1975.

A. Yes.

Q. Now, Mr. White gave us this morning a transcript of the hearings from that public hearing.

A. Yes.

Q. Was the paper that appears as Exhibit No. 8 prepared for the

purpose of the public hearing in Wisconsin?

MR. WHITE: Prior to the testimony or after the testimony?

Q (BY MS. OLIVER) Well, prior to.

A No.

Q Was it prepared after the testimony?

A Yes.

Q Okay, at the Deposition in August you stated you would look through your files to find out whether in fact you had prepared Exhibit No. 8. I take it you concluded that you did?

A That's correct.

Q That was prepared after the hearing?

A That's correct.

Q And Exhibit No. 8 was prepared by you?

A Yes, it was.

Q Okay, if I could refer you to page 19 in Exhibit No. 8.

A Okay, do you want me to use in your copy here?

Q Well, do you have a copy?

A I have one, yes.

Q In the middle of the paragraph or first full paragraph on page nine, the last sentence, it begins, "Does PCB exposure," do you see that?

A Yes, I see that.

Q Was it your opinion in 1975 that PCB exposure from eating fresh Great Lakes fish may be regarded as relatively low as

stated in that sentence?

A. On the day I prepared that document, it was.

Q. Okay, and that opinion has changed?

A. Yes, it has.

Q. And the change or modification of that opinion, I take it, is part or embodied in Exhibit No. 4, your 1976 final report?

A. That's correct.

Q. Do you recall today where you obtained the information on the 150 to 300 milligram per day, FDA no affect safety range?

A. I have considered that and I am not sure but what is printed there is a mistake. Because, in checking my documents I do not come up with those same numbers and the documents I'm referring to are material that is put in the Federal Register by the FDA and some of their calculations.

Q. That 150 to 300 milligrams per day, you can't correlate or relate any numbers in your 1976 study?

A. That's correct.

Q. Do you know if in fact there was a number affect safety range set by the FDA?

A. No, I am not aware that a number affect safety range so stated is established by the FDA.

Q. So, am I correct that your testimony Dr. Humphrey is that the conclusion that you drew in that paragraph in 1975 was incorrect?

A. Yes, was incorrect or was preliminary.

Q. Well, did you have preliminary data that supported the conclusion that exposure was relatively low?

A. Yes.

Q. Okay, and is that data in your report?

A. Yes, that's a part of the body of data in the report.

Q. So, your conclusion changed, not your opinion? Strike that, I'm sorry. Your conclusion changes, not your data?

A. Both changed. At the time of this testimony which I think was August of 1975 we had not completed the analysis of all of our data for the report which is Exhibit 4. So, on that day when I spoke I was looking at say 30 or 40 percent of the data. When the 100 percent of the data was factored and correlated that resulted in a report. And, therein lies, you know, considerable change of opinion.

Q. Okay, your report did not conclude did it that exposure to Great Lakes fish may be regarded as relatively high, did it?

A. Could you read back, did I -- I didn't catch the first part of your question.

Q. (BY MS. OLIVER) Let me rephrase it. Your report in 1976 based on all of your data and your analysis of that data did not conclude that exposure was high, did it?

A. Yes it did.

Q. Where is that finding or conclusion stated?

A. Okay. Now, I think we get into the definition of high. The report, Exhibit 4, demonstrated that people who consumed

Great Lakes fish had higher levels of PCB than those who did not. It further demonstrated that there was a valid correlation between quantification of fish consumed and PCB levels. Some of these ranged to, if I recall, well, a certain stated quantity. I believe 300 parts per million. This could be construed as high.

Q. Okay.

A. And when compared to a person who had less.

Q. What I am asking you is did you make a conclusion or a finding in your report that exposure, PCB exposure from fresh Great Lakes fish may be regarded as high?

A. Yes.

Q. Where is that stated?

A. I thought I had just answered that, but summary statement No. 2, there was a direct relationship between size and quantity of support fish eating and PCB levels found in blood.

Q. Well, my question Doctor is primarily you gave a conclusion or you made a conclusion that exposure was relatively low.

A. Uh-huh.

Q. Okay?

A. Yes.

Q. And then you say you combined all of your data and your report and I am asking you if you stated as firmly as you stated your preliminary statement that exposure was high?

A. And I said yes.

Q Well, you direct me to finding No. 2?

A Yes.

Q Okay?

A And finding No. 3.

Q Okay, what you're doing is reporting your data results, correct?

A Yes, that's what the report does, correct.

Q Okay, it makes no conclusion as to relative high or low exposure other than reporting the levels that you found?

A Well, stated as such, no.

Q Okay.

A But the implication of the report is yes.

Q Okay. Okay, I think I am finished. Take it away.

DIRECT EXAMINATION

BY BRUCE A. FEATHERSTONE

Q Dr. Humphrey, let's take Ms. Oliver's last point first. When you wrote in 1975 that PCB exposure from eating fresh Great Lakes fish, quote may be regarded as relatively low, end quote weren't you talking about the amount of Great Lakes fish consumption by your study group? In other words, you found that they were consuming less fish than you thought when you went into this study?

A Yes, but that's not the only factor.

Q Well, it's an important factor though.

A Yes.

Q Okay, what are the other factors that you are referring to in

1975 when you made that statement that appears in this date?

A. I would like to put in context when this Exhibit was prepared after my testimony at the Wisconsin hearing, the purpose of which was a hearing on rules relating to the discharge of PCB's into the waters. I was asked by a person at the Department of Natural Resources to give a summary of my notes to him and that's what this Exhibit represents. At the time that I constructed this the study which is Exhibit No. 4 was in its wrap up stage but not all of the data had been analyzed so on the basis of partial data I made certain conclusions and statements which when the full body of data was analyzed turned out to be inaccurate. Now, we did the study and one of the purposes of the study in 1973, 1974 was to find out how many fish people do eat out of the Great Lakes. And we had frankly speculated higher quantities than we found as the average. We did locate as you see in the report some people who do consume high amounts of fish, some individuals. Likewise, we hypothesized, if you consume high quantities of contaminated fish that would result in high levels of chemical in the body. Therefore, quantity of fish consumed, the amount of contamination in the fish, all would go to the blood level that was observed. And, therefore, -- well, those are the two primary factors. That, and the species of fish, certain species of fish will have high quantities of contamination than others. So, that when these comments were made we were in the

beginnings of analyzing the data. I had partial data and frankly at that point it was lower, the numbers were lower than I had expected they might be. They later turned out to be higher than that.

Q. Which numbers are you specifically referring to?

A. I am thinking of quantity of fish eaten and blood levels that were seen but when the data was fully analyzed there was a much broader range and, you know, my opinion and the conclusions were different.

Q. Well, is it your testimony Doctor that between the time you made the statement that is now Exhibit 8 of your Deposition, 1975 statement in Wisconsin, Wisconsin and the time that you wrote your 1976 report that your findings with respect to the quantity of fish consumed on an average by your study group changed significantly?

A. Yes, it did because we have analyzed the data for more people.

Q. Well, what did it change -- strike that -- what was your conclusion about the consumption quantities in 1975 when you wrote Exhibit 8?

A. That they were lower than we had anticipated or lower than we had hypothesized.

Q. And that remained your conclusion when you wrote the 1976 report as well?

A. No because these comments were on the basis of scanning part of the data, and apparently, it was that part of the data which

was -- they were some of the lower -- lower quantity consumers.

Q Well, going back to 1975, no not think back, flip to page 19 of Exhibit 3. Look at the first full paragraph on that page, middle of the paragraph, read and quote an evaluation of fish consumption for those classified as fish eaters, showed a range of 26 pounds per year or about two to twenty pounds per month. The majority of fish eaters fell in the 26 to 35 pound range with only ten persons indicated on consumption of about 85 pounds per year. End quote. Those figures didn't markedly change to the 1970 reportto 1976 report, did they Doctor?

A Yes, they did.

Q All right, which numbers changed and by how much?

A Number one, the upper limit, 85 pounds I believe turned out to be several hundred pounds per year.

Q Well, the year 1975 report doesn't put 85 pounds at the upper limit, it says ten persons indicated consumption above 85 pounds per year which would of course taking into account consumption of several hundred pounds per year, your 1976 report Doctor showed that the majority of the fish eaters fell in the 26 to 35 pound range, didn't it?

A That's correct, yes.

Q So, that finding didn't change from 1975 to 1976, isn't that right?

A That would be correct.

Q. And when you -- strike that -- now, let's return to the later sentence in that full paragraph. The first full paragraph on page 19 when you were talking about your preliminary findings, that the exposure from eating Great Lakes fish was low, you were talking about an average figure, weren't you?

A. I'm sorry, which sentence do you want me to focus on?

Q. The last sentence on the first full paragraph of page 19, the one that Ms. Oliver was directing your attention to.

A. All right, those PCB's exposure and so on?

Q. That's correct, that sentence when you were talking about exposure from eating Great Lakes fish as being " relative low," with majority of the exposed group you were talking about this average group of roughly 26 to 35 pounds per year, of consumption, isn't that right?

A. That would be correct.

Q. So, with respect to that majority group your findings didn't change from 1975 to 1976?

A. Which findings?

Q. The finding about -- the finding of the exposure was relatively low for that group?

A. No, it did change.

Q. Okay, but it didn't change because of the amount of fish consumption, you know, that was in 1975.

A. That's apparently correct, yes.

Q. Okay, now what changed?

A. The blood levels and if you turn to page 8 there is a copy for the whole section.

Q. Let's stop there for a second.

MR. WHITE: Let him finish his answer and then you can go ahead.

Q. (BY MR. FEATHERSTONE) Go ahead and finish your answer.

A. Well, I was saying if you turn to page 8, you know, we are taking one particular paragraph and a particular sentence out of a section which is called preliminary study results and on page 8 the first paragraph of that deals with the fact that an insufficient number of blood tests had been completed to permit data processing and interpretation at this time. And then, it goes on from there, and that's the point I am making is that at that point in time, yes we had some of the data, the blood test finished and we took a look at what it -- the levels were, but we were talking here about falling within a milligram per day range. To use your numbers, until you have all of your blood tests completed you can't make that calculation

Q. That's not right Doctor. Exposure is a function of how much you eat and how or what the concentration of PCB's is in what you eat, isn't it?

A. Yes.

Q. Okay. The blood levels -- strike that -- the PCB levels in the blood is a measurement of the effects of exposure on the blood levels?

A. Or dose.

Q. When you say that you mean a measurement of the effect of the dose on the human body?

A. No, a dose is quantity consumed, divided by body weight per unit time.

Q. That's right, but you don't measure a dose of PCB by looking at the levels of PCB's in the blood do you?

A. Okay, no. No, you don't. There is two ways to come at it. You can come either way, you can back calculate or you can --

Q. Well, the two ways you are referring to is one is the direct way, which is on calculating how many fish they eat and what the PCB levels in the fish that they eat are, right?

A. Yes.

Q. And the second way is in the indirect route which would, of course, admit is less certain which is to look and see what is in the human body and try and back that out to the conclusion about how much was in fact consumed, isn't this right?

A. Yes.

Q. All right, and then you would, of course, agree that the first approach is much more likely to be accurate than the second?

A. As far as measuring dose yes.

Q. All right. Now, let's go back to this later sentence on that first full paragraph on page 19. When you write, " PCB exposure from eating fresh Great Lakes fish," you were talking about the dose, aren't you?

A. I am talking about exposure.

Q. Okay, but you are not talking about the blood levels where the PCB levels in the blood --

A. At that point, apparently not.

Q. So, in effect what you are saying there is that the exposure to fishermen from eating PCB's or eating fish with PCB's in them, was relatively low, lower than you thought it was going to be?

A. Yes.

Q. And that finding didn't change from 1975 to 1976?

A. No.

Q. Now, I am not talking about levels of PCB in the blood, I am talking about exposure as you have defined it.

A. What I am trying to recall in thinking back was in gross terms, how many pounds did you eat, but in more precise terms we refined it and we broke it down into how many pounds of which species are eaten and I believe what occurred later after this was that more precise definition of exposure by in terms of pounds of fish eaten, the example would be it takes many more perch to equal what one lake trout would give you in exposure and that the conclusion changes because in the report we went into more detail as to breaking down the species of fish that constitute the total quantity, so, you know, that's basically the difference between these two time periods with respect to dose or exposure to the fish.

Q Are you saying that your conclusion with respect to the PCB dose changes significantly between 1975 and 1976 when you wrote Exhibit 8 and in 1975 and Exhibit 2 and 4 in 1976?

A They changed between those two documents, yes they did.

Q Let's turn to Ms. Oliver's section to the last point which is Waukegon harbor cohort. I notice from some documents that Mr. White produced in between the two sessions of your Deposition that there was considerable discussion between you and your staff and United States EPA about whether efforts should in fact be made to identify cohort of people who eat from Waukegon harbor, eat fish taken from Waukegon harbor?

A Can you identify the EPA you are referring to?

Q Well, I think Mr. Mullin was involved, I think people in Region 5 in Chicago were involved, specifically Howard Vare, I think.

A I've never spoken with Mr. Vare.

Q I think Mr. Budd of your staff was involved.

A Yes.

Q Okay, what was the rest of the discussion that you and your staff had with EPA about the definition of cohort in Waukegon harbor area?

A As I recall, the discussion would have to do with clarification of areas where we would extend the study, and in fact, that discussion continues today. I received some information this week with respect to some areas in Wisconsin. What we were

clarifying there was, all right, we were going to go out of state to some places that have, you know, concentrations or pocket contaminations, if you will, Waukegon has been identified as one of those. And more precisely detail how do we want to run the study there. What kind of cohort do we want to develope. Do we want the people who are exclusively eating fish out of the harbor or do we want to also have cohorts include people who are catching fish, of fishing both out in the big lake, things of that nature, and frankly the operational definition --

Q. All right, I want to focus on the operational definition. You were involved I take it in the discussion with your own staff and with EPA about what operational definition to be used to define this cohort from the Waukegon harbor area?

A. Yes.

Q. First of all, can you tell me today what the definition of that cohort is? In other words, how are you defining the people who are going to be included?

A. Yes I spoke to the questionnaire earlier but I didn't elaborate on it.

Q. I want it in detail Doctor.

A. We have received the requested information from the EPA and that is basically we want to develope cohorts on several sites of western shores of Lake Michigan, if you will, similar to those that we have developed in Michigan. Which

would mean we will go to some communtity such as Waukegon harbor and develope cohorts of individuals who are consuming fish, from the Great Lakes. Which by definition means they hire a boat or have a boat and go out off that port and go out and catch fish. In addition, we are going to attempt to locate as a part of that group but distinguishing subgroups who either in addition to or instead of catch fish and eat them out of a particular body of water of interest. You see, the harbor, and that's our working definition. So, so a cohort would be in a subgroup.

Q. You testified earlier that approximately ten people have been contacted in the Waukegon area and have been given blood samples, are these people who fit into the subgroup of those who catch fish and eat them from Waukegon harbor?

A. And I replied I am not sure but that our priority was to try to find that kind of subject first but I do not know whether or not that in fact is what we have accomplished at this time.

Q. In terms of -- strike that -- I want to ask you some questions about the definition of the subject group of people who catch fish from Waukegon harbor and eat that fish. What range of consumption are you looking for?

A. That's one of the things we are trying to discover.

Q. So, if I understand you right now all you are trying to do is to find somebody who at some time caught a fish out of Waukegon harbor and ate it?

A. Yes.

Q. And that definition that would include somebody who maybe caught two fish in a period of ten years from Waukegon harbor?

A. If that is, that remains to be seen, I don't know.

Q. But you are looking for that sort of person and then whether or not you include him in your cohort is, I guess, dependent upon how many other people you find who have in fact caught fish in Waukegon harbor and eaten those fish?

A. Well, not exactly as you are stating it, no. I mean you are suggesting a steering of the cohort development, that isn't there.

Q. No, what I am suggesting is that if you come up with maybe 20 people who over the course of ten years, each have caught one fish from Waukegon harbor and eaten it you probably wouldn't define that as a subject group of people who caught fish from Waukegon harbor?

A. If that's all we could come up with I would say that would be a very weak subgroup. Weak in the sense that what is it going to show for sure?

Q. That's exactly the sense of my question and I take it --

A. I am saying I don't know what we are going to find and that's one of the reasons we're there.

Q. Did you have discussions with EPA about whether you could in fact define a cohort of people who catch fish from Waukegon harbor and eat the fish?

A. I don't think they know, I probably asked the question because EPA has been sampling fish in the harbor from time to time, are there people there that catch fish and as I recall they don't know either and that's one of the tasks to find out whether there are.

Q. Who told you that EPA didn't know whether or not there were any people who caught fish out of Waukegon harbor and ate the fish?

A. In my discussion with the people at the meeting I said what kind of cohort is over there and they were vague, they didn't know.

Q. Who were these people specifically?

A. Mullin and Swain, and Nelson Thomas.

Q. And Swain, Thomas and Mullin are the people who are with EPA who you are working with in this on going project, right?

A. That's correct, as I indicated last summer they are at the Grosse Ile, facility and our study is administered through that office.

Q. Is it still even though the Grosse Ile was shut down?

A. They answered the phone one day after October 1st so I guess so, no actually I'm sorry, it was September 28th.

Q. There was some suggestion in some of the documents that Mr. White produced that EPA Region 5 had located approximately five people who at some point or another caught fish out of Waukegon harbor and claimed to have eaten the fish. Do you

know anything about that?

A. Yes, these are some leads that were forwarded up to us and we asked the Lake County people to follow up to find out if the people were real or where they were. I don't know if they were part of the folks that are being contacted right now or not and I don't know what the basis was for their being suggested.

Q. I take it when you attempted to define cohort Doctor that one of the concerns you have is that undue public estimate kind of distorts the answer you get when you go out in the field and interview people about their eating habits?

A. That is a risk of this type of study, yes, it can also be the opposite.

Q. With all of the publicity that the PCB situation in Waukegan harbor has generated in Chicago how do you take that into account in determining the validity of the responses you get from people you interview, how does that factor come in?

A. Well, the question will be the results of the blood testing. You know, blood levels probably aren't going to lie in the sense that a person can make a wrong estimate of the quantity of consumption of fish, but if they have been consuming fish which are highly contaminated for a period of time I would expect that their blood level would be high and that is a result that is a laboratory test. So, our mission is to try to identify people who have eaten fish out of the bay and

people who are actively consuming fish out of the big lakes from that locale. And, using the same criteria for defining this that we have used in Michigan and we will go through the routine of trying to pin this down.

Q. In other words --

A. The data will fall where it is.

Q. In other words, what you are telling me is you can't really make any special accommodations for the scare tactics that the United States EPA in the Waukegon harbor area?

A. I don't know what the United States EPA has said or done. I really don't know what the local publicity is.

Q. I didn't ask you what is, what has been --

MR. WHITE: For the Record, I would like to object to the characterization of the United States EPA desemination of information. The public may have a right to know.

Q. (BY MR. FEATHERSTONE) Well Doctor, I didn't ask you to summarize for me either the level of information released by the EPA to people in Chicago or in Waukegon harbor or the slant on it, or what you are feeling might be about how that would affect people in Waukegon harbor. In Waukegon harbor area, what I am asking for is there any way you can in fact take that into account, the factor that makes an accommodation for that kind of publicity as opposed to a situation where there is no advance publicity or very very

little?

A. I don't understand, what do you mean by taking into account?

Q. Well, taking into account --

A. You mean adjust?

Q. Yes, adjust for it, adjust for possibility that people might over estimate the extent to which they eat fish out of Waukegon harbor or indeed falter on their recollection, whether they did in fact eat fish in Waukegon harbor.

A. It is difficult to control, this is a human study, if they lie, they lie. You can't, you know, we attempt to develope questionnaire documents which have checks and balances in them which would show, would attempt to show if there is that type of flaw happening. If you are asking me can we run an experiment, then my answer is no, we can't.

Q. I didn't ask you whether we could run an experiment, that is perfect, I asked you how you could take that into account and your answer is you really can't.

A. It's difficult, that's my answer.

Q. The people from whom you have obtained blood specimens in the Waukegon harbor area, have you also interviewed them with a questionnaire similar to the one that you were using over in Michigan?

A. That is the intent that if we check the blood samples from somebody, we will treat them the same way we have treated fish consumers in Michigan which would mean they have been

interviewed, yes.

Q. When you say that's the -- well, I am confused with your answer. You said that that is the intent, have they been in fact been interviewed?

A. I don't know. They were there just this week and I don't know what the end result was. I would assume, my report from the field was brief, and it was that they had made contacts with some individuals and collected some blood.

Q. Has anybody defined the extent to Waukegon harbor, I mean wh you go to somebody and say have you fished in Waukegon harbor and eaten the fish taken from Waukegon harbor do you define Waukegon harbor for these people, do you have a map?

A. I am not sure how that is being handled in the field. In other words, I don't know if we are using a map or not. I would have to defer the answer until I could consult the field people, what their experience is, if the local people are quite familiar with the harbor then this is not such a definition, it is not needed.

Q. Well, I noticed in your 1976 study you gave your field people very elaborate insturctions on how to ask questions and how to fill out the forms.

A. Yes.

Q. So, hopefully you would reduce the -- any misunderstandings that might arise between the interviewer and the person b ng interviewed, is that right?

A. Yes.

Q. It strikes me that one of the problems you might have in the field, if you go out and interview somebody and say have you fished in Waukegon harbor, that person's hearing that question may well say yeah, I go over to the pier and I drop my line off the south side of the pier into water, these waters that are really Lake Michigan water, and not considered Waukegon harbor, how do you prevent that?

A. I will have to check with my field people to determine exactly how it is being carried out. That consideration has been take into account. We have discussed the development of the definition of the subgroup, the distinction between throwing your line on one side of the pier and a line on the other side of the pier for example.

Q. It has been discussed?

A. Yes.

Q. Did you discuss that with EPA?

A. I don't recall if I did or not. Basically, the design, development of the study is in our bag, it's our business, I have asked for clarification from the EPA but we are the ones that are developing it.

Q. I take it the reason why it is significant, whether the line is dropped on one side of the pier or the other is because there is a feeling that the PCB levels in the fish on one side of the pier are greater than they are on the other?

A. As I recall, that's in fact probably the case.

Q. What are we on in terms of Exhibit Nos.? This is 9. Would you mark this as Exhibit 9?

(WHEREUPON, THE COURT REPORTER MARKED DEPOSITION EXHIBIT NO. 9.)

(WHEREUPON, THIS MATTER WAS IN RECESS AT 1:15 P.M.)

(BACK IN SESSION AT 2:06.)

(BY MR. FEATHERSTONE)

Q. I've had marked as Deposition Exhibit 9, a multi-page document beginning with the identification number US26861. Dr. Humphrey, I hand that Exhibit to you and ask you to identify it please?

A. It is a questionnaire for recorded data, it has an old study written on the top, it appears to be the questionnaire that was used in our 1974 investigation.

Q. That resulted in the 1976 report?

A. Correct.

Q. And were you involved in the drafting of that document?

A. Yes.

Q. Did you do it in conjunction with some other people?

A. Yes.

Q. And who?

A. Let's see, they would people within our department, colleagues of mine.

Q. Were these people directly involved with the project?

A. Some were and some were not, one of who would be Mr. Marvin Budd, he directs my field work. Others would be people in the department, inadvertently, in various disciplines who looked at a reviewed comment and suggested and so forth.

Q. When you say in your department, is this the Michigan Department of Public Health?

A. Yes.

Q. Was the questionnaire reviewed by your superiors?

A. Yes.

Q. And I take it it received their approval before you used it?

A. Yes.

Q. I have had marked as Exhibit 9 of your Deposition, a multi-page document beginning with the number US, 26868, which is an interviewer's manual dated 1973-1974.

A. Yes, I see it.

Q. Okay, can you tell us what that document is?

A. Yes, it appears to be an instructual manual that would accompany the questionnaire which is Exhibit 10, which gives the direction to the field worker as to how to approach and ask, how to use the instrument.

Q. The instrument being the questionnaire?

A. The instrument being the questionnaire, that's correct.

Q. Were you involved in the drafting of Exhibit 9, the interviewer's manual?

A. It was done under my direction, I believe it was probably

drafted by other people in the department.

Q. I take it it's fair to say that the interviewer's manual was drafted so that you get as accurate as possible data from the questionnaire?

A. Yes.

Q. I was looking through the documents that Mr. White provided us with respect to the earlier study, the 1976 study, and it instructs me that you established rather elaborate protocols for the field data, for obtaining the field data, and then evaluating it, is that fair?

A. Yes.

Q. How long a period of time does it take or did it take to develope the protocols for obtaining the field data from the people you studied in this 1976 study?

A. I don't recall precisely.

Q. Are we talking about a period of months?

A. Yes, some months.

Q. Now, the people you had to go out and conduct the interviews, were those people from the Michigan Department of Public Health?

A. Yes, they are employees of this department.

Q. Okay, are they especially recruited to do that job? In other words, is there some care taken in the selection of those individuals who actually go out and conduct the interviews?

A. Yes.

Q. How were those people selected?

A. We are under a civil service system here in Michigan, different jobs have different type of classifications, so, that the nature of the job, the field work, field interviewing, then has certain qualifications. Certain people meeting qualifications are then candidates for positions when hiring is done and they're interviewed.

Q. Oh, I see, the people who are used to conduct the field interviews with respect to the 1976 study were in fact hired as interviewers, field interviewers?

A. Yes, we call them field representatives.

Q. And they're full time employees of the Michigan Department of Public Health?

A. Yes, they are.

Q. I take the procedures that you used in the 1976 study were preceived as commonly used in the field of epidemiology?

A. Yes.

Q. Let's go off the Record for a second.

(WHEREUPON, THIS MATTER OFF THE RECORD.)

(BACK IN SESSION)

Q. (BY MR. FEATHERSTONE) Doctor, would you please turn to the second to the last page on the questionnaire used in connection with the 1976 study, it is the page that lists the health conditions along the left margin.

A. Yes.

Q. And makes provisions for other material to the right.

A. I have it.

Q. With respect to each health condition, there is a block or a column labeled on-set date, what does that mean?

A. This means exactly what it says, if a person said they had one of these problems, the question was asked when did this start or you know when did this begin, and that would go under the on-set date.

Q. Were your field interviewers who were out collecting this data in 1973 and 1975 asked to restrict the person studied, the fish eater being studied to maybe the last five years or last year or was this historical data as far as this interviewer could remember?

A. I would have to consult the instruction manual. I believe it was to record what the respondant said.

Q. Well, I guess what I am driving at is to look at the first health condition which was stomach pains or vomiting for more than one week. If the person who was interviewed in 1974 and had this problem in 1976 but not since, would a response yes I had that problem in 1975 had been entered into the questionnaire?

A. I don't know.

Q. How can we find out?

A. Probably refer to your Exhibit 9. Yes, I believe Exhibit 9,

page 3 answers your question.

Q. Would you read what it says there, that answers the question.

A. Under how to record at each point where a question is given, and asked, when did you first experience this condition and if there have been any repeated episodes. And then it goes one to say did you see a doctor about it, record the month and year of on-set of recurrence.

Q. So, there is no limitation on when the interviewee might have suffered a particular health condition?

A. That's correct.

Q. And you testified last time that the average age of the fish eaters that you studied were approximately 46 years?

A. If that's what the records state, yes.

Q. Okay, if you would look at the last health condition, if you recall it, it says other.

A. Yes.

Q. Was there any effort made to assimulate the miscellaneous information you would have gotten in the other health category and to determine whether there was some specific health condition that isn't listed in 1 to 17 that might be associated with PCB's?

A. I am trying to recall. Obviously, this was reviewed and I guess that's where I would -- it was reviewed apparently and there was nothing striking under the other.

Q. That was going to be my next question. I take it if there had

been something that came up frequently and was listed in a category "other" it would have been identified and reported in your 1976 study?

A. Yes.

Q. What types of health conditions would fall in the category other, I mean, was the interviewer to ask about certain things not specifically listed in this chart or was it -- was he just to put down there whatever else was volunteered?

A. That's the point of the question, yes, whatever would be volunteered would be under there.

Q. Was the interviewee -- strike that -- was the interviewer out conducting the field interviews instructed to ask any of the fish eaters whether there was anything else that was unusual about their health history?

A. I would have to consult the instruction manual to answer accurately.

Q. Okay, would you do that please?

A. Okay, I do not. I don't know the answer to that because I do not see a specific instruction.

Q. Okay, and you do not remember what the instruction was?

A. No, I don't. Other than generally that that is typically put in if something is volunteered.

Q. The last time you testified that the finding of your 1976 report that there was no correlation between PCB exposure through the consumption of fish and any of the 17 or 18

health conditions that you actually looked for, was valid up to the point in time of the study in 1976, do you remember saying that in those words or substance?

A. Yes.

Q. Now, when you said it was valid up to that point in time you were referring to the time of your report in 1976?

A. When the question was asked which was in 1973 or 1974.

Q. Okay, all right. Would you put in front of you Exhibit 9, the interviewer's manual. Why was that drafted?

A. It was part of the protocol package when you formulate a questionnaire and you need to train people to use it, you need an instruction manual and that's what it is for.

Q. Did your study also have safe guards to make sure that the information was probably transcribed from the questionnaires to the computer or who was going to analyze it?

A. Yes, that is a part of the data processing which is done in this department by people trained in that.

Q. Do you have established procedures for that?

A. Yes, there are.

Q. And who then analyzed the health condition data that you gathered in 1973-1974?

A. We have a section within the department called Vital Records and Health Statistics.

Q. What do they do?

A. In that section are people with expertise in statistical

analysis of data. They service the various elements of the department which are doing studies or need statistical services and it's that section that examines the data and applies the statistical test.

Q. And on the basis of those statistical tests you reached the finding that you did about the absence of the particular health conditions you were looking for, is that right?

A. That's correct, they did the statistical testing, that is described in the report.

Q. The question here, Exhibit 10, is that the same question there that you were using in the Waukegon harbor area?

A. Yes.

Q. Have there been any modifications?

A. Yes.

Q. What are they?

A. Additions.

Q. What are they?

A. I don't know.

Q. Has the questionnaire that you were using in the Waukegon harbor area been finalized? In other words does it exist?

A. I don't know.

Q. Okay, in the new questionnaire if we can cross or use that phrase for Waukegon harbor, did you expand on the health conditions in any way, the list of the health conditions?

A. I don't believe so, no.

Q. Doctor, in some of the documents that Mr. White produced to us from your files, there is some memorandums that state that in your current investigation or field tests that the old cohort groups from the mid 1970's you have found a decline in the median PCB levels or maybe it is the mean PCB, first of all which is it?

A. Probably median.

Q. Okay, what does that mean, the decline in the median PCB levels?

A. That means that part of the data has been analyzed and at that point the median value is smaller.

Q. What's the significance of that?

A. I don't know yet.

Q. The questionnaire that you are using in your current study with the old cohort groups asks some questions regarding the amount of fish consumption?

A. Yes.

Q. A preliminary finding of your project is that the amount of fish consumption has declined since 1974?

A. I believe that's correct, at least in some locations.

Q. And a preliminary finding of your group has been that the drop in the median PCB levels in the blood is attributable to the decline in fish consumption, isn't that right?

A. That would be reasonable, yes.

Q. Do you know why fish consumption by these people has declined from 1974 to today?

A. It's the general belief in talking with participants that this is attributed more to fluxuation and success in fishing than any other factor.

Q. You mean they can't catch it to eat it?

A. They aren't catching as frequently. Also, in combination we have northern Lake Michigan, some situations of where the availability of the fish has diminished so that people who formally fished in a certain area are not catching them there. At least at the time, that's my impression from the field as to what is occurring there.

Q. Let's assume that the preliminary finding of the decline in the median PCB levels in the blood is in fact the finding, your final finding in this part of the study.

A. We are assuming this?

Q. That's correct.

A. All right.

Q. What does that mean in terms of a qonclusion about whether PCB's do or do not accumulate in the body, or whether there is or is not net accumulation of PCB?

A. Standing by itself, that would not answer that question.

Q. All right, let's not let it stand by itself.

A. All right.

Q. Let's not let it stand by itself. Let's assume that the median PCB levels do in fact decline and that is the finding of your present project. Now, how would you use that

information in making a determination of whether there is in fact net accumulation of PCB's by humans?

A. That data would have to be correlated with the quantity of fish consumed. At this situation, and of the level of PCB contamination in the fish that are eaten, if a person eats less fish and/or the fish was less PCB, then it is entirely possible that he has had a pronounced decline and exposure.

Q. And you would expect as indeed you may well have found according to your preliminary findings that with the decrease in the PCB exposure to fish or fishermen that the PCB levels in their blood would decline as well?

A. That is a possible outcome, yes.

Q. And indeed that's what the preliminary data seemed to show anyway?

A. Yes.

Q. Have you had any opportunity to discuss the epidemiological studies being done on fish eaters in the state of Michigan? I'm sorry, state of Wisconsin, I apologize.

A. What do you mean, could you clarify that?

Q. Sure, the state of Wisconsin has done or is doing at least two fish eater studies, isn't that right?

A. The state of Wisconsin, I am not aware of that, no.

Q. Well, are two epidemiological studies on fish eaters being done in the state of Wisconsin, I don't want to quibble over exactly who is doing it.

A. Okay, currently or historically?

Q. Either way.

A. I don't know.

Q. Well, if a memorandum that you authored in January of 1980 is talking about that, I take it if you don't know, you don't have the faintest idea what it is they found if anything in Wisconsin?

A. That would be right.

Q. And you haven't had any conversation with anybody about that?

A. I am familiar with the people on that. I think you are looking at that -- I don't know if those studies were finished or ever started, so no, I don't know what the results are.

Q. Were you asked to give any advisorship, were you asked for any advise in connection with the setting of the protocols for those studies?

A. No.

Q. So, you didn't have any formal or informal role in any of those studies?

A. No, I believe the memo may show the purpose of the meeting.

Q. Well, it does.

A. It was not to design a study.

Q. Well, I wasn't limiting my question just to the particular memo, I have that in front of me, or that particular meeting that is referenced in the memo, did you have any involvement beyond what's described in this memorandum?

A. Well, yeah, I guess you have to show me the memorandum so I can be sure I am responding to the same thing you are looking at.

Q. Well, I thought your memory was pretty good because you ascertained --

A. I can show you a memorandum on the board.

Q. Why don't we mark it then.

(WHEREUPON, THE COURT REPORTER MARKED DEPOSITION EXHIBIT NO. 11.)

THE WITNESS: Okay, I see the material.

Q. (BY MR. FEATHERSTONE) Have you reviewed Exhibit 11?

A. Yes.

Q. All right, have you had any involvement formal or informal with the two studies that are reported to be in progress in Wisconsin?

A. No.

Q. All right, just put that aside Doctor. Doctor, you testified at a later time that you have made some rough approximations of a ratio between the PCB levels in blood and the PCB levels in mothers' milk and the PCB levels in human adipose tissue?

A. Yes.

Q. Okay, would you tell me what the ratios are?

A. Generally speaking if blood has one, breast milk would have one hundred and adipose tissue would have between two and

three hundred.

Q. So, I take it if median PCB levels in the blood are dropping you would expect to find PCB levels in breast milk and adipose tissue declining in the same ratios that you just described?

A. Possibly.

Q. You say possibly, why do you hedge?

A. Because as I indicated earlier we don't fully understand what the dynamic, transfer dynamics are that are going on, so just because blood might be dropping I can't for certainty say that necessarily the other two are. Yes, that is a possibility but it may not be the case, I don't know.

Q. All right, is there anything you know of that would lead you to believe that if the ratio that you described holds a blood level increase the same thing doesn't hold if blood levels decrease?

A. Could you reread that back?

MR. FEATHERSTONE: I will restate it.

Q. (BY MR. FEATHERSTONE) You have given us a ratio or a proportion, if you will, between or among the PCB levels in the blood or PCB's, the levels you expect to find in the breast milk or PCB levels you expect to find in adipose tissue, is there anything that you can think of that might mean that that ratio holds as the PCB levels in the blood are going out,

but may not hold -- in other words, the ratio may be different as PCB levels go down? In other words, is there any reason to believe that what goes up doesn't come down?

A. No.

Q. I'm sorry.

A. I don't know, you know I . . .

Q. A couple more questions about this silo farmer project that you have at MSU now.

A. All right.

Q. Have you found that farmers who operate farms that have silos with a PCB compound on them have the elevated PCB levels in their blood?

A. Yes.

Q. Have you found any farmer or member of his family who has suffered any illness, disease or sickness that you can say with a reasonable degree of medical certainty was caused by PCB's?

A. No.

Q. You testified in response to a couple of questions from Ms. Oliver that you had looked at the transcript of your Deposition for the first couple of days, did you make any changes to the testimony you gave in August?

A. No, I have not.

Q. Do you intend to do so?

A. I don't believe so.

MR. WHITE: Just for the Record so we don't have any problem with this, a point of clarification, with respect to changes, he has not reviewed the document or been instructed to review the document as one to review it for signing the signature page. I just want to make that clear, he doesn't -- I don't know what the intent of your question is with respect to changes.

MR. FEATHERSTONE: Well, of course, Doctor what I want to know is do you have any intention of making any changes to the transcript of your testimony that you have reviewed on so far? That would change in any way the meaning of the testimony that you gave, in other words, if it is just a grammatical change, that doesn't effect the meaning of it, I don't care.

THE WITNESS: At this time, no.

Q. (BY MR. FEATHERSTONE) Do you remember last time Doctor I showed you a whole batch of Exhibits that were commonly referred to as mensitch Deposition Exhibits?

A. Yes.

Q. PCB data, from fish caught near Waukegon harbor by the state of Illinois, I hand them to you, all I want to know is before I show those to you at those Depositions have you ever seen them before, the documents showing the mensitch PCB data?

A. These are the one in August. I have seen these, is that your question?

Q. That's my question.

MR. WHITE: Can we go off the Record for a moment?

MR. FEATHERSTONE: Sure.

(WHEREUPON, THIS MATTER WENT OFF THE RECORD.)

(BACK ON THE RECORD)

THE WITNESS: In answer to your question, I don't recall ever seeing these before.

Q (BY MR. FEATHERSTONE) Okay, and then the documents that you are referring to are by way of shorthand notation, all the mensitch Deposition Exhibits that were referred to in your earlier testimony?

A. Yes, fish levels and such.

Q. Doctor, would you adjust your thinking cap back to the 1972 if you can. Before you began this 1976 project did you take a look at the literature about any human health effects from environmental quantities of PCB's?

A. Probably I did, yes.

Q. And I take it that since that time you have stayed reasonably current with literature with discussing or talking about any potential or real human health effects from the environmental exposure to PCB's?

A. Yes, I have tried to.

Q. And Doctor, do you agree with that statement of the Federal

government, "There currently are not technological or ecological data available to indicate that the levels of PCB's currently known to be in the environment constitute a threat to human health.

MR. WHITE: Would you identify when you attribute that statement on the Record to the Federal government, would you identify the source?

Q (BY MR. FEATHERSTONE) Can you answer that question? I will do that after I get an answer from the doctor.

A I am sorry. Now, I'm going to have to have it read back.

(WHEREUPON, THE COURT REPORTER READ BACK THE QUESTION.)

THE WITNESS: When was this dated?

Q (BY MR. FEATHERSTONE) I'm asking you whether you agree with it?

A No, I don't agree with it.

Q Was the statement of the interdepartmental task force on PCB's. Now, the statement was made in 1972.

A Who or what interdepartmental; of what?

Q Ask the Federal government, they put it together and entitled it that.

MR. WHITE: He just pulls these off out of --

Q (BY MR. FEATHERSTONE) All right, put your thinking cap on and adjust it to the year 1972 and I want you to respond

based on your knowledge of the state of the literature as of 1972. And, this is a quotation from the Federal government. The interdepartmental task force and if you want to know why it was called that, you better have Mr. White find out because I don't have the faintest idea, and it reads, it is the same quotation I just read you, "There currently are not toxicological or ecological data available to indicate the level of PCB's currently known to be in the environment to constitute a threat on environmental health as of 1972." Do you agree with that statement?

A. I think yes, I do.

Q. Okay, now do you agree with this statement. "No adverse effects have been associated with PCB's at the concentrations found in adipose tissues, blood, or milk of individuals whose only known exposures were from general and environmental contamination."

A. I agree.

MR. WHITE: Was that prefaced by a date or just a blanket statement for today?

MR. FEATHERSTONE: That was a blanket statement for today.

Q. (BY MR. FEATHERSTONE) Do you agree with this quotation. This is directed right at the subject of your profession Doctor. "The extrapolation from animals to man is subject to some uncertainty,corroboration of laboratory tests, data with sound

epidemiological information is desirable." Do you agree with that?

A. Yes.

Q. I should know what the answer to this question is from the way you have responded to a certain of Ms. Oliver's questions but I will ask it anyway, Doctor. Can you identify literature or reports that you say supports an association to use your words between PCB exposure and biochemical changes in humans?

A. Yes, I believe I can.

Q. Okay, what reports are you referring to?

A. Well, again, I have to respond as I did this morning. I am not prepared to quote them, it's within the context of my general knowledge and following the literature in this area that such reports exist.

Q. But you can't point to a specific one right now can you?

A. You said biochemical, yes, I believe one would be a report from the Center for Disease Control of a study in Alabama.

Q. What do you stand the word biochemical to include? I just want to make sure we are on the same wave length, if I have missed something.

A. To me that describes any, the chemical processes that are going on in the biological organism.

Q. Would you include lipoproteins in the blood?

A. Yes.

Q. Enzymes?

A. That would be another.

Q. Would it also include vital lung capacity?

A. I would call that more physiological as opposed to biochemical change or process.

Q. Are you aware Doctor that there are a number of studies that show that PCE exposure to workers in plants has not resulted in any abnormal change in any biochemical levels or signs or functions?

A. Yes, I'm aware of that.

Q. I take you have reviewed those particular reports to the extent they have been written up in literature?

A. I have recently seen some of them, yes, I don't know if I have seen them all.

Q. All right, with respect to the ones that you have reviewed, do you have any quarrel with the methodology followed by those authors?

A. No.

Q. In their studies?

A. No.

Q. Have you reviewed the Triana,Alabama epidemiological study that was done for the Center of Disease Control?

A. I have read it, I have read a report on it.

Q. Are you aware, Doctor, that the people in Triana,Alabama reported to have the highest DDT levels known to man?

A. Yes.

Q Are you satisfied Doctor that the authors of this Treana, Alabama report probaby took that finding about the levels of DDT into account when they wrote about the association between elevated blood pressure and PCB exposure?

A I am not sure, I don't know.

Q You would agree, of course, that that finding about the levels of DDT in humans in Treana, obviously, complicates the determination of the cause of the elevated blood pressure?

A Yes.

Q Have you yourself reached any opinion with a reasonable degree of medical certainty whether PCB exposure at the levels reported in the Treana, Alabama study leads to elevated blood pressure?

A No.

Q Doctor, you gave some testimony earlier this morning about the process of storage of PCB's in humans, about the circulation of PCB's in the blood of humans and the like, and you also gave some testimony about the uncertainties that exist today, about how PCB's get in the blood and how they get in the blood from the tissues and organs and so forth.

A Yes.

Q Doctor, was it known in the late 1960's that PCB's are stored by humans or is that a more recent development, has our knowledge of the science and the medical implication of this increased enormously since the late 1960's?

A. With respect to the first part of your question, I don't know. With respect to the second part, yes it has increased considerably.

Q. Oh, and when you said the first part of my question what were you referring to?

A. You said was it known that PCB stored in the human tissue in the late 1960's, I think so, but frankly I would have to review the literature and see what the dates are, when that became known.

Q. In other words you don't have a clear recollection of that one way or the other right now?

A. That's correct.

Q. Now, the second part of my question as you referred to in one of your most immediate answers was what, what were you referring to?

A. Has the body of the information and knowledge on PCB and the reactions of PCB in the biological system increased in the last decade or whatever it was and my response was yes, I believe it has.

Q. Would you say that body of knowledge has increased greatly in the last decade?

A. I believe so, yes.

Q. Doctor, can you say with a reasonable degree of medical certainty that any dredging of PCB's from the harbor in Waukegon harbor, will lead to any changes in the biochemical

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THIRTY-FIRST JUDICIAL CIRCUIT
INGHAM COUNTY, MICHIGAN

properties in any fish eater?

A No, I can't say that.

Q So you can't say with a reasonable decree of medical certainty that the dredging of the PCB's in Waukegon harbor will improve if you will the biochemistry of any fish eaters?

A No, I can't say that.

Q You testified last time that Michigan has taken a position in the presence of PCB's in mothers' milk and those are basically the words that you used?

A Yes.

Q What is that?

A That means that the Department of Public Health has issued a statement about that topic with advise.

Q What's the statement the state has issued?

A Basically, that mothers' milk is contaminated with PCB's. The Department has the results of a survey of nursing mothers which establishes a range and means and medians of those, of that contaminent level. And, that experts in the various appropriate technical fields have looked at this information and have considered its meaning, and that they have concluded that this is not sufficient reason for a nursing mother to not breast feed her child.

Q Is that a long way of saying that the advise or what was issued by the state of Michigan is that at the PCB levels presently found in mothers' milk there is no reason not to

breast feed the children?

A Yes, that was the last part of my statement. This is, of course, for general population people.

Q Was there any other specific advisory issued for any other group of people in the state of Michigan?

A No.

Q So it was intended to have general application?

A Yes.

Q How was the advisory pubished?

A As I recall it was probably a news release or something like that. We have an advisory with respect to eating fish which goes on the fishing license and so on and so forth and that tends to be repeated. The others, I think the question of PCB's in mothers' milk have come out, the Department have put together the information and then released the results. It's nothing, you know, the presence of PCB's in mothers' milk is not an 1980 new item, it's been known for some time.

Q Maybe I missed your answer but what was the advisory or lack of advisory issued by the state of Michigan?

A I believe it was March of 1981.

Q Did you participate in the consideration that formed the basis of the statements on mothers' milk issued by the state of Michigan?

A I was present, but I was not a participant in the sense that the panel that was assembled were invited people and I was

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THIRTIETH JUDICIAL CIRCUIT
INGHAM COUNTY, MICHIGAN

present. In fact, it was this room but I was not one of the panelists.

Q Did you participate in the discussion?

A Yes, I did.

Q Did you personally concur with the statement issued by the state of Michigan on the presence of PCB's in mothers' milk and the recommendation that there is no reason that at this time not to breast feed children?

A I concur with that yes.

MS. OLIVER: Do you have a copy of that news release in your file?

THE WITNESS: Yes, I do some place, yes.

MS. OLIVER: Could we be provided with it?

THE WITNESS: Sure. I also furnished you with the fish advisory.

MR. FEATHERSTONE: I think we have seen that.

Q (BY MR. FEATHERSTONE) Doctor, could you briefly tell me who was on this panel that you talked to, that you referred to?

A Yeah, five or six people, I believe pediatrics, from Michigan State University, William Wile, a toxicologist from Wayne State University named Reggie Areno, and there are some other people, I can find that out, they are not at the tip of my

tongue right this second, I believe about five people.

Q Were they all either state of Michigan employees or people who had done work in the state of Michigan?

A I believe none of them were state of Michigan employees but were outside of the state government and were invited because of their expertise in some field.

Q Were there any Public Health officials from any other states involved in this?

A I don't know, I can provide the list and I don't know, I don't think so.

Q Have you done any work Doctor looking at the effects of alcohol consumption on liver enzymes?

A Have I personally done any work?

Q Yes.

A I have not.

Q Have you in the course of your profession reviewed any literature discussing the effect of alcohol consumption on the biochemistry of people?

A I am generally aware of that, I can't say specific pieces of literature but it's germane to our long term PPB study, it would be germane to a fish eater study so, yes, generally I am familiar with that. That there is an association.

Q Well, you tell me what that association is?

A Only in general terms without consulting references I believe it's been reported that there is a correlation between alcohol

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THIRTIETH JUDICIAL CIRCUIT
INGHAM COUNTY, MICHIGAN

consumption and some aberration in enzyme levels.

Q Are these liver enzyme levels?

A As defined as liver function enzymes, and beyond that I can't get specific.

Q Well, do you remember what the daily or weekly intake of alcohol was that was necessary to result in this aberration of liver enzymes?

A No, I do not.

Q How about lipoproteins, the lipoprotein levels in blood, does alcohol consumption affect that?

A I am not sure.

Q Have you heard of something known as the Merrill Palmer Child Study?

A Yes.

Q What's that?

A It's one of the other studies that I referred to this morning in response to a question.

Q Is that the study by Miss Fine?

A Yes.

Q Okay.

A Yes, that's it.

Q Then maybe you've already answered all of the questions I have on that. I take it you don't have any working relationship with that project?

A I personally do not, our laboratory tests, specimens for them,

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and I know those individuals I have been in meetings with them but that is an independent study so I could corroborate in a sense, I would corroborate with any profession of the field.

Q And the work your department formally does for that study is to take samples and analyze them for PCB contents?

A Our department, our laboratory, receives coded samples and runs the tests and reports the results back to them, it's a contract to do some lab testing.

MR. FEATHERSTONE: I don't have anymore questions.

MS. OLIVER: I have none.

MR. WHITE: I have none.

(WHEREUPON, THIS DEPOSITION WAS CONCLUDED.)

STATE OF MICHIGAN)
) ss
COUNTY OF INGHAM)

I, Barbara A. Bostrom, Official Court Reporter, do hereby certify, in and for Ingham County, State of Michigan, that I conducted the examination of Dr. Harold Humphrey, the deponent in the foregoing deposition; that prior to the taking of said deposition, the said Dr. Harold Humphrey was duly sworn to tell the truth, the whole truth and nothing but the truth; that he was carefully examined upon his oath; and his examination was reduced to typewritten form by and under my supervision and the foregoing 121 pages constitute a true record of the testimony given by the aforesaid witness.

I FURTHER CERTIFY that I am not a reliatve, employee, attorney or counsel of any of the parties; a relative or employee or such attorney or counsel, or am financially interested in the transaction.

I FURTHER CERTIFY that on the request of Mr. James White, attorney for Plaintiff, I submitted the record of said deposition to the deponent who examined it and signed it.

IN WITNESS WHEREOF I have hereunto set my hand this 15, day of November, 1981.

Barbara Bostrom
Notary Public,
Ingham County

My Commission Expires:
September 11, 1982

_____
Dr. Harold E. B. Humphrey

FURTHER DEPONENT SAYETH NOT:

_____
Signature of witness

Subscribed and sworn to before me

this ____ day of _____,

_____

Notary Public, _____County

My Commission expres:

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