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it does to you. I am talking about health effects.

MS. PATTON: This is the point I made earlier, many of these people did initially make claims of health effects. We did not have them present testimony on those claims because of the reason you are talking about, the documentation of those claims is very difficult in some cases.

DR. BRICK: Was there any pattern in these claims, health similarities or adverse effects?

MS. PATTON: This is not a part of our hearing record. I will comment to you that in some cases it did come out but it was not part of the planned testimony.

I can give you information from our witnesses but it was not part of the hearing record.

Most of these people experienced a generalized kind of malaise in the sense of vomiting and nausea, headaches. They report flu like symptoms. This is not all of the people but some of them.

It is a pattern that goes with varying parts of that spectrum. I cannot tell you anything more definite than that. In some cases they did have medical documentation but we did not go into that for our hearing.

DR. BRICK: Thank you.

CHAIRMAN SHEPARD: Major Brown?

MAJOR BROWN: Did EPA in its label usage designation require the applicator to apply the pesticide aerially for under certain conditions, mainly, wind conditions?

MS. PATTON: In some cases it is the labels and in some cases it is state legislation. This is one of the things that is very variable across the country.

Many states do have requirements that it be required only when the wind is less than seven miles per hour or five miles per hour, the humidity is below a certain point and the temperature is below a certain point. This is to avoid volatilization drift.

The label has certain restrictions along that line although not as to temperature. The label says "keep out of water," without telling you how you are supposed to keep it out of water.

Oregon is one example of a state that has fairly stringent regulations in the sense that they require buffer strips in certain cases.

Across the country it is quite variable in terms of what the real requirements are.

The EPA labels say "keep out of water" plus a few other things. It does not have itemized prohibitions on use in a broad sense. It does in a narrow sense.

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CHAIRMAN SHEPARD: Dr. Lingeman?

DR. LINGEMAN: Did you say that EPA is not addressing the health effects?

MS. PATTON: We have not presented testimony on it.

DR. LINGEMAN: Is anyone in the country, in any agency systematically keeping track of people who complain of symptoms relating to those incidents?

MS. PATTON: The EPA keeps a file on the claims. There are numerous claims. The problem is with documentation of the claims. For the attorneys and scientists working on the case, this has been one of the most difficult tasks, locating records to document the things people say. In some cases we find them and in some cases we do not.

EPA plus a number of state agencies do in fact keep records of the reports people make to them. In some cases they are investigated and in many more cases, they are not investigated either by EPA or other sources.

I think the reason they do not investigate, when you talk to the people, is partly resources, partly it is not knowing what they will do once they investigate. I think it is that kind of a situation.

I do not want to overstate the case. There are reports that do exist. I would say for the most part

they are uninvestigated.

DR. LINGEMAN: Maybe there should be a national register of complaints filed in a systematic manner similar to the one with the VA's register for veterans.

MS. PATTON: EPA does collect those. It is a matter of the follow-up. That is where the question lies.

CHAIRMAN SHEPARD: What part of EPA is doing that?

MS. PATTON: Mr. James Boland and Mr. Frank DeVito are the persons that I think of being in charge. This is called the PIM system, pesticide incident monitoring system. Other state agencies feed into it.

Some of our case histories are located there. Others we located in the state offices themselves. In not all cases does it reach EPA.

There are a number of institutions that have things in place to deal with it but I am not sure just how coordinated it is.

CHAIRMAN SHEPARD: Dr. Murphy?

DR. MURPHY: You mentioned you did have a presentation regarding epidemiology. You mentioned the Alsea, Swedish and German studies.

Can you comment regarding the status of the

validity of those studies?

MS. PATTON: I would rather not. I am just trying to be judicious. Testimony is yet to come both from EPA and Dow on all of those studies. I think it is inappropriate for me to comment at this time.

DR. MURPHY: We have at various times heard from EPA sources, I think, public and private, that the Alsea study was good, that it was not so good, that it had changes of position.

In a nutshell, how did the presentations come off, equivocal or unequivocal?

MS. PATTON: Just on the Alsea study?

DR. MURPHY: Yes.

MS. PATTON: (Pause.)

DR. MURPHY: That is all right.

MS. PATTON: My silence should not be interpreted to mean anything other than I am an attorney attempting not to make any comment on the case.

DR. MURPHY: Thank you. I might say we are very privileged to have Ms. Patton here. We should make an attempt not to put her on the spot. She is in a very sensitive position.

Dr. Suskind?

DR. SUSKIND: I have one comment and one question. With respect to the Alsea study, those of you

who are not aware of it, there are two reports from Oregon State University which attempts to assess the validity of that study. I would refer you to that study. There are two volumes to wit. It was supported by the NIEHS.

I will not comment on the conclusions of that study. I will leave it to the reader to draw conclusions for him or herself.

The question is about the incidents reported which involved farm animals and which involved wildlife.

Is there any information you can give us about that even though the clinical information is perhaps not really discussable?

MS. PATTON: I am trying to limit myself to the testimony that has been presented as opposed to the other information that we keep receiving.

Because of the documentation problem, we did not present directly any testimony on the farm animal effects, even though the PIM system has such reports.

Attempting to trace them back and get veteranarian confirmation reports, we find it does not exist, not that they investigated and found nothing but for the most part, it was not investigated.

People planned to take the animals they thought had been affected and they did not follow up or they took

them to someone who did not examine them. It is a situation again of very limited follow-up.

The reason the case histories were limited to the residue and pathology information was that was the one place where there was follow-up.

We did have testimony from a witness in Oregon and this is in the hearing record, although it came out on cross examination. It was not a part of her direct testimony. In one of the Oregon forest areas, there had been reports of high incidences of abortion in sheep, I believe, near a spray area in Oregon.

That was undocumented. It was a sheep population that prior to spraying had given birth to so many offspring on a regular basis for a number of years and then in a certain year following spraying, there were 13 abortions which was very unusual to these farmers.

We know nothing more about it than that. It came out on cross examination. It was not something we had asked the witness to testify about on her direct testimony.

I cannot tell you anything more than that. There are many reports. The PIM system has them. Our rebuttal files have them, but they have not been investigated.

DR. SUSKIND: Are there any reports on effects on wildlife, on birds, forest mammals? When DDT was studied thoroughly or not so thoroughly, one of the obvious effects was on avian species and on other wildlife.

MS. PATTON: I am not aware of any studies in that area besides the studies of Dr. Young at the Egland Air Force Base. His studies, according to his testimony, indicate there are no such effects. This is his testimony. How this will be presented down the line, I cannot comment on at this time.

Let me back up on one point on your question about the Alsea study. Is it correct that NIEHS did support the Oregon State study?

DR. ROGAN: There is money for an administrative study and ad hoc studies, things like that being appropriated that do not require a separate grant. Whether or not those studies were funded out of that area, I do not know.

I do not know of a specific grant put in to do those analyses of Alsea I and Alsea II. I think the time span was too short. If it was funded by NIEHS, it was done so on that basis.

MS. PATTON: I was just trying to clarify that in terms of your record. That was the first time I had

heard NIEHS had sponsored it.

Anyone is welcome to the testimony of our witnesses. The transcripts are available. If anyone wants to review the cross examination of our witnesses, they are perfectly free to do so. I would be glad to send you transcripts.

I just did not want to comment on my own views of how that went. I will be pleased to send transcripts so you can make your own judgments. We can send you both the written testimony and the cross examination if you wish.

CHAIRMAN SHEPARD: Thank you. Dr. Brick?

DR. BRICK: As a general question and this has nothing to do with your case, since you are an attorney, there must have been some legal cases that have been brought against the sprayer, et cetera, by civilians who allege certain health effects.

Where can you get such information? Are you aware of any such cases? How would you become aware of any such cases?

MS. PATTON: There are cases pending now. Some people we considered to have as witnesses we decided against having as witnesses precisely because they had cases pending on this very question and we felt it might be an interference one way or the other.

I am not aware of any cases that have been decided at this point. I am not sure that many of them are actually underway. There are a number of them in the court that are very active right now.

DR. BRICK: Mr. Chairman, you might ask that question of the General Counsel. I think it is worthwhile to follow this up with reference to what Dr. Lingeman pointed out, some sort of a register on civilians who allege effects from dioxin, health effects.

CHAIRMAN SHEPARD: That is a good point, Dr. Brick. I have made a note of that.

I think maybe when Dr. Honchar speaks about the dioxin registry which I am very much looking forward to, we can address some of that to her. It may well be in the process of the dioxin registry, there is such an effort ongoing.

Dr. Gross, did you have anything more you wanted to add?

DR. GROSS: No, Mr. Chairman.

CHAIRMAN SHEPARD: Are there any other questions for Ms. Patton?

(No response.)

CHAIRMAN SHEPARD: We really appreciate your participation. Thank you for being here and bringing us up to date. I think it is an area we are all very

interested in and we will be following closely.

MS. PATTON: Thank you.

CHAIRMAN SHEPARD: I would like to remind our guests that there will be an opportunity to ask questions at the close of the formal agenda. I would encourage you to write your questions down. Mrs. Williams will assist you in that process. She has cards and writing materials in the back of the room.

I understand some of you have not yet registered. It is very helpful to us for all of you to register. If you have not done so, please do so at any point convenient to you.

I would like to deviate from the agenda slightly. I want very much for Mr. Cleland to be here for certain portions of the agenda but he is not due to arrive for another few minutes.

I would like to turn the floor over to Dr. Suskind and ask him to discuss two areas or to lead the discussion in two areas.

As you all know, Dr. Raymond Suskind has been following a number of the industrial exposures. We would like to have him bring us up to date as to his efforts in that area. If time permits, we would like him to lead a discussion on the foreign articles that have been alluded to so often.

Dr. Suskind?

REPORT ON FOLLOW-UP ON INDUSTRIAL EXPOSURE DATA AND DISCUSSION ON SWEDISH AND WEST GERMAN STUDIES - BY DR. RAYMOND SUSKIND

DR. SUSKIND: Thank you very much.

I have been asked to start the discussion of the current status of industrially exposed workers in the United States and also to introduce the discussion on the studies in Sweden which I think most of the Panel has reviewed or most of the Committee has reviewed, and the West German report.

Insofar as the work going on in the United States, I am aware of four studies relating to the two populations. One, the population exposed in the Monsanto plant in Nitro, West Virginia. The initiation of that exposure was in 1948. The first evidence of any health effects emerged from a run away reaction which occurred in March of 1949.

The population in that plant was exposed to a process making 2,4,5-T from 1948 until 1969.

A mortality analysis of workers who were exposed to the run away reaction, the TCP run away reaction, TCP is an intermediate in the manufacture of 2,4,5-T, was completed and published. I think the Panel has already discussed that at the last meeting.

A mortality analysis of workers in the same

plant, not only those exposed to the run away reaction which totaled 122 and probably the most heavily exposed to TCP and its contaminants from the kettle which was involved, very similar to the Seveso episode.

The workers who were exposed from 1955 on to the manufacture of 2,4,5-T, that probably will include about 400 total employees. A mortality analysis is being completed on that group.

In addition, 435 workers divided up into three different cohorts were examined late last year by a clinical epidemiologic study, hands on examination and the three cohorts consisted of persons with a record of adverse reactions, of chloracne and other symptoms, other clinical findings, who were exposed to the process, and an equal number or almost equal number of persons without record of adverse effects who were exposed to the process and then a control group of workers in the same plant who were not exposed to the 2,4,5-T process.

The analysis of that data is in process and we should have a preliminary report within the next couple of months.

In addition to that population, there is a study of workers in a plant which made pentachlorophenol from the 1940's up until 1978 in Sauget, Illinois. In that same plant, workers who were exposed to

pentachlorophenol were also exposed to ortho and parachlorophenol. An examination was done last October. The data from that study is just about completed and an analysis should be out very shortly.

I do know the Dow group is continuing to analyze the clinical information that it has accumulated over the years of two populations that were exposed to the manufacture of 2,4,5-T.

The first report about that first group was published in the January issue of the Journal of Occupational Medicine.

They are still gathering data on the second group. I have no idea when that information will be published.

Dr. Selikoff did an examination of the Nitro group but examined active workers rather than a group of cohorts which involved retirees as well as active workers.

There may be others going on that I am not aware of.

Perhaps we should pause and see if there is discussion of groups in the continental United States.

CHAIRMAN SHEPARD: Are there any questions for Dr. Suskind or any points of discussion?

Dr. Kearney?

DR. KEARNEY: Dr. Suskind, do you know the status of the study at Jackson, Arkansas that is underway?

DR. SUSKIND: Jacksonville. The data is being analyzed. This is the Vertec plant which made 2,4,5-T. Dr. Selikoff did a study, a hands-on examination, and did get some environmental information as well. I do not think that has been published yet.

DR. KEARNEY: We have heard much about these studies. Do you have any idea of a timeframe in which we will hear case by case the results of these investigations?

DR. SUSKIND: As you well know, computerized information which is programmed, sometimes it is not easy to predict when the analysis is going to be available. We thought for the Nitro study, that we would have had this information before now. Unfortunately, we have to compete for computer time and computer space and epidemiologic and statistical resources with the rest of our institutions.

I would assume with respect to the clinical epidemiologic results in the Nitro group, we should have a preliminary report in the next few months.

DR. HONCHAR: Dr. Suskind, I have a few questions of a design nature with regard to some of the studies you mentioned.

With respect to the mortality analysis of the Nitro population, you mentioned 2,4,5-T was being synthesized there starting in 1948 but you were looking at the mortality experience of people exposed since 1955.

DR. SUSKIND: The employment statistics apparently are not as accurate as they might be for the period from 1948 to 1955.

It would be more important to have the population -- we originally started out with that idea that we were going to take the whole population from 1948 on.

The number of records apparently that were missing, employment records, were such that the epidemiology group felt it would be better to take the group from 1955 on. That does not include the group exposed to the run away reaction.

DR. HONCHAR: If I could ask you about the control for that study. Can you easily summarize what their exposures might have been? You said they were from the same plant.

DR. SUSKIND: The plant manufactured 2,4,5-T incidental to its major manufacturing objectives, and that was to manufacture rubber additives. The plant originally back in the 1920's was solely devoted to the manufacture of rubber additives.

There are any number of compounds to which people might have been exposed to which also were toxic.

The group that was exposed from 1950 on some of them were exposed to paraminobiphenyl. There was a small epidemic of bladder cancer.

Some of the workers in that 1955 to 1968 group were also exposed to paraminobiphenyl and they developed bladder cancers and they are still being monitored for bladder cancer.

The population, the control population, is not necessarily one which is exposed to non-toxic materials. They also have been exposed to toxic materials.

I think this is a very important consideration. I think in the Swedish studies we have a difficult time knowing what else these people were really exposed to in the case control studies.

CHAIRMAN SHEPARD: Good morning, Mr. Cleland. We are most pleased that you could take time from your busy schedule to be with us this morning.

MR. CLELAND: Thank you very much. Good morning, all.

COMMENTS FROM THE ADMINISTRATOR OF VETERANS AFFAIRS

MR. CLELAND: You might have heard, but I would like to bring to your attention a study just released by the National Toxicology Program in regard to

200 male mice who were examined and their offspring failed to indicate that heavy exposure to simulated Agent Orange resulted in a loss of fertility or an abnormal number of offspring with birth defects.

Apparently the test examines some 3,000 near term fetuses and 2,000 live offspring.

According to Dr. James Lamb of the National Toxicology Program, and I quote, "We failed to get any indication of a significant increase in birth defects or decreased fertility."

Also quoting from Dr. Lamb, "These data therefore do not support the presumption that Agent Orange is responsible for former Vietnam veterans fathering children with an unusual number of birth defects nor for the veterans experiencing a loss of fertility."

What I would like for the Committee to do, if you will, is look at this report and get back to me in a month through Dr. Shepard.

This is one of the reasons I am glad we have an advisory committee to take a look at these reports as they come in. I would like for you to do that and get back to me in one month through Dr. Shepard.

Secondly, I would like to acknowledge the participation of veteran groups in this advisory group

and also that I understand the American Legion is going to be surveying its members to evaluate their evaluation of the VA and how we are handling Agent Orange, how we are examining veterans who claim Agent Orange exposure, in other words, our whole response to the issue.

Dr. Brick, I would say, we would be most interested in the results of the American Legion's study.

That is all I have at this time, Barclay.

CHAIRMAN SHEPARD: Thank you very much.

I think each member of the Committee has a copy of the study Mr. Cleland has referred to; we will be speaking about it more and we will look forward to your comments.

DR. HONCHAR: Dr. Shepard, may I continue with my last question?

CHAIRMAN SHEPARD: Surely.

DR. HONCHAR: With regard to both the Nitro and the Sauget cross sectional medical surveys you are conducting or have been conducting or are now analyzing, would it be possible for you to briefly summarize what some of the end points are that you are looking at?

DR. SUSKIND: With respect to the Nitro study, the end points are numerous. With respect to the Sauget study, it was really a very limited study and had

to do with the clinical examination of the dermalogical effects, the effects of the pentachlorophenol exposure alone or a mixture of pentachlorophenol exposure with the ortho and parachlorophenol.

There were just a very few people who were just exposed to ortho and parachlorophenol.

We were largely looking at the dermalogical effects by examination. We did have an opportunity to do a large number of laboratory studies which would indicate abnormal effects, adverse effects, if they could be related to the exposure or the degree of exposure to any of the two processes.

In the case of pentachlorophenol exposure, it ended in 1978. The ortho and parachlorophenol exposure is still continuing.

The small number of ortho and parachlorophenol exposures showed no chloracne.

It is difficult to say at this point that the pentachlorophenol exposure in combination with the ortho and parachlorophenol exposures produced any more severe effects or a larger number of effects than did the pentachlorophenol exposure.

The end points in the Sauget study largely are dermalogic manifestations as well as the laboratory abnormalities which may be found in relation to the

exposure.

Of course, in any study, the interview which includes family history and previous medical history and reproductive history and history of effects on other organ systems besides the skin, in the Sauget study, the medical records were very good. We could, for example, if there was an interview history of hypertension or cardiovascular disease, we could confirm it by medical records rather easily.

It was very interesting to us to find out and to discover how accurate the interview histories were in comparison to the records. The plant had a rather substantial medical insurance program for the whole family of the workers. All of that was reported and we had access to that.

Insofar as the end points for the Nitro program, if we have time I can show you a couple of slides of the many end points. They include reproductive, any increased risk for reproductive abnormalities, cardiovascular abnormalities, neurologic and behavioral abnormalities.

Some of this is very difficult to do in a relatively short examination. Each of these examinations took four hours. We were there for a couple of weeks.

The individuals were examined with an

interview plus the laboratory work and the hands on examination with pulmonary function, nerve velocity and ECGs and so on, which took about four hours.

The end points were those things we are concerned about as to increased risk which emerges from previous findings in the literature as well as animal experiment findings, increased risk for cancer, increased risk for hypertension, cardiovascular and coronary disease.

The things we were looking for were rather numerous and we felt that is the way it should be.

The program for this came essentially out of a meeting at the IARC in January of 1978 in Lyon. It was there the group discussed a common protocol to be used by four studies of industrially exposed groups that needed to be followed in order to determine what the long term effects were.

We essentially carried out the protocol which was discussed in Lyon in 1978.

DR. HONCHAR: Thank you very much.

MR. DeYOUNG: Dr. Suskind, who is sponsoring and funding this research? Is this a Federal program?

DR. SUSKIND: We as a Department are largely supported by the NIH, by the Federal Government. We have a center and the faculty of this center are largely supported by Federal funds. To carry out a large study

like this, we needed additional support, and the support after a little convincing came from the industry itself. That is to carry out the hands on examination and the travel. It was a very large group and it required a substantial amount of support.

Our center grant could not possibly support that kind of study. We did get support from the Monsanto Company for it.

The design of that protocol, every aspect of that study is of University of Cincinnati origin.

MR. DeYOUNG: Thank you.

CHAIRMAN SHEPARD: Are there any further questions on the continental U.S.?

DR. KINNARD: Dr. Suskind, I did not get the control group figure referred to for the Nitro, West Virginia study.

DR. SUSKIND: The control group was the group that was unexposed, never exposed to the 2,4,5-T process. They were exposed to other things but not to the 2,4,5-T process.

DR. KINNARD: How carefully were those controls matched with the experimentals? They were matched with what characteristics?

DR. SUSKIND: The matching was a very difficult thing to do in that instance because the control group

was composed largely of active workers and a few retirees. The people who were exposed went back to the 1940's and many of those retired or many of those left the company.

The exposed group is to some degree an older group that we have no way to avoid, if we wanted to have our control group from the company itself.

DR. HONCHAR: I assume you will also compare the exposed to an age-sex adjusted rates?

DR. SUSKIND: Yes.

DR. HONCHAR: Thank you.

CHAIRMAN SHEPARD: Dr. Suskind, I wonder if you would be willing to talk about some of the extra U.S. studies that are going on, for example, Sebaso? Are you prepared to say anything about the progress of that study?

DR. SUSKIND: Perhaps a little. I think those of us who were involved very recently in the National Academy of Sciences meeting with the Seveso group found there was some new information but not very remarkable.

There were suggestions of reproductive problems but only suggestions. There was no doubt there was chloracne in the children who were originally exposed to the effluents from that accident. There were many more cases especially children who went back to the homes

and zone which had been declared off limits. This zone had still to be cleaned up. I think Dr. Murphy knows more about this than I do. Perhaps he would like to comment.

The delay in the emergence of chloracne was simply because there was a delay in exposure of those children to the material which was still around in Zone A, I gather.

Perhaps Sheldon might comment on the new information.

DR. MURPHY: I think there was as you said suggestions of possible neurologic or neuromuscular effects in some of the exposed population but again this was not strikingly serious. It was determined more from physiological electromonographing studies.

As I recall it was a very preliminary report.

CHAIRMAN SHEPARD: Is the Seveso study using the same protocol?

DR. SUSKIND: No, they are not using the same protocol, not to my knowledge. They are wide ranging in their efforts. The reproductive follow-up is being done by one group and the communicable disease follow-up is being done by another group. The neurobehavioral follow-up is being done by another group. Coordination I gather is a problem there as well.

They have had their problems and they are not scientific.

MR. DeYOUNG: Dr. Suskind, I would like to hear a little more about the data or the observations that went into the conclusion that there is suggestions of reproductive problems. Can you be more specific?

DR. SUSKIND: I am sorry. If I had known we were going to discuss Seveso, I would have brought along some of this information.

There is a rather good review of the Seveso data by Bo Homestead in the International Archives of Toxicology. It is called "Prologamena to Seveso." It is a review of all the information the Italian workers have so far accumulated in relationship to other incidents like the Nitro incident and the West German incident and the Phillips dun Far incident and the one at Colite in England.

Since we have a charge to discuss the Swedish papers, I think we ought to do that. They are very interesting.

CHAIRMAN SHEPARD: Please go ahead.

DR. SUSKIND: There are really four papers from Sweden and one from Germany. The first one is a follow-up by Olif Axelson on the 348 railroad workers. This is a straight forward epidemiologic study. The

follow-up is what happened since they were last reviewed in 1973, I believe.

This is a group that was exposed between 1957 and 1972 to three amino 124 triazol and to several of the phenoxy acids.

I think you can take the information at face value but I think you have to be careful about interpretation because of the small number of tumors in each category, whether they are lung tumors or stomach tumors. There are usually one or two in the exposed group.

The total number of deaths was lower than expected and this is regarded as the healthy worker effect. I am not sure that concept applies to all types of industrial populations. I am not even sure it applies to this.

The comment is made by Dr. Axelson that this lower death rate is probably due to the healthy worker effect.

The total number of tumor deaths at an SMR of 1.4, 17 vs. 11.85.

Those who were exposed to the three amino triazol had as I recall two lung tumors but no stomach tumors. Those exposed to phenoxy acids alone had one stomach tumor and no lung tumors. In those who were

exposed to both, there was one stomach tumor and one lung tumor. What do you do with data like that? Can you conclude if you relate that one tumor to what is expected and the expected is 0.32, you get an SMR of 3.1. Is that significant?

I think there is a suggestion of some relationship. I would hate to say this is conclusive based on the minimal numbers of tumors in any category.

If you look at the total number of tumors that is what did these people have, they had any tumor you could think of. The interest was focused on the stomach and lung but there were an enormous number of other kinds of tumors.

You could not relate the exposure to any specific type of tumor and that is another problem.

I think you have to take it at face value. Among these railroad workers there were 17 that died of cancer and there was no indication that there was any higher risk for one type of cancer then there was for another.

Perhaps others would like to comment. Dr. Gross?

DR. GROSS: Was there any attempt made to combine tumors at different sites and look at combinations of tumors and different organ systems?

DR. SUSKIND: You mean combinations of tumors

or combinations of exposures?

DR. GROSS: Combination of tumors at different sites, tumors that may be related.

DR. SUSKIND: I do not think so.

DR. GROSS: One problem is that if the diagnosis is made in sufficient specific detail, any kind of tumor would be unlike any other kind of tumor. There are certain natural relationships, pathological, and one can think of tumors of the lymphoreticular system as a group rather than specific.

One can talk about tumors of the gastrine intestinal system as a whole.

You speak of a great spectrum of tumors in this population. The question is what attempt was made to group these tumors into some logical classification.

DR. SUSKIND: I do not think there was. As I read it, they have a laundry list of tumors in relationship to what was regarded as a specific exposure or mixed exposure.

The other problem with this study and I will have to tell you Dr. Axelson is a good friend of ours and he visited with us and asked us to comment on this and these are railroad workers from all over Sweden just like any other working group.

They may have different life styles than other

workers. There is no indication here that they did any thorough histories of use of cigarettes, alcohol, and I gather if they are like other people in that country, there is a substantial use of alcohol. Many of them still smoke.

Whether or not this group smoked more heavily than the expected group, I do not know.

Those factors are treated rather casually. There was a statement "The railroad workers smoke, the frequency of smoking is about the same or the same as the rest of the Swedish population." I think no attempt was made to really determine whether that was so or whether these people had any family histories of cancer which were different from the rest of the population.

None of that is in this information.

CHAIRMAN SHEPARD: The Committee has had the opportunity to review these studies. I wonder if any other members of the Committee would like to comment on the studies.

Dr. Murphy?

DR. MURPHY: I am not an epidemiologist. I was concerned also about the few numbers of tumors here and there were three stomach cancer tumors and not one.

Depending on which time you look at it, if you look at it in ten years induction latency period,

they were only looking at two, in connection strictly with the phenoxy acids.

Giving risk ratios, again, depending on whether you look at it for the total group and in this case you have 3.3 which does not seem so high to 7.7 dealing with these very small numbers.

As I understand these articles, very nearly the same risk ratios came out whether they looked at counties in northern Sweden, southern Sweden and then in one other study which I do not recall what the workers were. They were not railroad workers.

I quite frankly being a non-epidemiologist was quite struck by these things. I was concerned about this.

DR. SUSKIND: Are you talking about the case control studies or the railroad workers?

DR. MURPHY: I may be mixing apples and oranges here.

DR. SUSKIND: I am talking about one study. I think the case control studies have to be discussed differently.

DR. MURPHY: I am grouping the studies.

DR. SUSKIND: I think we ought to stick with the railroad workers study just like I stuck to the Nitro study. I think there what they did I thought was the best

they could probably do under the circumstances.

How much information they were able to get bears on the numbers of tumors is what I am concerned about. Here, too, in that railroad worker group, there was one lung tumor in the amitro group and two lung tumors in the phenoxy herbicide group, two stomach tumors.

In the combined group there was another stomach tumor.

DR. KEARNEY: Mr. Chairman, I know you probably want to get on. I would like to ask one question.

These studies have been discussed all throughout Government as you know, up and down every committee that is doing something on this issue has discussed these reports. It was discussed in the White House Interagency.

Could you give us a simple summary of what these studies tell us? The reason you were asked to assist us in the Advisory Committee is we did not have an epidemiologist on the Panel.

DR. SUSKIND: You still do not.

DR. KEARNEY: Maybe this is the closest we are going to get.

Could you give us a simple summary of what this tells us? What is the validity of this data in

helping us make judgments about the effect of phenoxies on cancer?

DR. SUSKIND: Are you talking about the railroad workers study or all four papers? I assume you are talking about all four papers.

DR. KEARNEY: Yes.

DR. SUSKIND: I think that is why we are discussing it. Is this a red flag and whether or not you have great confidence or less than that in the case control method which is a very interesting method. Some epidemiologists think it is the greatest thing since the wheel. Others feel it only provides association but not causation.

Even if it provides association, as I think the Hardell and Sandstrem studies do and the Eriksson studies do, we should be alerted. I think that is their importance.

In this country we have not conducted case control studies with respect to tumors and as they are related to exposure to phenoxy herbicides and maybe we should.

It may be a little easier to do in Sweden because it is a small country and they have a national registry which provides them with their controls. It is easy to match the tumor cases with the controls because

of the registry. It would not be so very easy in the United States. It would depend on the state.

DR. LINGEMAN: It could be done through the AFIP. We will be talking about this later. The AFIP have a large number of tumors of types that are pathologically confirmed.

DR. SUSKIND: These are mostly from the cases that have died largely.

DR. BRICK: I am aware of the small number of tumors. How does this compare with the Swedish incidence of cancer of the stomach or these other cancers throughout the Swedish population?

We know that in Sweden, cancer of the stomach is more common than it is in this country. Does this mean that this group of railroad workers had an incidence higher than the average population whatever their population?

DR. SUSKIND: Dr. Brick, in this group of 348 railroad workers, those who were exposed to phenoxy herbicides alone, there was one cancer of the stomach and the expected rate is 0.32. SMR is 3.1.

Can you make a decision on the basis of one case? That is what I am getting at.

I think it is still something that suggests

association and it should be followed up. The studies that really suggest association are the case control studies with respect to soft tissue sarcomas and lymphomas, both Hodgkin's and non-Hodgkin's lymphomas.

It is suggested. I think you need what else these people were exposed to. We have a problem of getting to know how much they were exposed to, the phenoxy herbicides or chlorophenols, how they were exposed and what else they were exposed to.

That is not available except descriptively but not quantitatively.

I still think with these four studies on hand, that we have the responsibility of conducting similar studies within the United States. We are certainly concerned about the association and whether or not we believe the case control method is good or not. I happen to think it is an excellent way of studying problems as they may be associated with factors, environmental factors, metabolic factors, whatever.

DR. SHEPARD: I wonder if I could ask Dr. Rogan to comment? He has reviewed these articles and has been involved in the Scientific Panel of the Interagency Work Group.

Dr. Rogan, do you have any additional observations you would like to make? Do you know of any

similar studies that could be used for a basic comparison to these studies?

DR. ROGAN: When we are talking about the railroad study we are talking about what is called a follow-up study that can be done in real time where you identify a group of people and follow them forward over years to see what happens to them, or it can be done in paper time where you identify a cohort of records starting at some time in the past and look now at causes of death.

This is a sort of mixture of those. Three hundred and forty-eight (348) people in such a study is a rather small number. The historic Dow and Hill study of smoking and lung cancer with 34,000 British physicians was controversial.

I think Dr. Suskind is right. A cohort study of mortality is a rare event on 348 people and it constitutes essentially a clinical observation.

Stomach cancer goes along with some of the anhydrousis syndromes and thus is familial and that should really be addressed in a study of stomach cancer and was not in this.

We have a clinical hint that something might be going on with stomach cancer in terms of chemical exposure or that families tend to work in railroad

workers union or tend to take the same jobs and those same families are the ones that get stomach cancer.

The reason for the doubts about case control methodology without getting at all technical is simply that you must ascertain exposure after the illness of interest has occurred, thus instead of identifying a population of people and following them forward in time, you identify a set of cases and inquire among them what their exposures historically might have been.

If there is a link in the minds of the cases that such exposures might have been bad for them, they may remember and thus report to you selectively that such exposure did take place with a greater frequency then controls who do not have the particular illness in question and thus may not be pressed to remember.

The enormous strength of control case studies is you can take relatively rare diseases and gather a great deal of information about them in a relatively short time at relatively little expense. For some of the major human carcinogens, that is the best role. For instance, the first major clue that something was going on came from case control studies.

The remaining problem with the three case control studies is they are essentially all from the same group. If there is some kind of bias it is not

obvious from the reports that exist and the instruments used by that group such that it selectively gathers information from cases on exposure to these agents and then we are stuck because we do not have external validation, that is, a validation of the same exposure history in the hands of another group.

Dr. Suskind mentioned other factors that might go along with these sorts of tumors and thus might compound the relationship, that is some other factor that you did not ask about that is in fact responsible.

There are to my knowledge no other strong factors for mycetoma tumors and the only factor I am aware of for Hodgkin's and non-Hodgkin's lymphoma is dilantin and that is kind of suspect. Presumably one could ask about dilantin.

Other exposures do not seem to me all that relevant in terms of a relative risk of six or seven. It is hard to build that into a study. You can do it but it is hard to build a bias into a study that gives you a six or a seven.

In this case what the six or seven would be is the cases report exposure about six times more frequently than the controls and through some statistical method that comes out to an odds ratio, relative risk sort of number.

I am left with three studies from a group essentially, although the authors change, using the same instrument presumably which is unvaluable from the papers which may or may not have something in it that leads automatically to that conclusion.

One wonders, for instance, how many other tumor types they tried and did not report on.

The follow-up study which is to be essentially a clinical observation because it is so small for a follow-up study, there might be something there.

I agree with Dr. Suskind that it calls for, as did DES, as did smoking and lung cancer, as did any other occupational and environmental carcinogen, independent observations in a different population, using a different instrument in the hands of other investigators.

CHAIRMAN SHEPARD: Thank you.

DR. SUSKIND: Dr. Rogan, when you say the same group, you are talking about Sweden?

DR. ROGAN: Yes.

DR. SUSKIND: Except they were populations from different hospitals. The soft tissue tumors were different people and different people from a different area of the country. We do not know about their mobility so we have no idea how long they lived or worked

in the southern counties in Sweden as compared to the central or north central province.

You are concerned that it was only done with a Swedish population. Is that correct?

DR. ROGAN: I am concerned that it was done by the same investigators. I think you have to evaluate for possible bias introduced by the investigators, certainly unconsciously, not purposely. You would like to be able to evaluate the validity of their observations from studies in different populations done by different investigators.

CHAIRMAN SHEPARD: Ms. Patton has just handed me a note of interest. Dr. Hardell, the principal investigator of the Swedish case control studies will be testifying before the EPA on September 8th and 9th. She thinks that is a pretty firm schedule but it may change.

I think it will be interesting to see what Dr. Hardell has to say.

Dr. Axelson, as many of you know, has already testified.

MR. DeYOUNG: This is new information in a sense. We finally have a scientific study speaking from a layman's point of view which if it is not conclusive proof that we have heard so much about, at least it is some association between certain cancers and exposure to

phenoxies.

Let me pose an extreme case in the hopes objections to the extreme case, if any, will yield some light on what we still have to determine.

The extreme case I would propose is we go on record as combining two factors, the association found in these Swedish studies with the mandate the VA currently has and has always had, to find reasonable doubt in favor of the veteran and that we recommend at this point for certain cancers that have been studied and associated, the VA would have an automatic finding of service connection for a Vietnam veteran for those carcinomas.

If something is wrong with that, what is wrong with it?

DR. SUSKIND: What you are now saying is there is more than association. It is causal. I do not think anybody here is prepared to say that.

DR. BRICK: What about reasonable doubt? Are you aware of what adjudication the Veterans Administration is?

CHAIRMAN SHEPARD: I understand it is horrendous.

DR. BRICK: We are talking about the veteran's point of view, reasonable doubt. Would this

association lend itself to credence if you say this is reasonable doubt, that such an association existed and the veteran was exposed in Vietnam and now has cancer of the stomach?

DR. SUSKIND: Judging from the data from Sweden, whether it is the railroad workers data or the case control studies, you could not even go to the point where you could say there is a reasonable doubt.

DR. GROSS: Would it not be true to say that no epidemiologic study no matter how good can ever establish an cause and effect relationship, it is always association, is it not?

DR. SUSKIND: Not really. I think cigarette smoking and DES, you have both epidemiologic evidence as well as additional toxicologic evidence.

DR. GROSS: Does toxicologic evidence establish a cause and effect relationship?

DR. SUSKIND: In the model system you use, certainly.

DR. HONCHAR: I think there is an important point to be made which is despite the strong evidence associating cigarette smoking and lung cancer, we cannot then take the next step and say based on that information that all cases of lung cancer in a smoker are caused by cigarette smoke.

DR. SUSKIND: Because there are non-smoking lung cancers.

DR. HONCHAR: Yes.

DR. SUSKIND: We are not considering the side stream exposure.

CHAIRMAN SHEPARD: At the risk of interrupting important discussion, I think we are going to have to move along and cover some other areas that I think are very important.

DR. MURPHY: The issue of lung cancer was just brought up. What would be a reasonable doubt situation there? Would you conclude someone with a history of smoking, let's assume smoking was a service connected activity, would you assume there was reasonable doubt in a case like that?

DR. BRICK: It would be allowed. You would not have to use reasonable doubt. I think the evidence on tobacco smoking and lung cancer is the guy who smokes for 30 years, three packs a day and he gets lung cancer, who around this table is going to dispute the lung cancer even without reasonable doubt may well have been related to smoking?

DR. MURPHY: Even in the Swedish studies regardless of how weak that evidence is or how strong you may consider it, there are limitations to that in

that they do have requirements for duration of exposure to be included as an exposure group. Am I correct?

DR. ROGAN: Yes.

DR. MURPHY: The latency period between the time of first exposure and appearance and when the analysis is done is another consideration.

CHAIRMAN SHEPARD: Let's go to the discussion on veteran attitudes. Dr. Brick?

REPORT ON VETERANS ATTITUDES BY DR. BRICK

DR. BRICK: The American Legion is trying to conduct among its members, 2.5 million of them, a study as to how they perceive the Veterans Administration with reference to Agent Orange. There has been wide interest among veterans because of the adjudication problems that have arisen.

There is a lot of emotionalism about this subject as all of us in this work know.

There is a bill before Congress. I think it is before Senator Cranston's Committee. It would take the burden of proof of exposure to Agent Orange off the back of the veteran. Under the present circumstances, the Adjudication Boards, Rating Boards, are wanting to have some proof that the specific veteran was exposed to Agent Orange.

That proof is not easy to get. All of you know

the problem with paperwork in the Government and trying to get it out of the Defense Department and some of that they do not have. They do not have the data, they do not have the documentation.

This bill would say that a veteran who has been in Vietnam, if he comes up with some complaint, some disease, then it has to be adjudicated on the question of whether this disease might be related to the exposure with resolution of reasonable doubt in favor of the veteran.

We are going to come up with that resolution of reasonable doubt. I am sure the epidemiologists do not like that phrase particularly because it could be interpreted in many ways.

The American Legion is dedicated to get the best scientific evidence we can with reference to the problems just as the Veterans Administration is.

I think the fact that in this Advisory Committee there are the group of diverse talents that we have seen here this morning discussing these scientific matters in a very unbiased fashion indicates that the Veterans Administration is doing as much as it can.

Some of the testimony given before this Subcommittee in the Senate was by a Dr. Epstein whom I do not personally know.

CHAIRMAN SHEPARD: Excuse me, Dr. Brick. It was the House Veterans Affairs Committee. The hearings were held on July 22nd.

DR. BRICK: Yes. Dr. Epstein reviewed these studies. He came out with the same problems all of you have as to the statistical validity of these studies.

He pointed as you did, Dr. Suskind, that there apparently is an association. He had lung cancer which was not played up very much but stomach cancer particularly and also testicular tumors which has not been mentioned here and soft tissue sarcomas.

One of our members just asked should not certain diseases be given service connection by presumption such as soft tissue sarcomas.

I do not think there would be any argument about that because this is a rare tumor. Hodgkin's and non-Hodgkin's lymphoma is a different ballgame. I do not know what the data is on that. I would leave that to the people in the field to decide whether there is enough data with reference to this.

I think I referred a case to you not too long ago, Dr. Shepard, which is being adjudicated before the Board of Veterans Appeals on one of these non-Hodgkin's lymphomas and the allegation that this Vietnam veteran was exposed to Agent Orange and is there a causal

relationship again with resolution of reasonable doubt.

The adjudication people in the Veterans Administration are very aware of the mandate they have been given by Congress to give reasonable doubt to the veteran.

Again we come back to these associations and unless the Veterans Administration does something positive and it is going to be Congress that is going to do it in a bill that is proposed on the hill, I think the veterans in general are not going to be very happy with the outcome of the work of this committee.

At the last meeting, Mr. Chairman, I wondered and I again wonder whether this is the proper body to make such judgments. What is going to happen knowing the attitudes of the veterans is that if the Veterans Administration finds and Max Cleland just told us about this report that was in the Saturday edition of the Washington Post that there was no relationship in these animal studies between exposure and birth defects, the Veterans Administration comes out with a negative report which may be the case scientifically.

Many of the veterans are going to say, there is a conflict of interest. The Veterans Administration is deciding that, let's have an impartial body decide it.

I suggested the National Institute of Medicine

of the National Academy of Sciences as the appropriate governmental agency to make a decision. I think it would be accepted more readily by the scientific community and I also think it would be more readily accepted by the veterans.

We have this Advisory Committee. We are going to have to face up to the problem in this Advisory Committee of coming out and saying we should give service connection to individuals with let's say soft tissue sarcomas.

Dr. Epstein in his testimony also pointed out that some of the individuals exposed did not have chloracne. Chloracne has been used as the synacronon of diagnosis of exposure to Agent Orange.

He pointed out that there is a multi-system disease with a good many symptoms, nausea, vomiting, weakness, fatigue, et cetera, that many of these individuals exposed had and that we do not know all of the chronic effects of this problem.

From a strictly scientific point of view, it might be of great interest twenty years from now when the Vietnam age group gets up into the 50's and 60's to see whether the incidence of cancer of the stomach, for instance, which is a declining disease in this country at the present time, shows a marked increase in that

group. That is going to be twenty or thirty years away and that is not going to help the problem that the Veterans Administration has now in adjudication.

I think we all have to keep in mind this problem of adjudication when we try to make judgments about the association of exposure to Agent Orange and the diseases the veterans present to the Veterans Administration.

Thank you.

CHAIRMAN SHEPARD: Thank you very much, Dr. Brick.

I think one of the problems, and I was there for the testimony, that the process that has been used in adjudicating claims would not apply in its present form to a rather vague disease entity, such as this multi-system disease or a broad group of illnesses.

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I think it is a nebulous task to make these associations. I think we must somehow address the issue or separate the issue of cause and effect relationship between Agent Orange and any disease, complex or system, from service connection.

As I understand it, the VA does not require any kind of a demostration of cause and effect. It is simply some establishment of disease arising from military service regardless of cause.

I would like to hear Ron speak about some of the perceptions of Vietnam veterans regarding the progress of our registry.

DR. GROSS: If I may follow-up on something, I was very much impressed by the question and I was impressed by the NDP report.

I do not know if Dr. Murphy would second me in this, but having had long experience in the valuation of reproductive studies such as were carried on out there and also with the varied abilities of the people to analyze data like that, I would urge you, sir, to consider the possibility of engaging an outstanding analyst in this area to give us the best possible analysis of the results.

If we have no such talent ourselves, perhaps we should go out on contract, a short contract. That would be the best way to have an evaluation of the conclusions that the NDP reached.

CHAIRMAN SHEPARD: That is a good suggestion. Thank you. Ron?

REPORT ON VETERAN ATTITUDES BY MR. DeYOUNG

MR. DeYOUNG: As a background to what I can say about veteran attitudes, my own connection has been rather heavy over the last three years with veterans who are not the satisfied customers of the VA but rather

the disillusioned and disgruntled people who have not been able to get the system to function.

Much of what I have heard if not all of what I have heard from veterans is extremely negative. It centers around a number of different phenomenon, none of which we are strangers to if we have worked in Washington at all; the size of the bureaucracy, the number of papers involved, the time in which it takes to get anything done.

If I can single one negative attitude out head and shoulders above the others, impersonalization. I would suggest insofar as we can alléviate this problem, we have done the veteran an enormous service.

There is something which I am not sure of the status of internally right now but which has been started within VA in response to this statement a number of months ago.

One of our associates in Chicago suggested the basic problem with VA service was it was always a different person you saw when you came in. There was no human follow-up to the thing, although there may be paper kept up. There was no feeling on the part of the veteran of progress because he had to start over each time he came in, essentially.

The Chicago man's suggestion was that a

TRIOSH team of sorts be established at each VA hospital so that it was the same doctor each time that the veteran came in for an exam. Insofar as that is functionally possible, it is my understanding that VA is moving in that direction.

I see that as a big advance. That certainly will go a long ways towards building trust on the part of the veteran because he has a human contact and not just a blank name, face, intern, whatever.

You have to remember in talking about Vietnam veterans attitudes that any generalization is false and this is to a limited extent, we are dealing with people who went over patriotically and came back disgruntled for one reason or the other.

That disillusionment with the war itself, with the military, with society at the time has lapsed over and by extension has fallen on the Veterans Administration. In many ways I pity the people at VA who have to work with this disgruntled veteran.

I can come at them as a peer but maybe you people cannot insofar as there are Vietnam veterans working for the organization.

Insofar as possible, please attempt to involve the Vietnam veterans within the VA directly with the veteran in the street; that bond that exists there

cannot be achieved any other way.

I have been getting less reports of problems lately. I do not know if that reflects the fact that my phone number has been changed or the fact that veterans are not complaining so much any more. If that is the case, then we can assume things are working better and from informal reports I have been getting from our people, it is better on paper.

There are isolated problems where a vet goes in and an appointment is not made out for him. This is nothing unusual. These are the kinds of things that the VA is coping with ordinarily.

I think there has been an enormous growth in the VA's procedures for handling Vietnam veterans who request an Agent Orange exam and insofar as the paper procedures can be carried out system-wide, I think you are getting some success.

CHAIRMAN SHEPARD: Thank you very much, Tom. Are there any questions?

(No response.)

CHAIRMAN SHEPARD: I would like to call on Mr. Charles Thompson from DAV.

REPORT ON VETERAN ATTITUDES BY MR. THOMPSON

MR. THOMPSON: Thank you, Dr. Shepard.

As I indicated at the last meeting, this is

obviously a very complex subject, not easily understood by many of the Vietnam veterans.

As Ron indicated, we have many Vietnam veterans who went over to Vietnam and questioned the military leadership and the type of war that was being fought. They now come home and are starting to question the confidence of our Government officials.

They were forgotten and scorned. Many of them felt this way. Now they feel they are being ignored on the subject of Agent Orange.

I have to agree with Ron on the impersonalization. I think it is improving. I think the Administration is taking a more responsible and sensible approach to the subject.

I think we need to continue this. We need to be more informative and more consistent in the type of information that is put out to the Vietnam veterans.

I think the new brochure just released is of great help.

We in the DAV as I indicated at the last meeting, when we come in contact with veterans writing in or calling in, we try to give them the whole gambit, not only the adjudication process, the examination process at the outpatient clinics or VA Hospitals but exactly what they are going to face when they file their

claim for benefits.

I would just summarize by saying that I believe it is incumbent upon this Advisory Committee to maintain its aggressive approach.

CHAIRMAN SHEPARD: Thank you. Are there any questions or comments?

DR. MURPHY: I recently was asked to talk to a group of people, some of whom were Vietnam veterans and some of whom were education or various advisory groups of Vietnam veterans in South Texas.

A couple things came up at that time that I would like to ask about or see what progress has been achieved.

In the registry, what interest do you have of getting Vietnam veterans to go in who do not have a complaint, either who had exposure but no complaint or someone who has not had exposure?

Are you interested in getting these veterans in?

CHAIRMAN SHEPARD: Very definitely. It certainly is known to all our medical facilities. We hope that through a number of different avenues we will be able to reach veterans and encourage them if they have a concern about exposure. We do not suggest they need to have any physical findings or any demonstrable ill effect.

We want veterans to enroll in the registry. This will give us a number of answers. It will give us a hint as to the magnitude of the problem as is perceived by the veteran population. It will give us an idea as to where these people are, what kinds of problems they have if they are experiencing problems but even if they are concerned.

For example, the whole issue of birth defects has caused a high level of anxiety. We get phone calls every day from veterans individually, collectively, through organizations, requesting advice as to whether a pregnant wife should have an abortion or whether the veteran should have a vasectomy because they have heard all these horror stories about birth defects.

We are encouraged by the male mouse study that at least insofar as animal work can be a signal, that there is not at least in this study a suggestion of increased infertility, birth defects, spontaneous abortions.

I think this kind of study is going to go a long way to allay the fears of those veterans who have raised this concern.

To answer your question, yes, we do want all veterans who have any kind of a concern to get enrolled in the registry. This way we can accumulate the data.

DR. MURPHY: I would think at least some cohorts, if that is the proper term, of veterans who do not have complaints and maybe do not have an exposure would be ultimately useful in your analysis of the data of those who do have complaints.

I think you have answered my question. The other thought is we happen to have in Houston at the Veterans Hospital there a very interesting man named Dr. George Cromwell. He also happens to know that I am on this Committee and has referred several individual veterans to me.

I have had a number of calls from veterans who for one reason or another do not want to go to the VA and have gone to private physicians and this issue of impersonalization almost seems as much a problem there in that I get the impression that there is a fair population of physicians in the country who do not know what Agent Orange is.

They might know what dioxin is and they might not.

What effort has the VA done through the medical associations to try and alert physicians, give them some education? I know medical schools have not in the past and probably still are not doing a great job of instruction on chemical induced disease.

CHAIRMAN SHEPARD: That is a very good question, Dr. Murphy. It is one we are very concerned about. In the press of other duties, I think we have not been as aggressive as we should and I hope will be in terms of informing the general medical public in this matter.

I think it is time for the VA to come out with some informational material for the medical provider at large.

One of the things we are doing for our own medical provider is an educational film relating to chloracne. I hope that will be a very substantial piece of training material.

We are also developing or we are now in the final stages of developing educational material for the veteran about the whole issue of Agent Orange. It is a kind of broadening out of what is in the pamphlet. This will be an audiovisual tape which will be available I hope within the next couple of months.

A follow-up to that will be a similar kind of educational audiovisual tape aimed at the physician community outlining some of the chemical, toxicological problems.

DR. MURPHY: Has anything gone into such publications as the AMA Journals, the Physicians'

newsletters that go out from these associations? Would it be difficult to get something in those?

CHAIRMAN SHEPARD: That is a very good suggestion; not to my knowledge from the VA. I think the time is now here for us to start working along those lines.

MR. DeYOUNG: In response to that, there have been several attempts from private physicians who have treated Vietnam veterans and Gilbert Bogan comes to mind from Illinois, one of our unofficial doctors from the Midwest.

We have had a small group of physicians in the Midwest and Chicago area who have been interested in tracking these veterans, sometimes on parellel tracks and some veterans are not going to the VA at all but rather to these private physicians.

Dr. Bogan published a letter in the JAMA of November last Fall which described his findings in a case of 74 Vietnam veterans.

The Veterans Task Force on Agent Orange is also in the process of trying to formulize the currently informal physicians' registry which we have. I would suggest any physicians who fit this description might want to be involved.

The National Veterans Task Force on Agent Orange is developing a referral network for Vietnam

veterans who believe they were exposed to Agent Orange while serving in the military who have various serious problems.

We are interested in receiving the names of sensitive, qualified physicians who might be interested in providing treatment.

Expertise in the following areas would be helpful; dermatology; oncology; genetic counseling; internal medicine; psychiatry; psychology and endocrinology.

This is being shepherded by Ms. Ruth M. Schaffer who can be contacted at our office in St. Louis. This is in conjunction with City University in New York.

CHAIRMAN SHEPARD: Dr. Suskind?

DR. SUSKIND: I would like to underscore the comments made by Mr. DeYoung and Mr. Thompson about the responsiveness of the local veterans medical units to requests or complaints or whatever the veteran brings in, with the claim that he was exposed to Agent Orange.

I also think it is an excellent idea to have a separate unit, a medical unit within the Veterans Hospital which does all of those examinations. Those are the experts, will be, should be. With the number of veterans that are likely to take advantage of this, it is terribly important that you have not the general outpatient clinic response, but that you have a specific

unit response.

I would hope that is being done or will be done.

CHAIRMAN SHEPARD: Each one of our medical facilities, all our hospitals and outpatient clinics, have a designated environmental physician. The way that is being implemented and each station may differ, but in the larger centers, the demand on one physician probably exceeds his capabilities to perform all the examinations but he has the responsibility of organizing in that facility whatever it takes to develop a responsive, compassionate program.

In some of the smaller facilities, I am confident the environmental physician himself is involved with the majority of the hands on contact.

DR. SUSKIND: The interest in doing this has obviously increased even from where I sit as not being a member of the Veterans Administration or one of their hospitals.

We had any number of requests from Veterans Hospital units over the country to put on programs, educational programs for their physicians, specifically addressed to the diagnostic, the assessment problems of the Vietnam veteran as it relates to Agent Orange.

This is only within the last two or three months.

The Council on Scientific Affairs of the AMA has just established an advisory committee on toxic substances. One of the issues that has been raised is what should the AMA do in its educational program about Agent Orange.

I think one of the things they would like to do is provide a forum for information and discussion of the clinical problems which might arise as a result of Agent Orange.

The man who is coordinating that activity is named Wheater. He is an industrial hygienist who is kind of acting as executive secretary of that office.

CHAIRMAN SHEPARD: Thank you very much, Dr. Suskind.

We are concerned that we get this information out beyond the VA so it will be general information. We are working towards that end.

I would like to thank the gentlemen for their comments. We highly endorse your efforts to work with us. We certainly want to increase that relationship and strengthen it.

I think we need to move on now. We have some very interesting activities that are either ongoing or to be proposed.

We have asked Dr. Rogan to say a word about

Dr. Ton-That-Tung's study. Those of you who may not be aware, he is a doctor in North Vietnam who has done a report on birth defects. In a word, maybe, Dr. Rogan, you can summarize your impression of that study.

REPORT ON PROFESSOR TON-THAT-TUNG'S LATEST STUDY
BY DR. WALTER J. ROGAN

DR. ROGAN: Basically this is sort of a three part report; one on a relatively large population, 10,000 or so; one on a smaller population, 4,500 and then some reports of outcome of pregnancies among individual former soldiers, some of whom came back from the South and were presumably sprayed or exposed, some of whom never left the North and thus who presumably were not.

DR. ERICKSON: May I ask what is the source of these documents that have been distributed to us?

CHAIRMAN SHEPARD: As I understand it, this was an article which was sent to somebody in Wisconsin with a handwritten note from Dr. Tung himself indicating he was in hopes that his article would be published in the New England Journal. To my knowledge, his article has not been published.

What we are referring to is a manuscript which was written in French and translated by a non-physician and perhaps even a non-scientist in Eau Claire, Wisconsin.

Some of you have been provided with the

original French manuscript. Those of you who have requested that have made a review based on the original manuscript and some of you have the translation which I understand suffers in some degree.

DR. ROGAN: Yes, in the literary degree.

DR. ERICKSON: What we have presumably is a photocopy of the translation?

CHAIRMAN SHEPARD: Presumably. I have no way to verify that.

DR. ROGAN: I have the manuscript in two forms in English, one which is presumably an earlier version and it has fewer references and the number of soldiers investigated in the third part is considerably smaller.

Working from two translations and my own horrible French, I have tried to figure this out.

The first thing I sort of looked for in the evaluation of a possible major teratogenic effect was the so-called signal anomaly, that is the kind of disease or structural malformation that is so unique, so rare, that it is striking and evidence in itself.

The classic example is the phocomelia, the limb reduction defects that follow exposure to thalidomide during pregnancy.

By my reading, there is no such signal anomaly here. There is nothing that occurs in many, many

cases similarly that is very unusual or unheard of outside these populations and would somehow lead you immediately to the conclusion that something strange was happening.

Being unable to find such an anomaly, once has to go back to rates, that is you define a population, you establish the number of outcomes of interest that arise from that population and you compare it to some other presumably unexposed group with the idea of drawing an inference about the differences in the rates.

A necessary step in drawing such inferences is that the presence of the anomaly structural malformation, whatever, does not in any way affect the likelihood that one will be reported on, in other words, the disease in question itself cannot affect the likelihood that you are going to be counting out of the population since almost always in human studies not everybody is counted and you cannot have a differential coming in.

I looked at the idea of trying to calculate rates from the data in this paper. For the first one we have 3,058 births arising from a population of less than 10,000 in four years.

Just crudely and arithmetrically, that comes out to 400 pregnancies per 1,000 population per year. That is an astounding rate, even in the emerging

countries where birth rates are very high and infant mortality is very high, no such rate as 400 was ever approached. Forty is the highest but there may be higher.

Somehow births are being ascertained better than population. We know more about babies then we know about people.

That makes it very difficult to calculate our rate because I do not know what it is arising from.

The list of anomalies allows one to look at the notion of mechanism, that is, one would hope to find anomalies in here that could conceivably result from male exposure, that is perhaps structural anomalies of chromosomes or the so-called signal anomalies like neurofibromatosis or acontemplasia.

What one is struck with is the absence of the common defects that we see in this country, Down's syndrome; hypospacias. They are not here. This is a funny collection of anomalies.

Anencephaly runs in families, conditional on a mother giving birth to a child with anencephaly, she has about a five percent recurrence rate and given she has had two such children, about 15 percent. This runs in genetic groups, higher in the Scotch Irish. I am not aware that it is higher in Vietnamese.

This is a lot of anencephaly. Since I do not know how big it is drawn from, I cannot say how big is "a lot." By the number of births, it should be a much bigger population than it is. I do not know given that whether this is too much anencephaly to say there is a background of anencephaly. It occurs unlike phocomelia.

Some of these are consistent with aneuploid babies, that is babies that have the wrong number of chromosomes. Some of them are consistent with the so-called embryonic band effects which are not thought to have an obvious genetic sort of mechanism but rather a physical sort of mechanism that goes along during the pregnancy.

The absence defects are very unusual in my experience and I am not really sure what to make of it.

The clefts and hairlips are the kinds of anomalies we see in this country. There does not seem to be too many of those given and I do not know what the population is.

What I am stuck with is I cannot calculate a rate because I do not know what the number was over. What I can say from the first study is there are among the children of soldiers who have returned from the South some congenital anomalies, whether that is more or less then I would have expected from such a group I cannot tell

because I do not know how big the group is. I suspect it is not what is reported in the paper because that is an unheard of fertility rate.

Batrachian abdomen, "batrachian" is a French word for frog. I have talked to some people who speak both teritology and French. They are puzzled by that word.

There are sort of slang terms in use in this country for some anomalies. The one that came immediately to mind was the prune belly syndrome which is absence of the abdominal musculature. It is an extraordinarily rare anomaly and should not account for the many times that it is present here, even among the so-called control groups.

I have looked through my book that talks about and shows pictures of children with structural anomalies. The closest I can come is either it represents anomalies along the line of the diastasis tuinfalliceals which are the ventral hernia anomalies where the abdominal musculature does not close around the umbilical cord or that it represents simply a frog or pot belly, thus, a swollen belly, thus acytees in the baby. This results from perhaps destruction of red cells, perhaps malfunction of the kidneys of the fetus.

Again, it is very unusual and is not described

in American nurseries. You do not describe as a structural anomaly a pot belly on a child. I am left with that. I cannot get a good answer for that.

Both Dr. Erickson and I have cased around trying to find out what that means.

I am stuck with the first one. The second one from the smaller group represents a much more reasonable birth rate for a population, down around 17 per 1,000.

The anencephaly is the anomaly of major interest. The problem we have here is as I said, anencephaly runs in families. Here we have it running in families. It is a rare event to have this number of anomalies in a small number of families but that is where those numbers come from, that is five, fifteen percent come from families that have experienced this.

We are not told specifically whether those families are ones with some kind of unusual exposure. In fact, they are not really much characterized at all particularly in terms of other family history of anencephaly.

One has difficulty interpreting this because of what exactly is the rate. These are non-independent sorts of observations.

The batrachian abdomen appears commonly and

I simply do not know its name in English.

I have two investigations of soldiers who have returned versus soldiers who were in and stayed. In my original French and in one of my English translations, it is a much smaller number. When I looked at it, I thought how did they find the individual soldiers that they interviewed, was finding them in some way related to the fact that the child was somehow abnormal. If that is the case, again one cannot calculate a rate because the probability of being found by the investigators is altered by the fact of what you are counting so you cannot count it.

When I got the second paper which had a larger number, that was sort of born out because they were able to find more and more people as the inquiry went on. We have not enumerated some kind of a population. It said there were one million such people and I counted all of them or a random sample of them and I counted the number who came to my attention.

Ancillary to that is some of the numbers that they have here. If you ask American women or women in most developed countries, not age-specific but overall, approximately what their spontaneous abortion-miscarriage rate has been, you will get a number something like 15 percent of pregnancies.

If you add to that premature deliveries, you will get some number higher. In North Carolina, for instance, the number of children born definitionally premature, that is under 2500 grams at birth, is about 8 percent.

What we have here is Group A, the soldiers returning from the South married to a Northern woman who give a combined history of both abortions and premature deliveries of 15.3 percent, a low number even given these people are reproducing perhaps at an earlier age.

The sterility number I am not sure what to do with because I do not know U.S. population numbers.

The unexposed group give a rate of 10.4 percent and also give a rate of zero out of 309 birth defects.

I think most people in developed countries would call a number of about three percent typical. Zero out of 309 would be considered to be unusual.

I have another little bit of evidence that the likelihood of being counted by the study is affected by the fact of an adverse outcome. Since that has happened or appears to have happened, I cannot calculate a rate.

What I am stuck with is there does not appear to be the so-called signal anomaly nor an increase in the

group of things that one argues as signal anomalies, that is dominant defects that arise from immutations. Examples are neurofibromatosis and achondroplasia.

There does seem to be an unusual amount of anencephaly with some dilution by the fact that there are anencephaly families in this study.

Parenthetically the second smaller province in my French is a subset of the first larger province. Thus I cannot tell how many of the anencephalics in the first part are the same as the anencephalics in the second part, thus, doubly counted.

There are soldiers who have returned from the South who have children with birth defects. There are also soldiers who never left the North whose children have birth defects.

The rate at which those different groups reported to this investigator are different but from the data presented in these papers, I cannot tell how different those rates are since I do not know out of what they have been drawn and with what pressure of selection.

The evaluation is I am stuck again with the notion of clinical observation. We have here a set of data with a clinical observation that these things have occurred.

Perhaps our focus in further inquiry can be directed a little better. Since I am without a signal anomaly, since I am confronted by the fact that the numbers do not jive with numbers I can generate outside this study and since I believe there are strong forces of differential ascertainment because the rates are low for spontaneous abortion, because the usual anomalies are absent, because the fertility rate in the one study is so high, because the congential anomaly rate in the second study is so low, I really cannot say anything other than this is a set of clinical observations, intriguing but essentially unvaluable in a standard sort of epidemiologic way.

5A CHAIRMAN SHEPARD: Thank you very much.

Dr. Erickson will give us an update on the status of another birth defect study, the outcome of which I think will be very interesting.

REPORT ON CENTER FOR DISEASE CONTROL PROPOSED BIRTH DEFECTS STUDY BY DR. J. DAVID ERICKSON

DR. ERICKSON: Just to recap what I said at the last meeting of this Committee, CDC has proposed to do a rather large case control study defining cases as babies who are born in the metro Atlanta area over the past decade with birth defects.

The controls were normal babies. It is to

determine retrospectively whether or not a greater proportion of the fathers of case babies had served in Vietnam in contrast with fathers of normal babies.

Around the first of July, Mrs. Harris, Secretary of HHS, gave CDC its marching orders and told us to get busy with the planning for this study. That is what I have been spending virtually all of my time and a good bit of my staff's time doing for the last four weeks.

I had two pediatricians assigned to me for the duration of the time it takes to finish with the generation of detailed protocol.

We hope to have that protocol completed in about a week and a half. At that time it will be submitted for clearance at CDC;sometime between mid-August and mid-September we will discuss the protocol with the Interagency Committee on Phenoxy Herbicides and Contaminants.

In mid-September CDC will assemble a small group of ad hoc consultants to review this protocol which will consist of consultants who will be two epidemiologists, a biostatistician and a medical geneticist familiar with problems of newborn babies.

Between mid-September and the end of October, we hope to have the protocol under review by the Office

of Management and Budget and hope to have things all squared away to begin hiring personnel at the end of October and collecting data beginning sometime around the first of the year, January of 1981.

We plan to be collecting data for one year and hope to have a final report submitted in July of 1982.

I would be glad to answer any questions.

CHAIRMAN SHEPARD: Thank you. Dr. Suskind?

DR. SUSKIND: What would be the size of your population, your birth defect population?

DR. ERICKSON: Over the past decade we have on file roughly 12,000 babies who were born with anomalies, roughly half of whom have what we would call a serious anomaly.

We are not quite sure yet how many babies will be targeted for study, somewhere on the order of 5,000 to 6,000 babies with malformations and something on the order of 3,000 normal babies, it is a very large case control study.

DR. SUSKIND: These would be babies born between 1968 and when?

DR. ERICKSON: Through 1980.

DR. SUSKIND: You are not going to be relating them to Vietnam exposure but you are going to be relating them to phenoxy herbicide exposure?

DR. ERICKSON: We are quite hopeful that we can tell whether Vietnam veterans in general are at risk of having babies with birth defects. We are not too optimistic about what we can do about getting down to the question of Agent Orange specifically. We are going to try.

Our basic outcome will be whether a man served in Vietnam or he did not.

DR. SUSKIND: I think we have the tendency to forget that in these United States, as pointed out by Dr. Kearney in a review some years ago, millions of pounds of 2,4-D and 2,4,5-T were used by gardeners, by home owners, by farmers.

The population that grew up through 1970, between 1948 and 1970 had more or less exposure to 2,4,5-T and 2,4-D is still available.

It is difficult to identify a non-exposed population. The relative exposure can be determined to some degree by interview.

DR. ERICKSON: To some degree.

DR. SUSKIND: Not very much.

CHAIRMAN SHEPARD: This is going to be the problem with almost any study we do that tries to relate exposure to herbicides in Vietnam and to separate that from other exposures, either here or there.

DR. ERICKSON: We will be gathering information about a wide variety of things that are thought to be possible causes or associates of birth defects. We will be able to evaluate those in the population at large and in the Vietnam veterans.

It seems to me you must keep in mind the idea that Vietnam veterans may be different from other men in a wide variety of ways other than the possibility of having been exposed to Agent Orange.

CHAIRMAN SHEPARD: Thank you, Dr. Erickson.

MR. DeYOUNG: In a sense that is all the VA needs to be interested in. I am not speaking now from scientific curiosity but from a benefit structure standpoint.

If the statistics show that simple presence in Vietnam differentiates you by a higher increase in birth defects then the rest of the population, that strikes me as probable cause to go ahead and review the benefits.

I do not feel personally that we have to be able to say, yes, this is Agent Blue that did this, or Agent Orange, or Agent White, or the crazy karmo over there. It is immaterial to a certain extent.

All we have to establish is those veterans do have problems at a greater rate.

I personally welcome this study with open arms.

CHAIRMAN SHEPARD: Next Dr. Honchar from NIOSH is going to tell us a little bit about the dioxin registry.

REPORT ON NIOSH INTERNATIONAL DIOXIN REGISTRY BY DR. PAT HONCHAR

DR. HONCHAR: I should start off first by making a distinction between the current effort underway at NIOSH to establish a U.S. registry versus discussions that are currently being held with regard to an international registry.

After I complete a brief description of the particular NIOSH effort in the United States, I will relate that to the discussions about an international effort.

Right now at NIOSH, I should say for the past year at NIOSH, an exposure registry is being compiled of all people in the United States who have worked at synthesizing 2,4,5-T.

The information being collected includes their work histories, how long they worked at this particular type of job and also information about the particular process in use at the industry where they were employed.

The ultimate goal of this registry will be

for its utilization in a retrospective cohort mortality study. That is, this group of people will be followed historically with questions asked about their cause of death and its comparison to expected rates and expected causes.

The registry will include populations from approximately ten different industrial sites within the United States including the sites mentioned by Dr. Suskind earlier.

The reason for embarking upon a registry of this type was to increase as much as possible the ability to detect problems within this population. That is, the larger the group of people being reviewed in a mortality study of this type, the more powerful will be the study to detect any rates that are different from expected rates and also to detect types of tumors which may be rare, for example, in the case of carcinogenicity.

I should add as a footnote that carcinogenicity will not be the only cause of death that will be under review by this registry but also non-carcinogenic causes of death; cardiovascular diseases and so on will also be considered.

With regard to a status report as I mentioned earlier, the registry has been under formation for

approximately a year now. It is still in the data collection phase. We are not to be polite meeting with as much cooperation from all industries as we would like and currently anticipate spending a bit of time enforcing subpoenas for data in the near future.

We hope to avoid that but it may be a possibility with some of the industries we are pursuing. There are other industries that we have not yet contacted that will be contacted in the near future.

I also said earlier that there are approximately ten industrial sites involved. Each site or I should say many of the sites as far as we have been able to determine were occupied since the 1940's when 2,4,5-T synthesis began by more than one industry, which complicates the issue incredibly. Basically we are looking for historical work histories and personnel records from an industry that may have vacated a site ten to fifteen years ago and was then followed by other companies.

The data collection is moving along slowly.

My last estimate of the completion time, that is the time until the first analysis could be expected from the entire cohort in the registry is late 1983. Given ongoing problems with regard to finding the data and gaining cooperation from the industries, that date may extend further into the future.

I do not present this information as a potential definitive answer to Agent Orange in Vietnam. I certainly would not make a recommendation at this time that if, given other information, that decisions about veterans in Vietnam be held off until 1983 or later.

Nonetheless, this study is important because it is an attempt to assemble a large group of people with known exposure to 2,4,5-T through the synthesis process and explore their mortality experience.

With regard to the international registry, given that the synthesis of 2.4.5-T is not a labor intensive activity, even workers from the ten U.S. sites may not provide a large enough number to allow the power we would like to see to detect unexpected rates or cause of death.

Going outside the United States and identifying and including people who have been involved in synthesizing 2,4,5-T from European producers would increase the power of the analysis even further.

There are discussions underway. Parties involved to date to my knowledge have been IARC, the International Agency for Research on Cancer; NIEHS

and NIOSH. Discussions are on the feasibility of basically replicating the effort as I am conducting it here in the United States outside of the United States, primarily in Europe where most of the non-U.S. producers have existed.

All efforts will be made for comparability in data collection if the international registry effort does begin.

I think that about covers the major points with regard to the activity. Does anyone have any questions?

DR. SUSKIND: When do you apticipate the total registrate population to be within the United States?

DR. HONCHAR: I really do not know. That is probably the $1,000 question. It is very difficult to estimate. We have not yet made our tour of all the industrial sites to collect data.

Even if I were to extrapolate right now from expected numbers given the time, to my knowledge, that 2,4,5-T may have been synthesized at a particular site and knowledge on a general level of about how many people may have been involved, the question still remains with regard to whether or not the personnel records are available for inclusion.

It is very difficult to estimate. I resist

consistently estimating.

DR. SUSKIND: What about units that have literally disappeared? Any number of industries that made 2,4,5-T in the late 1940's and 1950's are no longer in existence. Their buildings do not even exist.

DR. HONCHAR: That is very true. We are finding that in some cases, for example, a parent industry may have held personnel records. We are also exploring for some particular cases situations where hopefully the population could be reassembled or identified through Social Security, by a Social Security I.D. number, or Workmen's Unemployment benefits, things of that sort.

The effectiveness of that route of identifying the cohort is directly related to the particular activity at the site.

For example, at one site, dealing with the case of mysteriously disappeared records, I know there was no other activity at that site besides the production or synthesis of 2,4,5-T and 2,4-D. If in fact I can identify the cohort and their period of time or work at that site through some other means then direct personnel records of the company, that is a legitimate group for inclusion.

There are other means being explored. Obviously the first avenue is the particular companies.

CHAIRMAN SHEPARD: Are there further questions?

DR. GROSS: On the reluctance to provide records and the subpoenas, do you suppose if certain waivers telling the people that the displeasure of Uncle Sam may be visited to them if they do not cooperate would help? The statute of limitations must have expired.

Do you not believe that a great deal of records could be obtained from industry if such assurances were given that there would be no prosecution or regulatory action against them?

MAJOR BROWN: I think one of the problems you might have in that case is it does not limit the company from third party liabilities.

DR. GROSS: Civil type actions.

MR. DeYOUNG: The question of when that statute of limitations begins to run much less when it runs out.

CHAIRMAN SHEPARD: We are running a little behind schedule. I want to continue. I do want to have some time for questions. We will stay here for a reasonable period of time hopefully to answer those questions.

I would now like to call on Dr. Carolyn Lingeman from National Cancer Institute on

loan to AFIP, who will bring us up to date on the status of the AFIP registry and discuss a couple of proposals she has made.

REPORT ON AFIP REGISTRY AND PROPOSED STUDIES BY DR. CAROLYN LINGEMAN

DR. LINGEMAN: As you know, there is a registry of environmental pathology at the AFIP. This is the registry headed up by Dr. Nelson Irey who is doing pathologic documentation for the VA's registry on Agent Orange.

So far there have been 58 accessions there of which 14 are neoplasms. These do not fall into any kind of pattern. This is essentially a pathologic back-up for a cohort study. Eventually there might be possibilities of some type of epidemiologic analysis of this kind of material.

We certainly do need the pathologic documentation and perhaps the important thing is if there are 26,000 people now in the VA Agent Orange registry, maybe a bigger effort could be made to find out how many of those are neoplasms and get the pathologic material in for evaluation.

CHAIRMAN SHEPARD: Excuse me. Let me clarify a misconception that may be there. The 26,000 that I referred to are Vietnam veterans who have entered the

registry. We do not have anything like that number who have submitted any tissue. There probably would be a very small handful of those.

DR. LINGEMAN: If a diagnosis of neoplasia has been made, this would imply that a biopsy was done.

The other type of epidemiologic study which might be possible using AFIP material would be case control studies. I think there we have an opportunity which probably does not exist in very many centers, of having access to relatively large numbers of rare or infrequent neoplasms.

The AFIP has a registry of soft tissue tumors.

We have already had preliminary conversations with the Chairman of the Soft Tissue Pathology Department about a proposed study but do not know if it can be done.

As we develop plans for a study designed to confirm or disprove the Swedish studies, perhaps we will ask Dr. Suskind and others on this Committee to review the protocol.

Such a study may provide only negative

answers but as scientists, we are only obliged to provide scientific answers. These will not be social answers or legal answers. It is important that this Committee concern itself only with scientific issues, not legal ones.

One thing I do notice in the Swedish studies is that nine of the soft tissue tumors were angiosarcomas which as you know are extremely rare neoplasms in the United States. Only about 50 occur each year in the United States.

We have had a cluster of angiosarcomas in an industry that manufactured chlorinated compounds of a different type. As you recall, vinyl chloride has been associated with angiosarcomas of the liver. In the case of vinyl chloride, the angiosarcomas is what might be called a signal neoplasm.

In the Eriksson study there may have been an excess of angiosarcomas. As in the Swedish studies, we would attempt to determine whether or not people with soft tissue neoplasms might have been exposed to phenoxy herbicides.

But I wish to emphasize that these studies are only in the very early talking stages.

The other problem of concern to us is the

controls. We are currently working on another case control study involving neoplasms of the sinonasal tract, and are using cases from AFIP data base for controls. These are all sick people. Which ones do we exclude and how do we decide which ones to exclude? We can match the controls by age, sex, race and even geographic location by state.

We welcome comments from the epidemiologists as to what kind of groups we can use for controls.

CHAIRMAN SHEPARD: Thank you very much, Dr. Lingeman.

You did mention the testicular tumor?

DR. LINGEMAN: That was the other group we talked about. It turns out two of the three we have in the Registry so far are from the same patient. We actually only had two patients with testicular tumors. Both were young men. Testicular neoplasms are among the most frequent neoplasms in young men.

Others have mentioned testicular neoplasms as one type that may be showing up in the Vietnam veterans. Probably this is the second most important type of neoplasm for a case-control study. We will see what we can do.

CHAIRMAN SHEPARD: I think this is a very important announcement because the AFIP does have a vast store of material, and I guess all of it is computerized.

It has been put in there very carefully and can be analyzed relatively easily.

We are looking forward to the results of those studies. Thank you.

We would like to hear from Major Phillip Brown of the Air Force on the status of the Ranch Hand Study which as all of you know has gotten a lot of visibility. Due to the fact this is a cohort with relatively precise exposure data and probably the only such cohort that exists, we are looking with great interest to the development of this study.

Major Brown?

REPORT ON THE RANCH HAND STUDY BY
MAJOR PHILLIP G. BROWN

MAJOR BROWN: Thank you, sir.

I think it would be worthwhile to review a little bit of the past history, hopefully most of you know of it but maybe not all.

The Air Force as early as 1978 was volunteered to begin to examine the possibility of an epidemiology study regarding the Ranch Hand personnel that flew the missions in Vietnam.

It has taken us many months to get to the point now, as of 1 August to have a recommendation by the

Interagency Work Group to the White House recommending that the Air Force do the study.

At this time it is my understanding that this recommendation is under consideration by the White House. Until such time as we get guidance, the Air Force will still be in the situation of waiting but still doing some work.

We have identified the population in terms of the exposed individuals. We are now certain there are 1,160 personnel that flew the herbicide in Vietnam over the years. We had originally said an estimate of 1,200. We came out fairly close.

We have started the process and are well along the way of identifying the controls for those individuals. We believe there is going to be an extremely tight match because we have a very large population for the controls.

We are in the process of locating the individuals that flew, thanks to the legislation that occurred in Congress recently. We were able to contact the I.R.S. and by that legislation they have been obliged to tell us the last whereabouts of these individuals via their income tax returns.

It has been extremely helpful. It is one of those rare events that occurs every once in a while.

We are doing an extremely large amount of work. We are refining the protocol. The Scientific Panel of the Interagency Group recommended a twenty year follow-up. That may have great precedence within the Federal sector for a study, since I am not aware of any that has been programmed for that long.

This has obviously taken some thinking in terms of the Air Force about programming and the size of contributions that might be required to do the study.

CHAIRMAN SHEPARD: Thank you. Are there any questions for Major Brown?

MR. DeYOUNG: You say you have a large control population from which to draw. What kind of group is that? Air Force personnel who have not been to Vietnam?

MAJOR BROWN: These are Air Force personnel who were in the Vietnam theater of operation.

MR. DeYOUNG: Not involved in the Ranch Hand?

MAJOR BROWN: That is correct, not exposed.

MR. DeYOUNG: I believe there was some talk at our last meeting about having this Committee review that protocol. Is that an offer from the Air Force or a request from the Committee or am I totally misremembering it?

CHAIRMAN SHEPARD: I do not recall. There are some members of this Committee who also serve as members

of the Scientific Panel of the Interagency Work Group. I do not recall any specific offer or commitment on the part of this Committee to do that.

DR. SUSKIND: Has the logistics of carrying out the study been explored?

MAJOR BROWN: As you are well aware, Dr. Suskind, because of your studies, that is a major problem. We are aware some of these individuals no longer reside in the United States. We will have a logistics problem. We have been exploring that to see what is the best methodology for it.

There are a number of options and no particular option has yet been identified.

CHAIRMAN SHEPARD: Thank you very much, Major Brown. We will follow the progress of this with great interest.

Dr. Kearney would like to tell us a little bit about the activities of the Department of Agriculture and their involvement with the whole issue of herbicides.

REPORT ON DEPARTMENT OF AGRICULTURE ACTIVITIES BY DR. PHILIP KEARNEY

DR. KEARNEY: Mr. Chairman, it is running late and I did prepare some written comments. In the interest of time, I will just pass these out to the Committee.

It describes the title of the contact person,

the date of completion. I see nothing wrong with anyone contacting these people to learn the status. I do not know that they need discussion.

CHAIRMAN SHEPARD: Thank you very much. I appreciate your sensivity to the lateness of the hour. I really appreciate your putting this together.

As many of you know, the use of herbicides obviously impacts heavily on the forestry and agricultural industries of this country. Those agencies and activities involved in that work are following this whole issue very closely and are conducting studies parallel to some you have heard about.

I apologize for the fact that we have run over by about half an hour. I do want to take some time to recognize some of the questions to come forward.

Let's take a short break and return for questions and answers.

(Whereupon, a short recess was held from 12:03 p.m. to 12:10 p.m.)

CHAIRMAN SHEPARD: Let's reconvene, ladies and gentlemen.

We have a number of written questions. We will attempt to answer as many of them as possible.

I feel a little uncomfortable about asking the members of the Committee to stay beyond 12:30 p.m. or

12:40 p.m. I will be happy to stay for as long as necessary and do my best to answer questions that have come in.

In the event that we do not get your questions answered, we will answer you in writing if we have your names and addresses.

I have a group of four typewritten questions with the name of Frank Latonzee from Citizen Soldier. We will start off with one of Mr. Latonzee's questions.

I will read the four and maybe you can identify the most important one you would like answered first and then we will continue with the others.

Why has not the VA developed a standardized clinical protocol for examining Vietnam veterans by all VA facilities?

I can answer that there is a reasonably standardized protocol in the form of our instructions to VA facilities. There is something of a protocol that is in the form of instructions to the VA facilities as to how these examinations are to be conducted.

Obviously if you are dealing with a large population, both of veterans and physicians, with a wide variety of ailments, conditions or complaints, it is very difficult to standardize a protocol. There will be an individual variation on the part of the physician

as the needs require.

Why is no data taken from veterans'wives?

Why has not the VA implemented standardized precoded questionnaire forms for all VA facilities? That has been done.

We do have a standardized questionnaire. Maybe you have a more specific question relating to that.

What protocol has the VA established to help incarcerated veterans obtain Agent Orange examinations?

I can very quickly answer that. The VA is not authorized to enter penal facilities. We will make available to any medical departments of those facilities our questionnaire and the instructions so in the event the medical departments of those penal facilities are capable of carrying out the same instructions that we provide to our own physicians.

We would be happy to receive the data which comes forth from that.

Why has not the VA actively pursued the development of bioassay methods other than fat tissue analysis including the new RNA blood analysis techniques which were developed in-house by VA doctors in the Bronx VA?

I do not have the information to answer that. Dr. Hobson?

DR. HOBSON: I think they are referring to the RIA. There has been some work done in an attempt to identify TCDD in blood. At the present time that has not proved sensitive enough nor has it been validated to the point where it has any usefulness in correlation with exposure in the past.

The other thing in that regard is while you can detect dioxin by various methods, immediately after exposure to the blood, material does not hang around in the blood for a long period of time. It is disposed of by the body either by discretion or by depositing it in fat and other tissues.

The likelihood of finding circulating dioxin ten years or so after exposure is a priori, pretty slim.

CHAIRMAN SHEPARD: Thank you.

We have a group of questions from the Veterans of Vietnam War, Post #1. Is this from Pennsylvania?

MR. BISSLAND: Scranton, Pennsylvania.

CHAIRMAN SHEPARD: We welcome your participation and are pleased you saw fit to take the trip.

Some of these are in the form of questions and some are in the form of comments.

Is the VA Hospital going to continue with

present tests or will they be upgraded?

I am not sure if you are referring to a specific VA hospital. I will answer the question assuming you mean the VA hospital system.

We are in the process as I think I indicated earlier and if I did not, I meant to, that we have observed some problems with the use of our questionnaire. We think there are some questions there that most veterans find difficult to answer and probably there are questions that perhaps are not there and should be there.

A subcommittee of Dr. Page's group is working hard to revise the questionnaire and improve the questionnaire. As soon as that has been approved by the Agency and has been tested and has been found to be an improvement on the existing system, we will circulate it for implementation.

What methods and to what extent will be used to determine dioxin present in veterans?

I think Dr. Hobson has alluded to that. Maybe I could amplify it a little. The whole technique of measuring dioxin in the body is a very, very difficult one. We are talking about parts per trillion of dioxin in body fat, that is, the limited work that has been done in that area already.

The fat biopsy effort that has been undertaken

was a test of the analytical technology that exists in the country. There are relatively few laboratories that are capable of doing this very sensitive test.

I think the studies that have been done or the attempts to measure dioxin in the body first of all are exquisitely difficult and furthermore, we do not have a strong impression that there is a high level of correlation between measurable detectable levels and exposure to Agent Orange.

I think that brings into question the usefulness of this very difficult and expensive test.

If other members of the Panel have anything to add to my answers, please feel free to jump in.

What percent of disability will be awarded and when?

(LAUGHTER.)

CHAIRMAN SHEPARD: I think I understand where this question is coming from. The whole problem of disability compensation continues to be of concern.

As I think I mentioned earlier, we are working hard to make the point that the disability does not have to be related to any demonstrated exposure to Agent Orange or any other substance. The association of a disability with military service is the only requirement. To date, that process continues.

We are looking in all our studies for evidence of linkage of Agent Orange or service in Vietnam to disabilities. Certainly the data that comes from our registry should give us a clue as to what disabilities do exist in the Vietnam veteran population.

T-3B

MR. BISSLAND: When a veteran does go to a VA hospital for an examination, what is done with that data that is taken by the doctor?

If there is an ailment, they have a tendency not to notify the veteran of the ailment and as a case in point we had a member who had an Agent Orange examination and the liver case came back and proved there was something wrong with his liver.

He went back for another test and it was not as bad as it was before. A week later, he was cured. Remarkable!

CHAIRMAN SHEPARD: That is not unusual. It is quite common in liver ailments. For example, hepatitis and jaudice is a group of diseases which affect the liver. One of the ways of detecting that other than the yellow appearance of the eyeballs or the skin is through a battery of liver enzyme tests.

Characteristically, this is a self limiting disease and the enzymes return to normal in a varying amount of time.

It is not unusual for somebody to have hepatitis and to recover spontaneously. In fact, correct me if I am wrong, there is no known cure or medicine for that particular illness.

What you described is not an unusual thing.

You asked a question about follow-up.

MR. BISSLAND: We have patients who do not know what is happening. They go for tests and hear nothing more.

CHAIRMAN SHEPARD: That I have heard and it is regretable. I hope when that is the case it means the studies have come back normal.

We are pursuing efforts to improve the follow-up procedure. I feel very strongly that regardless of what the results of your examination are, that each veteran should be informed and we have that obligation, and invite him to question the results in any way he sees fit.

We are attempting to improve our follow-up process.

Since present studies will not be completed for some time, what about vets who are suffering now and if vets die in the meantime, will their families be taken care of or will their death certificate read "cause unknown"?

There are a lot of questions in that comment. Let me take the first part. Since present studies will not be completed for some time, what about vets who are suffering now?

Any veteran, be he a Vietnam veteran or any other veteran who is eligible for care in a VA hospital obviously can have his problems taken care of now. The question of eligibility is a fairly complex one and I do not think I will take the time now to describe it in detail. Part of that is the fact that I do not know all of it in detail.

If there are illnesses demonstrated at the present time, there are mechanisms for having that illness treated in VA facilities.

About the Vietnam veteran who dies, will his family be taken care of; that is a little out of my area of expertise. It is my understanding that death benefits and survivor benefits are available under certain circumstances.

DR. HOBSON: If I could make a comment, these questions that go to compensation and pension are coming to the wrong people. I think there is no one in the room right now who is in compensation and pension.

I think frankly it is going to be misleading if we attempt to answer them here. We may give you

misinformation. Since this was a scientific panel, they were not asked to be represented on it. I think these questions are probably a little out of line although they certainly are germane and ones that demand answers.

This is just not the proper place to get the answers.

CHAIRMAN SHEPARD: Thank you.

Many veterans are regular blood donors. Many of these veterans are finding they have dioxin in their blood. I would question that.

MR. ROXBY: I work with people who have the medical reports back that say they have a percentage of dioxin in their blood.

DR. HOBSON: Which hospitals?

MR. ROXBY: The Wilkes-Barre Hospital.

CHAIRMAN SHEPARD: We will look into that. I am not aware of any VA facility that is measuring dioxin levels.

MR. ROXBY: If the tests are accurate and true and this man does have dioxin in his blood, does this or does this not put some type of contamination in to the recipient of that blood?

CHAIRMAN SHEPARD: Obviously if someone had dioxin in their blood, it would represent a contaminant. I really question the ability to my knowledge of any VA

hospital measuring dioxin levels in blood.

MR. ROXBY: You are questioning the VA hospital in Wilkes-Barre.

CHAIRMAN SHEPARD: I am questioning the source of that information.

MR. ROXBY: That can be documented. It did come from a VA hospital.

CHAIRMAN SHEPARD: We will certainly look into it.

Those are all the questions I have. There is one request from Mr. Roxby to address the Committee. I would entertain such an address for a few minutes.

MR. ROXBY: If I wanted to say everything I have to say, you would be here another three days about what has been going on with me since 1974.

All I have been hearing about is chloracne. It is the only thing being related to exposure to Agent Orange, TCDD.

The Comptroller General had a study made with other findings possibly with the soils. If I take my shirt off, I can show you. I know how much pain there is having this stuff on your body. The weakness is unreal. I cannot get out of a chair without help sometimes. Weight loss, almost 50 pounds in four years. Nausea, I cannot eat or drink without losing half of it

five minutes later. Urinary tract, I have no control half the time. If I have to go, I have to make sure I am there or I will go where I am at.

My sex life is completely shot. I am 34 years old. I do not know what it is to go to bed with a woman and that has been for four years now.

Mobility and drive; I cannot move my arms and legs. Anger and frustration, no one would like to get up and argue with me, I would blow them away.

Stiffening of the hands, arms, legs, the neck muscles, headaches, breathing difficulty, swallowing, I am almost on baby food. I have had diarrhea for four years.

All this, every one of them has been documented in the article published by the Comptroller General. There are follow-ups on it. I had a copy sent up from the VA hospital in Lancaster.

I am just wondering why all these symptoms can be in a book and I have them and I will go back in the hospital like I have been for the last six years, why the only issue coming up is chloracne. Chloracne seems to be the littlest problem of them all listed.

It is the smallest but it is the only one being thrown in our face. For all this, I get $5.00 a month disability. I get $165 after that because I am

house bound and need regular aid. That is my disability.

CHAIRMAN SHEPARD: Are you getting care in your VA hospital?

MR. ROXBY: Anything I want. I get my care at the Wilkes-Barre Hospital and I have been treated at both the Philadelphia VA and the Wilkes-Barre. I have been treated for everything from frostbite to burgers disease from Vietnam.

CHAIRMAN SHEPARD: Have you filed a claim?

MR. ROXBY: They do not seem to have records of my having an Agent Orange test. I have to go through it again. The papers for my claim are going in again for the second time.

CHAIRMAN SHEPARD: I certainly sympathize with your problem. I hope you are getting good care at the Wilkes-Barre Hospital. I want to encourage you not to try to conclude that your problem which is a very serious problem and just looking at you I would suspect it is scleredema in some form, the symptom complex you described is fairly classic for that condition.

MR. ROXBY: I have been doing a good deal of reading on what I have been treated for. The symptoms I have will point to slceredema but they also point to dioxin poisoning. You have them back to back.

They were rather tell me I have scleredema,

non-service-connected instead of turning around and saying I have dioxin poisoning. That is what it comes down to.

CHAIRMAN SHEPARD: You are approaching the problem from the point of view of filing a claim. I do not have the expertise and we do not have all the records here to examine but I think you should pursue the possibility that this may have been a service connected problem.

The issue of relationship to dioxin is probably not your strongest case. A much stronger case is the fact that you had some of the early signs of this condition while you were in service or shortly after service.

MR. ROXBY: I had the rash right down my entire left side going across my chest. It does not seem to relate. I have been getting nowhere as far as the Veterans Administration is concerned.

Every time I fill out a form to send it in, I have to start looking through papers and so forth describing when it started. After I send that form out, I get another and they want the same information.

CHAIRMAN SHEPARD: Let me say we will look into it. We will be in touch with the hospital in Wilkes-Barre.

MR. ROXBY: I have also been denied copies of my medical records and tests which I believe is illegal under the Freedom of Information Act.

CHAIRMAN SHEPARD: We will be happy to look into that and get back to you.

DR. HOBSON: Request under the Privacy Act and not under the Freedom of Information Act.

MR. DeYOUNG: We have had that happen to people in the Midwest as well and our response is to simply march into the Director of Information Office for that particular hospital and ask politely in an assertive manner, insist on your rights under the Privacy Act. You are entitled to a hand carried copy of any tests as of that date.

MR. ROXBY: At the Wilkes-Barre Hospital you will be marched out the door. I sent away for my records in Missouri under the standard Government form stating what records I wanted. I was denied those records. I was sent back my discharge papers and that was it, my 242.

MR. DeYOUNG: Did they specifically say you could not have those records?

MR. ROXBY: They specifically did not send those to me.

MR. DeYOUNG: They did not understand you.

MR. ROXBY: Conveniently misunderstood me. If I wanted a copy of my DDT-14 form, I would have asked for it.

MR. DeYOUNG: The grapevine tells me that the records at Missouri that you are asking for, all those requests are simply piling up on some fellow's desk, some GS-9 down there who sits there scratching his head and saying, what do I do with these? No one has worked out the system for coping with those responses yet.

I am not trying to make excuses for the Government. That is not my job.

The bottom line to the vet is do not hold your breath for those records because you are not going to get them.

CHAIRMAN SHEPARD: That concludes the written questions. Dr. Rogan?

DR. ROGAN: I would like to add in reference to my discussion earlier that the crude birth rate in the North Vietnamese study was 75 per 1,000 population year. The 400 was a per woman year number adjusted for a spontaneous abortion rate of 15 percent. Thus, 400 pregnancies per 100 woman years.

CHAIRMAN SHEPARD: Thank you.

I would have the Committee stand adjourned

and would like to express my great appreciation for the participation of all members of the Panel, the forbearance of the audience and their interest in this issue.

I again want to express my appreciation for all the hard work that has been done to coordinate this meeting and look forward to seeing you again.

Thank you.

(Whereupon, the meeting was adjourned at 12:35 p.m.)

C E R T I F I C A T E

This is to certify that the foregoing proceedings before the Veterans Administration, Advisory Committee on Health Related Effects of Herbicides, Wednesday, August 6, 1980, were had as herein appears and that this is the original transcript thereof.

MARILYNN M. NATIONS

I hereby certify that the proceedings and evidence herein are contained fully and accurately, as corrected.

BARCLAY M. SHEPARD, M.D.
Chairman
VA Advisory Committee on Health-Related Effects of Herbicides

November 3, 1980

ALVIN L. YOUNG, Major, USAF
Consultant, Environmental Sciences

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

**(Sixth Meeting
November 6, 1980)**

December 1980

Washington DC 20420

VETERANS ADMINISTRATION

ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES

- - -

Thursday, November 6, 1980
Veterans Administration Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D.C.

The Committee met, pursuant to notice, at 8:35 a.m., Barclay M. Shepard, M.D., Chairman, presiding.

ATTENDEES:

Barclay M. Shepard, M.D., Chairman,
Veterans Administration

Ronald W. DeYoung, National Veterans
Task Force on Agent Orange

J. David Erickson, D.D.S.
Center for Disease Control

Thomas J. FitzGerald, M.D., American
Legion, for Irving B. Brick, M.D.

Adrian Gross, M.D.
Environmental Protection Agency

Lt.Col. Richard A. Hodder
Uniformed Services University of
The Health Services

Ralph Ross, Ph.D., Department of
Agriculture, for Philip C. Kearney, Ph.D.

Carolyn H. Lingeman, M.D.
National Cancer Institute

Sheldon D. Murphy, Ph.D.
University of Texas Medical School

Charles A. Thompson, Disabled American Veterans
For Robert H. Lenham

C O N T E N T S

P R O C E E D I N G S

Dr. SHEPARD: Good morning. Welcome to our quarterly meeting of the VA Advisory Committee on Health-Related Effects of Herbicides. We are pleased that you are all here, both as observers and as members of our Committee, and we hope this will be another productive session.

I have a few announcements to make.

We are very pleased to have a new member of the Advisory Committee in the person of Lieutenant Colonel Richard A. Hodder. I hope he'll arrive shortly. He has been invited to be a member to replace Colonel Thiessen who has resigned from our Committee due to his retirement from the Army.

Colonel Hodder is currently Director of Epidemiology in the Department of Preventive Medicine and Biometrics at the Uniformed Services University of the Health Sciences, a new medical school on the Bethesda Naval Hospital Campus.

Dr. Hodder is a medical epidemiologist, and we are very pleased that he will be a member of our Committee, and we look forward to working with him.

I have a letter from Dr. Abraham Lilienfeld which I would like to read to you. This was addressed to Dr. Haber, since Dr. Haber was my predecessor in this job:

"You may have wondered about my absence at the Herbicide Advisory Committee meetings during the past several months. What happened was that in April I was made Director of the MPH Program at our School, at the request of the Dean. This includes an effort to review the program, evaluate it, and make curriculum changes necessary, etc. This has, as you might expect, taken an inordinate amount of time in the last 4-5 months.

"In view of these additional responsibilities, I regret to say that it will be difficult for me to continue to serve in an advisory capacity. I'd rather admit this than find myself in the position of not being able to attend meetings on designated days or to respond to a variety of requests.

"I feel certain that you understand my position in this matter.

"Best personal regards, Sincerely, Abraham Lilienfeld."

We regret Dr. Lilienfeld's resignation, but certainly understand with the press of duties in his new responsibilities, his inability to continue as a member of this Committee, and we are now making efforts to secure a replacement for him.

We are very pleased to have with us this morning Dr. William Gaffey, Manager of Epidemiology in the Department of Medicine and Environmental Health for the Monsanto Company in St. Louis. Dr. Gaffey co-authored a recent study analyzing

the relationship between TCDD and the cause of death of 58 employees potentially exposed to the contaminant during 2,4,5-T herbicide production at the company's Nitro, West Virginia, plant.

Dr. Gaffey has very kindly consented to appear on the program today and bring us up-to-date on some of the recent studies that he has been conducting.

As in previous meetings, we will have a time for questions at the close of our formal presentations. I would encourage all of you who have questions to please write them out and send them forward so they may be included in our discussion period. There are cards, pencils, and so forth in the rear of the room. If you have a question, please so indicate and our secretary will be happy to provide you with the materials.

We have received a notice of some correspondence relating to a reference that was made at a previous meeting -- not a recent meeting. It was before I became Chairman. I think Mr. Ron DeYoung had made a comment at the December 12 meeting concerning the possible destruction of records as a result of a fire in the Regional Office in Chicago.

We have looked into this matter and I will include the report of that fire in the minutes for the sake of completeness. I will just read to you a portion of that report so you will understand what the bottom line is.

This was a fire that occurred on January 31, 1979. The fire caused extensive damage within the Adjudication Division of the Chicago Regional Office.

"The Adjudication Officer's office was destroyed and other areas adjacent to that room were extensively damaged by fire and water.

"There were no veterans' records in the Adjudication Officer's office at that time. Some veterans' records in the Assistant Adjudication Officer's office were scorched from the intense heat, as were some in the filing cabinets nearest the fire, but there was no irreparable damage.

"Several efforts were made to obtain an explanation of Mr. DeYoung's allegation of the loss of Agent Orange 526 claim forms. All 526 forms were accounted for in the individual veteran's claims folders. It was learned that a handwritten listing in the Adjudication Officer's desk contained the names and file numbers of veterans who had filed claims identifying Agent Orange as the disability which had been received by that office. This personal reference list was destroyed but was re-constructed based on records maintained elsewhere in the Division."

So just for those of you who might have had some lingering doubts about claims that had been destroyed that apparently did not occur and there was no loss of that process as a result of the fire.

MR. DeYOUNG: Excuse me. I double-checked that. My concern in asking the question is answered. The way it was brought to me by the veterans who were concerned about it was that a locator list of some sort which maintained the contact or could potentially maintain re-contact with these 500 and some odd veterans was destroyed.

Now, it's my understanding that this has been recompiled, so that that fire at the Chicago RO will not cause any problem, as I understand.

DR. SHEPARD: Thank you.

To those of you who have not signed in, please do so in the book at the rear of the room. We are very anxious to maintain a list of attendees.

Also, we would like to establish and maintain a mailing list of interested individuals. Please include your address so that we may send you materials from time to time-- notices of meetings, and that sort of thing. We would appreciate your doing that.

Just a few other brief comments. As indicative of the continuing high level of interest in the Agent Orange program and issue, there has been considerable interest on the part of congressional committees. And as many of you, I'm sure, know, we have had during the past

few months three hearings -- on September 10th, the hearing before the Senate Committee on Veterans Affairs; on the 16th of September, a hearing before the House Committee on Veterans Affairs; on the 25th of September, the House Committee on Interstate and Foreign Commerce, Subcommittee on Oversight and Investigation.

That latter one is the first time that the VA had been asked to testify before that committee.

For any of you who are interested, we have copies of the prepared statements that were used, and we would be happy to supply those to you. I think, as a matter of fact, in the package to the members, there is a copy of one of those hearings statements.

Some of you are aware of the fact that I was privileged recently to attend, in Rome, an international workshop on dioxins. This was held the 22nd through 24th of October. I'll just make a very brief report on that meeting.

The meeting was sponsored by a number of groups, two international societies: One, the International Society of Environmental and Analytical Chemistry, and the International Society of Toxicological Environmental Chemists.

In addition, the Instituto Superiore di Sanità, which, I guess, would correspond to the National Institutes

of Health in this country, a regional office set up in Seveso by the Lombardy region, the National Research Council of Italy, and the Hoffman-LaRoche Company of Switzerland were involved.

It was a very full three-day meeting. Sessions went from nine o'clock in the morning until seven-thirty in the evening, and was very well attended. I would guess there were 100 to 150 scientists and participants. A total of 56 papers were presented in six general areas.

First, a section on analytical methodology, in which many papers were presented on such interesting topics as isomer differentiation of the 22 isomers of TCDD. We've been talking a lot about the difficulty of separating these 22 isomers, not all of which are toxic, but some of which are very toxic. And it was interesting to learn that the technology does exist for the separation of these isomers.

Another section on environmental fate and levels discussed the effect of the environment on these chemicals.

There was one very interesting section entitled The Incineration Story. There's a very high level of concern in many parts of the world on the effects on the environment of municipal and chemical incineration, solid

waste disposals and chemical disposals. And many interesting theories were propounded as to how some of these chemicals are formed and released into the atmosphere. So there was a very interesting section on that.

There was a section on biochemical toxicology and metabalism; another section on animal toxicology; and one section on observations in men.

There will be a transcript of the proceedings of this meeting, which I hope will be out in another couple of months. I will receive a copy as an attendee, and I think it will be interesting to make distribution of that information and incorporate it in our body of information.

It was very interesting to me to see how many individual company scientists are really concerned about the TCDD and related compounds. It was really an eye opener to see the high level of interest and the efforts that are going into solving some of these problems.

We think in this context of herbicides as being the main issue, and, of course, for the Agent Orange problem it is. But there are many other sources of dioxins. In fact, the ubiquitous nature of dioxins is something I had not fully appreciated. And this was brought out in these discussions.

Well, so much for that. I recommend Rome to you. It's a beautiful city. The weather was lovely and

we really enjoyed being there.

Any questions on that? As I say, we will have the proceedings of the meeting.

DR. MURPHY: Dr. Shepard.

DR. SHEPARD: Yes, sir.

DR. MURPHY: I recently saw a three-line newspaper statement about a suspicion that 200 or 800 sheep had been grazing in the Seveso area and had become ill. Was that discussed at that meeting?

DR. SHEPARD: No, it wasn't discussed. It happened while the meeting was going on. This was on Thursday the 23rd of October, right in the middle of the meeting. I didn't hear about it until I got back. Apparently it appeared in the press, and I was asked to look into it and report on it to the Administrator.

As a result of my having been in Rome, I knew who to call, and I did call and found out. Yes, there were 200 sheep that had been grazing in the vicinity of Seveso, or that 200 of the sheep which had been grazing died in a short period of time. The situation was carefully analyzed by the Italian government operation in that area, and it turned out that these 200 sheep were part of a flock that had been brought from some great distance to graze-- I don't know whether they were being brought to market or exactly what.

But anyway, they had stopped off in Seveso, and because some of the area has been restricted in terms of farming, there was a very lush field of grain and grass, and so the sheep dined copiously on this and all got the bloat. Apparently this is a common occurrence under these circumstances.

Sixty some odd sheep were autopsied. They actually analyzed the livers of these sheep and found no dioxin. It was interesting getting that information.

One thing I should have mentioned: On the human effects, observations in man section of the conference, I was hoping that we would get some rather definitive information on Seveso. There were three or four reports on the early experience in Seveso.

As a matter of fact, there was a dermatologist from England, Dr. Crow, who presented some beautiful slides and gave a very learned discussion on chloracne and described the incidence of chloracne among especially children in Seveso.

There are two or three commissions working on studying and following the human effects. They reported very early fragmentary information. But it's interesting that they have expressed and are looking at many of the same concerns that we are in this country, and particularly birth defects and incidence of cancer. Their very

preliminary impression is that there is no significant increase in the incidence of cancer or birth defects, but they quickly admit that it's still very early to tell. The Seveso incident occurred only four years ago, and so that their epidemiological data is still not collected and analyzed. They were presenting some preliminary reports, and we'll be following that course very, very closely.

Well, let's move on. We have some reports on updates of VA activities which we'll discuss briefly. On the subject of our literature analysis that was mandated by Public Law 96-151, we have had a number of proposals to the request proposal. We have reviewed these proposals and have selected the top three and our contracting office is now reviewing those. Hopefully, we will have a contractor selected in the next two to three weeks so that we can proceed with that analysis.

I expect it will probably take several months to complete, but we are anxious, of course, to see it under way.

DR. MURPHY: Can you tell us who the top three are?

DR. SHEPARD: I think that is privileged information for the time being. I am not sure whether they have been contacted yet. I hope they have. I think that information will be out very soon.

DR. LINGEMAN: Dr. Shepard?

DR. SHEPARD: Yes.

DR. LINGEMAN: Dr. Kraybill was the one who served on

this committee, and can you tell us who else served on this committee?

DR. SHEPARD: Yes, Dr. Robert Miller, Dr. Adrian Gross, and a research librarian from the National Library of Medicine, Joan Burnside.

Any other questions on that?

I will ask Dr. Hobson to bring us up-to-date on the epidemiological study.

DR. HOBSON:

Since most of you know the story of this epidemiology study I will review it extremely briefly for those of you who do not. The same Public Law 96-151, mandated the VA to conduct an epidemiological study of the effects of phenoxy herbicides in Vietnam.

The Request for Proposal was issued. We received bids under it. The technical selection of the successful candidate was made, and before the actual negotiation began the matter was referred to the General Accounting Office which is now in the process of considering it. The best estimate we have of the date at which that consideration will be completed is sometime around December 1st or the middle of December. The sooner the better so far as we are concerned. We would like to proceed with the negotiation of the contract

and get the design of the study under way.

DR. SHEPARD: I failed to mention that Dr. Hobson has now joined our office, and we are most pleased to have him as a member of our team.

Next I would like to call on another member of our staff -- Excuse me, I'm sorry.

MR. DeYOUNG: Am I to understand, then, that when the GAO finishes in December that the VA will -- the contractor will pick it up and begin work then?

DR. SHEPARD: Hopefully so, yes.

MR. DeYOUNG: Well, we have to negotiate it with him.

DR. HOBSON: That's not the final step in the process.

MR. DeYOUNG: Do you have any projection for a start date?

DR. SHEPARD: We have stopped guessing.

MR. DeYOUNG: In 1981?

DR. SHEPARD: Hopefully. That is for the design of the study now. We have to keep making that distinction. This contract is for the design of the study, not the conduct of the study. We have to have a design before we have a study.

Any other questions on the epidemiological study?

Okay. I would like next to introduce another member of our staff, Miss Nancy Zanis, who will bring you up to date on the Agent Orange Registry.

MISS ZANIS: All of the VA Medical Centers and Out-patient Clinics quarterly send us a copy of the Agent Orange

exam and the Agent Orange code sheet for each veteran that is examined. The information is sent to my office and we collect it and send it to the Department of Justice for use in the litigation cases that are going on.

In October we sent them 52 boxes of these documents, and we plan to send them quarterly shipments as we receive them.

The Medical Centers and Outpatient Clinics also send us quarterly a copy of the code sheet on the veteran. These code sheets are sent to the Medical Administration Service here in Central Office. The code sheets are reviewed for accuracy and completeness and then are mailed to the St. Paul Data Processing Center where they are input into the Agent Orange Registry.

There are approximately 16,000 records in the Registry at this time. We are currently working on updating the ciruculars and instructions dealing with the Agent Orange issues. We are also working on a follow-up questionnaire which will be sent to the veteran, all the veterans in the Registry. These questionnaires will request his current address and we will also ask him some general medical questions. The information will be returned to us and we will input this into the Registry data.

DR. GROSS: That is 16,000 records, not 16,000 claims.

MISS ZANIS: 16,000 records.

DR. GROSS: How many claims would that be roughly?

MISS ZANIS: I am not sure.

DR. SHEPARD: This doesn't have anything to do with claims, Dr. Gross.

DR. GROSS: Not claims. I mean persons --

DR. SHEPARD: Yes, approximately -- in excess of 30,000 individuals who have been examined, there is a lag time between conducting the examination and actually getting that information into the data file.

DR. GROSS: All right, sir.

DR. SHEPARD: Any other questions on the Registry?

QUESTION: Would you clarify what you mean when you say "sent to the Department of Justice for purposes of litigation?" I don't understand what you mean.

MISS ZANIS: We just box up all of the Agent Orange documents that we receive here (code sheets, questionnaires, and medical documents) and supply the Department of Justice with copies of that material. They have to make them available to the attorneys.

DR. SHEPARD: Yes, Dr. Murphy?

DR. MURPHY: Has the VA or Congress or anybody

allocated any additional funds to the hospitals and the environmental medicine or environmental physicians for staffing or updating the staff to handle both the increased load that -- incoming patients as well as the question of follow-up which we hear so often is something that the veterans are displeased with? Has there been any assistance to the hospitals in the field?

DR. SHEPARD: No. The hospital --

DR. MURPHY: Anybody working -- I gave you that -- I've got a very vocal one in Houston that keeps asking me.

DR. SHEPARD: To date no additional resources either monetary or personnel resources have been allocated to the medical centers for the purpose of carrying out this effort. It has been thought that when you look at each facility, although we have had a total of 30,000 examinations, with the exception of a few stations in which there has been considerable activity, Minnesota, for example, the actual number of exams is somewhere between 1 and 200, maybe up to 300 in some of the busier places, so that it has not been a major impact on any one medical facility.

That is not to say that there is not some substance to the fact that this has been a task that has been laid on to

our facilities without additional resources, and, therefore, there may be some concern. I think that as time goes on, well, let me say that we are looking into the impact in certain medical centers and there are a number of medical centers who which have expressed concern and so forth. So we are looking into the issue of whether or not additional resources need to be allocated in order to continue the efforts of the Registry, but so far I think that resources have not produced -- or lack of additional resources have not produced a significant negative impact on the process.

DR. FITZGERALD: Dr. Shepard, perhaps I could help Dr. Murphy. The VA in its budgeting does not budget by line item, and as such, the hospital has significant control over the utilization of its entire budget, and they will utilize their budget, I'm sure, wisely as far as the needs for any given time in the institution.

DR. MURPHY: Well, that is a good point, and it had occurred to me that maybe the solution was not an increase allocation, but a reallocation of resources. and I have a very limited exposure to that, but I have the impression that that is not so easily accomplished. You have one environmental position responsible for this who in probably most cases, hasn't much background in this area. The physician has had to reeducate him or herself, has no additional staff, and sometimes perhaps really gets cut short in being able to accomplish

what they themselves in their own conscience feel is a good job in response to that.

I, for one, would like to go on record as recommending that perhaps this office do what they can to encourage the chiefs of hospitals of whoever to look into the needs of these environmental physicians.

DR. SHEPARD: Yes, certainly that has and is a continuing process. We are making every effort to encourage, guide, what have you, motivate Directors and other responsible individuals in our medical facilties to provide all the available support to this effort. We, of course, here Central Office are providing information, and are maintaining contact. We get many calls from environmental physicians, and I hope are providing the support that they need.

If anybody knows or has some evidence to the contrary, we would certainly like to know about it.

DR. MURPHY: Well, in that vein I would like to add one more thing to the record. Henry Cromwell, a physician in Houston, has called me and I have referred him to you. He has recently said that he has received information and thanked me although I deserve no thanks for helping him get this, but I think he is wrong. I didn't really help him. You did.

DR. SHEPARD: Well, you encouraged him to call.

DR. MURPHY: He appreciated all that.

DR. SHEPARD: Fine. Thank you, Dr. Murphy. Any

other comments? Yes?

MR. DeYOUNG: I have some questions concerning the Registry, Mr. Chairman.

DR. SHEPARD: Yes.

MR. DeYOUNG: The Registry in the field is kind of a sore point. I want to clarify this because some of my questions may strike you as impertinent otherwise.

The VA is professing or holding up the Registry as one of the prime objectives of the Agent Orange research, and as such, I am concerned about its efficiency and the speed and accuracy with which it is going to give us answers.

If I have got my figures correct we are talking about 30,000 plus exams now nation wide, around 16,000 of which are currently codified and computer manipulable if that is the right word. Is that correct, that a little over 50 percent are not in computer form?

DR. SHEPARD: Close to that, yes.

MR. DeYOUNG: What is the story on the rest, the other 14 and some thousand?

DR. SHEPARD: Let me just correct what may be a misconception on the Registry. I've said this many times, but I guess it bears repeating. The Registry is in no way to be considered a research tool. Okay? The Registry is an effort to identify those Vietnam veterans who are concerned about their exposure to Agent Orange and its possible health

effects, and that is all the Registry really is.

Now, in the process of doing an examination and asking the veterans to answer questions, obviously there is information generated in that process. That information is being fed into a computer data bank in order to enable us to look at what kinds of problems the veterans are experiencing, their symptomatology, and, hopefully, to come up with some description of the state of health of these individuals. But beyond that, we cannot make any claim that this is in any way a part of an epidemiological study or really any kind of a research effort other than to say that we are interested in finding out what kinds of problems these veterans are experiencing and take a look at their health problems.

Another important purpose of the Registry is that it will provide a mechanism for getting back to these veterans and calling them in for further study, further examination, information sharing, and that kind of thing, as scientific evidence is accumulated from other sources.

We do have or we are developing a description now of some of the information that I alluded to.

MR. DeYOUNG: Will you wait until the 30,000 are complete before you begin to get a picture out or will you process the 16,000 some that are in there already?

DR. SHEPARD: We are getting reports on the ones that are now in the computer bank. By virtue of the fact that

the information is rather general in nature, it's difficult to make any conclusions as to the types of physical findings or abnormalities, that are being encountered. We are taking a look. In other words, we have a description of groupings of physical problems. We are not trying to get more detail in terms of what exactly those problems are.

MR. DeYOUNG: Okay.

DR. SHEPARD: We can tell you what percentage of the group has complained of what kinds of symptoms.

MR. DeYOUNG: This strikes me as essentially the same thing that the Task Force members did informally two and almost three years ago which is to take reports of the symptomatology and signs and so forth from the veterans and simply write this down and count recurrences and so forth. That is what we are talking about, so it is not hard research in the sense that the National Cancer Institute would recognize.

But even so, I mean assuming that it is even for the moment garbage, when will some pictures begin to emerge from this, when will we begin to see a computer profile coming out here?

DR. SHEPARD: Well, as I say, we are working -- I can't, if you want a date as to when this will be accomplished, it is an ongoing process. There isn't a finite termination date. This is an ongoing process.

The reason for the lag between the 30,000 examinees and the 16,000 that are in the computer is it takes a while to encode this information, to edit it, make sure we don't have repetitious information, and get it into the computer in a form that can be retrieved.

I would think that in the not-too-distant future we will be coming out with a description of what we have in the computer file now. We are working on accumulating that information. We are beginning to get reports in, and I think before long we will come out with a simple statement as to a description of that. Any other questions on the Registry?

MR. DeYOUNG: Excuse me. It is my understanding that there is a new form being generated to save the step of hand coding. Is that correct? Where does that stand right now? As I understand it, right now you are generating two sets of documents, one that is being done at a local level at the RO, and then that is being converted to a coding form for the computer use. Now, I had heard some rumors to the effect that a new form was being created which would mesh those two and eliminate a step and, thereby, speed up the process. Is that correct?

DR. SHEPARD: Okay. What we are going now because we have learned a lot from what has already happened. Some of the things that we have learned are that many veterans don't

have very accurate information on their exposure. The useful information, the physical finding kind of information, the objective findings that physicians examining these veterans have noted, is not being encoded in a readily usable form, so we are going back to do a major revision of the Registry in order to make the information more usable and also -- in other words, ask the questions that we think we can get answers to and get more usable medical information into the computer so we can then analyze it, evaluate it, not analyze it, but retrieve it more directly. I think there is a rather indirect process that we have to go through in order to retrieve detailed information.

MR. DeYOUNG: Will there be any reexamination of veterans necessary for that or is it all compiled?

DR. SHEPARD: No, I don't think -- see, the basic process will not change. A questionnaire will be answered. A physical examination will be done. A base-line group of laboratory studies will be done. So that process need not be changed. The processes of that part of the process is fine. The part of the process that isn't fine is how that information gets encoded, how it gets put into the computer bank, and the usefulness of it and its retrieval process. That is the thing that is going to be changed.

MR. DeYOUNG: Will the 16,000 that have already been processed be reworked in the light of this new method or will

they be handled as they are right now?

DR. SHEPARD: We will hope that we will not have to reexamine the veterans. We hope we will not have to bring them back for a reexamination. We hope that the information that is currently in the record can be reworked in such a way as to be encoded properly using the new format. That is one of the points we are going to be looking at very closely to see what is there now and how that can be reworked in order to make the information more useful.

MR. DeYOUNG: Thank you.

DR. MURPHY: You mentioned that Minnesota was different than the rest of them and you said you had --

DR. SHEPARD: Right. Okay. The state of Minnesota decided to organize an outreach program and contact virtually every -- attempt to contact virtually every Vietnam veteran in the state. This was helped by the fact that Minnesota provided a bonus to Vietnam veterans. The bonus list promoted the organizing of cities, counties, and towns for this effort. The other factor that made this state exceptional was the fact that in Minnesota apparently there is a very strong, well-coordinated, group of veterans' organizations and apparently a higher representation of Vietnam veterans in the traditional service organizations thatn exists elsewhere in the country. That combination of factors enabled the state to organize an outreach program which resulted in several thousand Vietnam veterans applying for the examination at our hospital in Minneapolis.

That is why a hospital in Minneapolis has many more examinees on their records than the other hospitals. It simply was an outreach program that was initiated by the state in conjunction with the veterans' groups.

Now I have heard rumors to the effect that other states are thinking about doing a similar effort. I was recently out in California, and I understand that there is a movement afoot to initiate a similar program in the state of California. We hope to stay ahead of that in order for us to be prepared to handle these veterans in our medical facility in a smooth and expeditious way.

I must congratulate the hospital in Minneapolis for taking on a tremendous workload without very much advance warning, and they really did a superb job.

MR. DeYOUNG: One final thing on the Registry, please, Dr. Shepard. Could the Committee be provided with copies of the working papers of the Registry, samples and so forth of the codifications and the exam forms and such?

DR. SHEPARD: Yes, we plan to before we reach anywhere near a complete revision, we plan to discuss it with this Committee and representatives of veterans' organizations and involve them in the process of the formulation, definitely.

MR. DeYOUNG: Thank you.

DR. SHEPARD: Well, let's move on. Donald Rosenblum,

also on our staff, will mention a new initiative of our office, namely the Agent Orange Bulletin, which we had hoped to have ready at this time. Mr. Rosenblum.

tart 1B MR. ROSENBLUM: Thank you, Dr. Shepard. The Agent Orange Bulletin has been established primarily to provide environmental physicians and other medical staff at VA installations with information regarding the recent developments concerning herbicide orange and related matters. Copies will also be made available on an individual request basis to other interested parties. A copy will be sent to all Advisory Committee members.

The first issue of the Bulletin will soon be available. It will include articles concerning the VA's response to the Agent Orange matter, namely, the establishment of the Office of Special Assistant to the Chief Medical Director for Environmental Medicine headed by Dr. Shepard, the Policy Coordinating Committee chaired by VA General Counsel Guy McMichaels, this Committee, our Data Analysis and Chloracne Task Forces, and the Agent Orange pamphlet and videotapes.

The first issue also contains the analysis of the European studies by Dr. Hobson, some Agent Orange examination statistics, library notes, a calendar of events, and an article concerning progress in the epidemiological study, and literature review.

Comments, criticisms, and articles from environmental

physicians and other interested staff members are encouraged. We would also be delighted to receive input from members of this Committee.

Material should be sent to me, Donald Rosenblum, Mail Symbol 102, VA Central Office, Washington, D.C. 20420. The Bulletin will be published on a periodic basis approximately once every two months. Thank you.

DR. SHEPARD: Any questions on the Bulletin? We had hoped to have one ready for this meeting, but it's just short of that, but we are encouraged that it will be coming out very soon.

MR. ROSENBLUM: Very soon. Thank you.

DR. SHEPARD: Okay, Mr. Layne Drash will bring us up-to-date on the progress of the videotape.

MR. DRASH: Thank you, Dr. Shepard. Good morning, everyone. Very quickly I would like to give you a rundown of what we are doing in regards to our educational efforts, not only for Vietnam veterans and their families and the general public, but also educational videotapes or films with which we can educate our health care staff, including our environmental health care physicians and dermatologists and whatever staff are concerned with working with veterans coming in for the Agent Orange exams.

We are actually speaking in terms of two videotapes. The first one is in the final stages of preparation. On

October the 16th an unedited copy was shown to the Administrator and to members of the Central Office staff in which they reviewed it, made comments, and at which time the suggestion came up from the Administrator that we should share this with the major service organizations for their comments and review and suggested changes.

Consequently, on October 26th, I believe, the service organization representatives did meet in Central Office and reviewed the videotapes and provided comments to the VA, and some of these recommended changes have been put into the particular film that was reviewed at that time. The film that was reviewed was the one that was made to be shown to the veterans and the public. It provides a very brief overview of the utilization of Agent Orange in the Southeast Theater of Operations including Vietnam and gives a rundown on many of the VA's activities, including the Agent Orange Registry in dealing with this very complex issue.

We are looking for a target date of around the first week in December in having this particular tape ready for distribution to the field. Our distribution of the videotape as we see it now and this was discussed only yesterday in the Policy Coordinating Committee, again chaired by Mr. Guy McMichael, General Counsel. The distribution, as we see it, would be -- we would provide one copy to each of our 172 VA Medical Centers, 1 copy to each of our 8 independent Outpatient

Clinics, 1 copy to each of our 91 Outreach Centers, and we will maintain copies here in Central Office for utilization by service organizations and the general public, and we will be providing probably 1 copy to each of the 57 VA Regional Offices that are scattered throughout the nation.

I won't go into the details of the film too much. I believe Mr. DeYoung is going to discuss that during his part of the program.

The second videotape that we are talking about is really in the conceptual stages at this point. It is a much more difficult film to put together because it will be utilized for the training of our environmental physicians and our dermatologists. Consequently, we have to take a different approach in preparing this since it will be a staff training instrument.

It may be more than one videotape. It may be something that is supported by written materials to support the program that is presented. We are looking -- we don't have a target date really for that film, but we are starting to work on it at this point with the Regional Medical Education Center in St. Louis, and I would anticipate that it would probably take about a year, give or take a couple months, for a final unedited copy to be ready for review.

I would be glad to answer any questions you might have on either of the films.

MR. ENSIGN: I'm curious if you have any plans to utilize public service types of commercial television cable networks around the country to show this film. Have you thought about that?

MR. DRASH: Yes, when we distribute these to our field facilities we would anticipate that they would utilize it for public service announcements or what have you. We have built within the first videotape that we prepared the potential for commercial breaks, so it could be utilized for that purpose. We are encouraging that the videotapes for the veterans be utilized within the areas of our Outpatient Clinics where they can be shown either upon request or they can be put on a continuing rotating basis for showing to the people that come into the Outpatient Clinic. Then it will also be available by virtue of anyone writing into the VA Central Office and requesting to see it.

So it will be available to the media. It will be available to the general public, and what have you. Any other questions? Thank you.

DR. SHEPARD: I might just add that we definitely would encourage use by the media. In fact, the film has been structured so that it can be readily used by the media, so we are hoping that that will occur.

And I would also like to announce that we are going to show the tape at the close of this session, so you'll see

in your programs at 11:30 we'll be showing the tape.

Any other questions?

I see they have turned the heat on. I hope we will thaw out shortly.

Next I would like to call on Dr. Carolyn Lingeman from the Armed Forces Institute of Pathology and the National Cancer Institute to discuss the status of the AFIP registry and also review the protocol for the soft tissue sarcoma study that is being proposed. Carolyn?

DR. LINGEMAN: We will discuss these together because they are both involved in the same set of materials. I would like to start off by saying that maybe there are some people who do not know what the AFIP is. The Armed Forces Institute of Pathology (AFIP) was founded more than 100 years ago by the Army. The purpose was to collect and review materials from Civil War casualties to better learn to prevent and cure diseases that were responsible for these casualties. In those days many deaths were due to tetanus, malaria, and other infectious diseases that took more lives than the acute battle wounds

So it is very fitting, I think, that more than 100 years later, the AFIP resources are still available and can be used to combat the new horrors of modern warfare, namely the chemicals. The AFIP now has nearly 2 million accessions in its 33 registries.

The AFIP Registry listed on the program is a pathology registry which was started by Dr. Nelson Irey who is Chairman of the Department of Environmental and Drug-Induced Pathology at the AFIP. This is one of the newest registries. There are 33 registries in all.

Most of the AFIP registries are devoted to single organ sites. For example, there is a Registry of Hepatic Pathology for liver diseases. There is another egistry devoted to the diseases of the lung. There is also one for soft tissues. Dr. Irey's registry, which is about four years old, was formed to collect material from people who believe that they had been exposed to environmental agents. Two years ago Dr. Irey began the Agent Orange Pathology Registry to collect material specifically from Vietnam veterans who believed that they had been exposed to herbicides.

Presently there are only about 90 accessions in the Special Agent Orange Pathology Registry. We hope to find out ways to improve the communications with the pathologists or whatever we have to do to get more material in.

About 40 percent of all AFIP accessions come from service hospitals, Air Force, Navy, and Army hospitals all over the world. Sixty percent are from civilian sources. So there is quite a collection of materials to be studied and quite a bit of individual expertise among pathologists on the staff.

I have the opportunity to utilize the materials, to do some of the cancer studies.

With Dr. Shepard's help I hope to go through the records in the VA's Agent Orange Registry to identify the cancer patients and see if we can get biopsies from all of these patients sent to the AFIP for review.

Many epidemiologic studies are hampered by lack of consistent pathology diagnoses.

DR. MURPHY: I would just like to ask, the is Dr. Irey's -- is that right, Irey?

DR. LINGEMAN: Dr. Nelson Irey.

DR. MURPHY: And that is the AFIP Registry setup specifically for suspicion of chemical-induced disease, do I understand that?

DR. LINGEMAN: There are actually two registries

involved. One is the Registry of Environmental Pathology. The other is the Agent Orange Pathology Registry, which is actually part of the Environmental Pathology Registry.

DR. MURPHY: But that only has 90 entries, is that --

DR. LINGEMAN: So far the Agent Orange Pathology Registry has only has 90 entries.

DR. MURPHY: Does this -- you mentioned biopsy. What effort has there been to particularly focus on dermatoses of various kinds? I got a question from one of our physicians who reads the minutes of these meetings. About two meetings ago -- I've forgotten the names of the principals involved -- but there was a recommendation that people report and send in biopsy materials related to various dermatoses. I am sorry I can't be more specific than that.

He was questioning me about who takes these -- where can I get the information -- is this the Registry that would receive that or is Dr. Irey the person that needs to be contacted?

DR. LINGEMAN: Yes. The reason I say approximately 90 is because some are not completed. The Registry is continually being updated. We have had several skin biopsies from Vietnam veterans but none are chloracne.

But the average dermatologic lesion that is seen at the VA hospitals does not warrant a procedure like a

biopsy. Only severe lesions would be biopsied. Most of the time this would not be done unless maybe there was a suspicion that it was chloracne.

When Dr. Irey receives a skin biopsy he routinely sends it to the Department of Dermopathology where we have a group of pathologists who specialize in diseases of the skin examined it. The diagnoses are made by pathologists with great experience in diseases of the skin

It is possible that some skin biopsies may have gone to the Skin Registry directly without our knowing about them. We are constantly working within the AFIP to alert pathologists in the other departments about our interest in material from patients who may have been exposed to chemical,

DR. SHEPARD: Yes. In that connection, Carolyn, I think that we need to redouble our efforts to contact all -- certainly all -- military hospitals and all civilian hospitals to encourage them to identify Vietnam veterans and send either surgical or autopsy materials to the AFIP. In conjuntion or in connection with that effort we have taken some steps. We have reissued our VA circular on the subject. We have made it the subject of a recent hot-line discussion with all of our medical facilities. In addition, we have asked the Department of Defense to request that the word be reemphasized to all military hospitals and it is my understanding that a memorandum

has gone out from the Secretary of Defense or the Undersecretary of Defense for Health Affairs to all three Surgeons General for dissemination to all military hospitals, and I hope we will begin to see some reflection of that.

So we will continue to encourage all medical facilities, be they Federal or non-Federal to send in and identify Vietnam veterans and make these materials available to the AFIP for their review and to be entered into the Registry.

Yes, Dr. Gross?

DR. GROSS: I would just like to make a comment. Dr. Lingeman is much too modest to mention that the AFIP is probably the finest pathology institution in the world as far as competence, material. Every pathologist is practically busting his or her tail end to spend a period of study there, education, looking at this tremendous collection.

Another question, Dr. Lingeman. Is there available in the Registry material on experimental animal studies that have been involved in dioxine phenoxy herbicides or is that in the veterinary, and if so, what is the connection? Do you plan to access experimental materials?

DR. LINGEMAN: We will try to get some of this material. In fact, we hope that the National Cancer Institute will eventually make the AFIP its final repository for all experimental work that its bioassay program has done. This is what I would like to see done. At the present time this

material is housed in a different facility and it is considered privileged information, but eventually we would like to see that happen.

There is a very active veterinary pathology registry which interestingly was formed to take care of the horses when the cavalry was the big thing, and it sort of changed its pitch over a period of time too.

DR. GROSS: There are military dogs now and --

DR. LINGEMAN: Right, military dogs. All the materials, by the way, from the military dogs are there and available for study and are being studied. There is a yearly report that goes out from the Veterinary Pathology Department.

I would like to say that I am not being modest at all , Dr. Gross, because I am paid by the NIH and I have the privilege of working at the AFIP , so I will agree with you. This is a world-renowned institute of very fine pathologists who are recognized everywhere.

DR. SHEPARD: Any other questions on it? Yes, sir.

MR. DeYOUNG: Yes, just for clarification, now. I understand that -- if I understand this correctly, all biopsy material now from VA institutions is automatically forwarded for a Vietnam veteran, is that correct? Or is there some identifier that is being used?

DR. SHEPARD: Any Vietnam veteran who undergoes a surgical procedure or who dies in a VA facility and on whom an

autopsy is performed, each one of those medical facilities is being directed to send material to the AFIP. Now, when you say automatic, nothing is automatic.

MR. DeYOUNG: Well -- I understand.

DR. SHEPARD: But, obviously, there are several human factors involved, and so we are trying to -- as I say we are redoubling our efforts to try and make sure that all such materials do get forwarded to the AFIP.

MR. DeYOUNG: Is it standard procedure, then, for all cancer biopsies to be forwarded to AFIP for a Vietnam veteran, living or deceased?

DR. SHEPARD: That would be included in a surgical procedure, so biopsy material, autopsy material --

MR. DeYOUNG: We had mentioned autopsy, but I wasn't sure about surviving those.

DR. SHEPARD: Right, surgical material.

DR. LINGEMAN: Dr. Shepard, isn't it true that as part of the VA's pathology quality control program -- that a certain percent of biopsies and autopsies from all the VA hospitals are sent automatically to the AFIP?

DR. SHEPARD: I am not sure of that detail.

DR. HOBSON: That is true. That is part of the quality control of the pathology work done in the Veterans'

Administration. I don't know the details of it, but the material is sent routinely to the AFIP for checking on the VA pathologists.

DR. LINGEMAN: I think a certain percent are sent. Usually if a case is not identified as an Agent Orange case, we may not see it. We have a problem with the medical profession as a whole because in the average medical history, an environmental history is not taken very well, if at all. Once in a while the patient's occupation will be asked, but often it is not. I think we have a big job to educate the medical profession starting with students in medical school, to get the physicians in the habit of asking about the occupational history. Usually when a request is made to a pathologist to give a diagnosis on a biopsy, there is not much history given. We would like to get the surgeons in the habit of putting the environmental history on the pathology request form.

Some think that the pathologist does a better job if he makes a diagnosis without knowing the history. Maybe he can be more objective if he is looking at the slide and saying, "I think it's cancer," or "I think it isn't," without being influenced by the fact that it is an Agent Orange case. I don't know.

DR. SHEPARD: Yes, sir.

MR. ENSIGN: I want to be sure I understand. Then

any Vietnam veteran who develops a malignancy or has a biopsy taken, this Institute would be interested in receiving material from that person's physician in some way? That is known as the policy you are trying to engender?

DR. LINGEMAN: Right. I think that many of these biopsies are being done in civilian hospitals, and I think this is something maybe the veterans themselves should be acquainted with so that they can ask their doctor to ask the pathologist in that private hospital to send / the biopsy to the AFIP should be earmarked to go to the Special / Pathology Registry. Otherwise, it will go to the Accession Department, and if it is a liver case, it will go to the Liver Registry and so on. If perhaps the veterans' groups themselves could publicize this just a little bit it would be helpful.

DR. SHEPARD: Another question I haven't been quite clear on, Carolyn, where actually should it be sent in the AFIP, to the Department of Environmental Pathology?

DR. LINGEMAN: Yes, it should/be labeled: Attention, Agent Orange Registry.

DR. SHEPARD: Thank you.

DR. GROSS: Would you want all these things to come to you routinely even if nobody suspected exposure to Agent Orange? You would be flooded with material there.

DR. LINGEMAN: Well --

COL. HODDER: That's what we want.

DR. SHEPARD: That's what they say that want.

DR. LINGEMAN: The AFIP is set up to handle huge volumes of material. They have had almost 2 million cases already, and --

DR. GROSS: Yeah, but that's in 100 years.

DR. LINGEMAN: Right. The AFIP is a mass production facility. I don't think there is a fear of being flooded. If it comes to that, I think maybe that would be some impetus to add some new staff. I don't know.

DR. SHEPARD: Okay, Carolyn, then, would you like to go on to tell us a little bit about the progress of this soft tissue sarcoma study?

DR. LINGEMAN: Okay. I would like to preface that by talking just a little bit about the carcinogenicity of dioxin and herbicides in general. I think it is generally agreed that 2,4-D and 2,4,5-T in themselves are not believed to be carcinogenic, but that they actually have not been too well tested. The tests are inconclusive.

However, we do have evidence that TCDD itself is a carcinogen in rats and mice

in several body systems when given orally. The National Cancer Institute, under contract to a private organization, is in the final stages of preparing reports on two studies of testing dioxins, both by the dermal and by the oral route.

And the final reports are under review, but should be available in a short period of time, and we will make these available to the committee. They will be public information for anybody else who wants them.

The preliminary reports confirm the carcinogenicity of TCDD, so that is not an issue.

Results of mutagenicity studies are somewhat inconclusive, and I think there is a need for these to be repeated and reevaluated.

We have a report by Dr. Henry Pitot which was circulated to the Committee members, a report which appeared in the October 1980 issue of "Cancer Research" reviewing and reporting on some new experiments concerned with the mode of activity of TCDD in its carcinogenic activity. You may be aware that being a carcinogenesisin a human or animal system can involve several different mechanisms. It does not seem from what is known that TCDD acts directly on DNA. It seems to work by a different mechanism and we are not certain what it is. Some experiments reported by Dr. Pitot seem to indicate that possibly TCDD acts as a cancer promoter. This is shown in an experimental system, a two-stage system. In order for TCDD to be carcinogenic, an initiator is required. This means that another chemical or virus or radiation of some cases would be required to act on the DNA first, and, not being

carcinogenic in itself, to make this cell vulnerable to the promoting activity of dioxin.

There are other examples of cancer promoters, including phenobarbital. That is again an experimental system. These are experimental results which cannot be extrapolated directly to human studies. We should however take these experimental observations into consideration in planning the epidemiologic studies. We believe that the carcinogenicity of TCDD requires a long period of time rather than a single exposure.

If TCDD is a cancer promoter in man, we don't know what the initiator might be, and this is an area for research.

I would like to review, then, the types of epidemiologic studies we might wish to do when trying to determine whether TCDD is a carcinogen in man. There are two basic types, the cohort study and the case control study. One good example of a cohort stury is that of the Swedish railroad right-of-way workers who have been exposed to a variety of herbicides, including the phenoxy acids.

The problem in a cohort study is that cancer is a relatively common disease and usually has a long incubation period so that long periods of time and large naumbers of people are required to provide meaningful results. Unless you encounter an unusual histopathologic type of neoplasm and you don't see the same one in controls, it is frequently difficult to determine whether significant differences exist between the two groups, this is, between the exposed and the non-exposed.

If frequent types of cancers such as those of lung or colon or the lymphatic system, sophisticated types of mathematical analyses may be required to determine if differences exist between the groups, and this is not always easy.

In the case of TCDD it is encouraging to note that in a cohort study of more than 100 men exposed 30 years ago during the industrial accident in Nitro, West Virginia, there were no excess cancers reported. So after 30 years that is a significant thing. However, it was a small number of people.

Among the 80 or 90 accessions that have been received so far by the AFIP Agent Orange Pathology Registry, relatively few have been neoplasms, and these have been the usual kinds that we would expect in men of this age group. We haven't seen anything yet to suggest an excess of any type of cancer in Vietnam veterans. We will need many, many more cases before any such judgement can be made.

I would like to say that we do have some statistics which can tell us how many cancers would be expected in men of various age groups. These have been collected world-wide by several different international organizations. We can predict that in young men, particularly those age 30 to 35, which would be the age group in which most Vietnam veterans are at this time, we can expect so many neoplasms of certain types. Cancer is a very common disease. It occurs at all ages. Men in their 20's and 30's are particularly susceptible to cancers of the lymphatic system and cancers of the testes. We can predict, from records of the Connecticut Tumor Registry that 6 or 7 out of every 100,000 white men ages 30 to 35 will develop neoplasms of the testes each year, and about half of them will die from the cancer.

If we project that figure over 10 years, we can calculate that 65 men of every 100,000 in the age group 30 to 35 would get a neoplasm of the testes in ten years. If we use a cohort of 500,000 men in that age group, 325 men would be expected to develop cancers of the testes in 10 years.

We can do the same thing for Hodgkin's Disease or for malignant melanomas or any other cancer, so that over a period of time, if we have enough people in the Registry, we can have some idea of how many cancers to expect and we can perform some statistical analyses to see whether the number observed were actually more than expected.

The other type of study which we can do is the case control. The AFIP offers a very, very fine repository of cases to do this kind of study. We have decided to do the soft-tissue neoplasm study first for two reasons. One is that there are two reports in from the Swedish literature that an excessive number of people exposed to phenoxy herbicies developed neoplasms of the soft tissues. Second, we were able to negotiate quickly with the Chairman of the Department of Soft Tissue Pathology at the AFIP who has agreed to let us use all the cases which are sent into his registry for consultation. Dr. Enzinger is a world authority on this subject.

Soft tissue neoplasms are frequently difficult to diagnose and they are frequently difficult to classify. They involve many different tissues such as muscle, fat, blood vessels, nerves, or connective tissues. We will have an opportunity to see if any one of these locations predominates in Vietnam veterans. We have been asked whether we are going to repeat the Swedish studies. The answer is we are going to try to do it better.

Our epidemiologist is a member of the Environmental Epidemiology Branch at the National Cancer Institute. He and hsi colleagues are preparing a questionnaire at the present time, and we hope to have this ready to go within the next few months.

We don't know how many soft tissue neoplasms are in the Registry at the present time, probable several hundred a year, so we probably will have a significant number to work with. However, some people have pointed out

that the time of exposure may not have been long enough. Now, you will recall that in the Swedish studies the time periods between first known exposure to herbicides and onset of a neoplasm ranged from 6 to 27 years. Some of the Vietnam veterans served as early as 1962 and 18 years would have passed. So we may be getting into this latent period.

If we don't get significant results in the first phase of the study, this can be extended. We will begin with cases diagnosed between the years 1975 to 1980. I think we should point out that soft-tissue neoplasms are very, very malignant neoplasms as a rule, and they kill rapidly, but some patients live a while. We will ask both the patients and the matched controls who do not have neoplasms whether or not they were in Vietnam, whether or not they believe they were exposed to herbicides, and whether there were opportunities for exposure to herbicides or other chemicals, carcinogenic chemicals, in the civilian sector .

We hope to figure out a way to check these out. If a person gives a positive history we hope to be able to check with the Department of Defense and find out if there is reason to believe that this veteran was in the area in which the herbicides were used. We also hope to be able to check out civilian exposure, and this will not be easy, actually very difficult to do.

I think most of the Committee members have had opportunities to look at the protocol which is still a preliminary one, and we will welcome suggestions from anyone as to how this study could best be handled.

DR. SHEPARD: Thank you very much, Carolyn. I would like to comment on that that last statement of Carolyn's, that you have been provided copies of the preliminary protocol.

Carolyn, I am sure, and I know we would be very interested in receiving comments from any of you who have expertise in this area. Please review that and get back to Carolyn with your comments.

Let me just ask a couple of questions now. Do you project a time when we will have a completed protocol? Are you trying to develop a more complete protocol detailing some of the --

DR. LINGEMAN: Right. We are in the process of developing a more complete protocol, and I hope within the next few months that we can have the final version of the study design for you.

DR. SHEPARD: Thank you. Now, we would like to have the opportunity to review that too.

DR. LINGEMAN: Before we start the study you will have that opportunity.

DR. SHEPARD: I might also suggest that the scientific panel of the Interagency Work Group probably would also like to take a look at that.

DR. GROSS: Dr. Lingeman, two things. With reference

to whether the exposure was non-military or military, that -- is your object is not necessarily to establish only a cause-effect relationship with military wartime exposure, but any phenoxy herbicide, even if it is compact lately to establish a cause-effect relation, is that correct?

DR. LINGEMAN: Yes.

DR. GROSS: The other question is on the epidemiologic study, how do you proceed, either prospectively or retrospectively or both because it makes a great deal of difference as to the number of subjects that you need. If you do a retrospective study, well, you focus on the particular cancer or disease. Then you need much fewer subjects to determine the association, because you in effect ask what is the association with the effect. If you go prospectively you need many thousands as you correctly pointed out.

DR. LINGEMAN: The case control study --

DR. GROSS: Is a prospective one.

DR. LINGEMAN: Well, it is retrospective in that we are taking the patients who have the cancer and saying, "Did you serve in Vietnam? Were you a farmer? Did you ever work for the Forestry Service? Did you ever work for the Highway Department? What did you do there?

DR. GROSS: You tried to establish an association?

DR. LINGEMAN: Right, so in that sense it is

retrospective.

DR. GROSS: I see.

DR. LINGEMAN: Now, it is prospective in that as every year we will update this and take the newest cases while they are still as near the date of diagnosis as possible. Many of these people are already dead. We will be writing to relatives of many of them rather than to the patients themselves. The relatives never can give quite as good histories as the patient themselves.

The first phase of the study will involve all cases diagnosed between 1975 and 1980. After 1980, we will get a computer write-out of the next set of patients that have been diagnosed in each quarter and write to them, and the matched controls at the same time. Concerning the earliest cases, as time goes on, the worse the memory is. Many patients will be lost to follow-up.

I think if we keep the study updated quarter by quarter, year by year, then we will get better histories as time goes on. Now, we may be able to get some significant information the first time around and we may not. We may get nothing. We may come up with things that are only marginally significant or we may not be able to answer any questions at all. We will try to continually analyze the results as we go along and continually update them.

We plan to then also start a study on the lymphatic system pretty much at the same time as this one, and the study design for that is still under review. As time goes on, if it looks like from the Special Pathology Registry that we are getting an excess of one kind of neoplasm, then we will start a study of that one also.

Dr. Shepard has mentioned that cancer of the testes might be the next

one to study because there is a great deal of interest in them because they occur in young men. Many of the epidemiologic features of these are unknown. Dr. Mostofi of the Genito-Urinary Registry of the AFIP says he is interested in study causes of testes and the bladder.

So, as time goes on, I think we should be flexible in our attitude. If it looks like the soft tissues isn't going to yield anything, maybe we should shift gears and emphasize something else. I think this is the value, then, of the cohort study, that it will point out to us that maybe this neoplasm is unusual and maybe we should look at that one instead or take the resources and spend more effort on that.

DR. SHEPARD: Okay. Thank you, Carolyn. Are there any other questions for Dr. Lingeman? Yes? Dr. Erickson.

DR. ERICKSON: In your outline of your study design you say that controls are going to be chosen from among accessions, patients who don't have neoplasm diseases. What is the spectral illness types that will be you control?

DR. LINGEMAN: I knew you were going to ask that. We plan to use patients whose biopsies were sent to other AFIP Registries. We could limit this to a single Registry such as the Dental Registry, which would be primarily gingivitis and relatively non-life-threatening diseases. We have talked about that. There just may not be enough of them.

We do not want to include neoplasms of any type. We want to exclude skin lesions. Anything that could be confused with chloracne should be excluded.

A lot of biopsies from well people are sent to the AFIP. I think that some decisions have to be amde about what -- how sick should they be, how well should they be. Hepatitis would probably be a poor control because

herbicides can damage the liver. It would not always be possible to exclude a chemical as the cause of the hepatitis.

So, we have some very hard decisions to make there.

I think the AFIP epidemiologists might also suggest that in addition to "sick" controls sent to the AFIP whose biopsies are/ we should also select a group of well controls, maybe through the National Death Registry or one of the other tumor registries. I don't know. What are your suggestions?

DR. ERICKSON: It's a complex problem. The NCI often uses a census as set up by telephone scheme. Thereby controls from that census of well people.

DR. LINGEMAN: Yes, this is under consideration. We will give it a lot more consideration to that before the final decision is made.

DR. GROSS: But commenting in relation to that, I think probably you would want your control to reflect closely a population of veterans who are generally in better health than the general population. They are examined initially to be inducted into the Armed Forces, drafted, whatever, and so probably the general level of health in veterans is superior to what you would find in the Connecticut Tumor Registry even if you match by age.

You would want something quite comparable to the veteran, not only in age, but in being in the military service in the first place.

DR. LINGEMAN: Well, I think we probably will end up with veterans both who have cancers who have served in Vietnam and those which have not which are sort of built in controls.

We are going to include women as well as men, so that will be another set of controls. Women with the same kinds of neoplasms who have probably not served in Vietnam. I think very few women were in Vietnam.

DR. GROSS: Yes. It will be difficult to get many cancers of the testes in them.

DR. LINGEMAN: No, you certainly wouldn't.

DR. HOBSON: Do you intend in selecting your controls to match deceased with deceased controls and living with living controls?

DR. LINGEMAN: Yes, we will get reports from relatives of those who are deceased as opposed to --

DR. HOBSON: Right.

DR. LINGEMAN: Right. We have taken that --

DR. HOBSON: I gather from your little brief outline that you intend to match --

DR. LINGEMAN: Yes, as nearly as we can, but people move around a lot. Some of the materials we get come from armed service bases all over the world. These are not where the people lived or grew up, so you've got a lot of confounding factors in there. We are going to try to match them closely by age, sex, race, where we can. Nowadays, the hospitals are not asking race routinely. We need to know the race because there are differences in cancer rates. For example, cnacer of the testes is rare in black men for reasons we don't understand.

Hodgkins Disease does not occur as frequently in black men as in white men.

We will try to match them by those factors that we can control.

MR. DeYOUNG: I have a concern about using the AFIP itself as a source of control, and the reason I have that concern -- I may be all wet -- I don't know -- is because the limited information that we have been able to turn up from the military shows that 2,4-D at least and some 2,4,5-T was used quite extensively on military bases as a routine grounds management tool, and as such, I'm not certain that this would enable anyone that is involved with the Armed Forces to be used as a non-exposed control. Now, I am not sure that is critical with this particular study, but I think it needs to be looked at. Possibly we need some more information from DOD on just how extensive these things were, even in a non-tactical application when, for example, Chanute Air Force Base in central Illinois where I am from has extensive records on 2,4-D in the early '60's.

However, the records on 2,4,5,-T have just disappeared so we have no proof one way or the other on that. This is up through '72 they used 2,4-D. Through '71 they have

records on it, going all the way back into the '60's. I can only assume the same was true with 2,4,5-T and if this was, will this scotch the control group for it?

DR. LINGEMAN: Well, most of the AFIP accessions are from civilian sources, 60-40 now. We can take one civilian and one military for each patient. That is something we have considered.

Using the military man for a control may not a good idea because we can't get the geographic factor matched

MR. DeYOUNG: One more piece of meat for your grinder.

DR. LINGEMAN: The average civilian has had great exposure How that will ever be resolved I really don't know. This stuff has been around since the 1940's.

MR. DeYOUNG: Good luck.

DR. SHEPARD: Dr. Hodder is with us now from the Uniformed Services University of the Health Services / and we are very pleased to have him as a member of our Committee. Did you have a question, Dr. Hodder?

COL. HODDER: No, I just wanted to comment just in answer to perhaps your question is I think you are going to really need multiple controls. I don't think you can get away in this type of an accession system which is not a random sample. It is a well-organized system as multiple sources are bias. You are going to need different -- the question of getting a control group very much different from the cases then you are not going to be able to speak to what caused the difference. So if you will take a control group that was totally non-exposed to military you wouldn't -- there is a considerable selection by -- it is just in the military population of its own.

It is a different population because you exclude people with underlying conditions that may effect disease outcome. On the other hand, you do have to control somewhat for the base that your are looking at, so you would probably have to use a military control group, the random sample group or the 10 percent sample. I think to adequately compare that you have to look at these two groups, two or three control groups.

DR. GROSS: One more comment. Dr. Lingeman, isn't it true that the vast -- I am acquainted with things that come to the AFIP, other registries -- isn't it true that the cases that tend to be accessions sent to you by civilian pathologists or military are really non-routine type things? They present

some sort of difficulty where they would like consultations, so their routine garden variety cases really do not get sent to the AFIP?

DR. LINGEMAN: That's true. It depends on the pathologist. Some pathologists in a big medical center who have consultants right within their own group are less likely to send them in than the pathologist who is practicing in a small hospital out in Nebraska somewhere who doesn't have access to expert opinions.

DR. GROSS: But the clear-cut case is less likely to be sent to you than one with problems?

DR. LINGEMAN: Right. The AFIP is more likely to get the difficult ones. On the other hand, this may work to our advantage because we have the greatest difficulties in epidemiologic studies of common cancers. In other words, if the Vietnam veterans have a lot of lung cancers we have to get a smoking history to correct this and for many other things. The unusual can sometimes give us more information about a common environmental exposure.

DR. SHEPARD: Fine. I think we should take a few

minutes break before we get to Dr. Gaffey, so if we could reconvene about 20 minutes after the hour.

(Whereupon, a short recess was taken.)

DR. SHEPARD:. We will resume our deliberations. If you can please take your seats, ladies and gentlemen.

Next on our program is a presentation by Dr. William Gaffey who is with the Department of Medicine and Environmental Health in the Monsanto Company in St. Louis. He will give us some, I think, new information on some of the studies that they have been conducting relating to the Nitro, West Virginia episode. Dr. Gaffey.

DR. GAFFEY: Thank you very much. My time is limited so I will talk fast and leave off the pearls, but perhaps a little background is appropriate first.

The Monsanto plant at Nitro, West Virginia, is a mixed chemical plant, and from about 1948 to 1969 it manufactured 2,4,5-T. This was, of course, contaminant with dioxins, and we can't now reconstruct with any precision the amount of that contamination, but we are sure it was there because we have had scattered cases of chloracne during the period that the manufacture took place.

We have recently, starting about two years ago, begun a series of studies of the plant, particularly the workers exposed to 2,4,5-T. These have typically been cohort studies of mortality in which we identified populations that were

exposed in the past, including both those who left employment, those who stayed, those who retired. We followed them, determined whether or not they had died. If so, gotten the cause of death and calculated on the basis of our observations how many deaths we would expect from different causes assuming -- on the basis of the U.S. male population.

So these studies have generated observed deaths by cause which we have compared with expected deaths. One such study has been published. It was a study of 121 men who were -- all of whom got chloracne as a result of exposure during an explosion in the manufacturing process in 1949. No excess mortality was found in that group. However, it was small. There were only a total of I believe about 30 deaths.

What we have tried to do is to do a study of a larger group of people employed over time in that unit. This is a preliminary report, and you will see the sense in which it is preliminary as I go on. I welcome suggestions about the kinds of analyses we might do further.

Now, what we had hoped to do in this study was something very straightforward. We hope to identify everybody who had ever worked at the Nitro plant from World War II up until about the end of 1977, follow them all, calculate their mortality, then divide them up into those who were exposed and those who were not, and have two straightforward studies.

Well, we are going to do that, but we have two

difficulties. One is that it is extraordinarily difficult to find out whether a man was exposed. A man has a work history with a couple of hundred jobs in it. If one of those jobs has the right department designations, he was exposed. So finding the exposed people is something like trying to find everyone in the telephone book whose middle name begins with J. They are all there and they can be found, but it is a tedious job and we are doing it.

What we managed to do in this case in fact was to identify every person who had worked for at least one year as an hourly worker at Monsanto anytime between 1955 and 1977. Before 1955 records on people who left were incomplete, so we simply had to make that starting date, 1955.

We followed these people. There were 885 of them. We managed to find all of them. Of those there were 164 deaths. What we did was to use this information to calculate observed and expected deaths in the whole population. Then our best look at exposure at this instant was done in the following way.

We took the people who had died, 164 of them, and for those made a classification of exposed versus unexposed, and then within the exposed deaths and within the unexposed deaths we compared the distribution of causes with the distribution that we would have expected in a typical U.S. male group of U.S. male deaths that were matched for age and year of death.

So, in other words, what we have here is what might

charitably be called a hybrid. Part of it is a regular cohort study of the whole plant, and then within those who have died we have looked at the distribution of causes of death in those who were exposed compared with those who were not in order to see whether there are, in fact, any differences. Are there a greater percentage of deaths due to cancers in the exposed versus the unexposed?

So, very quickly, let me show you some background information on the group that we studied. Oh, let me stop for a moment. Dr. Lingeman mentioned that the calculations involved here are a little bit complicated, and what we have done is use the standard program which was developed at Harvard and is generally available for these kinds of studies.

Let's look a little bit at the kinds of people we studied. May I have the first slide, please?

I must apologize for these. They were made from a draft and probably are not large -- as large as they ought to be, and later you will see an example of how a table should not be made.

(TABLE 1)

But at the moment, this is age distribution, and you can see that these people were hired, the bulk of them, age 20 to 29, so the median age at hire is in the 20's. So we are looking at a group of people who, when they came to work, were in their mid-20's. Next slide, please.

(TABLE 2)

When did they get hired? Well, again, the median hire date is somewhere around 1940, so, again, roughly speaking, the population was in their mid-20's when they were hired, and they were hired sometime in the '40's, the typical person. Next slide, please.

(TABLE 3)

How long did they work? Well, this is not in 2,4,5-T. This is their total duration of employment at Monsanto, and you find it's kind of uniformly spread. About a quarter of them were short-termers, less than 10 years, and a quarter each in the 10 to 20, 20 to 30, and 30 years plus. But it is interesting, and of the group approximately half of them worked more than 20 years which means that we had for about half of them we had more than a 20-year latency period.

(TABLE 4)

Let's look at the next slide. This is an example of how not to make a slide. I'm sorry. There is too much information on it, but perhaps I can point out the things that are of interest.

What we've done is use causes of death as they are classified in standard Government publications of mortality by cause. The death certificates that we got as part of the study were coded by a state health department so that the determination of the cause of death was done as part of that department's

routine on the same basis as the determinations underlying the national statistics.

Don't worry about these too much. These are just the code designations in the WHO classification system for causes of death. We observed a total of 163 deaths. We would have expected 158 based on U.S. national figures. That says that the overall mortality is 3 percent more than expected. I will have more to say about this later.

If you look down -- I've got observed and expected deaths and I have a column here that says SMR. That is the ratio of the two of them expressed as a percentage, so if this value is over 100, it means that the observed deaths were in excess of what one would expect. This is corrected for age and for date of birth.

The things that strike you -- some of these things are not important, like all malignant neoplasms from the 13 percent excess -- that is not important. What is important is the specific site which contributes to that excess, and if we look down here, essentially what we find is respiratory and a rather spectacular increase from bladder cancer and some increase in arteriosclerotic heart disease.

Well, also external causes of death; accidents, violence, homicide, suicide. Perhaps we had better dispose of this one first. Here we have a mortality from bladder cancer that is nine times as high as expected. Yes?

DR. GROSS: Just a question of clarification. When you talk about cause of death did you -- what exactly is that? Is that a primary or a single cause of death or it indicates that -- suppose they were multiple diagnosis. Suppose somebody died of pneumonia, but he happened to have had bladder cancer. How would this be counted in your table?

DR. GAFFEY: We have used the underlying cause of death.

DR. GROSS: A single one for a --

DR. GAFFEY: A single one. The ground rules for determining that cause of death are essentially the WHO regulations except that we sent the certificates to a coder in the state health department who routinely codes that. In the example you gave, if the man had died of pneumonia and had been suffering from bladder cancer at the time, the cause of death would have been pneumonia, if the doctor filled out the certificate correctly, because the primary dependence on the certificate is on the judgement of the doctor. If he puts the -- The certificate says, "This man died from A due to B due to C," and if in the physician's opinion, the cause of death really was bladder cancer, he would have put, "This man died of pneumonia, the immediate cause, due to bladder cancer." If he had so noted we would have said bladder cancer.

There are difficulties with cause of death on death

certificates.

DR. GROSS: Yes.

DR. GAFFEY: And the only thing that can be said for them is that we have no alternative. You see, these are people, most of whom we get the files of the Social Security system. We have no way of reaching them. We can find out if they died and we can get their death certificates because those are generally public documents, but for better or worse, we are stuck with the death certificate diagnosis, and so if we were able to get information on pathology, for example, our certification would be much more correct, but it would then not be comparable with the national statistics.

Our problem is to preserve the proper degree of mediocrity in determining cause of death, so that we can be comparable to the public figures.

This excess here comes from an entirely different cause. One of the things manufactured at Nitro is something called paramenobithenol, PAB, which is a bladder carcinogen. Manufacture of that ceased in 1954 I believe or '55, but the people who were exposed to it were placed on a roster and followed and examined regularly because the exposure was known to have placed them at a risk of bladder cancer, so of the 9 bladder cancers here, 7 of them were on that follow-up roster and had been exposed to PAB, so I think that fairly well accounts for that.

The others? Well, let's look at the next table and we can get a little more detail on some of these things.

(TABLE 7)

This one you're really going to need a microscope for. I must again apologize. We looked at this information by year of hire on the theory that the earlier the hired date the longer the latency, and, of course, as you would expect, those hired after 1960 are remarkable healthy, didn't have any time to die.

Some of these other things are -- we see about the same pattern of excess. We've got excess respiratory cancer roughly the same in these two periods. We've got the excess bladder cancer, again as I recall all of the 7 PAB bladder cancers were in this date, so when you take those out, we don't -- there's not going to be much going on.

Again, although I don't have it in the table, if you were to look at the observed expected ratio for arteriosclerotic heart disease, it also is high here, here, and it's gone from here. Next slide, please.

(TABLE 8)

Now, I want to talk about among the deaths the division of these people into whether or not they were exposed to 2,4,5-T. Now, exposure here means that they worked in the unit from which the material was manufactured. We don't have any air sampling measurements or anything of that kind that

gives an objective evidence of exposure, but we presume anybody who worked in the unit had at least an awful lot more exposure than anyone in the general population would have had.

It turned out that of the 163 deaths, 58 had been exposed, 104 had been non-exposed, and 1 we didn't know, so that 1 is missing from our substantive analysis. Next table, please.

(TABLE 9)

This is the one that is interesting.

DR. GROSS: Excuse me. Back to the previous slide, how would this compare with the population during that time? I mean this is -- well, what is the ratio of exposed to non-exposed in general?

DR. GAFFEY: I don't know which is one of the reasons that this is a preliminary study. That is -- see, this --

DR. GROSS: Again, to exaggerate here, suppose that you had four or five times non-exposed people during that time to expose. This would be very significant, would it not?

DR. GAFFEY: Yes, it would.

DR. GROSS: I see.

DR. GAFFEY: Yes, it would, and what we are in the process of doing is making that determination so that we can indeed say that. Next slide, please.

(TABLE 9 still being shown)

Yes, the difficulty here is that what I am going to show you now is how -- here we have -- I have looked here in the exposed and unexposed only at malignant neoplasms because they seem to be the causes of interest. No, I'm sorry, I'm sorry, that is not true. I've got the rest of it down here. Yeah, I've got the whole thing here.

What I have done, however, is I've said, "All right, given that we have a group of deaths, here are the numbers of these deaths in each cause. Here is the number in each cause that you would expect from 58 deaths in a matched deaths from the U.S. male population."

So I can look at this distribution, but it doesn't really tell me here whether 58 deaths is too many which is the point that you were making.

DR. GROSS: Right.

DR. GAFFEY: That is one of the things that remains to be unscrambled here, but for what it's worth, if we look at the cause distribution we see that the proportion of deaths due to cancer in the exposed group is slightly less than you would expect, in the non-exposed group slightly more.

Some of the same things turn up here that we saw in the overall plant. We have an excess of lung cancers. Now that occurs in both groups. It looks here as if 168 is a lot bigger than 125, but that's if there were one case less or one

case had been misclassified, that would be reverse so it's not terribly overwhelming.

A rather monumental excess from bladder cancers again. That, again, is the PAB group shown here. Some excess in diseases of the circulatory system, again heart, but the crucial thing is that the excesses that one sees and the deficits are pretty much matched in the exposed and unexposed group, so if you were to look at these -- this distribution and this one, what you would find yourself saying, I think, is that there doesn't appear to be any difference to speak of between these two groups, but putting them all together we would be a little bit worried about lung cancer and heart disease, irrespective of the exposure to the 2,4,5-T, but just as a study of this plant.

Now I will leave that up there for a while because this is really the point of the whole exercise, and you may want to look at it and ask questions about it. Yes?

MR. EWELL: My name is Michael Ewell. Doctor, during what -- I have two questions for you. During what period did Monsanto manufacture 2,4,5-T?

DR. GAFFEY: I think it started in 1948 and I know it ended in 1969.

MR. EWELL: In '69?

DR. GAFFEY: Yes.

MR. EWELL: Let me preface my other question by a

brief comment. It recently came to light that Dow Chemical informed the Government, the Defense Department, of the existence of Dioxin in 2,4,5-T in 1962 saying that it was believed to be a potential health hazard at that time, and, according to Dr. Robert Bachman of Harvard Medical School in his Ph.D. thesis which was published as an appendix in Thomas Whiteside's book, "The Pendulum and the Toxic Cloud," Dow sent a letter to Monsanto and other manufacturers of 2,4,5-T in 1964 alerting them also to the fact that Dow was beginning to experience among its work force certain health problems that they attributed potentially to Dioxin.

The question was, what was Monsanto's reaction to that letter in 1964? How did that affect Monsanto's policy?

DR. GAFFEY: I am afraid I don't know. I've worked with Monsanto for less than a year and a half, so this is -- I'm not aware of the events that you're talking about.

MR. EWELL: Who could answer that question at Monsanto?

DR. GAFFEY: My first thought is our public information people. There is a Mr. Daniel Bishop whose telephone number I don't have, but Monsanto's -- well, I can give you my card and you can call me and I can tell you how to reach him.

MR. EWELL: Okay. Thanks a lot.

DR. GAFFEY: You're welcome. One more comment about

this while we're waiting for questions. Among the defects of the study the obvious one is that we haven't yet characterized the exposure of the people who are alive. The other problem is that we compared this mortality experience to that of the U.S. male population. In other words, we haven't taken account of regional differences. We are acquiring the capability to do that, but we don't now have it.

But it does turn out that in the -- West Virginia has a higher mortality both from lung cancer and from cardiovascular disease than the rest of the state -- rest of the states -- and the Kanawa Valley in which the plant is located has a higher mortality from heart disease and lung cancer than West Virginia does, so there is some question as to the extent to which these excesses may be due to our using a national standard rather than a state or a county standard. Yes.

COL. HODDER: Well, that was one of the things that concerned me. Actually if we compare an occupational cohort against the national cohort --

DR. GAFFEY: Yeah, sure.

COL. HODDER: -- we would expect lower than the 100 -- your SMR should be lower.

DR. GAFFEY: Yes, for everything except cancers and certainly, particularly cardiovascular disease, it ought to be lower, but as I say, what I think -- so there is no doubt that part of this excess is due to the fact that we're using

a national standard when perhaps we should be using a state or more local standard.

DR. GROSS: A cohort of people employed in these kind of jobs is the important point because their standard of health would be different than the general population.

DR. GAFFEY: Yes, and to the extent that we study occupational cancers this is not too serious a problem because the evidence seems to be that the healthy worker effect doesn't extend much to cancer. As soon as we get into cardiovascular disease we are in trouble. We are in trouble, and so I don't really know -- I would still like to see how this compares with the local rates because if that excess disappears, I would feel comfortable. If it didn't, I would say, "Well, we're going to see what -- do something like a case control study to unscramble more carefully the exposures," because the other thing we have done here, of course, is we have ignored all other exposures at the plant.

For the purposes of this particular study we have concentrated on 2,4,5-T and said everybody either is or is not and have taken no account of the other things that he was exposed to.

MR. DeYOUNG: Well, you said earlier that when a person is simply working in a particular unit where T was handled constituted exposure. Is the other side of the coin as open-ended? In other words, does non-exposure simply mean

that they did not work in proximate contact with the material?

DR. GAFFEY: Yes.

MR. DeYOUNG: So it's not that they were wearing special suits or something of that nature?

DR. GAFFEY: Oh, no, it meant that they did not work in the area in which the material was produced.

MR. DeYOUNG: Well, this is --

DR. GAFFEY: So our definition of exposure is geographic location with respect to the unit that produced it.

MR. DeYOUNG: I appreciate the difficulties. We're having the same trouble with the Vietnam troops.

DR. GAFFEY: Uh huh, yes.

MR. DeYOUNG: It's simply being there.

DR. GAFFEY: We did try one more thing. We are trying to get a roster of everybody who got -- who made a medical claim for chloracne which is another way of characterizing exposure. We are having difficulty because the degree of specificity of medical claims, particularly 10 or 15 years ago, is not that great. Dermatitis, was it or wasn't it?

Our policy so far has been to say, "Well, when in doubt, call it chloracne," but that may be the wrong thing to do. We may be diluting our chloracne group with people on other dermatitis. Anyhow, we're trying to assemble a roster. What we will do with it I am not quite sure. It presents a problem.

DR. SHEPARD: Thank you. I have a couple questions from a Melena Barkman. Is she here? Okay. I'll read your question if that is all right with you.

First question: Why does the study group not include persons employed between 1948 and '55?

DR. GAFFEY: Because those records are a mess. We don't know what happened. Those persons who terminated after '55, records were retained for them. For the period before 1955 we can tell by looking at Social Security quarterly returns that there were people in the plant whose records are not there, who terminated and whose records were in some way or another destroyed.

The records that are there are also incomplete. We have done some straightening out of them, but there is enough missing data on terminations that we would bias the study if we tried to take the people that we knew about. So we for these reasons stopped at '55 because it was rather a sharp dividing point in the plant records. Terminations after '55 are stored in a different place and are relatively complete. Terminations before '55 are stored in another location and are not complete. It's just a fact of the archives of the plant.

MS. BARKMAN: I was just wondering if Dr. Suskind's morbidity study wouldn't help you to find the people that were exposed in the spill of 1949.

DR. GAFFEY: No. You see we gave him that information, and that was based -- and we do not know who was exposed in the 1949 spill. All we know is who was exposed and got chloracne, because we identified that group by looking at medical treatments right after the incident. These people got chloracne and they got kind of sick otherwise, so there were presumably more people involved in the explosion and the cleanup who did not get chloracne and, therefore, never came to medical attention and we don't know who they were.

MS. BARKMAN: And there were no company documents or records that supplied --

DR. GAFFEY: No, because these were not people who worked in the unit. See, the unit blew up over a weekend, and the 120 that we are talking about were people from other units who were called in to clean up, so nowhere in their record does it say that they worked in the 2,4,5-T unit.

And so presumably other people who were involved in the cleanup and who did not get chloracne are sitting out there with the exposures, but we have no -- in the absence, since there is no medical record because they didn't get chloracne, there is no work history record because they weren't assigned to that unit. We have no way of knowing who they are.

MS. BARKMAN: And there is no report at the spill that names these people?

DR. GAFFEY: No. I haven't seen any. I've seen

reports that named the chloracne cases and people who presented themselves as being sick. I am aware of no document that names the people who -- that names people other than those who got chloracne.

MS. BARKMAN: And you did not include the chloracne named individuals in the study?

DR. GAFFEY: If they were still working in 1955 they were in the study. I can't tell you off hand how many of them were. I suspect most of them were in here.

MS. BARKMAN: That goes to my next question I think.

DR. SHEPARD: Okay. How many of the 58 decedents were working during the 1949 spill?

DR. GAFFEY: I don't know at this moment. My guess is that almost all of them were. That is, in the original -- in the group in the original spill we found 30 deaths. The only way one of those deaths could be missing from this study would be if the man had quit before 1955, and I don't think that happened. That is information that is easy to find. I just don't happen to have it at my fingertips.

DR. SHEPARD: And the third question, what is the 95 percent confidence interval around your estimate of risk for liver cancer and all cancer?

DR. GAFFEY: I don't have the confidence interval, but I could tell you that it includes 100 because the liver cancer -- we had no deaths from liver cancer which I guess is

significantly low, but not all that low. We would have expected six-tenths of a death and we got zero. I'm afraid I don't know what the confidence interval is.

For all cancer I haven't calculated it, but since I know it's statistically significant, I know the confidence interval includes 100.

DR. GROSS: Dr. Gaffey, do you believe that Monsanto would be willing to encourage the people or the estates of the people that died and morphologic material exists to make this material available to Dr. Lingeman's Registry, particularly in the case where people had known exposure to that or studied it?

DR. GAFFEY: I am convinced that my boss who is the Medical Director of Monsanto would be strongly in favor of that. What we can actually do I don't know, but as far as taking a position on that, I am in a sense in the classical bureaucratic position. I haven't cleared it with my boss, but I know that -- I feel confident that he would be certainly anxious to assist in this.

DR. SHEPARD: The following question, then, do you have any information as to how many of these were autopsied?

DR. GAFFEY: No, I don't because theoretically on a death certificate there is a place that says "Autopsy," and says, "Yes/No," and the most common thing you find is

that neither of them is checked. And more than that, many autopsies are performed after the death certificate is filed, so the certificate goes in with no autopsy. Theoretically, if the autopsy changes the cause of death, there should be an amended certificate filed, but if it doesn't change the cause of death, it won't be filed, and so even when you see a notation of no autopsy, there may in some cases be an autopsy.

So we didn't try to make this distinction because it wouldn't have helped us as far as our comparison with population figures in which this distinction is usually not made.

DR. SHEPARD: Dr. Lingeman?

DR. LINGEMAN:

If on the death certificates a diagnosis of cancer is made or if it is even worse, if the particular kind of cancer is named, but there very likely wasn't a biopsy -- how many hospitals are there in Charleston?

In Louisville around the time of the vinyl chloride thing, there were about eight hospitals involved. A man from CDC went around to each one of the hospitals with the names -- and said, "Do you have any tissue on this man or that man?" And so it is possible to get those kind of material although the hospitals may not save material after --

a certain time. They will save their slides up to -- so this material is very difficult to get really. You can come up with about a 50 percent retrieval rate, but it is possible. It just takes a lot of work to go from the death certificate to the physician who signed, ask him where the operation was done.

Sometimes the death certificate will contain the information that the patient died in a certain hospital where it's easier if it's diagnosed there.

DR. GAFFEY: It is a little more difficult than that because in many states we can't get a certificate without promising we won't contact anybody named on a certificate.

DR. LINGEMAN: How about West Virginia? Is it --

DR. GAFFEY: I don't recall. That is not an insurmountable obstacle because you can always go back to the vital register and explain what you are doing and very likely he will say, "All right," you know.

DR. GROSS: Dr. Shepard, I would like to make a motion that this Committee express a desire to the Monsanto Company to help facilitate making this material available to Dr. Lingeman's registry if possible.

DR. SHEPARD: Fine. I think that is a very appropriate suggestion. If it is all right with you, I will take it upon myself to draft a letter to the Medical

Director of Monsanto and request that they make the records available in such a fashion that a follow-up effort might be entertained in trying to retrieve the tissue material.

MR. DeYOUNG: Excuse me, Dr. Shepard. One final

Start 2B question for Dr. Gaffey. I noticed that you mentioned that external causes of death were up in this population. Has there been any workup whatsoever on that category more intensive than simply saying it's up?

DR. GAFFEY: No, we haven't.

MR. DeYOUNG: Would that data be available for study?

DR. GAFFEY: Well, we have the individual death certificates with the causes of death, so we would know whether it was homicide or an automobile accident or what have you. I frankly suspect that one of the causes in which the excess would disappear if we used the rates for that state.

MR. DeYOUNG: Do you suspect that external causes are outdated in West Virginia?

DR. GAFFEY: Yes, that accidents, homicide are higher than the national average.

MR. DeYOUNG: I for one would be interested to see a categorical breakdown similar to this for simply that category. It has been our experience with the veterans involved that -- or -- let me back up -- if the allegations

from veterans are correct and they seem to me to be, there are some personality changes in aggression and things like that which may go into making up an excess of violent death, and I for one would like to see the statistics on what kinds of external causes were involved.

DR. GAFFEY: I am writing myself a note to send you a listing with no names, but with the cause as written on the certificate and probably the age of death, something like that, so perhaps later I can get an address to which I can send this.

MR. DeYOUNG: By all means.

DR. SHEPARD: Maybe, Dr. Gaffey, if you could send that to me and then I will distribute that information to the members of the Committee.

DR. GAFFEY: Fine.

DR. SHEPARD: Yes, Cheryl?

MS. BEVERSDORF: Has this ever been published?

DR. GAFFEY: No, it has not because we are concerned about the issue that Dr. Gross raised, that as it now stands we don't know how many living people were exposed, and I don't propose to publish it until we have a more complete characterization of the exposure status of the people who are alive. I am perfectly prepared to talk about it. There is nothing confidential about it. It's just that publication means subject to a period of review

and so on, and it's desirable to publish, but I don't think the study is clean enough as it stands to really justify publication.

MS. BEVERSDORF : Do you have any idea when --

DR. GAFFEY: I would guess in a couple of months because the unscrambling that I'm talking about is now going on.

DR. SHEPARD: Thank you very much, Dr. Gaffey, for that fine report, and we will be looking forward anxiously to the final public report. We really appreciate your taking your time to come.

DR. GAFFEY: Thank you.

DR. SHEPARD: We are running a little bit behind our agenda, however. I think we are doing reasonably well. Next I would like to call on Mr. Charles Thompson who I hope will be able to say something about the Senate Veterans Affairs' Committee questionnaire. Maybe, Charlie, if you could just give a little bit of background as to how that came about and then your understanding of where it stands now.

MR. THOMPSON: Yes, I certainly will. Thank you, Dr. Shepard.

First, I am certainly glad that we have reached a happy medium with the air conditioning and heating system in this building.

Just for an historical outlook on the questionnaire itself, approximately June of 1980 we were contacted along with other major veterans' organizations from the Senate staff asking us if we would be interested in disseminating a questionnaire, non-scientific, out to our field representatives concerning VA examinations on Agent Orange.

We had a chance to meet with the staff, go over the questionnaire, delete and amend. We finally had it all together and we sent out approximately 4,000 questionnaires. The DAV sent out approximately 1,500 to 2,000 of these questionnaires.

There was some concern with regard to not only the type of examination that was being given, also counseling. There was some regard to the physicians' thinking on Agent Orange, not all that conducive. They expressed the thought that many of these veterans did not have legitimate claims. We were certainly concerned with this.

Also we were concerned with the follow-up that was given Vietnam veterans and the counseling. There was none. They were given blood tests, various other kind of testing, and the veteran was never contacted again. We were certainly concerned about this.

As of this date, and I thought I was going to have some backup here, Molly Milligan from the staff was going to be here to give you a current assessment of the

questionnaire. However, I have been informed that she was a little ill. I am not sure if that has to do with the elections or not, but --

DR. SHEPARD: She was here a little while ago. I saw her, didn't you, Cheryl?

MR. THOMPSON: She had a chance to give me a current tabulation of the questionnaire, the questionnaire itself, and a state-by-state breakdown of who has responded. and I have copies here for everybody on the Committee. I don't think I really need to delve into it because really out of those 4,000 responses only 124 have been returned so far, so it is still a tad bit early to reach any conclusions on it.

DR. SHEPARD: I understand you -- only 120 have been returned of the total that your organization sent out?

MR. THOMPSON: Approximately 124. This is all totaled out of the 4,000 that were sent out. This was by the DAV, the VFW, and the AMVETS, and of course the American Legion had their own questionnaire made up and sent out.

DR. SHEPARD: Okay. Thank you very much. I might just point out that we are very interested obviously in this questionnaire and the one that the American Legion is working on, and we certainly will make good use of this information and use it as a method, hopefully, for improving

the whole process.

We have conducted also a very small sample, a satisfaction questionnaire. We have approximately a 50 percent return and we will be sharing that information with the Committee also.

MR. THOMPSON: One other thing, Dr. Shepard. Mollie Milligan did indicate to me that this Committee would be kept abreast when a conclusion is reached or when further documentation comes in, and you will be provided with copies then.

DR. SHEPARD: Yes?

MR. ENSIGN: I'm struck -- that seems like a very low response rate. Just to be clear, the 4,000 were sent to Vietnam veterans in your organization who had made an Agent Orange claim or was it just sent generally to your membership?

MR. THOMPSON: Okay, first of all, it was not sent to the membership. It was sent to our National Service Officers in the field that deal directly with the veteran population. The DAV, speaking for the DAV, we have offices at every VA Regional Office throughout the country. Our people, when an individual goes in for an examination, our people counsel with them and when, in fact, a Vietnam veteran would come in, we would give him this questionnaire, and he would, in turn, fill it out or

supposedly try to fill it out and send it back directly to the Senate Committee on Veterans Affairs.

I can't speak for exactly how the AMVETS or the VFW disseminated the questionnaire, but that is how we did it.

MR. ENSIGN: How long ago did you mail yours?

MR. THOMPSON: Well, that was -- that's only been a few months ago.

DR. SHEPARD: Thank you, Charlie. Any other questions?

SPEAKER: Could we have it passed around now?

DR. SHEPARD: Yeah, that would be fine.

Okay, why don't we ask Ron to tell us a little bit about his view of the videotape which we will be seeing shortly, and we will get comments afterwards as well, I am sure?

MR. DeYOUNG: I would hope so. I hate to do these things in a vacuum.

The videotape that Dr. Shepard is referring to was tentatively titled "Agent Orange: A Time for Reason." It was produced, as you heard earlier, by the St. Louis Regional Medical Education Center of the VA, and it was set up for three major purposes.

In a concept team meeting, oh, possibly eight months ago at this point, we identified three major

purposes that we wanted to serve with such a videotape, and those were to give basic scientific and military information about Agent Orange and the other herbicides to veterans, to begin to fill some of this ignorance gap that we had since this broke over two years.

The second point was to allay unnecessary fears among the veterans population, specifically in the area of birth defects, cancer, and the extremely traumatic incidences, and that to put some perspective on the fact that a pregnant wife of a Vietnam veteran is not 100 percent certain of giving birth to a child that is deformed, and so forth.

The last and possibly the most important use of this videotape is to encourage and lay out the guidelines by which a veteran would participate in the VA programs. What we are looking for here is some steps towards a constructive solution of these, although we knew that wouldn't come overnight.

Information was gathered from the VA, of course, and from different branches of the VA, from benefits and medicine and surgery and so forth. Much of the basic information that went into the scientific background of the tape is from the Air Force, from Major Al Young whom many of you have met here in the past, along with most of the medical information about symptoms, body systems of

interest, and so forth.

Information was also from veterans through veterans' organizations, and much of this has gone into the underlying fabric of the tape, although you won't hear any direct quotes.

The final element was individual scientists, literature reviews, and so forth which went into this.

I am especially interested to see this Committee's reaction to the scientific information that we put in the film -- in the tape. The question that I would ask the Committee and the audience, for that matter, to keep in mind is this thing scientifically accurate? Does it say all we can say about Agent Orange in the layman's terms and still be honest, objective, and obtain these other objectives that we started out for?

As I would think would happen with any process like this, the final product that we have at this point in no way resembles the original we started with. It is, as Dr. Gaffey said, rather generously a hybrid, and I would expect that ears will perk up to statements depending on your own point of view.

That's what I am looking for personally in this. Please respond in the future -- the short future -- with what sets off your alarm bells. That is what we need to know. We need to know where we are going wrong, if

anywhere, in this tape.

DR. SHEPARD: Again, thank you, Ron. I think that is a nice wrap-up of the process. We have had the opportunity to review this as Layne has said. You will notice that on the tape, and by the way I have not myself seen this latest version although I think it won't be very different from the one we recently saw, it has not been completed yet. There will be some gaps in the video portion of it, I believe, gaps which are still being finalized.

Because we are anxious that the public media will make use of this tape, there I think is the opportunity for public service announcements. So there will be breaks from time to time.

The question of the name, the title, of the tape has been raised. It was originally suggested to be "Agent Orange: A Time for Reason," which at first blush seems a fairly benign name. However, after some reflection somebody thought that the hidden implication might be that if you don't agree with this tape you are not reasonable, and so we had made a suggested change and the Policy Coordinating Committee has made that recommendation that we rename it "Agent Orange: A Search for Answers," which I hope will not offend anybody's sensibilities.

Okay, I think that since we are now talking about

the tape and that seems to be the current subject, why don't we go ahead and show the tape, although this will be shifting the agenda around a little bit, and then that will naturally flow into an opportunity for comments, not only on the tape but any other questions that members of the Committee or members of the audience may raise.

Can you all see it?

(At this point the videotape "Agent Orange: A Search for Answers," was played.)

THE NARRATOR: During the years of American involvement in Vietnam the United States military personnel fought two on-going battles, one with the enemy troops and the other with the dense jungle that hid the enemy and his movements, provided a screen for ambushes, and in general made an already difficult situation worse.

While this human enemy proved to be illusive and often hard to engage, the jungle provided a more obvious target and one that would yield to herbicide technology. The weapons used against this enemy went by many names, orange, white, blue, green, purple, pink, each for a slightly different target vegetation, but the same result, defoliation.

Defoliation by herbicide was one of the truly successful campaigns of the war. Unfortunately, exposure to the herbicides was not limited strictly to the vegetation

in Vietnam. American troops loaded and executed the spraying missions. American troops patrolled defoliated jungle. Some American troops lived in camps where perimeters were defoliated to provide a clear field of fire and reduce the likelihood of surprise enemy attacks, and, although similar herbicides had been used for agriculture and forestry in our own country for 15 or 20 years before the Vietnam conflict, the full range of health effects from human exposure are still a matter of scientific and public controversy.

And so, the legacy of Vietnam may still be with us. No longer in the headlines of daily body counts or nightly news footage of combat action, but in the names Agent Orange, Dioxin, and in the concerns of Vietnam veterans who fear possible ill health as a result of herbicide exposure.

This program will not get involved with the controversies surrounding the Agent Orange issue. Scientific and medical research will eventually provide those answers. While much is being said on both sides of the issue and new developments are appearing regularly, many questions still remain unanswered. This program will tell you what is known and agreed upon regarding the human effects of herbicide exposure. You will see locations of major herbicide spraying missions and the military units that were active

in those areas of Vietnam.

Most importantly, you will learn what the Veterans' Administration is doing about Agent Orange and how you can help yourself and the VA's efforts by cooperating in several VA programs. This will be a low-keyed reasoned approach to your questions surrounding Agent Orange.

It is a very emotional issue, we realize. Veterans are concerned not only with their own health, but with the health of their families. Some veterans feel a time bomb of herbicide effects lurking within their bodies even though they might not have any symptoms now. There is fear of birth defects, of cancer, of psychological changes.

Perhaps the greatest anxiety comes from the fear of the unknown, of what is not known about the effects of herbicide exposure at present. We can suggest few answers, but we ask you to listen to this program and to consider the information presented, and we ask you to take an active role by participating in the Veterans' Administration activities related to Agent Orange.

In a moment we will take a brief look at herbicides themselves, what they are, why, and how they were used in Vietnam.

American farmers and forestry workers have used herbicides since they were developed in the 1940's. They

have been used in large quantities around the world on the whole without causing any immediate hazards. Herbicides are chemicals used to kill unwanted plants, weeds, and other types of vegetation.

The commonly used herbicides work generally by dehydrating the plant or by depleting its food supply. Although herbicides were not developed specifically for military use, they were used in Vietnam to achieve several tactical objectives, primarily to limit the risk of ambush by depriving the Vietcong of cover and to reveal the staging areas of Vietcong activities.

In addition, herbicides were used on crops to deprive the enemy of food. While the majority of herbicides were applied on contested territory, the chemicals were also used to clear some American base and camp perimeters for defense and along supply routes and communication lines.

A breakdown of total herbicide use by objective would be roughly 90 percent for forest defoliation, 8 percent for crop destruction, and the remaining 2 percent for clearing of base perimeters. Several herbicides were used in Vietnam. They were code named Orange, White, Pink, Green, Purple, Blue. These names did not reflect the actual color the substance, but rather markings on the barrels indicating which herbicide was contained. Of the group, the herbicide Orange accounted for 94 percent of all

the herbicides used in Vietnam between 1962 and 1971.

Herbicide orange itself is a thick, reddish brown, foul-smelling, 50-50 mixture of two phenoxy herbicides, 2,4-D and 2,4,5-T. When 2,4,5-T is manufactured there is an unavoidable byproduct produced, a contaminant known as TCDD or dioxin. In its pure form dioxin is one of the most highly toxic chemicals known to man. It is dioxin that is currently the subject of the closest scientific study and debate.

It was present in minute amounts in the herbicide Orange sprayed in Vietnam and used in this country. We will discuss dioxin more when we begin to consider possible health effects from herbicide exposure.

Herbicides were first brought into Vietnam in 1962 and used on a limited basis until 1965. Because of the remarkable success of this technique, the use expanded in 1965 through 1969. The spraying missions using herbicide Orange were stopped in 1970.

Herbicides were an effective tactical weapon used successfully in support of troop operations. Their use probably saved thousands of lives. Herbicides were disseminated in several ways. Ninety percent of all herbicides applied in Vietnam were sprayed by thick-wing aircraft in the Air Force Ranch Hand Operation. The aircraft used were camouflaged C-123's. It is important to note

that only between 8 and 10 percent of Vietnam's land mass was sprayed, and, for the most part, in areas where our troops were not located at the time of spraying.

Other but lesser used methods of disseminating herbicides were by helicopter and by spray equipment mounted on trucks or boats or by hand-operated backpack units. It should be remembered, though, that by far the greatest amount of herbicide was sprayed by camouflaged C-123's.

In addition to herbicides, there were other chemicals used in Vietnam. For example, insecticides were used to control one of the most dreaded and deadly diseases of the war, Malaria, so although you might remember being sprayed or walking through recently sprayed jungle, it doesn't necessarily mean that you came into contact with Agent Orange. It could have been any number of substances.

This map indicates areas of major herbicide spraying missions and also the location of the Corps Areas. This is general information and will only give you an indication of the major spray sites. As you can see, the total area sprayed was relatively small. Just because you were in a unit near a heavily sprayed area doesn't mean that you were exposed. Likewise, just because you weren't assigned near a spray zone doesn't rule out the possibility that you might have been exposed.

Also, if you were involved in one these key mission areas, there is a chance that you came into contact with herbicides to some degree. Ashaw Valley, DMZ, Rung Sat, south and southeast of Saigon, these were areas of concentrated spraying.

Now that you have seen the areas of the heaviest herbicide application in relation to major military units, let's speculate on some of the ways that you might have come into contact with herbicide orange or its counterparts. These are hypothetical possibilities, impossible to document or prove.

They seem to fall into three main categories: direct contact, actually handling the herbicides or being directly sprayed; entering a recently sprayed area; and exposure through food or water. The veterans at greatest risk of exposure are those 1,200 in the Ranch Hand Operation. This operation involved actually handling the herbicide, loading the drums for the sprayer, flushing the spray system, riding in the cargo bay with the herbicides.

Associated with Ranch Hand Operations are ground support personnel, those who might have drained the residue out of the drums or operated the machinery for moving the drums about, or maintenance crews who might have come into contact with herbicide residue while working on the Ranch Hand aircraft.

There are others in other branches of the service who might also have come in direct contact with Agent Orange. Perhaps you loaded herbicides from a drum to a backpack sprayer or even operated the sprayer yourself. Perhaps you were involved with handling the drums, transporting them from the dock to a holding or loading area. You might have been a door gunner on one of the helicopters that was also used for spraying herbicides, or you might have actually served on some spraying missions.

These are all occupations that are considered to have the highest risk of exposure because of the chance of actual direct contact with the herbicides. We are not suggesting any conclusions about health effects from this exposure. We are only trying to point out the individuals who have the greatest chance of being exposed.

Many veterans express concern over whether or not they could have been exposed to Agent Orange by patrolling or walking through treated jungle. You probably would have known if you were in a defoliated area. Brown, dried leaves or no leaves at all, trees dying from the top down. Plants and foliage generally show maximum effect of herbicides after a period of a few weeks.

However, dioxin begins to photo-degrade or break down in sunlight within a few minutes, so if you remember being in a defoliated area like the one described, chances

are that the area had been treated weeks earlier and that much if not all of the dioxin was in the process of breaking down.

In addition, the triple canopy of the jungle intercepted most of the spray. Therefore, the amount of herbicide and dioxin actually reaching the jungle floor was probably small. Again, the risk of contamination most likely decreased with time.

The likelihood of significant exposure from eating local food is slight. As for crop foods, the appearance and odor would have made them highly undesirable sources of food. The look and smell would have made the food unmistakably inedible.

But what about cattle, chickens, hogs? If they had grazed or fed on contaminated food, would the dioxin be contained in the meat or fat? Studies are currently under way to determine if dioxin enters and moves up the food chain. While the results are still uncertain, uptake in domestic animals has not been shown to result in significant human exposure.

It is impossible to estimate how much herbicide may have been in the water in Vietnam, but it is safe to assume that run-off from the jungle or actual river bank spraying did contaminate some bodies of water to some degree. Herbicides and dioxin tend to settle out in water

since they do not dissolve in water, and have a higher specific gravity.

The particles of herbicides sink to the bottom and once settled in the silt at the bottom tend to persist. Whether this exposed you to Agent Orange is impossible to say. It depends on the water supplies you drank from. As with food, the odor and the look of herbicide Orange in water would have been very offensive. You probably would not have wanted to drink the water.

In a moment we are going to talk about the medical effects of herbicide and dioxin exposure as much as is known , the long- and short-term symptoms, what the VA plans to do and is doing and what you should do if you think that you might have been exposed in Vietnam.

We mentioned earlier that dioxin is a very toxic chemical. For this reason, humans cannot be intentionally exposed to dioxin for scientific studies. Researchers, then, have had to work with animals. From laboratory mice to Rhesus monkeys there have been many studies. Some of them have been very well conducted and have provided clues to the possible effect on humans.

Laboratory studies have shown that dioxin exposure causes cancer, birth defects, weight loss, skin lesions in some animals. The major difficulty with animal studies is that you cannot directly apply the results to

humans. For example, these studies often use extremely high doses or unusual methods of exposure like direct injection. Animals studies give some insight into the possible chemical effects in man, but it is misleading to make direct comparisons between humans and animals.

And so, the body of information on the effects of these chemicals on humans has had to come from the study of positively documented cases of direct exposure. While these studies are not as complete as scientists and researchers would like, they have given us some preliminary glimpses into what we might expect and they provide the only real look into the health effects of dioxin contamination, but, like the animal studies, it is impossible to draw one-to-one comparisons between these accidents and the types of exposure that were likely to occur in Vietnam.

For one thing, concentrations of dioxin in the herbicides used in Vietnam were much less than these accidents. Also, the exposure in Vietnam was probably less direct. Nonetheless, toxic effects occurring shortly after heavy exposure to dioxin are well known and well documented as a result of these industrial studies.

We are going to break our description of symptoms into two categories, acute, meaning those symptoms that occur soon after exposure, and chronic, meaning those symptoms that persist over a long period of time. Let's

start with the acute symptoms. Again, some of these symptoms are well known and documents from proven human exposure to dioxin in industrial accidents.

Physical symptoms include tingling in the hands and feet, aching in the joints and muscles, headaches, nausea, a skin condition, chloracne, and general weakness. Other less specific symptoms are weariness, loss of drive, and perceived personality changes; for example, an increased tendency to lose one's temper or irritability.

With the exception of chloracne, these symptoms generally tend to clear up by themselves and in a short period of time.

As for chronic or long-term effects, the only condition which has been absolutely linked to dioxin is chloracne. Since chloracne resembles common acne in appearance, it is often difficult to diagnose and may require a special examination by a dermatologist.

Chloracne is generally considered to be evidence of exposure to dioxin. In fact, some scientists believe that humans without chloracne probably have not suffered the toxic effects of TCDD or dioxin. Vietnam veterans have experienced many kinds of skin diseases. Most of these problems are quite common and would not prove herbicide orange exposure. It is important not to confuse other skin conditions with chloracne. A physician will have to make

that diagnosis.

Several changes in other body systems have also been suggested as possible long-term effects of dioxin exposure. There are no positive findings as of right now, but research is continuing. From a review of past experiences with herbicides, these are the body systems of concern to researchers at this time: the skin, liver, the nervous system, the reproductive system. A few reports have suggested the possibility that herbicide or dioxin exposure might cause psychological changes, birth defects, or even cancer, but it is important to remember that right now there is still no definite scientific proof.

At this time the data that are available do not warrant any kind of panic reaction or radical treatment. At the present time there is no good scientific evidence linking birth defects in the children of Vietnam veterans to herbicide exposure.

The time bomb theory that dioxin is stored in your fat cells waiting to be released if and when you lose weight has not been scientifically proven. It is probably more harmful to your health for you to be overweight. Stay in good physical shape. Keep up your exercise.

You may feel frustrated and disappointed that you still aren't getting absolute answers to your questions and concerns about Agent Orange, and, frankly, the VA shares

that disappointment, but no one can give you all the answers when no answers exist. That doesn't mean, however, that the VA is unconcerned or idle. In fact, the VA is actively engaged, not only in providing examination, care, and treatment, but also in research, information gathering, and cooperation and participation with other agencies probing the herbicide issue.

In April of 1978 in response to rising concern about the health effects of herbicide use in Vietnam the VA formed an advisory committee on the health-related effects of herbicides. Its purpose was to exchange information about herbicides and the possible health effects of exposure and to advise the VA on future courses of action including research.

The VA is also currently reviewing all of the world literature on herbicides and dioxins, but committees and literature reviews, as important as they are, may not mean much to the veteran who thinks that he or she might have been exposed to Agent Orange and may be suffering from the effects.

When you have a medical problem you consider related to herbicide orange, let the VA examine you. If you have a technical question on Agent Orange, ask advice of your VA medical center or clinic. If you want to file a claim for any health problem, you can get help from the VA.

Try not to be alarmed by hearsay. The Agent Orange coordinator, also called environmental physician, at your nearest VA medical center is one of your best sources of information. If you have filed a claim related to Agent Orange or you are examined by the VA, any disability will be researched for a possible link with military service, Agent Orange or otherwise.

Results of your examination will be put in your permanent file for possible use in supporting any future claim you file. Data from your examination will be correlated with those of other veterans in search for common problems. If such problems are found, the VA will be able to contact you for a follow-up evaluation.

In addition to the above, compensation may be available if you have a disability incurred or aggravated by military service. The only requirement is that the disability be confirmed and it must be related to the time period that you were in military service. There is no requirement to link it to a specific cause such as Agent Orange.

When you come to a VA medical center or outpatient clinic and say that you might have been exposed to Agent Orange, you will be asked to help fill out a questionnaire. You will be asked when you were in Vietnam, what your job was, where you were stationed, what your health was like

while you were in-country, what you've been doing since Vietnam, and similar questions.

It is not the purpose of this questionnaire to establish eligibility for care or compensation. The VA is not interested in this information for purposes of either granting or refusing treatment. The information gathered will be entered into a central computer where it will form the basis of the Agent Orange Registry. More about this registry in just a minute.

After you have helped gather this information, you will be given a complete, thorough physical examination, not just an examination for what your symptom or complaint is, but a total physical that will examine all body systems. Even if you do not have symptoms you will be given this examination.

The results of your physical, the laboratory tests you received, and the information gathered from the questionnaire, will all be entered into the Agent Orange Registry that we mentioned earlier. Any veteran who served in Vietnam who wishes to will be examined and entered into this Registry. The data may be supplemented as needed over the years through a series of follow-up examinations performed by the VA. This data will be analyzed on a regular basis in order to detect any significant trends or changes in the health of these veterans or

to determine if any particular diseases are occurring with an unusual frequency.

This Registry will also allow the VA to keep in contact with you and other Vietnam veterans possibly exposed to Agent Orange.

If there are relevant breakthroughs or discoveries regarding either diagnosis or treatment, you can be contacted and promptly advised of the new findings.

The VA is also participating in the Armed Forces Institute of Pathology Registry. The purpose of this Registry is to collect and review tissue material obtained during surgical procedures and autopsies on Vietnam veterans. These tissues are sent to the Armed Forces Institute of Pathology where they are evaluated and reviewed. A report of the findings is then submitted to the VA. The tissues are retained at the Institute so that they may be used for further studies as needed.

Some of the studies being considered are the detection of unusual or unique tumors , the search for an unusually high incidence of a tumor from a particular part of the body or occurring at an unusual age, or the discovery of a group of similar cases in a particular military unit.

In addition to participating in these date-gathering activities, the VA is involved in several

educational efforts, not only for veterans but also for VA health care personnel. This television program is a part of that effort. Another program provides VA health care personnel with the latest scientific and clinical information on Agent Orange.

The VA is developing a program for statistical analysis of the Agent Orange Registry and hopes to compare the health of those in the Registry with the general population. The VA also plans to conduct a scientific study of Vietnam veterans who may have been exposed to herbicides. This study will try to determine if there are specific herbicide-related health effects within the veteran community.

It is hoped that the preliminary results of this study will be available in the next two or three years. The VA is also following several specific research areas which include the study of toxic effects in the laboratory animals and birth defects in mice. The VA will continue to cooperate with other agencies, individuals, and groups who are studying the herbicides.

It is you, the Vietnam veteran, who has the biggest stake in the Agent Orange issue. The VA was playing a leading role in gathering all the facts, and we are depending on you for help. If you served in Vietnam and have reason to believe that you have been exposed to

herbicides, come to a VA medical center or outpatient clinic and participate in the Agent Orange Registry. If you have physical problems or complaints, the VA wants to know about them and help in any way it can. You can assist the VA by bringing any medical record which you may have, both civilian and military. These records may show that you have sought treatment for ailments in the past that might relate to herbicide or dioxin-related problems.

In addition to being helpful to the Registry, this information may be helpful in determining your eligibility for treatment and compensation.

The controversy surrounding Agent Orange will probably continue for some time yet, and the VA will continue to support you in every way possible, exploring new avenues of research, providing thorough examinations and follow-ups as needed, and disseminating any and all new or important information.

If you would like more information about Agent Orange, contact your nearest Veterans' Administration Medical Center or Regional Office. If you have any questions about general benefits or compensation, contact a representative from the Department of Veterans Benefits. In addition, veterans' service organizations can provide a wide range of assistance and information.

The process is long and frustrating, and sometimes

it seems that not much headway is being made, but every day brings us closer to the answers.

Do your part. Contribute to the effort. Keep informed. Keep in good health. Keep in touch. If you are still in contact with buddies from Vietnam who are worried about Agent Orange, tell them about the VA's program and ask them to get involved with the Registry.

The questions are complex and the answers are few. Cooperation and understanding from the VA and you are valuable first steps in coming to terms with Agent Orange. Our greatest hope lies in the resources we share together.

DR.SHEPARD: Okay. Let me just say one thing about things that will be changed. Some of the wording on the description of the registry, which we've talked about. There was a statement to the effect that these data will be scientifically analyzed and compared to other groups. That isn't accurate, and that's being changed, to more accurately reflect my earlier comments about the registry. That is being changed.

Now, do you have any comments? Yes, Dr. Murphy.

DR. MURPHY: One thing that I sort of felt was not emphasized, and I think it might be helpful, is this idea of preventing panic, if you will. And that is there was little or no discussion of the relationship of dose. The implication was either you were exposed or you were not. But how much you were exposed, of course, is an important factor, as well, as to whether one sustained an injury or not.

I thought that was not brought out as much as it might have been as a part of that.

MR. DeYOUNG: Thinking back, I can recall some discussion on it in the original content meeting. And I'm not sure whether it was consciously decided to drop it, or whether it went through attrition, because I don't think we could achieve some sort of unanimity about what kind of statement to make about dose relationship.

If anyone here could make a statement that we can all live with, I think we could include it. I can remember comments being made during the development of it that it was not a clear-cut dose response relationship in laboratory studies. And in the field the question was raised by the Air Force: how do you define a dose, you know, what is the model here. So it got very, very muddy.

DR. MURPHY: This is a principle, not a fact that you are dealing with. All toxic effects are dose-related. I suppose you could disagree with that a little bit as far as allergic reaction.

MR. DeYOUNG: As a general statement, it's true, though.

DR. MURPHY: The other thing that I was a little concerned by: Just before or while this was going on I was going this memorandum that was distributed.

I was struck by the responses, as small sample as it is, the responses that told how little the physicians seemed to know.

One thing -- and, again, I may have missed something right at the beginning -- but this compound was referred to as dioxin and TCDD, and to my knowledge never referred to as tetrachloridibenzo. 2.4.5-T was called phenoxy herbicide, never chloral phenoxy herbicide.

To most physicians, ignorant as they might be about these particular things, chloral is something that I think -- let the physicians answer about that -- keeps their attention a little bit. They know something about chloral. And that was never brought out.

Now, I recognize this is not for the physician community. But I think it wouldn't hurt, perhaps, to educate your veterans that dioxin is just, you know, sort of a very loose term. And I'll tell you a story that the first time I heard about this, my boss at that time came and asked me, "What do you know about this dioxin that somebody just discovered?" And it took me several weeks to figure out what he was talking about, because when you go look up "dioxin," or once upon a time when you looked up "dioxin," you didn't find it. You found "dioxane." You had a hell of a time finding it.

I think a little bit more precision in terminology, even though you have to, of course, use the common terminology, it wouldn't hurt to incorporate it. Maybe not this film, but certainly in a physician-educating film.

MR. DeYOUNG: The position we all finally fell back to was, "Well, this is what the veterans community knows it as." You know, "Let's talk in the language they'll understand," and make an attempt to at least clear

up the fact that not all herbicides were Agent Orange, and that it's kind of a generic noun for the six actual colors that were used, and so forth.

We dealt with that, although you're right, we did not ever say tetrachloral bibensodox, and so forth.

DR. SHEPARD: I think your comment about education, first of all, we had some time constraints to make this a useful thing. And so there was probably some detail that was not used.

The question of the understanding of the target audience: In trying to focus on the issues that were of prime concern, I think it's safe to say, first of all, we are not, as Layne indicated earlier, we are trying to develop educational tapes for physicians that will go into considerably more depth on the thing, and hopefully some of that will spill into the veteran community, as well. So that we won't just be getting physicians, but other individuals interested in the program.

Yes, sir.

DR. GROSS: I see this videotape as having sort of a dual purpose. First of all, to allay fears, panic, whatever; and, also, to help per se the veterans to come in, register and submit to examination, and so on.

I wonder if it wouldn't have been proper, along with the first objective, to have stated, perhaps, that

for those people, the Operation Ranch Hand types were certainly exposed to massive levels of this, but that in fact many serious health effects have not been indicated so far.

DR. SHEPARD: Yes.

DR. MURPHY: Well, I think some people have a question whether they had the most exposure. That's come up before. I don't know if anybody is sure they did.

MR. DeYOUNG: Well, this again was discussed in the development. And it was agreed that it was the most probable high exposure level.

I personally feel that the GIs in the field may have received a good deal higher dose through the water and ambient contamination than we imply in this tape. It's never stated specifically. It really does try to walk a fence at times; there's no question about that, to me.

I think if we fall off the fence it's on the side of conservatism. Rather than saying, "Oh, my Lord, this could have done all sorts of horrible things to you," we say, "Well, it probably didn't or you would know it by now." It's that kind of implication.

My recollection is that the Air Force representatives were quite insistent that the Ranch Hand people had the model for high probability of exposure.

DR. GROSS: In quantity.

MR. DeYOUNG: In quantity and repeated doses and such, yes. There's no question that there could be an isolated incidence of a man ingesting an amount of it, you know, from a dump, instead of an actual spray operation, or something like that.

DR. LINGEMAN: I'd like to know if the veterans in this combat area were aware of this, I understand, very penetrating odor? And did the veteran usually know what it was? Did he ask, "What is that stuff we're smelling?"

MR. DeYOUNG: The common answer was it was bug spray, or weed killer -- generic stuff of that nature.

DR. GROSS: Defoliation, they knew about defoliation.

MR. DeYOUNG: Oh, certainly. It was accepted knowledge at the time. But it was the kind of thing that was like when we leave this meeting, someone may ask you what color the walls were. And although you knew there were walls in the room, you may not have noticed what color they were and you may not recall it, because all rooms have walls, and all jungle operations had defoliants. It was that kind of thing. Nobody looked twice to see what the chemical was.

And certainly no one was specifically interested in the scientific names of the chemicals, and so

forth. It was weed killer.

DR. SHEPARD: Does that answer your question, Carolyn?

DR. LINGEMAN: Well, I just talked to a woman who claimed that the forest near her house was sprayed, and she said, "Oh, this odor was horrible; it smelled sort of like vinegar and it came out and spread across the whole area." I wonder if the veterans themselves could distinguish these odors? Were they aware of a vinegar-like odor? Or was it sort of a hazy idea that these were chemicals? Did anyone ask them, "Could you smell this vinegar-like odor?"

MR. DeYOUNG: I don't recall anything as specific as vinegar. "Chemical stink," "horrible smell"--those kinds of things -- much, much less specific than "vinegar-like smell."

I'm not sure we could be that specific.

DR. LINGEMAN: In designing our questionnaires, we came across that question. What do we ask them? "Were you aware of herbicides being used?" Were you aware of chemicals being used?" "Do you know what the chemicals were?" Is that the way we should ask the question?

MR. DeYOUNG: You may get very few positive answers to those questions, no matter how you ask them,

because the average GI would simply not know what it was. He may remember things like a horrible odor, but telling the difference between malathion odor and Agent Orange odor, that's another story entirely.

DR. SHEPARD: I think we might be of some help to you in formulating some of your questions, because we had the experience of the current registry questions, and I think we have a fairly good idea as to what questions have been productive and what questions haven't been. So I think maybe we can get together on those.

DR. LINGEMAN: We don't want to suggest -- I think there is a way to word a question so that you don't put words in their mouths.

DR. GROSS: Good idea.

DR. SHEPARD: Yes, sir. In asking questions, may I suggest that you identify yourself.

MR. BOCHICCHIO: Bochicchio, American Legion.

Reference was made to probably the highest vulnerability to the exposure of Agent Orange referred to the Ranch Hands, consisting of approximately 1200. Do we have any record at all of how many of these so-called 1200 have come in so far and have indicated a malady or a complaint about their physical condition and allegedly maybe saying that it may have been caused by exposure to the herbicide?

DR. SHEPARD: I'm sure the Air Force has some feeling for that. I don't have any hard data or even soft data. I have asked that question of people in the Air Force, and I have the impression that they are not aware of any increased incidence of either complaints or documented problems among the Ranch Hand group.

MR. BOCHICCHIO: I have not only an official reason for asking the question, but my son was a pilot and he flew and sprayed herbicide in a 123 for close to 13 months, and he's yet to be contacted by any group. And we are hoping that some day he might be.

DR. SHEPARD: Is he on active duty?

MR. BOCHICCHIO: No, he is not on active duty.

DR. SHEPARD: I feel confident that the Air Force will very shortly be contacting the identified members of the Ranch Hand group.

You say he was actually involved in the spraying missions?

MR. BOCHICCHIO: Very definitely. And incidentally his former commanding officer is sitting right there in the corner.

DR. SHEPARD: Yes. I'd like to recognize Colonel Charles Hubbs, who is a technical advisor to this Committee, and was himself in Vietnam, and as I understand, was involved in the Ranch Hand operation there.

Perhaps you would like to have a word or two, Colonel.

COLONEL HUBBS: I don't have any comment. Thank you.

CHAIRMAN SHEPARD: Okay. Nice to have you here. Yes.

MR. ENSIGN: My name is Tod Ensign, with the Citizen Soldier organization. This is the first chance I've had to see the film, so I have a lot of reactions. But there are two that strike me that I think border -- they are omissions that border, I think, on distortion of the record, serious distortion.

One is the fact there is absolutely no mention of the fact that the program was ceased in 1970 or '71, according to some accounts, because of a major international controversy over the health effects, particularly upon the Vietnamese civilian population.

I think that's a pretty serious omission. And parenthetical to that is the fact there is no mention of the fact that Dr. Tung, among other Vietnamese scientists, has published a number of studies which demonstrate certain human health effects. He has one now that has been completed that is undergoing review for publication in this country.

The second part of it is, and even more offen-

sive to me, is the implication that there's no controversy in this country over the widespread use of this in domestic agricultural and forestry operations. And I think when you consider that the EPA only for the second time in its history used its emergency powers to withdraw 2,4,5T from most use in this country in March of '79, I think that certainly is an omission -- I realize the purpose of this is to reach veterans and talk to them about the problems they uniquely experienced, but I think that there should be some recognition of the domestic controversy and the international controversy over the uses of these compounds even right up to the present time.

DR. SHEPARD: Thank you. I think, again, I agree, I think that we could have emphasized more of the controversy. I think, however, that our concern for allaying concerns or avoiding raising unnecessary concerns is something we have to keep in mind, also. And if one emphasizes or highlights controversy without going into considerable depth and evaluating the controversy and coming up with a bottom line which may not still be there, which isn't there, really-- that part of our goal in this may have been overtaken.

DR. MURPHY: Dr. Shepard.

DR. SHEPARD: Yes, sir.

DR. MURPHY: I would think that you are walking

a very narrow line there to achieve that without losing credibility. And that's why I think you've got to be very careful. You know, it isn't going to do any good if the target population says, "Well, you know, we've talked to scientists and we've read this, and you don't even mention it."

I think, you know, sometimes you might have to do a little explanation and educating as to details.

DR. SHEPARD: Yes.

DR. MURPHY: That's another thing I didn't mention before that I thought was somewhat of an omission and played down was the implication that you can't make any direct -- and that's true, in a sense -- extrapolation from animals studies to human effect. But a lot of the animal studies are causing people to ask the questions. And, you know, if you say it doesn't really mean anything--

DR. GROSS: I thought this was mentioned in the film. There was a clear statement that TCDD is a highly toxic material. And this is well known and animal studies are available. I looked for that myself, and I thought I saw it in there.

DR. MURPHY: Well, there's a difference of opinion on how much.

DR. SHEPARD: One thing I might say. I hope part of the use of this film will be to stimulate

discussion, and hopefully veterans seeing this film will then grasp the opportunity to discuss some of the issues and some of the unanswered questions with environmental physicians and other individuals in the medical centers. And I hope this will serve as a tool to open up a dialogue. I think this would be helpful.

MR. DeYOUNG: I have a specific question that I would like to get a few responses to, at least. I'd like some opinions on the scientific validity of the section that discusses the photo-degradation in sunlight of dioxin. This is a piece of --

UNIDENTIFIED SPEAKER: Self-study.

MR. DeYOUNG: Yeah. It's documented in a number of different ways. I mean I have studies given to me by various people that purport to prove that it breaks down very quickly in sunlight, and that when you put it in shade or under water, it persists for a much longer period of time, and so forth.

Is there any commonality? Is there any consensus in the scientific community as to where we are on this?

The bottom line question is: Is the tape middle-of-the road scientifically sound in saying, first, that it begins to degrade very quickly in sunlight? The implication given by that passage is that it becomes

safer the longer time goes on.

And secondly, the passage that discusses the jungle intercepting the herbicide and the dioxin before it gets down to the jungle floor, and, therefore, the chances of contamination were slight, or something like that.

Is there any reaction to these?

DR. GROSS: I thought it was proper because it is known that this is a fact now. How specifically well documented it is, we don't know.

On the other hand, no claim was made. They talk in general about chances. I remember the arrows with only a small part within, and there is no reason to doubt that. It does degrade. Under the action of light there is photo-degradation. But how much, there was no claim being made here specifically.

MR. DeYOUNG: There was no specific claim. But it strikes me that the implication of the passage, however, is that a relatively short amount of time renders it much less harmful than it originally was. Is that an appropriate statement?

DR. MURPHY: Well, I don't know.

MR. DeYOUNG: I don't, either. I have some reservations about this passage.

DR. MURPHY: Sure it does. A relatively short

amount of time renders a monomollecular layer of that pretty quickly. You know, it degrades, detoxifies quickly under sunlight. But I don't know how fast the whole residue would degrade, if there was a residue there.

I think that there's no real scientific error in what was said there. I think it's a matter of emphasis and a matter of degree. I had somewhat of a sense that you were implying, you know, in two or three days with the sun shining on a defoliated area, it would be gone. I doubt that that would be the case. It might be after two or three weeks.

MR. DeYOUNG: Thank you.

DR. SHEPARD: There is research being done on that, though. In the Rome meeting there were some references to photo-degradation. Although I can't put my finger on it right now, it is an area under scientific investigation. And there was nothing said in Rome that would not go along with what is said here.

DR. ROSS: I would like to comment on that, also. I paid particular attention to that. I think that in a general sense, I think it was a very straight-forward end to the film that if the majority of the spray remained on the foliage, and depending on the climatic conditions, whether it was a rainy day or cloudy day, certainly if it was a very bright day, most of the dioxin, yes, would de-

grade on the foliage. But I think the literature also substantiates that a residual part of it would go to the ground and combines very readily with the soil and it has a much, much longer half-life.

So the question there would lie, how thick the jungle would be, how much would remain on the foliage, and so forth.

I think that you would probably get a majority with maximum exposure on the foliage, which, indeed, I think your film accurately reflects that.

MR. HANSON: My name is John Hanson. I have a couple of observations and a couple of questions.

One, the videotape, in discussing the different methods which were used to spray Agent Orange from trucks, back-packs, airplanes, and the like, said that it was used to clear some base camp perimeters..

I think that perhaps that is not an accurate indication of the degree to which base camp perimeters were sprayed. I think you will find that probably most base camp perimeters were sprayed. Not all were sprayed with Agent Orange; some were sprayed with Agent Blue, which is cacodylic acid. Of course, it's an arcetic.

So I think that perhaps that is not an accurate characterization of the use of herbicides to clear base camp perimeters. The first hundred meters outside any

base camp was a free spraying area. There was no required approval for it to be sprayed, and it could be sprayed any time the commander in charge wanted it sprayed.

I think that perhaps ought to be looked at as to whether or not you ought to change that in the tape. I believe the tape said it was used to clear some base camp perimeters. What I'm saying is I think a more accurate statement would be that it was used to clear most base camp perimeters, because I certainly don't think that you want to mislead a veteran who was inside a base camp and spent most of his time there, so that if only a few base camp perimeters were sprayed, it may diminish his potential for having come in contact with herbicides.

Second, the tape does mention some of the animal studies that have been done and some of the findings in the animal studies, and does point out that while there have been some good results here-- and I'll try and state this as close to the tape as I can -- that the animal tests may be misleading indicators of human effects.

I think that's pretty close to what the tape says. I think the word "misleading" was used in there. However, at the end of the tape, when you go into the section that talks about what the VA is doing, one of the things it said that's doing is helping to conduct more animal tests.

Well, in the tape you're telling the veteran, on one hand, that animal tests, while they might be interesting, are misleading indicators of human effects. And my question is: Why does the tape at the end say, you know, the VA is involved in having more animal tests conducted?

I'm certainly not questioning whether animal tests are useful or not. I'm saying that there's a basic inconsistency in the tape with regard to your views on the value of animal test results.

DR. SHEPARD: Will you check that?

DR. GROSS: I didn't hear the word "misleading."

DR. SHEPARD: I didn't, either.

DR. GROSS: Because I would have violently objected had I heard that.

MR. HANSON: Well, perhaps I mischaracterized it. But I think the tape made it very clear that animal test studies, they cast a lot of doubt on their applicability to human health effects, or even as an indicator of human health effects.

MR. DeYOUNG: I can give you the quote, if you like: "Animal studies give some insight into the possible chemical effects in man, but it is misleading to make direct comparisons between humans and animals."

DR. GROSS: That's a little different.

MR. DeYOUNG: It's been changed a little since then and I'm not sure exactly how.

DR. GROSS: I would object to this statement.

MR. HANSON: You know, it's interesting, but the the question is, what are human effects? We know what effect it has on some species of animals that it's been tested on. But if the question is human effects, and the tape states it is misleading to apply--

MR. DeYOUNG: Directly apply.

MR. HANSON: To directly apply animal test results to humans, I would certainly raise a question at the end: Why is the VA going to spend money doing more animal tests when they have already said in the tape that they may not be good indicators of humans? Why isn't that money being spent to focus on human health effects problems?

DR. SHEPARD: Animals are first.

MR. HANSON: I realize that, Dr. Shepard. I'm not questioning that. But I'm saying I think it's misleading.

DR. MURPHY: Of course, I'm a little defensive about this, too, being an experimental toxicologist and not believing epidemiology ever gives you a conclusive answer. I just think it's bad practice to give the implication that you can't, that animal tests don't have

some pretty important function in interpreting human health effects.

So I would hope this could be softened as much as possible. Mr. Hanson is bringing this out.

Another aspect of this is, you are going to turn this around and use animal data to support the indication that birth defects don't seem to be happening, or don't seem to be a likelihood. You know, you can't--

DR. SHEPARD: You can't have it both ways.

DR. MURPHY: That's right.

DR. GROSS: Well, I just hate to say that animal findings are misleading indications as perhaps too strong. You may question the relevance of animal findings, which is all right. But to actually go as far as to state they are misleading, that would be a misleading statement itself.

MR. DeYOUNG: We'll look at a constructive clean-up on that one.

MR. HANSON: Let me make a couple of other observations, if I might.

A previous questioner mentioned that there was nothing in here to indicate that studies done by Dr. Tung in Vietnam had been included. And it brought to mind something that I did not recall mentioned, and perhaps there's a good reason why--I don't know.

In discussing whether or not dioxin could have gotten into the food chain, I recall a study done by Dr. Messleton and Dr. Vohlman at Harvard, that they had done studies in Vietnam and did find traces of dioxin in fish in a river in Vietnam.

Now, I don't know whether that study has been generally accepted as some indication that dioxin did get into the food chain or not. If it is a good indication, then I think it might be a good idea to consider showing that a study was done on it. I think to my knowledge, it was the only study done on this aspect in Vietnam.

I don't think the scientists from the National Academy can get back into Vietnam, but perhaps you ought to look into whether or not that kind of information should be included, as, indeed, it might be the only indication of whether or not dioxin could get into the food chain.

Finally, I believe you mentioned that at the request of the Administrator, certain service organizations were asked to comment on this tape. I have a couple of questions with regard to that.

One, what service organizations were asked? Were the same ones asked to comment on the tape who were asked to comment on the draft pamphlet about Agent Orange? If they weren't the same groups, why not?

I think that really what I'm getting at, Dr. Shepard, is I think this is an important step as far as the VA is concerned, and getting out its message on how Agent Orange was used, what the effects may or may not be, and what the Veterans Administration is doing about it. Since there seems to be a very critical group of veterans as to what the Veterans Administration has done, it might be good before this tape is sent out and disseminated all over the country that you insure that you at least listen to the comments of those types of groups.

I certainly think that perhaps they could provide some insights which may be beneficial to making sure the tape is a reasonably balanced representation of the body of knowledge that exists with regard to Agent Orange.

That's all I have.

DR. SHEPARD: Thank you, John.

Any other comments? Yes, Dr. Erickson.

DR. ERICKSON: A request. I became aware this morning that I'm confused and it seems, perhaps, several other people are confused about this registry and what its purpose is. It occurs to me that we have never seen anything written about the registry; we've nevef seen the questionnaire.

I wonder if you could arrange for the Committee to receive documents of that sort.

DR. SHEPARD: Certainly. I'm somewhat embarrassed to think that this Committee had not been provided with copies of the questionnaire. That information appears, I feel confident, in some of the material that you have. It may not have been ferreted out and highlighted.

For example, I think we circulated the testimony of February 25th to all members of the Committee, and that does appear in there, Dave. But we were probably negligent in the fact that we haven't highlighted it. And we will certainly be happy to do so.

The questionnaire, of course, was formulated fairly early.

DR. GROSS: That's the questionnaire that is appended here? I saw a questionnaire here some place.

DR. SHEPARD: I don't think it's in the package you received today, but in the previous materials that have been provided to you, I think you will have it. But certainly, anybody who wants a copy of that we will be more than happy to provide it.

Go ahead, Dave.

DR. ERICKSON: Beyond that, I wonder if you have some written material describing the registry and its anticipated usage. Apparently, your position on that has changed from the time the tape was written to this

morning, and I guess my gut reaction is that either of those extremes may be too severe and you might have some possibility of getting something quasi-scientific out of your registry.

DR. SHEPARD: That question has been raised, and I think the temptation is to say that after we get this information, we will make some analysis of it. I'm not a statistician by any stretch of the imagination, and perhaps I should be rapped on the knuckles for even implying that that might be the case. So I'm understandably, I think cautious about claims for the registry.

But, yes, we do have some descriptive material. We would be happy to provide that. Yes, sir.

MR. SMITH: Richard Smith. In the videotape was listed the various ways you could come in contact, a soldier could come in contact with Agent Orange-- walking through a sprayed area, drinking the water, or the direct contact, by handling the substance. And my question is: If the substance breaks down slower once it is in contact with the dirt, if you were digging in and spending a lot of time in a hole, wouldn't your risk be maybe a little bit more than walking through a sprayed area?

DR. SHEPARD: Do you mean like in a foxhole where spraying had taken place previously?

MR. SMITH: Yes.

DR. SHEPARD: I think that certainly theoretically may well be the case. Again, it's a question of documenting that. And how much of it, I think the point has been made, and I think accurately, that relatively little of the material actually got onto the ground in those areas where there was thick overgrowth of jungle. That was primarily the areas where it was used.

How much of it actually penetrated the ground, I just have no way of knowing, and I'm not sure that anybody has actually assayed that. Dr. Hobson.

DR. HOBSON: The Air Force studies that were carried out at Eglin Field very carefully went into that. Dioxin remains in the very top layers of the soil. So I would imagine, although I am not sure, if you dug a hole and threw the dirt out, you would be below the level where there was much dioxin. And there was very, very little there anyway. It does not migrate within the soil to any extensive degree, as I recall.

MR. DeYOUNG: I have one last area of concern to me. When the development of this script was begun, we were in a pre-Hardel situation. We did not have the Swedish study, some of the later things on soft tissue carcinomas, and so forth.

I'd like to get a sense from the members of the

Committee that are qualified to comment: Are these things important enough to now justify some subtle rewrites to include this and the fact that the AFIP study will be forthcoming? Are we far enough along on that that we can say something?

DR. SHEPARD: I'll be happy to hear from other members? I have my feelings on that, but let me hear from the rest of the Committee first.

DR. FITZGERALD: I'll approach that, if you want me to.

DR. SHEPARD: Sure.

DR. FITZGERALD: I would think that that information is available to the examining physicians and will be stressed in the VA indoctrination of these physicians, so that they would be the ones that would be looking for soft tissue tumors. I think it would be kind of difficult to get it across to the general population to any significant degree without getting scare tactics going again.

MR. DeYOUNG: I understand that will be extremely difficult to phrase, because we start talking about things like "significant," and all of a sudden--

DR. FITZGERALD: That's right.

MR. DeYOUNG: -- it changes its meaning, you know, from a statistical to a common conversation.

The question that I have, of course, is: Is it fair -- possibly the right word is "hide" material information which may or may not be difficult to understand, but at least to my personal values, it should be in there.

DR. FITZGERALD: I don't think there's any attempt to hide it.

MR. DeYOUNG: No. If it had been meant that way, I wouldn't even mention it.

DR. FITZGERALD: But I think here, again, it's not possible to go through a symptomatology that would be complete and accurate for every individual who does not have technical knowledge about that symptomatology. I think it's extremely important that the Veterans Administration make their physician-examiners aware of the potential incidence of soft tissue tumors so that they are looking for it.

I think the question that goes out to the veteran asking about the existance of malignancies as a whole is quite appropriate.

DR. GROSS: Perhaps a middle ground would be--and I believe that to be the case--that one is looking into perhaps this kind of association. We are concerned about this because of suspicions or evidence whether there is increased risk. You don't have to say whether it is significant or not, but efforts are currently under way,

without coming to any sort of conclusion that such an association has been made.

DR. SHEPARD: One thing that I think we strive for in a tape such as this, that we hope will have a useful life, is not put things in it that may be changed in the near future and, therefore, bring the credibility of the entire tape into question.

In other words, that was why, I think, the business of avoiding controversy, because controversy shifts.

DR. GROSS: Yeah, prevailing winds.

DR. SHEPARD: And we get an awful lot of sway back and forth as to controversial areas. If you build too much of that kind of thing in there, I think you run the risk of limiting the usefulness of the tape for providing general background information.

That isn't to say that we shouldn't come out with a follow-up tape, an update, or other material, not necessarily a tape. We tried to keep it fairly basic, fairly solid information that was not likely to change in the near future.

MR. DeYOUNG: I have one last concern. It's something that does not confuse. The hand-out that Mr. Thompson passed around points up that although this is a very limited response, that many of the criticisms of the

veterans who did respond center around the environmental physicians and other attending staff at the hospital.

In light of that criticism, I think it may be incumbent upon us to go back and take a look at our statements about the environmental physician being your prime source of information to the veteran, and so forth. That is a theoretical ideal; there's no question about that. The question is how well it is actually coming out in every instance, and I think we need to, at minimum, take steps to insure that the environmental physician is well informed and presents the image of being well versed.

DR. FITZGERALD: Ron, I think I would like to answer that, again. And that is that, yes, this is a concern to the veterans service organizations as to how the individual veteran is being received, how his complaints are being taken care of. And each of these service organizations have memberships that are pursuing this. And indeed, if there is an individual hospital where this is occurring, we want to know about it, and then we send our membership out there to assure that the proper care is being received by that veteran.

We have done this on at least one incident at a hospital and found that the information that was originally portrayed was not necessarily completely borne up. The individuals who would be complaining quite

frequently are the ones who have a cause that they are trying to pursue and do not necessarily, unfortunately, represent the majority of individuals that are being seen at that hospital. So we have to be sure that we are dealing with a factual situation and not an emotional situation.

Yes, we do pursue this very vigorously, the same way we do for the treatment of the veteran for anything, not related to environmental or anything else. And we are specifically asking from our membership for incidents of this nature so that we can examine it.

DR. SHEPARD: Thank you.

Tod, you sent up some questions earlier. Did you want those dealt with now, or can I get back to you? I think I can answer them fairly quickly, but maybe I can talk to you separately. Or would you like for them to be part of the discussion?

MR. ENSIGN: I would like to have them part of the discussion.

DR. SHEPARD: Okay. Tod Ensign from Citizen Soldier asked the following three questions:

"This past week I was told by Dr. James Dwyer and Bob Smith of the State University of New York, Stoneybrook, that they have heard nothing from any member of this panel as to the preliminary study they have conducted

on 1,313 Vietnam veterans who completed our medical questionnaire." "Our" being a Citizen Soldier questionnaire, I presume. "As you know, their findings suggested a causal link between exposure to herbicide in Vietnam and ailments long associated with exposure to TCDD.

"I would like to know what plans, if any, this panel has for consulting and cooperating with Dr. Dwyer and Dr. Smith so that the maximum scientific benefit can be obtained from human health data we have collected on 5,000 Vietnam veterans."

First of all, I'm not aware that we were sent this material. It's my understanding that this material was sent to the inter-agency work group and is currently under review or to be reviewed by the scientific panel of the inter-agency work group.

If that answers your question, I think that I have heard from the inter-agency work group and I understand that this will be a subject on the agenda for the upcoming meeting. We'll be following that with great interest.

The second question: "In a recent newspaper which we sent to 14,000 Vietnam veterans we mentioned the herbs-tapes and their value in tracing exposure history for individual veterans. A large number of veterans have called to ask how they might gain access to this record.

Have you given any thought to possibly making a copy of the herbs-tapes along with detailed maps of Vietnam available at each of your 172 medical facilities?"

The herbs-tapes themselves are, as you know, are the data on the spraying missions that took place in Vietnam. I think it is not accurate to say that they deal with individual veterans. They talk simply about the sprayed areas. I think to make a correlation between the tapes and individual veterans would have to require a unit diary history indicating where the unit operated and at what time.

The matter of giving thought to maps of Vietnam, we haven't, at least I haven't, taken that into consideration. Maybe other members of the Committee have thought about it. I'm not sure, other than general geographical information as to where in Vietnam the herbicides were used--that certainly could be done. To include on that map such information as to when the spraying missions were conducted in each area of Vietnam, I think becomes a little more complex.

Certainly I think that any veteran or any group of veterans who are interested in knowing about where the spraying missions occurred, that information is available, and I'm sure we would be happy to share it. The Department of Defense, of course, is the agency that

has the most detailed and accurate information in that area. They have made it available to us.

But I think to make it, you know, a general distribution, I think might not serve the best interests of the veterans. I think that probably questions relating to specific units and when the herbicides were used, you know, coming from the veterans groups it would be fine. But I would be happy to hear any suggestions along those lines.

The third question: "In reviewing our files on Air Force personnel who were handlers of Agent Orange in Vietnam, it appears that a significant proportion were on TDY, temporary duty,during such exposure and hence may be missed in the Air Force's proposed study of 1200 Ranch Hands. Have you given any thought as to how such additional personnel might be identified and included in the Ranch Hand study?"

I, of course, have not. I'm not directly involved in the Ranch Hand study myself, although as a member of the inter-agency work group and of the scientific panel, we've been very interested, and so forth. But I can't answer the question as to whether non-designated Ranch Handers or other Air Force personnel who might have been on temporary duty as Ranch Hands have been identified.

Dr. Hobson, do you have something to add?

DR. HOBSON: At a meeting of the scientific group, at which Dr. Shepard was not present for that part of the discussion, the Air Force did go into this question. They felt that it would not be possible to identify those people through any records that are extant. Therefore, they felt that they could not expand it. They looked rather desperately, as I understand, for a way to expand the size of the Ranch Hand group in order to make this study of greater significance. They have been unable to do that.

Since that is quite a "clean" population where there is a great deal known about them, to add people where exposure is suspected but not known, would weaken the study. So they have not been able to do it.

DR. SHEPARD: Any other questions or comments?

MR. DeYOUNG: I'd like to come back to the second question there. The herbs-tapes that were mentioned along with map print-outs and other information on what we have been able to collect on troop movements at least are available through the St. Louis office of the task force.

DR. SHEPARD: Thank you.

MR. DeYOUNG: A couple of housekeeping items:

Is the transcript of the last meeting out yet?

DR. SHEPARD: It will be soon. I think it's in its final phases of correction.

MR. DeYOUNG: Very good. Have any of the Committee members responded to the requests for evaluation or review of the European studies that were dispersed at the last meeting? Do you have anything in writing on that yet?

DR. SHEPARD: Yes, we have. What I'm hoping to do is to collate those and send them around for a final Committee -- well, what I will do is draft what I consider to be a Committee consensus and then circulate those for information and comment.

Thank you very much for attending the meeting and we look forward to seeing you at the next one.

(Meeting adjourned at approximately 12:40 p.m.)

REPORTER'S CERTIFICATE

I hereby certify that the foregoing is a true and accurate transcription of the proceedings of the meeting of the Advisory Committee on Health-Related Effects of Herbicides held at the Veterans Administration Central Office, Washington, D.C., on Thursday, November 6, 1980.

DOyne W. Spencer
Certified Shorthand Reporter

I hereby certify that the proceedings and evidence herein are contained fully and accurately, as coorected.

BARCLAY M. SHEPARD, M.D.
Chairman
VA Advisory Committee on
Health-Related Effects of Herbicides

December 23, 1980

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

(Seventh Meeting February 4, 1981)

April 1981

Washington DC 20420

VETERANS ADMINISTRATION

ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES

Wednesday, February 4, 1981
Veterans Administration Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D. C.

The Committee met, pursuant to notice, at 8:30 a.m., Barclay M. Shepard, M.D., Chairman, presiding.

ATTENDEES:

BARCLAY M. SHEPARD, M.D., Chairman
Veterans Administration

IRVING B. BRICK, M.D.
American Legion

RONALD W. DeYOUNG
National Veterans Task Force on Agent Orange

ADRIAN GROSS, Ph.D.
Environmental Protection Agency

LT. COL. RICHARD A. HODDER
Uniformed Services University of the Health Services

NELSON IREY, M.D.
Armed Forces Institute of Pathology
for: Carolyn H. Lingeman, M.D.
National Cancer Institute and Armed Forces Institute of Pathology

PHILIP C. KEARNEY, M.D.
Department of Agriculture

ALBERT C. KOLBYE, JR., M.D.
Food and Drug Administration

ROBERT H. LENHAM
Disabled American Veterans

MARION MOSES, M.D.
Mount Sinai School of Medicine

SHELDON D. MURPHY, Ph.D.
University of Texas Medical School

RAYMOND R. SUSKIND, M.D.
University of Cincinnati College of Medicine

C O N T E N T S

P R O C E E D I N G S

(8:30 a.m.)

CALL TO ORDER AND OPENING REMARKS

DR. SHEPARD: Good morning, ladies and gentlemen. I think we best get started. We have a very full agenda this morning. It is indeed a pleasure for me to welcome you all to this quarterly meeting of the VA Advisory Committee on Health-Related Effects of Herbicides.

I think it is safe to say that this Committee has acted in a most responsible manner and has provided a tremendous amount of input to the Veterans Administration. It has provided avenues of communication between the VA and other Federal and non-Federal agencies.

So, it is really a pleasure for me to host this meeting and to welcome you all to it.

We have with us, besides the members, a group of distinguished visitors. I am most pleased that these individuals have taken time from their busy schedules to be with us and share information in their particular areas of expertise.

We are most delighted to welcome Mr. Fredrick Mullen from the Veterans of Foreign Wars; Mr. James Striegel from JRB Associates; Dr. Giuseppe Reggiani from Switzerland; Dr. Clifford Roan and Mr. Harold Collins, who will bring us up to date on some very interesting work

that has been done by the National Agricultural Aviation Association, and we are particularly pleased to have our friends from the Air Force, Major Al Young and Col. George Lathrop.

I would just like to spend a few minutes bringing you up to date on some highlights of activities being undertaken by the VA, but before I do that, I would like to introduce two new members of our Committee. First of all, Dr. Marion Moses, who comes to us from Mount Sinai Medical School and is in the Department of Environmental Sciences. She works very closely with Dr. Selikoff in the Environmental Sciences Laboratory.

Welcome to our Committee, Marion; it's nice to have you here.

We also have Dr. Albert Kolbye, who comes to us from the Food and Drug Administration and has had considerable experience with the issue we are addressing.

Dr. Kolbye, it is a real pleasure to have you with us.

DR. KOLBYE: Thank you very much, sir.

DR. SHEPARD: We regret that a very faithful member, Dr. Carolyn Lingeman from National Cancer Institute could not be with us, but she is ably represented by Dr. Nelson Irey, who will have a word to say about the status of the AFIP Agent Orange Registry.

Dr. Nelson Irey, a long-time member of the staff at AFIP, also has a distinquished career in the Army. He is heading up the AFIP Registry so it is, indeed, a pleasure to have you with us, sir.

We are very pleased to report some new developments since our last meeting. We have now awarded the contract for the long awaited literature analysis. We are delighted that JRB Associates was the successful bidder. We will be hearing a little later on in the program from Dr. Jim Striegel who is heading up that project for JRB.

We have finally completed and distributed to our field activities the videotape on Agent Orange, which some of you have seen the previous editions.

As I say, the final edition is out and has been distributed to all our medical centers, our regional offices, our readjustment counseling centers, our information service office area directors, and is currently being shown to the veterans for whom it was intended.

We have issued our first copy of the Agent Orange Bulletin and members of the Committee have it in their packets, and we are working feverishly on getting out the second edition.

The epidemiological study is, I hope, its last stages of development as far as the contract award is

concerned. Some of you may be aware of the fact that the Government Accounting Office has been reviewing that process and has made a report. We are now awaiting the final decision from the courts as to our ability to proceed with that important effort.

The Agent Orange Registry continues apace. We now have well in excess of 40,000 veterans examined at our various medical facilities and we have in excess of 20,000 of those individuals enrolled in the computer data bank. So, we are now beginning to look at some of the data that is in the data bank. We have already developed procedures for analyzing and evaluating the information that is in the registry.

We will be reporting on that at our next meeting most likely.

I would now like to introduce Dr. Nelson Irey who will just say a brief word about the status of the AFIP Registry.

AFIP REGISTRY

DR. IREY: Thank you, Dr. Shepard.

The Armed Forces Institute of Pathology has been designated as a center for collected of biopsy and autopsy material on Vietnam veterans. We also have been designated as a center for a similar purpose by the Surgeons General of the Army, Navy and Air Force. We also

received a certain amount of material from civilian hospitals and pathologists unrelated to the Government agencies.

The majority of our material, however, is coming from the VA medical network. So far, we have about 170 cases. We are trying to find out what the medical problems of the Vietnam veterans are currently as reflected in biopsy and autopsy material. 160 or 170 cases is a rather small number, but they are beginning to come in in much greater numbers in the last three or four months.

We are looking for trends, peaks either in anatomic sites, or in diagnoses. So far, having analyzed in a preliminary fashion the data of these roughly 170 cases, we have found no peaks, no trends in either of these major areas.

Dr. Lingeman, who is the regular member here, who I am representing today

is conducting a case control study on soft tissue sarcomas in conjunction with, in cooperation with Dr. Franz Ensinger of the AFIP, who is in charge of the soft tissue department, and that is in its incipient stage and has nothing yet to report through her.

Thank you very much, Dr. Shepard.

DR. SHEPARD: Thank you very much, Nelson.

A couple more housekeeping notes that I should have mentioned earlier. First of all, we are happy to announce that Dr. Patricia Honchar, from the National Institute of Occupational Safety and Health has been appointed a regular member of the Committee. She has attended Committee/meetings as an alternate on a number of occasions.

The person for whom she was an alternate, Mr. Richard Lemen, because of press of other duties has resigned from the Committee. Dr. Honchar has very graciously accepted the appointment in his place.

She was to have been here to report on the Dioxin Registry on which she has been working so diligently. Unfortunately, something came up at the last minute which prevented her from being here, so she sends her apologies. She will be preparing a report in the not too distant future as to the status of the Dioxin Registry, and we will circulate that to the members of the Committee for their information and consideration.

For those of you who have not registered, we would like to keep a record of visitors and guests, so please be sure that you sign in at the back of the room, if you have not already done so.

As in past meetings, we will make a portion of the program available for questions to the members of the

Committee.

In the event that any of you have questions for members of the Committee please indicate this to Don Rosenblum, who is in the back of the room. He has cards on which to write questions. At the end of the formal agenda, we will open up the floor for questions to members of the Committee.

One of the strengths of this Committee, I feel, is the representation and the participation of our dedicated service organizations and we are most pleased to have their participation.

I would now like to call on Dr. Irving Brick, who represents the American Legion and ask him what is new in the Legion that would be of interest to our Committee.

REPORTS FROM VETERANS SERVICE ORGANIZATIONS

DR. BRICK: Good morning.

The Legion continues to be bombarded with requests relative to when the Committee's work is going to be done and what is going to come out of this Committee's work. The level of interest in the Agent Orange issue seems to have peaked a bit. I don't think that it is as intense as it was, but there is still a lot of interest in it.

The American Legion is conducting with its

service officers in the field a questionnaire of veterans relative to how this problem is being handled in the individual medical centers.

I think the preliminary data would indicate that there's a wide variance relative to the knowledge that many of the medical centers have, and I am sure that Central Office is attempting to, by various publications such as the bulletins which go out, such as the Agent Orange Bulletin and the Vanguard, to disseminate current information relative to the problem.

In rating, my participation has a lot to do with cases before the Board of Veterans Appeals and we are not seeing many cases. We're not seeing a host of cases, but we are seeing sporadic cases which come to our attention and usually -- as a case I handled just yesterday, a 34-year old veteran with cancer of the bladder whose urologist claims that this is related to his exposure to Agent Orange.

In order to give the veteran a shake at some kind of medical opinion, when he gets an opinion such as this from his own physician, who is a certified specialist in urology in this particular instance, I am hopeful that your office, Dr. Shepard, in Central Office will be of assistance to the Board of Veterans Appeals, if you are requested to give opinions on matters such as this.

I think the set up that was established with you as the Chief and the Special Assistant for Environmental Medicine will serve a useful purpose when rating boards avail themselves of this expertise in your office, and I trust that this is going to be helpful in these matters.

Members of this Committee should understand as far as veterans are concerned, the bottom line is compensation. I know that is difficult for some of the members of this Committee to understand, but particularly when economic situations is as stringent as it is and the budget is going to be stringent, we are told repeatedly on TV and papers and from the White House, that I think we are going to be faced, service offices in the field and people who work with veterans organizations here in Washington are going to be faced with many, many more claims of this sort.

I think that the Veterans Administration should gear up to handle these claims in a sympathetic and as fair a manner as possible with the limited knowledge that we have at the present time relative to the Agent Orange problem, and its causation of various alleged diseases.

Thank you.

DR. SHEPARD: Thank you very much, Dr. Brick.

I appreciate your comments about the role our office should play relating to the Board of Veterans

Appeals. It is perhaps not coincidental that just yesterday, or was it Monday; I guess it was Monday, we were privileged to give a briefing to some key members of the Board of Veterans Appeals, informing them as to the agency's ongoing activities and plans for the future, and, also, encouraging a closer relationship, a closer dialogue with that most important effort of the Veterans Administration. In fact, we have now referred a case for our contributions, in terms of helping make some difficult decisions. I certainly share your concern that there is still, and I suspect there always will be, a lack of understanding in the medical community on this complex problem.

It is unfortunate that individuals are persuaded to make comments such as you have indicated. I think with a physician making the comment that an individual's bladder cancer was likely caused by his exposure to Agent Orange which is not fully supported by the scientific data, just serves to further raise the concern of veterans quite apart from the compensation issue. This is also very important, of course, but when comments or information such as that are widespread, obviously, you are going to raise concerns. And so, I think, that this Committee can serve a very useful function in trying to sort out the

facts and put these things in perspective.

I'd like next to call on Mr. Robert Lenham for his comments.

MR. LENHAM: Thank you.

I share similar views with Dr. Brick. We continue to see throughout our offices, veterans coming in and we are experiencing frustration on the national service officers' part in as much as we really don't have anything that we can conclusively reiterate to the veteran with respect to the issue.

Doubly so, the veteran is frustrated when he files a claim and basically is going through the motions, so to speak, and also when he goes to the VA hospitals and has medical examinations.

Some of the inquiries that we have seen from the veterans come from the medical examinations and they feel evidently going in that they will be able to get some type of a result or some type of a comment from the examining physician of, you know, whether or not they have in fact dioxin in their system, and some type of a positive or negative answer either way that would guide them. And they don't have any feedback from the physicians. That adds fuel to the fire in the frustration level.

It is one that all of us are dealing with. We have no other choice right now until we can get some

conclusive studies that will provide us with the guidelines on which to go. And I think for the better part, that the national service officers out in the field, you know, have handled themselves quite well. But you can see where some frustration comes because they have to deal with these veterans daily, and don't really have anything to offer them.

We have gotten over probably 2,000 inquiries now directly into our headquarters, and more so out in the field, so the interest and the concern is still there. And will still be there, I think, until this Committee comes out with some conclusive evidence.

DR. SHEPARD: Thank you.

I appreciate it.

Yes, sir.

DR. GROSS: I have two questions on this. Number one, what has been the impact of this little orange bulletin that was issued whose purpose was to allay fears, such as you speak of the need for gathering information. That's question number one.

Question number two: what are the service organizations themselves doing to explain the workings of the Committee, the area -- the stage at which the science is here. We're waiting for lots of things; we really don't know. What are you folks doing to put certain minds at

rest?

MR. LENHAM: Okay. On your first question with regards to the VA's pamphlet on Agent Orange, we have gotten comments back that it is superficial. It is something that is trying to relieve concerns, but it is not working. Now, this is comments from the veterans.

The answer to your second question with respect to the organization, our organization has a monthly magazine which goes out to over -- well, over 700,000 individuals. We periodically put updates in that magazine with respect to what this Committee is doing and what other research is coming in with respect to the issue of Agent Orange so that we can apprise our members of where we are right now.

And then the national service officers in there own areas conduct what we call open meetings where they go out and speak to the veteran populations, to our chapter members and apprise them of where we are right now with this issue.

That is the efforts that our organization, the DAV has taken.

DR. GROSS: Do you feel you are being effective with these things?

MR. LENHAM: Well, effective as much as we can be with what we have to work with. We are keeping them

apprised out in the field with as much knowledge as we are obtaining here.

DR. SHEPARD: Thank you very much, Bob. I appreciate your comments. I think that in the press of all of our other activities, we have perhaps not maintained as close liaison with service organizations here in Washington as we could have in this particular issue. The thought occurs to me that it might be helpful for us to perhaps provide, on a regular basis, some material that you could include, inyour own judgment, in your various publications, and use that avenue to, at least, inform veterans as to what the VA is doing.

MR. LENHAM: We would welcome that.

DR. SHEPARD: Good. In the matter of the follow-up, and I should have mentioned that earlier, many of you know that we conducted a rather small survey.

A questionnaire was mailed to approximately 100 randomly selectly veterans in seven of our medical centers to get some kind of a feel as to their impressions of the Agent Orange exam experience.

It came back -- we were gratified that we got over 55 percent response from that questionnaire, which is I think, a pretty good average when you consider responses to questionnaires in general. We tried to keep it simple and easy to answer.

One of the things that came through from that was that we havenot done as well as we should have in terms of insisting that follow-up information be provided to veterans following their examination.

In a number of instances, I think, what has probably gone on is that the veteran has been told that if you don't hear from us that means everything is okay.

We don't feel that is totally satisfactory in an issue that raises as many concerns as this has. Consequently, we have just recently gone out with a circular to all our medical facilities giving some very specific guidance as to how the veteran will be informed as to the results of his physical examination, the laboratory data. Whether the results were negative or positive, they will be given a formal notification and will be counseled at the conclusion of the physical examination as to the physical findings. So, we are hopefully closing that gap.

We are in hopes that as time goes on, veterans will feel that they are getting better follow-up information.

Thank you, Bob,

I would next like to call on Mr. Fredrick Mullen, Veterans of Foreign Wars.

Is Mr. Mullen here?

MR. MULLEN: I think that just about all veteran

service organizations are experiencing the same difficulties as pointed out by both Dr. Brick and Mr. Lenham.

Both the service organization representatives and the veterans are up against a "no-win" situation at this point. There is nothing we can do in representing these veterans to allay their fears and to assure them that everything possible is being done.

What we do experience is a lot more questions regarding heavy metal exposure. We don't believe enough study has been done in this area.

There was approximately 3 1/2 million pounds of heavy metals disseminated in Vietnam. And when you consider that 5 milligrams constitutes a toxic dose, then we believe that there is reason for concern in this area.

The Veterans of Foreign Wars would like to see more done in this area of screening by the Administration such as nail and hair samples and a possible patch test in the cases of skin diseases.

Just about the only skin disease at this point that is being related to exposure of any type is chloracne. And when you consider that the different skin diseases caused by exposure to arsenic are protean, then, again, we believe a lot more cases can be allowed based on arsenic exposure alone.

Again, we are up against a "no-win" situation at

this time and we would like to see more done and a little bit more speed put into the study that is being conducted at this point.

Thank you.

DR. SHEPARD: Okay. Thank you very much for sharing that with us, Fred.

As I say, again, I hope that as time goes on we can keep the lines of communication very clearly open.

If you have concerns in areas in which you feel that the Committee should consider, then I hope you will free to bring them to our attention.

MR. MULLEN: Thank you very much, Dr. Shepard.

Yes, Dr. Murphy?

DR. MURPHY: Mr. Mullen, when you mentioned heavy metals, are you referring to the arsenic containing herbicides?

MR. MULLEN: Specifically arsenic, the inorganic compounds.

DR. MURPHY: The inorganic?

MR. MULLEN: Yes, sir.

Trivalent and Pentavalent.

DR. MOSES: That's organic.

MR. MULLEN: Excuse me, organic.

DR. KEARNEY: Excuse me. I think what we are talking about is MSMA.

DR. MURPHY: Could you say what that is, Phil?

DR. KEARNEY: It's the monosodium salt of methane arsenic acid. I guess we would really call it an organic form. It is the plus five form, but I understand what you are saying.

MR. MULLEN: I understand that the inorganic arsenic would be, I believe, more toxic --

DR. KEARNEY: Yes.

MR. MULLEN: -- but once this organic chemical gets into the soil and the acid and the soil combines, I believe that there is potential to decompose into an inorganic state.

DR. KEARNEY: That's correct.

MR. MULLEN: And this would be carried in the streams, in the marshes and we have experienced a lot of complaints specifically regarding skin diseases of the feet which are almost more often than not diagnosed as unknown etiology, and we believe that if patch testing is done on people who still have these skin conditions -- if patch testing is done, there may be a correlation between the arsenic exposure and the specific skin diseases that these veterans are experiencing at this point.

DR. KEARNEY: Very good.

MR. MULLEN: Yes, sir?

DR. SUSKIND: Mr. Mullen, I'm wondering whether

you are aware of the intensive studies that were carried out through the Armed Forces of the problems of the feet of combat troops in Vietnam. These studies were carried out by the University of Miami group, headed up by Dr. Harvey Blank, and I believe that the studies have been published.

The problem was generally known asimmersion foot

MR. MULLEN: Yes, sir, I am well aware of that. That's been a problem in all three wars.

DR. SUSKIND: And many of the veterans had sequelae as a result of that problem and I am just wondering whether that was also being considered as a possibility rather than the cacodylic, or whatever the cadodylic was?

MR. MULLEN: Well, we're not disputing the fact that a lot of these cases of skin disease are caused specifically byimmersion foot or by fungal infections, but we believe that if there is positive patch testing and a skin condition arises, which is almost identical to the skin condition which this veteran has, then surely that raises reasonable doubt as to the etiological agent,or factor which caused the problem.

Again, we are not specifically limiting our complaints regarding arsenic exposure to skin conditions. A lot of these complaints from veterans involved the gastrointestinal system and the central nervous system,

and, more specifically, peripheral neuropathies and GI bleeds, and dysentery-type states. And I believe it is more than circumstantial or coincidental that the presenting symptoms that we find in these service medical records are almost identical to the presenting systems that one would find in cases of minimal arsenic exposure, or cases of a toxic level, 5 milligrams or more.

So, we are not specifically limiting this to a foot condition, or a skin condition, but rather we would like to give the Veterans Administration a tool by which to allow a lot more of these claims because, as Mr. Lenham says, the bottom line is compensation, and that is our sole purpose to see that these veterans get what is coming to them.

At this point the Veterans Administration tells us: we don't have any way, the scientific community doesn't give us anything to go on. There is no correlation betweeen dioxin exposure and disease.

Now, the VA has also come out with a directive stating that if you were in Vietnam and you claim exposure, we will concede exposure unless you were a desk jockey. Well, this does nothing for the veteran because he still goes in there and he is told "no." Okay, you've got exposure. Now, prove what you have got is caused by that exposure. Well, he can't, and we believe that by more

study into this heavy metal problem, that they may have means by which to allow some of these cases.

DR. SUSKIND: Thank you.

DR. KEARNEY: Mr. Chairman, just one point of clarification.

Dr. Suskind is right, it is cacodylic acid rather than -- it is a derivative of it.

MR. DeYOUNG: This is not the first time that I have heard the expression of concern about the Agent Blue that was used.

To that same end, a researcher in Chicago about two years ago started taking samples of hair and nails from certain Vietnam vets in a pilot study. I do not know what the results ofthat study are, but I guarantee I will find out for you.

MR. MULLEN: I believe there were 17 positive samples found, and I think it was Dr. Bederka , if I am not mistaken.

MR. DeYOUNG: It was, and that number strikes me as familiar, too, but I'll make sure of it.

MR. MULLEN: Yes- Nothing more has been done since that point that I know of.

DR. SUSKIND: When you talking about the examination of hair and nails it is important to consider how long after the exposure these samples were taken. If it were

10 years after the exposure, you wouldn't expect to find it in hair and nails. If it were two months after the exposure, you still would because the presence really depends upon the growth of the hair and the nails. And there are time limits to finding arsenic or any other heavy metal for that matter in hair and nails depending upon the rate of growth for the hair and nails.

MR. MULLEN: Well, from what I understand, it can take as long as 10 years in some cases for this to be excreted in certain individuals. Now, it is subject to different idiosyncrasies in individuals, but there is also some -- through some research I've done, I have found that there is potential for storing arsenic in the liver and kidneys.

Again, we are talking about the service medical records. We are looking at the findings of the presenting symptoms that we are seeing there. Alopecia and skin conditions, gastrointestinal symptoms, and I believe if you find this set of symptoms and this veteran has any residual whatsoever from that particular problem, that it should be service connected because there is certainly reasonable doubt there.

DR. MOSES: One of the things that has to be considered in arsenic is seafood. It happens to be fairly high. If you want to do your study,

you might want to consider whether they live on a coast or not. Although you are right about it can take a long time, that is assuming that there are added continuing exposures.

MR. MULLEN: Well, we are talking about in most cases, these people were in the field sometimes in excess of a year.

DR. MOSES: No. I mean, since 1969 or '70 when they came back.

MR. MULLEN: Oh, I see.

DR. MOSES: You would have to assume that for 10 years nobody had any exposure to arsenic and we're all exposed to arsenic, anybody who eats fish is certainly.

In fact, when you want to do a urinary evaluation for arsenic, we always ask people to stay away from sea-food for at least three days because we don't feel that we can get an accurate measure.

The other point with hair and nails, you're right, it is important, but it is extraordinarily difficult to sort it out. I'm not saying you shouldn't do it. We should try to do all things that we can to get any biological indicators we can, but you may find yourself in a situation that you have got numbers, letters, values that you just don't really know what they mean because of contamination of other sources. But I think it is

a good point and needs to be addressed absolutely.

DR. SHEPARD: Dr. Kolbye?

DR. KOLBYE: Just so those remarks are not misinterprested as indicating that our fish supply is poison, I'd like to point out that those arsenicals are in the organic form and very readily and quickly excreted from the body and pose no public health risk.

(Laughter.)

DR. MOSES: I'm sorry if I offended anybody today.

DR. SHEPARD: I failed to indicate that Dr. Kolbye is Associate Director of the Bureau of Foods for the FDA and so his point is well taken.

(Laughter.)

DR. SHEPARD: Many of you are aware, I'm sure of interest directed towards other ecosystems, including the fish life in the Great Lakes, which has received some recent attention.

Dr. Kolbye and I attended a meeting at the State Department a while back at which this issue was raised so that obviously there are many other agencies that are interested and working hard on this very complex issue of potentially toxic substances in the environment.

MR. MULLEN: Thank you very much, I appreciate it.

DR. SHEPARD: Let's move along now to the next portion of our agenda, and we are very fortunate to have Jim Striegel here who will tell us a little bit about JRB's efforts to enlighten us all and bring together a vast quantity of literature and sort it out for us.

LITERATURE ANALYSIS REPORT

DR. STRIEGEL: Let me first say that I am pleased to participate in this effort.

As a bit of history, about a year ago the Congress passed Public Law 96-151, which required the Veterans Administration to conduct a couple of studies, one of which was a review of the worldwide literature on herbicides used in Vietnam.

JRB submitted a proposal in the middle of the year and were awarded a contract for nine months just before Christmas.

To introduce ourselves, JRB is a part of Science Applications, Inc., which is a high technology research company with offices in 70 cities around the country and about 4,000 scientists on the staff.

Our work is primarily in environment, energy and health.

We recognized immediately that a great deal of work has already been done on reviewing this literature. We would solicit your assistance in

consolidating this material one more time in one more pile to be gone through by a group of scientists.

We have already met with Dr. John Moore of the Interagency Work Group to Study the Possible Long-term Health Effects of Phenoxy Herbicides and Contaminants. We are contacting several of the people on this panel and other researchers in the Federal Government who have been working on the problem of herbicide exposures in Vietnam. We have obtained the assistance of scientists like Dr. Abraham Lilienfeld of The Johns Hopkins University; Dr. Steven Safe at Guelph University, who is working on the Canadian study of TCDD; and Dr. Walter Melvin at Colorado State University; and other people who have been working on this project, in essence, since the issue arose 10 years ago.

I would like now, just briefly, to discuss the nature of the project. As I said, it is once more to collect and gather and review in one place the published literature on all of the herbicides used in Vietnam, which includes about 15 compounds. The major concern, of course, is with the phenoxy herbicides.

We are right now going through the process of contacting people who have been collecting that literature and have researched it. We have established in our firm a system for tracking the literature as it comes in and making sure it gets assigned to the correct scientist for review.

We are now in the process of collecting literature. We have access to everything that the Veterans Administration itself has on hand. We also have access to the Environmental Protection Agency's files on both the suspension hearing and the cancellation hearing for 2,4,5-T, which amounts to something on the order of 3,500 documents. A great many of these/legal/ documents are having to do with the hearings rather than/ the scientific literature, but we have access to / all of them. And we would like to be guided to other sources of information as we gather this material.

We will begin very shortly to conduct update searches on more recent literature that has been published since the EPA hearings, and beyond what is on hand at the Veterans Administration.

The literature will be reviewed and annotated, roughly beginning in February, for its validity, for the findings and the validity of those findings, for the nature of the studies described.

Our staff includes toxicologists, epidemiologists, pharmacologists, chemists, plant physiologists, geneticists, occupational medicine physicians.

We will, by mid-March present to the Veterans Administration a draft bibliography, simply a listing of the articles that we have found to fit our relevancy criteria for the nature of the study we're conducting, and

to be the articles that we will continue to review and annotate in depth.

Later in the year, as the material is compiled into categories and specific issues, problem areas, or information gaps are identified, the material will be passed through a senior science review of both in-house scientists and consultants like Dr. Lilienfeld and Dr. Safe , and others. And by mid-September, we will produce the report.

We currently envision the report to be in two volumes. The first volume will be the narrative discussion: a brief overview of the use of herbicides in Vietnam ; a discussion of the published literature on the botanic effects, environmental transport and fate, the nature of exposures, issues such as species variability; and we hope to compile a good summary of all of the industrial accidents as well that have taken place.

Then a chapter that will address, in fact, the human health effects ,emphasizing long-term chronic and delayed toxicity, potential for mutagenicity, teratogenicity carcinogenicity, as addressed in the literature.

And then a chapter on the findings of the literature review itself, which will include the conclusions of the literature, the assessment of the science contained in the literature, and particular attention to the limitations and gaps in information that

currently exist.

The second volume of this report would be, in fact, the annotated bibliography of all the literature that was reviewed, which might be quite extensive. We also hope to include in the report / an appendix to address current protocols that are being developed for epidemiological studies and some prospective work. All literature reviews must stop at some date if you are going to publish a report.

We would like to try at least to keep our attention to studies that we know are coming into the literature that have been identified for us. We would try to address these in some kind of an appendix as well.

We will try to get to -- our objective is to get to all of the literature, all of the scientific literature that exists in the published domain. And we hope that you, those who have been working on this project for the past many months and years, can help guide us and help us get to those resources so that our efforts can be devoted to the science assessment rather than to what can be a very expensive process of identification and acquisition.

DR. SHEPARD: Thank you very much, Jim.

Are there any questions from members of the Committee?

Dr. Murphy?

DR. MURPHY: Will your literature review cover

herbicides in the broad sense, or will it be focused on Agent Orange and the constituents and contaminants thereof?

DR. STRIEGEL: The terms of the project are to address all herbicide use in Vietnam, about 15 Many of these were used only on an experimental basis and there will be very little published literature on many of them. So, by the structure of the published literature, we will be directed to where the problem has been perceived to be, which is, of course, TCDD and the phenoxy herbicides primarily, and other herbicides that have been raised in the published literature.

DR. KEARNEY: Just a suggestion. I noticed you said, "botanical effects." I wouldn't get bogged down in this. We were asked recently to supply some information. I think the Department forwarded 15 pounds of literature. I think the veterans and this Committee would be better served if we looked into more the health related aspects of the thing because that (i.e., botanical effects) is a maze that you can get into and never get out of.

DR. SHEPARD: Dr. Suskind?

DR. SUSKIND: I'm just wondering whether or not this is to be a critical review of the literature or just a review of all entries that are found? A critical review of the literature would, of course, be much more useful to scientists, whether they were conducting

epidemiological studies or conducting laboratory studies.

DR. STRIEGEL: The intent is certainly to do a critical review, to assess the nature of the study reported in the literature, to make our assessment, our science assessment of the validity of the population used, or the structure/methodology used, and to assess the findings that were reported and to make some kind of judgment on our valuation of those findings.

DR. SUSKIND: Are you going to use consultants for such a critical review? I would imagine that JRB doesn't have all of the disciplines which would be necessary to do a thorough comprehensive review.

DR. STRIEGEL: As a matter of fact, the answer to that is, yes, on both counts. JRB and our parent corporation, Science Applications, Inc., covers virtually all of the scientific areas required. However, we also have on our staff consultants whom we have proposed and who have agreed to work on this project. So, we will use both senior scientists reviews from in-house and from consultants.

DR. KOLBYE: May I just inquire. Is this going to be what I would call in my own language, an unfocused review, or are you going to pose several critical questions and direct your attention to those questions with emphasis during the course of your review?

DR. STRIEGEL: In the opening stages of the project it is unfocused, in the sense that we are gathering everything we can get. Then to review it and find where, ultimately, where it will focus on issue areas that are identified in the literature. But the initial attempt is to throw the net as widely as possible.

DR. KOLBYE: The reason I'm thinking about this is that one of the issues is with respect to the TCDD. It deals with its mechanism of toxicity with reference to the induction or influencing the incidence of cancer. And it would be of great interest, I think to look at liver toxicity in an animal study, the various animal studies, and perhaps specifically to review some of the histopathology from some of those studies if we have dose-response data.

And a literature review per se might not get at some of the more critical questions that deal with a hyperplastic toxicity, for example.

DR. BRICK: Who is this contract with, VA?

DR. STRIEGEL: Yes, the Veterans Administration is the funding agency.

DR. BRICK: Well, this is a point that I would like to address. If you are going to do a thorough review of the literature, as it was pointed out, and good, we say, you are going into botanical, I don't want

to use a dirty word, but Dr. Kearney kindly points out correctly, you'll get lost in a bog and a morass.

Now, this Committee is interested in the health effects as they pertain to human beings and I think if you cut away all this malarkey about the scientific stuff in plants, the environment, et cetera, and focus only health related problems, if this is what's not going to be done in your program, this is a waste of money. It is a waste of money completely.

I'd like to know what the terms of the VA to this project are? What are the terms?

DR. SHEPARD: We can certainly provide you the RFP, Dr. Brick.

Let me just say in defense of Jim, and I was involved in some of the early discussions, I think that the botanical aspects are simply -- correct me if this isn't your understanding, Jim -- but I think that we just needed a short part of the review to indicate what are some of the basic mechanisms in plants -- on which herbicides work. In other words, how do herbicides work? Not a long discussion of the pros and cons, the detailed minutia of photosynthesis and the effect of herbicides on them. Not at all. So, please don't get the impression that we have a built-in danger that we are going to get bogged down with botanical morass. It is, of course,

our primary concern to review the biological aspects of this substance and not the botanical.

Yes?

DR. MOSES: I would like to ask Al Young, hasn't that already been done by the Air Force?

MAJ. YOUNG: Well, we just recently published a book on 2,4,5-T and the botanical aspects were very heavily covered. The only reason it's important, of course, is because much of the material in Vietnam was applied to foilage. If it is rapidly absorbed, that means thereis less in terms of exposure. This emphasis ought to be brought out.

If it isn't absorbed and it is on the surface, then you see exposure would be much greater. So, those kindsof mechanisms ought to be brought out as it influences exposure. But as to the mechanism of how these things work, there are 20,000 articles of efficacy that do not need to be looked at. We've already finished that study & published it.

DR. BRICK: Good. You better give it to him.

(Laughter.)

DR. SHEPARD: That would be most appropriate and perhaps I'm not remiss for having already done that. But we are still in the relatively early stages of this project, and I think it would be a good idea, Jim, if we could

circulate to members of the community our next status report so that they would be apprised of where we are.

DR. STRIEGEL: Certainly.

DR. SHEPARD: And also solicit their comments, and we would like to keep them abreast of the progress. And please, members of the Committee feel free to give Jim or myself any input that you think is appropriate.

DR. STRIEGEL: Yes, do.

DR. SHEPARD: Dr. Suskind?

DR. SUSKIND: I'm sure Dr. Striegel knows that there have been many literature reviews of phenoxy herbicide.

DR. STRIEGEL: Yes.

DR. SUSKIND: And some of us actually felt that, oh, here is another one. I don't know whether that comment really has any merit any more. Certainly it isn't appropriate. But, what I would suggest is that you and JRB determine where those other literature surveys are so that you could have access to them.

DR. STRIEGEL: I think we have several in-house already.

DR. SUSKIND: Well, there may be many others that are actually related to on-going research work and they are not published.

DR. STRIEGEL: Yes.

DR. SUSKIND: I can name four or five centers of phenoxy herbicide research which must have literature surveys in order to function. And so I think that if you were aware of that, and this is not just Federal agency activity, I am talking about university activity.

DR. STRIEGEL: Yes

DR. SUSKIND: That it would be helpful to you and it might even shorten or decrease the work load. Nine months is not a long period of time to do this. So, I think JRB is going to need all the help they can possibly get.

DR. STRIEGEL: Thank you. I agree entirely.

DR. SHEPARD: Do you have a comment?

DR. MURPHY: I think maybe Dr. Suskind answered my question because, when we were naming months, September was sort of a key one. I wonder if that was this year or --

DR. STRIEGEL: Yes, this year.

DR. MURPHY: -- because I would agree with Dr. Brick's comment to the extent that you do have -- I think for this particular effort, at least, it should be focused toward human health effects. On the other hand, I think one shouldn't denigrate mechanism studies in the sense of basic research that leads to an understanding of potential for human health effects. And there has been some very

interesting and perhaps meaningful research done in that area with cellular reactions and so forth, but I think it needs to be taken into consideration. I can't imagine how you are going to be able to do this by September unless you do as --- approach it by a fairly specific question and really zero on that. And I would think you would want to use your own staff and consultants in a very directed manner.

DR. STRIEGEL: Yes, that is it exactly, and part of the reason I'm here today.

DR. KEARNEY: For example, Mr. Chairman, there is -- the National Academy Science spent two years putting together a rather large arsenic report which covers many of the subjects which we discussed earlier here today, the chemistry of arsenic in soils, the health effects, the sources. That would be useful to you.

DR. SHEPARD: And, please, if any of the members of the Committee have any knowledge of similar efforts that have been done, please share them with us, because this will be very helpful, as Dr. Murphy has so appropriately pointed out, the time left for the accomplishment of this effort is short indeed.

DR. MOSES: I don't understand the terms of this contract. What if it does turn out that nine months just really isn't going to bring forth this child? Then

what happens? Is there something in the contract to extend this or do you just say, this is what we have and here it is, or -- Because this could be very important. It seems to me if you find that you are overwhelmed and can't meet this deadline, what has been arranged for that?

DR. SHEPARD: Well, I'm not an expert in contract negotiations, but I would hope that there would be a safety clause or something that would allow JRB to appeal for some more time.

DR. BRICK: Dr. Moses, may I address that point?

DR. MOSES: Yes.

DR. BRICK: There is a publication in this town called, Washington Monthly. It's a very delightful publication in which a current issue -- a couple of months ago -- talked about Government consultants and Government contracts and the ploys that are used with reference to a contract being written for September, let's say, as in this case, and that's part of the ploymanship of the contractors, because they never get finished by the appointed date, and they always go for an extension. And I don't know the dollars here, the numbers of dollars we're talking about, but they are probably considerable. And if you want to know how this works, I would recommend this article in the Washington Monthly to you.

(Laughter.)

DR. KEARNEY: It goes on, the whole publication is devoted to brinksmanship in the contract, consultant situation in the Government. And it gives a very, very good exposition of how this works.

DR. MOSES: In view of Dr. Brick's remarks, I would recommend that the human health aspects be done first, please.

DR. BRICK: Dr. Shepard, did you read that issue?

DR. SHEPARD: No, sir, I haven't. I have some homework to do, I see.

DR. BRICK: Charlie Peters is the editor of the Washington Monthly, look it up in the phone book and call Charlie up and he'd be glad to give you a complimentary issue of that particular issue. It's a very delightful issue.

DR. SHEPARD: Fine, thank you.

Yes, sir.

DR. SUSKIND: I'm going to be the devil's advocate here for a moment. This is not to disagree, but only to point out an important principle, and that is: if we limit our studies in the field of toxicology to humans, we would know very much less than we do now. That is all I am going to say.

DR. SHEPARD: I think we have to look at it from a broad brush perspective.

DR. MOSES: Yes, absolutely. But I still would like to reinforce the fact that the questions the people really want answered are effects on human health, and any way that you could try to stay in focus. It gets very difficult to stay in focus because most of the data is toxicological data on animals. It is there; it is much easier to control, and it is much clearer. And I hope -- you are aware of that, I'm sure

DR. SHEPARD: Well, one of the things that I've asked Jim to look at is the body of data that addresses the industrial exposures, because I think that needs to be brought together, at least in my early perception of the problem. I think that we have a lot of data in various places and one of the reasons that we are so happy to have Dr. Reggiani and Col. Lathrop here today is to perhaps fill in some of those gaps, but I think we really need to take a look at that part of the (exposure problem) -- this is the human laboratory to a large extent. So, I think that information really needs to be pulled together.

I don't know how much of it can be pulled together in this relatively short time-frame, but at least we need to perhaps document what we know and then point to data that still exists or is in the process -- in the pipeline, so to speak, that we can hopefully focus.

I think it is also safe to say that this kind of

thing, as Jim has said, is a never-ending evolution. That it will never be complete by the nature of the fact, and so that is why I have also indicated that we need to build into this project a mechanism for tracking on-going information.

MR. DeYOUNG: Something that is becoming important, as I think about it, is the question that we've all been kicking over in the past of what weight to give the animal data. How tightly to apply it to humans and I would appreciate it very much, and I'm sure the veterans would appreciate it very much, if this report would help clarify that rather than further muddying that question, which is where it now stands.

There is an enormous reticence that we are feeling in the VA to use the animal data as basis for disability compensation or for something legalistic, and we need that clarified as much as possible. This critical evaluation can include the weighting to give animal data. That would help tremendously.

DR. SHEPARD: Okay. Thank you very much, Jim, it has been a very good discussion, I think, and we will all be following your project with great interest, I am sure.

Thank you for sharing it with us.

DR. STRIEGEL: Thank you.

DR. SHEPARD: I would now like to move on.

I am happy to note that we are well on track. I'd like to call on Col. George Lathrop of the U.S. Air Force.

Let's see, George, you need some viewgraphing.

COL. LATHROP: Yes, sir, we're going to have to ask you to move.

DR. SHEPARD: Okay.

Let's just take a moment and stretch.

(Brief pause in the meeting.)

PRESENTATIONS AND DISCUSSION

STATUS OF RANCH HAND STUDY

DR. SHEPARD: I would like to introduce Col. George Lathrop, who has been working long and hard on the Ranch Hand Study, an effort that all of us are looking to with a great deal of anticipation and we're indeed very happy that George could take time to be with us and give us an update on the status of the Rand Hand Study.

COL. LATHROP: Thank you very much, Dr. Shepard.

I wish to thank the Veterans Administration for the privilege of presenting a study design synopsis of the Air Force Ranch Hand Study, as well as a capsule of its current status.

At the outset, I'd wish to underscore the deep and long-standing commitment of the Air Force to conduct

this study.

The Surgeon General of the Air Force, General Paul Myers, has made numerous trips and personal appearances to reinforce that commitment and to insure that proper and adequate resources are assigned to this project.

Moreover, the Air Force has insisted that this study be conducted with utmost scientific care consistent with the inherent constraint of a sub-optimal population size.

Accordingly, we have subjected this design to an unprecedented four-stage independent peer review process as well as an assessment by the Interagency Work Group, the latter of which led to the White House direction to proceed with the study.

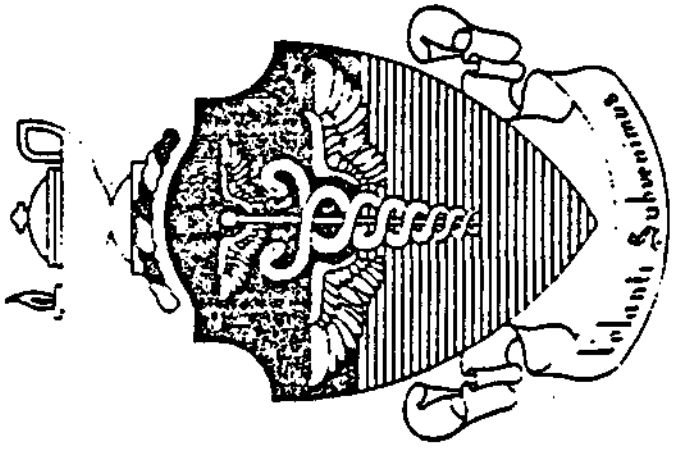
I'd now like to turn to some basic aspects of the overall epidemiologic study design. The Air Force study goal is straightforward: assess health effects, identify individuals with adverse health effects, both physical and psychological, if such exist.

As a corollary to our primary goal, I think it is clear that any valid medical information arising from this effort will be placed into a mosaic context with other studies to provide a scientific underpinning of the compensation decision.

The purpose of the study is simply to determine

VIEWGRAPHS ACCOMPANYING
COLONEL LATHROP'S PRESENTATION

RANCH HAND II



USAF SCHOOL OF AEROSPACE MEDICINE
BROOKS AIR FORCE BASE TEXAS

AIR FORCE RANCH HAND STUDY

STUDY GOAL

- ASSESS HEALTH EFFECTS
  - IDENTIFY INDIVIDUALS WITH ADVERSE HEALTH EFFECTS (PHYSICAL AND PSYCHOLOGICAL)
  - IDENTIFY OTHERS AT INCREASED RISK

SPINOFFS: STUDY WILL

- PROVIDE MEDICAL DATA THAT WILL HELP CLARIFY THE COMPENSATION ISSUE

PROJECT RANCH HAND II

PURPOSE OF THE STUDY: TO DETERMINE WHETHER LONG TERM HEALTH EFFECTS EXIST AND CAN BE ATTRIBUTED TO OCCUPATIONAL EXPOSURE TO HERBICIDE ORANGE

EPIDEMIOLOGIC STUDY DESIGN

COMPONENTS OF THE PROBLEM

HAVE THERE BEEN, ARE THERE CURRENTLY, OR WILL THERE BE IN THE REASONABLY FORESEEABLE FUTURE , ANY ADVERSE HEALTH EFFECTS AMONG FORMER RANCH HAND PERSONNNEL CAUSED BY REPEATED OCCUPATIONAL EXPOSURE TO 2,4,5-T HERBICIDE AND ITS CONTAMINANT, TCDD (DIOXIN) ?

AIR FORCE PROJECT RANCH HAND

EPIDEMIOLOGIC APPROACH

STUDY PHASE	METHODS
• MORTALITY STUDY	PERSON TRACKING, RECORD REVIEWS
• MORBIDITY STUDIES	BASELINE QUESTIONNAIRE, PHYSICAL EXAM
• RETROSPECTIVE	
• CROSS-SECTIONAL	
• FOLLOW-UP STUDY	ADAPTIVE QUESTIONNAIRES, PHYSICAL EXAMS

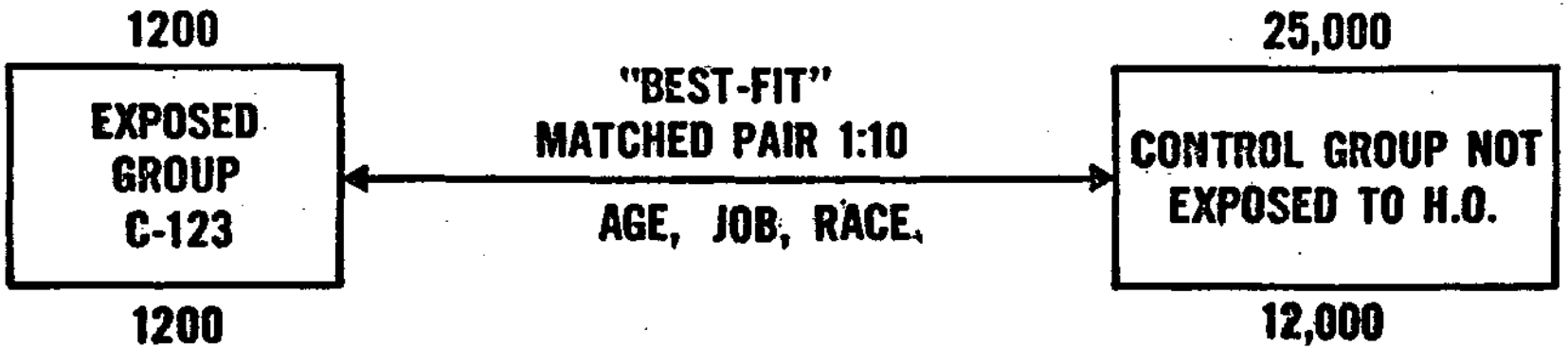
THREE PHASE APPROACH REQUIRED

RANCH HAND PERSONNEL

POTENTIAL FOR EXPOSURE

PILOTS, CO-PILOTS, NAVIGATORS	LOW
CREW CHIEFS, MAINTENANCE PERSONNEL	MODERATE
CONSOLE OPERATORS	HIGH

RANCH HAND II
EPIDEMIOLOGIC STUDY DESIGN
RATIONALE FOR MATCHING PROCEDURE



MATCHING PROCEDURE RATIONALE:

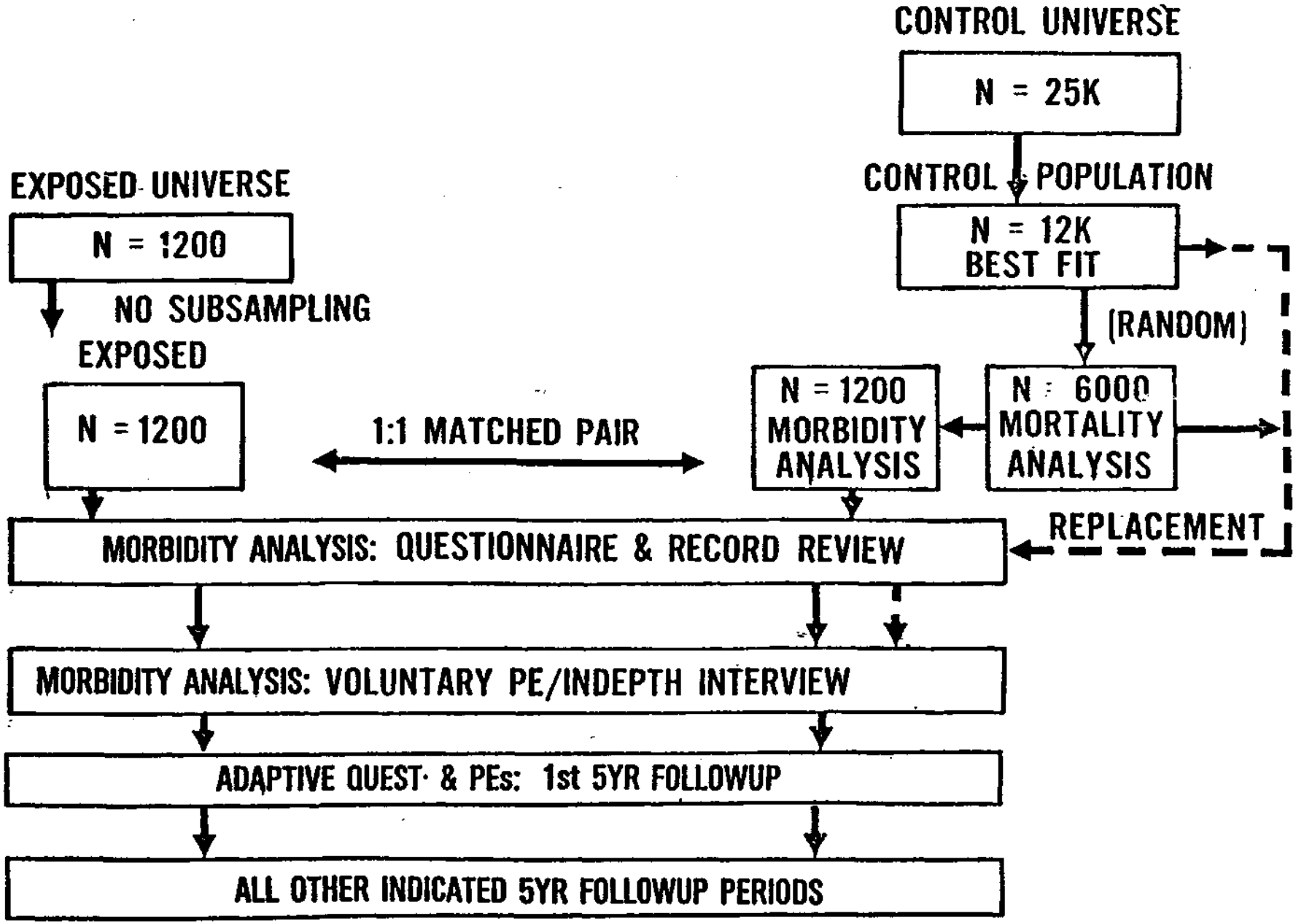
- **MAXIMIZES STUDY POWER**

COMPUTER MATCHING

RANCH HAND TO CONTROL, 1:10

- 74.6% EXACT MATCH, BIRTH MONTH, JOB(S), RACE, SEX
- 95.2% ± 5 MONTHS OF BIRTH, ALL OTHER VARIABLES EXACT
- TIME SPENT IN RVN CONTROLLED BY STRATIFICATION

STUDY DESIGN SCHEMATIC



CURRENT STATUS

- POPULATION ASCERTAINMENT AND MATCHING ARE COMPLETE
- MORTALITY STUDY WELL UNDER WAY
- QUESTIONNAIRE DEVELOPED BY NORC AND AWAITING OMB CLEARANCE
- PRETEST POPULATION IDENTIFIED
- STUDY SCHEDULE DEPENDENT UPON OMB AND D&F PROCESS

RANCH HAND II
FLYING PROFILE

- MILITARY
  - ACTIVE DUTY 63
  - RESERVE/AIR NATIONAL GUARD 39
  - TOTAL 102 *
- CIVILIAN
  - FEDERAL AVIATION AUTHORITY (FAA) MEDICAL CERTIFICATES FOR FLYING 88 *

* FIGURES NOT ADDITIVE

RANCH HAND II

POPULATION STATUS AS OF 1 DEC 80

- **STATUS OF TOTAL RANCH HAND POPULATION - 1196**

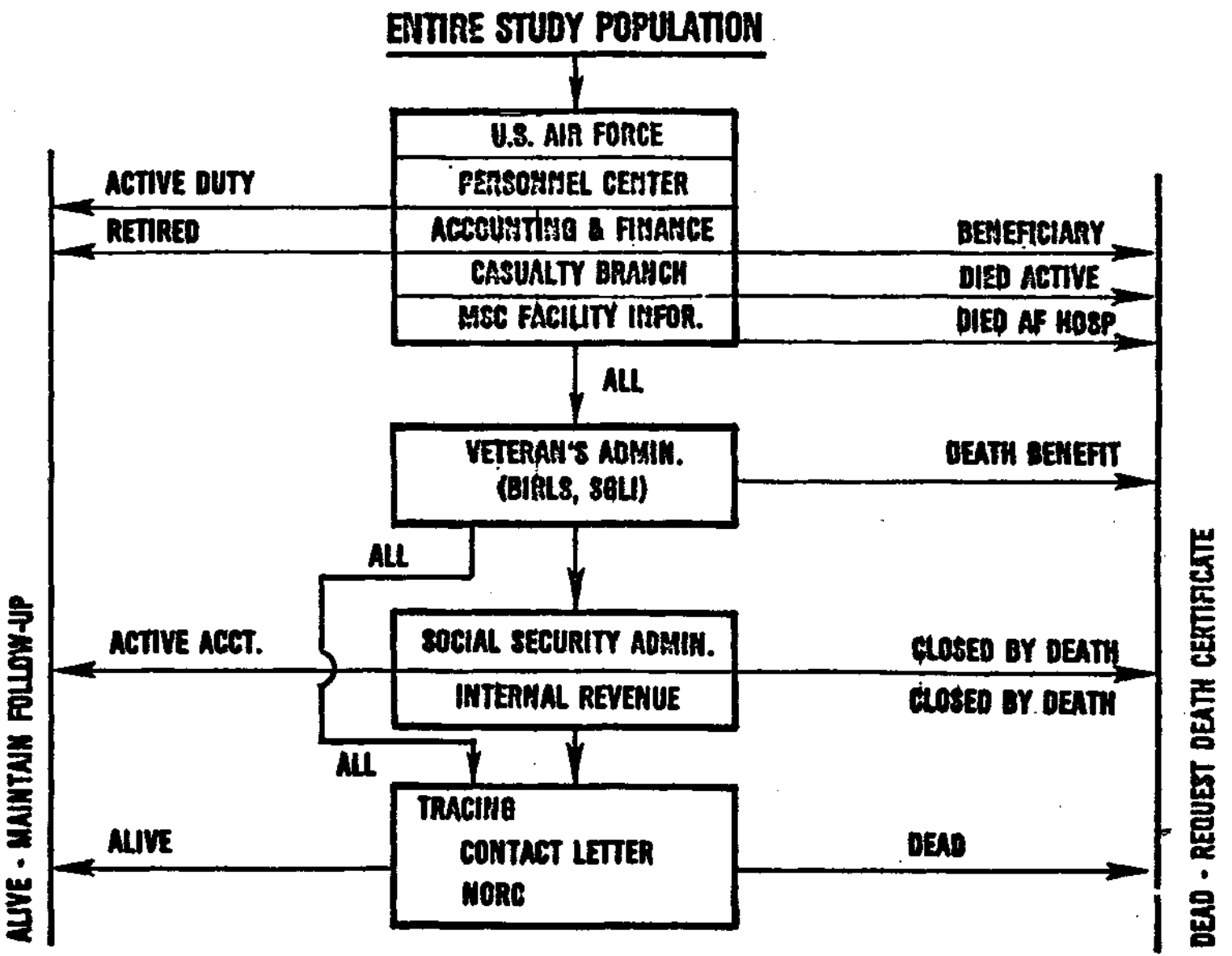
	OFFICER	ENLISTED	TOTAL
* ACTIVE DUTY	129	111	240
RESERVE/AIR NATIONAL GUARD	47	19	66
RETIRED	208	283	491
SEPARATED	50	299	349
DECEASED	24	26	50
TOTAL	458	738	1196

* AVERAGE OF THREE INDIVIDUALS RETIRING MONTHLY

RANCH HAND II MORTALITY STUDY
KNOWN CAUSES OF DEATH AS OF 1 DEC 80

• ACCIDENTAL DEATHS	
– KILLED IN ACTION (VIETNAM)	19
– AIRCRAFT (NONBATTLE CASUALTY)	9
– OTHER (MOTORCYCLE, AUTO)	2
• UNKNOWN CAUSE	7
• DISEASE STATES	
– HEART	5
– CANCER (LUNG, RENAL)	3
– LIVER (CIRRHOSIS)	4
• SUICIDE	1
TOTAL KNOWN DEAD	50

RANCH HAND II MORTALITY STUDY



whether long-term health effects exist, and whether in a cause and effect fashion, we can relate them to exposure to Herbicide Orange.

Because of the circumstances of exposure of our population, it is proper to view the issue in terms of time and ask the following question: have there been, as determined by retrospective techniques, or are there currently, as possibly measured by physical examination techniques, or will there be in the reasonably foreseeable future, as measured by comprehensive follow-up studies, any adverse health effects resulting from exposure to the dioxin?

To answer the question in terms of time, a three-phased epidemiologic approach is necessary. An overall label for this kind of a study in a nonconcurrent prospective study and incorporates a mortality effort, morbidity studies and a long-term follow-up study by the techniques and methods that you see outlined here.

I would point out that the mortality study will be conducted in-house by Air Force personnel. The morbidity studies or physical examinations will be handled by contract to the Air Force. Questionnaire techniques will also be handled by civilian organizations under contract to the Air Force.

In terms of exposure to Herbicide Orange, our

study subjects fall into three broad categories, as you see depicted here. The folks who sat up front in the aircraft, in our judgment, received reasonably low exposure to the herbicide;

the crew chiefs and folks who took care of the aircraft, a moderate exposure. The people who received tremendous doses of the herbicide were the enlisted personnel located in the rear of the aircraft who operated the console tank containing the herbicide.

We have capitalized on these qualitative differences and have recently conducted some operational herbicide simulation studies in aircraft to quantify these differences in exposure.

And exposure index will be calculated and will be used in a regression or covariant sense to any detected clinical end point in the study.

In addition, I would point out that even under conservative biomathematical models, the ranch handers received approximately 1,000 times a higher dose than the average dose of an average ground troop.

We have chosen a tightly matched pair design to provide maximum statistical power, vis-a-vis primary stratification techniques. Our population size is roughly 1,200. Our control universe is roughly 25,000. We will make a 1 to 10 best fit match to give us a

control population of approximitely 12,000.

While we cite here that we're actually measuring or controlling for three variables, we are actually controlling for four since all members of both the ranch hand and control population are male.

I think these statistics verify the high degree of matching precision that we are able to achieve. 75 percent of our controls matched exactly down to the month of birth with all other variables matched exactly to each ranch hander. Moreover, 95 percent can be matched plus or minus five months of birth.

Initially we felt that we would like to match for the time spent in Vietnam, but computer records were inadequate to make this as a proper match variable and, therefore, our plans at this time include stratification at analysis to take this into account.

As important as the degree of match, I would point out that our control group is essentially pure and was definitely not exposed to herbicides to a significant degree. Other contemplated studies of military population which lack this feature, clear cut exposure/nonexposure, will ultimately be subjected to a substantial dilutional bias in our judgment.

This is a complex slide that gives you the overall picture of the epidemiologic study design. As you can see

on the left, our universe is roughly 1,200 for the ranch handers. We plan absolutely no sub-sampling within that group. Our control universe starts at about 25,000. With a 1 to 10 match, we then fall to 12,000. We'll take a 50 percent random sample of that group, clearly matched to the ranch handers to designate a mortality study of a 1 to 5 design.

As you can see from that point, members are selected from the mortality cohorts in a pair design, giving us a 1 to 1 pair design for both the questionnaire and physical examination aspects.

Yes?

DR. GROSS: Col. Lathrop, what is the distribution of those 1,200 exposed, that you call, ranch handers in terms of this low, middle and high exposure to pilots, to console operators?

COL. LATHROP: I have a graph later on that basically gives those in sequence.

DR. GROSS: When you say "ranch handers," that includes all of them?

COL. LATHROP: That includes everybody.

DR. GROSS: I see.

COL. LATHROP: And I am not sure it has always been clear, but there are probably members within the ranch hand group that received zero exposure.

DR. MOSES: How would that happen?

COL. LATHROP: Administrative officers who never got into the aircraft.

Nevertheless, the only mechanism we have to identify the ranch handers is exhaustive searches through our computer records and archives to come up with a very discrete population designated as our study population.

Because there will be a graded difference of exposure between enlisted / and officers, again, using the mathematical models that we have developed, we can then estimate an exposure dose for each individual. That is one of the key strengths of the ranch hand study, the fact that we will be able to use that exposure concept as we see clinical endpoints emerge within the study.

I would point out that our follow-ups are set for a minimum of 20 years and are designated specifically for years 3, 5, 10, 15 and 20.

As to current status, matching is totally complete. The mortality study is well underway at this time and I will show you figures on that in just a moment.

A questionnaire to be administered to both study and control members has been developed by the National Opinion Research Center and we are currently awaiting OMB clearance before administering that. We have a pre-test population identified. We are set to go. Our entire

schedule is now set to the OMB clearance.

I've mentioned the D&F process, determination and finding process. I am informed by Major Brown of the Surgeon General's Office that that possible delay no longer applies and so we are now dealing apparently strictly with an OMB clearance problem.

To give you an idea of some of the features of our flying population, many of them are still actively flying, both military and civilian. This can conceivably present some problems in terms of physical examinations within the study itself.

As pointed out here in the slide, these figures are not particularly additive at this point. We have requested the FAA to clarify those on flying status by tracking them out as to exact flying category.

Exact population size is 1,196, broken down into the following distribution, Dr. Gross, this roughly answers your question. About 20 percent of our people are still in active duty; 5 percent reserve or National Guard; 40 percent retired; 30 percent separated; roughly 5 percent deceased at this time.

In terms of accrued exposure categories, Dr. Gross, they would fall in the officer and enlisted category for the moment, but actually we've split down specific jobs in terms of a matching variable into five

separate categories.

As of this time, we have 50 recorded deaths within the ranch hand population, distributed as you see here. It is apparent that most are involved in aircraft accidents automobile accidents, and so forth. We are actively pursuing the seven of unknown cause at this time.

This is a schematic to show you the various steps to properly conduct a mortality study within our current administrative set-up. As you can see, the top block represents going through the Air Force personnel and financial systems; both the ranch hand and control population have passed this point. We have now entered both computer tapes into the VA system and we are somewhat anxious to get the results back. We are promised preliminary results somewhere on the order of three weeks from now.

Following that point, we will enter the Social Security and IRS system to make further determinations as to alive/dead status. Our primary difficulty at that point, once we gather all deaths from both the study and the control group, will be to pursue death certificates, and, more importantly, to take those death certificates and specifically correlate them to all known medical records on each individual within the study.

In summary, the Air Force is well down the road in conducting a detailed and comprehensive epidemiologic

study, one that we believe is worthy of the issue itself.

Mr. Chairman, I thank you for the kind invitation to speak to your group today.

DR. SHEPARD: Thank you very much, Col. Lathrop, itwas very enlightening. We, as I say, endorse your efforts and are following your pursuits with great interest.

Yes?

DR. MOSES: Maybe I missed it, but I didn't realize the numbers for the low, moderate and high exposure groups, the numbers of people that will be in the study that are in those groups? Do you roughly know what that is?

COL. LATHROP: Yes, we know. We just didn't have the appropriate slide and I would hope to answer Dr. Gross' question by a crude breakout of those still on active duty, officer and enlisted.

I would also point out, as we've had the pleasure of going through four peer reviews on this, the normal review time for this particular protocol is eight hours and we've seen it extended to 16 hours. So, I will apologize if I've omitted details with you today.

DR. SHEPARD: Dr. Kolbye?

DR. KOLBYE: First a request. I would appreciate if it is possible to include the slides in the transcript so that when we are reading the transcript of the proceed-

ings here, we see the slides, if that's possible. Just submit some Xeroxes.

Secondly, in terms of prospectively tracking the mortality of these populations, are you matching for other characteristics so that you are hopefully able to sort out some of the risk factors like smoking and diet, which can markedly influence the incidence of cancer -- and alcohol intake?

COL. LATHROP: The match would perhaps be an incorrect terminology.

DR. KOLBYE: Okay.

COL. LATHROP: Wewill clearly stratify for those variables to be sure.

DR. KOLBYE: Fine, thank you.

DR. SHEPARD: Yes, David?

DR. ERICKSON: Colonel, at one point in time I believe you were concerned that a number of officers would be commercial pilots at this time. Do you have any further information on it?

COL. LATHROP: We have not been able to clarify the FAA figures further than what I have shown today. We will simply have to see the various categories of the flying certificates that FAA has given out. Many of the folks that are separated or retired fly as a hobby and not necessarily in the 747 above you right now. But we need

to know the exact figure to be sure, and we will do so.

MR. DeYOUNG: Possibly I missed it earlier, where is that 25,000 control universe drawn from? Those are Airmen of one sort or another?

COL. LATHROP: These are Airmen, both officers and enlisted specifically flying cargo aircraft in the Vietnam environment. We felt it very, very important to select a control population that was exposed to the same environmental circumstances as our study population.

MR. DeYOUNG: But they are people with Vietnam service?

COL. LATHROP: Oh, yes, to be sure.

MR. DeYOUNG: Okay.

COL. LATHROP: Well, let me categorize that. They spent a great deal of time in Vietnam. They may not specifically have been assigned to Vietnam.

MR. DeYOUNG: Meaning they might have flown in and out?

COL. LATHROP: Surely.

MR. DeYOUNG: Oh, I see.

Also, in conversation with some Army types and Air Force, I can't be real certain at this moment, whether the man was an Army flyer or an Air Force flyer who I talked to, but I recall him telling me a story of the

time the fill nozzle stuck open on one of the tanks and the Herbicide Orange spouted up and out of the tank and showered the crew. Will this kind of unusual, but high significant exposure be dealt with in the questionnaires that lead up to this?

COL. LATHROP: Yes.

MR. DeYOUNG: That will be taken into account?

COL. LATHROP: We think that is very important, Mr. DeYoung. We grant that that is obviously a subjective means of looking at the exposure, but we are obliged to do so. The anecdotal stories of many of these flyers are genuinely terrifying. One would not expect a pilot and navigator sitting up front in the aircraft to get outside the aircraft literally with their flight suits dripping with the herbicide, but that, in fact, was the case in many circumstances.

Again, we've done the simulation studies to look at the vapor trails within those aircraft in various operational configurations, i.e., flying 150 knots indicated air speed, 150 feet off the deck with the rear cargo door open. All pilots and navigators flew with the cockpit windows open because of the intense ground fire. And what happened when one of those pipes burst, that you are talking about, or that main tank took a hit, that vapor was literally pulled forward into the aircraft and out

the cockpit windows. So, the folks up front, indeed, received very substantial exposure, but, again, in relative terms nothing like the poor fellow in the back. He was doused repeatedly.

MR. DeYOUNG: All right. What I am asking, I think, in generic form is you are not going to be married to that mathematical model --

COL. LATHROP: Oh, no.

MR. DeYOUNG: -- when the anecdotal information shows up?

COL. LATHROP: No. As a matter of fact, when you do mathematical models, you can easily put in subjective data into those and caveat it in a variety of circumstances.

DR. SHEPARD: Dr. Suskind?

DR. SUSKIND: I am going to ask some questions about the protocol and the implementation for the morbidity study. I gather it is going to have several parts?

COL. LATHROP: Yes.

DR. SUSKIND: One will be a questionnaire --

COL. LATHROP: Yes.

DR. SUSKIND: -- and then a hands-on examination with everything that that entails. Can you tell us a little bit about the nature of the questionnaire with respect to your own requirements, as well as what the

contractor may have as a point of view about getting information to the participation of the examining physician -- the participation of the examining physician in eliciting critical historic information which has to relate to past morbidity, as well as current health effects? Here it is, 15 years away from exposure, people may have had--hypothetically--have had chloracne for two or three years and then it disappeared, but that is an important historic piece of information with respect to morbidity.

COL. LATHROP: That is a giant question, Dr. Suskind, and I am not sure I can adequately answer it, except to say that we have taken extreme care to assure that the various study phases are done, in essence, by blind protocol assessment. That is, the results of that questionnaire will not be revealed to the examining physician. The review of systems to be conducted for the physical examination will not be revealed to the primary examining physicians.

There will be an examination collator, if you will, a master internist who will take all laboratory data, historical data, physical examination data and attempt to put them into context for a diagnosis. We grant that this is a very unusual way of conducting a physical examination, but we feel that because of the

controversy with regard to many of the clinical end points one is obliged to do this on a blind basis.

To specifically get into the questionnaire, we have attempted to mirror the thrust of the physical examination to the questionnaire. Our primary purpose of using questionnaire techniques is to capture data that would ordinarily be lost under low compliance rates.

So, we are attempting to gather by questionnaire some aspect of what we are also going to be detecting, hopefully, at physical examination.

DR. SUSKIND: May I just ask one other question?

Then the examining physician is largely going to be examining without questioning?

COL. LATHROP: That is correct.

DR. SUSKIND: That has its problems.

COL. LATHROPL Yes, but certainly within his sphere of diagnostic capability, he will obviously be free to ask any questions related to his particular area of expertise, including past review of systems.

DR. SUSKIND: Okay.

DR. KEARNEY: Col. Lathrop, you spent considerable time with your people at the White House meeting overgoing your study. I think you spent six hours with us, and one of the issues that came up there, and I thinR it is critical to your evaluation, is the degree at which

you can get commercial pilots, who are now commercial pilots, to participate in your study.

You remember that commercial pilots are extremely reluctant to undergo physicals other than what he needs to get his license.

COL. LATHROP: Any pilot.

DR. KEARNEY: Any pilot. And it seems to me that this is a critical population because we have here an able-bodied population and if these are not included in the study, it may skew it to the left or right. Have you resolved the issue of participation of commercial pilots in this study?

COL. LATHROP No. Again, we well recognize the potential for that problem to exist, we would hope that in our one on one interaction with these individuals that we would be able to persuade them to volunteer for one more herbicide mission, if you will, and participate in the study. It is a totally voluntary study, absolutely no coersion will be used to gain entry to the study. We are still exploring a variety of mechanisms to induce participation of all study members, and that includes pilots as well.

MR. DeYOUNG: I would like to echo Dr. Kearney's concerns on this issue. I had a very long conversation a year or so ago with a man who was at that time flying

helicopters, commercial for an off-shore oil company. He took himself off flight status, for which I have an enormous respect for the man, because he said his temper and personality was to the point where he did not trust his own judgment in the aircraft any longer. And I think you are going to have the devil's own time trying to get this kind of information from these particular people. I think we are going to have a bad enough time with the physiological problems, but if you start looking into the realm of personality changes and psychology, I think it is going to become even more evasive.

I have some serious reservations about the results specifically in that area.

COL. LATHROP: Well, I believe overall that that issue will be balanced because the problem will equally exist with members of the control group.

DR. SHEPARD: Thank you very much, Col. Lathrop. I really appreciate your remarks.

I think I am going to deviate from the agenda a little bit. Since we are talking about people flying missions, using defoliants, I think we will now here from our friends from the civilian sector, Mr. Harold Collins and Dr. Clifford Roan.

Mr. Collins, would you like to come up and introduce yourself.

CROP DUSTER STUDY (REPRODUCTIVE MORTALITY AND MORBIDITY - PESTICIDE EXPOSURE)

DR. SHEPARD: We are very fortunate to have these gentlemen with us this morning because they represent the, should I say, a similar group of individuals who have been involved in the agricultural and forestry use of herbicides.

Mr. Collins?

MR. COLLINS: Dr. Shepard, good morning; ladies and gentlemen.

We have brought with us this morning copies of the original NAAA Health Survey / delivered to my association by Dr. Roan of Hopes consulting, Inc. These documents / are for distribution now to any of you who would like them.

My name is Harold Collins and I am employed by the National Agricultural Aviation Association as their Assistant Executive Director and Director of Government Affairs. We are headquartered in Washington, D.C. The national association is a federation of state associations throughout the United States.

Our membership includes agricultural aviation businesses, which we refer to as ag operators; it includes agricultural pilots, allied industry representatives from those entities which supply either product or services to our ag operators, and international individuals or companies who have a common interest in agricultural aviation.

Now, the reason for NAAA's participation in this meeting today is to provide this advisory committee with the reasons for and the results of an association sponsored epidemiological study of ag pilots and their families. The title of this study is: "An Investigation of the Possible Effects of Pesticide Exposures on Reproductive Mortality and Morbidity."

With me today is Dr. Clifford C. Roan, senior consultant for Hopes Consulting, Inc. HCI conducted this study for NAAA. Following my description of the beginnings and purposes of this study, Dr. Roan will summarize the results, following which we will try to answers any questions which you may have.

Initiation of the NAAA study was formally accomplished in 1978. At that time, the controversy between those for and those against pesticide use had been underway since the 1950s. Notwithstanding more than two decades of study, the public was still denied a resolution to the dispute.

There seemed to be no acceptable way to equate pesticide exposure in controlled laboratory studies on animals with the real world exposure among humans. That assumption led the association / some interesting conclusions.

Ag pilots in this country are voluntarily and repetitively exposed to pesticides at levels greater than

the general public. Since most agricultural aviation operations are small businesses, it happens that spouses of ag pilots often serve as mixers, loaders, and flaggers for pesticide operations during the early years of the business. This exposure happens to coincide very often with the primary child-bearing years of that spouse.

It seemed logical, therefore, to us that a health study of ag pilots and their families would provide an excellent source of information to help determine the impact of pesticides on human health.

In that regard, NAAA sent letters to the United States Environmental Protection Agency, the United States Department of Agriculture and the Federal Aviation Administration requesting their financial assistance to conduct this project.

Following receipt of negative responses to all of these requests, the Associations' Board of Directors approved funding of the project as long as that study would be scientifically adequate considering our limited resources.

Hopes Consulting Incorporated designed that study, which met the Board's standards. The study was implemented under the following conditions: One, a review of the proposed study by qualified scientists prior to its initiation.

Two, confidentiality of the information for individual study participants.

Three, full payment of the HCI fee for conducting the study in full prior to the beginning of the analysis of the data.

Four, approval for HCI scientists to publish independent reports on the data without any future NAAA approval, and, finally, five, provide NAAA with peer review of all subsequent published reports.

To date, all of these conditions have been met The first public report on this study was presented on December 3, 1980 during NAAA's annual convention in Las Vegas, Nevada.

That report has been made available to you here today. It demonstrates that ag pilots and their families do not experience reproductive mortalities and morbidities different from the siblings of ag pilots in spite of their higher and repetitive exposure to pesticides.

Association members believe that this study is a unique and substantial health documentation which must be considered when evaluating the effect of pesticides on human health. NAAA further hopes that future reports developed from the data base already on hand will be similarly valuable.

This Association has many veterans in its member-

ship. For this reason, we are especially pleased to offer the NAAA report to the Veterans Administration for review and evaluation. We share the concerns of veterans and others regarding human physical ailments attributed to pesticide exposure.

We are equally concerned, however, that the enormous publicity given to pesticides could detract from scientific and medical detection of other potential sources for these human sufferings.

NAAA will continue to support and endorse efforts that will further reduce the potential for human exposure to pesticides. We hope that studies of other populations, groups who are exposed to pesticides, will also be further developed for your consideration.

And, now, I ask Dr. Clifford Roan to present the details of the NAAA study.

DR. ROAN: I would have to say for those of you-all on the panel who happen to be epidemiologists, you have my sympathy. I regard an epidemiologist as a seriously handicapped scientist .

(Laughter.)

DR. ROAN: If I were to do this study over, I would probably do it on the basis that alphabet A through L would breed on the last day of odd numbered months and odd numbered years, and N through Z the converse of that,

and A would dictate who bred with who.

(Laughter.)

DR. ROAN:

Our data that you have before you are based on a pilot and his reproductive performance of record versus that of a sibling, and their reproductive performance of record.

This gives us about as good a sociological demographic match as you can come up with. I am facetious by nature and I have to observe that epidemiologically a divorce and remarriage is also an abomination. Whose children are we talking about?

The data that we have may appear to you as though we were deliberating juggling the population base. We were not. These questionnaires were distributed based on the fact that it was his money, his wife, his children, the Association. We figured that 75 percent of them might respond. So we provided questionnaires in sets, one for the pilot and one for the sibling for 75 percent of their membership of record in their 1979 membership directory. We provided all others that they might ask for if they wanted more.

And then we took back what we got. It was truly

voluntary. As they came in, it indicated on the cover sheet that it was a pilot, the pilot's brother, or a pilot's brother-in-law. They had the same serial number basically on the form. We considered that initially we had a matched set.

Then we discovered that not all pilots were married and had progeny of record, at least. So, since we were studying reproductive mortality and morbidity that had to drop out. I'm just being honest.

(Laughter.)

DR. ROAN: Then we went a little further and we found a grave mistake in design of the project, and that is that the male was primarily the exposed person. We have, as Harold said, some wives who have acted in varying capacities, but there was not a very great number of those. So, on reproductive morbidity, birth defects, we requested that information only from the male part of the form.

This would seem insignificant if it weren't for the fact that sometimes a sibling, the sister, for instance, would answer the questionnaire completely, her part, the female part. We had no data from the male. We had the same thing occurring in the other half.

The brother would answer all the questions and

the sister-in-law would say it is none of your damned business what pregnancies I had prior to marriage, which was one question we asked. And we just didn't get them.

So, really, these are -- the data you have are matched the way they came in. We didn't juggle anything.

I'll give you the conclusions right now. This is the population, a group of agricultural pilots and their reproductive performance contrasted with siblings and their reproductive performance. You have copies of the questionnaire and the report that you have before you and can see just how we got the information.

Now, this distribution of data returns is purely arbitrary. I just drew lines, divided it in four quadrants. I could divide them up any other way you want to. We have them coded by state. We have them coded a number of ways.

This is what we got in. We cut them off on the 30th of June 1980. That is what we have in our files. Now, they aren't matched obviously all they way along. All we are talking about now, the data you will see, are pilots and matched siblings. Grossly matched. Page one, it's a brother or brother-in-law. And we went on down and we found out we had to throw them out.

DR. MOSES: Excuse me.

DR. ROAN: Yes.

DR. MOSES: How many did you send out? What does that represent? Is it 20, 30, 50, 100?

DR. ROAN: We sent out over 1,200 sets.

DR. MOSES: Does that mean 2,400 people then?

DR. ROAN: Yes.

DR. MOSES: 1,200 sets, 2,400 people?

DR. ROAN: A pilot and some siblings. And we got a -- you can add them up there, the total returns we got.

DR. MOSES: Yes, I already did.

DR. ROAN: Remember, this was voluntary; there was nothing compulsory on these people.

We followed up.

DR. MOSES: 592 is what I get.

DR. ROAN: Yes, that sounds about right. The match -- we'll come down to the matched populations in detail a bit later.

DR. MOSES: So about 25 percent then?

DR. ROAN: Came back.

DR. MOSES: Less than 25 percent?

DR. ROAN: Yes. Actually, which isn't too bad on a mail questionnaire, essentially a mail questionnaire that is voluntary, send it in and you look at all the questions we asked. We would have like to have had 350 matched sets, but we had to work with what we had. The

population is not all that great, but it is the best there is.

All right. Now, you see right away we begin to have differences in match. They don't come out the way they should, but, in general, this is merely to demonstrate with reference to age, weight, height, age, education, these populations were basically similar, which isn't amazing for siblings.

Now, their general reproductive performance, these are where we had matched data either from the male or the female. Regionally, they bred about the same in the northwest as they did in the southeast and there is no statistical difference between pilots and siblings in the gross number of pregnancies.

All right. The number of pregnancies of pilots wives versus the pilots sisters and the pilots wives where there were sisters-in-law. We subdivided the population, the pilots with sisters and the pilots with brothers. And there are no statistical differences in these matched T-tests, just establishing a little bit more that the population to the extent possible, were comparable.

The distribution of pregnancies by age. There is no significant difference in these data as to when the pilot's wives compared to the pilot's sister. Another

population of pilot's wives which differs from the first group because they had only sisters-in-laws that we could compare.

So, their breeding age was essentially the same.

Now, putting them all together in one lump sum, that is, just combining the other two, the age of the mother when the event occurs of any birth. I'll have to go back and look that one up because that refers just to miscarriages, and I think it probably does.

There were no differences.

Now, live births, miscarriages and still births, this includes birth defects. This, I would define as reproductive mortality. Here again, regionally, based on these artificial regions, there are no differences.

Now, there are two ways of doing this, and not being that much of a statistician, but we did have statistical advice so I did it both ways, the number of incidents per family live births versus miscarriages and still births, I can't explain this; this is the way it came out. The siblings had a higher rate of miscarriages and still births than the ag aviation families. This is the way it came out.

When we considered the number of individuals that experienced these, there were no differences. The fact has been explained to me by Dr. Matanoski

that the fact that an individual has one or more miscarriages is more significant for this study than if they had half a dozen. So, we've got it both ways.

Now, we've got birth defects. Our big problem was we asked for birth defects only the male part of the form. So, we have a different side of the population, but anyway you slice it, there are no differences in these data as tabulated here.

Now, we went to another statistical technique for evaluation, matched from our binomial distribution, we looked rather diligently to detect differences; to see if there were any, and there were none.

Now, we took all pilots and brothers-in-law, no difference.

I guess that's all of them.

Now, some other thing we did, which we haven't got recorded, we had quite a list of birth defects from trivial to those that were regarded as being highly significant. So, we grouped these out to see if one classification of birth defect was masking another. We found no differences there.

We started grossly. First of all, we find out whether there were any differences in the population. If there were, then we would work our way down and try to find out why. Now, the data you do have before you, which

we haven't analyzed completely yet, we asked these pilots what kind of chemicals they had worked with since they had been in the business by the category of chemicals, insecticides, fungicides, herbicides, et cetera, all the way down, and the years in which they worked with them.

Then we asked what crop they had spent their time treating because knowing the crop they were treating; knowing the decade in which they were doing it, we could pretty well reconstruct what they were exposed to.

Right now we have an argument among the team doing this as to how much further we should go in massaging these data to see where the differences fall out.

We have another meeting scheduled for the 27th to debate what we should do, or should have done with the data.

I would like to acknowledge that what you see before you are my words, mine exclusively. You will also see a listing of the team that worked on that. Dr. Matanoski , an epidemiologist; Dr. Trout, a statistician; Fritzi Pylant a systems analyst; Ken Olds a pesticide chemist; Peggy Wheeler, a public health nurse and Carolyn McIlnay a home economist.

These are the people that basically designed the questionnaire and told me what to do. And I have, to the

best of my ability followed their advice and instructions. This is a preliminary report. There is a lot more to be done.

When you look at the questionnaire, we've got data on cancer. I heard somebody asking earlier about smoking and drinking; we have that on both the male and female. All of these data will ultimately be ferreted out and we will see what we can find out.

Now, the next stage -- I don't know which way to go -- we can take this matched population and we can go into everything we've got on them, or we can take the greater population, which is unmatched, and see what those characteristics are as far as initially reproductive mortality and morbidity.

We did do one other thing for those who are epidemiologically oriented, Dr. Matanoski , is a female, and I discovered several differences between males and females, more than I knew existed, but in this case it seems that females tend to be more sensitive to significant life events than males. Therefore, the pilot, if he filled out the form, might not remember all the miscarriages his wife or wives had. And this is reasonable.

So, we checked the female versus the male and we could find no differences in that reporting. In fact, in most cases where the form is filled out completely, it

was in one set of handwriting. This is not a statistical, scientific verification; this is a sensation from looking at it and it is exactly what I would do, should I get a questionnaire like this, I would ask my wife. And I think this is what happened here in many cases.

I couldn't tell you when my father died right now, but my wife could.

Now, do you nave any questioms on what we've done ?

Yes, sir.

DR. SHEPARD: You may have mentioned it and I may have missed it, did you give us the distribution of the kinds of herbicides that were used?

DR. ROAN: No, sir.

DR. SHEPARD: Okay. Is there any assessment of that -- of the data?

DR. ROAN: I have it. I have that available.

DR. SHEPARD: Okay.

DR. ROAN: We just haven't ferreted that out yet because we had no differences.

DR. SHEPARD: Okay, fine. I just wondered -- just in a broad brush sense, was 2,4,5-T heavily represented in the herbicides you used?

DR. ROAN: In certain areas, yes. That on people who had been working in the Great Plains area on wheat,

that is what they put the most of on.

MR. COLLINS: In the questionnaire, Dr. Shepard, the question is: do you work with phenoxy-type herbicides or have you, and within which time frame?

We would be able to detect then by area of country and go back and verify those who worked on range land, rights-of-way where you might expect products like 2,4,5-T and 2,4-D to have been used.

DR. HODDER: When you say the sibs of pilots I got the impression you sent one questionnaire --

DR. ROAN: A set. 2 questionnaires bearing identical serial numbers. Identical in ever way. You fill out one, the pilot; you mail the other to a cooperative, or transmit the other to a cooperative sibling by whatever means are available.

DR. HODDER: -- so, then you left the selection of which sibling to send it to up to the pilot?

DR. ROAN: Yes. That is right.

DR. HODDER: That, of course, raises some question of bias. The question that I am interested in is: are you looking into the people who do not respond -- and is this going to be a one-pass procedure? Are you going to look at the population that did not respond and see in a small subset, at least, if they are substantially different from the responders?

DR. ROAN: We could do that.

DR. HODDER: With this high a non-response rate, I think you either have to do that, or you really can't generalize except to the people that you specifically questioned.

DR. ROAN: That is true, but here, again, remember we have -- you respond or you don't respond. I have absolutely no control over you. Some of them got busy and just didn't get around to it. I am part of a respiratory disease study started by the University of Arizona; I am a scientist of some sort. I haven't been filling out the damn thing for the last couple of years. I don't know of any good reason why I haven't except everybody wants to fill out forms. And these people are just like any one of you. There are some potential biases in here. That is recognized, except for this, and I will defend this population strongly on that. They are equally concerned. I have no reason to suspect that they are suppressing it.

I will give you an example of one pilot. I couldn't give you names of people, but there was one pilot that had one hell of a job figuring out what sibling. He had 19 brothers and sisters.

(Laughter.)

DR. MOSES: What did you do about other children?

DR. ROAN: They dropped out. Just for the bene-

fit of the women in the audience that poor mother experienced 17 pregnancies. She had three sets of twins. I do remember, because it was so outstanding, the form listed: mother's health is fine. This is not the pilot; this is the pilot's mother. The father's health: fair.

(Laughter.)

DR. HODDER: The reason I bring that up is that if you allow the pilot to choose which of thesiblings --

DR. ROAN: Yes.

DR. HODDER: -- for example, I could see him in a sensitive situation, he may choose not to send that questionnaire to someone who just had a miscarriage rather than bring that question up to them. So, I think to prevent bias in that situation, you really have to sample the sibling --

MR. COLLINS: I would like to say, Dr. Hodder, that our members are intelligent enough to have thought of that. With regard to this kind of a survey, I suspect that their concern over pesticide exposure would overrule any thoughts they might give to some deception in the handling of the forms.

We, at our next Board meeting, however, are going to solicit the membership again to reinitiate those persons who did not yet participate primarily at the suggestion of Dr. Matanoski who would like to see a higher population

study.

DR. HODDER: I would agree with you up to a point. The problem is that when you have less than a 50 percent response rate, it is hard to say that there are no factors that make people not send things in.

MR. COLLINS: There may have been. This is all we could get.

DR. ROAN: I know of no study where you get a response rate of much above 30 percent voluntarily when you mail out questionnaires.

DR. MOSES: I would just like to respond to that.

Many of the acetic gas studies that were done had quite much higher. There were some problems in the control population didn't get as good response --

DR. ROAN: That's right.

DR. MOSES: -- because as I noticed in yours you had an 18 percent response from your sibs and a 32 percent response. Assuming 1,200 went out to each one and a 32 percent response from the pilots themselves --

DR. ROAN: Yes.

DR. MOSES: --or whoever the initial people were. Some of these went as high as 80, 85 percent, and even those are not -- you would really like to see it better, but there was an effort made -- and I think this is extraordinarily important and I would like to support

Dr. Hodder's point, that you really must know who those people are and why they didn't respond, because they may be very different in many ways from the people that did respond.

I would -- incidentally, I hope Dr. Erickson is going to make some response to this since this is his area I would very much like to know what his impressions are if he doesn't mind giving them.

DR. ERICKSON: I'm afraid that the presentation has been brief enough that I am confused. I don't understand all of the procedures which were used in forming matched pairs here and there and they seem to vary in number, and I just don't feel that there are enough details presented for me to make any evaluation of it at the moment, and in order to help make that evaluation, I think it would be very useful if you could provide us with the questionnaires that were used.

DR. ROAN: You have them.

DR. ERICKSON: No, we don't.

MR. COLLINS: They have neither the questionnaire nor the list of the consulting group.

DR. ROAN: We can provide you with the questionnaire. In fact, I have overhead projection if you want to go through it.

DR. ERICKSON: Pardon me?

DR. ROAN: I have slides of each page -- it's a 16-page questionnaire; it is quite detailed.

I can make them available.

DR. SHEPARD: What I would like to do, as we have with other reports of this nature, is to ask that they circulate the reports and all information relating to the reports to members of the Committee and ask for their comments, the whole Committee, and maybe I will ask specific questions from specific members, depending on their expertise and then make this report -- this consensus or grouping of responses available to the Committee as a whole and to the Association, because as you indicated in your preliminary remarks, you would welcome such comments --

MR. COLLINS: We certainly would.

DR. SHEPARD: -- and we would like to stay in touch with you and keep abreast of your on-going efforts.

MR. COLLINS: Thank you.

DR. SHEPARD: Any other questions to these gentlemen before we go on?

(No response.)

DR. SHEPARD: Thank you very much. I really appreciate your coming and sharing your data with us.

And with us is a distinguished foreign guest, Dr. Giuseppe Reggiani, who comes from the Hoffman-La Roche Company based in Basel, Switzerland. Dr. Reggiani has

been working very closely with the Seveso episode and we are very fortunate in having him with us today to give us an update on the data that has emanated from that incident.

Dr. Reggiani.

UPDATE ON THE SEVESO EXPERIENCE

DR. REGGIANI: Thank you very much, Dr. Shepard and may I say, first of all, that I am very pleased to be here and would like just to express my gratitude to you, Dr. Shepard, and to the Veterans Administration for the kind invitation.

It is, in fact, an honor and a privilege for me to speak to many people that I know well and that I respect and admire, not only because of their professional skill and competence, but, first of all, for the honesty of their minds.

I am very sympathetic with the problems that you are facing here in the United States, Dr. Shepard, and the Veterans Administration at large, because it is very, very close to the experience that I have had myself after the accident in Italy. The problems that 2.5 million veterans, I believe, and their families and relatives live under the same psychological stress that has been experienced by the citizen population after the accident in July '76, with a difference that now that

population has seen what happened during these five years, at least for the acute phase or short-term phase of possible health effects, but that, unfortunately, cannot be applied today for the Vietnam veterans, not yet.

I assume that you expect me to offer to them some information which would be able to relieve that kind of anxiety, that kind of tension, and I hope that I would succeed.

I consider myself an expert in relieving anxiety and tension because in the early '60s, I developed with the clinical trials, Librium and Valium, and have been successful in their purpose.

(Laughter.)

DR. REGGIANI: Now, let's hope for the best.

Now, first of all, the source of my data, which I will present here today to you, will be just a few highlights because the amount of data is very large.

The source of the data are, first of all, the reports of the medical commissions in Italy, locally in the region where the pollution is located and our medical commissions or scientific advisor commission to the Italian government -- it is their reports upon which I am basing my data today, and they are updated up to November 9, 1980.

The second source is my discussion with the members of these commissions in Rome

and in Milan and discussions that I had last October in Rome and recently at the beginning -- the middle of January with Dr. Marcus Klimber. Dr. Klimber is the chairman of the International Steering Committee, the committee which is in charge of monitoring, guiding, suggesting -- making suggestions to medical commissions in Italy.

I believe that it is not necessary for me just to enter into the question of the environmental situation there. I have given the most recent publications to Dr. Kearney and Mr. DeYoung, and if you want to have copies of them, I can provide that. In these documents you will find that the analysis of the soil, of the vegetation, of the water, of the air, of the biological material has been followed up during these years and that in part of Seveso there is still a certain amount of TCDD.

The amount of TCDD, as I assume it is already known to you, but I would be glad just to show -- I believe that is just the amount which has been calculated during the months which have followed the accident. You can see that there is a total of about 600 gram of TCDD which have been found between the parts which has fallen on the soil, or which has been absorbed by the vegetation and the part which is still in the

rafters, or on the roof of the factory, and that's just -- I don't need just to enter into the methodology of the analysis, I assume that you believe that it is 2,3,7,8-TCDD and not any other isomers.

Now, the second aspect is the question of the exposure or, first of all, the classes of the populations -- or the populations which has been exposed. Depending on the content of concentration of TCDD in the soil, they had been divided into three zones / three zones of different exposures selected for the medical health survey.

The first part, there are a group of 730 people of Zone A with the highest concentration, 245 micrograms per square meter, which have been exposed during the first two weeks That can be considered the population acutely exposed and which had been evacuated.

A part of that population, about 450 people, returned to the zone -- to the part of the Zone A which had been decontaminated about 1 1/2 years later.

They can be added to the second group, the group of the Zone B where the average concentration of TCDD in the soil is 3 micrograms per square meter where the total is about 5,000 people.

And then there is Zone R where there are only scattered parts which contain very low quantities of TCDD and where there is a large population.

And then as in matching populations for the purpose of examining the health conditions of these populations during these years and other communities outside around these core -- central core have been added to that for a total of 220,000 people.

Now, let's go back to the classes which have been examined closely. That means, for instance, the Zone A people, the people in the Zone B, which means those which certainly had the opportunity to have risk of exposures.

How was it controlled? How many have been kept under control during these five years. For the Zone A, in particularly, almost 100 percent have been followed up and they are still under control.

For the Zone B, a part of that has been controlled up to 100 percent, for instance, the children between the ages -- the school children between the ages of 6 and 14. And they are still under control.

Then the plant workers of the Emazo factory, 160 people. They have been under control during these five years without any loss at all.

The decontaminators, for instance, those people working in the soil of Zone A, 40 decontaminations of

the soil of the gardens, of the houses for a total of about 800 people. They have always been kept under close control 100 percent.

The military personnel in charge of just keeping guard around the Zone A which is still today fenced in, which is just behind fences.

Then all pregnant women of Zone A, B and R. All newborns of these three zones. All hospitalized cases, of course, coming from these zones, and all death cases, not only for those three zones, but for the whole territory.

Just to give you in respect of the 5,000 people of Zone B, how many are not compulsions to present themselves they had just to volunteer and in respect of the laboratory data, the chemists -- the serum chemisty, for instance, blood examinations, and so on, urine analysis about 80 to 82percent have volunteered and have been examined at different stages.

During these five years, of course, passing with the the time, the interest or the eagerness to volunteer for that type of examinations decreased because people realize that they were in good health.

Now, can we say that these populations have been exposed to TCDD? What evidence have we to show, in effect, that they have been exposed and have absorbed TCDD? Yes, we have some evidence for that. One case

that's a woman who died in February of '77. She was in the Zone A close to the factory, certainly in the part of the Zone A with the highest concentration contamination of TCDD. She remained there during two weeks and she was evacuated. She was hospitalized in the beginning of October of the same year for phlebitis. Then in the hospital after two weeks she developed a jaundice. From the jaundice, it was discovered that she had a tumor of the liver. In fact, it was not of the liver; it was of the pancreas and she died in February of '77.

Fortunately for us, the tissues have been preserved and have been analyzed. They have been analyzed, first of all, in Italy, but unfortunately, the limit of detection was insufficient. It was 250 ppb and, therefore, they have been sent to the UK, and that is just the concentration which has been found.

The total for the body was 40 micrograms. Keep in mind, February '77. If we would assume, for instance, a half life for TCDD for the human being of two months, this person, this woman would have had at the beginning, at the moment of the highest exposure, about 280 micrograms of TCDD in her body, about 5 microgram per kilogram.

Another example, breast milk, the breast milk obtained from women of the Zone A has been sent to Harvard to Dr. Masselson, to Dow, and to Dr. McKinney

at the National Institute of Environmental Health and Sciences in North Carolina, that is just the results of the three samples. Dr. Masselson is the one who says that his limits of detection is 1 ppt.

The National Institute says it is between 2 and 5. Anyway, we have at least other hints that, in fact, these populations has been exposed and has absorbed TCDD.

Another example, yes, now moving up to the clinical --

DR. SHEPARD: Dr. Reggiani, were these samples taken from those numbers of different individuals?

DR. REGGIANI: They are code numbers. There are three different samples.

DR. SHEPARD: Oh, I see.

DR. REGGIANI: They are three different samples, code numbers and out of that, that code numbers, they have been sent to Dr. Masselson and to Dr. John Moore in North Carolina.

DR. SHEPARD: Thank you.

DR. REGGIANI: And to Dow, of course.

Now, another example, another evidence that the population has been exposed, in my eyes at least, chloracne. This is what happens between '76 until today. In fact, just now, by the middle of February, the latest screening of the children which is just running now will

be ended. And you can see that the adult populations of Zone A and B, and part of Zone R, as well as all the children of the zones with the highest TCDD in the environment have been examined and a certain number of them have developed chloracne.

And it is possible -- and Dr. Suskind, will support me saying that that's an evidence of exposure to TCDD.

Now, let's see whether there is any correspondence, any correlation with the level of exposure.

You can see in this table where you have the frequency of chloracne for the children living in Zone A; for those living in the Zone B, and for those living in Zone R. You will see that the highest frequency is at the zone where you have the highest contamination. That means, the children who had the opportunity to get in contact with the highest concentration of TCDD. Now, what happens -- now, I'm moving on to the clinical part just to give you the situation as it is today.

What happened to these children? You can see that from the table here that the grading intensity of the disease of chloracne, it is just a shift from the highest number five with the highest most severe aspects of chloracne to the complete disappearance, healing of that in '79 and practically today there is no more new cases which

which have appeared.

I consider that these three items are just the evidence that this population has been exposed to TCDD and has absorbed TCDD.

Now, the other parameters -- the other health parameters which have been examined in this population, I will take the liberty to do it last, because it is the most difficult to explain.

Let's move to the nervous -- peripheral nervous system. In the peripheral nervous system, there are practically no clinical signs of any effect on the peripheral nervous systems, but they have been revealed in some cases if specific methods of detection have been used. In that case, I'll just give you an example of the examinations of the peripheral nervous systems with the measure of the conduction velocity. In that case, the motor conduction velocity -- both motor and sensory conduction velocity has been examined.

There are just two populations, one is just the Zone A, 414 people and the region is just one community, which is one part of the 11 which are under health survey and you will see they have found at that moment; 9,077 no differences.

If you have to consider that that is a rather highly industrialized territory where you have a lot of

chemicals in the environment. Many of them are chlorinated chemicals. TCDD is not the only one. Therefore, the medical commissions in Milan decides to do a different kind of approach to the question of the neuropathy or the possible neurological effect in a different way.

They have changed the populations. They have taken one group of the Zone A, 277, and then they have taken a certain unexposed control group about 100 miles away, just living in a small village on a lake peaceful place where there is no pollution, no contaminations, no chlorinated chemicals in the surrounding.

And then you can see that there are no differences practically, at least, not in the neuropathy of known etiology and not in the neuropathy of unknown etiology, not for what can be considered the clinical science of neuropathy. There are differences in the symptomology that can be explained by the fact that the populations living in the zone was, of course, to a certain extent primed with the idea of having something. The other was completely unaware of anything.

But then if you examined them closer and taking some samples or individuals of these populations which have not only neurological symptoms, but also either signs of liver impairment or chloracne, then there is higher frequency in Zone A.

Whether this chloracne was of TCDD origin, or of other chemicals, is not known because during these studies the dermatologists have found something which they were not aware of, that's that chloracne in industrialized zone has a baseline of about 0.1 to 3 percent of the whole population.

DR. SUSKIND: Were the nerve conduction velocity studies also done in this comparison?

DR. REGGIANI: Yes.

DR. SUSKIND: That's not listed; is it?

DR. MOSES: Is that what neurological syndrome means?

DR. SUSKIND: The nerve conduction velocity.

DR. REGGIANI: Oh, I'm sorry. In this case, it has not been done.

DR. SUSKIND: So, you are just really comparing neurological syndrome --

DR. REGGIANI: Only syndromes, yes.

DR. SUSKIND: -- with people having liver problems --

DR. REGGIANI: Yes.

DR. SUSKIND: -- chloracne as compared to the control?

DR. REGGIANI: Excluding under the liver problems all those drinking wine; all those having other problems

with the liver, all that.

DR. KOLBYE: I just wanted to ask on the liver impairment, could you explain a little bit more how that is defined? Is that enzymatic abnormalites, or what?

DR. REGGIANI: It is only based on the serum chemistries, and only based practically on three or four analyses the two transaminases, alkaline phosphatase gamma GT.

DR. KOLBYE: Thank you.

DR. REGGIANI: When can we decide that it is a liver impairment and when can we decide that it is only compensation in the function?

I have heard many opinions on that. Some pathologists, specialist tells me that the liver can be considered damaged only if the normal values, the standard values is at least three times higher. In between the standard value and the highest values, three times the standard, that is only in effect a compensatory effect -- of the organs trying to eliminate it, to metabolize it, just to do something with it.

But, I repeat, it is just a question of opinion, I am just repeating.

In these cases, they were considered a liver impairment, but they had not very high values in their

functions.

DR. KOLBYE: Thank you for that clarification.

DR. REGGIANI: Now, let's go on now to another aspect --

DR. MOSES: Excuse me.

DR. REGGIANI: Yes?

DR. MOSES: Dr. Reggiani, are you going to show us any more on nerve conduction velocity? I am familiar with Dr. Balari's work in which I think some evidence of abnormal nerve conduction velocities were found, if my reading of those papers is correct?

DR. REGGIANI: Dr. Moses, I could keep on showing you a lot of data, then I would be here tonight and Dr. Shepard told me that at 12:00 o'clock we have to adjourn because the meeting room has been --

DR. MOSES: Well, but I think that it is important that the group know that there are some reports from Seveso, and I am mentioning Dr. Balari's work, in particular, in which nerve conduction abnormalities apparently have been found, or there is a question about whether or not there may be some nerve conduction abnormalities in Seveso, the Zone A people, as compared to another group of people who didn't have the dioxin exposure.

DR. REGGIANI: Yes. Yes, I'm aware of that. He has just found that. If you want, I can give you then

the details of that study?

DR. MOSES: -- well, that is up to the group. I just was mentioning it as being something that has been reported.

DR. REGGIANI: Yes.

DR. REGGIANI: But, again, they were just the same two populations. Just the same two populations which I have here. One which is living far away, certainly not exposed to any chlorinated chemicals and one, on the contrary, living there in that surrounding.

I don't need to say -- it is not that I do not believe the method of study. I have been told that if you repeat the examinations twice in the same day, you will have two values just in the same day.

I don't want to discredit the approach or the methods of study the peripheral nervous system; I am only saying that it is probably not the only method to detect an effect.

Now, if you don't mind, I'm trying just to keep my time.

Again, the rate of malformation, the birth effects have been a problem because the people there, the medical commissions have been confronted with the usual problems which you have in birth defects. The birth defects which have to be notified are, by law, always

just a limited number of, or perhaps only one class of all birth defects. Therefore the frequency in the population is always very low. In Italy, in that part, for instance, where they have to notify for the law only the practical -- the hip dislocations that they had occurred, the frequency of .05 per 1,000.

Now, at the moment the chart just includes other types of birth defects. Immediately, the frequency, the rate increased and since the populations, and, of course, the doctors there in charge at that time of the study, became aware of the problem more and more with the passing of time, with passing of the years, the number has steadily increased. Today, we have a much larger frequency a larger rate than it is been found in the past. That does not mean that in the past the same rate was not present. It was not detected.

But what is important is that during the period for instance, in Zone A, the pregnant women have been exposed to the highest concentrations of TCDD between '76 July until the end of '78, Zone A and Zone B.

By pure chance, all the newborns of these women were normal. I believe the total is 104 and one would expect that at least two or three of them to have some malformation, some major malformations. Perhaps seven or eight, if you want just to include the minor malformations,

but they hadn't.

I'm just keeping the situation as it is today. The frequency of abortion has been a problem, too, and it still remains a problem.

If we take the frequency of abortion for the whole population, dividing, of course, between the amount of the communities with the highest part of the territory contaminated, 50 percent which is the first line over there, and the other two communities with only 20 percent of the territory contaminated. And then we compare that with the frequency of abortions with the seven townships which are outside the contaminated zone, and we relate that to the frequency of the province of Milan,

then we don't see any difference in the course of the years, certainly not in '76, '77, '78. Still today there is no difference.

But, of course, these values, or this kind of frequency is diluted in the whole population. And perhaps only a few women have been affected and have had abortions because of TCDD. If you put that all together in the whole group, this small number will disappear.

Yes, that is the way it has been for the time between '76, immediately after the accident, the third quarter and the fourth quarter and for the 1977, and

I don't have here the last values for the last quarter of '77, but they are unchanged. There is, in fact, a fluctuation in the frequency of abortions in that period where certainly there was the highest risk of the contamination. But, again, there is no difference between just the parts of the territory divided in relations to the contamination -- the amount of contamination.

Now, I will skip the part concerning the immune capability and the chromosome irregularity because in respect of the immune capability something strange happened and that is that children with and without chloracne, which have been examined six times during these five years have some parameters, for instance, for the analytic activity of the complement, they had an increase in six out of six examinations. They had an increased mitogenic response in three out of six examinations.

And they had an increased number of peripheral blood lymphocytes in two out of six examinations.

Everybody is at loss just to try to give an interpretation to these values, and it the recommendation of the International Steering Committee where, by the way, Dr. Selikoff is on the International Steering Committee, and he was there in January, and they have recommended that the study of immune capability should be carried on.

Now, for the chromosome analysis, no differences have been found in different groups which have been examined.

Now, let's go to the liver functions. I have already given you an idea of the problems of how to interpret the story of the liver function. There is, I believe, about 245,000 analyses which have been stored in the computer for these populations for about 22 different analyses, and among them, of course, the transaminases, the gamma GT and the alkaline phosphatase

In fact, there have been continously fluctuations in these. At the beginning, many of these cases where they had some increase, had an enlargement of the liver, which then later disappeared. But all that did not help very much. None of these people developed jaundice, except what you can find, as usual, in particular populations. Therefore, one member of the International Steering Committee, Dr. Donald Young, who, I believe, is the head of the Central Laboratory of the Mayo Clinic recommended abandonment of that type of approach, to change that and to use a new approach which I will show you.

He recommends these four analyses -- abnormal liver functions should be based on these four analysis: alkaline phosphatase, aspartase transferase,

alanine aminotransferase and gamma GT.

Now, what happens if these values are not normal? Well, if they are, all of them, all four aren't normal, then people have to be followed up. That is if they are only partly -- some of them are normal, but have just to be repeated and see what happens.

If they all four become normal, then we will have to follow-up. If they are only some of them, or one of them are abnormal occasionally, then they -- should be ignored.

I have no comments on that kind of approach. Perhaps, you to tell me how to interpret these new approaches.

Up to now, I believe about 70 cases have been found with all four analysis abnormal, which then will be followed.

Another analysis, which was interesting can be applied, of course, only for the children is the analysis of the urinary -- the (inaudible) as a sign of liver enzymes activity. And, in fact, they are higher in these regions for the children with chloracne than for the others. So, that is a new aspect which will probably be considered.

In other words, we are going away from the pure pathology, clinical pathology and moving to a more

sophisticated examinations where sub-clinical signs are considered.

Another aspect which has been examined is, of course, the porphyrin in the urine. It has been said that in cases with severe exposure to TCDD in the past accidents in the industry have developed porphyruria --

Now, again, the eliminations in the urine have been examined on several occasions in the populations that I have mentioned, but, again, there have been fluctuations. The value which is considered to be just the ceiling of 200 micrograms per liter have reached sometimes more than that, but by and large it remained always just in that --

Only two cases have developed porphyruria -- a man of 24 years, living in Zone B, a man of 24 years and his sister of 20 years.

And Dr. Sisk has examined these cases -- not only, he has examined all the members of the same family and the relatives living far away from Switzerland. That, in fact, he has presented these cases in Rome during the symposium. In fact, they are members of a family with a genetic error of metabolism.

These cases have been -- these two, man and woman has been treated with edroxy chloroquin

two tablets per week for about four months and all signs have disappeared today.

Now, what happens now beside all that?

I have already mentioned that the whole population, the mortality and the morbidity of all populations under survey, one way is dividing by zone of intensity of contaminations, as I showed in the beginning. We have already some data about the death statistics of the Seveso region for the total death rate, for the cancer death rate, and, of course, it is too soon to be meaningful. And for the cardiovascular mortality, there is differences for these five years. And all that will continue and the follow-up is meant to be carried on for at least for 20 years.

And that is the end of what I intended to present to you.

Thank you.

DR. SHEPARD: Thank you very much, Dr. Reggiani. It is very interesting data and I am sure itwas frustrating to you as it is to us not to be able to devote more time to this, but as time goes on, I hope we can stay in touch and be kept abreast of the data as it develops.

Are there any quick questions of Dr. Reggiani?

Yes, Dr. Suskind?

DR. SUSKIND: This is an enormous source of

excellent information and one of the things that you indicated was that there are -- you're conducting studies of decontamination workers.

DR. REGGIANI: Yes.

DR. SUSKIND: So that you have baseline pre-exposure information?

DR. REGGIANI: Exactly.

Yes, that is right.

DR. SUSKIND: How far along is that? You say there are 800 --

DR. REGGIANI: The moment that they are enlisted, they are, of course, examined clinically. The history -- clinical history is taken.

DR. SUSKIND: How long have they been followed so far? A year, two years, three years?

DR. REGGIANI: Since they have started. Not only that, there are always new groups getting in and coming out. The first group entered the Zone A for decontamination of the Zone A 7, -- 6 and 7, the lowest contaminations already at the end of December '76. They worked there until May '77. Then later on in October, the people came back again. Then our group of decomtanina-tors entered our part of the Zone B and now they are working in the Zone A with the highest contamination. And all of those are still kept under control.

DR. SUSKIND: What I am asking though is that those early decontaminators, were they examined before they went in?

DR. REGGIANI: Yes. Oh, yes, of course. They had to be admitted. If they had some evidence of disease, and so on, they were excluded.

DR. KEARNEY: Weren't many of the decontaminators members of the Italian Army?

DR. REGGIANI: No, none of them were members of the Italian Army.

DR. KEARNEY: I thought they were.

DR. REGGIANI: No. They are members of the agencies, special agencies that do that kind of cleaning procedures.

DR. SHEPARD: Thank you very much, Dr. Reggiani, we really appreciate your taking the time to be with us.

I'd like now to ask -- we are again going to deviate from the printed agenda for a moment and ask Dr. Erickson to bring us up to date on his experiences on the CDC study.

STATUS OF CDC BIRTH DEFECTS STUDY

DR. ERICKSON: As most of you know, CDC is in the beginning stages of doing a case control study to try to determine whether Vietnam veterans are at some increased risk siring babies with birth defects.

Study cases will be babies who were born with congenital malformations in the metropolitan Atlanta --

DR. SHEPARD: Excuse me, could you get a little closer to the microphone.

DR. ERICKSON: -- the study cases will be babies who were born with congenital malformations in the Atlanta area over the past decade and who have been registered in the Center for Disease Controls Congenital Defects Surveillance Program. Study controls will be normal children who will be ascertained through the State of Georgia Vital Records system.

Basic study procedure will be to locate the parents of these case and control babies, interview all available willing mothers and fathers of these babies -- asking them about a wide variety of risk factors which may be associated with the occurrence of birth defects and including fairly extensive questioning about service in Vietnam for men who were identified as being Vietnam veterans.

The protocol which we developed has had a rather extensive review. It underwent a special in-house scientific review at CDC. We brought in a panel of university based scientists to review it. It had a review by the Interagency Work Group on Phenoxy Herbicides. Four veterans groups were given the opportunity to review

it. At the moment it is undergoing final review at the Office of Management and Budget. We expect final clearance from them sometime this month.

We have had a rather major change in procedure. It was decided early in November that rather than hire the people who will be doing the interviews -- rather than hiring people to work directly for CDC, that CDC would contract with a private concern to do the interviews. CDC will retain all scientific direction and do the analysis of the data and the final reporting.

Specifically, what we will do is contract out for the tracing of the parents of the cases in controls and the conduct of the interviews.

We are just about to release a request for proposal and expect to get responses from prospective contractors sometime in the spring to finally release -- finally award a contract at the end of summer -- late summer of this year./ We expect to begin a pilot study in August or September, to begin a full study in December or January of next year, and to have a final analysis and report ready, hopeful, sometime around the end of 1983.

I think that about sums up the major points. We have been very busy with this, but it is all rather mundane housekeeping chores that we need to do to get the

study rolling.

DR. SHEPARD: Thank you very much, Dr. Erickson. Are there any questions of Dr. Erickson?

DR. MOSES: Yes. I was wondering how many babies are in that 10-year period?

DR. ERICKSON: Well, we now have cases of babies on file from 1968 through the present -- or babies born between 1968 and through the end of 1980, which was the target time period. We had somewhere between 12,000 and 13,000 babies. Not all of those babies will be study babies.

DR. MOSES: How many will? Do you have any idea?

DR. ERICKSON: Roughly around 7,000 study babies who are cases. We have approximately 3,000 normal babies and the families participating in this control.

DR. SHEPARD: Any other questions?

DR. MOSES: Can I ask Dr. Erickson another question?

DR. SHEPARD: Sure.

DR. MOSES: This is specifically for the Atlanta area, as I understand it?

DR. ERICKSON: Yes.

DR. ERICKSON: Is CDC going to be doing anything else nationwide regarding this? I'm sure that was thought about.

DR. ERICKSON: Yes, right.

CDC has been collecting data on babies born with birth defects in the metro Atlanta area since '68. We do collect data nationally and have been doing it since 1970. It is very difficult for us to get certain kinds of information in our national study. The registry we have of the Atlanta babies is very complete -- a very complete ascertainment of babies with birth defects. The kinds of information that we are able to gather is also rather extensive because we have our own people visiting the hospitals in the Atlanta area. They are extracting the kinds of information that we want from hospital charts.

So, that, for example, we have full names of the mothers and fathers and their addresses at the times of births and telephone numbers, and things like that on file.

We do not have that sort of information available on a national scale, nor is there so far as I am aware any registry similar to our metro Atlanta registry which would allow you to have a starting point for a case control study, at least not a relatively easy start.

DR. MOSES: Thank you.

DR. IREY: How many cases did you say you had of --

DR. ERICKSON: Well, there are somewhere between 12,000 and 13,000 babies in our file out of a population of roughly 300,000 births.

DR. IREY: Yes

DR. ERICKSON: Now, a lot of these babies have what we would call minor defects or minor developmental anamolies which we do not intend to study. We were taking what we class major malformations and that amounts to somewhere between 7,000 and 8,000 babies. Major malformations being defined as one which there is a serious life threatening defect, a defect which requires substantial surgery or might engender a substantial psychological problem for the baby.

DR. SHEPARD: Thank you very much, Dr. Erickson. It is very good to hear that progress is going on and I am sure that we will be following this work very closely.

Next, I would like to call on Dr. Moses to give us a little thumbnail sketch of some of her activities in the Mt. Sinai group.

CLINICAL RESEARCH AT ENVIRONMENTAL SCIENCES LABORATORY

DR. MOSES: I am from Mt. Sinai, from the Environmental Sciences Laboratory, and we have done a fair amount of work in this area. We studied workers who have been involved in the manufacture of 2,4,5-T in one instance. These are Monsanto Chemical

Company workers in Nitro, West Virginia. And we have also studied another group of workers involved in the manufacture of 2,4,5-T and 2,4-D, and these are Vertac Chemical Company workers in Jacksonville, Arkansas.

Before I give you any information at all, I want to make very, very clear to everybody here that we did not study cancer; we did not study birth defects. What we did was a current health status evaluation of worker populations, both retired and active workers at these two particular industrial sites.

The only reason I want to say that is that many people think that by doing such studies -- we did a morbidity study -- that we are going to be able to provide answers about some of the birth defect and the cancer information. The type of study we did does not lend itself to such answers. I think we are going to have to wait for Dr. Erickson's work and the mortality studies which will give the answers.

Now, what I would like to do today is maybe hold up a tiny little candle to throw a little bit of light to give you some results -- some very preliminary results of our investigation of the Monsanto employees. And let me make clear, again, also, that this is preliminary, it is limited. We do have a lot more data. We are in

the process of looking at it and my hope is that within the next few months we certainly will have reports on both of these surveys ready for the National Institute of Environmental Health Sciences who sponsored this through their grant mechanism which is how these studies were paid for.

I think I will start with giving you some of the information about Monsanto. I guess all the questions will be later, but please feel free to interrupt me now as we go along, if you wish.

Could I have the first slide, please?

This is just to give you some background. Monsanto acquired this plant in 1929. They mostly made rubber additives. They still do to this day. Over the years there's been really literally hundreds of different products and intermediates and compounds and chemicals that the workers at this plant have been exposed to.

It was from 1948, when they started making 2,4,5-T acid, to when 1969, they ceased production.

Monsanto, in this facility, did not make Agent Orange. They made 2,4,5-T acid, which was then shipped out, esterified and mixed with the 2,4-D ester to make what we know as Agent Orange. Agent Orange was not made at this facility.

Now, we arrived on the scene 10 years after the last known production, 1979 was when we did our study. This slide shows you that they used tetrachlorabenzene with methanol and caustic to make trichlorophenol. It was the trichlorophenol reactor where the run-away reaction occurred and this was the same type of thing that happened in Seveso that Dr. Reggiani was just talking about except that they used ethylene glycol instead of methanol which is the only basic difference.

Now, this slide shows the way we are analyzing the data that we collected in the study. This is to give you an idea of what the exposures were and what we're using for a marker of exposure, which is chloracne. Now, the reason we can use chloracne in this population (there are 226 workers that we are reporting on that are involved in this analysis) is that a very high percentage of these workers actually did have chloracne. The reason we know it was a problem is as happens when workers have work-related problems, they give it a name, and they did give it a name. They called it "weed bumps," because they called the chemical / they made "weed killer," and they had skin problems with it.

Also, this was not one of the more pleasant jobs there and the union negotiated for a small -- slight addition of what they call premium pay for people who

worked in this particular location with this particular product.

Now, let me just -- this may be a little complicated. Now, this slide is how many had chloracne to show you -- this means never, past and current. What we did, we divided the people into those who had never had chloracne, and that was about half the people that we saw. Then there were people who had had chloracne in the past, but they didn't have it now. By now, I mean, on physical examination, and we did have a dermatologist, Dr. Crow who came over from England. He is a well known authority in this field. He's an industrial dermatologist, who saw every single person.

We also had Dr. David Bikers from Case Western Reserve, who is also a dermatologist and they evaluated every single person for their current skin condition, and those are the people that ended up in this category of having current chloracne.

Now, this slide shows what we found related to exposure. We divided people into four groups. Those who had no exposure to the production of 2,4,5-T (actually trichlorophenol and 2,4,5-T). People who had minimal, who had moderate and heavy exposure.

I don't have time now, but in the write-up, we'll tell you exactly what criteria we used to put people

in those categories. Then what I was very pleased to see because we did these separately, the chloracne was done separately from the exposure. When we put it together, we found what we expected to find. The people who did not have chloracne decreased as exposure increased.

Exposure is increasing across this way. And/or you could say thing, the people who never had, but currently have chloracne, there was a definite increase as exposure increased.

And I would like to respond to something Mr. Mullen said earlier that there was no relationship between dioxin and disease. I don't necessarily think that that's the case. There is certainly clearly a relationship between exposure and chloracne. Now, what exactly that relationship is, we don't really know because if you see here, you will note that 24 percent of the people who had heavy exposure, that's 22 people who had heavy exposure, in 2,4,5-T production did not get chloracne. And we noticed also that we have a person over here -- we still can't explain that, -- who had chloracne in the past. That may be related to some other industrial exposure. We really don't know why that one person clearly probably did have chloracne in the past, but did not have it currently.

So, this is just to sort of set the scene

because I am going to show you some data now in which we looked at -- I'm just going to give you the biochemist the liver function tests and the lipids, because this is something everybody is interested in. Cholesterol or triglycerides we know have been reported to be abnormal.

Liver function tests are extraordinarily important and I am going to show you some frequencies of abnormalities based on these groups and based on whether or not they ever had chloracne.

If there aren't any questions, I'll go through that.

Yes, Dr. Gross?

DR. GROSS: In the second --

DR. MOSES: Here, minimal?

DR. GROSS: -- yes. What is missing from 100 percent, 64, 9 and 7 hardly adds up to 100.

DR. MOSES: 64, 74 -- yeah, we are missing -- that's probably -- it's a very good pick-up, this is wrong here. It doesn't add up. The percentages seem to be off. That should add up to 100 percent.

Thank you. I'll change that.

DR. SUSKIND: Marion, even though you want to delay in explaining how you arrived at minimal, moderate and heavy --

DR. MOSES: Oh, sure I can --

DR. SUSKIND: -- I think it is kind of important because it is critical.

DR. MOSES: -- sure. Okay.

DR. SUSKIND: And I hope you don't mind if I ask some questions about --

DR. MOSES: No, absolutely not.

DR. SUSKIND: -- how this was determined. Obviously since you didn't have access to work histories, which wouldn't have helped you anyway --

DR. MOSES: Well, we did.

DR. SUSKIND: -- the interview was the main source. What did you do with the intermittent exposure people, the maintenance people? Where did you put them, in minimal, moderate, heavy?

DR. MOSES: Okay. Let me -- okay, I'll take the time because I think it is important, I will take the time to tell you how people ended up in these categories.

We got very, very good occupational histories. We spent a lot of time. We have very skilled occupational history takes, who took these histories, and we took the time and we asked them -- did you work in building 41? We want to know that. Or building 34 or building 92 where we know production occurred.

remembered
Some of them. But we also asked them exactly what did you do? Exactly what was your job.

Now, you are relying on people's memory. There is no question about that. People's memories, we're finding out, in taking a good occupational history, is much, much more reliable than relying on company work records because all the company work record tells you is where in terms of payroll; or in terms of getting somebody on a
were
computer printout where they assigned. That does not necessarily mean that's where they worked, or that is
worked
what they did. Or they may have only for one day, particularly in terms of the clean up after the accident. We certainly know that a lot of people ordinarily were not assigned and never had anything to do with trichlorophenol production did end up at the clean-up.

Now, if we found that out and if we know, they automatically went into this category. So, the 25 people that we saw who were in some way involved in the clean up, automatically went into the heavy exposure group.

I should tell you that the company went through a lot of different changes. Production started off in one building -- two different buildings actually and eventually the 2,4,5-T was dried in several buildings throughout the plant. Eventually they put most of it under one roof in building 92.

DR. SHEPARD: Excuse me, Marion --

DR. MOSES: Yes.

DR. SHEPARD: -- you are going to have to speed up a little bit.

DR. MOSES: Oh.

DR. SHEPARD: If you can just kind of give us a quick overview --

DR. MOSES: The only way I can tell you -- the only way I can tell you, explain this is to tell you exactly how people were exposed to this, and then I can tell you how they got into the different categories.

If they were involved in the drying -- if anybody was in a room where it was dried, and it was dried in several buildings, but they weren't actually involved in the process or the manufacturing, they ended up in the minimal category because they had a potential exposure to 2,4,5-T. Actually, it was 2,4,5-T acid.

If they actually were involved in putting their hands inside the autoclave and digging out the wet cake, they ended up in the heavy exposure group.

If they worked in the lab and sometimes they did a specimen / of 2,4,5-T, and sometimes they didn't, but they did have direct contact with it, they ended up in the moderate exposure.

We were very conservative where we put them.

in heavy exposure category
Everybody that's / , really belongsthere. Anybody that was involved in maintenance -- was involved in maintenance in a 2,4,5-T building, ended up here.

Now, we just didn't say that anybody that was in maintenance automatically had heavy exposure, you didn't know. It depended on when they did maintenance, and if we thought it might be heavy, we put them in here. But we were very, very conservative.

In general, I think, it shows that it probably works is that we did see the relationship in which the exposure categories related to the chloracne.

This is why I didn't want to go into it because it is very complicated.

Yes, sir.

DR. PAGE: The column to your far right, that would be 50 percent of those heavy exposed to trichlorphenol 10 years after they were exposed?

DR. MOSES: That's right. Well, it is even more. I am going to show you a slide that shows --

DR. SHEPARD: Excuse me.

I am going to have to restrict questions from the floor and really we are going to have to restrict questions from the Committee.

Would you please go ahead and complete your presentation / . We have a whole other segment of the agenda we

have to get through and there's a meeting in this room at 1:00 o'clock. So, we are under a time constraint. I'm sorry.

Go ahead.

DR. MOSES: Okay. What this represents here is that 71 people of the 226 that we saw had current evidence of chloracne. Half of the people that we saw had chloracne currently, or had had it at some time in the past.

Now, this directly answers the gentlemen's question in the back. Of the people that we saw, half of them had had their chloracne more than 20 years. This is based on asking them how long they had had it.

So, it is very persistent.

Now, this slide -- forgive me, I don't know if you can see it -- I am going to just tell you basically what we found here.

I put cholesterol on here not because we found an increased prevalence of abnormal cholesterol, but because people are going to want to know what we found. That's the only reason it is on here.

SGPT and SGOT and GGT are all liver function tests and are very, very important in this. They are here because we did find an increase prevalence of abnormalities.

If you will see,
(DEX means drinkers excluded) we took out moderate, heavy and problem drinkers and that was considered to be anybody that drank more than two beers a day.
Very fortunately, this group, were not heavy drinkers. 71 percent were non- drinkers or ex-drinkers.

Now, we didn't see anything with cholesterol.

We saw related to chloracne an increased prevalence of abnormal triglycerides.

Now with SGPT, I really can't say very much because the numbers are really very small, but I am going to show you the means test. And the SGOT, there were no abnormalities here, but there were only three people abnormal in the other groups. I think the numbers are really too small to say anything, but there were abnormalities.

GGT, when you take out the drinkers, there is clearly an increased prevalence of people with an abnormal GGTs in the chloracne group as opposed to the group that did not have it.

For triglycerides, you will see that related to exposure, there was an increased prevalence of abnormalities. The same it goes for SGPT / SGOT, and much, much more clearly in the heavy exposure group with GGT.

I emphasize these are abnormals. These are above what our laboratory was and I would agree with -- I shouldn't say I would agree with, but Dr. Reggiani mentioned a three -- it must be at least a three level of increase for them to be considered abnormal.

Dr. Popper , in our laboratory, feels it should be doubled before it's considered clinically significant, which means there is liver injury. And I think that is a very important point that has to be made.

Now, we also looked at -- and I have a whole series of slides that I am not going to be showing you -- we looked at -- comparing the means, the mean differences of these tests that I showed you and many, many others. All of them, the BUN, all of it. These were the only ones that showed up being significantly different. The means of / the SGPT, the SGOT and the GGT in the minimally

versus the heavily / exposed were significantly different.

And to get back to Dr. Suskind's question here. The reason we use the minimal and the heavy is that we were pretty sure everybody that was in those groups belonged there. We weren't so sure about the moderates. Some of the people who were in the moderate group, we weren't sure whether they fit in the minimal or the heavy. These groups we're sure that these 45 people minimally exposed belong here and these 93 people heavily exposed/-- relatively sure they belong here.

And these were found to be significantly different. That does not mean that they were abnormal though.

In terms of chloracne, the SGOT and the GGT, which are both liver function tests were shown to be significantly higher in the people who had chloracne as opposed to the people that didn't.

The triglycerides were found to be significantly higher / only in relationship to chloracne but not in relationship to exposure.

Now, I will summarize right now.

We weren't, for all sorts of reasons that we know about, able to quantify the exposure. In 1949, when this accident occurred, nobody even knew what -- that it was dioxin, or what it

was that caused the chloracne.

Now, an effect became demonstrated in what I have just shown you, is that we did show some effects or some trends.

Now, the real question is: has injury occurred? And I think on the basis of this data, we can say that we really don't know. Certainly, if there is an effect, it is a very minimal one, and it is possibly a statistical one. And the reason I say this is because there were many people -- some people in our sample with heavy exposure who had had severe chloracne but at the time of our examination no longer had chloracne and had normal liver function tests. It is very important to make that point.

Now, we also found the opposite, almost any combination. We did not find any abnormalities in porphyrinsin the urine. And none of the other tests, the BUN, etc. CBCs, we're looking at those. There may be some minor changes there. Nothing really significant. But basically I have shown you in the biochemical parameters on our first look, and we're going to be looking into this a little more of what we found. And later on -- and if there isn't enough time later on, during the meeting if anybody else -- I'd be happy to answer anybody's questions arterwards.

Do I have time to take any questions if there

are any now?

DR. SHEPARD: I'm afraid not.

We are reserving time -- we have already run out of assigned time, but we will run over a little bit and have some time for questions following Major Young's presentation.

So, we are very happy to have Major Alvin Young from the Air Force who is Mr. Agent Orange.

ENVIRONMENTAL FATE OF TCDD

MAJOR YOUNG: Back 12 years ago, I would have said that was a compliment --

(Laughter.)

MAJOR YOUNG: -- when I first began to work with orange and dioxin. It was a very exciting time to be affiliated with the program. But as the years have gone by, one now doesn't know whether it is good to raise your hand and say, I know all about it, because that sometime doesn't attract the kind of attention you'd like to have it attract.

I would like to explain to you a little bit about the work we've done at Eglin Air Force Base. A very unique situation. As Dr. Reggiani pointed out a few moments ago, 260 grams, approximately, of TCDD were disseminated on the area of about 700 acres in Seveso, but at Eglin we have a one-square mile site, that is 640 acres

LONG-TERM FIELD STUDIES OF A RODENT POPULATION CONTINUOUSLY EXPOSED TO TCDD

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Field investigations were conducted during 1973-1978 on populations of the beach mouse, Peromyscus polionotus, from a unique 3.0 km^2 military test area (Test Area C-52A, Eglin AFB FL) that was sprayed with 73,000 kg 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) herbicide during the period 1962-1970. No residues of 2,4,5-T were detected at 10 parts per billion in any soil sample collected during 1971-1972. Residues of 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) were still present in 1978. During 1974-1978, 54 soil samples were collected to a depth of 15 cm on the test area. TCDD levels ranged from <10 to 1,500 parts per trillion (ppt). The median concentration was 30 ppt while the mean was 164 ppt. Liver tissue from 36 individual beachmice inhabiting the test site contained 300 to 2,900 ppt TCDD. Although a close relationship between soil and liver levels of TCDD was observed, i.e., high liver levels of TCDD were consistent with high soil levels of TCDD, bioconcentration factors (mean liver concentrations divided by mean soil concentrations) ranged from 6 for females to 18 for males. Whole body analysis of fetuses from test area females indicated apparent placental transport of TCDD. Histopathological examinations were performed of 255 adult or fetal beachmice from the test area and a control area. Examinations were performed on the heart, lungs, trachea, salivary glands, thymus, liver, kidneys, stomach, pancreas, adrenals, large and small intestine,

spleen, genital organs, bone, bone marrow, skin and brain. Initially the tissues were examined on a blind study basis. All microscopic changes were recorded including those interpreted as minor or insignificant. The tissues were then re-examined on a control versus test basis, which demonstrated that the test and control mice could not be distinguished histopathologically. The mean number of fetuses per observed pregnancy was 3.1 and 3.4 for the test area and a control area, respectively. A single female beachmouse is capable of producing litters every 26 days. At this frequency, the animals collected in 1978 may have been at least 50 generations removed from the population studies in 1973. A two-factor (treatment and year) disproportional analysis of covariance of organ weights revealed that liver weights for pregnant females were significantly heavier ($P<.01$) between the control and test area beachmice, and these differences were consistent over the five years of observation. These studies suggest that long-term, low level exposure to TCDD under field conditions has had minimal effect upon the health and reproduction of the beachmouse.

Vu-graph I

TEST AREA C-52 A

EGLIN AIR FORCE BASE, FLORIDA

. A TEST RANGE USED IN THE DEVELOPMENT OF DEFOLIATION SPRAY EQUIPMENT FOR SOUTHEAST ASIA

. HERBICIDES SPRAYED ON THE TEST AREA, 1962-1970.

Vu-graph 2

TEST GRIDS AND QUANTITIES OF 2,4,5-T APPLIED TO TEST AREA C-52A, EGLIN AFB FL

GRID	AREA (HA)	YEARS	2,4,5-T (KG)
I	37	1962 - 1964	39,550
II	37	1964 - 1966	15,890
IV	97	1968 - 1970	17,440
		TOTAL	72,880

Vu-graph 3

ECOLOGICAL INVESTIGATIONS, TEST AREA C-52A
1973 - 1978

SOIL RESIDUES: 2,4,5-T, TCDD

- TERRESTRIAL ECOSYSTEMS
  - VEGETATION
  - ANIMALS
    - VERTEBRATE
    - INVERTEBRATE
  - MICROORGANISMS
- AQUATIC ECOSYSTEMS
  - ANIMALS
    - VERTEBRATE
    - INVERTEBRATE
  - MICROFLORA

Vu-graph 4

ECOLOGICAL SURVEY, 1973 - 1978
TEST AREA C-52A

NUMBER OF SPECIES	ORGANISMS
123	PLANTS
77	BIRDS
71	INSECT FAMILIES
20	FISH
18	REPTILES
18	MAMMALS
12	AMPHIBIANS
2	MOLLUSCS

170 BIOLOGICAL SAMPLES ANALYZED FOR TCDD

Vu-graph 5

CONCENTRATION OF TCDD (PPT) IN TEST GRID SOILS

GRID	NO. SAMPLES*	RANGE	MEDIAN	MEAN
I	22	< 10 - 1,500	110	326
II	6	< 10 - 470	30	117
IV	26	< 10 - 150	19	27

*0 - 15 CM INCREMENT

Vu-graph 6

DISAPPEARANCE OF TCDD FROM SOILS OF GRID I (PARTS PER TRILLION)

PLOT* NUMBER	AUGUST 1974	JANUARY 1978
1	1,500	420
2	610	300
3	1,200	580
4	270	100
5	440	400
MEAN	804	360

*FIVE SUBSAMPLES FROM EACH 1-M^2 PLOT COMPOSITED (0-10 CM DEPTH)

Vu-graph 7

INVESTIGATIONS OF BIRD SPECIES
Test Area C-52A

77 Species Observed

DOMINANT SPECIES	TCDD RESIDUE ANALYSIS (PPT)			
	No. Samples*	Organ	Range	Mean
Southern Meadowlark	3	Liver	100 - 1,020	440
	1	Stomach		10
Mourning Dove	2	Liver		50
	1	Stomach		10
Savannah Sparrow	1	Liver		69
	1	Stomach		84

*Composites from at least 6 birds

Vu-graph 8

INVESTIGATIONS OF INSECTS
Test Area C-52A

71 Families Observed

FAMILY	TCDD Residue Analysis (ppt)
Grasshoppers	ND (3)*
Crickets	26
Composite of Soil/Plant Insects	40

*Detection Limit

Vu-graph 9

INVESTIGATIONS OF MAMMALS, TEST AREA C-52A

SPECIES	TCDD RESIDUE ANALYSIS (PPT)		
	ORGAN	CONCENTRATION	DETECTION LIMIT
DEER	FAT	ND	4
	LIVER	ND	5
	KIDNEY	ND	4
OPOSSUM	FAT	ND	10
	LIVER	ND	10
RABBIT	LIVER	ND	8
	PELT	ND	2
COTTON RAT	LIVER	10 - 210	
BEACHMOUSE	LIVER	300 - 1,500	
	PELT	130 - 140	

Vu-graph 10

STUDIES OF THE BEACHMOUSE, PEROMYSCUS POLIONOTUS
Grid 1, Test Area C-52A, Eglin AFB FL

LOCATION / Maturity, Sex	YEAR 1973	1974	1975	1978	Total
CONTROL AREA					
Mature					
Male	4	11	3	2	20
Female	3(3)	8(3)	3(1)	2(2)	16(9)
Immature					
Male	1	1	0	0	2
Female	0	2	0	0	2
Fetuses	12	11	3	5	31
				Total	71

( ) Number of Pregnant Females
Fetuses/Pregnancy = 3.4

Vu-graph 11

STUDIES OF THE BEACHMOUSE, PEROMYSCUS POLIONOTUS
Grid 1, Test Area C-52A, Eglin AFB FL

LOCATION	YEAR				
Maturity, Sex	1973	1974	1975	1978	Total
TEST GRID 1					
Mature					
Male	18	14	7	7	46
Female	15(6)	9(6)	6(4)	6(6)	36(22)
Immature					
Male	8	3	7	6	24
Female	1	4	3	3	11
Fetuses	25	9	12	21	67
				Total	184

( ) Number of Pregnant Females
Fetuses/Pregnancy = 3.1

Vu-graph 12

MEAN LIVER WEIGHTS (MG) OF PREGNANT BEACHMICE
TEST AREA C-52A

LOCATION	YEAR	LIVER WEIGHT (MG)
Control	1973	929
	1974	765
	1975	934
	1978	919
Grid 1	1973	1, 247
	1974	1, 019
	1975	1, 109
	1978	1, 101

STATISTICALLY SIGNIFICANT!

Vu-graph 13

HISTOLOGICAL PARAMETERS

HEART
LUNGS
TRACHEA
SALIVARY GLANDS
THYMUS
LIVER
KIDNEYS
STOMACH
PANCREAS
ADRENALS
LARGE/SMALL INTESTINE
SPLEEN
GENITAL ORGANS
BONE
BONE MARROW
SKIN
BRAIN

ALL MICROSCOPIC CHANGES RECORDED. TEST AND CONTROL MICE COULD NOT BE DISTINGUISHED.

for you, that received almost 3,000 grams of TCDD. In the course of developing the spray equipment for Vietnam, we disseminated the actual herbicide on the test site. We were not evaluating the herbicide, we were evaluating the spray equipment. It didn't all come down at one time; it was distributed over time. And that is the important point to remember. Had it been 3,000 grams at one time, I'm certain we would have had people say something about health effects.

But because it was stretched out over a period of eight years, and I was one of the participants in those programs, then I think we've seen a different picture.

Let me get right into the slides very quickly. I am only going to cover some of the key points. The actual data we have span 10 years and it is voluminous. I can talk about birds; I can talk about fish; I can talk about deer, opposum, you name it; we can talk about it. Microorganisms, soil, but I am going to focus it on just a couple key areas.

Eglin is located in the northwest corner of Florida. On test area C-52A, as I mentioned, the herbicide was disseminated by aerial means into an area of approximately one square mile, 162,000 pounds of 2,4,5-T were disseminated in the time period from 1962 to 1970.

The uniqueness,however, of the dissemination is

what is important in that we had some sites that received the 2,4,5-T herbicide /in the '62 to '64 time period --other sites in '64 to '66,and yet a different site in '68 to '70, therefore, they are separate / sites -- they don't overlap. They are separate entities and because of the complexity of our monitoring system, we have excellent records on how much herbicide was placed upon each site.

What we lack, however, is the actual dioxin content of the material. We have some archive samples. We have analyzed those archive samples. The archive samples for orange indicate a mean concentration of 1.91 ppm. The archive sample for purple, the early material applied on grid one. sample of purple was 45 ppm. That is a tremendously high concentration of dioxin relative to orange.

Even more important there, we find that that site is the site that was first treated. So, from a time period you are going to see some very interesting data.

What we have looked at are the following components, and we have a number of publications out, and some currently coming out.

Here is the one square mile fully-instrumented test site. In the center of that test site for those who may or may not be able to see it, there is in fact

a square concrete pad where a 300 foot tower is located. To your right is grid one. Up to your left, the bare area is part of grid three.

Here is grid one. We're going to focus primarily on grid one, the site that received all that Herbicide Purple.

In 1970, at the termination of all test programs, grid one was still bare and I will show you a picture in a moment to show you what it looked like in 1964 at the termination of that program, of the actual dissemination.

One of the beauties about this one square / mile instrumented grid is that there is water occurring on these areas and, hence, one can also establish data on the movement of dioxin within an aquatic ecosystem, not only terrestrial, you see, on land, but also in water.

Again, this is a picture of grid one, the south end in 1970 and the bayhead , this is where water will begin for a small stream. The bayhead starts right off of grid one and then becomes a stream that goes for 2 1/2 miles and empties into Chectawhatchee Bay, an area where there are shrimp and oysters. One might say, well, that would be interesting to follow that from start to finish; and, indeed, we have -- a very thorough study.

These are the organisms we havelooked at. Not

all of them have been analyzed for TCDD. There are certain ones that are obvious for analysis for TCDD. There are others that would not be. But we have analyzed over 250 biological samples for TCDD and you might think that is not much, but I can assure you that with the state-of-the-art, pressed at its very limit, a single part per trillion we are pushing the state-of-the-art and we have pushed three laboratories almost to their full capacity to produce these data over a period of about five years.

The next slide, please?

This is 1964, a photograph taken in 1964 of grid one.

The next slide is a picture of the same site taken from the same point in 1967.

Next slide -- oh, I'm sorry, this is much too dark, but it was taken in 1978 and I can tell you that there are trees out there today. We have seen a very extensive ecological recovery, a succession of vegetation come in, establish itself to the point where in a few years if we want to be able to move freely over this area, we are going to have to spray it with herbicide.

The soil at the test site Eglin is a very sandy soil. One might expect to see rapid penetration of herbicide. Our studies, spanning many years, have shown that indeed the phenoxy herbicides moved down into that soil profile,

but most of the phenoxy herbicides, 2,4-D and 2,4,5-T disappeared very quickly.

As a matter of fact, the microbial degradation was so rapid out there in some of the years, for example 1969 and 1970, when we were studying it, an application of orange would only persist anywhere from three to eight days. It would be degraded that fast. So, you would have microorganisms tuned to degradating this material.

The next slide.

These are the dioxin levels, and they represent samples collected from in 1974 to 1978 for the various grids. Grid one, the grid that received the purple and hence the highest concentration of TCDD, the mean concentration was 326 parts per trillion in that site that received the herbicide so many years ago. So, much, much higher in TCDD content. That certainly confirms the fact that it was much more contaminated material than that which was applied to grid three, an area that received a tremendous amount of herbicide, Herbicide Orange. Note that very little persistence was indicated simply because there was not much dioxin.

The next slide.

These are some data from grid one, and it addresses time. What these data show you is that on grid one, one would expect from these data -- and there are

and there are not enough data points here to make a good conclusion -- but we would say the half life was 3.4 years for TCDD in the soil. But what is wrong with that? What is wrong with it is when you go back and figure out how much TCDD was probably placed on grid one, you find that the mean concentration, the top six inches, would have been 49,000 ppt versus today what is there (326 ppt). So, greater than 99.9 percent of all the dioxin is gone, as best we can figure. So, although we still see persistence, persistence is related in this case to the massive amount of TCDD that was there.

Sure it breaks down or it disappears, but when you have such a tremendous quantity, one has to put this in perspective.

Now, let us go back and talk for just a minute of how this compares to what happened in Vietnam. The Eglin test site received 1,900 times more herbicide than would have intercepted the ground in Vietnam. 1,900 times more. That puts it in perspective for you. And had we then the capability of looking at the very low parts per trillion, we would have never been able to see in Vietnam some of the data that you are going to see today from the Eglin test site. We would not have been able to collect it.

Our first analyses in '72 and '73 came back negative; there was no TCDD there because we didn't have the detection

limit required. But in '73 and '74, when we began to develop the detection limit, we began to find it. It didn't just all of a sudden appear; it was simply a matter of developing the instrumentation to find it, the state-of-the-art.

Next slide, please.

Okay. The beach mouse, Peromyscus polionotus, it is a small animal only about 13 grams, but that animal predominates on grid one. And because the laboratory studies of mice have been so significant; for example, the mouse is the most sensitive animal for teratogenesis in the case of dioxin. The most sensitive indicator, cleft palate, is the characteristic to look for. So, we focused on a population of animals that were indeed highly contaminated.

The next slide, please.

I am going to ignore now the rest of the studies and focus on the beach mouse because those are where our best and most thorough data exist. We have followed almost 50 generations of beach mice since 1974 and we're still doing work in this area.

Okay, the little beach mouse, a lovely animal to study.

Next slide.

We have had the opportunity, because of the sandy soil -- this is a beautiful part to study the habitat. Now, most people

do field work by using traps, not at Eglin. The shovel is the tool, because it is a very sandy soil and we can dig out the nest, the female, the male and the offspring. It is fantastic. We have whole families of mice available to study. We have the capability also of looking at individual livers, both in the female and the male, and I am going to show you some data now that shows you the significance of this.

The next slide.

Look at these data. For those of you that have never seen these kind of data, these are really unique data because we have a single female that we have analyzed from a burrow that we have also examined and the nest and the soil levels of TCDD. We know what her liver level is because that is the site of the accumulation for most dioxin in the beach mouse. There is no fat in beach mice. They are always on the edge of survival. Always looking for food. They don't have time to put fat on.

And you always find that females are almost always pregnant.

(Laughter.)

MAJOR YOUNG: Another survival characteristic of the beach mouse. The pregnancy period is 28 days, therefore one can follow many generations very quickly.

The hide, this is the fur or the pelage is contaminated, and this route, of perhaps

contamination. We'll talk about it in a moment.

There are beach mouse the pups. These are young mice that still cannot get out of the nest, but we took those pups; and looked at liver level of TCDD and the hide level. She was pregnant with four fetuses. We were able to then aseptically remove those from the female and analyze them for dioxin. What you see is that they are contaminated also, suggesting placental transport for TCDD. Very interesting!

We were able to look at the burrow two, which was right next to this and found the same sort of situation. We combined the two males from those two holes. Males always accumulate more TCDD than the female. There is a concentration factor of 8 for the females no matter where you're at on the test site, and there is a concentration factor of 18 for the males. And it is so consistent. In the laboratory it is about 25, you see, for the males. So, our field data and the laboratory data are very consistent.

Next slide.

Now, in this case we are going to a site that is much more contaminated and because the soil is much more contaminated, one sees higher levels in the female and higher levels in the male. And, again, the female in this case was pregnant and the whole body analysis of the pups was 150 ppt,

which reflects the increased amount of dioxin in the environment.

The next slide.

How long does it take a beach mouse to be contaminated? That is a very important question. If you were to go into the site, how long must you be affiliated with that soil before you pick it up?

In the case of the beach mouse, the half life of the beach mouse is about 90 days because of very heavy predation, but that is enough time for a beach mouse to become contaminated, as we will show you.

We took beach mice from a control site; raised many of them in the laboratory; released some 300 in the field in this one particular experiment and then recaptured them at various times. And what we found was about 90 days was required for contamination.

The next slide.

These are the important data. Over the years from '73 to '78, we have had four intensive years of sampling control and test populations of the beach mouse. An important point is that if you sample too hard on year number one, 1973, you will eliminate your population for future years, you see, because you wipe out your population. You must always be careful about not taking too many

beach mice or you will eliminate your population, and that is why the numbers are fairly low.

Let's take a look at the next -- by the way, the parentheses refer to the number of pregnant females, the number of fetuses per pregnancy is 3.4 for our controls.

Next slide.

It is 3.1 for our animals from the test site. In this case we have 184 animals we've looked at. You can see the number of fetuses, 67 versus the number we had for the control. That number is not different. 3.4 is not different from 3.1.

The next slide.

Now, we have taken all of these animals, fetuses, immatures, matures. We've submitted them in a blind system to the Armed Forces Institute of Pathology. We only told them that they were beach mice.

They, then, did a complete work-up on 18 different systems. We're talking about the brain, the genital systems, liver, and so on. A very, very thorough work-up. They did it first on a blind basis and then we went back and told them which ones came from the test site and which ones came from the control. They, then, reexamined on that basis. Histologically we saw no differences between exposed and control population.

Next slide.

One of our scientists then pursued the liver though ultra-structural studies. Now, we are looking at the endoplasmic reticulin, smooth and rough because if we do not see it at the histological level, the cell level, perhaps subcellularly we can see a difference. And he found no differences.

But we did see a toxicity symptom.

The next slide.

One potential toxicity symptom we found was an increased weight of the liver and, specifically, in the female because almost all females were pregnant, the difference occurred in this a pregnant beach mouse. If the animal was not pregnant, one found that the female was immature and was not capable of conception.

The males did not show the same increase in liver weight.

But look at this characteristic over time, all four years, spanning a five year period, showed the same exact trend. Highly significant.

So, what I am saying is: we have seen in a study these of animals over a 50- generation period, no anamolies in terms of histology or reproduction. We have seen a potential toxicity symptom which was an liver increase in weight.

That is it in a nutshell, Doctor, that's very

quick.

DR. SHEPARD: Thank you very much.

I have just been informed that we don't have to evacuate the room at 1:00 o'clock as I originally though.

I would like to make, first of all, a couple of announcements and then open up the floor to questions.

When we last met, I think I reported to you that I had recently been privileged to attend a meeting in Rome on the impact of dioxins on the environment. This meeting has been alluded to by Dr. Reggiani, who played a prominent role at that meeting. Dr. Moses was there, chaired one of the sessions.

Because of the high level of interest in that meeting and the excellence of the subject material and the way it was presented, a number of us have been interested in the possibility of having a follow-on meeting this year, this calendar year somewhere in the States. This will allow for greater U.S. participation. Plans are currently moving forward to have such a meeting here in Washington the last week in October. We are working with a number of organizations and we will keep you informed on the progress of that meeting.

Another activity to which I did not allude, and should have, of great interest to the VA is the fact

that a number of states are conducting activities and have organized commissions on Agent Orange. I have been privileged to be in touch with some of these states. I was first asked to testify before the Minnesota State Senate Veterans Affairs Committee. I was subsequently asked to attend a meeting in New York State. The Agent Orange Commission of New York State is well underway. in its plans for a mortality study headed up by Dr. Peter Greenwald, the Director of Epidemiology for the State Department of Health in New York.

I was more recently privileged to attend the meeting of the New Jersey State Dioxin Commission -- excuse me, Agent Orange Commission, and I note, with pleasure, that some members of that Commission are with us today.

I certainly encourage the states to undertake appropriate areas of research. The one plea that I make is that they not start epidemiological studies which would conflict with studies that have already been mandated by Congress to the VA, not that I think we're any better able to conduct these studies, but it is possible that we will be studying some of the same population groups and that might pose a problem.

There are a number of areas of research which would appropriately be addressed by the states,

as New York is already doing. I would encourage state representatives to look upon those as examples of very fruitful work that can be productive.

I would now like to open the meeting to questions from the floor.

COMMENTS AND DISCUSSION

DR. SHEPARD: I have one question from Todd Ensign of Citizen Soldier, this question is directed to Dr. Reggiani.

If there is no evidence of significant difference in long-term health effects between Seveso residence and nonresidence, for what reason did Hoffman-LaRoche recently agree to pay $109 million as settlement of all claims arising from the 1976 accident?

Do you have that --

I don't like to put Dr. Reggiani on the spot, so -- if he has that information and wants to share it with us, we would be delighted to have it.

DR. REGGIANI: May I have, again, the question. just to be sure that I don't say anything stupid?

DR. SHEPARD: If there is no evidence of significant difference in long-term health effects between Seveso residence and nonresidence, for what reason did Hoffman-LaRoche recently agree to pay $109 million as settlement of all claims arising from the 1976 accident?

DR. REGGIANI: I do not exactly understand the question. The fact that no health effects, meaning by that, toxic effects have occurred does not mean that the population there did not suffer.

I am, perhaps, the one who is responsible for that effect. When the accident occurred and we started analyzing the vegetation--during the first two weeks -- around the factory, or let's say a certain part of the territory there were that large amount of TCDD. It was possible to make a map to locate geographically exactly the position and the concentration of the contamination of the territory contaminated.

I went to Italy. I requested the Italian authorities to evacuate the population from that part of the territory. Now, that is in itself was an adverse effect. If I would come over to your house and I would ask you to just leave the house, leaving behind all your belongings taking along with you your kids, your wife and then leave your job, your surroundings, your neighbors, friends, and go away to a small room in a hotel and stay there, and then you would ask me why and I would have difficulty in explaining to you why. Of course, at that moment, I said, but you know, TCDD. You never heard about that, but it is the most toxic man made substance which we know of.

Therefore, we have a lot of toxicity around here and you are in risk, and you have to get away.

And so the question is: whether you would pay for that? Of course, we would pay that.

The next question would be: how long? I would say, I don't know. Perhaps forever. Perhaps you have lost your house forever. Isn't that something that we have to pay for?

Concerning the question of health effects, we are happy that there have not been any. But an accident occurred there; and we were responsible for that. It occurred in our plant and I think that is just what we had to do.

DR. SHEPARD: I think probably, if I may interpret the question, what may have been in back of the question. Was there anything that was being compensated for in terms of health --

DR. REGGIANI: No.

DR. SHEPARD: -- resulting from this explosion?

DR. REGGIANI: No, not at all.

The question of health effects will come up at the moment when we will have the trials in court and that will be probably next year in the spring or autumn. The judge who is holding the investigation of that case has received claims from 17 people, mainly children with

chloracne. And that's all for the time being. No claims with respect to any other effects. No claims in respect of neurologic effects, liver. No claims for birth defects or abortions. No claims for any other parameters which have been examined, There are only 17 cases, three of them are adults, the other are children and they have chloracne.

We know the complete history of all of those and they will have to be compensated. Well, in fact, we will make the compensations already before the trials because in that case, too, it is our responsibility.

Now, perhaps if you don't mind, Dr. Shepard, about this $109 million, I mean, a part of that has been paid to the Italian state because they have a lot of expenses. They had to mobilize the Army; they had to do a lot of things and a part of that has been paid to the authorities of the Lombardy region for a lot of work that they have done.

A part of that money has been paid directly to the people living in the surrounding area -- in these 11 communities because, for instance, all the agriculture activities had been stopped. There are just several square miles there where only now the normal activity, the growing of crops, vegetables in the garden, and so on, is just starting again, but it had been stopped all these

years. All the vegetables, all the crops have been collected and analyzed, and then were set aside, but have not been sold. And then there were a lot of small industries in these 11 communities which have a loss in their profit and we had to compensate for that.

But that's just to give you some idea of what these $109 million represent and why they have been paid.

DR. SHEPARD: Thank you very much, Dr. Reggiani.

A couple of other questions from Todd Ensign. One addresses the videotape. Is it essentially the same as the one shown last December?

It is essentially the same.

Number two, many of us were shocked to learn of secret tests performed on prisoners performed by Dr. Albert Kligman under contract by Dow in 1964 to '67. What steps has this Committee taken to obtain details from all such studies, including any which may still be undisclosed?

I think Dr. Hobson may be able to answer that. He has looked into the matter to some extent.

Larry, could you enlighten us on that subject?

DR. HOBSON: The results of those tests reached the public knowledge because of the testimony at the EPA hearings and were reported by one of the men from Dow, who did not himself conduct the study. I understand that

a more complete description of the tests and the results is available and we hope to have it fairly soon.

The question of obtaining results of other previously unknown studies is a little difficult for us to tackle. We have no police rights to insist that people report to us data they have not previously seen fit to report. And you can be sure that whenever we hear of any such thing, we will go after it.

I might say that these were not secret tests conducted as best as I can determine, and from what I know of the situation at that time. They were tests conducted on prisoners, to be sure, and they were done for a private company. They were not put into the public literature, but it was known to the prisom authorities that they were being conducted. I would hardly call them secret tests. I think that is a little overstatement of the state of affairs.

DR. SHEPARD: Thank you, Larry.

DR. KOLBYE: They were skin painting studies, too, weren't they?

DR. HOBSON: Yes.

DR. KOLBYE: Right.

DR. SHEPARD: If anybody else from the Committee has knowledge of this, please feel free to speak up.

DR. HOBSON: Incidentally, there was some distortion of this in some of the newspaper reports. It sounded as though he had injected or fed this material to the prisoners. He did not. He applied it to a small area of skin on the body, not internally.

DR. SHEPARD: Are there any other questions from the floor?

(No response.)

DR. SHEPARD: I apologize to Dr. Moses for having cut her off so quickly. We can now open up the questions to her.

Yes?

DR. KOLBYE: Dr. Moses, was there any problem when viewing the data concerning prior exposure of present chloracne with confounding exposures to other chemicals that induce chloracne?

DR. MOSES: No. We didn't really find that to be a problem.

It was something that we were quite concerned about. It turned out not to be a problem because most of the workers at this particular plant started working there after high school or when they came back from the service and generally stayed there. We did take lifetime occupational histories on all of the people. Except for that one case that I showed you

who possibly may have had some PCB exposure, we were able to clearly establish that it was related to their work at Monsanto.

DR. KOLBYE: Just to follow that through. There were no other chemicals other than the 2,4,5-T made during that plant or in that time frame?

DR. MOSES: Now, there was --

DR. SHEPARD: Let me just say, the microphones without the lights are not for purposes of PA, they feed into the reporter's apparatus, so the PA ones are hooked up with the lights.

DR. SUSKIND: Dr. Kolbye, I think you were here at the last Committee meeting. I wasn't here., but Dr. Gaffey presented a recently completed study, which was publicized, about 884 workers in that plant working from 1955 on, who were on the record as having been employed from 1955 on. One of the confounding problems -- there are many confounding problems because this is a plant which manufactures, as Dr. Moses so well pointed out, rubber additives since 1929, and there were many chemical agents, but in the '50s, the thing that arose, an outbreak of bladder cancer due to paraaminobiphenol -- some of the 2,4,5-T exposed people were also exposed to paraaminobiphenol. Some of the people who were even actively employed at the time Dr. Moses did her

study were on monitoring -- biological monitoring for bladder cancer and had cystoscopies yearly, about every six months.

But there were other chemicals as well. Some of them/with known toxicity, so that there are confounding --

DR. MOSES: Yes, but if I could --

DR. SUSKIND: -- but not with respect to chloracne.

DR. MOSES: -- with respect to chloracne, which I think is what the question was.

I would like to make it very clear that possibly the others, and if someone wants to discuss the bladder cancer, that's an important thing to discuss, but in terms of chloracne I think it is very clear from the company and from the worker and from what we know has been made at that plant, that the chloracne in this group was clearly related to trichlorophenol manufacture. I don't think there is any -- I don't think Dr. Suskind would question that, if that's the question.

DR. SUSKIND: Thank you.

DR. SHEPARD: Are there any other questions for Dr. Moses?

Dr. Gross?

DR. GROSS: I have a question for Major Young. In view of the distinction that Dr. Moses seems to draw

between an effect and an injury, would you consider a statistically significant increase in liver weight of a beach mouse, what effect and injury, or both?

MAJOR YOUNG: Dr. Reggiani said a compensation.

(Laughter.)

MAJOR YOUNG: Well, certainly it may be a sign of toxicity. As to whether the liver is injured we see no pathological anamolies in the liver, but it cannot be ruled out as a sign of toxicity.

Interestingly enough, all the digging of those Eglin soils was done those were done by one research team for all those years. You talk about digging fox holes, it was absolutely something to see a team go after a beach mouse. They live 18 inches down in the soil and you dig up about 12 feet of tunnel to get to that beach mouse.

So, a few years ago, in 1979, two of the members of our beach mice digging team volunteered for a fat biopsy and participated in the VA biopsy study. Their fat levels were found to be negative for TCDD. I thought it was very interesting, but it is only two people; but it was two people though who spent a lot of time digging in the soil. The one individual had 6,000 hours of documented work on the test range; the other about 1,500 hours of documented work, for what it is

worth.

DR. SHEPARD: Any other questions?

Dr. Murphy?

DR. MURPHY: Dr. Young's comment about fat biopsies reminded me of -- do we have any more information regarding biopsy results -- results of biopsy analysis in the --

DR. SHEPARD: Larry, do you want to address that? Larry has been working very closely with this issue.

DR. HOBSON: This touches a very sore nerve with me.

The study that we undertook was really done as a feasibility study to see whether we could get useful and feasible results by biopsy using a specific technique, namely that of Dr. Michael Gross. Dr. Michael Gross has not yet completed a manuscript to publish his methodology. Since ours is a feasibility study specifically related to that methodology, we can't very well publish prior to the appearance of his technique.

He tells me that he is now in the last revision of that paper and as soon as he gets the paper to me, we will be prepared to publish our results simultaneously.

I do want to correct something that Major Young said, and I suspect this is because he hasn't had the full disclosure of this, so I will take the full responsi-

bility for that. Of the three Air Force personnel, one of whom was Major Young; the other two he mentioned. There was one individual who had a negative result. The other two had a very low content, much as we found variations in content to people who had never been, as far as we know, in any contact with Agent Orange or presumably TCDD, we can say that.

DR. SHEPARD: Yes, Dr. Suskind?

DR. SUSKIND: I wonder if I could follow-up on a comment made by Dr. Hobson on apparently never exposed to TCDD. I think all of you know that 2,4,5-T was used in millions of gardens throughout the country from 1968 until 1970, and I am sure that those of you who are gardeners still have cans of herbicides in your garden room which may have TCDD in it, as well as 2,4,5-T. So that there is -- it would be very difficult to find people who grew up in the period of 1948 to 1969 and who were adults during that period who were not exposed -- through 1948 to 1970 who were not exposed to TCDD.

So that getting controls for anything that you do with 2,4,5-T is a very difficult thing. You'll have to wait a long time to get nonexposed people.

DR. SHEPARD: I think what Dr. Hobson may have meant was that people exposed or not exposed to Agent Orange rather than TCDD per se.

DR. SUSKIND: Well, I just want to point out that the formulae that was used in every man's garden, every person's garden contained largely 50 percent 2,4,5-T and 50 percent 2,4-D / It was very similar to Agent Orange.

DR. SHEPARD: But probably in a more diluted form, don't you think?

DR. SUSKIND: Yes, indeed it was.

DR. SHEPARD: Yes, sir.

Mr. Collins?

MR. COLLINS: If I may, Dr. Suskind, my name is Harold Collins. I'd like to point out the terminology here. I've worked with 2,4-D and 2,4,5-T since 1959. 2,4,5-T is not normally a garden chemical. It has been used on turf around the home and was used so for a long time providing for exposure to a large segment of the human population, but it is not a chemical normally associated with garden-type food production.

DR. SUSKIND: I am talking actually about the esters of 2,4,5-T, not the free acid, and, not now, but if you would like the trade names of garden weed killers with contain esters of 2,4,5-T, I would be happy to supply them to you.

MR. COLLINS: That's fine.

DR. SHEPARD: Any other questions or comments from the Committee, floor?

Yes, sir?

DR. MURPHY: Dr. Young, what is the sensitivity of the beach mouse to the acute toxicity of TCDD?

MAJOR YOUNG: What's the LD-50 of the beach mouse?

DR. MURPHY: Right.

MAJOR YOUNG: It is unfortunate, I can't give you that answer.

DR. MOSES: Why not?

MAJOR YOUNG: Dr. Moses is asking why not. We were not in position to do those studies in-house. We have had a number of organizations actually offer to do that. We have not pursued it, but we do have the beach mice to do that. It takes quite a few. And that is one of main reasons that we haven't wanted to deplete our control site. We haven't found very many sites where you can get beach mice that are not contaminated with other chemicals.

You see, the Florida area has a dog fly problem and years ago DDT was sprayed massively to control the dog fly. The Eglin test site -- test area C-52A was a closed range. It never received any other material to any degree. So, as you do a background analysis, as Dr. Gross of the University of Nebraska did for us, we submitted those animals to him, our control populations and

our test populations and he came back and said, those are the cleanest animals I have ever seen for chlorinated hydrocarbons with the exception of dioxin in the test animals.

We got animals from the beach and submitted those and they were loaded with DDT. They were loaded with PCB and so one of our concerns has been, we do an LD-50, let us take animals that are not contaminated with these others and challenge them. But we haven't been able to build up a significant population.

We did, by the way, in of our laboratory studies have a quite large number of animals. Then we found out that the bedding they were using was contaminated with PCB and those animals all had to be destroyed and not brought into our test group.

It is a very frustrating issue in that regard. Likewise, I would like to see the liver studies done because I think that increase in weight may reflect enzymatic changes.

DR. MOSES: You mean the semi-induction? Induction, I mean?

DR. MURPHY: Your electronmicroscopy didn't show that, did it?

MAJOR YOUNG: They didn't show any abnormalities. But that still doesn't say that there's a very low level

of biochemical change there might in fact be biochemical changes, and not reflected by the smooth endoplasmic reticulin.

DR. SHEPARD: Any other questions or comments?

(No response.)

DR. SHEPARD: In keeping with our regularly quarterly schedule, I would anticipate that our next quarterly meeting of this Committee would be the first week of May, but we will get that word out to all of you well in advance of that time.

If any of the members of the Committee have suggestions for appropriate agenda topics, agenda items for our next meeting, please get in touch with me; we need your input, or anybody else for that matter.

Thank you very much.

(Whereupon, at 12:40 p.m., the Advisory Committe on Health-Realted Effects of Herbicides, was adjourned.)

REPORTER'S CERTIFICATE

I hereby certify that the foregoing is a true and accurate transcription of the proceedings of the meeting of the Advisory Committee on Health-Realted Effects of Herbicides, held at the Veterans Administration Central Office, Washington, D.C., on Wednesday, February 4, 1981.

Loretta F. Rodd

I hereby certify that the proceedings and evidence herein are contained fully and accurately, as corrected.

BARCLAY M. SHEPARD, M.D.
Chairman
VA Advisory Committee on
Health-Related Effects of Herbicides

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Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

**(Eighth Meeting
May 5, 1981)**

July 1981 Washington DC 20420

WJM/cb

VETERANS ADMINISTRATION

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ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES

- - -

Veterans Administration
Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Tuesday,
May 5, 1981

The Committee met, pursuant to notice, at 8:30 a.m., BARCLAY M. SHEPARD, M.D., Chairman, presiding.

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I N D E X

P R O C E E D I N G S

[8:42 a.m.]

CALL TO ORDER AND OPENING REMARKS

Dr. SHEPARD: Good morning, Ladies and Gentlemen. I believe we are ready to begin our program.

We would like to welcome you to our quarterly meeting of the VA Advisory Committee on the Health-Related Effects of Herbicides.

This morning, we would especially like to welcome Mr. Fred Mullen who is a newcomer to the committee. Those of you who were with us at our last meeting remember Mr. Mullen as having addressed the issue of arsenicals and cacodylic acid, and the concerns that some individuals have expressed in this regard.

Mr. Mullen is here as a representative of one of the well-known national service organizations, the Veterans of Foreign Wars.

We also regretfully announce the resignation of Mr. Ron De Young who has served as a very active member of this group. Because of the press of other duties, he felt obliged to resign from the committee. His replacement has not yet been named, but the matter is under consideration.

It has been just over a year since I was tasked to head up the Agent Orange activities of the Veterans

Administration and, as part of that, to chair this committee. I must say that it has been a source of considerable gratification to me to observe the hard work and efforts of the members of the committee.

I wish to express my personal appreciation for your continued interest and very valuable contributions. I think that this committee has established an enviable record in its pursuit of many aspects to a difficult problem.

I know that I speak for Dr. Custis, the Chief Medical Director, and certainly for Mr. Cleland, the past Administrator. I am sure that when he is confirmed, the new Administrator will be most interested in getting an update of the activities of this committee.

I had hoped that would have already taken place. I was hoping to make one of the highlights of this meeting an introduction of our new Administrator. He was nominated last week and has not yet been confirmed. We hope it won't be long now.

We have a full agenda this morning. We have a few people who are here as alternates: I would like to recognize Dr. Thomas FitzGerald, who is no stranger to many of you, I'm sure. He served many distinguished years in the Veterans Administration and now works at the American Legion.

Good morning, Dr. FitzGerald.

DR. FITZGERALD: Good morning.

Dr. SHEPARD: Dr. Henry Spencer is here, representing Dr. Adrian Gross, for the Environmental Protection Agency.

Dr. Albert Kolbye, who is a relatively new member of the committee from the Food and Drug Administration could not be with us this morning; but Dr. Samuel Shibko will represent him in our deliberations.

First of all, I would like to be sure that all of you have signed in, so that we can keep a record of attendance. If you have not done so, will you please do so at the break.

I hope there is still some coffee available. Feel free to help yourselves.

I would like, first of all, to call upon Dr. Matthew Kinnard who works in our Medical Research Service and has been tracking the Epidemiological Study efforts over the past year and a half.

He has some very exciting news to share with us, and without stealing his thunder I will turn it over to Matt.

EPIDEMIOLOGICAL STUDY

DR. KINNARD: Thank you Dr. Shepard.

First, I would like to express, on behalf of Dr.

Larry Hobson, his regrets that he could not be here on what I think is one of the more important advisory committee meetings since they began because of what has transpired since the previous one.

Dr. Hobson is the senior VA representative on the Interagency Research Radiation Committee, which is convening right now at the National Institutes of Health.

I am pleased to announce that at long last an award has been made--

--to the University of California at Los Angeles School of Public Health for the design study for the epidemiology investigation of Agent Orange. The award was signed Friday, May 1.

The amount of this award is approximately $114,300. The principal investigator of this design study is Dr. Gary Spivey, who will be ably assisted by Dr. Roger Detels, and Dr. Jess Kraus, and a number of other lesser-involved individuals on the design study.

I think it would be in order to give a brief resume of the background and expertise of the three principals on this contract.

Dr. Spivey is an Associate Professor in the School of Public Health at UCLA. He obtained his Bachelors Degree from the University of California at Davis, his MD at the University of California at San Francisco, and his MPh at Johns Hopkins University in Baltimore.

Dr. Spivey holds membership in a number of

prestigious professional associations and has been the recipient of numerous awards and honors. His publication list is very impressive and ranges over a number of areas; however it is concentrated in the area of environmental contamination.

Dr. Spivey's support mainly has been in the form of grants and contracts from EPA, from NIOSH, from NIH--mainly from the National Cancer Institute--and also he has been awarded from the State of California.

Dr. Spivey is the principal investigator of the design study.

Dr. Roger Detels, who initially was listed as co-principal investigator on the project, however, since the time of the initial submission of the proposal has been elevated to the status of Dean of the School of Public Health.

Dr. Detels obtained his Bachelors Degree from Harvard University, his MD from NYU, and a Master of Science Degree in Epidemiology from the University of Washington at Seattle.

Dr. Detels, not unlike Dr. Spivey, has an impressive list of publications and memberships in numerous honorary societies.

His support has mainly been from the National Institutes of Health, specifically from the National Institute of Neurological Communicative Disorders and

Stroke, the National Heart, Lung and Blood Institute, the National Institute of Environmental Health Sciences, the National Cancer Institute, and the National Institute of Child Health and Human Development.

Needless to say, his publication record is monumental.

Finally, Dr. JessKraus holds an Associate Professorship in Epidemiology at UCLA School of Public Health.

He obtained his Bachelors Degree from Sacramento State in California; he also holds a Masters Degree from the same institution; he has a Master of Public Health from Berkeley, and a PhD in Epidemiology from the University of Minnesota.

He has had numerous assignments both in the Midwestern U.S. andin the State of California. His professional affiliations as well as his publication record are impeccable.

He lists a total of 44 publications of which he is at least senior or second author on, and a number of others are in press.

Now, in terms of the Epidemiology Design Study, the agreement calls for a preliminary design to be submitted in approximately 60 days from the time that the award was received.

It is my understanding that the award was signed and mailed on last Friday, so it is assumed that it will be in the hands of the investigators later this week.

Once designed, the study will be sent to Central Office where it will be distributed for review by representatives from four prestigous groups namely: the V.A. Advisory Committee on Health Related Effects of Herbicides.....

..... the Office of Technology Assessment, the National Research Council of the National Academy of Sciences, and the Interagency Work Group on Phenoxy Herbicides.

This is not anticipated to be a highly-polished copy because of the short turn-around time and because it will receive extensive input from these various groups.

I might mention, at this time, that the veterans will have access tothe UCLA group by means of the representatives from the veterans organizations on the Advisory Committee.

At this time I will pause to allow the committee an opportunity to ask some questions. Dr. Shepard, I am sure, would be very happy to assist me in answering any questions that any of you might have regarding the epidemiology contract.

QUESTION & ANSWER SESSION

Dr. SHEPARD: Any questions from members of the committee? Yes, Dr. Suskind?

DR. SUSKIND: The total time for the preparation

of this program is 60 days?

DR. KINNARD: Well, as I said, Dr. Suskind--and Dr. Shepard might wish to comment further that--this design is not intended to be final. For lack of a better term, this is a rather preliminary-type design study that will be circulated for review among the four groups that I previously mentioned for input.

DR. SUSKIND: As a cost-conscious investigator I am just wondering about the total amount of man-hours that are going to be spent on this effort in relation to the $114,00. Can you answer that?

DR. KINNARD: I can answer it somewhat indirectly, and Dr. Shepard may have a further comment.

In addition to Drs. Spivey, Detels and Kraus, thereare named in the protocol six or seven other individuals who will be taking part in the designing of the study.

DR. SUSKIND: And these people are going to spend full time in the preliminary design of an epidemiological program?

DR. KINNARD: Their efforts are not all full time, I am sure. I can't give you details as to what percent of time each one will be spending.

DR. SUSKIND: Would it be possible for this committee or any of us who would wish to see the

application of the UCLA School of Public Health?

Dr. SHEPARD: Yes.

DR. SUSKIND: I would like very much to see that.

Dr. SHEPARD: Maybe I can just clarify or amplify a couple of points.

I have not recently reviewed, in detail, the of participation of each individual member of the team.

Dr. Spivey, as I understand, will be in charge of the project and will be essentially full-time on the project.

Dr. Detels, who is Dean of the School of Public Health of UCLA, obviously cannot spend full-time on the project.

And I think that the others on the team will also be somewhat part-time participants.

The 60 days is allocated for a preliminary design which will then be subjected to a series of peer reviews, as Dr. Kinnard has indicated.

The contractor will still be responsible for following, monitoring and incorporating the comments of those various peer review groups, so that his duties will not be discharged at the end of 60 days.

After the peer review group he will be given an additional 30 days to incorporate and come up with an

essentially finished product.

So I expect that, since we could not accurately predict the length of time that the peer review effort would take, it's kind of open-ended in terms of exactly when the final product will be delivered. We would anticipate having these peer reviews run concurrently, not sequentially, so that would shorten the time for the reviews.

I would hope that we would have something close to a finished product in a period of some six to nine months from now.

Are there other questions?

DR. SUSKIND: The total amount of effort on the part of the contractor would be about 90 days though. Is that right?

Dr. SHEPARD: Well, I would say for intense effort, yes.

There is one additional effort that is mentioned in the contract, and that is: during the conduct of the study, the actual conduct of the study, the designing contractor will be responsible for monitoring that process.

So there will be an ongoing requirement for the contractor to stay abreast, current, and be available for a kind of monitoring of the conduct of the study.

DR. SUSKIND: Who are the physicians in the

development of this study?

DR. KINNARD: I don't have all of the CVs, but Dr. Spivey holds an MD Degree, and he is the principal investigator.

Also Dr. Detels, who was listed as co-principal investigator on the original proposal, has an M.D. degree, as well as some of the other individuals; but I don't have a complete listing of their degrees.

Let me say one other thing. In addition to what Dr. Shepard has said, I don't think it would be advantageous to put an inflexible time limit on the follow-up design study once the four groups have commented.

I think Dr. Shepard would agree with me, that the VA is interested in the best possible design. So in order to incorporate appropriately all of the relevant suggestions, I think the VA would be remiss for not giving the designers an adequate amount of time to do this.

DR. KEARNEY: Dr. Kinnard, do you have a press release or any information on this?

Dr. SHEPARD: Surely.

DR. KEARNEY: Could we get hold of this? Because there has been a lot of interest in this, and if we could get a release on it it would be helpful. A lot of the journals that we work with have been quite interested in this.

DR. KINNARD: No problem.

Dr. SHEPARD: Surely.

Our information service has prepared a press release. I'm not sure it has appeared in print--I don't know, Dr. Kearney. Mr. Strat Appleman will get us a copy of that.

DR. LINGEMAN: I would like to ask if this is only for the study design? And then another contract will be awarded later to actually conduct the study? Is that right?

Dr. SHEPARD: That question is still open. The determination as to who will actually conduct the study has not been made.

There have been a number of suggestions made as to how that should be accomplished, but I think it is accurate to say that we do not have a decision.

When asked that question my standard answer is that we will look to the contractor as well as to members of the peer review groups to provide us with some guidance as to how the study should actually be conducted.

Until we see the design I think it is a little premature to decide who would actually conduct the study.

DR. FITZGERALD: Again, Barclay, in that regard, an admonition: As we have said before, we do not imply that the VA would not do a good job; it could do the best

possible job and still be suspect to the general public. So, if at all possible, we would advocate that somebody other than the VA do this job, at least have an intimate part of it; otherwise your end product will not be credible in the eyes of a good many people.

I do not mean to say that, as I've said before, as an indictment of the VA; but I think it is a reality of life.

Dr. SHEPARD: I agree. My guess is that no one group will be solely in charge of responsibility of the conduct of the whole study.

I suspect, as has been experienced by the Air Force, that even if the VA remains in control of the conduct of the study--and that question hasn't been answered yet--that parts of it would be contracted out. It may be that the whole thing will be turned over to an outside agency.

DR. FITZGERALD: As part of the concern that was expressed by Dr. Suskind concerning this contract, is it not true that you have to have an acceptable product from the contractor before you are accepting it, regardless of the 60 or 90 days?

Dr. SHEPARD: That is my understanding.

Are there any other questions of Dr. Kinnard?

[No response]

Dr. SHEPARD: Thank you very much.

We are fortunate to have with us this morning Dr. James Striegel, who will give us an update on the other effort mandated by Public Law 96151, namely the analysis of the world literature on phenoxy herbicides.

Jim?

LITERATURE ANALYSIS REPORT

DR. STRIEGEL: Good morning. It's a pleasure to be back here again.

As you will recall, JRB Associates has been tasked to identify, acquire, annotate, conduct a critical review and report on the worldwide literature on all of the herbicides used in Vietnam.

We are currently about halfway through this nine month effort; we are on schedule; we have identified about 1400 articles that meet our relevancy criteria, which primarily have to do with exposures similar to the Vietnam-type exposures in otherwise healthy adult human males.

We anticipate that 1400 or 1500 is probably about as many as we are going to find.

We have recently gone through a hand check of our bibliography and have identified about 250 of those articles which are now being deleted upon review of the hard copy itself as not precisely relevant to our criteria. And there were some duplicates and other material in it; so

that has been cleaned out.

We have about 900 articles inhouse; we have about 250 currently on order, and over 300 have already been annotated.

The critical review of the material will begin very shortly. As we get various stacks of paper on mutagenicity or teratogenicity together, the critical review of the scientific merit will begin.

For the record the herbicides of interest that we are working on include Agent Orange and Orange 2, both of which were 2,4-D and 2,4,5-T; Herbicide Purple, which was 2,4-D and 2,4,5-T; Herbicide Pink, which was only 2,4,5-T; Herbicide Green, 2,4,5-T; Herbicide White, which was a combination of picloram and 2,4-D; Herbicide Blue, which is cacodylic acid, an arsenical; dinoxol, which was a combination of 2,4-D and 2,4,5-T, which was used in small quantities in test cases in South Vietnam; trinoxol, which was 2,4,5-T, also used in small quantities; and then a variety of other non-arsenical, non-phenoxy herbicides that were used in small quantities in test cases: diquat, bromacil, tandex, monuron, diuron and dalaphon.

Now, we are not far enough along in this study for us to be making any kinds of statements about definitive findings or the quality of the science, as you can tell by the numbers that I presented a few moments ago.

However, if Dr. Shepard and the committee will permit me the leeway of denying tomorrow everything I am about to say today, when I read, when we get further into the science, I would like to hazard a few points that we are kind of making our way toward in our studies.

First of all, to begin with the water and work our way to the wine, bromacil, tandex, monuron, diuron and dalaphon have a low order of toxicity. In the words of one of the pharmaco-toxicologists that workson this project, "They are phenomenally non-toxic."

The diquat, another one of the non-phenoxy, non-arsenical herbicides used, is very much less toxic than its structural analog paraquat which hit the newspapers a couple of years ago when the Mexican government chose to spray it on the marijuana in Operation Cobra.

The Herbicide Blue, the arsenical containing cacodylic acid: there is a large amount of literature on arsenic and the other arsenicals--not a great deal on cacodylic acid per se. We have not yet gotten into considering the health effects of that substance.

Picloram, which was in Herbicide White with 2,4-D, we have not gotten into studying yet.

Now, the phenoxy herbicides and 2,3,7,8-TCDD, which are orange, purple, pink, green; and dinoxol and trinoxol, which were used in small quantities.

As I'm sure all of the members of the committee are aware, the earlier studies used dioxin-contaminated 2,4,5-T without specifying the level of contamination, which tends to abrogate their help in the kind of study we are doing.

There are very few animal studies on reproductive hazards from exposure to the male only. There are naturally, as you would expect, no controlled human studies with defined exposure to the phenoxy herbicides and/or TCDD exclusively.

There are very few animal studies on oncogenisis and chronic exposure. The oncogenicity studies in humans involve exposures to various and often unidentified herbicides.

There are many studies of the mechanisms of immunosuppression, enzyme induction, tissue distribution and pharmacokinetics.

As for the industrial accidents and exposures, there are common symptoms reported, but there are also symptoms unique to each incident. In all cases there were other chemicals involved, and there have been reports in some of the cases of behavioral symptoms associated with the accident, and we are thus far unable to resolve whether some of those behavioral symptoms are attributable to TCDD, as some of the authors have suggested, or simply

to the experience of going through an accident situation.

There are, of course, major species differences in TCDD toxicity, including both hepatic and teratogenic effects; but in all species there is delayed toxicity, extremely low LD-50s, thymic toxicity, and weight loss.

The dermatological effects seem to be limited at this point in our study to rabbits, monkeys and humans.

In general 2,4-D and 2,4,5-T both are moderately toxic in all species,it appears. Both appear to be teratogenic in the absence of TCDD in certain species under certain conditions--that based on female exposure studies.

Both appear to be mutagenic in forward mutation tests, not in backward mutation tests; and both appear to be negative in dominant lethal tests.

It would appear at this time that both are unlikely to be toxic to humans or animals at agricultural-use levels; that the potential toxic levels would be reached only in an accident situation.

2,4-D and not 2,4,5-T causes myatonia at high levels of exposure.

The mechanisms of TCDD toxicity are unknown. We know that it is a very powerful enzyme inducer, and there have been some suggestions that that would be one way of studying that problem; and work is being done in that area.

From the literature that we have seen thus far, which I remind you is partial--none of these statements that I have made should be considered conclusive at all--it would appear to be not possible to predict body burdens from military exposures in Vietnam.

2,4-D and 2,4,5-T do not persist for very long, perhaps less than six months; they do not bioaccumulate in the soil or in terrestrial or aquatic species; the published literature indicates that they are rapidly absorbed, rapidly distributed, not biotransformed, and rapidly excreted.

There is very little useful or no published information on the frequency of chloracne or other relevant symptoms in Vietnam veterans.

Because of TCDD's inordinately high level of toxicity extremely low levels of exposure become relevant, and that becomes very difficult to measure, of course, in retrospective, historical perspective; which tends to preclude this possibility of obtaining relevant body burden information from the published literature we have seen thus far. There is yet much for us to see, as I have indicated.

I would like to thank the members of the committee who provided me with leads, advice, direction, and resources to go to, at the last meeting.

I think we followed up on just about all of them in the last three months. They have been very helpful. We, again, look forward to any advice that you can provide to us, and we actively solicit this.

I would also like to offer my congratulations to Dr. Spivey at UCLA. I know Gary Spivey and Jess Kraus both; I have worked with them. They are extremely talented epidemiologists, and I give them my very best wishes on what will undoubtedly be a very difficult assignment.

Dr. SHEPARD: Thank you, Jim.

Jim's gracousness is highlighted by the fact that JRB also submitted a proposal for the design of a study, and I think it is a tribute to that organization that as soon as they were informed of the successful bidder that Jim personally communicated his congratulations to UCLA and offered the services of their literature research to that effort.

So I think you are to be congratulated, also. They are good friends.

Are there any questions from the members of the committee?

QUESTION & ANSWER SESSION

DR. MOSES: I was curious -- we are talking about herbicides, and I realize we are in herbicide-related health effects, but we do know that a tremendous

amount of malathion, for example, was used in Vietnam.

My understanding is, and I want to know if this information is available, that apparently a fair amount of pentochlorophenol was also used. Does anyone know anything more about that? And also apparently maybe chlordane.

My question is: these chemicals are also known to have certain types of adverse effects, and are these going to be incorporated into this also? Or is it basically going to be just herbicides? Or is it going to be more topical chemicals that were used that may cause health effects?

DR. STRIEGEL: Our current mandate is to address the herbicides used in Vietnam--the 15 or so that I mentioned at the outset.

I think I have some literature that chlordane and malathion at least were used in Vietnam in quantities. They are not within our mandate at this time.

Dr. SHEPARD: May I amplify that?

This question, of course, has come up. As a matter of fact it is in proposed legislation that the epidemiological study as well as the literature analysis be broadened in its scope to include other potential chemical and environmental factors, to include the insecticides, and some of the anti-malarial drugs that were used, as well as other substances.

Our response to that to date has been that, as far as the literature analysis is concerned, it was not part of the original mandate of Public Law 96-151.

The contract for that effort has been awarded; the work is well under way; and to interrupt that contract at this point, to expand the scope of that contract, we think would frustrate the efforts of that contract.

We think, however, that certainly the question is germane, and we are currently considering the possibility of either negotiating an add-on contract, if you will, or possibly a separate contract to study some of the other potential problems.

DR. MOSES: Just to get this on the record, the concern is that if pentochlorophenol was used, I don't know how many people know that that also is contaminated with dioxin, not the 2,3,7,8-TCDD but three other dioxins; and that may or may not be important.

The other thing is there is some question now, and maybe someone here knows, about the possibility, and I understand there is controversy, regarding carcinogenicity of malathion and mala oxon. And, chlordane is clearly a known animal carcinogen.

So I think that that should also be appreciated in the record.

Dr. SHEPARD: Thank you, Marion.

Any other questions from members of the committee to Dr. Striegel?

[No response]

Dr. SHEPARD: Thank you very much, Jim; we appreciate it.

DR. STRIEGEL: Certainly.

Dr. SHEPARD: The one thing that Jim didn't mention, I don't think--maybe I missed it--is that we anticipate the completion of his effort along towards the end of September. We are very much looking forward to that.

In response to the question on the news release, we have copies of that, and Mr. Appleman assures me that we will be getting more copies in a few minutes. This is the news release on the signing of the contract for the design of the epidemiological study.

DIOXIN CONFERENCE

Dr. SHEPARD: As I reported at the last meeting, we are working towards holding a conference on dioxins this October.

Some of you have already been provided copies of the proposed agenda for that meeting, and we will shortly have additional copies.

I just wanted to emphasize that we are moving forward and will be very soon announcing this through

various professional journals and other opportunities for disseminating this information.

We are very anxiously looking forward to this conference. I think the way it has been put together and the anticipated deliberations and reports that will come out of this will make it a most exciting conference.

If, after you have had a chance to peruse the agenda, you wish to address questions, and we have additional copies of the agenda in a few minutes, we will have some time for that later.

Dr. Suskind?

DR. SUSKIND: At the last meeting we talked briefly about the sponsorship of this meeting. I am wondering how that is going, and what your thoughts are or the thoughts of the VA about it.

I was led to understand that this would not be VA-sponsored, and that it would probably have sponsorship by several professional societies with financial help from the private sector.

Dr.SHEPARD: Well, I am not sure about the latter point, Dr. Suskind. I think that we have not made a final determination in terms of whom all the sponsoring organizations should be.

We are not advertising it at the present time as being a conference that will be sponsored by the

following organizations.

We have certainly solicited requests from various organizations for participation: for proposed speakers, comments on the agenda, and that kind of thing. So there are a number of organizations that are interested in the conference; but we have not solicited a list of sponsoring organizations to date.

DR. SUSKIND: Putting on a conference like this requires a fair amount of financial support, and I am just wondering how you anticipate supporting the conference.

Dr. SHEPARD: It will be supported largely by registration fee, and we are looking to other sources of financial support.

In the audience we have Dr. Richard Tucker. Dick, do you want to just stand up?

Dick Tucker has worked very hard on this. He represents SETAC, the Society of Environmental Toxicology and Chemistry, and has been working with us and organizing the meeting.

We have strong support from our colleagues in Europe and countries in other areas of the world. Dr. Otto Hutzinger, whom many of you know and who was largely responsible for the Rome meeting, has worked very closely with us.

We hope to have identified the key

very soon
participants--the chairmen, if you will--of the various sessions.

Dick, is there anything else you would like to say?

Dr. TUCKER: No, nothing at this time.

Dr.SHEPARD: Again, if you have any suggestions or recommendations please feel free to communicate those to us.

Yes?

DR. KEARNEY: The Division of Pesticide Chemistry of the American Chemical Society at Atlanta did want to express their interest as being a co-sponsor here, and I believe the Division of Environmental Chemistry has expressed a similar desire.

Dr. SHEPARD: Very good. That is good news. We had informal contacts with them, and we have had that impression; but we are glad that it is now a matter of record.

DR. KEARNEY: They are quoted now into that.

Dr. SHEPARD: Great. Thank you. That is good news.

All right, let's now move on to the next item on the agenda; namely a report from our service organizations.

At this point let me remind you that at the end

of the meeting we have designated some time for participation from the floor. If you have questions that you would like to address either to the committee as a whole or to individual members of the committee, Don Rosenblum has cards.

If you just raise your hand, he will provide you with cards on which to write questions and forward them to me, and we will take them up at the end of the meeting.

At this time I would like to call on Dr. FitzGerald, representing the American Legion.

REPORTS FROM VETERANS SERVICE ORGANIZATIONS

DR. FITZGERALD: Thank you, Dr. Shepard.

First of all, I would like to thank the VA for carrying through on a previous suggestion that we made about the playback to the individual veterans concerning the information obtained from the health examination that they had received at the VA.

I think that now the VA has provided each of the hospitals with a form letter which goes out detailing the information that was obtained on the individual examinations.

I again caution the VA that diligence to be sure that this is continued is of utmost importance.

Likewise, the question of the treatment of the individuals' complaints, regardless of whether they have

any relationship to Agent Orange, at least the thing that precipitates the individual coming to the Veterans Administration is a specific complaint, and it is urgent that these be paid attention to and be taken care of.

There is another difficulty that has arisen, and that is that individuals who approach the VA for an examination for Agent Orange are not knowledgeable in many cases as to the mechanics of the Veterans Administration.

They interpret the fact that they make an appearance at the Veterans Administration as a simultaneous formal claim of compensation. This, of course, is not true.

I would suggest that the medical administration personnel who first interrogate these people clarify this with the individuals and make arrangements, if they so desire, to follow through with the Department of Veterans Benefits.

I think that is all I have at this time.

QUESTION & ANSWER SESSION

Dr. SHEPARD: Thank you very much, Dr. FitzGerald.

In regard to your latter comment, you and I talked on the phone the other day about that point e have already set in motion a series of inputs into conference calls, alerting all our health care facilities to

that point and making the strong point that the initial contact person in the medical administration services at each of our facilities make it very clear to anybody coming in for an Agent Orange examination that this does not constitute a claim for disability, but that there is a separate process for that.

So we certainly appreciate your comments and your excellent suggestions, and we will take them into consideration and implement them.

Are there any questions from members of the committee to Dr. FitzGerald?

[No response]

Dr. SHEPARD: Thank you very much.

I would next like to call on Mr. Robert Lenham for his comments.

MR. LENHAM: Thank you. I would like to agree with the comments that Dr. FitzGerald has just made.

I would also like to express from an organizational standpoint the delight in knowing now that a design study contract has been awarded. I think that it is going to be helpful when we can go to the veterans and let them know that progress, although it might be slow, is being made and that a design study contract has been awarded, and we can give them some knowledge and some input on what might happen in the future as far as a timetable.

We have seen somewhat of a decrease in the number of inquiries that are being made by veterans, and this may be in part because they know that answers just aren't available right now; and, as such, maybe they are thinking--and this is speculative--that we will wait until we can go in and maybe gain some positive results from, say, an examination, or maybe a claim for disability, et cetera.

From an organizational standpoint, I know specifically from our National Service Offices, we have noted a decrease.

The concerns that we still see coming in by and large are related to the issue of birth defects, and certainly we will be interested in receiving, when it is available to us, Dr. Erickson's research on that issue.

We are pleased about the progress, again, that the VA is making, particularly with the award for this design study.

Dr. SHEPARD: Thank you very much. Mr. Lenham represents the Disabled American Veterans, and we are always happy to hear from service organizations' representatives. We consider these inputs as key to our operations.

I think this is one of the features that makes this committee rather unique from other deliberative groups, because we do have a broad input participation,

for which we are very appreciative.

In regard to the birth defects we are very sorry that Dr. Erickson couldn't be here today. He was planning to be here, but at the last minute he had to cancel because of other pressing duties, and I gather they are related to the TCDD study.

I think that what has happened is that there are a number of contracts out for the administration of their questionnaire.

I can tell you that his absence here does not reflect any lack of enthusiasm on his part. I talk to him frequently, and it is my understanding that they are well along in having designed their questionnaire, and the questionnaire and the study protocol is currently at OMB for review.

I think I am correct in stating that they anticipate starting up the administration of their questionnaire sometime in the early fall.

So that effort is ongoing, and although we won't have answers from it in the very near future I think that the answers that we do get should be a great help in our deliberations.

QUESTION & ANSWER SESSION

Dr.SHEPARD: Are there any questions?

[No response]

Dr. SHEPARD: Thank you, Bob.

Now I would like to call on Mr. Fred Mullen from the Veterans of Foreign Wars.

MR. MULLEN: Thank you very much, Dr. Shepard.

In picking up on Mr. Lenham's statement regarding the decrease in the amount of claims that are coming in, I believe this might be a result of the negative results of the studies on Agent Orange alone that have been coming out.

Being faced with this type of information, a lot of veterans just throw up their hands in disgust, and they won't pursue.

The JRB study, broadening the scope of the herbicide picture and not limiting it to only dioxin or to Agent Orange, may affect an increase in the number of claims coming in simply because there is some factual evidence that some of the other herbicides that were sprayed are carcinogenic, teratogenic, mutagenic.

In particular I am referring to the arsenicals. Now, we talked a little bit about Agent Blue in the last meeting, and following that meeting I did some hunting around and found a 1977 National Academy of Sciences study conducted on arsenic.

One of the recommendations of that study was that someone pick up the ball and carry it regarding the

in vivo change of organic arsenicals to inorganic state.

Another thing that I found out was that a lot of the studies that had been conducted with arsenic were conducted with rats, which were the least likely to yield any favorable information.

Now I am glad to see that Dr. Striegel is getting into the cacodylic acid research, and I'm wondering if that is going to be part of the UCLA study.

Dr. SHEPARD: I certainly would think so, yes.

As you know, Public Law 96-151 mandates we focused on the phenoxy herbicides. It is pretty evident, at the present time, that other than the Ranch Hand study, in which the exposure data is well documented and was pretty much confined to phenoxy herbicides, we will not be able to identify with great surety ground troops who were specifically exposed, and to what extent.

So I think of necessity any epidemiological study of troops in Vietnam will have to include other exposure factors.

We are certainly looking into this, and, again, we have been asked this question many times both by the general public and by members of Congress, and we have testified to various Congressional committees on this point.

As you probably know, there are a number of pieces of legislation, as I indicated, that would mandate the broadening of the scope of the epidemiological study. Our standard answer is that we agree with the science panel of the Interagency Work Group that it is going to be difficult if not impossible, to establish with certainty which ground troops were exposed to phenoxy herbicides.

But we think that until we have our contractor aboard and he has had the opportunity to review the data sources, that we should not make a judgement. We should let the contractor be the one to make the judgement on the subject of exposure data and how it bears on the epidemiological study.

MR. MULLEN: Dr. Shepard, I would like to bring up one more point, and that is regarding identification of those persons who may have been exposed.

The Agent Blue was used almost 50-50 on cereal grain destruction. The other 50 percent was used solely on base perimeters for a zone of fire.

So every ground troop in Vietnam has been exposed to that chemical. And more often than not the area sprayed had listening posts, outposts with the foxholes you sat in, and theywere damp or had water in them, and they certainly had Agent Blue in them.

Dr. Moses has just made a little note to me here.

DR. MOSES: If I had known you were going to say it I wouldn't have made it a note.

[Laughter]

MR. MULLEN: Well, just to add a little levity, maybe we should start looking for those Vietnam veterans who are now hippies. You say you can't find arsenic in the hair after it has been cut.

If we round up some of these hippies, I am sure that in the ones with the long hair we will find some positive results.

[Laughter]

Dr. SHEPARD: Yes, Dr. Lingeman?

DR. LINGEMAN: / Concerning comments about the carcinogenicity of arsenic or and other toxic effects in man? Arsenic has been known for some time to cause a relatively specific type of skin lesion--a precancerous skin lesion--known as Bowen's Disease. P athologists are very capable of recognizing this.

Now in the Registry of the AFIP, so far, we have not seen any Bowenoid skin lesion in Vietnam veterans.

We will be looking for this, because we have been alerted to the fact that this lesion is associated with chronic arsenic intoxication, most of which has followed medications with arsenical compounds such as Fowler's solution.

Some of the people at the AFIP, Drs. Graham and

Helwig of the Dermapathology Department there, did some work on this several years ago and actually found that there were excessive levels of arsenic in the Bowenoid skin lesions themselves.

So the AFIP is not only prepared to diagnose this Bowenoid lesion, but also to measure the arsenic levels in the lesions.

Because the hair grows out, I think the skin might be a better place to look for it.

Dr. SHEPARD: Dr. Suskind?

DR. SUSKIND: On the troublesome subject of arsenic I think the record should be set straight.

To my knowledge organic arsenic, of which cacodylate is an example, has not been known to cause kerotoses, pre-cancerous or otherwise, or squemacell carcinomas.

This is largely the result of either ingestion or inhalation per cutaneous absorption of inorganic arsenic.

The orcharders in the Northwest are susceptible to it because they use lead arsenic.

When Fowler's Solution was commonly used, and in some instances it is still used, some people who were taking it developed kerotoses and some of them developed

squemacell carcinomas.

I am old enough to have seen a fair number of those, because arsenic during my days at medical school was still used.

I think that one also has to recognize that the arsenic does not stay in the horny layer, whether it is the horny layer of the skin or the hair; because the hair grows and it grows out, and there is no locus of arsenic after the hair grows out. There is no locus of arsenic in the skin with the normal desclamation of the horny layer.

So even in Bowen's Disease you don't find arsenic in the Bowen's lesions a long time after the arsenic has been ingested. I believe this is fairly well known. One wouldn't expect to find it because the arsenic doesn't remain in the skin, but the effect of the arsenic is still in.

May I change the subject?

Dr. SHEPARD: Certainly.

DR. SUSKIND: I am interested to hear that there is a decrease in complaints. I believe that the decrease in complaints is due to a variety of things, among them are factors that have already been mentioned.

I feel strongly, however, that in local areas a great deal of help, especially about the anxiety relating

to health problems, has been provided by the storefront VA counseling services.

They have been of enormous help, and I find it rather difficult to understand why the support for such services is to be decreased or even discontinued.

I would like to ask what the position of the three veterans groups is about this very, very useful service.

DR. FITZGERALD: I would be glad to address that, Dr. Suskind.

The American Legion has been on record as supporting, at least for another two years, the continuation of the storefront activities.

We recognize what you are saying, that they have served a purpose beyond what they were originally intended for.

Indeed, they have come to be looked upon by the public as identical with the problems of Vietnam veterans, and this may or may not be true but nevertheless it is a fact of life.

I would like to magnify what you have surfaced as far as the anxiety is concerned. I think that this is a very real situation at the moment, and it gives me the greatest of concern as far as the individual veterans are concerned, primarily from the news media putting out of

proportion the information that is currently available on Agent Orange.

Whether, indeed, we come up with a positive effect of Agent Orange on other diseases in the future, all of us are keeping an open mind; but to the uninitiated, at the moment, this has proved to be a present problem.

I will give you specific examples: The fear of having deformed children is primarily the one that comes out most frequently.

Individuals who are having spermatic cord ligations simply because they are afraid of siring disabled children -- this is how real it is in the veteran population that is just reading the media.

MR. LENHAM: I would like to add to that from the DAV. We have testified both before the House and the Senate subcommittees that this program, the Vet Centers, needs to continue.

It is doing the job that it was set out to do, and more. That was to specifically deal with the Vietnam veteran and the enormous problems that have been given to him as the result of an involvement in a very unpopular war.

We have over 70 outreach centers that are in existence and were in existence prior to the Vet Center coming about. Together we have worked hand-in-hand, and we

will continue to do so.

It is an avenue and a tool that is working, and to even entertain the thought of throwing that tool away would be of extreme detriment to a veteran population; not only to the veteran but to his family members as well, because they share the same concerns. I think we need to recognize that.

Dr.SHEPARD: Fred?

MR. MULLEN: I agree with both Dr. FitzGerald and Mr. Lenham. I would like to also say that at present the VA is not geared toward genetic counseling or family planning, and I think that this should be looked into.

These veterans who have, for physical or psychological reasons, been afraid to sire or who have sired deformed children, we believe that they should be supplied fee-basis genetic counseling by the Veterans Administration.

We believe this should be done because by the time we find out that herbicides do or do not cause this problem the damage will already have been done, and we believe the counseling has to be provided now rather than waiting for an answer to that one particular question.

Dr.SHEPARD: Let me just respond, too.

As you know, this has been a source of considerable Congressional interest. In hearings that have been

held over the past few weeks the issue of the outreach program, the so-called "Readjustment Counseling Program", has been brought to the forefront.

I was involved in hearings of the Senate Veterans Affairs Committee last week, in which a considerable amount of time was devoted to this specific issue.

I may lose my job if I say this, but I'll say it anyway: I think it is safe to say that there are a significant number of individuals within the Veterans Administration who would like very much to see this program continue.

It was an OMB decision. Since we all are members of the executive branch of the Government, obviously we have to be guided by the decisions of the Office of Management and Budget.

However the Congressional interest has been to such an extent that I am moderately hopeful that that decision may undergo some revision. The outcome may in fact be that for the near term, at least, the Readjustment Counseling Program will be continued.

DR. SUSKIND: I don't think it would be inappropriate then that this committee, as an advisory committee to the Veterans Administration, go on record in the support of the continuation of the counseling services. I so move.

Dr. SHEPARD: I think it is an entirely appropriate move, Dr. Suskind, and I am sorry Dr. Crawford isn't here. He was here earlier. I am sure that he would be most gratified to hear your comments of support.

If that is the will of the committee, we will enter into the record that the committee strongly supports the continuation of the Readjustment Counseling Program, and we will make this known to the Administrator and other interested groups.

Unless I hear some dissension to that position, we will make that a matter of record.

Thank you, sir.

QUESTION & ANSWER SESSION

Dr. SHEPARD: Are there any other comments or questions for our service organization representatives?

DR. KEARNEY: Just one question: Can anyone give me more information about the proposed meeting on Agent Orange at Washington University? Does anyone have any information on this?

MR. FURST: I t is Memorial Day weekend. The 22nd through the 24th of May. Friday, Saturday and Sunday.

DR. Kearney : Thank you.

DrSHEPARD: Jon Furst from the National Veterans Task Force on Agent Orange is in the audience, and

during our discussion period I hope that Jon will provide us with some information. It is largely through his efforts that this symposium is being organized, and I hope we will have some time to discuss the details.

DR. KEARNEY: Thank you.

REPORTS FROM STATE GOVERNMENTS

Dr. SHEPARD: Over the last year I have been impressed by the amount of attention that various State organizations have developed regarding Agent Orange.

I have tasked our office to be kind of a clearinghouse of information for State organizations. Some States have actually had legislative enactments establishing Agent Orange commissions, and this has taken on a variety of efforts.

I am pleased now to recognize two State organizations who have representatives here today; namely the State of New Jersey and the State of Wisconsin.

There are other States which have become organized. The State of New York has a dioxin exposure Commission. Dr. Peter Greenwald, who directs the Department of Epidemiology in the State of New York Department of Health, will be in my office this afternoon, and we are going to have a dialogue among the various State organizations.

We will attempt to share information and

bring each other up-to-date as to where they stand, and we will attempt to be of mutual help.

I would like at this time to call on Mr. Wayne Wilson from the State of New Jersey Agent Orange Commission so that he can give us an update.

With him is Dr. Peter Kahn, also with the New Jersey Agent Orange Commission.

Wayne? It's good to see you.

I had the privilege of attending one of their meetings, and I'm very grateful to see them here.

MR. WILSON: My name is Wayne Wilson, and I am the Executive Director of the New Jersey Agent Orange Commission.

I left the house at 3:00 this morning, so you will have to bear with me a little bit, okay?

First off, New Jersey was the first State in the nation to establish a State Commission with a definitive legislative mandate.

I think primarily our mandate calls for us to do three primary things. Those three areas include providing direct counseling, legal assistance, and outreach efforts to veterans. We are also mandated to gather various types of data and to examine closely the possibility of doing a number of studies.

Possibly Dr. Kahn may be able to discuss

briefly some of that work.

Our seven commission members are unsalaried. By law four must be Vietnam veterans, and they are. The other three primarily come from the medical and scientific fields.

I did not prepare any remarks this morning, because I wanted to take this opportunity to kind of tell you like it is, very briefly.

We are using, in terms of outreach activities, six Veterans Administration facilities, primarily for the purpose of having Agent Orange screening examinations done.

I would not go around the State of New Jersey without coming here and saying the exact same thing that I say across the State. We have done approximately 30 to 40 programs and have talked to and listened to thousands of Vietnam veterans and their families.

Frankly, as I sit here, I am critical of the Veterans Administration; and I am not at all sure that everyone senses the urgency that the thousands of veterans and their families have communicated to us.

I think that is very important, because I think that's what it's all about. We have found within the six area VA facilities we use,many, many inconsistencies.

I do not share some of the comments made by some

of the veterans representatives here that this business has peaked or is on the decline.

I think that veterans are frustrated at where they can turn for help and assistance, and I mean immediate help.

If you will go to New Jersey you will see wherever there is an organized effort to serve the veteran, specifically in terms of Agent Orange, you will find large numbers of claims being placed, larger numbers of people requesting information, assistance and examinations.

I think the veterans and their families are looking for facts. Mr. Cleland described this as a dirty little cold book that will help allay the fears of Vietnam veterans. It does not.

I don't think that benefits counseling should be done by medical service administrators or doctors. Most veterans, when they get their Agent Orange examination, hit the bricks wondering what happened.

Some of the things that have been said here this morning are not what we are finding in talking to thousands of veterans, not only in New Jersey but in Pennsylvania and Delaware.

For example, I think Dr. FitzGerald said that each veteran who is examined now receives a form letter detailing the exam results.

Let me tell you that the East Orange Veterans Administration Hospital provides a four-lined form letter that says, "Your tests were within normal limits." There are no details of the examination results.

In fact the East Orange Veterans Administration Hospital is sending letters to veterans which say, "We have noted minor abnormalities. Please consult your personal physician."

We say to East Orange, "Why are you telling veterans to consult their personal physicians?"

They tell us, "No service connection has ever been substantiated," and therefore there is nothing they can do.

One other thing. We met last week with representatives of the East Orange VA Hospital, prior to coming down here, to see if we could clearly set up some procedures and possibly help them from taking the bad rap that they do take.

I don't think that we were successful. Among the suggestions that we made was to possibly take a GS-3 or a GS-4 clerk who, as a last contact with the veteran, could just ask that veteran, "How did it go? Do you have any questions?"

They told us that they didn't think they could find anyone in the hospital good enough to do that job.

East Orange Hospital at the present time is allowing our commission to schedule four examinations a week. Four.

We estimate that with an estimated 56,000 veterans in the State of New Jersey it will take them 267 years to completely examine all of our people.

We have asked for an increase. Now they will allow us, as of last week, to do six per week. And for good measure they will throw in a group from one of the veterans organizations on one Saturday a month.

Veterans know that every VA medical center is doing their own thing. And as one VA administrator told me, "We are allowed to bend the rules."

Now, time won't permit me to go into all of the details; but I come here as an executive director of a program, and I am telling you what veterans are telling me.

They are frustrated. They do not perceive the Veterans Administration as caring about their medical problems, specifically Agent Orange.

I am not a scientist, I am not a physician, I am not a lawyer; but I am a Vietnam veteran, and I hear my fellow Vietnam veterans.

They cannot come here. But if they could they would communicate to each and every one of you what they feel in their hearts about the problem of Agent Orange.

I don't think it should be dismissed. I think there is an urgency to get on with doing what has to be done.

I read the official transcripts that come out of these meetings, and I have forwarded to Mr. Young and Mr. Sommer from the American Legion what we feel are questions that have not been answered.

All too often things run -- I can't believe the timetable. For example, the literature analysis--it's way behind.

I asked the Department of the Army what their policy was on Agent Orange. They sent me a January 2, 1979 memc that grossly understates the problem.

We have large numbers of active-duty personnel in New Jersey, and they don't know where to turn for help.

Speaking of VA outreach centers, we had a call from a woman whose husband has tried to commit suicide three times. She sought our assistance, and we referred them to the Philadelphia Vets Center. When I called the team leader he said, "Wayne, I'm sorry; he's got three ahead of him today." And two outreach centers, one in Newark and one in Jersey City, will not get it for the State of New Jersey.

I don't know how many of you folks out here have been in one of those VA outreach centers, but I have. They are not situated in very swank places in the city, but

they have seen over 52,000 Vietnam veterans. I don't know how many had long hair or not, that's not important to me.

I would advise you, and I would encourage you, and I would even challenge you to come on up to New Jersey and spend a day with us, and really talk to the Vietnam veteran and his family and hear what they say and feel what they say, and hopefully care about what they say.

That's all I have to say. Thank you very much.

[Applause]

DR. SHEPARD: Peter, do you want to give us a progress report?

Let me just say that we will be meeting with Wayne and Peter this afternoon, hopefully, and we will go into more detail.

I certainly would like to say right now, Wayne, that I appreciate your input, and I will hope to redouble our efforts to try to resolve some of these problems.

DR. KAHN: Thank you.

I want to reinforce the sense of urgency that one gets in speaking in the field, as Wayne says, to literally thousands of veterans.

The commission organizes programs at the rate of a couple of week, frequently. I often go to these, as one of the scientific members of it, where, free from the hysteria of the popular press, I try to present what little

bit is known about the toxic and potentially toxic effects of herbicides.

Even though Wayne keeps trying to make me speak for less and less time at each meeting, that never seems to work, because we always get flooded with questions.

Often they are of an intimate, personal nature which people are so concerned about that they will stand up in a public meeting of a couple of hundred and present their intimate personal problems. It takes a certain amount of concern for someone to put up with the embarrassment that comes with such a presentation.

I get phone calls in my laboratory. I have a string of messages every day. How they found my office number I don't know, but nevertheless I get flooded with calls. I try to answer every one, which means that I am going to wake up with a long black thing growing out of my ear one day.

But that sense of urgency is really out there, and it is particularly out there among people who have had relatively few medical problems and who see things coming at them now that they fear might be due to Agent Orange.

It comes also from people who are perfectly healthy but who fear, as one of the earlier speakers mentioned, that there would be a problem in the fathering

of children.

It comes across not just as a scientific issue, something that I will one day write about,

but it comes across as human beings with whom you sit down and drink a beer. And they are worried.

At Saddle Brook, in Northern New Jersey a couple of months ago, we had one of these programs to about 250 people in the VFW Hall.

One of the men there, who was a Korean War veteran and who had never been to Vietnam, said that if another war were to come that he would take his family to Canada.

I then asked the group there, based on their own experiences, whether they would send their sons into the service. You could hear a pin drop in that room. And these are men who served in World War II, in Korea, and in Vietnam. We had veterans of all three wars present.

The message is loud and clear: The Government is perceived as treating shabbily those who fought the last war. And as long as it is so perceived, who will you get to fight the next one?

Now the matter of the science involved in this comes up, because I present to the veterans at these talks what the commission is attempting to do with minimal

resources.

And there is nothing difficult in the science to be done about finding out whether there is or is not a definite connection between Agent Orange and subsequent medical problems. There is nothing in that science that is beyond the comprehension of anybody who can read a newspaper.

It may take a little time to explain it. You may have to explain some words of four and five syllables that are not in common use; but if one is willing to take that time and make those explanations everybody out there can understand what we are about.

And I do that. And they strongly want the work to be done as quickly and as expeditiously as possible.

Now, in poking about, looking for expertise that I don't have in epidemiology and toxicology, and so forth, I have gone about talking to colleagues who have that expertise.

I am finding out that vast resources are not needed to do the necessary work. One needs some, but you don't need millions and millions of dollars.

There are many, many potent scientific questions that can be asked of existing records, and I don't see that work being done, and our commission is picking up on some of it.

In that connection the Veterans Administration

has been kind enough to tell us that they will make available over the next several months a computer tape--or a series of three, actually--which will give us the names and addresses and perhaps some other information about New Jersey veterans of the Vietnam era.

We have been trying since last July to get that information. We don't have it yet. We do have the promise that it will be forthcoming in the next several months.

It has taken great pressure to spring that information loose.

A variety of arguments have been given against making that information available to us. They all smack to us of bureaucratic foot-dragging.

Now that the information is to be made available to us, we are told that there are restrictions on its use. It may only be used to "aid in the filing of claims and to dispense information concerning Agent Orange. It may not be used for research purposes."

I find it incomprehensible as a scientist as to why the use of the names and addresses of New Jersey veterans for the research purposes mandated by law in the commission's setting up -- as to why we can't do that.

We are not about to go and do things to which the veterans do not give consent. If a man is asked to participate in any kind of a study, he is asked to give his

full formal consent to go in and spend a boring Saturday filling out a form in the company of somebody who knows what it is all about.

And if a man is willing to do that, knowing he is blowing a nice Saturday afternoon to do it, I certainly think we should be empowered to ask him if he is willing to do that.

You know, when people tell me I can't do obvious, simple, sensible research that the veterans themselves say they want done, I get a little hot under the collar, and I think suitable pressure from this committee might help us release that restriction.

DR. SHEPARD: Thank you. It's news to me.

DR. KAHN: I wanted to get that on the record. I figured it was news to you. I didn't think you would be a party to anything like that.

DR. SHEPARD: Believe me, we will certainly search out the facts behind that. I was not aware that there was any restriction being placed on tapes. It is not the purview of our office to make these decisions; that's why it is news to me.

DR. KAHN: I know that, but I just wanted to apply pressure.

DR. SHEPARD: I'm glad you brought it up, and hopefully in our meeting this afternoon we will have

somebody there who will be able to answer that question.

Yes, Marion?

QUESTION & ANSWER SESSION

DR. MOSES: I would like to ask Mr. Wilson a question.

What do you feel is the greatest need, in terms of your presentation, for more of these psychological testings? Or do you think there is more need to do physical examinations?

I realize the needs are great, and it varies, but what do you see in terms of New Jersey as the greatest need right now that your commission needs help with, in terms of directly helping a veteran?

MR. WILSON: We need the availability of Veterans Administration resources.

In terms of psychological counseling we know, for example, that many veterans who go in for Agent Orange examinations will end up, as part of that process, in seeing someone in NNP--a psychologist or a psychiatric person.

Let me give you an example. A veteran went into East Orange Hospital for an Agent Orange examination on December 8, 1980, reporting severe skin eruptions on major portions of his body that were interfering with his employment as a mailman.

He was examined and was rescheduled for a follow-up examination on May 7, 1981--five months to have a dermatologist look at what the man reported to be a severe problem.

We were told that East Orange only has a part-time dermatologist consultant come in one afternoon a week. That is completely unsatisfactory since I assume most people know that many veterans, whether it is chloracne or regardless of what it is, are reporting a number of skin problems associated possibly with their service in Vietnam.

It would only seem reasonable to me to have provisions made so that we don't make a person wait five months.

That veteran, in our survey, said, "I don't believe it." And I didn't believe it either, until I, in fact,wrote the director.

DR. MOSES: But do you think this should come through the Veterans Administration? You are not recommending that they should go to dermatologists and send the bill to the VA, are you?

MR. WILSON: I think the Veterans Administration should make available the resources and the personnel and the money to get the job done in terms of Agent Orange screen exams. If you are not going to do it, then you

might as well stop telling veterans you will examine them for nothing.

Because, I'll tell you, four exams a week -- we are not getting anywhere that way. And I think we have to be realistic, and we are not being realistic.

When you tell a veteran--we are booked up now until July at the rate of four a week--that he has to wait until July or August to be examined, he doesn't perceive the Government as really concerned.

DR. KAHN: Could I field this question?

DR. SHEPARD: Yes, though we are going to have to move along.

I just want to interject that this is the first time I have heard this problem about East Orange. I'm not suggesting it's not entirely practical, but I would have hoped that Wayne would have brought it to my attention earlier so that we could have done something about it.

That is the sort of thing I can do something about.

DR. MOSES: I can tell you of another VA Hospital who only has a dermatologist one day a week.

MR. WILSON: Don't hold me to just East Orange. It's just East Orange today.

DR. SHEPARD: I just cite East Orange as an example of ways in which we should keep our lines of

communication open, because that is an area where I can be of help.

I can also assure the committee and the audience that it is the Veterans Administration's goal that no unreasonable period of waiting time be imposed on the veteran who is requesting an Agent Orange examination. That is our goal now, whether that is the way it is carried out universally, I can't of course answer that. But it is our hope that that is the case in the majority of instances.

DR. SUSKIND: I think that this discussion is really very helpful to the members of the committee who don't know what is really happening in any boondocks except their own.

My experience with the VA Hospital in Cincinnati is very different from your experience at the VA Hospital at East Orange.

Perhaps the reason for it is that it is university associated and fully staffed with dermatologists, pulmonary people, toxicologists, and so on.

So I think it is a matter of the availability of the resources.

I was interested in hearing one comment by Dr. Kahn, and I wondered if he might answer a question about it.

Can you give me an example of what scientific

questions can be answered easily, as that is what you said.

DR. KAHN: Yes.

You ask the question first as to whether a larger number of Vietnam veterans have died than one would expect in similar economic, age, demographic circumstances.

New Jersey maintains a computerized registry of death certificates which contains some information that is written on the death certificates. It also contains an access number by means of which the death certificate can be pulled from a paper file.

It also has a fairly slick operation in terms of computer programming that permits you to probe those death record files.

I presume that most of the States have similar arrangements, although no two will be identical.

It is not very expensive to do this, and our preliminary look at it at the moment--we are going to do such a survey--looks as though it is going to cost us between $2 and $2 & 1/2 per death record that we search. Okay? And the State Government will make available the funds to do that.

Now, this is something which is quite circumspect. On the death records there are causes of death listed, and States here vary on the practice that they use in tabulating such information.

In New Jersey the final cause of death is not always what is put on the computerized search. What they put in is the principal cause.

So for a fellow who expires of pneumonia brought on as a result of cancer, what will be listed is "cancer" and not the pneumonia. So at least they are a leg up on practices in some places.

We are going to do such a search. It is not going to cost us a lot of money. So there is one thing we can do.

Another one: The State has begun setting up and has just about got operational a tumor registry. In it, at the moment, are all tumors that have been diagnosed in the State of New Jersey since October of 1978.

Now the progress of cancer being what it is, most of those people are still alive. And so, one can ask the question--if somebody finds his way into the tumor registry, is he or is he not a Vietnam veteran? And is the incidence of such things higher or lower than what one would expect in persons of his or her age and other circumstances?

These are just a couple of things that one can do. I have a list of others.

DR. MOSES: It seems to me, though, that this would depend on getting the names and addresses and getting

information from the Veterans Administration.

DR. KAHN: Square One.

DR. MOSES: Yes. I don't see how you could do it without that.

DR. KAHN: Sure.

DR. SHEPARD: You are bringing up a good point, Peter; but we are going to have to move along, because we have gentlemen from Wisconsin with us.

But what you allude to in terms of a mortality study is precisely something that we will discuss further this afternoon when Dr. Peter Greenwald will be with us, and that is something that we are doing with the State of New York. So the opportunities are there, and we heartily endorse those efforts; in fact, we are cooperating very extensively.

So that is another puzzlement as far as why this information is not usable.

Thank you.

Now, I call on Dr. Anderson and Don Laurin from Wisconsin to tell us a little bit about their State activities.

It is a great pleasure to have these gentlemen with us today, and they will be meeting also with us this afternoon.

DR. ANDERSON: Thank you very much. Both of us

are glad to have the opportunity to travel out here to the East.

We have the same concerned veteran population that you have heard about, and we have a very similar type of reaction.

I would like to just spend a very brief time outlining the history of our program and where we are at today, and perhaps at another time with more time available we can present some of our results when we get them tabulated.

Back in 1979, I think along with the frustration that you heard just before us, the State Legislature in Wisconsin had a very vocal group of veteran constituents and felt that they were quite frustrated with providing them with adequate assistance.

So, beginning in June of 1980, they appropriated $124,000 to establish an outreach information identification program.

This was to have several main goals. One was to determine how many Vietnam veterans we had in the State, and what their current perceived health problems were, and what we could do to assess their impact on the State health care delivery system.

One thing that we were very fortunate in was that when the Selective Service was disbanded, the Department

of Veterans Affairs for the State was given custody of the DD214 discharge papers for all of the veterans in the State of Wisconsin.

Utilizing those some 200,000 records we were able to handsort and select out all of the individuals with the Southeast Asia Service Star, which all of the Vietnam veterans received.

So we were somewhat fortunate in having a fairly well-defined denominator population of 58,400 veterans from Vietnam service.

This group, of course, does not include those individuals who have since moved into the State, although our program is directed at providing them information.

But our basic group of names that we use to send out information to identify individuals came from this 58,400.

We also then began to develop educational materials. There was clearly a need in the State for people to find out how they may have been exposed, what sorts of problems have been associated, and where they could go primarily for assistance.

This was primarily a young population, many of whom did not have ready access or had not previously gotten into the health care delivery system.

So when they became ill or they had questions

or problems; many of them did not have a private physician that they went to on a routine basis, and we sensed that there was some floundering on their behalf as to "How do I get into that?"

Don can tell you a little bit more about the various other organizations that we are working with; but we perceive that one of our tasks, as your task here is, is on a State basis to provide coordination and assistance to the various organizations that are trying to assist the veterans, and to work very closely with the State medical association to identify individuals who could act as resource persons for the veterans.

We also, of course, encouraged all of those to get into the VA to be examined; but we did try to seek alternate sources for those individuals who needed more continuing care on a local basis.

So ours was very much of a coordinating activity. We have been involved, especially Don, in developing slide tape shows. We are in the process of putting together with the WHA-TV, the public service television group in Wisconsin, a television program, and we have had numerous call-in radio programs.

We also run a hotline for information to the vererans.

To date, with our last mailing having gone out

about a month ago, we have received out of that 58,400 some 30,000 returns. I think that speaks for the concern in the community for a rather brief mailed-out informational sheet which we ask them to return.

You have to be aware that of course this goes back to addresses from 1962, and some of these individuals are deceased. So we feel our response rate is quite respectable at this point with only having gone with a mailing.

We of course are working very closely with the Department of Veterans Affairs and their county service officers who work with many of these individuals on a daily basis and will also be providing input for us.

At this point, since we don't have all the results in and we are a small program, the staff of which you are seeing here --

[Laughter]

DR. ANDERSON: -- I think you can appreciate the magnitude of the response; but I am happy to say that by the end of June we will have all the information in, and we will begin to come out with some of the summary statistic information.

Yet, as I say, we ask some very simple questions. It was perceived health problems--and I stress the "perceived."

At a later date we hope to have State resources to corroborate the information provided through the various State records that are available.

These are also available in the State of Wisconsin. We do have a genetic network of counselors for birth defects who will begin channeling information in to us as well as providing assistance to actually any child that is born in the State with a defect, of course whether they are born to a veteran or not.

Of the information that we have gotten back, roughly 15 percent of those veterans returning the form told us that they did think they were exposed, and they wrote down some justification for that exposure. Sixty-six percent said they were not certain, and 19 percent definitely said they had not been exposed.

So I think you can see that there is a considerable need to get information out, especially to that 66 percent who may have problems or may not, but are very concerned as to could this be related, maybe I have been exposed, how could it have happened. They just haven't gotten that information yet.

Interestingly, also, four percent of our returnees have in fact been into the VA and have been examined. Roughly 40 percent of the individuals requested additional literature or information, and an additional

20 percent said that they would be very much interested in participating in a more-detailed study or investigation; again, showing the concern that these veterans have and their interest in the problem.

I think, at this point, that gives you the basic background of our program, and I would like Don to speak for three to five minutes, as we were told, on his experience with the hotline in dealing with the veterans.

MR. LAURIN: First of all I would like to say that the gentleman from New Jersey expressed a sentiment that I have been hearing from the veterans in the State of Wisconsin.

There is a lot of concern and anxiety among the Vietnam veterans, their families, and their wives, that their problems may be due to Agent Orange exposure.

We were lucky in Wisconsin that we had a list already available to us of the Vietnam veterans. Because of that we have been able, as Dr. Anderson mentioned, to send this questionnaire out to 58,000 veterans.

I think that when we get done compiling all the data we will find out that we have over 60 percent response rate from our survey. I think this is excellent.

It also shows the concern that the veterans in Wisconsin have.

We have also sent out over 40,000 of these

brochures which we had printed up called "Questions and Answers About Agent Orange." We are printing another 40- or 50,000, and they will also be distributed around the State.

In Wisconsin we also have a very good network of veterans organizations. We work very closely with the Veterans of Foreign Wars, the American Legion, Order of Purple Hearts, Vietnam Veterans Against the War, and almost every Vietnam veteran and veteran organization that there is.

We also work very closely with 72 county veteran service officers. This has made it a lot easier for us to get information out to the veterans, because when the veteran wants to file a claim he goes through his county veteran service officer.

We set up the hotline a little less than a year ago, and already we have had over 4000 telephone calls. I have not personally answered that many phone calls, but I think that the calls coming in have given us a good idea as to what the veterans of Wisconsin would like to see, as far as programs for them and their families.

The joint finance committee has allocated $66,400 to the program, to be carried forward for another year. What we would like to do in this coming year has three parts:

We would like (1) to continue information and our education coordination and promotion; (2) we would like to have an extended outreach program, where we would like to get more of the veterans into the VA hospitals to be examined. We would also like to see their children be examined.

As we had mentioned, only 4-5 percent of the veterans from Wisconsin have gone to the VA for an examination. This is an extrememly low number, considering the fact that we have contacted this many people.

I have been informed by the Veterans Administration Hospital in Madison, Wisconsin, that approximately 50 percent of the veterans who call up and have an appointment to come in for an examination eventually do not show up.

There must be a reason for this. I think the reason is because a lot of the veterans have received letters already from the hospitals telling them that there is no association between the problems that they perceive they have and with Agent Orange.

This is one of the reasons why we have decided to produce a television show which will be aired throughout the State of Wisconsin, and hopefully on PBS nationally, which will give answers to the veteran as to what the Veterans Administration is actually doing.

We hope that this will encourage the veteran to come in and get the examination. We feel that, if they are having problems, that those problems should be taken care of, whether or not they are due to Agent Orange.

If they are having physical problems, they should be treated.

Also, we have had a tremendous response from the private physician community in the State. The Wisconsin State Medical Journal recently printed an article called "Agent Orange-The Physician's Dilemma."

The article listed a protocol for treatment or examinations of Vietnam veterans, and we think this is very helpful.

We have also been sending out examination protocols to other physicians who request them. I think we have had approximately 10 or 15 requests so far.

A lot of the Vietnam veterans from the State have to travel long distances to get to the Veterans Administration Hospitals--in some cases up to 300 miles. This is very inconvenient for them, especially if they don't receive any travel pay.

This is why we feel it is important that private physicians get involved. It is also important because a lot of physicians do not know too much about environmental medicine.

Veterans have been going to their private physicians for a long time and have been getting the runaround, basically saying "We don't know what the problem is--go to the VA."

So this is a great help, I think.

With increased awareness have come questions concerning who is the greatest risk and what these risks are.

Being informed of a potential hazard is insufficient. Studies in other States have suggested that veterans reporting skin conditions have a higher incidence of liver problems and birth defects among their children.

Rumors are many and facts are few. I believe that the program which the State of Wisconsin has right now, can begin to provide leads and some scientifically-defensible analysis.

We will search for more funding to continue the program, and this will be sought very rigorously. We would like to see more funding, because we believe that once initiative is lost, a big part of the program is lost.

So, we thank the committee here for the support that we have gotten in our program when we have called up and asked for materials or advice or information as to how we can better deal with the veterans in Wisconsin, and we would also like to thank other States who have also

given us advice and help in how to run our program.

Thank you very much.

DR. SHEPARD: Thank you. Are there any questions from members of the committee?

QUESTION & ANSWER SESSION

DR. FITZGERALD: I just wanted to bring to your attention the fact that you said there is a concern about travel funds for the veterans to get to the VA Hospitals.

If they have a scheduled examination at the Veterans Administration Hospital they are entitled to travel funds. A drop-in, no; but a scheduled examination entitles them to travel funds.

MR. LAURIN: Well, is that only if they file a claim?

DR. FITZGERALD: It has nothing to do with a claim. If they have a scheduled examination at a Veterans Administration facility, they are entitled to travel funds.

DR. SHEPARD: They have to request it, though; isn't that right, Dr. Fitzgerald?

DR. FITZGERALD: They have to request it, yes. They cannot just be a drop-in.

DR. SHEPARD: But do they have to request the reimbursement? It isn't automatic, in other words.

DR. FITZGERALD: That's right.

MR. LAURIN: Okay. I think that is where the

problem lies, in that the veterans don't request it. They think that it is coming to them automatically.

DR. SHEPARD: So that would be something you would have to sort out.

Dr. Moses?

DR. MOSES: I was curious about this county veteran service officer role; is that peculiar to the State of Wisconsin? Or is this something that all States have? And is it a part of the Veterans Administration?

DR. SHEPARD: Many States have it.

DR. MOSES: Is it from the Veterans Administration? Or is this something from the State?

DR. SHEPARD: A State organization.

MR. LAURIN: A State organization; correct.

DR. MOSES: That sounds like a very good point of contact and a good field way to work on services to veterans.

MR. LAURIN: New York State has such a system.

DR. MOSES: Does New Jersey?

DR. KAHN: Yes, we do.

DR. MOSES: Are they involved in what you do?

DR. KAHN: Yes, they are intimately involved.

Our office is down the hall from the State Office of Veterans Affairs.

DR. MOSES: Is that county veterans service

officer a veteran usually?

DR. FITZGERALD: He is usually a member of one of the veterans organizations.

DR. SHEPARD: But he is paid by the State.

DR. FITZGERALD: He is paid by the State, yes.

DR. SHEPARD: Are there any other questions by the members of the committee of our friends from Wisconsin?

[No response]

DR. SHEPARD: Well, thank you very much, gentlemen. I will look forward to your participation in our meeting this afternoon.

Let me say again that this is the first of this kind of information sharing that we have had, and I hope that it is the first of many.

I want to reaffirm the position of our office to act as a clearinghouse for the exchange of information, advice, what have you. I am delighted that you have heard from these two States, and I am sure that this will be one of many forthcoming.

Let us now move on to the next item on our agenda. Dr. Lingeman, would you please introduce Dr. Cantor?

DR. LINGEMAN: I would like to first point out that the title of the talk is somewhat misleading, in that

the Soft Tissue Sarcoma Report is not really what Dr. Cantor is going to talk about.

And that is something that has been talked about as a possible project involving a cooperate effort between the AFIP as a source of location of soft-tissue tumors, and a possibility of an epidemiological study rising out of that.

But the NCI has been engaged in several other types of studies which definitely have to do with the carcinogenicity of herbicides.

Some are in the final stages, some are in the planning stages; and therefore Dr. Cantor, of the Environmental Epidemiology Branch of the National Cancer Institute, is here to summarize the efforts of his department with reference to the herbicides.

STUDIES OF THE ENVIRONMENTAL EPIDEMIOLOGY BRANCH-NCI

DR. CANTOR: Thank you very much for inviting me here today, Dr. Shepard.

Actually the study that we are planning is one-quarter of this presentation; so we will at least be talking about that a little bit.

The Environmental Epidemiology Branch at the National Cancer Institute is involved in a wide range of epidemiologic studies where cancer is either known or suspected to be the end point of particular exposures.

In the area of herbicides we were led to this area from three general concerns.

One is a general concern about pesticides of all kinds and exposures that both the general population and in particular farming populations have.

The second is a series of studies based on mortality records. The first level of studies that was generated by the system of county cancer-mortality records, kept at the National Cancer Institute, in which correlations first of all with leukemia and farming seemed to be evident. The second are other studies where non-Hodgkins lymphoma seems to be elevated among people in farming areas.

The third general impetus for these studies stems directly from the Swedish studies by Hardell, Erickson, Axelson and other workers, which I'm sure most of you have heard of, where they saw associations between both soft tissue sarcomas, non-Hodgkins lymphoma, and I believe Hodgkins Disease, and related that to exposure to chlorinated phenoxy acidic acids.

I have brought along three viewgraphs today.

[Showing of viewgraph]

DR. CANTOR: This first one is a very general description of the four studies I would like to discuss with you.

NCI STUDIES INVOLVING POSSIBLE HERBICIDE EXPOSURES

STUDY	INSTITUTE	DESIGN	SIZE
AERIAL PESTICIDE APPLICATORS	NCI/FAA	COHORT MORTALITY RETROSPECTIVE FOLLOWUP	N = 10,000
SOFT-TISSUE SARCOMA (FEASIBILITY)	NCI/AFIP	CASE-CONTROL INTERVIEW	N = 100
PEST CONTROL OPERATORS	NCI	COHORT MORTALITY RETROSPECTIVE FOLLOWUP	N = 4;500 (2,000 LICENSED II CATEGORIES WITH POSSIBLE HERBICIDI EXPOSURES)
LEUKEMIA/NON-HODGKIN'S LYMPHOMA	NCI/U.MN	CASE-CONTROL INTERVIEW	N = 300 LEUKEMIA N = 300 NHL

Since I do have particular viewgraphs on the first two that are mentioned there, I'll just discuss right now the third and the fourth.

Perhaps before going into that I will just mention that here we see representatives of two general types of study.

The first and third studies, that is, aerial pesticide applicators and pest-control operators, are studies in which the study group is based on exposure.

That is, aerial pesticide applicators have known or suspected exposures to pesticides. Pest-control operators also have exposures to pesticides of various kinds.

Both studies share the characteristic that they are retrospective follow-up studies in which mortality is used as the end point. We do seek out death certificates in these studies.

The second and fourth studies are both case-control interview studies in which entry into the study is based on diagnosis of a particular disease in an individual.

Then we will go ahead and choose matched controls and interview the controls in the same way, and then look for differences between cases and controls in terms of their exposure.

Now, going on to the third study, this is a study which is near completion. The cohort is based on pest control operator licensing records from the State of Florida; and these were people who were first licensed from the mid-40s to the late-60s.

We have almost completed follow-up on this group of 4500 persons, of which about 2000 are licensed in categories with possible herbicide exposures.

What that means is that every time Florida gives a license to a pest-control operator they are licensed for specific types of pesticide application. One of those categories is weed-killers in lawn and weed control.

As I say, we should have results from that study certainly by the end of this year, and probably in three months, I believe.

The last study mentioned there is a little misnomer. It should be leukemia and non-Hodgkins lymphoma. The data collection is being done under contract to NCI from the University of Minnesota. Drs. Lenos, Shumann, and Gibson at the University of Minnesota are just/now going out in the field to do a case control interview study of patients diagnosed with either of these two diseases, either in the last year or for the next two years. Based on previous records, we plan in that study to have 300 leukemia cases, 300 cases of non-Hodgkins lymphoma,

and matched controls.

Now, one of the primary purposes of that study is to look in great detail at occupational exposures, specifically farming exposures.

The questionnaire, which is now nearing its final stages, goes into great detail in asking about particular crops that were grown and livestock that people kept and particular herbicides, fungicides and insecticides that were used. We ask it in a number of ways--by generic name and by brand name. There is a tremendous complexity of brand names that have been used in the past.

The study is being conducted of all cases identified in hospitals within Minnesota, but includes only residents who are living outside of the Minneapolis-St.Paul area. This will increase the probability of getting the population that is at least 25 to 30 percent farmers, at some point in their lives.

Let's turn now to the next viewgraph.

[Change of viewgraphs]

DR. CANTOR: This goes into some detail on the study of aerial pesticide applicators.

This is a study that we are doing in conjunction with the Federal Aviation Administration. The FAA requires of all commercial pilots that they take a medical exam, at least for Second Class Pilots, once a year.

AERIAL PESTICIDE APPLICATORS (NCI, FAA)

- RETROSPECTIVE MORTALITY STUDY
- COHORT SIZE 10,000
- FAA MEDICAL EXAM FILE, 1965 - 1979
- 2 COMPARISON GROUPS
  - FLIGHT INSTRUCTORS (FROM FAA RECORDS)
  - U.S. GENERAL POPULATION
- FOLLOWUP IN PROGRESS
  - FAA RECORDS
  - SOCIAL SECURITY ADMINISTRATION
  - MOTOR VEHICLE BUREAU
  - TELEPHONE DIRECTORIES
  - OTHER
- EXPOSURE INFORMATION IS LIMITED
  - INFERRED FROM RESIDENCE
  - EMPLOYERS (??)

At this medical exam the pilot reports his primary type of commercial aviation activity. One of the 10 categories that they use is pesticide applicator.

We have identified approximately 10,000 individuals who, at least once between 1965 and 1969 said that they were aerial pesticide applicators. Most of these people, in fact, at their yearly medical exam, reported this year after year.

We will be following up this group through the FAA records themselves, Social Security Administration records, Motor Vehicle Bureaus and telephone directories and also with other resources, perhaps including voter registration records, to establish the vital status of all individuals as of a closing which is now tentatively set as mid-1979.

Through Social Security we have already identified 550 deaths within this group of 10,000; and my suspicion is that there are at least 200 or 300 more that will be uncovered.

In this study we will be using two comparison groups.

The comparison group should be chosen so as to be as much like the study group as possible.

If only the U.S. general population were used for comparison, it could be argued that there is something different about

people who fly planes, either in terms of their general health, socio-economic status or area of the country.

To address this issue, we have selected a matched control group of 10,000 flight instructors from FAA records.

They are matched on age and area of the country.

One of the problems in this study will be the kind of exposure information which is available.

We will first analyze this group by area of the country, to see if there are any unusual patterns of mortality by region.

Secondly, we will go to employer records.

If there is anything unusual going on in the population at large or in any particular regional groups, we will seek this additional information. But I think we have to recognize at the outset that characterization of exposure will be a major problem.

The next viewgraph, please.

[Change of viewgraphs]

SOFT TISSUE SARCOMA (NCI., AFIP)

- CASE-CONTROL DESIGN
- CASES FROM RECENT AFIP ACCESSIONS
- DESIGN AND FEASIBILITY PHASE
  - QUESTIONNAIRE DESIGN
  - TELEPHONE INTERVIEW OF 100 CASES OR NEXT OF KIN RESIDING IN "HIGH EXPOSURE" AREAS
- QUESTIONNAIRE DESIGN
  - DEMOGRAPHIC BACKGROUND DATA
  - OCCUPATIONAL HISTORY
- PLANS FOR SELECTION OF ADDITIONAL CASES AND OF CONTROLS WILL FOLLOW FEASIBILITY PHASE

DR. CANTOR: This viewgraph describes in brief the study that Dr. Lingeman referred to, which is presently in the feasibility phase.

Eventually we will have a case control study underway, and the cases will be identified from recent accessions of the Armed Forces Institute of Pathology.

Soft tissue sarcoma presents tremendous diagnostic problems, and for that reason a fair percentage of all of the soft tissue sarcoma diagnoses or potential diagnoses in the United States wind up at AFIP. So at least we have the possibility of getting about 30 percent of the cases?

In the feasibility phase, we will select 100 cases--100 male cases--that have been identified by AFIP from areas which are identified as high-exposure areas.

What we mean by high-exposure areas would be areas where herbicides have been used in quality, such as wheat-growing areas, and rice and forestry areas.

At the moment we are looking into various ways of accessing the AFIP files, and we are in the discussion

phases of developing a telephone questionnaire which will obtain demographic data for these individuals and as detailed an occupational history as can be obtained with a telephone interview.

This will, of course, include a history of military service.

After the feasibility phase we will develop plans for selection of additional cases and of controls.

That's all for my formal presentation. I will be happy to entertain any questions that you might have.

DR. SHEPARD: Surely; and thank you, Dr. Cantor.

Does any member of the committee have questions of Dr. Cantor?

QUESTION & ANSWER SESSION

MR. SULLIVAN: I have one. Would mind saying why you picked the sample size of only 100 for the last study?

DR. CANTOR: That's a feasibility phase of the study; that is not the final study design.

What feasibility means is that accessing cases through AFIP presents certain difficulties that should be recognized.

First of all, when AFIP obtains information

about a person they get it directly from the pathologist and not the primary-case physician. So getting back to a case or the next-of-kin, if the person is deceased, will involve first going to the pathologist, then to the primary-care physician before we reach the patient.

We have a little bit of experience with this in one or two other studies, but we feel we need more before deciding on the final design of this particular study.

In our judgement 100 cases will be quite adequate to give us enough experience to be able to deal with that question.

MR. SULLIVAN: What kind of confidence level do you expect to draw from only 100 cases?

DR. CANTOR: None at all. I repeat This is a feasibility phase of a study The detailed study design will not be in existence until after we have finished this phase.

MR. SULLIVAN: Thank you.

DR. SHEPARD: Dr. Suskind?

DR. SUSKIND: The AFIP has been collecting biopsies and autopsy material of Vietnam veterans who have had cancer, I do believe. Is that not so?

DR. SHEPARD: Yes. But not exclusively. We are establishing an AFIP registry of any Vietnam

veteran. Yes, there are some cancers among them.

DR. SUSKIND: Would any of the soft tissue sarcomas of the feasibility study come from that group? Or is it likely that some of them might come from that group?

DR. CANTOR: I will have to turn to Dr. Lingeman to help me on that.

DR. LINGEMAN: These are the cases which would be accessioned routinely to the AFIP in a different registry from the Registry of Environmental Pathology cases. These would be accessioned by the AFIP and referred to the Registry of Soft Tissue Pathology. All of soft tissues, diseases not just sarcomas are accessioned and examined by pathologists who specialize in these diseases. We obtained a computer writeout listing every case of soft tissue sarcoma accessioned that was in the AFIP in the last five years in the Registry of Soft Tissue diseases.

Now it may turn out that some of these cases are also in the Agent Orange Pathology study.

DR. SHEPARD: Any other questions from members of the committee?

[No response]

DR. SHEPARD: Well, thank you very much Dr. Cantor. We certainly appreciate your sharing that with us, and I hope we can look forward to a further update on

these
efforts.

RECESS

DR. SHEPARD: We are running a little ahead of schedule. Let's take about a four-minute break.

[Whereupon, at 10:50 a.m., the meeting was recessed.]

AFTER RECESS

[11:00 a.m.]

OPEN DISCUSSION - FUTURE EDUCATIONAL EFFORTS

DR. SHEPARD: In the announcement letter for this meeting the members of the committee were asked to come to this meeting prepared to advise us--this is an advisory committee--to advise the VA on ways in which we could improve the process of educating our medical staff and other health care providers on the whole issue of Agent Orange and related matters.

I would like now to have a rather open discussion in the committee. If any of the committee members have prepared such recommendations we would like to hear from them now. If any of them have taken the time to write them down, we certainly want to incorporate them in the proceedings of the meeting.

So I will now open it up to general discussion on ways in which the VA can improve its educational process for physicians and other health care providers.

As you know, we have provided a 30-minute video tape that was designed for the purpose of hoping to educate concerned veterans.

Now we need to get perhaps more scientific information together; so I will just open it up for discussion.

Does anybody have any suggestions?

DR. KEARNEY: Barclay, this may come as a little different approach to the thing; but in agriculture we are concerned about technology transfer of, say, research to the farming community.

Over the last 30 to 40 years we have been extremely successful working with our extension service and ID information people.

It is a very good success story of translating information to our county agents at the county level to work with the farm community.

I am suggesting that we have some techniques and equipment and approaches that might be helpful to you.

As a third party, which does not understand the difficult subjects like what we are dealing with on a medical basis, you might want to chat with them as to how they would handle such a situation; because they come at it not understanding all of the great technology and medical

terminology, but they would come at it as a third party who has had a lot of information-exchange experience, transfer of technology, taking a complex message and making it fairly simple, and a good web of distribution.

So we would make available to you these people we have who are illustrators, broadcasters, information specialists, who might be of some assistance to you--that is, as a third party looking at a difficult subject and making it somewhat understandable and responsive.

DR. SHEPARD: Thank you very much, Dr. Kearney. That is very kind of you.

That is something that we need to always remember, that not only is the factual information important but also the way it is presented.

You can have a very good idea, but if it is not presented in such a way that it is readily understood then it is of little use.

Yes, Dr. FitzGerald?

DR. FITZGERALD: You mentioned the difficulty of keeping the environmental physicians aware of the desirability of certain examinations and facts concerning Agent Orange.

You also have a changing population in these physicians who are examining. Might it not be helpful to utilize the hospitals in close geographic proximity to the

area that might be of concern?

You might have these environmental physicians, newly appointed or the ones who might not be doing as good a job as some of the others, to visit a hospital where you think the job is being done well.

We had criticism, for instance, of East Orange. It might be applicable there, because certainly the information that we are getting at the present time is that the examinations are being accomplished within a reasonable period of time.

Most of the information that we are getting is that they are being scheduled within three weeks. The longest is usually five weeks, but most of them are within two to three weeks.

DR. SHEPARD: I'm glad to hear you say that, because that has been our hope.

Of course we have embarked on a number of initiatives. We have now set up a conference call system on an every-other-month basis.

If we have something urgent that needs to get out, as I indicated on this matter of setting the record straight on Agent Orange exams versus claims, we have already scheduled for Dr. Turner Camp's weekly conference call, the conference call for administrative services, and our own conference call.

We also have our Agent Orange newsletter, which will soon be coming out in the next edition. So we have a number of opportunities.

But I am concerned more specifically at this time -- I don't want to exclude any discussion, but what I am particularly interested in is putting together an educational package that will best serve the needs of our environmental physicians.

Of course, another thing is that we are trying to make the dioxin conference, and this is one reason why I have been so interested in it, this fall, another educational symposium for our environmental physicians, similar to and perhaps more scientifically oriented than the one we had last May.

DR. FITZGERALD: We also received some criticism of East Orange as far as that dermatology examination is concerned, and we are in the process of trying to get information about that.

DR. SHEPARD: Does anybody else have any suggestions? Dr. Suskind?

DR. SUSKIND: I have some questions about the differences between the circular which expired on April the 16th, which concerns the examination of veterans who have been exposed to Agent Orange, or who believe they have, as compared to the new one.

Since we just got this new one in today's folder, I wonder if you would be able to tell us what the differences are, if any?

DR. SHEPARD: The differences are not substantial. The previous circular had some ambiguities in it, and the code sheet--the encoding document--which was used for purposes of entering the data that evolved from the examination or laboratory studies into the computer data bank is now in a more readable printed form and hopefully will obviate some of the errors that have been made in that process.

But there are essentially no major substantive changes between the two circulars.

DR. SUSKIND: To follow up on this, what is being done to train the physicians who are likely to do this examination, properly?

I believe there were two or three workshops, training programs, in the last couple of years. I remember the first one.

Are there any plans to have periodic training sessions for the examining physicians?

DR. SHEPARD: I gather what you mean is in terms of actually the conduct of the examination itself.

DR. SUSKIND: Well, I think that, while forms are useful in that they highlight the questions that need

to be asked, whether by discussion or by physical examination or by laboratory examination, the most important aspect of this is how well-trained is the individual to do this?

DR. SHEPARD: That's a good point, and I guess that's part of the reason this time has been allotted to our deliberations.

If you have some specific suggestions we would very much appreciate them.

To answer your question have we conducted any training programs, other than the two educational conferences we have had no formal training programs.

DR. SUSKIND: Has there been any attempt, for example, to assign teams of physicians at installations specifically for the examination of Vietnam veterans?

This would probably get rid of the possibility of anybody doing it--that is any VA medical officer doing the examination--but rather people who are trained to do the examination, and who know what they are looking for.

DR. SHEPARD: Let me make sure I understand your question. No, there have not been any formal efforts at training teams of physicians in VA hospitals.

We have identified, in each of our medical facilities, an environmental physician with whom we

hopefully maintain an ongoing dialogue.

We provide him with what information we have; they call my office--I must take four or five calls a day from environmental physicians--with a variety of questions.

In terms of specific instructions on how to conduct an examination for Agent Orange, we have not done that. But if you have some suggestions along those lines, we sure would like them.

DR. SUSKIND: In order for this epidemiological study to be successful, you are going to have to do just that.

I am saying that if it is important for a well-conducted clinical epidemiological study to have trained people with a manual of examination, then it is equally important at each of the VA hospitals doing the routine examinations to have the same kind of training; perhaps not a manual as will be eventually developed for the clinical epidemiology examination, but --

Otherwise, the examinations are going to continue to be catch as catch can examinations. That's why we are hearing from hospitals, such as the one in East Orange, that the veterans are not getting proper attention.

DR. FITZGERALD: I think I can clarify that a little. It is my understanding, Dr. Suskind, that the

designated environmental physician is doing the Agent Orange examinations. Now, is this not so?

DR. SHEPARD: In the majority of cases I think that the examination is, for the most part, being conducted by the environmental physician.

I know that in some cases environmental physicians supervise other physicians.

The State of Minnesota conducted a very vigorous and very successful outreach program.

They mobilized their county officers, they identified the Vietnam veterans, they encouraged Vietnam veterans to present themselves to the Minneapolis VA Hospital, and that hospital was suddenly inundated with a large number of requests for Agent Orange examinations.

Much to their credit, they took on this enormous workload with considerable expertise, and they conducted over 1000 examinations in a very short period of time.

It would obviously be impossible for one physician to do all of that; so that's perhaps an extreme case.

But Dr. Petzel, who is the Chief of Staff of that hospital, organized a system in which he set up teams to conduct these examinations.

It is difficult to generalize, because different

circumstances exist in different parts of the country; so I think in the past we have done things on a case-by-case basis, if you will, depending on the needs at a given location.

I certainly agree with you that it would be ideal if we could have environmentally trained or physicians trained in the particular needs of environmental problems.

Unfortunately, the VA has not been structured over the years in this area. Consequently, as I have said so often, when the Agent Orange problem hit us we didn't have, and still to a large extent don't have, the particular expertise to deal with this.

The purpose of the registry, first and foremost, was to identify Vietnam veterans concerned about possible health effects, to get some rough idea as to the current state of their health, and to document this, and to enter them into the registry so that in such time as the more elaborate and more sophisticated research efforts started to produce data, we would have the opportunity and the capability of reaching these veterans.

But certainly your point is well taken, and if we had the resources we would --

I would like to remind the group that all of this registry has been done essentially without any additional

resources being devoted to it; so there are great expectations, and obviously we would like very much to do a lot more than we have done to date.

I am not begging the question; I wish and I hope that we will, over the years or the months to come, put more and more of this kind of expertise into the field.

But, again, if you have specific suggestions about how we could affect such an effort, we would very much welcome them. We really need that advice from you so that we can present it to the new Administrator or the Congress or the President himself, if need be. If additional resources are required to affect a more productive program, then we can highlight those.

Yes, Dr. Moses.

DR. MOSES: You know, for quite a bit of time I have felt about this whole Agent Orange situation, in terms of the veterans, that we are suffering from what I call "the myth of the experts."

Most doctors that I know are fairly intelligent people, and they know how to do a physical examination.

It seems to me that what is needed at the first point is a very traditional, ordinary kind of physical examination.

Veterans ured to call me and say, "I want that Agent Orange test," or, "I want that dioxin test," or

they tell me, "You are the only one that knows how to do this test," in this area, or whatever.

I think that really isn't the case with the greater percentage. It seems to me that there ought to be--and I have discussed this with other people here in this room--that there could be some initial level at which we know all doctors function quite adequately, and I know that the VA doctors can function quite adequately in this.

So this fulfills the veterans need who comes in and says, "I have a problem." There are very traditional ways to assess whether there is a problem, what is their past medical history--all the information here can be incorporated as an adjunct to the past medical history.

Then it seems to me there has to be a next step for certain veterans who will fall out from that, who have additional problems, who may have specific problems of interest.

I think there are two areas that have been brought up ad nauseum which is the same thing that I see in the veterans that I see: skin problems and worry about problems with their children, either children they already have who have learning problems or who are hyperactive.

Very rarely is it actual birth defects themselves. It is usually a behavioral or an activity-type of problem. I don't know if this has been the experience

with other people or not.

It seems to me, if the VA really wants to do this it can help itself a lot by letting the traditional doctors do the traditional things and save the experts and the people that they train--and I have an idea of how you might do that, too--to train those people to deal with what falls out from that initial examination.

It is not really a screening. I think this was a big mistake in the beginning--people thought they were being screened. I think they need a very detailed medical examination which the VA is quite able to do.

Now, in terms of skin--and, Dr. Suskind, one of the people on this committee, is quite able to help with this--I think a good slide show on chloracne, showing what it looks like in the acute, a severe situation, can be used.

We have some and I'm sure Dr. Suskind does, Dr. Taylor, Dr. Carter--there are lots of people who have some of this--for the physician showing what chloracne is, with some expert commentary from someone like Dr. Suskind, to answer some of the other questions.

That could help a lot with people who are seeing something that couldn't remotely be that, but who have no idea what it is. I think that could be done very easily.

I think the other area where a slide show should

be used, but I don't know who the experts in this area are, I think someone should attempt to deal with this whole genetic question and prepare a slide show on that.

There is nothing wrong with saying, "We don't know." I don't see anything wrong with that.

I think that could take care of those two problems. You could put those things together, duplicate them, ship them out.

EPA has done this very successfully with pesticides, training people in the migrant health clinics regarding toxic exposure to pesticides, and what physicians should do, and how to treat, and that sort of thing.

I don't know if this is within something the VA could do, but I think it is a very simple thing, would not cost very much money, and I think it could really help.

DR. FITZGERALD: I agree with Dr. Moses, but there is one factor in this that I think is essential; and that is to have this designated physician doing these examinations not because of his expertise, per se, but because of his sympathetic approach to the individual.

All too frequently a physician who does not have this interest at heart will feel provoked at having to do such an examination. That is why I think it is essential that an individual who is anticipating doing this type of

examination and who will be sympathetic to the veteran is a major portion of this.

Then I agree with you, if he finds anything, to refer to an expert in the field.

DR. SHEPARD: Dr. Hodder?

DR. HODDER: There is one point I would like to make. People look at the epidemiologist as someone who goes out and gets data; but we have also learned some other things along the road in terms of how getting data can be a problem.

You mentioned that this isn't really screening, but in some respects certainly it is a screening program. One of the great dangers you can get into in a screening program is looking for too much.

What I am particularly interested in concerning that is, when you look for a screening test, you want a definite series of steps that you are going to make after that to be laid out.

That allows you to do a cross-benefit analysis of, "I'm looking for a possible condition; I have to do this type of diagnostic test and perhaps this type of intervention," which also entails a certain amount of risk. So we have a cross-benefit type of thing.

We could certainly find pancreatic cancer, for example, using a cat scan; but with the false positive and

requiring abdominal surgery to rule that out we would probably cause more damage than good.

I am concerned about the educational component here when you develop such a large battery of tests, that you are going to get an awful lot of false positives in this.

Therefore, I think one of the guidelines that also needs to go out is what one does if one gets a mild elevation of billirubin, say or a mild elevation of alk phos / otherwise in fact, the screening program potentially could do some harm that was not intended.

DR. MOSES: Could I respond?

DR. SHEPARD: Sure.

DR. MOSES: I feel very strongly about this, and I am going to speak very strongly about it.

I think we have to separate epidemiology and service. These veterans are not coming to be part of the study. They are coming because they want to know, "Doc, what's wrong with me?" And, "Can it be treated--whatever it is?"

I think that there is a lot of confusion on this score, and I think that is a lot of the problem with doing what really needs to be done.

Many of the veterans now know that there are not definitive answers to a lot of these things, and I

have found veterans very acceptable to the concept, "Well, let's just find out what's wrong. Let's see if you are okay. We'll check everything."

And then I say, "We may not know if this is from Agent Orange or whatever exposure, and if there is anything wrong we will follow it up."

That is why we don't take anybody in our clinic unless we know that we are going to be able to follow these things up, and we make a commitment to follow these things up.

Now that is very different than sending out a big circular, getting all of the veterans to come in to do an epidemiological study; although I agree with Dr. Suskind, very much so, that whoever is doing either one of these things should be knowledgeable.

But I feel that we are going to be doing a disservice to veterans if we bring them in for examinations under the term "service," and try to use that information as an epidemiological survey, when that well might be self-selective, they are coming in for all kinds of reasons.

I think that is one of the problems that we get into, that we want to give service and say, "Well, as long as all of these people are coming in anyway, let's get this information and get that information."

I frankly don't think that that's an epidemiological survey. We have talked about this, Barclay, several times.

I think what has to happen is we have to give service to these veterans, as well. To me, that's still what is missing. I am still getting calls from veterans all over the country.

We should give them service if the VA is doing its job. When the veteran is going there and getting the service, really all they want to know is about them, personally.

I think that is do-able, I really think that is do-able, and I think it is a very different question than trying to answer the epidemiological question of liver disease, of skin problems, cancer, and birth defects. I think that is a different question.

DR. HODDER: I think we are talking on two different points here, actually.

The point I am concerned about is, if you take apparently healthy 40,000 people and do an SMA-12 on them, that chances are the positives you are going to get out of that screening are predominately false positives rather than true disease.

What I am concerned about is that a physician used to health care, rather than in a context of looking

at healthy people, must be aware that there is a different pattern of follow-up to a positive alk phos, for example, in the healthy population than it would be in someone who comes in complaining of being ill.

That is what I am concerned about. I think there is an educational component that ought to go out, so that the physicians don't find themselves doing a more extensive battery of tests than they ought to be doing.

DR. MOSES: Well, that is what this second level thing that I suggested is.

For instance, one decides at what level of alk phos you are going to trigger this second exam, or whatever. And that could be done by the initial examining physician; say they know that this person has a heavy alcohol intake, it well might explain it all, and they may not even want to proceed any further.

That is going to give back to the primary physician -- there are going to have to be these kinds of decisions made all across the line or, I agree with you, you are going to be overloaded with data and you are really not going to know what it means.

But I still think that particular individual really doesn't care about somebody else's alk phos. They care about their own. And I think that's where the VA is missing the boat.

I really think the VA is missing the boat on this. It is not because they don't care.

We heard it today, and I think we heard it very strongly. I don't know how pervasive a problem that is, but if it is, I think we should try to address that and not our epidemiological concerns as scientists. We must address that also, but I think that is being addressed.

I think this other thing isn't being addressed, and, even though it is problematic, if you do the tests -- that's the thing about doing tests on people: you are stuck with trying to figure out what it means if you get a positive result.

DR. HODDER: But what I am saying is that for a doctor who is used to doing a battery of tests on an ill population, the cost-benefit component favors doing an invasive test even because his yield is very high on a population that is walking around.

So what I am talking about is, the training of a general internist. For example, the hypertension workups years ago were developed in the tertiary centers by such people as John Laragh and people at Columbia P&S. The general physician started to use that workup, and they were doing IVPs on just about everyone, the incidence of dye actions and other problems from the testing

procedure was worse than what you would have had if you hadn't bothered doing it.

DR. MOSES: Do you think there is anything in this protocol like that? I didn't see anything.

DR. HODDER: Not if there is guidance; but if you are doing an SMA-6 and an SMA-12, for example, on a lot of those tests 5 percent of your population is going to be read as abnormal.

So if you take 20 tests times .05 for each one, you are going to have an abnormal test on probably 20 or 30 percent of your people.

Now what I am saying is in that case you need guidelines to tell people not to jump on a testjust because they get one thing a little high. Repeat it in a certain period of time or match it up with other data/-- you know, if he has a little SGOT elevation/, but everything else is absolutely normal and he doesn't have any liver tenderness or anything, ignore it.

That is what I am saying. I think there is an ecucational component here which is independent of Agent Orange which may be very important to prevent an inadvertent problem--over-workup.

DR. SHEPARD: I think that is a good point. DR. Lingeman--you had your hand up a minute ago?

DR. LINGEMAN: I think it's very nice that we

have so many other sectors involved in this--the State Health Departments, and so forth--and I think they should be commended.

I think each one of these can take a different aspect and study one problem intensively, and yet not dilute the effort.

If we study 100,000 veterans we may be diluting the quality of the care and the examinations.

We need to use more of the private sector, I think. And I would like to see more of the private physicians instructed on what the issues are.

Most people who are working already have some sort of health insurance, so why tax the already over-taxed VA system when we do have other possibilities?

People sometimes live great distances from VA hospitals and would rather use their local physician and their own health insurance to do this, and they may get a better examination.

I mean that they will get more of this personal attention you are talking about with someone who will sit down with them and relieve their anxieties. I think we are creating psychiatric problems in some of these cases.

DR. FITZGERALD: Unfortunately, Dr. Lingeman, the statistics in 1979 showed that of the veteran

population who were hospitalized or were under care of the Veterans Administration, the non-service connected veteran, only 49 percent had outside health care insurance.

DR. LINGEMAN: Well, we still need to do some education, both of the VA physician and the non-VA physicians. I think we could use the medical channels such as the AMA, and I think the AMA convention should have a big exhibit the next time they meet, in Las Vegas or wherever.

[Laughter]

DR. MOSES : Maybe they should meet in Orange County.

DR. LINGEMAN: But the local medical societies could also be brought into this with various educational programs. Specialty organizations, such as the International Academy of Pathology, for example, of which I am a member and which has a committee that sponsors our registry, is a good place to educate the pathologists on what is Agent Orange? What is chloracne?

The average pathologist cannot look at a slide and say it's acne, let alone it's chloracne.

We wanted to prepare an educational kit, and we had to go to Japan to get a case of chloracne.

DR. SUSKIND: Well, I think that it would appear that those who are looking for things like chloracne, and

have to go to Japan to find them, don't know what is happening in the United States.

DR. LINGEMAN: I called Dr. Taylor and asked him if he knew where I could get some biopsy material from chloracne, and he was not able to furnish it. You don't biopsy, ordinarily, lesions suspected of being chloracne do you?

DR. SUSKIND: Yes, we do biopsy. When we did our study in Nitro we biopsied a lot of cases.

DR. LINGEMAN: May I ask you where those tissues are now?

DR. SUSKIND: They are in my office.

DR. LINGEMAN: Would it be possible to get some just to prepare educational material for pathologists?

DR. SUSKIND: Very easy to do that; sure.

I am a little concerned that we are off the subject. I really am. I think what we really need to do is to train the doctor, not just in the physical examination.

I agree with Dr. Moses that a screening examination can be a thorough routine physical examination; but what kind of history is necessary? The history is not an ordinary history. The history is not just a good medical history but a focus history--you are looking for something. And you are looking for a lot of things; so that your history has to be keyed to the problem, just

like you do in cardiovascular examinations or pulmonary examinations.

The historical information is a critical part of this assessment. So the physician should, indeed, know something about why he is asking these questions. And that requires education.

You simply can't throw this in the lap of a doctor and say, "Do it," because it isn't going to work out. You have to educate him; you have to train him; and you have to give him reasons why he or she is doing it.

Frankly, it is not necessary to train the VA general physician or internist to be a dermatologist. It isn't necessary to do that.

It is necessary, and we have had conferences with the VA Dermatology Advisory Committee, which is a very good one, on even training dermatologists as to what chloracne is.

I have to tell you that the head of that committee came to the conclusion that there is no difference between chloracne and acne vulgaris. He couldn't see the subtle differences.

DR. KINNARD: Chuck, I would just like to underscore what Dr. Shepard said earlier concerning what the VA has actively done in terms of training their environmental physicians.

Now, I wasn't involved in this activity when the environmental physicians were selected, so I don't know what the basis for that selection was.

I do know that last May at the Sheraton in Silver Spring there was an Agent Orange conference in which each one of the environmental physicians at the VA medical centers were invited, and most of them attended. This conference was designed to update knowledge on what we had found out about Agent Orange since the previous conference was held.

I recall one of the hallmarks of that conference was that there was a film shown which depicted the way that a person presenting themselves at a VA medical center with complaints about Agent Orange, how they should be handled from the standpoint of the psychological input as well as the actual examination by the environmental physicians. The film that showed how it should be done and how it should not be done. Now, I don't know whether there was supposed to be any follow-up from that. I think the REMC in St. Louis made that film.

Yes, there has been a considerable amount of effort going into the training of the environmental physicians to respond to both emotional concerns as well as the actual medical concerns of these veterans.

MR. MULLEN: Dr. Shepard?

DR. SHEPARD: Yes.

MR. MULLEN: Getting back to last May at the Sheraton, when you selected these environmental physicians and appointed them, I specifically recall a lot of them in the audience being hostile to that appointment.

In fact some of them even voiced the opinion that the whole Agent Orange situation is political, that it is not medical and shouldn't be taken care of in the hospital.

Some of this hostility is reflected in the complaints that are being rendered by the people who are being examined. I think that is one of the biggest problems.

DR. SHEPARD: I certainly accept that to a certain extent. I think it is also safe to say that we often hear from the vocal minority. I would hate to have it characterized, or I will not allow to go unchallenged the impression that the majority of our environmental physicians don't care about the program or don't think it is a medical issue.

That certainly has not been my experience, and I have talked to a great many of them.

As I said, no additional resources were placed in our medical facilities; so the whole Agent

Orange program has been conducted with existing resources, both personnel and dollars.

So the task of carrying out this program has been in addition to their regular duties. That's one of the problems, I'm sure. There are many problems.

But my experience has been that our environmental physicians, as a group, are doing extraordinarily well. I think they have been very responsive to suggestions that we have made.

As I say, I get calls very frequently, albeit I may get a self-selected group of environmental physicians but I am continuing this.

I will give you some examples of where I think they have gone far beyond what was expected.

In Eugene, Oregon, about 10 days to two weeks ago there was a large West Coast gathering of Vietnam veterans.

I was asked to go out, but unfortunately had another commitment, and I couldn't go. On very short notice--and my notice was very short--I called on two of our environmental physicians, one at Palo Alto and one at our VA Hospital in Seattle, Washington.

They leaped to the opportunity. This was on the Easter weekend, the Saturday before Easter--not a very convenient time.

They both went out very willingly and gave of their time to conduct an educational conference on Agent Orange. And that is just one example of many that I have.

Not only are they dedicated to the program, I think they are knowledgeable. My impression is that many of them have gone out and educated themselves.

We constantly get requests for materials. I wish we could provide them with more material. That is basically what I had this part of the agenda devoted to. I want some help from you as to what more additional information we can be providing them, and how we should be providing it.

DR. MOSES: Why don't you use them as traveling road show?

DR. SHEPARD: They do that all the time. The environmental physicians go out and educate each other. They often visit each others' facilities. And we encourage that whenever possible.

I think that has been a very useful discussion. I would now like to open up the discussion to the floor.

COMMENTS AND DISCUSSION

DR. SHEPARD: I have a question from Peter

Kahn which I think we have already dealt with, and we will certainly go into it in more detail this afternoon.

Todd Ensign, from Citizen Soldier, asks of Dr. Striegel: "There are, of course, no studies of direct effect on humans. How does he characterize the Dow-financed work of Dr. Albert Kligman on prisoners in Philadelphia? Is his work part of the literature being reviewed?"

Unfortunately, I don't think Dr. Kligman ever published his results; but Jim, would you like to address that?

DR. STRIEGEL: Yes.

We do have access to the information about Dr. Kligmann's work from some testimony that was provided to the Environmental Protection Agency, and that is included in our data.

DR. MOSES: That brings up an interesting question about how much unpublished data there is. When you were here before you said that there was going to be no unpublished, right?

DR. STRIEGEL: No. The mandate we have is to consider the published literature; however in cases like Kligman , being a perfect example, studies where there is something controversial that we know of, we make an effort to get those in.

DR. SHEPARD: Thank you.

Is there any other discussion, comments, questions from the floor?

I would like to recognize Jon Furst, who is, I believe, the President of the National Veterans Task Force on Agent Orange.

MR. FURST: The chairman.

DR. SHEPARD: Jon, what can you tell us about the upcoming meeting? Why don't you come up here and have a seat?

MR. FURST: Many of you are familiar with the Task Force. Ron De Young was the representative of the Task Force.

It is a coalition of about 25 groups at this point. We are having a conference at American University here in Washington on Saturday and Sunday of the Memorial Day weekend, that is May 23rd and 24th.

There are a number of people who will be there: the Stellmans--some of you are aware of Dr. Jean and Dr. Stephen Stellman.

Dr. Barry Commoner has expressed some interest; but I won't commit.

The idea was to provide a forum where veterans could be exposed to people who are familiar with the literature in various ways; not only the medical literature

and the scientific literature and what is and is not known and what is expected, et cetera, but also the legal and the legislative, and all of the various efforts that are ongoing from veterans' standpoints on small scales to State-size scales to national scales, et cetera.

We hope that it will be an extremely profitable situation as far as information goes for the veterans themselves.

We are inviting the veterans, we are inviting the veterans' family members, we are inviting all interested individuals in the community who can attend.

I am able to inform you that preregistration can be accomplished by contacting our conference coordinator in New York.

Professionals and others are requested to pay a $40 registration fee. Veterans assistance organizations are requested to pay a $15 fee; and veterans are requested to pay a $10 fee.

Preregistration, if you will bear with me I will read it once slowly so as not to take up your time.

"Preregistration can be accomplished by contacting Ms. Ruth Schaeffer--S-C-H-A-E-F-F-E-R. She is the task force's conference coordinator. She is available at the Veterans Affairs Office, City University of New York, 535 East 80th Street," and I recommend that

you add after the East 80th Street "Caldwell" so that the Post Office knows what building, "New York, NY 10021. Her phone number is (202) 794-5757.

"There is an additional $5 fee charged if preregistration is not accomplished."

DR. KEARNEY: We are quite interested in this. Do you have any paper on that? Could you provide, perhaps the committee members with some background on that? A list of speakers or registration or any information you have would be helpful.

MR. FURST: Sure. I will get things to you. I have the addresses here.

DR. KEARNEY: Very good. Thank you.

MS. JORDAN: I was given a number at A.U. where I could call and get any information I wanted on that. Do you have that number?

MR. FURST: Yes. Actually I can be reached. My wife and I have been in town for a month, and we are working at A.U. now, and we will be there until after the conference.

You will forgive us for our untidy timeliness--we are living out of a suitcase and have been for a month and will be for another month.

You can reach us at 686-2741 in Washington. That phone is provided by the graciousness of the National

veterans Law Center, which is allowing us a place to spread our paperwork.

Thank you very much.

DR. SHEPARD: Are there any other questions for Jon?

[No response]

DR. SHEPARD: Thank you very much, Jon.

Mr. Kaatz has forwarded a question, and I must confess that I cannot quite make out the first one. Would you like to ask the question directly, Mr. Kaatz?

MR. KAATZ: Well, it's more of a topic, maybe, for the panel to think about, more than anything else.

It would seem to me that if you are looking primarily for sources of topological insult in trying to examine a veteran, you are never going to find it in the examinations that are being conducted.

Number one, logic dictates that when you have a situation where we are concerned about the issue of teratogenisis, particularly of herbicides, you are going to examine the veteran; but you are going to examine the child and you are going to examine the spouse.

Maybe you are not going to physically examine the spouse and the child, but at least they should have done something to obtain general releases from these veterans in order to get the medical records of those veterans who

are concerned about birth defects in the children, especially where there are actual cases.

Now, I am a veteran with two children, both of those children have birth defects; and I have been somewhat critical in the last year, as Dr. Shepard and some of the other people on the panel know, as to what has been going on.

Personally, I don't see where Agent Orange comes into the picture in most of these cases; but what I am saying is that if the VA had gone out in the very beginning and conducted a comprehensive physical examination, to include a genetic study on the veterans, and had taken a look at the child's birth and medical records, and had taken a look at the spouse's medical records, you would probably eliminate about 70-80 percent of the cases.

I have two children who are in a program with 505 other children at a major medical center. The children go there on a regular basis; we have full-time staff of competent doctors and geneticists, and everything else that is needed.

There are veterans' children in that program, and the veterans' children are not treated as an issue of Agent Orange. One of the things that upsets me and upsets a lot of veterans and parents around this country is the fact that there is a lot of hype--and I can only call it "a lot of hype"--being put out by some veterans organizations that have

actually terrorized parents with disinformation. This is completely uncalled for. That's one problem.

So we have a group of fathers or parents going over to the VA, expecting to get an examination that is going to bear out some type of information as to say whether or not they should have children in the future, or "Should my wife have another child? Or should she abort her next baby?" and so forth. This has terrorized the parents.

Most of the fathers with children who have birth defects, complex medical disabilities --we are working people, we go to work, we are involved in business--it is usually the wives who are taking the children to various programs around the countryside.

The wives get exposed to one or two veterans unannounced groups who visit these programs and say, "Well, did you see this report? Agent Orange causes cancer, and Agent Orange causes this; and dioxin that is stored in husbands and your fat tissue is going to be transferred in sperm to the wife, and you are going to have a child who will have a birth defect."

That's when I became involved in this issue. I blew my top. A group of fathers in one program got together and said, "Look, there is not going to be any more of this terrorization of wives or families in the

area that we are in. We don't allow it, number one."

Number two, in the Veterans Administration, somewhere along the line, the people around this table are going to have to forget about these epidemiological studies for the moment and go back to the very, very basics--and I have been dealing with this issue for 10 years--and that's (1) doing an examination on the veteran that is comprehensive, and doing at least a genetic study.

Now, Dr. Moore, whom I respect very highly and have read a lot of his studies and a lot of information that has come out of NIH, says, "Logic dictates that if there was some permanent damage to the spermatogonial cells," that would be an issue of concern here as far as teratogenisis." I don't see it. I don't see that damage, in my own case there is no scientific data to support it and I don't see it among the veterans in our program, or anyplace else.

Now, logic also dictates that if you do a genetic study on the child, even if you don't do a genetic study on the veteran, it might show some form of genetic effect. We are not saying that this could indicate cause and effect either.

What we are saying is that there are a hell of a lot of other medical problems among veterans may be virally-related, may be related to dormant viruses or a number of other factors; but nobody is going to pin it down until you take the veteran and look at the veteran as a

family group, because that is what we are all concerned about--we are concerned about children here; we are not so much concerned about ourselves.

If the VA says I am a very healthy man, if they send me a letter, okay--I am healthy. I am concerned about the children more than anything else.

The VA does not have any outreach program where they say to the veteran, "Okay, here we have a child involved in the issue. You have two children; you were exposed to Agent Orange," and I was--I know what the herbicide is.

I don't see the VA referring these parents or referring any of these children to any kinds of medical programs. And this is a problem, a very big problem, for this reason.

I came in contact with the president of one veterans organization who spent five hours in my house. He told me how he represented 10,000 veterans in his organization.

He was going out there and trying to set up a clinic in humanistic medicine to examine veterans and children so they could be treated.

Now the major issue here is treatment of the veteran. You know, most of us are willing to sit back and say, "Okay, you people are scientists. Five or ten years from now you might come up with some answers."

But in the meantime the major concern among the

veterans is the children--not anything else, not even his own health in most instances, but the children.

And until such a time that somebody sits down and establishes a protocol for doing these medical examinations the way they should be done -- and I listened somewhat to what Dr. Moses says. I agree with what she has said in context: it is not being done right. Improper instructions are going out to VA doctors, and the doctors in a lot of cases are not asking the kinds of questions that should be asked when we are concerned with the genetic insult.

Particularly when the veteran walks in the door and has a child who is disabled as a result of birth defects that's probably the reason he is there.

Now, I have talked to a lot of these people and have observed first hand what goes on at VA facilities. He walks out and two weeks later gets a letter saying he is perfectly healthy, okay? Fine. He is perfectly healthy; but he still has a child who has a problem and the veteran may also have a medical condition.

Unless the issue is addressed to that child we are never going to solve this problem, okay?

In my own case, and in cases of the veterans who are affiliated with our parent organization in this one medical center, we don't see the Agent Orange as being an issue here. We do see a major national health issue concerning care for the veteran and child.

What we do see is a hell of a lot of other

medical factors that are affecting veterans. The VA is not addressing them. The veteran walks out with a letter, and that's all he has.

The VA doesn't say, "Okay, we have a medical facility in this county that can provide genetic counseling for the children, that can do some genetic studies on them."

It's a very simple thing to do. It's a smear from the throat or it's a blood test--you grow a culture. Something very, very simple that should have been very basic, in the very beginning. It has not been done.

The thing that disturbs me most of all is that the Veterans Adminstration doesn't even have a facility anywhere in the United States capable of doing a single genetic study. You know, I just find that incredible.

Now, if they don't have it, they should have a doctor sitting there saying, "Okay, you have children or a child--what's wrong with the child." Let's get a general release on the child's medical records; get a general release on the wife's medical records; we'll get a panel of doctors at a VA Hospital who are experts in various fields around the table, and we will go through these medical records.

You will probably find out that a lot of cases involving / cerebral palsy , spinal bifidus , and a dozen other

incapaciting diseases are probably malpractice in some cases, or other incapacitating conditions that have nothing to do whatsoever with Agent Orange.

Of all the veterans that I have seen--and I have talked to several hundred personally--I do not see Agent Orange as the issue here.

Until the people around this table sit down and structure and define a physical examination that has to be done to include comprehensive review of the medical records of the veteran, spouse and child the issue will never be resolved!

I think you can eliminate about 70 percent of the claims, and maybe even higher. There are doctors in this country, experts in this country, that I've talked to who are seeing a large number of cases of cerebral palsy among the children of veterans. In most cases, according to one prominent neurosurgeon in this country, 70 percent of those cases are the result of malpractice, and have nothing to do with Agent Orange whatsoever.

But what do we see? We see a load of hype in the newspaper, a bunch of organizations handing out literature about Agent Orange, and the parents become terrorized. And the next thing you know the whole fiber of that family is destroyed.

DR.SHEPARD: Excuse me, Mr. Kaatz I am going to have to interrupt you. I appreciate your point,

and it is a need that we have recognized.

MR. KAATZ: I have one other point.

DR. SHEPARD: I'm sorry, the time is up. We have one other question. If we have time then we will come back to you, okay?

But I do want to address the concern about the genetic counseling. It has not gone unrecognized as a need and as a void. I think that we need to start taking some initiatives in terms of filling that void.

I have a question here. I think we will have to ask Dr. Shibko it if he can, since he is representing the EPA today.

This is from Mr. Ryan Kruger: Why were the cancellation hearings on 2,4,5-T stopped? And what is the status of the out-of-court settlement that has been reported to be appearing?

DR. SHIBKO: I think you mean Dr. Spencer.

DR. SHEPARD: I'm sorry.

DR. SPENCER: I wish he could answer it.

[Laughter]

DR. SPENCER: As a matter of fact I did get in touch with a lawyer last night, at your request in fact, and unfortunately I don't have anything to report to you; because, probably a good analogy would be, if our State Department had as good a tight lip, we would probably not

be in as bad a shape as these people who were running it, because I got absolutely nothing from them.

I can only say that they are negotiating, hopefully for the good of the people, that they are supposed to go into report to the judge whether to continue the hearing for cancellation or whether to continue negotiation, or just what they are going to do, as of this Friday.

That is, in essence, all that I know about it.

DR. SHEPARD: I think we need to appreciate the fact that this has been a matter under considerable investigation, and we are in a sense putting Dr. Spencer in a little bit on the spot to speak for the EPA.

Perhaps suffice it to say that the hearings have been suspended, and the parties are in the process of negotiation.

Are there any other questions from the floor?

[No response]

DR. SHEPARD: All right, Mr. Kaatz, you have it.

MR. KAATZ: In this country, right now, there is a $40 million program called the NTP, or National Toxicology Program.

I don't see that program being effectively integrated into this issue concerning veterans and of Agent Orange. It would seem to me that some based on

studies and the protocol that has been established around this table, for studies are duplications of what is going on in the National Institute of Environmental Health, what is going on in the FDA, what is going on in the Department of Agriculture out there in Pine Bluffs.

When I find that people like Dr. Young, Department of Agriculture especially, who is the head of the Division of Teratogenisis, has not even consulted on matters concerning Agent Orange, particularly when they are concerned primarily with 2,4,5-T and other types of pesticides and insecticides, I don't see that $40 million integration into this picture.

It seems to me that a lot of these problems are already in the process of being examined by the National Institutes of Health and other government laboratories under this $40 million NTP program.

I see that the VA is doing a paper chase on worldwide literature and review, when we have a National Library of Medicine, we have a National Institute of Health that has a computer division specifically designed to establish and set up models for computers, and doing epidemiology surveys and everything else.

I see a tremendous amount of duplication and a

lot of wasted effort, when the VA could be turning to certain agencies of the government rather than giving contracts out duplicating the efforts of other government institutions.

If you take the Annual Report of the National Institutes of Health, you probably have the resources of some of the best medical and scientific experts / research programs, in the world. I don't see the integration of resources available, / nor do I see the effective /integration of the National Toxicology Program in solving the overall issue.

DR. SHEPARD: Can I answer your question?

MR. KAATZ: Yes.

DR. SHEPARD: Okay.

We had hoped that Dr. Moore would be here today. He is a member of this committee and is the Deputy Director of the National Toxicology Program.

He has recently published the results of a laboratory study that he conducted specifically on the subject of genetic effects that might be expected to result, in which he exposed a group of male mice to the ingredients of Agent Orange.

So there has been some effort. You have heard from members of the National Cancer Institute, which is an arm of NIH. Dr. Lingeman, specifically, is a member of our committee. She works there.

And Dr. Cantor was here today from the AFIP.

So I think it is safe to say we have made some efforts to bring in other Government agencies. One effort that you may not be aware of and which I should have alluded to earlier is the very good work of the Inter-agency Work Group, which represents a number of Government agencies including the VA, DOD, and the Department of Health and Human Services. Dr. Moore is the Chairman of the Science Panel of that group

So I think there has been an effort to integrate a lot of Government efforts.

You commented about the National Library of Medicine in doing literature searches. The contract that Dr. Striegel alluded to earlier and reported on is not a literature search. As far as I know nobody has undertaken an indepth analysis of the world literature on this subject; so this is really a first. We went the contract route because we thought we could get it most quickly that way, and probably most cheaply.

So that may, in part, answer some of your questions, some things that you simply weren't aware of, Mr. Kaatz.

MR. KAATZ: What I am saying is, if you take the Annual Report of the National Institute of Health, and if you break that annual report down and see the kinds of services that can provide to the

American people in this country, I see no need to go out and award contracts to anybody.

What I see here is a lot of duplication of research efforts and a lot of very poor coordination.

Now, one example of this is the CBW example. If you go back to military history of World War II and look at the old "War Research Service" that George Merck headed--he was a very brilliant man--he brought together 3900 experts who examined the chemical warfare programs of two nations, Japan and Germany.

As an end result of that they came up with a lot of peaceful uses of chemicals in agriculture, namely 2,3,4,5-T. Now, what I do not see here with this Agent Orange issue is the kind of effort that George Merck made during World War II on bringing the kind of people together to resolve this issue at hand.

I think if they were brought together the issue could be resolved. I beg to differ. While there are representatives here of many of the Institutes within National Institutes of Health, I do not see the key experts in this country involved in this issue that have the experience or the know-how,or have been working for the last 30 or 40 years in the field of toxicology.

Now, I have talked to a few of them, some of them being Nobel Prize winners. They are not here; and that's what concerns me.

If we had a Chemical-Nuclear-Biological attack tomorrow morning, everybody in the whole country would be concerned about/teratogenesis, the subject of and they would bring these people together and say, "Okay, we have a potential vulnerability / to humans, let's deal with the situation."

I don't see that here. I don't see the kind of effort that was made during World War II in solving the /problems, present It's just not here. It's not at this table.

The agencies that should be here are not here; the people that should be representatives from the National Institutes of Health are not here; and I see $40 million dumped into a National Toxicology Program designed to solve problems like this.

If they can't solve a problem like Agent Orange, I don't know how they expect to solve any other kind of problem as far as toxicology in this country.

You have to get the people who know what they are doing together. Now, a lot of the people at this table are well-qualified; but what I am saying is that George Merck had 3900 people out there, and I think it's time that we try to fall back on some of those people. They are still around in this country. They know more about toxicology and chemical warfare and would be able to provide a significant contribution to solving this issue.

I think if anyone had an idea of what was going

on with herbicides some of those people should. They dealt with the issues. They are the ones that turned the herbicides over to the chemical companies for peaceful uses in 1946; and that's the basic issue here.

DR. SHEPARD: Thank you, Mr. Kaatz. I appreciate your comments.

Are there any other comments or questions?

[No response]

DR. SHEPARD: Well, thank you again for your indulgence and participation in another very worthwhile meeting.

Thank you.

[Whereupon, at 12:05 p.m., the meeting was adjourned.]

C E R T I F I C A T E

This is to certify that the foregoing proceedings before the Veterans Administration, Advisory Committee on Health-Related Effects of Herbicides, Tuesday, May 5, 1981, were had as herein appears and that this is the original transcript thereof.

WILLIAM J. MOFFITT

I hereby certify that the proceedings and evidence herein are contained fully and accurately, as corrected.

BARCLAY M. SHEPARD, M.D.
Chairman, Advisory Committee
on Health-Related Effects of
Herbicides

June 30, 1981

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Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

(Ninth Meeting

August 19, 1981)

September 1982

Washington DC 20420

VETERANS ADMINISTRATION

ADVISORY COMMITTEE ON HEALTH-RELATED EFFECTS OF HERBICIDES

Veterans Administration
Central Office
Room 119
810 Vermont Avenue, N.W.
Washington, D.C.

Wednesday, August 19, 1981

The Committee met, pursuant to notice, at 8:30 a.m.
BARCLAY M. SHEPARD, M.D., Chairman, presiding

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PROCEEDINGS

CALL TO ORDER AND OPENING REMARKS (8:30 a.m.)

DR. SHEPARD: Good morning, I think we'd better get started. We have a full agenda this morning. I would like to welcome you all once again to our quarterly meeting of the VA Advisory Committee on Health-Related Effects of Herbicides. It's an ongoing pleasure for me personally to continue this forum which I think serves a useful purpose in bringing together large segments of our interested population. He have here both scientists and representatives of veterans organizations. I think this forum affords the opportunity for a meaningful dialogue and I hope a useful one. We have some welcoming today. Jon Furst, has officially been designated a member of this committee. He is the chairman of the National Veterans Task Force on Agent Orange. Jon, it's a real pleasure to have you as a full-fledged member of our committee.

MR. FURST: Thanks.

DR. SHEPARD: We also would like to recognize Major Al Young who has come to us on loan from the Air Force. Many of you know Al Young to be a leading and very knowledgeable authority on the subject, having done much of the scientific work himself and having contributed extensively to the whole

body of knowledge as it relates to this complex issue. So we're very pleased to have Major Young with us on our staff and we are very grateful to the Air Force for loaning him to us.

We also would like to recognize a number of distinguished visitors who are with us this morning. First of all, Dr. Robert Bernstein, the Commissioner of Health for the State of Texas. Dr. Bernstein had a distinguished career in the Army and was, I believe, at the time of his retirement, the Commanding General of Walter Reed Army Medical Center. We are very pleased to have you with us this morning, sir. He will address the committee later on in the program. With him are some other representatives from the State of Texas, and we are very pleased to have them with us. Representative Larry Shaw, I haven't met him yet, but, he may be here. If he is, I wish to thank him for his presence. He was the drafter of the Texas legislation. In an ongoing attempt for us to act as a clearinghouse for information with various state organizations which have taken an active role in the concerns as they relate to veterans and Agent Orange, we welcome him.

We will be having a meeting this afternoon in my office with some of the representatives of the state organizations.

Another individual whom we'd like to recognize is Mr. George Brett who is the Executive Director of the Agent Orange Commission in the State of New York. George will be with us a little later on. We'd also like to recognize Mr. Mike Leaveck who represents the State of California. As you know, California has recently initated legislation for efforts relating to the Agent Orange issue.

Since our last meeting, as you all know I'm sure, we have a new Administrator of Veterans Affairs. Mr. Robert Nimmo from California has been duly installed as the new Administrator. He wanted very much to be with us this morning, but because of conflicting commitments, he could not. However, he has sent you his greetings in the form of a tape and we'll now ask that that tape be played.

MR. NIMMO: MESSAGE FROM THE ADMINISTRATOR (tape) Well the fact that I'm not able to be with you today is my loss, not yours. I'm much more interested in learning your thoughts on Agent Orange than giving you mine.