Uploaded to VFC Website

November 2012

This Document has been provided to you courtesy of Veterans-For-Change!

Feel free to pass to any veteran who might be able to use this information!

For thousands more files like this and hundreds of links to useful information, and hundreds of "Frequently Asked Questions, please go to:

Veterans-For-Change

Veterans-For-Change is a 501(c)(3) Non-Profit Corporation
Tax ID #27-3820181

If Veteran's don't help Veteran's, who will?

We appreciate all donations to continue to provide information and services to Veterans and their families.

https://www.paypal.com/cgi-bin/webscr?cmd=_s-xclick&hosted_button_id=WGT2M5UTB9A78

Note: VFC is not liable for source information in this document, it is merely provided as a courtesy to our members.

In terms of including the Vet center leadership in our conference calls, I wholeheartedly agree, and I think I am right in recalling that we have made that suggestion. If I am not mistaken, we have asked -- certainly we have invited Vet center people to come in to the medical centers to be a part of that. I think I am right in stating that the networking process for conference calls does not include the Vet centers. In other words, they are not hooked into the VA conference call process, for reasons that I am not aware of.

But we have suggested that team leaders, at least, be present in their cognizant VA medical centers during the time of the conference call. We will try and work on that more, so that they are, in fact, more closely involved.

We certainly want to

stay in close touch with the Vet center program directors. But sometimes that liaison doesn't always occur as much as we would like it to in the field. So, we will continue to work on that.

MR. WALKUP: I would like to clarify the subcommittee's primary concern about the agenda this morning. At least my primary concern, and the concern of some other people was not so much the methodological discussion, as it would seem like our time would be better spent if we

dealt with studies that had outcomes related to what we — we were talking about prospective studies this morning. Once we get to a study that is reporting results, then I think it is entirely appropriate that we look at the methodological underpinnings of those results.

But to take the entire committee's time to deal with studies that maybe the scientific panel could have some input on, design considerations, doesn't seem to make a lot of sense. That would appropriate happen in the scientific subcommittee, and then once we have the results come in, maybe then the full committee could be involved in that.

DR. SHEPARD: I certainly agree with that.

Any other comments or questions?

Dr. Hodder, would you care to summarize the deliberations of your subcommittee, please?

DR. HODDER: In addition to the agenda, we had one follow-up from the morning's meeting. Dr. Irey explained his contributions to the study of neoplasms by Dr. Kang.

Dr. Irey is well known to us. I won't summarize his background. He also explained the role that AFIP had in the study.

The only question he was asked was about the timeframe of the study and, at this point, because of

technical aspects, they cannot really estimate how long it will take.

At that point, I turned the meeting over to the able hands of Dr. Matt Kinnard, who presented the second part of the agenda, which was the VA in-house, solicited, Agent Orange Research Studies. He did review for us the background of that, dating back to the August '81 special solicitation for research proposals on Agent Orange and Blue.

As you probably recall from previous meetings, 36 protocols were submitted of which 10 were approved; four of those have been presented to us, and three were presented today.

Despite the timeframe, he did caution us that many of the presentations this morning would be preliminary, in part simply because they are in ongoing stages of research, and also because lab safety issues had caused some delays, initially.

The principal investigator, Dr. David Allison from the VA in Albuquerque, New Mexico and Dr. Julianne Meyne, made the presentation. They were studying in two strains of mice, one that had a very high suseptability to dioxin, was dioxin receptive C-57, and one that was resistant to dioxin, the DBA mice. They looked at two aspects, one was cytogenetic

abnormalities in these mice, and another liver toxicity.

As an aside, if any of the investigators feel that a point is not being made correctly, I would like them to correct me.

fn terms of cytogenetics, they decided three methods for looking at this, one was well known to most of us using colchicine, a typical way of looking at the chromosome smears. That methodology using three doses showed no difference and no evidence of aberrations.

A second way, takes advantage of the way the red cell matured. Before its final step it excludes the nucleus; if they have any chromosome aberrations, tiny little micro-nuclei are formed and these are not lost, the newly formed red cells show these tiny micro-nuclei. Again, looking at 500 red cells in each mouse they were not able to tell any difference in the animals exposed and not exposed.

A third method called cysto-chromotive exchange, also looks at the new chromosomes in the metaphase plate that is done by giving the animal uridine which replaces thymidine and that way they have two colored chromosomes, if there is a break in the cross over, they produce reversed bands.

Again, they were unable to show any significant

effect.

They did mention some limitations in this phase and they have not done any chronic studies, that is the next step. They will also look at some variations of time, not just 24-hours.

The second part of their study, the histopathology, they gave animals different doses and to summarize this very quickly, they looked for focii of inflammation and necrosis in the liver. They found in animals with high dioxin, C-57, that at doses of 25 and 50 mg/kg half of the animals had these changes; at 100, 83 percent had it and at 150 mg/kg 91 percent of the animals did.

The more resistant animals, DBA, at the highest dose only had 55 percent with focil of hepatic inflammation.

The second study, the effects of low dose — I'm sorry, the effects of TCDD on Hepatobiliary Function in Animals, Dr. Nicholas Calvanico presented from the Wood VA Center in Madison, Wisconsin. The principal investigator was Dr. Fujimoto. They used an endogenous protein marker to measure the hepatic function after exposure to TCDD. They took advantage of the fact that as IgA goes through the liver it is married up with the secretary component and that if this is interfered with, then the free forms of IgA would be much higher — because they would not be able to be

married to the component and released in the bile.

And, again, the liver is damaged by the TCDD and the IgA will not be able to be excreted in the bile — what he was able to show, that if he looked at the ratio of IgA to IgG in animals, he was able to show that relative to control periods at four, seven and 10 days after the animals were exposed to TCDD, that the IgA, in fact, did as expected in his hypothesis, go up relative to IgG, which did not change. And he was able to show that the liver was not able to take the IgA out.

They are going to investigate further the ability of the (inaudible) to express SC on the surface and the loss of the ability to transport bound IgA, or perhaps synthetic IgA — this is not know. He also has to look into questions as to whether this is reversible or dose dependent.

Then there was the study by Dr. Donald Vessey, looking at the question of Herbicide Metabolisms effects on glutathione as a transfer system. He had two questions, toxicity of 2, 4-D and 2, 4, 5-T in animals that he wanted to study for two purposes.

The first one, the one he has not accomplished yet, was the question of whether these agents metabolize to more toxic compounds that would be found in normal animals; he has not been able to do this yet.

The second is whether the 2,4-D or 2,4,5-T would interfere with the metabolism of other toxins. The particular enzyme system that he looked at for this was glutathione as transfer agents. He gave several reasons, one is that almost always these will metabolize a toxic compound to a much less toxic level, than they found in most tissues of the body.

And to summarize it briefly, what we found was that there are two classes, one class was inhibited and another group were actually activated by this.

That summarizes the papers. The other issue is similar to the one Fred has brought up, the question of what part of the scientific presentations belong in the general meeting and what part belong in the subcommittee.

I think he summarized that very well. We consider that the methodologic aspects of preliminary studies or the early design phase really are probably more appropriate heard in the subcommittee, and. very brief summaries of ongoing work, or perhaps more details on the final study be presented.

DR. SHEPARD: Fine, thank you very much.

Any questions from members of the committee for Dr. Hodder?

(No response.)

DR. SHEPARD: Okay, I would like to open it up for discussion from the floor, and we have Mr. Vic Griguoli. He would like to come up and make some comments. Why don't you come up and make your comments, and ask your questions, Mr. Griguoli?

MR. GRIGUOLI: First of all, Dr. Shepard, I want to thank you and your committee, and the people out there for giving me this opportunity to speak at this hearing.

You see, I have four questions. I am going to ask the first two, but don't give me an answer, until the end, because I have two other ones.

Why only government studies, and why not more — any more independent studies?

In 1958, I had the opportunity to come to this country, I came from Italy. And before I came over here my uncle served in the military for the United States, but he returned back to Italy. And he told me that, "Son, you are going to a great country, the land of opportunity and the land *of* justice for all", right?

Well, my opportunity came in 1966, when I was drafted. Well, I didn't want to be drafted, I wanted to travel, I wanted to enjoy and maybe go back to Italy, you know, with the Air Force or the Navy. So, I joined the Navy, and thank God, to this day, I was very happy and I would do it over again.

On my first tour of duty I was on USS LPD-7, the second one the USS Meeker County, LST-980. We went up and down the Delta, I was in DaNang, I was in Quafet (phonetic), Chuli (phonetic) and the DMZ. And on both these two ships we made our own water, and as you know, dioxin becomes its most toxicity if it gets into water.

Okay, my problems started in '68, when I started developing a little bit of skin problem, that wasn't bad at all. In 1970 – well, when you are in the Navy you can get trauma from this thing, you know, so I had three left before coming back to this great country. And the Gooks had planted 40 pounds of TNT on the USS Meeker County, up in the Delta and we were loading up ammunition and bombs to take to Cambodia.

And a boot seen a clean line coming from the pier to underneath the ship and called to the CO upstairs. So they called general quarters, well they told us to empty out most of the crew and just keep the essential people on board. Well, I was one of the essential people, I had the main phone system, I was responsible to the captain, for the people in the forward section of the ship and the Out part of the ship.

Well, when the UDT, Australian and Korean and United States seal came back up from underneath the ship and they said that there was TNT underneath. I did the

three Ps, I peed in my pants, and I passed out. I said, "My God, I have three days, I want to go back home". Well the lieutenant slapped me and took the earphones away from me — that's all for that anyway.

But in 1974, I got married, and that is when my problem really started getting bad. Thank God today I am married to a wonderful girl, she was a reborn Christian at a young age, my skin, my body — I have boils, blisters. I lost all of the skin on my lips, the roof of my mouth, and I have boils and blisters on my back that give such an odor that it stunk.

She wanted to leave me, but I thank God she stayed with me, because I probably wouldn't be here today.

In 1976 we had our first son, two weeks old he had skin problems. In 1979, I had a little girl, skin problems.

During 1978, you know, through the headlines in the newspapers and the media, I seen about Agent Orange. Well, I went to the VA to get tested, because they told us when we were up and down the Delta that they were spraying for mosquitos, and I didn't think so.

The first one, it was an Indian doctor, a female, nothing against her, she was a good woman, she took my temperature, my blood pressure and looked at the upper half of my body. She said it was negative.

Well, I was not satisfied. I asked for another screening, I went to East Orange VA, New Jersey – East Orange. The head skin specialist over there, also gave me a test, stripped from waist up, he poked his finger into my chest, and said, "Son, there is nothing wrong with you". I had boils, blisters all over my body still, and there was nothing wrong with me.

I said, okay, then the next thing I done, I wrote to Max Cleland, who at the time was the administrator of the VA. Well, I got results, I got a decent test by another doctor at the East Orange VA. And one of the doctors there had mentioned about the sperm test, and they did a sperm test on me – I don't know how many other guys they do it on, but mine was very, very low, like 88 million units, versus 200 million is the nice top figure.

You know, I didn't run back to Italy, or go to Canada, and I have an adorable son, and I would like them to have that in their mind, that there is a beautiful opportunity and freedom, and justice for all in this country, but that is only up to the VA system and the chemical companies which want to give us $180 million which I totally oppose. We would like to have a hearing in court.

And now my third question is, being from 1976 to 1980 – I don't think I mentioned it to you people, I was

on Prednisolone by the VA, I was getting shots and I was taking pills. What can this do to my body?

And my last question, my famous president of the United States, John F. Kennedy, which I will never forget him — he said, "What can we do for our country? Not what the country can do for you."

Well, we did, the Vietnam veterans did what they had to do, they went to Vietnam and fought, not like the other guys who ran to Canada. Now, what can the VA and the government do for us?

I thank you very much for giving me this time.

DR. SHEPARD: You can sit down, if you want to, and I will attempt to answer some of tnese questions, as may the other members of the committee • Your first question, I think, was why is only the government doing research in this area?

And the impressiion is that the government is the only body doing research in this area, the federal government, and that is not entirely true. We hear more about it here, because we report research efforts that are going on. But you have heard some research efforts report-ed by Dr. Anderson, there are many state governments involved.

And there are private studies going on. I don't have a list of them in front of me, but there are a variety

of studies going on.

So, the research is not restricted to the federal government, and appropriately so. But the ones that we talk about here more are the ones that we are probably the most familiar with and are aware of. I hope that answers that question.

I think you have the impression that dioxin is more toxic in water. I am not sure that that is the case. One reason I say that is that dioxin is heavy than water and it is highly insoluable, so it does not tend to dissolve in water and it tends to sink in water.

So, whereas it would be possible to get some dioxin, if it were an emulsion, or some kind of a stirred up form, it is unlikely that people drinking water would get very much dioxin.

MR. GRIGUOLI: I have a report saying that through water —

DR. SHEPARD: I am just not familiar with that being a common route of ingestion. It has been alluded to, and it is a theoretic possibility, but because of the two reasons I stated, it is highly insoluable and it is denser than water. It is unlikey that there has been a lot of dioxin mixed in drinking water.

Now, it is very difficult for me to answer questions specifically related to your health problems,

without knowing a lot more about what was done. If you wish, I would be happy to request your medical records. I don't know if that is the best way to go about it though.

I think the best way is for you to go back to the hospital where you are being treated and ask the doctors who are treating you some of these same questions, because they have the medical records in front of them, and they are much more familiar With your medical aspects in the case.

And I think if that doesn't work, if you are not satisfied with that, I would be happy to help out in anyway, and members of my staff would, too, in anyway we can, to make sure that that happens.

MR. GRIGUOLI: Thank you.

DR. SHEPARD: Thank you for coming.

Are there any other questions? Let me announce, first of all, that we are very happy that Dr. John Levinson is back with us today. You may recall a couple of meetings back he presented a statement, and Dr. Levinson and I have been in discussion since that time, both by phone and by letter. And he has requested some time to address some of the questions that were brought up before, and also, share with us some of the results of his recent visit to Australia.

I think that while the rest of you are

writing your questions down, I will turn the floor over to Dr. Levinson, and invite him to come up and discuss some of the issues we talked about.

Dr. Levinson.

FOLLOW-UP QUESTIONS AND REMARKS/OBSERVATIONS IN AUSTRALIA/NEW ZEALAND

DR. LEVINSON: Thank you, Dr. Shepard.

On December 6th, at the 18th Quarterly Meeting of the Veterans Administration Advisory Committee on Health-Related Effects of Herbicides, I presented a paper entitled "Agent Orange, the Perspective on Responsibility". In that presentation I was most critical of the VA, and the manner in which it was studying the Agent Orange issue, and how it was discharging its responsibilities to the veterans of that miserable war.

I was unable to attend the 19th meeting of the committee in March, as at that time I was in Australia, and New Zealand, studying these same issues and the relationship of their veterans with their Veterans Administration.

During this past month, I have perceived a new spirit of cooperation from our VA. For this I am, indeed, most appreciative. In recent weeks, I suggested to Dr. Shepard, director of the project, that the questions I raised some six months ago, might be answered at this forum. He and his staff have kindly offered to answer and update us on these, which I hope will be constructive for all of us.

Dr. Shepard, if I may, I would like to present the following questions, and ask if you might answer them for us.

DR. SHEPARD: Certainly.

DR. LEVINSON: My first question relates to Dr. Van Tigglen's research on dioxin as a cause for a toxic neurasthenia. I visited with Dr. Van Tigglen in Melbourne, at his hospital, saw what his research was, saw some of his patients. And I wondered if you heard more, does your committee have any comments on his work, and is any of this type of research to be done in the United States?

DR. SHEPARD: I am not personally familiar, Dr. Levinson, with the details of Dr. Van Tigglen's research, that is the results of it. I am aware that he is doing work in this area. I am not familiar with the report, maybe others of the committee have read his work, and would care to comment on that.

Dr. Hobson, are you familiar with Dr. Van Tigglen's report?

DR. HOBSON: I. am familiar with the publications, I have not talked with Dr. Van Tigglen. The publications do not contain any control observations, only clinical observations, pure and simply, without any kind of control with which to compare his findings. As a consequence it is a little difficult to say what the results are.

DR. SHEPARD: Maybe you would be willing to share with us what your impressions of his research Were, and then I can answer the question about are we doing anything like that.

DR. LEVINSON: I think a lot of his data is, indeed, soft, but what he is basing it on is a choroid plexis block where vitamin levels change in the spinal fluid and the block could be due to dioxin, as well as other factors, drugs, alcohol and so forth may be related.

He is treating people with massive doses of vitamins and he claims that he is getting a dramatic response in a certain portion of these veterans, and he thinks it correlates reasonably well, in his preliminary work with those that he has done with cerebral-spinal fluid tests.

As I said, this is preliminary work. I talked with the VA in Australia, and they were to decide as of this month, or not, whether they were going to fund a major research in this area. Because if there is validity in his work, it might be a way that we can sort out some of the toxic neurasthenias, some of the toxic changes in the central nervous system that might be related to chemicals.

Indeed, I think most of us speculate most of them aren't; they are the usual stress situations that one has seen from various wars. But I think that if there is

a chance to have something scientifically proven, it is worth looking into.

The only counsel I would offer, since you are developing a very nice liaison with the Australian government on this, is to check with their VA, see if they have funded it; what their thoughts are. It might be a project on a clinical basis that would be worthy of consideration in working with our Veterans.

DR. SHEPARD: Certainly that is a very good suggestion. I would like to know more about his work.

In response to your question about are we doing anything similar, I am not aware of anything, although it might be something we might suggest to the Ranch Hand people who are studying in detail individuals who were heavily exposed. And, also, to the CDC people, who are developing their epidemiologic studies.

DR. LEVINSON: I know he has spoken in this country about it, he has spoken in Europe, he has spoken in Australia and a lot of people take it seriously. So, I think it is worth following up.

DR. SHEPARD: Right.

DR. LEVINSON: My second question, we had only approximately 10 diagnosed cases of chloracne — I learned today it was 17 -- in our Vietnam veterans, as of six months ago. This is in sharp contrast to the 200 cases

diagnosed at Seveso. Might this be explained on a different diagnostic criteria, and how do we explain this? Might you comment on the many chronic skin diseases in our Vietnam veterans that they feel are herbicide related?

DR. SHEPARD: I am not sure that Dr. Fischmann agreed that there were 17 cases diagnosed. There are 17 cases that are being service-connected, with the presumptive diagnosis of chloracne, or something sufficiently akin to chloracne that developed during the course of service in Vietnam that would weigh in favor of a service-connection.

I think she also stated that there is only one case that she, personally, has diagnosed as being chloracne, but they are in the process of reviewing the other 16 cases, to determine whether or not these meet the criteria for a diagnosis of chloracne.

DR. LEVINSON: Do we have a unified criteria that all the doctors working with the VA are scrupulously adhering to? I think it is a vague disorder to try to pin down; I wonder how we are in that regard?

DR. SHEPARD: Dr. Fischmann, would you be willing to come up and tell us a little bit more -- to answer Dr. Levinson's question?

There are criteria that Chloracne Task Force have developed, I think she alluded to them this morning. But maybe she would like to comment further on that.

DR. FISCHMANN: Yes, all of the dermatology consultants for the Agent Orange Registry examinations of skin problems have copies of the Chloracne Task Force diagnosis criteria.

You question about the Seveso incident, that was a very unusual industrial accident in that the toxic cloud was released outside the factory, not inside as had always previously been the case. In other words, the people living down-wind in what was defined as Zone A, the highest toxic zone, had a large blast of a high dose of the toxic chemical.

It is thought that the children — there were 187 cases of chloracne and the majority were children, there were very few adults. It is thought that the children were more affected for two reasons: first, lots of them were outside at the time playing, and that they subsequently played — continued to play for some weeks in the soil of the area, so that their exposure would have been considerably high.

Is that the answer to your question?

DR. LEVINSON: I am sure we could go on for a long time. I have so many questions on chloracne and I am sure you have the same problem. It was interesting to me that two years ago in Vietnam they had allegations of herbicides causing many disorders; but when you said that these

people had chloracne, the doctors would frown: they didn't even understand what chloracne was – they had never seen cases. And the opinion over there was you don't have to have chloracne to develop disorders – there are a lot of scientific questions, back and forth on this.

Thank you.

DR. SHEPARD: Thank you.

MR. WALKUP: There is one other issue, of the 17 cases, the service-connected is a determination by a rating panel about whether someone is eligible for certain VA benefits. And it is a bureaucratic, not a medical determination to some extent, although it is supported by medical evidence.

There are in the Registry, as I understand it, other cases of chloracne which have not gone before a rating panel, but there are 17 who have been through the rating panel process, and received the determination that they are service-connected, due to chloracne, or something like it.

Is that correct?

DR. FISCHMANN: That is correct.

DR. LEVINSON: I wrote up these questions before I knew you intentions.

Thank you very much, Doctor.

What reports do we have of the success of our

Vietnam outreach program, and is this meeting the needs?

DR. SHEPARD: Well, it just so happened that Dr. Ray Scurfield on the Central Office staff of the program spoke and gave a presentation to Fred Mullen's subcommittee, and it may be that Fred could answer that question, based on Dr. Scurfield's presentation.

Let me just point out that the VA Agent Orange Project Office has no formal connection to the outreach program, although obviously we keep in close touch, and at the field level, there is a lot of interchange between these groups.

Fred, do you have any comments?

MR. MULLEN: Ray was of the opinion that the program is working very well. There seems to be an increase in the number of in-country Vietnam veterans that are being seen, as opposed to Vietnam Era veterans. And I think one of the major problems that he focused on was the fact that a lot of veterans are considering this a medical disability and he doesn't want it to be considered as such. He wants it as a counseling, medical, et cetera to be provided the full range of service to a veteran, that he would not otherwise get at the VA medical facility. But to include some medical counseling.

The only other problem that he may have hit on was the fact that the areas in which the outreach centers

are located may hot be accessible to larger numbers of veterans, most of them are located in transitional areas, like on the edge of an urban-rural setting, so as to cater to the larger populations of Vietnam combat veterans who may be concentrating in that area.

I wanted to make one comment on that, regarding the fact that they do not see very many female Vietnam or Vietnam Era veterans in these facilities. And I believe perhaps that reason is that because these outreach centers are in transitional areas, and perhaps in low income areas, that women may be reluctant to travel into those areas to seek this counseling.

Now, that is just an observation on my own, but for the most part, he seemed to indicate that the program is working very well. And other than those minor problems that I just outlined, I don't think they are having much problems.

QUESTION: Did you mean outreach in a general sense, or are you honing in on Agent Orange outreach specifically?

DR. LEVINSON: *I* say outreach in a general sense. But I know right next to my office, exactly next door, is the one in Wilmington, Delaware, and I have a great inter-play with these people, and they have evening sessions, day sessions, and *I* think that a lot of their issues are

directed at problems that the veterans perceive as Agent Orange related.

So, I tend to put the two together very closely.

MR. WILSON: Let me just say one thing, since they are right next to you, Dr. Levinson, are you aware that center that is right next to you in Wilmington, Delaware, is supposed to provide coverage to the four southern counties of New Jersey?

Will you please call me from your office, if you ever see them heading over the Delaware Bridge, toward those southern counties of New Jersey, okay — we haven't seen that yet?

DR. LEVINSON: You mean, they are supposed to go out and see you people?

MR. WILSON: Yes, that is part of their coverage area, the four southern counties, and obviously, their staff is short, over-worked and they can't do it.

DR. LEVINSON: If you will leave me your name, I will make sure I talk to them about it tomorrow morning.

MR. WILSON: I have already talked to Dr. Kaufki.

DR. LEVINSON: Okay, fine.

In Wilmington, we have an Agent Orange nurse program, which has been most helpful to the veterans. I think I spoke about that before, where there is a nurse that does the initial history, spends time with the

person, time that the busy physician often doesn't have, trying to put together what the physical and the studies showed later on, and it seems to be working out very well.

And my question is, is this, or a similar concept being tried in other VA hospitals? Have any specific changes been made at the various hospitals to foster a better working relationship between the Vietnam veterans and the VA?

DR. SHEPARD: In answer to your first question, Dr. Levinson, I am aware of a very good system at Wilmington, and we have received many favorable comments on the program there.

We have thought about initiating such a program in other hospitals, however, it is difficult for our office and the other elements of the VA to move people around in the field very easily. And that, coupled with the fact that we have left the management of the local Agent Orange program pretty much to the responsibility of the Chief of Staff and his people, because in varying parts of the country there are various characteristics of the population that are served, and so forth.

We have noted the fact, suggested that if other hospitals wanted to implement such a program, that Wilmington would serve as a very good model.

I know at least one other instance in which there

is a nurse working very closely with the environmental physician . In a sense although maybe not modeled after the Wilmington set-up, it operates very similar to it.

There are many out-patient clinics or ambulatory care services that have nurses on the staff that do a lot of the same kind of work that goes on in Wilmington. It is certainly an interesting process, and one that perhaps we could explore more thoroughly.

In terms of your second question, on any specific changes made at the various hospitals to foster a better working relationship, that's been paramount in our discussions with the VA medical centers. We have tried to stress the importance of this relationship, and I think have met with pretty good success.

I have visited a number of hospitals from time to time, and that is always one of the questions that I have, and that I am on the outlook for. So my impression is that there is a good working relationship, it has improved over the years. I am always eager to know of instances in which that is not the case, so I can, perhaps, improve the situation, or suggest improvement.

So, I am always very receptive to hearing reports of instances where this does not seem to be the case. But my perspection from visits I have made, is that there is

a difference in the relationship.

DR. LEVINSON: Dr. Ronald Codario has made much of elevated porphyrin levels in the urine of many hundreds of Vietnam veterans he has studied. He feels these changes are directly related to toxic chemicals and to a multitude of symptoms. Although, many of us have questioned the validity of his claims, I have suggested, and also others since that time, that similar research be done by the VA to help settle this issue.

Recently I received a copy of a letter to Dr. Shepard, from Dr. Hansbarger, who is director of health in the State of West Virginia, urging the same sort of a program. And I just wondered what the position of the VA is on this, and whether it is worth pursuing?

DR. SHEPARD: Again, we have discussed it, and I am anxious to hear from other members of the committee. But let me just respond to the specific question, what is the VA doing in this regard? We have not put into place a systematic process for these porphyrins throughout, and including that as part of the routine examination in the Agent Orange examination process, for a variety of reasons, not the least of which is it would be difficult, I think, to ascribe causation systematically.

However, I know of instances where certain VA medical centers have taken this on as sort of an informal

research project. I can't give you — I haven't had a chance to dig out which ones those are.

Dr. Fischmann is very interested in this area, and she has been measuring porphyrins and, she is leaving for a long trip tomorrow to get some more information on chloracne.

DR. FISCHMANN: We have looked at 100 veterans on the Agent Orange Registry , in two porphyrins were found in both the urine and stool, and in 34 porphyrins were found in the stool. We are recalling all of these veterans to get retested. We have only got a few of the new tests back. I would say roughly about 50 percent are negative at this time. We are collecting 24 specimens and having the exact quantity determined, at which time we will be looking carefully at what may be causing the problem.

QUESTION: I have a question, it has nothing to do with the committee, you have talked about why doesn't somebody do something, other than the VA.

You probably know the work of Dr. Suskind in Cincinnati, he spent a lot of time working on this porphyrin business. I think he is completely independent, he believes -- and I was talking to him about it only a few weeks ago — he believes there is really no relationship

he, of course, has had a lot of opportunity to study the people in the explosion at the hydro plant, where they have a very good follow-up. I think he is a very competent scientist in that field and one has to listen to what he says.

DR. LEVINSON: I certainly respect exactly what you say, and I have seen that paper. The reason I bring it up is Dr. Codario's work is widely quoted in a book that was rather sensational, and I think it behooves the VA to take a position and try to go and show some good work, either repudiate, or say what it is.

And, unfortunately, the veterans cling to something like that, they are not aware of the other scientific work and they think that the Veterans Administration is neglecting them.

And my only counsel would be if you have some reports like that you alluded to, and they are being done informally, somewhere they should be collected and put together with this, to try to counter these claims, if you feel you have sufficient data, so people know. If you don't have sufficient data, then a study is in order.

I don't mean to suggest studies for studies' sake but I think it is so important that people understand. And I always remember the first night I was in Vietnam, 21 years ago, somebody said something to me that always stuck in my

throat, "The whole problem over here is we don't understand them and they don't understand us". And I think a lot of that goes on with the Veterans Administration and the veterans. And I think we have a great responsibility to try to clarify that, and put our science in meaningful areas for these people.

DR. SHEPARD: I certainly agree.

DR. LEVINSON: Next, I expressed deep concern in the entire Agent Orange Registry for histories and physicals. And I question, is the coding being done better? Are follow-up letters being sent out more timely? The first GAO study was highly critical of the data in the Agent Orange Registry, has a follow-up study been done, and what are the findings?

DR. SHEPARD: There are several questions there. I am not sure exactly which coding problems you are referring to, but let me assume that you are referring to the concerrs raised by the first GAO report.

All of the data collected for the first GAO report ante-dated our registry revision. When I say registry revision, I mean the revision of the code sheet, so that the results of the GAO report does not take into consideration the revised coding process that now exists.

I believe that the new coding process is better,

in several ways. It is more precise, it details more medical information and hopefully, it is something that is relatively better designed, better instructions, less ambiguities and all of those things.

I think from my perspective it is an improvement on the previous process, the previous system.

The question about the follow-up letter, we hope that the follow-up letters are going out in a timely fashion. I am sure that some medical centers do a better job of it than other medical centers. We don't have, I must confess, a good monitoring system for determining exactly how rapdily the letters are getting out.

I think you would agree that devising such a monitoring system would be somewhat difficult. So, we have to trust our local VA staff to do a good job, and I think, in most instances,that is the case. I have heard of one or two instances where the letters have not gone out in a timely fashion. But when I have become aware of it, there has been some explanation. In some instances, the letters are not sent out pending results of additional examinations, that is consultations, laboratory studies and so forth. And, therefore, the letter cannot be complete, until some of those studies are returned, or some of the consultations are complete.

We put out a circular

addressing specifically the whole issue of the follow-up letters, that is urging hospitals to not hold up the follow-up letter because of incomplete laboratory studies. If, after a reasonable period of time, the laboratory studies are not back, or the consultation is going to be delayed for whatever reason, certainly a letter should go out summarizing the existing information and maybe making some reference to additional studies that are anticipated.

So, we are trying very hard and we attach a great deal of importance to the letters, and we are trying very hard to make that system work well.

DR. LEVINSON: The other thing, is the GAO doing another study on this?

DR. SHEPARD: Yes, as a matter of fact, we have a member of the GAO study staff in our audience. If she would care to speak, I would invite her to, I will not insist on it. She has just recently joined the team, but in answer to your question, yes, the GAO is doing a follow-up study . I am not sure exactly what their timeframe is, but they have gotten specific direction now to proceed. So, we will be seeing another GAO study in the future.

DR. LEVINSON: Thank you.

Of the various studies being done in our country,

now coming in on a more timely schedule, so often in the past we have heard this one is put off because of various problems and so forth – do you think we are moving along on a better schedule, in general?

DR. SHEPARD: In general terms, yes. I think that we have a good example of that. Of course, the Ranch Hand Study which was being held up, a very important study, has been reported out. It is an ongoing study, it is not finished by any means, but two major phases of it have been reported.

The CDC Birth Defects Study, also, a long awaited study has been completed and we expect to see the results of that in the very near future.

The VA Mortality Study is moving along well, and we hope to see the results of that in the very early part of next year.

So, when you say "more timely", I guess all of these studies, as I am sure you appreciate, being complicated with all of the built in problems and concerns about data analysis, and more precisely, exposure information, make these studies difficult, and therefore, time consuming.

The CDC large epidemiological study is moving forward, they have issued a number of RFPs for contracts for various portions of those studies. So, I think that they are moving along as quickly as they can.

DR. BARNES: I would just observe that part of the activity we have going on now is that there are just more studies in the pipeline. We are now seeing the fruits of studies that were initiated two and three years ago. And that is why we are going to be able to see these things coming out more rapidly, and *I* suspect that this will come to some sort of peak here in the next several years and then taper off.

DR. SHEPARD: Thank you.

Please, any members of the committee, chime in, *I* don't want to monopolize this.

DR. LEVINSON: The last question I have, various monograms and video tapes were being prepared by the VA on Agent Orange, have they been completed? Are they readily available for our veterans?

DR. SHEPARD: Okay, also this morning at the Information-Education Subcommittee meeting there was a briefing by Mr. Dan Jones of our learning/resource center in St. Louis, who I believe gave an update on the status of the video tapes.

And, Fred, maybe you could comment on that. I was not there for his presentation, perhaps you could comment on what was said?

MR. MULLEN: Well, you will have all of the scripts by September, at the latest October, and we should be able

to review the initial script, which is supposed to be for the veterans. As you know there are three films, one geared toward the veteran for informational purposes, letting him know what to expect. One is for the environmental physician, to keep him aware of the importance of the issue.

And the third is geared toward the in-take and administrative personnel at the individual VA medical centers.

At this time we were assured that before the thing goes out, we will, in fact, as a committee, have a chance, a guaranteed opportunity, if you will, to review those before they are released to the field. They are hoping to get the scripts done by September.

DR. SHEPARD: Any other comments?

We have been working very closely with Dan Jones and the resource center, and I think they are coming along very nicely on that.

DR. LEVINSON: Just a few comments on this recent trip I took to Australia and New Zealand. I would like to share with you several of these findings.

As you know, Australia has a Royal commission now investigating the entire question of not only Agent Orange, but of all of the chemical exposures to Australian servicemen during the Vietnam Conflict. And as I understand, there

are 45,000 plus of these men. The tradition of a Royal Commission is a long and honorable one in that country. A special commission of this type is formed when the government feels there is an important issue to be settled. Historically, 80 percent of the time the findings of a Royal Commission will be accepted by the government and in a real sense become the law of the land.

I was excited to find that everyone I talked with in that country had the highest respect for the concept of the Royal Commission, and all who I came in contact with who knew the people on this particular commission felt they were both honorable and capable men and women.

I had the opportunity to spend several days with these people and I found Judge Phillip Evertt, as well as his associates, to be most able people. The president of the Australian Vietnam Veterans Association, Phillip Thompson, has the highest respect for this commission.

When I asked him what would be his position and that of the Australian Veterans, if the commission did not find most all of their Agent Orange allegations to be true, he stated without blinking an eye, that if that was the finding of the Commission, he knew it would be a proper finding and they would rest their case. This, to me, was a very exciting thing.

Although the Australian Vietnam veterans have

some of the same antagonisms with their VA as one sees in our country, it was exciting to see them have a focal point, namely the Royal Commission, where they could both work through and hopefully, they will resolve the problem.

It would be wonderful if some mechanism like this might be worked out in our country to heal the lingering wounds of the war. Somehow, we must find a constructive focus to resolve these issues.

Victor Johnson is the president of the Vietnam Veterans Association of New Zealand. He advised me that their government feels that with only 3,000 plus veterans there is not a large enough group to run meaningful studies. Therefore, they are watching closely the studies that are developing in Australia, as well as those in our country, to help settle their problems. Indeed, the responsibilities to our Allies in that conflict do continue.

I could go on in some length, but I think it is time to quit, and, again, Dr. Shepard, I wish to thank your group for this new feeling of cooperation that I have gained in these recent weeks. I hope that all of us will carefully re-examine our positions and try to be more constructive.

Thank you very much.

DR. SHEPARD: Thank you very much, Dr. Levinson. We appreciate you coming down.

DR. LEVINSON: Thank you.

(Applause)

DR. SHEPARD: We have a couple of other questions, there is a Mr. Frank Dulaney from Connecticut. He has traveled far and wishes to comment. Mr. Dulaney.

MR. DULANEY: I suppose *I* would stand in counter-point to the gentleman that just spoke a few seconds ago, he talked about how the veterans of Australia have so much faith in their institutions that they will come clean with them, so to speak.

I represent a number of veterans who don't have much faith in these institutions. And, unfortunately, you ladies and gentlemen that sit at this table, represent the institution we trust the least.

I have a question to pose to you, but I don't expect an answer. I don't want an answer. I am going to give you an example of why I pose the question. The question is: You are going to gather data and on the basis of that data, hopefully, scientifically gathered, you are going to be making decisions about whether the health of certain veteran is, in fact, associated to the service in Vietnam.

That, I take it, is the ultimate goal of this Commission.

We don't trust you. We don't trust you for this reason: you have already started to gather much of that

information, this is Volume I of a two-volume study, conducted October '81, you spent about $112,000 to complete the study.

And what I want to show you today is an example of what the VA has done with the information gathered. We have very confidence that the information was gathered correctly, and that the analysis of literature of this particular volume was done properly, and that the annotated bibliography is fair and accurate, as the record stands.

Let me make two specific points. Dr. Rose Pappick is the Chief of Hemotology and Oncology at the West Haven VA. She also is intimately associated with the University — the Yale University School of Medicine. I asked Rose to make some comment for the record in support of my case for service-related compensation for my blood disease which has been diagnosed as aplastic anemia.

And I will quote the letter to you, it is very short: "Mr. Frank Delaney is a patient, followed in the Hematology-Oncology Clinic here for peripheral blood septaemias and bone marrow abnormalities associated with a sodigenetic effect. These findings are observed in patients exposed to environmental mutagens. In view of the history of exposure to Agent Orange, _we feel the probability of his exposure as an ideologic agent or causing agent is a distinct and serious consideration".

She wrote that letter for *me* on February of 1983, and through the process of appeals and all, the final decision that was brought down, dated 17 February 1984, was, and I quote, "Not new and not material".

Well, it is new because I submitted this letter as something new, something that was not submitted in the process. And I find it very odd that whoever makes these kinds of decisions, whoever can make these kinds of statements and the denial of an appeal, or an approval of an appeal, can deny the credentials of a doctor of the reputation of Rose Pappick. Not only is she on the teaching staff of the Yale University School of Medicine, but Rose has been invited to China a number of times to lecture, and she has been invited to the Continent to lecture; she has a number of colleagues in Paris, France, also.

She is literally world reknown in her field. Her associate, Dr. Larry Solomon, another Associate Professor of Medicine at Yale University School of Medicine, is equally as reknown, and he supports her 100 percent in this particular aspect.

There is one reason why Frank Dulaney, as a veteran, doesn't trust whatever you come up with here. You may come up with good data, but don't trust that you are going to use it well.

Case in point number two, on that same letter,

dated 17 February 1984, a very unequivocal statement was made in the Notice of Denial. The adjudication officer said, and I quote, "There is nothing to date in the medical literature which connects exposure to Agent Orange to aplastic anemia", end quote.

That was, again, as *I* say, 17 February 1984. Exactly a month later, 17 March '84, through the good auspices of my representation, Congressman Bruce Morrison, *I* received Volumes I and II of this review of literature. And I started to read it and what I found were 29 articles that showed dioxin affecting the purple blood, the bone marrow and chromosomes exactly the way I have been affected: White blood cell depressed, hematocrit depressed, hemoglobin jdepressed, platelet count depressed, red blood cell count depressed, decreased cellularity of the bone marrow, decreased productivity of the bone marrow and deletion of the seventh chromosome.

I am not a scientist, my degree was in philosophy, but I have an appreciation for logic. And logic tells me this, on page 4 of Part II of a form that the VA has for doctors to fill out called something like "Initial data base, possible exposure to toxic chemicals" as part of the Agent Orange screening exam.

At the top of page 4 is CBC, that's the first place they look, the complete blood count, the peripheral

blood. On the basis of that, if a doctor sees anything wrong, he wants to go a little further, wants to get a little more intimate with your body, and in my case they did. They did a bone marrow biopsy and an ancillary study done with that, because it doesn't cost the patient anymore pain, they sent the sample of that somewhere down to Atlanta, I believe, and a cytogenetic study was done, also.

The reasons the doctors made a cytogenetic study along with the bone marrow biopsy was to see if there was any chromosome damage, because those doctors, both the hematologist and the pathologist at West Haven VA are competent and know well, and can document the fact that if there is chromosome damage, there is a highly likelihood of exposure to a toxic mutagen, a toxic chemical, or ionizing radiation.

And then we can take a look at the veteran's history and start to isolate some of these other items. On that basis, it would appear to me that if I can find 29 articles as a layman, that point to every significant aspect of my peripheral blood, my bone marrow, and the deletion of the seventh chromosome, and that those are the same items that a doctor uses to say "Frank Dulaney, you have aplastic anemia", then why doesn't that suffice to have a service-related claim granted? Why isn't that enough?

Well, I don't know the answer to that, I don't even want an answer to that, because I am going to get a lawyer to really hash it out.

But there is something interesting, I kept reading further in this article; 7-21, Chapter 7 deals with chronic exposure to TCDD and the other various dioxins that are analyzed here. Sub-section 5 deals with hematological effects; sub-section 5.2 specifically deals with the hematological effects of chronic exposure to TCDD.

Now, let me remind you of that very unequivocal quote made by an adjudication officer, dated 17 February 1984, "There is nothing in the medical literature to date that relates exposure to Agent Orange to aplastic anemia".

I refer you to page 7-21 of Volume I of the Analysis of Literature, lethal, and I quote, "Lethal hematologic changes have resulted from chronic exposure to TCDD. Death was attributed to aplastic anemia in 25 percent of the rats that succumb to dosing at a level of .001 to .5 parts per billion TCDD in feed for 65 weeks". The study was conducted by Van Miller and Allen, 1977, and is listed here in a publication dated October 1981.

Yet on 17 February 1984, a full two and a half years later, the VA contends "There is nothing in the medical literature that connects Agent Orange to aplastic anemia".

I have made my point, I don't expect – if there are questions, I would be happy to answer them.

I had a little disagreement out in the hallway, when we broke up for subcommittees. A gentleman from Minnesota, he made a mention about "nobody can have their Fountain of Youth forever".

Don't misunderstand why veterans are fighting, we are fighting for one thing, we are fighting to let you know we got wasted over there, and the same thing that wasted us over there, is wasting you right now, in your landfills and in your ground water, in the food you eat. You are being fooled, and all of you are part of it.

I sit here and listen to all of you talk, I hear a gentleman say "Perhaps the data is too scientific, and we shouldn't present it at a public forum".

I hear you talk about, "Well, we are going to start this study, and it is going to take a little while". I hear the scientists talk about taking a year and a half to create a safe environment, so they can study dioxin.

If you had only taken that same care in applying dioxin, we wouldn't have had the problem we have today.

The point I want to make is this, we don't have time. Tomorrow, Wednesday, I am going in for another transfusion, I have lost count of the number of transfusions I have had. I have had them every two weeks, since November

of 1982. The pathologist that originally studied the bone marrow claimed that this was a pre-leukemic condition and he has, in fact, found leukemia at this point. They did a bone marrow, the 13th bone marrow was performed last Tuesday, and they are looking to substantiate some rate of growth in those leukemic cells and talking about applying chemotherapy.

Because of the disastrous situation of my own bone marrow, my risk, or my ability to live through the chemotherapy has been rated at somewhere between 20 to 40 percent.

I think I represent a lot of veterans in this case, veterans who have run out of time, veterans who have run out of patience.

What I want to say to you is this, you are demanding too rigorous a system, too scientific an overlay. If I can find 29 articles that show the most significant part of your body, your blood-forming system — blood-forming system has been admitted by Dow Chemical in July of '83, in the New York Times, to be one of the areas most severely affected by exposure to dioxin. Dow Chemical knows it. You know it now.

You have enough information now to start granting service-connected disability to those men who are badly wounded, who have lost their jobs because their health is

so poor, and you can give back to them a sense of pride that they are not simply complaining about some "unfounded feelings, or some vague disappointment about Vietnam". I think most veterans are like myself, *I* volunteered for the Marine Corps, I volunteered to fight in Vietnam. And for some very strange reason, I would be happy to do it again.

But in light of what I have seen from my institutions here in the United States, you will never get another Dulaney. There will never be another Dulaney boy that fights for this country. The sons of the working class have been ripped off too long. And if I may sound like a Socialist when I tell you I am a "died in the wool Democrat", there will be no more Dulaneys for your war. You are not ever going to rip us off like that again.

And I consider what you are doing here today a rip off.

Thank you.

(Applause.)

MR. MULLEN: Just a point of information, I, personally, resent the implication, myself or the service organization I represent is working in collusion with the Veterans Administration to make decisions adverse to veterans' claims.

Secondly, I do not sit on this panel representing

the Administration. Again, I represent a non-profit charitable service — veterans service organization, as do several of my colleagues around this table. There may be some misinformation there, but again, I resent that implication.

MR. WILSON: You are at least honest about what Fred said, don't worry about it.

DR. SHEPARD: Any comments that members of the Committee would care to make?

MR. WALKUP: I would like to express my appreciation to Mr. Dulaney for keeping us honest. I think we don't hear often enough what you have said. And I think what you had to say is quite a number of us have had to say when we started out. And it seems like the more we get into the details, the more we lose the point. And that seems to have been the history of Vietnam, as well as the history of the treatment of the Vietnam veterans and the history of the treatment of Agent Orange.

I wish we could get back to just the bottom line, okay, what are we going to do about Agent Orange? I almost said when the question before came up about where are at in the outcome of the studies. The epidemiological study that has been turned over to the CDC because it didn't work out in the VA is going to come out in 1989, or 1990. And that will have some suggested implications for

further research which will draw us on for a number of other years, and the Dulaneys and Walkups, and the rest of us of the world will be long gone by the time we come up with any conclusions.

I think somehow it is time that we get past having these internal and infernal meetings. I mean, this is the fifth year, and make some determinations about what we are going to do about people while we go ahead and proceed with the research.

DR. SHEPARD: Thank you, Hugh.

For my part, I would like to thank Frank for coming down from Connecticut. I think it is very important for this committee to hear your comments, Frank.

If I may suggest, there is a gentleman in the audience who represents the Department of Veterans Benefits, (DVB), /and I would ask Max either to come up and comment, if he wishes, or at least to talk to Frank, and maybe give him some reaction, or whatever.

This is Mr. Max Woodall, Director, Compensation and Pension Service, Department of Veterans Benefits for the Veterans Administration.

MR. WOODALL: First of all, Frank, I would like to tell you, I am a Marine Corps veteran from another era you may not even have heard of. We used Agent Orange, too, 32 years ago. And my children are going to serve in the

Corps, and I would go back, if they would have me in the Corps, again.

As Director of Compensation and Pension Service, I would tell you that we will try to make — establish direct service connection wherever we can, Frank. And I had a whole lot of buddies in both the Korean Conflict and the Vietnam Era that I realize were exposed to this agent, and we don't know all of the answers. But I would like to discuss your case with you and see what we can do, as far as direct service connection is involved.

I would also like to tell you that, generally speaking, in most regional offices I think the people handling the cases out there are trying to reach that direct service connection, if they can. And we encourage that, wherever they can.

Frank, I know in your particular case, you have problems. My grandfather was raised and grew crops in a farm in Idaho, and you name it, we have used it, ground up — they used to sell it by eight or 10 different names, we used to clean up irrigation ditches with it. And I remember one of the ways that we used to goof-off in the summer, we used to spray each other with it to cool off, the dumbest thing we could do, when we were teenagers.

So, there are a lot of things that in the back-ground and in my mind, but I want to assure you from

DVB's point of view, we are going to do everything we can to try to establish service connection claims where we possibly can.

And, Frank, after this meeting is over, I would like to talk with you about your individual claim.

DR. SHEPARD: Thank you, Max.

MS. DE VICTOR: I am Maude de Victor, your predecessor, Mr. Peckarsky and the wonderful Ms. Dorothy Starbuck both have put in writing on VA letterhead "The Vietnam veteran will not be paid, because the cost would be prohibitive".

A second fact, sir, is that in the treaty that Mr. Nixon signed at Versailles ending the hostility, there was a reprobation provision there, the United States government does not wish to pay the Vietnam veterans, sadly, as it may seem, because they will have to deal with the reprobation provision in the treaty, and thus open themselves up to be taken into world court for crimes against humanity, just like we did Germany during the Nuremberg Trials. These are the realities, these are statements that have been placed on Charlie Owen's C Folder. I do not know where it is, but Mr. Peckarsky and Ms. Starbuck wrote the administrative determination and you may find them for your own information.

DR. SHEPARD: Thank you.

(Applause.)

DR. SHEPARD: We have several questions from Mr. John W. Cooke. Would you care to come up, John? Why don't you ask your questions dir'ectly?

MR. COOKE: Dr. Shepard, Committee, I don't want to belabor the medical issue too much at this point, I think it is something that we all have to honestly consider and re-evaluate it in an expeditious manner.

I am a Vietnam veteran, I have a picture-perfect situation, such as Mr. Dulaney's there, chronic active hepatitis, neurosis, I have a lymphatic problem with my system, I have hyperspleenism, various disorders.

I went to fight for this country and I would go and fight again, I love this country. God gave us this country and blessed this country, and I thank God that I am able to sit here because I was sprayed on, I was injected with Dapsone / experimental malaria drug and I drank and was ingested by a food chain with Agent Orange, Agent Blue, Agent Pink and various other ones.

My children are going through rash problems, my family has abandoned me, both parental and wife. Every-time my children have gone -- T and A, removed there is something underlining that now, it is appearing. And every time I think of the situation, the trauma and

emotion was expressed adequately before me. But the points I am addressing today are some of the bills, the validity of some of the programs, definition and just different projections.

And I will read what I have for a time factor: Validity of the Ranch Hand program, exposure to the herbicide was 30 seconds to two minutes discharge time; to ground troops who were sprayed upon and ingested Agent Orange in food, water and soil chain, and knowing that dioxin is photo-seeking and interacts with the soil and finally comes to rest in the most toxic state in the water concerns me. How valid is the Ranch Hand report, and can we use it for criteria at this point?

I saw a film in reference to this at a VA medical center, Lyons, New Jersey, in 1981. I was in the medical center a year and a half, I had Dr. Hyman Zimmerman come out and do a day and *a* half on my case alone. He is a very well known liver disease specialist, if not the best in the country, number two in the world, I think, Dr. Shula Sherlock is a little more reknown. Which really has no significance, but I can't argue the fact that they have given the best doctors available.

I have learned to work with the system, I have learned the system works with us, but there are things that have to be dealt with still, as far as expediting

this matter is concerned.

What actions will be taken in reference to exploring the medical abnormalities which are confusing the studies on Agent Orange, Agent Blue, Agent Pink, Agent White, and other medications or chemicals in Vietnam exposed to the populous of Vietnam veterans in compliance to Mr. Daschle introduction of HR 2017; projection and definition of HR 1961, HR 2017, S 991; HR 1961 just allows for Agent Orange and doesn't include any of the things that we have heard today in reference to other indicators. A compromise between HR 2017 and HR 901 to allow for coverage of all chemicals and medications used in RVM and to accuate verification of long-term effects is needed. We need a definite deadline, we need dates, we need goals on these.

We can't project 1989 again.

Another concern is an international pool on medical awareness and open-ended funding. For example, I used Dr. Kahn over here, who probably is one of the biggest assets in expediting relief and suppression of all those involved. Dr. Kahn was to an open association of analytical chemists that was jointly held with the a Canadian association in Ottawa on June 9, '81. One full day of presentation and discussion of advanced methods for identification and quantative measurement of dioxin

and related chemicals in very small quantities, parts per trillion, were discussed.

Also, with these advanced techniques dioxin and dibenzyol furans have been detected recently in persons who were exposed 13 years ago linked with 2,4-D, and 2,4,5-T in reference to — this was a community effort between Canada and our Dr. Kahn over here. They have tests already in reference to pooling information — Captain Al Young was contacted by the government in reference to possible litigation to effects of Agent Orange.

They came up with the statement that it can deceive the DNA message chain allowing for substantiation of mutagenetics, tetrogenetics and the fetus without any effect on inceptors.

Now, along with other warnings, as early as 1880 and 1889, multiple accidents in Italy, Sweden and America. We can't just refute that, we knew what we were doing here, and with this knowledge and the result of Dr. Kahn's interaction with the medical community in Sweden, we can only allow for positive results by taking action in getting funded, getting the world community involved in things like this.

Those are just things I would suggest for Dr. Kahn because I have done a little reading on Dr. Kahn.

Now, the last point, and the most important to me

is the question of the chasm that we have created and how do we bridge that chasm between our politicians, our military, with Vietnam to encourage those individuals who are going to be fighting for this country. I heard an affidavit read by a young gentleman the other night, his father died because of Agent Orange, this fellow wants nothing to do with our country, nothing to do with our country.

The young fellows, they see what is going on, the discontent, the deception; there has to be some sort of honor and encouragement given back to these fellows who want to fight for this God-given, God blessed country. It is imperative.

A couple of suggestions that I am going to give you, if you will accept them. Let's all get back to a God-given direction; use our political system as President Reagan just asked for in an expeditious fashion for an a decision on $8 billion for the beginning of 1985 fiscal year for Salvador — our problem is from within.

We have the monies, we have the knowledge, let's start acting.

The last thing I would like to share with you is this verse 2 Chronicles 7-14, If my people who are called by my name shall humble themselves and pray and seek my face, and turn from their wicked ways, then I will hear

from heaven, and will forgive their sins and heal their land. We have dealt a devastating blow through chemicals, not only in RVN , but as we have heard, there are almost 8 million affected in this country with dioxin. We have to do something about healing this, "The truth will set you free" the Bible says. We have to realize that here, "The truth will set you free". We have the answers, we have the money, it has to be dealt with immediately.

We have created a moral and damning cancer, in such an insidious form at all levels, we may not be able to turn it back. And God may not allow his blessing on this country too much longer.

Thank you.

(Applause.)

DR. SHEPARD: Thank you.

We have one request from Allen Falk, Chairman, New Jersey Agent Orange Commission.

MR. FALK: I will be short because of the hour, and basically, the last few speakers have brought forth the message that I wanted to bring. And that is you can't let the gap between Vietnam veteran work going on here stay at the level that it is.

At the subcommittee meeting on education and information, Dr. Scurfield reporting on the counseling centers, just briefly, reported on the number of words that

they are finding in the contacts with the veterans, the words are rage, anger, bitterness and frustration.

And just to hear the words doesn't really get through the meaning of what goes on. And just last week the New Jersey Commission held their public hearings on the proposed settlement in the federal suit, and we had hearings in two different parts of the state. And at the hearing I was at we had 30 veterans come up and speak in an allotted 10-minute time period. And you have to be in the room to feel the anger and frustration, and I don't think that is getting across.

And it is not so much for themselves, in most cases it is the belief that it is hurting their families and their children. And we are talking about a very different burden of proof here, we are talking about the burdens of proof that will suffice before a Federal District Court, we are talking about a burden of proof that will suffice to allow a scientific committee to approve publication in a medical journal.

And even if you reach those levels of proof, through this committee and the research efforts that are being made, you have totally failed, unless you reach the most important burden of proof of all, and that is in the mind of the Vietnam veteran.

And as you can see, the Vietnam veteran is not

stupid, the Vietnam veteran may be very highly educated, and he may not have much education but very good "street smarts". And he has made a decision based on his own moral burden of proof, and in most cases that is probable cause or a reasonable belief that there is enough medical evidence out there to convince him that, in effect, he was poisoned by serving his country.

And you can understand when this leads to the frustration. And to believe not only that it is affecting you, as you have seen here, but it may be affecting your family and your children. That is an enormous frustration and it is not abnormal, it is totally normal.

So, you have a burden of proof of doing one of two things, and you have failed until you have done that. One is convincing the veteran that he is wrong, that the burden of proof has been met and the scientific evidence is overwhelming, so that he will then accept the fact that no, he wasn't poisoned, that these sad, tragic occurrences would have occurred, whether he went to Vietnam, or not.

Or, secondly, if you can't do that and meet the burden of proof, to accept the fact that you can't do it, therefore, that burden of proof has been met and you must then — in effect, society and the government must apologize for what it did, and start taking actions to compensate and to attempt to treat and do research on this level.

From what I saw at our hearings, it really has nothing to do with money, or the amount of money that is going to be in a settlement, it has to do with each individual veteran accepting either the fact that he wasn't poisoned, or an acknowledgement that he was and that there is going to be a fair and just disposition of that, and there is going to be a concentrated search for answers. And, hopefully, for treatment to reverse this trend.

And I don't think when the veterans come up here and tell you this that it is in anyway a personal attack, it is just that they are trying to get the message across that this frustration is out there, and that you are a long way from convincing the veterans who are suffering from these problems, that it is not because of their exposure to Agent Orange.

Thank you.

DR. SHEPARD: Thank you.

(Applause.)

MR. FALK: We are going to bring a busload of New Jersey veterans down to the next meeting, a busload of 50, so that you can see what we see at the public hearings, and in our dealings with Vietnam veterans.

DR. SHEPARD: Yes, Frank?

MR. DULANEY: Just a comment, in light of everything that has been said. I have to reiterate, the quality

of medical care has beyond excellent, it has been the best that is humanly affordable and humanly available. The doctors have continually shown by their expertise and by their professionalism that I can trust them with my very life, and have, in essense, done so.

If I have impuned anybody individually, I apologize. My intention was to tell you that you are part of being ripped off, just like I am.

I hope that stands *as* an understanding of where *I* am coming from.

DR. SHEPARD: If I may speak to that. I certainly did not take any of your comments as a personal indictment of the VA, certainly not of the medical department of the VA, and certainly not of the work of this committee. And I think, basically, you were supporting the idea of research.

I share, also, your frustrations in dealing with a very difficult health problem. And I am sure, potentially, a life-threatening health problem, that must be of grave concern to you and to your family. And I would hope — and I appreciate your comments supporting the care that you have received in the VA system. I think that is very good of you to do that, and *I* would hope that other veterans hearing you would feel that they do have that same opportunity available to them.

MR. DULANEY: Only the West Haven VA, I haven't been to the other hospitals.

DR. SHEPARD: I understand that, and of course, you are citing a specific example. But I would suggest that there are other VA hospitals that provide similar levels of expertise and I certainly appreciate your coming here, Frank, and sharing your concerns with us. It is very important that we hear those.

Any other questions or comments?

Yes, Peter?

DR. KAHN: I have one comment, and that is part of the reason why veterans come down here, and come to the hearings -- the people in New Jersey, who express rage and frustration – is that the country, as a whole, the VA included, has placed upon science a burden that science can't meet.

If you want a slap-dash job on this kind of work, one can turn that out in a matter of months; if you want it done right, it takes time. There is no way of getting around that constraint on good research.

The question is what do you do in the interval? You have a choice, really, of making one of two kinds of errors, one error would be to do what the country is basically doing now, saying we will grant minimal health and compensation for the Vietnam vets until science is

able to prove, beyond a reasonable doubt, in the sense of a murder conviction, the connection between exposure to the defoliants in Vietnam and later medical problems.

That is an error, because if it is later shown that there is such a connection, then there will be all of these men who have been left to twist in the wind in the intervening time, at a time when they needed the help most.

Most of us think that that is a horrible error, and so we would rather not make that error, we will make no error instead, but that is not what we are doing. The alternate error would be to say, yes, the science takes time, the science is difficult. We don't really know what to do with the science in many cases. And, therefore, in the intervening time, any Vietnam vet who has something which is by any reasonable, plausible connection, not necessarily iron-clad, connected with exposure in Vietnam, will be taken care of in all ways necessary, including his children, if need be.

Those are the two errors we can choose between, giving the care when it is needed, knowing that it may prove not to be service-connected, or not giving the care, and finding later that it may be service-connected and we should have done it.

By making that kind of error, and imposing on

science the burden which it cannot meet, what we do in the end is we discredit science. As a scientist, someone who has invested his life in that, that bugs the hell out of me.

Now, most of us will grant that many good things have come from science. How many of us are alive today because of penicillin?

If you discredit an enterprise, then good people will no longer go into it, and if good people no longer go into it, then the river of good that it has produced will run dry.

That's all I have to say. It is not really a scientific statement, but it it more of a moral and political statement, and it is in line with what the veterans have said here today.

We have a problem here which is not basically scientific, it is, in effect, a moral cancer.

(Applause.)

DR. SHEPARD: I am sure that many of us share that same frustration and eagerness not to —

DR. KAHN: Or you could even solve the problem. I don't mean you, personally, for God's sake, the country can solve the problem, make a presumption in favor of the men, while the research is done.

DR. SHEPARD: Well, certainly the Congress —

DR. KAHN: This committee can make that recommendation, that way you can get the press off our backs and let us get on with doing the research right.

The committee might want to consider that, at a formal session — this is a rump session.

DR. SHEPARD: Well, of course you will appreciate that this involves more than just this committee, it involves more than just this agency.

DR. KAHN: I understand that.

MR. DULANEY: He's on the right track.

DR. KAHN: At least get the pressure off our backs, so we can do the research right.

DR. SHEPARD: Any other questions, or comments?

(No response)

DR. SHEPARD: Thank you very much for your indulgence, and I thank you for a very good meeting.

(Whereupon, the meeting was adjourned at 2:35 p.m.)

Vu-graphs accompanying presentation by Dr. Kang (see pages 73-78)

Joint VA/AFIP Study of Malignant Neoplasms Among Vietnam-Era Veterans Hospitalized in the VA Medical Facilities

Agent Orange Projects Office, DM&S, VA
Pathology Service, DM&S, VA
Armed Forces Institute of Pathology

Research Questions

1. Among the Vietnam-era veterans who have been hospitalized in the VA medical facilities, does the histopathology and anatomic site of cancer among Vietnam veterans differ from those of non-Vietnam veterans?

2. Among the above group of veterans, is overall cancer or a particular type of cancer more frequent among Vietnam veterans than non-Vietnam veterans?

Table 1
Number* and Percent Distribution of Primary Diagnosis
Among a Sample of 13,000 Vietnam era Veterans.

Diagnosis	ton-Vietnam	Vietnam	Total
Infectious & Parasitic	182	178	360
Neoplasms	240	157	397
Endocrine, immune disorder	142	83	225
Blood and Blood forming organ	32	20	52
Mental disorders	2,540	1,648	4,188
Nervous system	288	181	469
Circulatory	455	263	718
Respiratory	405	245	650
Digestive	813	567	1,380
Genitourinary	304	231	535
Skin	364	322	686
Skeletal, connective tissue	462	383	845
Congenital anomalies	55	34	89
Symptoms, ill-defined conditions	469	334	303
Injury & poisoning	1,043	791	1,834
Other	122	93	215
	7,916	5,530	13,446
	(58.9%)	(41.1%)	(100%)

*A random sample of 13,446 Vietnam era veterans from the PTF for FY 1969-1982.

Table 2
Number* and Percent Distribution of Primary Diagnosis
Among a Sample of 900 Vietnam era Veterans.

Diagnosis	Non-Vietnam	Vietnam	Total
Infectious & Parasitic	10	4	14
Neoplasms	15	7	20
Endocrine, immune disorder	7	10	17
Blood and Blood forming organ	2	1	3
Mental disorders	258	150	408
Nervous system	16	11	27
Circulatory	35	29	64
Respiratory	18	12	30
Digestive	42	39	81
Genitourinary	18	12	30
Skin	12	14	26
Skeletal, connective tissue	35	30	65
Congenital anomalies	3	3	6
Symptoms, ill-defined conditions	28	8	36
Injury & poisoning	34	16	50
Family history of disease	12	11	23
	545	357	902
	(60.4%)	(39.6%)	(100%)

*A random sample of 902 Vietnam era veterans from the PTF for PY 83/84.

Table 3
Number* and Percent Distribution of Malignant Neoplasms
from the VA Patient Treatment File for FY 1981

Primary Site (ICD)	Number of Cases	Percent
Buccal cavity and pharynx (140-149)	143	7.8
Digestive system (150-159)	172	9.4
Respiratory system (160-169)	269	14.8
Bones and joints (170)	21	1.2
Soft tissue (171)	31	1.7
Skin (172)	50	2.7
Other skin (173)	193	10.6
Breast (174, 175)	13	0.7
Genital/Urinary system (179-189)	272	14.9
Eye (190)	3	0.2
CNS (191, 192)	59	3.2
Endocrine system (193, 194)	22	1.2
Lymphoma (200-202)	131	7.2
Multiple myeloma (203)	5	0.3
Leukemia (204-208)	37	2.0
Other and ill defined (195-199)	401	22.0
	1,822	100

*Malignant neoplasms diagnosed in Vietnam era veterans who underwent surgery in VA hospitals and were discharged during FY 1981.

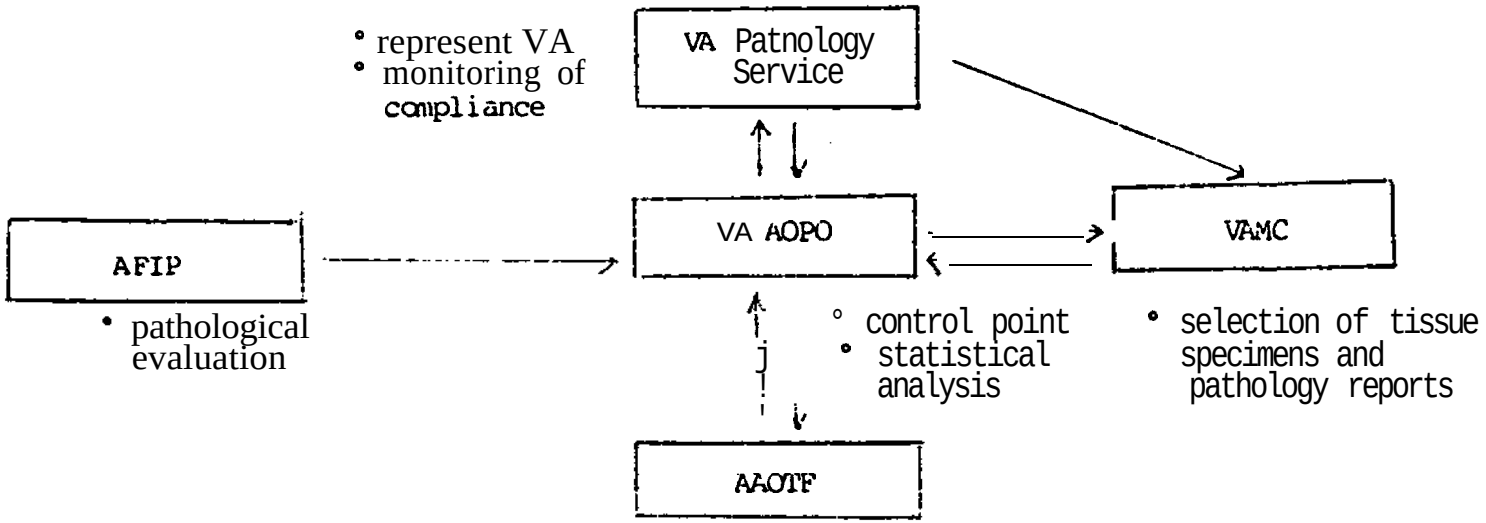
Table 4
Sample Size Determination

Sample Size

R	P_1 0.01	0.05	0.10	0.20
1.5	10,364	1,966	916	392
2.0	3,100	531	266	108
2.5	1,602	296	133	51
3.0	1,027	187	82	29

Alpha = 0.05
Beta = 0.10
R = relative risk
P_1 = proportion of particular malignant neoplasm to overall cancer in the reference population.

Study Procedures



Analyses

1. Vietnam service

a. Anatomic site
b. Histopathology

2. Agent Orange exposure likelihood

a. Anatomic site
b. Histopathology

3. Comparison of VA and AFIP pathological diagnoses

SUBCOMMITTEE ON EPIDEMIOLOGY/BIOSTATISTICS
June 5, 1984

Dr. Richard A. Hodder called the meeting to order. He stated that he would ask Dr. Nelson S. Irey to speak first because he had a pressing engagement and wouldn't be able to stay.

Dr. Irey stated that Dr. Kang will send cases of malignant neoplasm to him at the Armed Forces Institute of Pathology. These cases will be referred to the appropriate anatomic area group and then the results would be sent back to Dr. Kang. When asked about timeframe for study he stated he could not answer and suggested Dr. Kang's office would be in a better position to do so.

Next, Dr. Matthew Kinnard gave a brief update of the R&D program. He stated that out of 36 solicited proposals, 10 were approved and funded. Due to safety considerations, there was a six to eight month delay in beginning studies, in order to ensure safety in laboratories. All 10 investigators' plans have been approved by Central Office and the research is now underway. Dr. Kinnard then introduced the three invited VA investigators and stated that the findings which were about to be discussed were preliminary and cautioned any media people present to take that into consideration in their reporting.

I

Dr. Julianne Meyne, Ph.D., consultant on Dr. David Allison's study at the VAMC Albuquerque, New Mexico, entitled "The Effects of Low Dose TCDD on Mammalian Chromosomes and Liver Cells," made the first presentation. She stated that the two major divisions of the study include cytogenetics and liver histopathology. Two strains of mice are being used in the studies. The first study on chromosome aberrations employs five mice per dose of TCDD. The mice are sacrificed 24 hours after TCDD injection and bone marrow preparations are closely observed. Dr. Meyne showed slides of chromosomes in various states of mitosis. The study results to date show that there are no detectable cytogenetic effects from the injection of low doses of TCDD in mice. Higher doses of TCDD were used than was originally planned because there was no significant effect seen with lower doses. This is an acute study as compared with the sub-acute study of people involved in the Seveso incident. Acute studies were done initially to familiarize the investigators with the type of response they could expect to see in their subjects and to establish a workable dose level of TCDD for the chronic studies planned for later.

II

Dr. Nicholas Calvanico, a co-investigator with Dr. James Fujimoto, prinicipal investigator of the study at the VAMC Wood, Wisconsin, presented the current results of their study. The study is entitled "The Effects of TCDD on Hepatobiliary Function in Animals." The test chemical being used by this team of investigators is also TCDD, which is reported to be one of the most toxic of the chlorinated dioxins. It has been shown to be lethal to all animal species tested to date. Lethal doses of TCDD, of course, vary widely from species to species. This group is testing the effects of TCDD on liver function in rats. They chose to use IgA as an endogenous marker as opposed to an exogenous marker. In most species, the percentage of circulating IgA is very low. It is, however, the body's first line of defense to outside influences. Rats were sacrificed at four, seven and ten days following injection of TCDD. An increased level of the IgA fraction was seen but no increase was seen in IgG fraction. It has been reported that this increase in IgA results in liver malfunction. The increased level of IgA has been theorized to result from either (1) loss of the liver's ability to transport bound IgA; (2) an increase in the synthetic rate of IgA; or (3) a decrease in the catabolic rate of IgA. Key questions which the group plans to pursue in the future are: (1) Is altered hepatic function reversible? (2) Are the effects observed dose dependent? and (3) What is the relationship of the animal studies to the situation seen in man?

III

Dr. Donald Vessey, Ph.D., principal investigator of a study at the VAMC San Francisco entitled "Metabolism of the Herbicides Present in Agent Orange and Agent White" gave the final presentation of the morning. The basic objective of this research is to determine whether 2,4-D and 2,4,5-T interfere with the liver's ability to detoxify other toxins encountered by the body. Structural similarities between herbicides and known substances important in drug metabolizing enzymes suggest that this is possible. Glutathione-S-transferase was chosen because it is the liver enzyme that consistently leads to detoxification of metabolites. Starting with G-T-ases from rat supernatant, Dr. Vessey was able to separate the mixture into six different forms belonging to two distinct classes of enzymes. The first class was extensively inhibited by the presence of 2,4-D and to a lesser extent by 2,4,5-T. Specifically, a 50% inhibition occurred between 0.2 and 0.5 millimolar concentration of the herbicide. This is equivalent to an oral dose of 100 mg/kg of body weight. The second class, referred to as the B-class of enzymes was activated three

fold by 2,4,5-T and one and three tenth fold by 2,4-D. The B class is known to be involved in the detoxification of organic peroxidases. In view of these findings, the investigator wanted to know if 2,4,5-T stimulates the metabolism of organic peroxidases. It did not. This finding suggests separate mechanisms occurring at separate sites on the enzyme. The real interest is what happens in human liver. Most forms of the enzyme in human liver are in the B class. The investigator also wanted to know if activation occurs in the presence of 2,4,5-T. To test this, he obtained a single wedge of human liver and partially purified it into four fractions: three basic fractions and one acidic fraction. He found that three basic forms were inhibited by *2,4-D* and 2,4,5-T although to a lesser extent in the human liver than in the rat. The acidic form was not inhibited at all. Future study will focus on dioxin pretreated animals' ability to subsequently metabolize 2,4-D and 2,4,5-T.

SUBCOMMITTEE ON VETERANS' EDUCATION/INFORMATION

Mr. Fredrick Mullen, Sr. (Paralyzed Veterans of America), Chairman of the subcommittee, convened the meeting at approximately 10:53 a.m., Tuesday, June 5, 1984. Other subcommittee members and alternates present were: Mr. George T. Estry (Veterans of Foreign Wars); Mr. Hugh Walkup (National Veterans Task Force on Agent Orange); and Mr. Walter Phillips for Mr. Charles Thompson (Disabled American Veterans). Officials from several state Agent Orange commissions were also present.

Old Business

Hugh Walkup stated that he had not received a copy of the minutes of the last subcommittee meeting, and he thought that it had been decided that subcommittee members would receive copies of these minutes. All other members of the subcommittee stated that they had received their copies along with copies of the draft transcript of the full committee meeting. Mr. Walkup stated that he would look again in the packet he had received and see if his copy was there. Wayne Wilson of the New Jersey Agent Orange Commission and Chuck Conroy of the West Virginia Department of Health stated that the States had not received copies and felt that they should be included in the mailing.

Videotapes

Mr. Danny Jones of the Regional Learning Resources Center, VAMC St. Louis, Missouri, discussed progress on the Agent Orange videotapes. He stated that they will hopefully have the scripts of all three videotapes ready prior to the next meeting of the Advisory Committee in September, and will be sending the scripts for comments. The first videotape will be the one for veterans' information, and they hope to shoot it in September or October.

Mr. Wayne Wilson said that members of the subcommittee had criticisms of the previous videotapes, especially regarding stereotyping of Vietnam veterans. He stated that he hopes this will be taken care of in the new videotapes.

Mr. Mullen stated that members of the subcommittee were assured that they will have the opportunity to review the scripts before the tapes are released this time, and he is confident that they will have this opportunity.

Discussion of Veterans' Concerns

Litigation

The question was raised, "when the Agent Orange Registry information was to provided to the Court, what considerations went into providing this information, and could it be used against veterans?"

Mr. Fred Conway of the General Counsel advised that the VA is party to the litigation and was ordered by the court to provide names and addresses. He stated that the VA tried to resist, and did have a protective order issued. The information provided was records of individuals who participated in the Agent Orange exam program. Dr. Shepard stated that the records provided the Court did not include all medical records--just Agent Orange exam information.

Mr. Mullen asked if all information in the Agent Orange Registry has been given, does that mean that all those records were reviewed, or will they wait until a veteran opts in or out? Mr. Conway stated that to his knowledge, none of the records have been reviewed.

Wayne Wilson stated that he feels it is time the General Counsel begins to look out for veterans' concerns. Veterans have provided private information to the VA, which the VA then turned over to the Court. Their concern now is that the U.S. Government may turn up as a defendant, and what will happen if veterans turn up as plaintiffs. Mr. Conway again emphasized that the VA had no choice but to provide the information.

Mr. Walkup recommended that the committee should request the names of all persons who had access to the records and advise the veterans of who had access. He stated the committee should then recommend return and destruction of the records.

Dr. Shepard stated that we would have to look into the legal implications of the VA before making such a recommendation to the Court. Mr. Conway said that he would check with the Department of Justice.

Mr. Conway was asked if he has been involved in H.R. 1961. He stated that he has been monitoring it for the Agency. Mr. Conway was then asked what is the VA's position regarding H.R. 1961. He stated that the VA does not believe there is evidence that the three disabilities mentioned in the bill are related to Agent Orange. The VA has taken opposition to the language of the House version but has not taken opposition to the Senate version.

After Mr. Conway left the meeting a gentleman from the audience commented that he takes time out to attend the full day's meetings and resents the fact that the VA cannot have a representative here for the full time to answer questions. Mr. Mullen advised him that at the time the agenda was drawn up no one knew the litigation was coming up, Mr. Conway did not know he would be called on to answer questions and had prior commitments.

Readjustment Counseling Program

Dr. Raymond Scurfield, Assistant Director of the VA's Readjustment Counseling Service, discussed the Readjustment Counseling Program. He stated that there are now 136 Vet Centers, staffed by mental health counselors. So far this fiscal year 90,000 Vietnam Era veterans have been seen in Vet Centers.

The Vet Centers deal mainly with veterans who have readjustment problems, including Post Traumatic Stress and related problems.

Throughout this fiscal year, 4% of the veterans seen have expressed concern about Agent Orange. This figure is the percentage for all veterans coming into the centers. 55% of the veterans seen in the vet centers are Vietnam theater veterans, which almost doubles the percentage 4% figure of all Vietnam Era vets. The number of veterans who report Agent Orange concerns doubled in May. Dr. Scurfield also stated that some veterans have expressed confusion as to the Agent Orange exam.

Mr. Walkup asked how this data is gathered, and if there is a checklist used. Dr. Scurfield explained that it depends on each individual who comes in--for some there is a structured intake interview, and for others there is a very loose structure--a few questions are asked to see why the vet is coming to the Vet Center.

A member of the audience asked what is being done for the suburban working vet who is having some problems but is trying to maintain a piece of the pie? Are you open evenings? Dr. Scurfield responded that there is an active outreach program--they don't just wait for veterans to come through the door. Wayne Wilson stated that New Jersey Vets Centers do have evening hours and evening programs.

Mr. Walkup asked how Vets Centers outreach programs relate to Agent Orange. Dr. Scurfield stated that the centers serve to link vets with the rest of the VA and to recommend the Agent Orange exam and getting on the Registry.

Mr. Mullen asked, since the outreach program has been instituted, are outreach centers privy to conference calls? Dr. Scurfield stated that team leaders were to be informed of conference calls, but he doesn't know if they were or not. Mr. Mullen recommended that team leaders should be, if they are not already, privy to conference calls.

Mr. Estry asked if the outreach centers are gearing up for female Vietnam Era veterans. Dr. Scurfield replied that there are women's working groups, and that they are developing brochures and programs specifically for women Vietnam Era veterans. He stated that the staffs are oriented to female veteran issues, and they are also making efforts to hire more female staff.

Mr. Walkup stated that he feels it is ridiculous to have only one hour for the subcommittee meeting, and to have only 15 minutes for Vets concerns. He felt that there should be a recommendation that the subcommittee be given more time.

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

Twenty-First Meeting
September 12, 1984

December 1984 Washington DC 20420

VETERANS ADMINISTRATION

Advisory Committee

on

Health-Related Effects of Herbicides

Veterans Administration
Central Office
Room 119
810 Vermont Avenue, Northwest
Washington, D. C.

September 12, 1984

ADVISORY COMMITTEE PRESENT

BARCLAY M. SHEPARD, M.D., Chairman
Director
Agent Orange Projects Office
Veterans Administration, Washington, D.C.

GEORGE R. ANDERSON, M.D.
Occupational Medicine and Toxicology
Texas Department of Health
Austin, Texas

GEORGE T. ESTRY
Appeals Consultant
Veterans of Foreign Wars
Washington, D.C.

THOMAS J. FITZGERALD, M.D.
Medical Consultant
National Veterans Affairs and Rehabilitation
American Legion
Washington, D.C.

MARION MOSES, M.D.
National Farm Workers Health Group
Keene, California

JOSEPH MULINARE, M.D.
Centers for Disease Control
Chronic Disease Division
Atlanta, Georgia

NOEL C. WOOSLEY
National Service Director
AMVETS
Lanham, MD

ALTERNATES/SUBSTITUTES PRESENT

PETER C. KAHN, Ph.D.
Associate Professor of Biochemistry
Rutgers University
New Brunswick, N.J.

WALTER PHILLIPS
Disabled American Veterans
Washington, D.C.

HUGH WALKUP
Department of Human Resources
Seattle, WA

AGENDA

PROCEEDINGS

Call To Order and Opening Remarks (8:30 AM)

DR. SHEPARD: As usual, we have a fairly full agenda. This is the 21st quarterly meeting of the VA's Advisory Committee on the Health-Related Effects of Herbicides. As usual, this morning's meeting will be open to the public, and we're delighted to have so many visitors with us.

In order that we can keep track of your attendance, will you please make sure that, if you haven't already done so, would you please register in the anteroom of the conference room,

As usual, we will also have a question and answer period at the close of the meeting, or before the close of the meeting, towards the end of the meeting, and people are encouraged to ask questions. Please submit your questions

to Don Rosenblum, at the back of the room. We'll attend to those during that portion of the agenda.

We're sorry to report that Dr. Lingeman will not be with us, today. She has been a very faithful member of this committee, but, unfortunately, there was a death in her family which has precluded her from being

with us. But, we do recognixe her continued devotion to this effort, and we express our condolences.

Just a few mintues ago, got a call from Dr. Hodder.

There has been an emergency and he will not be able to be with us. I have asked Dr. Kang, of our staff, if he will fill in for Dr. Hodder, in Chairing the Subcommittee on Biostatistics and Epidemiology, which will meet in this room, when we break into our subcommittee meetings.

The next meeting of this committee has been scheduled already for December llth, that's a Tuesday, December llth, in this room.

A great deal has occurred since our last meeting, in June. As I'm sure many of you know, CDC has released the birth defects study that they have been working on so assiduously, and we're very pleased that Dr. Mulinare will be briefing the members of the Committee on the results of that study. He'll be prepared to answer questions from those of you who may have questions about either the methodology or the results of that study.

An article, as you probably know, appeared in the August 17th issue of the Journal of the American Medical Association, which summarized the report,

and it is my understanding that CDC is in the process of preparing a full report, and that, I gather, is in the... (Dr. Mulinare held up copy of the full report.) It is ready. Must be still wet.

We're still working hard on the development of a lay language summary of the latest review of the literature on herbicides, with special focus on health effects of exposure to herbicides. We hope to have that out before the end of the year.

In addition, we are working hard on developing a series of videotapes, up-dating --- research and other related matters concerning the whole Agent Orange issue.

There's been a considerable increase in the request for Agent Orange examinations. We feel that this is in some way related to the court action that is going on in New York. But, there, in the months immediately preceding the settlement announcement, initial examinations averaged about 2,000 per month.

In February, there were 1848 initial examinations.

In March, 2,137.

In April, 2,071.

The initial examinations totals, then, jumped to 3,212 in May, 4,010 in June, 4,153 in July. So, the number seems to be climbing. It's almost a doubling of the average monthly exam rate, which had been running about

2,000 over the last several years.

We are continuing work on our monograph series. We are happy to announce that the monograph on cacodylic acid is essentially complete. We're putting the finishing touches on the one on the phenoxy herbicides. Dr. Betty Fischmann has been working very hard on finalizing the plans on the chloracne monograph, and we're moving along well on the monograph on birth defects and genetic counseling.

Well, let's move into our prepared agenda, and I'd like now, to call on Colonel Al Young, who will bring us up to date on the status of International Dioxin Research. While Al is coming to the podium, I'd like to make special recognition of the presence of Dr. Michael Adena, who has rearranged his schedule and is here from Australia, and will be addressing the committee, so we're delighted to have Dr. Adena with us. He is the senior vice statistician, working on the Austrailian/Vietnam Veteran Health Studies, and will bring us up to date on the status of those efforts. We are very happy to have you with us. Al?

STATUS OF INTERNATIONAL DIOXIN RESEARCH

DR. YOUNG: Good morning, ladies and gentlemen. In terms of some of the international activities that are going on, I thought you would like to receive some

of the latest information. On September 20th through 22nd, the Italian Government, Ragione Lombardia is sponsoring an international symposium on, what they call the "International Experience with Dioxins and Related to compounds: Comparisons and Collaborations." This is going to be a technical program, related to the clean-up operations, and a lot of the environmental studies that have been conducted.

We've had a great deal of confusion about where the Italians were going to go with this particular symposium, and we now find that they are not going to emphasize the human, at this point in time, and the epidemiology studies that they have conducted; but, rather focus for this particular symposium, on data related to environmental fate, clean up technology, and some of the problems and some of the results that they have had with respect to that.

I have brought handouts on the program for that particular symposium, and I'll place that in back in case any of you are Interested.

The fourth International / Symposium on Chlorinated Dioxins and Related Compounds has been scheduled for October 16th through 18th, in Ottawa, Canada. This particular program will focus on international activities involving, not only toxicology, environmental fate, but

also on the human, and they plan a series of presentations on the status of epidemology studies in various countries. The Italians will be presenting a general paper there, on the work in Seveso, Italy. There will also be papers from various investigators in the Unites States. There will be a presentation by investigators from Germany, Netherlands, and Denmark. So, that should be very important series of presentations on what's happening overseas, in the Dioxin arena.

A third item, although it's not an international conference by any means, but I think you should be aware, and Dr. Adena is here, today, but, in case many of you are not aware..the Royal Commisssioner, overseeing the hearings, on the subject of Vietman and Agent Orange in Australia, does plan to attend and visit, throughout the United States, in early October, well, late September through mid October. An agenda is just now being coordinated with the Australian Embassy. The Royal Commissioner and a couple members of his staff anticipate visiting San Antonio, to review the Ranch Hand results, the Center for Disease Control, to review the progress of their studies.

To visit St. Louis, and a review of on the Twin Study, to visit Ray Suskind, and the work that he has done in Nitro, West Virginia. To visit the State of New York's

study team and look at their studies on mortality and soft tissue sarcomas. He will then be in Washington, he anticipates visiting a number of the veteran groups and those arrangements are trying now to be made. And, of course / a number of other agencies that have programs on Dioxins and related studies.

A couple of publications out of the International Community, have been received by me, and / I thought some of you might be interested. Some months ago, as a matter of fact, to in January of 1983, there was a symposium held in Ho Chi Minh City. An international symposium with a good many investigators from various western countries attending, and interacting with the Vietnamese on studies that they were conducting; i.e., /the Vietnamese, with some American assistance, in Vietnam.

We've been waiting a long time for those proceedings. Last week those proceedings were released. It's a book entitled "Herbicides and War, the Long Term Ecological and Human Consequences." It's edited by Art Westing. I brought for you, the cover page with the address on where to order that book. I do not know the price of it, but it has just been released. I thought I might just highlight some of the chapter areas, because I know there's a good deal of interest

in this. In addition to going into th. forest . . . ecology and terrestial animal ecology, they also studied reproductive epidemiology, cancer and clinical epidemiology, experimental toxicology and cytogenetics. And then they conclu with Dioxin chemistry. So, there are three chapters devoted to some of the human health studies that have been going on in Vietnam.

I have not read the book, yet, and I can't comment on the material.

Coming out of Australia, just very recently, Jack McCullock's book, "The Politics of Agent Orange." I don't have a flyer on it, but I'll have the front cover, the inside cover with the address and so on, reproduced for you, if any of you are interested.

I just received this morning, from Canada, a brand new publication by the Quebec Government, entitled, "2,4,5-T Exposure On Quebec Forestry Workers." This one is in French, but I have English copy coming, and I will make that available to the Committee.

Two other publications are coming out that you should be aware of. The Proceedings of the Rockefeller Symposium on the public Health Consequences of Low level Exposure to the Dioxins, will be released within the next few weeks. That publication is finished, it's been printed, and distribution is now just beginning to take

place. For that, I will get a flyer and put it out for distribution, too.

Michigan State University's proceedings of "Dioxins in the Environment" has been completed. We should be receiving flyers on that very shortly, for distribution.

I think that is just about a summary of what's been going on. If I can answer any questions..

DR. SHEPARD: Are there any questions from members of the Committee?

Do we have an agenda, now, for the Ottawa meeting?

COL. YOUNG: Yes.

DR. SHEPARD; Has there come out anything since the original flyer that came out?

COL.YOUNG: No. No. That was a very sketchy agenda. We did not receive, from the Fourth International Symposium, a detailed agenda, yet.

DR. SHEPARD: Is that forth coming, do you know?

COL.YOUNG: I certainly hope so. We're coming right down to the line.

DR. SHEPARD: Fine. Any questions for Colonel Young? Peter?

DR. KAHN: The Rockefeller Symposium is published by

Rockefeller
University Press.

COL. YOUNG: No, Butterworth Press. Peter, I will have a flyer on that. I'll make these available out in back.

DR. SHEPARD: Thank you very much. I'd like now, to call on Dr. Michael Adena to tell us a little bit about what's going on in Australia, concerning the Veterans studies.

AUSTRALIAN VETERANS STUDIES

DR. ADENA: What I want to do is just introduce some of the Australian Government's sponsored studies on Vietnam veterans. I'm actually as Dr. Shepard said, with the Australian Veterans Health Studies. I've been the statistician involved in the analysis of these two studies.

The Australian Veterans Health Studies is a scientific research team set up by the Australian Government and actually within the Department of Health. And they produce reports or have produced reports to the Department of Veteran Affairs. It's the Australian the Australian Government.

The birth defects report, which you doubtless all heard about, came out in February, '83, and Dr. John Donovan was the person who was in charge of that research, and was the senior author of the report.

The mortality report, which I'll give a little

bit more detail on, today, is due to come out next month or possibly in November. Unfortunately, that does mean that I can't reveal the exact detail of the results. And that work has been organized by Dr. Michael Fett. There was to have been a morbidity study, but that has, in fact, been cancelled, and the Australian Veterans Health Studies might well be in their last week of existence, at the moment. I haven't checked. In other words, this report should have gone off to the printers, this one is done and this one a month ago, I think. So, this organization will, may well cease to exist very soon.

You've already heard about the Royal Commission. It's a special judicial inquiry. It's an independent judicial inquiry. The judge for that is a highly respected judicial figure in Australia. And it's considering not only Agent Orange, but other chemical exposure in Vietnam.

I'll just give you a little bit of background about the mortality study. The mortality study was a cohort study done on 46,000 national servicemen. National serviceman is the Australian term for draftee. That in fact, is all national servicemen, with Army service between 1965 and 1971, and all of those could have gone to Vietnam. All of the intakes that had people going to

Vietnam are included in this particular study.

That included about 19,000 Vietnam veterans and about 27,000 others staying in Australia. The terminology is a little bit different between Australia and the U.S. We call these Vietnam veterans and we call these people non veterans, where, as of course, in the U.S. they are all veterans, in that they've served in the Army.

This accounts for about half of the people that went to Vietnam. - a little bit under a half of the people that went to Vietnam from Australia. One reason for chosing national servicemen is that they are probably a more homogeneus group than the regular soldiers. They are usually aged about 20 at enlistment, although it is possible in Australia, it was possible in Australia, to obtain, to defer for educational reasons, for example.

It was a random ballot, and there was a medical examination. So, in fact, quite a number of, well, the people that got into the Army, were generally fit. And that has consequences in the analysis as you'll see.

The idea behind the study, of course, is to find out who was alive at a particular date. The particular date for this study was the very beginning of 1982, and for those who are dead, we want to know when

did the person die and what did they die of. In the protocol for the study, which I presume you have seen, there was mention of cancer for example, some soft tissue carcinomas. There was also some thought that suicide, might be higher among veterans than among non veterans. So, there were specific causes of death that we can consider in the analysis.

Perhaps the best thing for me to do is to emphasize the quality of the data, tfhe matching procedures that we used were very stringent. That was matching for names of people, to find out whether the people were alive. In Australia, voting is compulsory and in fact, most people were picked up as being alive, at the first of '82, because they were registered as voters.

As I say, voting is compulsory in Australia, so in fact, that register is a good check-up of who is alive in Australia.

There are also procedures involving test subjects, checking ap whether the procedures of matching in say, the electoral roll and in the other registers that we used, were working satisfactorily, and also whether the procedures, the matching in death registers, which, unfortunately, in Australia, there are a large number of different death registers. One for each

state and territory.

The completeness of follow-up. Suffice to say the follow-up was very complete, so we don't have a lot of people for whom we don't know whether they're alive or dead, at that date. And for, I think about 98% we know whether they were alive or dead on that date. There was also stringent checks made on the cause of death. We didn't just take the cause of death as written down on the death certificate. All the medical records of the people who died were carefully reviewed by an independent group of physicians. And for cancers, they were reviewed by a well respected figure in cancer histology.

The analysis is really the area in which I'm interested in. The biostatistical technique that we used was log-linear regression analysis for the death rates. But, in fact, in the report that comes out, it's, that's fairly much disguised. Most of the tables can be summarized in a normal sort of way.

Variables for analysis: We had quite a number of them. I don't want to go into all of them now. But, from Army records we have pre-enlistment factors like education, we had also those measured on enlistment, they were also measured during service, and also variables measured

at discharge. And we had a large number of variables measuring we had a large number of variables measured in Vietnam. The Australian studies, it's not possible to get a proper herbicide exposure index, so, another proxy for exposure in Vietnam has been used. Principally, the calendar at the time people were in Vietnam, the calendar year, and also duration, classified by service in Vietnam.

There's also, I believe, which particular problem or any particular job that he did in Vietnam, and there's also a battle casualty index. But, in terms of looking at Agent Orange, there is no specific measure Confounding. Eortunately, we found only one and so the results are fairly, fairly clear cut, at least from an analysis point of view.

It was also impossible to compare with the Australian rates of death. I should say that these young men were medically selected on the basis of their general fitness to go into the Army, and in fact, their subsequent death rates are below that of the Australian population. That does mean that as a study, it has the problem that there are relatively few deaths, which, if you're looking at the young men, there tend to be very few deaths.

We did, however, find, that those who served

a
in the Army for only/short period of time, that none of those, in fact, got to Vietnam, but had to have at least nine months training in Australia before they were eligible to go to Vietnam. Usually, they went on tour / of one year to Vietnam, if they would go to Vietnam. It turns out those people that were discharged by the Army early, had high death rates, so that's one of the quirks of the analysis.

And, the analysis did look at specific causes I mentioned. Soft tissue cancers and I also mentioned suicide. But, I think I'll stop my presentation, here, and answer questions.

DR. **SHEPARD:** Are there any questions from the members of the Committee? **Yes,** Joe?

DR. **MULINARE:** Are there any provisions, when you say **this,** when talking about the demise of your group, were there any provisions for extending the mortality study to, as looking at the cohort in years to **come...** To look at, as they happen.

DR. **ADENA:** Well, **that's. .again,** without, to say what the
wishing / report might say, **that's** one of the implied suggestions that perhaps it would be a good idea to look at in another ten years. To carry out the same exercise
Veterans Health
again. But, at the moment, as I say, Australian / **studies,** the organization **that's** carried out that **work,** will cease
automatic provision
to exist very soon. So, **there's** no / for extending the

problem.

MR. WALKUP: Could you review for us some of the reasons that the morbidity study was not extended?

DR. ADENA: Well, it was basically, it was going to be very expensive, and it wasn't altogether clear that there would be any, that the results that would come out of it would be clear. The study population was not going to be, even with a study which I understand is expensive, of about nine minion dollars, the number of subjects that could be studied would probably not reveal much information, unless they were very gross health affects, morbidity health affects, and we would have expected those to have been detected, for example, in a mortality study.

Another constraint was that the Royal Commission is under a lot of pressure to report very quickly. In fact, they were to have reported, I think it was earlier this year. They've now been extended to next year. I had hoped that the morbidity study would have gone on for some seventeen months, and would have delayed the Royal Commissioner in presenting his report. So, there are two of the reasons. There well may be others in that they, all of the reasons haven't been made public, for public discussion, on that issue. There was

something that the Royal Commissioner had wanted, but since he was told that he had to report early, he couldn't have his morbidity study.

DR. SHEPARD: Are there any other questions from the members of the Committee?

UNIDENTIFIED SPEAKER: I think I missed it but, did you tell us what the follow-up rate was? How many of the deceased veterans you had actually found as a whole?

DR. ADENA: The number of deceased, we think that it's possible from looking at the test subjects, that we may have missed .4 rercent. But, we, in that total, we had about 600 deaths, and so that's about 1.2% of all the people in the cohort, within the study, the outcome was death. Most of the people were found after the first of 1982 that is, on the electoral Troll in July of '82. It was both & computer search and some manual search.

After looking for their names in the electoral roll , the names are being checked back with the Army to make sure that the correct names are being searched for, and it was, and there was also a search done in the electoral roll of the preceeding year.

A lot of the, some people have, of course, not been found because they left Australia. They had left

Australia, so they are recorded on the Immigration fiche of the arrivals and departures, held by the Department of Immigration, and that accounts for base, more proportion, more people.

The other registers that were searched, are death registers where we searched for the deaths, the Army, itself, since some of these people are still serving. There were a number of other sources, which are not biassed for veteran status, but, which may pick up enough people who aren't, for some reason, on the electoral roll.

For example, corrective service people who are in prison or have been in prison recently. Credit Bureau, banks, so that perhaps gives you a rough idea of the possibilities of the comprehensive search for the followup.

DR. FITZGERALD: I would assume that your experience in Australia would be similar to the United States in this age group, in that it would be anticipated that the majority of these deaths in that age group would be ---accidents---.

DR. ADENAs About 3/4 are due to external causes. And motor vehicle accidents is the most important single cause. About 10% suicide. Of the total deaths, about 14%, I think, might be cancers. That's exactly as you would expect from the Australian, from the Australian

of those death rates of other Australians.

DR. SHEPARD: Are there other questions? Thank you very much, Mike. I hope that you will be able to stay, maybe meet with the Subcommittee on Epidemiology and Biostatistics because I'm sure they may have more questions.

DR. ADENA: Dr. Shepard, I would like to thank you for letting me speak here.

DR. SHEPARD: My pleasure. Good morning, Dr. Moses. Dr. Moses has come from the West Coast, I believe, and we're very happy to have..

DR. MOSES: Yes, I want you to know there aren't very many cab drivers in this town that knows where this place is. That's why I'm late.

DR. SHEPARD: I hope they didn't take you to the hospital.

DR. MOSES: That's where they wanted to take me. The Veterans Hospital.

DR. SHEPARD: Glad to have you with us.

DR. MOSES: Thank you.

DR. SHEPARD: Okay. I'd like now to call on Dr. Mulinare to give us an overview of the famous birth defect study that he just completed.

CDC BIRTH DEFECTS STUDY

DR. MULINARE: Good morning. The opening goal

for us at CDC is to look at birth defects and try to determine what causes the defects. We do epidemiologic studies to try to find out what type of paint may be associated with birth defects, because, for the most part, 80% of all birth defects have unknown causes.

The kinds of studies that we try to do, to try to determine whether there are strong associations, that it is something strongly associated with a particular kind of birth defect. For example, this would, that most of you are aware of, is maternal age and Down's Syndrome or Mongolism. When we do these studies and we see that association, we know that something about the mother, as she gets older, that causes her to have a child with Mongolism. What we don't know exactly what it is, and ultimately, what we want to do is find out why a mother who is older, tends to have a child with Down's Syndrome.

We do know that it's a chromosomal defect. That is, there is an extra chromosome somehow. It gets from the mother or the father, to the baby, but no one really knows what exactly causes that to happen.

The kind of epidemiologic studies that we do, when we did, here, with this birth defects study, are the kind that give us an opportunity to look at associations. And we can do that, and we have to do it

that way because birth defects; as individual birth defects, are extremely unextremely rare. Some are extremely rare. But, in general, are rare. That is, they will happen in 1 in one one thousand births. Overall, though, when you add up ail birth defects, then we find that, overall, anywhere from 2 to 3% of children who are born in the United States, do have a major structural birth defect.

In order to study this, you can do it two ways. You can do it by studying the babies, that is, find babies that have birth defects, then go back and look and see what kinds of factors might be associated with the birth defects.

Or, we can take a group of mothers and follow them through pregnancy. Get histories of these mothers or fathers. Find out what they were exposed to, and then wait to see what happens to the baby.

If we did it the second way, it would take a long time. In fact, because birth defects, in general, are rare, it would also require quite a few families.

To do it an efficient way, a more efficient way, takes into account resource limitations. We chose, and we only had one option, to take our surveillance system, which has been going on and it lasted for 15years, take the babies who have birth defects, that is, concentrate

the number of babies with birth defects, and then go back and ask the parents about things that happened in their lives, either around the time of the pregnancy or before the time of pregnancy, to come up with associations. Unfortunately, this does not give us the opportunity to say that there is a direct cause and can affect relationship.

It just gives us the opportunity to say that something that is associated with child, a baby having a birth defect.

The question that raised early this morning was, why, only Atlanta? Why do the study only in Atlanta when there are veterans all over the United States who are very concerned about this problem.

Well, Atlanta is the only place in the United States that has such a surveillance system. With such records that we could efficiently and in a timely way, actually get the information that we needed to find the parent, or try to find these parents, and then get information from them, through an interview. There is no other place in the United States that can do that.

If we wanted to start from scratch, start with, say we wanted to do a study, imagine what it would take to accumulate 15 years of data, in terms of locations from a population scattered across the United States, in

order to start the project. It would be roughly akin to spending 15 years trying to accumulate it. It would be a very difficult thing to do. Resources would probably conclude doing it in a short period of time.

And this is why we felt that we had the opportunity in Atlanta, to perform a study, in a timely way, but, at the outset, we defined limitations to what we could do, and that included being able to study only children who were born with major structural defects. And we did not have any information or records on babies who might have mental retardation. We did not have any information on families who ---miscarriages in the families. We don't have any information on our records with regards to behavioral problems.

And, up front, we said that we couldn't study these particular problems, and that's why we have limited our study, or we had to limit our study, to major structural birth defects.

What we know about birth defects, and I just want to spend a minute talking about causes of birth defects, is, based on what happens when a mother is exposed to some agent while she is pregnant. And, you all are fairly familiar with well established causes. For example, Rubella, which is a viral infection, and if the mother is infected with German Measles, at a

particular time in the first three months of pregnancy, her baby will have a series, a group of defects, which characterizes the Rubella Syndrome.

There was also in the '60's, Thalidomide, which causes the same type of thing, particular exposure to a particular time during the pregnancy, and it causes also a group of birth defects. It is different from Rubella.

These are well established. We know that these agents caused birth defects. What's not so well established, is, whether there are other environmental agents that cause birth defects, when mothers are exposed to them in the environment.

What we know about fathers is that there are no well established causes. That is, there is no evidence, that I know of, where we know that there is anything in the environment or any drugs that a father may be exposed to, that will cause a birth defect.

But, there are some opinions as to what might cause birth defects. Or what might be associated with birth defects, and these are the things that people have proposed. Gene mutations and chromosome mutations. This is where, actually, a checmical might affect the gene or chromosome. While we don't know what the cause is, we do know, in the last five or

six years, that 25% of babies that were born with Down Syndrome have a chromosome that comes from the father. Now, there is the extra chromosome that a baby is born with Down Syndrome, actually comes from the father. But nobody knows why. And nobody knows why that happens or what causes it. That would be an example of association, but, now knowing the cause.

The third possibility is a possibility of an environmental exposure to a mother because the father has chemicals on his clothes, or chemicals carried in the father's semen. These are hypothesized, but there is no evidence to say that these actually occurred.

We asked a major question. Our major question was, are Vietnam veterans at increased risk for fathering babies with major structural congenital malformations or serious birth defects?

Now, we asked this question because of the limitations and the opportunities that we had, as I previously just mentioned to you. When we did a case controlled study, that is, we took babies from Atlanta, and these babies all had birth defects. And we ended up with approximately five thousand babies with birth defects. And these babies were registered in our families program.

We compared these babies, that is, we took

chose these cases, and then we chose a group of randomized controls, from the Atlanta area, from about three hundred thousand births, and chose these babies, and there's approximately three thousand controls. And then went and asked them questions. That is, we had a telephone interview that lasted about 45 minutes, and we separately interviewed the mother and the father, to try to find out what kinds of things they might have been exposed to, or what their back, with other drugs they might have taken, what their occupations were, a whole series of questions.

We were able to find a total of 70% of the mothers, that is, interviewed 70% of the mothers, and we consider only 56% of the fathers. That is, it was much more difficult to find fathers than mothers.

And when you look at it, you'll see that we also had a, it was easier to find white parents than it was to find other parents. And other parents in Atlanta, is principally, are principally blacks. And, as you can see, actually, we only found 32% of the black fathers, which makes us feel, at this point, it's difficult to generalize about black fathers, specifically.

But, we still can make generalizations about the entire population.

The good news about this is that what we were able to find, a very similar proportion of parents between cases of controls. As you can see, the numbers are very close. 74 and 76, 666, 5661, and this kind of study, that's very important.

Most of the people we didn't find were, was because we couldn't locate them. Very, very small proportion of them refused actually to be interviewed. Most people cooperated.

We asked fathers if they believe they had been exposed to herbicide, like Agent Orange, in the interview. As well, we also took information from the fathers as to their location, their occupation, and the time that they were in Vietnam, and compared those to herbicide application records. And created an exposure scale. And that exposure scale was 1 to 5. The lowest opportunity for exposure to the highest opportunity for exposure. And this way we tried to judge the opportunity for being exposed to Agent Orange.

This is a very difficult thing to do. It was a lot for work for the people involved, and is now called environmental support group that I formerly called Army Ageny Orange Task Force. Did a lot of work on this, and spent an enormous amount of time trying to correlate the locations and the occupations

of the herbicide exposures. It was very, very difficult, it was not easy to systemize. We spent a lot of time, we devoted a lot of time to doing that. But, we, and we felt that this was a good effort, and we worked very hard at it. And we're proud of the effort. It's just very difficult to come up with exact exposures to Agent Orange. We don't have a blood test. There's no radiation badges that all the service men wore that tell us how much Agent Orange they had been exposed to.

And so, in some ways, this is also a subjective evaluation. But, what we did to try to reduce the bias of knowing whether the father had a child, had a baby who had a birth defect or not, was we did not tell, in fact, I didn't know, either, as we were working on this, whether the baby of this particular parent was a child with a birth defect or not. And hopefully, this reduced the bias that people might feel would be apparent with knowing what the case was.

We had large number of defect groupings that were studied. One was all case babies, and that's our major conclusion was based on that, that particular group.

We also had groups of defects. That is,

we studied cardiovascular defects, we studied neural tube defects. We studied gastrointestinal, anything that was related to the gastrointestinal track. That was another group.

A third group was the individual defects. We also studied spina Bifida or individual heart defects, like VSD, which stands for Ventricular — Defect. That's a hole in the heart.

And we also created a special defect group, called domumutations, because we know that there is an association in fathers, with age and some very rare defects. And we put together all those very rare defects into one group to see if we could see if there was any relationship between the father and those particular defect groups.

We also, well, in that vein, we studied four hypotheses. The overall hypotheses was with regard to number 2, the Vietnam veterans, are Vietnam veterans at higher risk at father babies with birth defects.

As well, we studied, we used what we call an exposure opportunity index, which as I explained, the scale from 1 to 5, to try to determine the opportunities for exposure to Ageng Orange.

And we also studied what the men said themselves,

in the interview itself. In order to do this, we had to separate the veterans and Vietnam veterans. And the comparison group was important because we know that in general, we know that veterans are healthier than non veterans. And I'll go into that a little bit further, if anyone has a question about that.

Our results were based on total of 696 Vietnam veterans. You can see that 8.9% of Vietnam veteran fathers had a baby with a birth defect, and 9% of Vietnam veteran fathers in the control group, had birth defects.

And that means that, if you look at the 8.9% and the 9%, and you say it's pretty close, and, for this particular study, all defects combined, that there is no significant difference. There is no increase risk for a father having a child, fathering *a* child with a serious malformation. And that's demonstrated in our logistic regression odds ratio. That is the relative risk of .97, effectively saying that there is no difference between the Vietnam veterans, either in the case group or in the control group.

We did, as I mentioned, we did a 96 defect group, and we did four study hypotheses, and we did a lot of statistical tests. And, when you do a lot of statistical tests, you actually expect to find some

positive findings. And our study was no exception to this. We actually did find some positive findings, and they are described in our long report. Of those positive findings that we have in the long report, we've chosen to talk about five, and we feel that these are well worthy of discussion, and that's why we had decided to talk about them. But, there are a few others, and I can explain, go into a little more detail. People have, are aware of those other ones, and if they have any questions about it..

But, basically, what we found, as statistically significant findings. And what this means is that, a mathmetical test was done,and it found, on the basis of the statistical test, that these were positive. That is, they were exceptions to our general rule of statistics.

This in no way gives us any indications as to whether or not these are biologically significant or not. And there is a series of criteria that we used and we talked about to discuss that perspective.

But, the statistically significant findings that we have are, that the estimated risks for fathering babies with spina bifida were higher for Vietnam veterans who received higher exposure opportunity index scores. That is the score done by the environmental support group.

The Vietnam Veterans who received higher scores

had a higher estimated risk for fathering babies with cleft lip, with or without cleft palate.

Vietnam veterans who received higher scores had higher estimated risks for fathering babies with defects, classified in the group, "other neoplasms." And this group included the benign and malignant neoplasms, and was a wide variety of them. Possibly 10% of them were malignant neoplasms. That is, those that are considered to be serious cancers.

And for Vietnam veterans in general, have a lower risk for fathering, excuse me, babies with cardiovascular defects, classified as complex defects. That is, actually, when you look at Vietnam veterans, and you compare them with other people, if a man served in Vietnam, he actually had a lower risk for having a child with one or more heart defects.

And finally, Vietnam veterans have stated that they had contracted malaria, in Vietnam, had a higher estimated risk for father babies with hypospadius. Hypospadius is a defect where the opening, the penile opening, at the end of the urethra, is actually not in it's normal location.

From our study, we came up with an overall conclusion, and this overall conclusion is relative to the all birth defects or all case babies grouping.

And we feel that the data collected contained no evidence to point to the position that the Vietnam veterans have a greater risk than other men for fathering babies with all types of serious defects, serious structural birth defects combined.

What we can't do with this study is prove that there is an association that there is some factors associated with the service in Vietnam, that might cause a birth defect. We cannot prove it one way or the other. It's quite possible, even based on our results, that there maybe a very small group of defects, of rare defects, that are caused by something that's associated with Vietnam. Also may be a small group of individuals who were in Vietnam who may be having children with a specific type of birth defect.

Our study cannot prove or disapprove that that is possible. There is no, we can't determine a cause and effect. What we can say is that there dosen't seem to be an association, and we feel that the evidence is very strong that a Vietnam vetern who is no different than any other father, in the general population. That he has the same risk as any other father in the United States, that is two chances or three chances out of a hundred, to have a child with a birth defect.

And if you do a little bit of simple mathematics

estimating that there are about 2½ to 3 million men who served in Vietnam, that if one Vietnam veteran had one baby per family, then there would be an estimated, somewhere between 50 and 100 thousand, actually, babies, with serious defects, would be born to these families.

I think I'll stop there and open up the forum for any questions that might be asked.

DR. SHEPARD: Thank you very much, Dr. Mulinare, for a very comprehensive and lucid presentation of a very complicated and very thorough study. Thank you very much. Are there any questions for Dr. Mulinare? Yes, Dr. Anderson?

DR. ANDERSON; In your interviews with the parents, did you include birth defects or congenital anomolies in the parents, associate that with something in the child?

DR. MULINARE: Yes. We actually had a special group, we wanted to determine whether there would be any other factors that might influence our study results, and we had a panel of specialists at CDC get together and decide what those potential factors might be. And they felt that there were four factors that might influence our results.

One was maternal education, which is a, sort of

an indication of a socio-economic status, maternal education, maternal age, which we know, may have an influence.

Maternal alcohol consumption, and whether or not the mother, the father, or any siblings had a birth defect. And when we looked at all of these, we essentially found that there was no influence on previous history of parent or child having a birth defect, related to the study question in itself.

DR. KAHN: Joe, what's not clear in that statement is, whether there was no influence after you subtracted out any effect for that. Therefore, was there simply no effect of maternal alcohol consumption, etc., on the...

DR. MULINARE: We looked at one of the analyses, the third analysis, was to look at 108 co-variables. Of those, within those 108 covariables, included looking at maternal alcohol consumption in a couple of different ways. And when we did that we found a couple of associations, but, none of them raised the risk very much. The magnitude of risk was not enough to even warrant further study. So, we look at them as individual factors.

DR. KAHN: That's still not clear. Does this mean that since we know there is an effect/maternal of

alcohol consumption, for example, or maternal age, did the study detect these effects?

DR. MULINARE: No. I mean, it didn't, for this particular study.

DR. KAHN: It means you should have detected it.

DR. MULINARE: We would hope, well, that there is a large literature, and it depends on the information that you get with regard to exposures. When we looked at the ones that we though we would find and we wanted to find, we did find single one that we felt was most well documented. And that was maternal age with Down Syndrome. That is, when we did our 108 covariables, and we went through all of the different defects, with maternal age, maternal age came up as a ---for Down Syndrome.

DR. KAHN: But the other..

DR. MULINARE: But the other is different. There was no other significant..

DR. KAHN: The question is why?

DR. MULINARE: It's an idiosyncracy of the data set, and the data that's collected.

DR. FITZGERALD: Did you determine the absence, presence of alcoholism in the mother, strictly not her statement?

DR. MULINARE: Yes.

DR. FITZGERALD: And that might be the answer to it.

DR. MULINARE: I mean, that's, it's really relevant only to the data set, itself. I mean, other data sets might find that as a confounder--that's really confounding, as a problem.

DR. SHEPARD: Dr. Moses?

DR. MOSES: I thought there were two very fascinating things about this study. One was that you found the inverse, in terms of the heart defects, when you consider that those are basically increasing in the population, at least from the 1970's and the 1980's, there has been a big increase in heart defects, and I would like you to comment on that. And the second thing that I would like you to comment on, do you plan to go anywhere with this malaria question? I think it's very fascinating. DO you think it's the malaria? Do you think it was the drugs that were used to treat the malaria? Or, do you think it's just a statistical finding, and may not be anything at all?

DR. MULINARE: The heart defects increasing in the United States, we have, in our monitoring systems, noted an increase in ventricular septial defects, in the United States, to a couple of our surveillance

systems. And we feel that it's not artifactual, it dosen't have to do with more doctors diagnosing more heart defects. That may also reflect an increase in other heart defects, but I'm not aware of the general increase in all heart defects.

It's an interesting question because, like you say, it's opposite to what we've been seeing. And we don't knew why it's happened. In fact, it's a potentially very interesting study question. But we don't have an answer for it.

As far as the malaria question, concerning them, even the heart, the complex cardiovascular defect. These are all part of that group of statistical significant findings, that we expected to find. They are included in a large number of statistical test just as we've got some positive results, we've also got these results in a complex cardiovascular, which is "negative result," if you want to call it that, but it's something that's not indreasing the risk, it's actually lowering the risk of a father have a birth defect.

Presently, because of the constraint of the relative risk, that is the degree of relative risk, is fairly small. We think it's probably a chance event . .

DR. MOSES: The malaria?

DR. MULINARE: Yes. But, we have no way of knowing whether it is or isn't. It could be associated with something in Vietnam, and as you suggested, it's possibly it's associated with the infections. It's also possible to associate it with the drugs that men took, prophylatically, that is to prevent malaria. Yet, another question that we asked and another one that we looked at, was, of those men who took those drugs, did they have an increased risk of having or fathering a baby with a birth defect, and they didn't.

So, there's some inconsistencies, which also makes us feel that it might be a chance event.

DR. SHEPARD: Yes, and I might also point out for those who are not aware, that the vast majority of people who served in Vietnam, did, in fact, take prophylactic medication. It wasn't just people who developed malaria that were medicated. There was a different set of drugs that were used for those people. Yes, Hugh?

DR. WALKUP: Did you ask them whether they took Dapsone or chloroqwine?

DR. MULINARE: We asked them, we debated this a long time. Because if you ask people in this room

the drugs that we take, in a calm environment, and..

DR. WALKUP: Did you ask them if they took the white ones or the orange ones?

DR. MULINARE: Yes, we did. We asked them, and we haven't looked at that information. It turns out that a couple of the pills are the same color. But, there are, Dapsome, I think is a different color from the chloroqwine, and we just haven't looked at the specifics if, well, because the number is small. And what we want, what we are looking for in this, is an overall effect.

DR. WALKUP: I have some other questions that I would sort of like to follow-up with.

DR. SHEPARD: Hugh, excuse me. I would just like to point out for the benefit of the Committee, that Dr. Mulinare has very kindly consented to spend some time with both subcommittees. So, there will be an opportunity to ask him both general questions for people in the subcommittee on education/ information, which would be the meeting in another room shortly, and also, to come back to the subcommittee on epidemiology and biostatistics. So, you're going to have several cracks at him, and I hope Joe will be willing to stay for the conclusion, wrap up session.

DR. MULINARE: I have a plane reservation at

11:00. No. I would like *very* much to be able to ...

DR. **SHEPARD:** Thank you very much. I think we better move on with the agenda, and if you **could..**

DR. **WALKUP:** I think there is **one,** I **don't** know if the gentleman from Australia is going to be able to be here later, **but,** for purposes of comparison, they used a veteran versus in-country veteran **test---** In some respect, they did what you were doing, was going to a control group and comparing with veterans and then comparing Vietnam veterans against the non-veterans control. Could you explain some of the reasons for those different approaches?

DR. SHEPARD: Excuse **me..I've** talked to Dr. Adena, and he will be here, and I think **that's** a very interesting question. A good comparison of the two **studies.** .

But, I would like to wrap-up the agenda for the preliminary session, and we can carry on with other things. *I* would like to call on Dr. Han **Kang,** of our **staff,** to give us an overview on some of the activities that he has been involved in.

Dr. Han Kang, as you know, is the Director of our research division, of the Agent Orange Project **Office.**

OVERVIEW/UPDATE ON ACTIVITIES OF AGENT ORANGE PROJECTS OFFICE - RESEARCH

DR. KANG: Because of the interest of time,

I will not spend a lot of time describing each study. Note that these studies were already reported to this group, at the last several meetings, except number 7, the NAS evaluation study.

Just briefly, the Vietnam Veterans Mortality Study is the comparison of mortality patterns among 75 thousand Vietnam era veterans. We would like to compare causes of death between Vietnam and non Vietnam veterans.

The second study, the VA/AFIP Soft Tissue Sarcoma Study is a case control study, the same design as the birth defect study of CDC in which individuals with soft tissue sarcoma (cases) are compared with individuals without STS with respect to military service, and other environmental risk factors.

This is our on-going effort of Agent Orange Register review. We have a computerized Agent Orange Register, 86 thousand on the old code sheet, and 40 thousand on the new code sheet. We have evaluated information on old code sheets, and we reported the results to you last September at this time. We are in the process of reviewing the information on the new code sheet.

The Patient Treatment File review: Question has been asked many times whether Vietnam veterans who come to VA for treatment, have different problems than non Vietnam veterans.

So we have looked at 13 thousand Vietnam era veterans hospitalized in VA hospitals between 1969 and '82, and we reported that to you at the last meeting in June. We are in the process of up-dating that review.

Number 5, VA/EPA Dioxin study, Dr. Kutz and Joe Carra will discuss the protocol in the afternoon meeting.

A Review of the Soft Tissue Sarcoma cases in PTF for Vietnam era Veterans. We have identified over 400 cases of soft tissue sarcoma in the Patient Treatment File, and we have reviewed the pathology reports for those cases, and I presented that data last time,

What we're doing now is to follow-up. We're asking each VA hospital to send in the pathology specimens for those soft tissue sarcoma cases. We want an outside expert to review the actual specimens and make an independent patholigical diagnosis.

Number 7 is NAS BIRLS evaluation study. This is a very important study, in bur opinion. We assume that most of the veterans deaths are known to the VA for one reason or another.

According to World War II veterans, about 95% of their deaths were reported to the VA. We don't know that figure for Vietnam era veterans. So, we have a contract with the National Academy of Sciences, Medical Follow-Up Agency. We're looking at two thousand white and two thousand non-white Vietnam era veterans, and trying to find out how many of those four thousand Vietnam era veterans deaths were reported to the VA.

You know, in addition to those seven on-going studies, we plan to add two more activities. First, a pathological evaluation of malignant neoplasms. This effort was described to this group at the last meeting.

We would like to sample about five thousand cancer cases in the VA hospitals among Vietnam era veterans, and compare the histopathology between Vietnam and non-Vietnam veterans.

The number 2 is an in depth review of suicide among Vietnam veterans. Needless to say, there is a growing concern that suicide death might be higher among Vietnam veterans. So we would like to take a closer look at suicide based on the information we are gathering for the mortality study.

This is a current status, as of August of 1984, of the VA Soft Tissue Sarcoma Study. We have contacted about 400 hospitals, which send one or more cases of soft tissue sarcoma to the AFIP for consultation.

One hundred seventy one hospitals sent in all the information that we ask for; one hundred eleven hospitals initially agreed to participate in the study, but haven't sent in the necessary information. And 86 hospitals are reluctant to participate and we are still making contact to pursuade then to participate in the study.

DR. MOSES: Excuse me. Ts that the VA Hospital, why would they be re..I don't understand.

DR. KANG: Only about 8% of study hospitals are VA hospitals. 80% are civilian hospitals.

We submitted an application to the OMB for the questionnaire, and the OMB asked the Agency to submit the study protocol to the Science Panel of Agent Orange Working Group, so, we presented the protocol yesterday. I expect to receive a favorable response from AOWG.

This is the status of the mortality study. Of 75,108 cases we're looking at 52,000 were found to be eligible, and all the military information on them is abstracted. 19,000 were found to be ineligible and for 3,600 we are still in the process of getting data for those individuals.

DR. SHEPARD: Did you mention what constitutes ineligibility.

DR. KANG: The way we sample the 75,000 is we include all those individuals for whom the VA doesn't have service date, and the VA doesn't nave a branch of service information for them.

So naturally, we have a number veterans from an ineligible branch of service, and having ineligible service dates. For example, Air Force, Navy, Coast Guard, are ineligible. Somebody who entered service after 1973 or was discharged before 1965 is ineligible. Because of the lack of information in our files we broadened the definition of study subjects.

For example, we found about 1/3 or a quarter of the study subjects are not eligible for the study.

As to the death certificates, we have received some information on 99% of the individuals. Now, there are some problems. We have about 57,000 death certificates, 3433 abstracts and 4455 cards. 4455 returned cards means the GSA or the VA regional office returned our request, saying that they don't have any death information on those individuals.

Therefore, we have a lot of problems. For batch one, two, and three for 12 to 15% of the deceased veterans, we don't have cause of death information. And for our last batch, batch four, that 12% we don't have cause of death information. That amounts to tracing about 9 to 10 thousand individuals to find out in which state those individuals died, and go back to the state vital statistics register's office, and ask for death certificates.

For all the information that we received, this is the current status. For 50,000 we are able to obtain medical information. For 61,000 we have demographic information. All this is in the computer now. 2,000 are in coding process. 1500 are being processed for demographic and 5,000 are being processed for medical information.

These are the steps we have taken to obtain death certificates for those 9 or 10 thousand individuals. Our regional offices and Federal Archives Record Centers of GSA, send death records to Moshman, our contractor. Moshman will separate out whether the information is codable or non codable and then the contractor will send all the problem cases to our office. Then we cross-match all those problem cases against our military files, to see whether they are qualified for the study.

If they are not eligible, they are out of our search process. And if they are eligible, run it through the BIRLS and try to find tetter information, such as a new social security number, or a new location of their XC- folder. After we have done that for a death that occurred after 1979, we go to the National Center for Health Statistics. They maintain a National Death Index. We try to match with NDI and find out place of death.

For those who died in 1978 or before, we go through all these processes, Social Security Administration, and other VA departments, for better information. Once we find the possible locations then we send the request to each state for death certificates and the certificates come back to our contractor for abstracting and coding information from the death certificate.

The VA/EPA Adipose Tissue study. Since 1970 about 12,000 specimens had been collected in the National Human Adipose Tissue Survey. Among these there are 528 specimens, collected from potential Vietnam veterans that is, males born between the years 1937 and 1952.

Out of 528 study subjects we were able to obtain either a social security number or a name from 494 hospitals. Now, we're in the process of making a determination whether any of these individuals served in Vietnam or military; if they served in Vietnam, their exposure possibilities, in cooperation with the Army Agent Orange Task Force, are determined.

Mr. Joe Carra and Dr. Kutz will elaborate on the status of this study at a later time.

That is pretty much the activity we're engaged in now, and if you have any questions I'll be happy to answer them.

DR. SHEPARD: Any questions for Dr. Kang?

All right. Thank you very much, Dr. Kang. I'd like now to call on Dr. Michael Kafrissen, from the Center for Disease Control in Atlanta, to bring us up to date on the status of the major epidemiology study that they are engaged in. Mike?

CDC EPIDEMIOLOGY STUDY

DR. KAFRISSEN: For those of you who haven't met me, I'm Mike Kafrissen, a physician with CDC, and among my other tasks, I am chief project officer of the medical examination phase of the Agent Orange and Vietnam experience studies that we are conducting.

First, let me preface my remarks by saying I'm pleased to tell you that we continue, on schedule, with our major milestones of our studies, and have no reason to believe that at this point, that we're going to have a problem meeting our completion goals.

For those of you who aren't all that familiar with all of our studies, and given the time constraint, I'll try to give you a capsule version of each of the three major studies, what the major tasks are for each of these studies,

and what our current status is in the completion of each of the major milestones.

The first study is the Vietnam experience study. For this study, we have chosen a random sample of

42,500 files from the National Personnel Records Center lists in St. Louis, using those numbers that ought to correspond to men who would have left the service at about the time Vietnam veterans were leaving the service.

The design of the study is to compare a group of men who served in Vietnam, with men who served in the military at the same time, but, in Germany, CONUS (Continental U.S.) and Korea.

The file is reviewed (RCPAC, ESG) to determine qualification for our studies (one tour of duty, E5 and below, service during the appropriate years). We then make a mortality assessment. Following the mortality study of these populations, we shall locate interview, and examine these men.

We're hoping to interview 6 thousand men in each of these two groups, for a total of 12 thousand, and then we do physical exams on 2 thousand of these men chosen at random, from each of these groups of six thousand for a total of four thousand physical examinations.

Where are we right now? With these activities, selection of potential participants, we have completed the selection of the initial 42,500. Additionally, we have selected, that is, we've generated more numbers should our participation rates require greater numbers. So that process has been completed.

On the preliminary qualifications, that is, an activity that is performed by the Department of Defense, in St. Louis, that has been progressing well within schedule. The full requalification and the abstracting taking information out of the 201 file, the DOD's Environmental Support Group is on schedule. In fact, I have already gone through about 23,000 of the 42,500 files, and are generating potential participants.

What's coming up. Once the contracts, which I'll be discussing as we go along, are let, we will be locating these potential participants, soliciting their participation for the interviews and the examinations. Again, I'll talk about that in a little bit more detail when I discuss the contracting process.

A second study, the Agent Orange study, is limited to men who served in Vietnam. We're going to compare a population of men who were lightly exposed to Agent Orange, a group that were very similar, however,

were not likely exposed to Agent Orange, and , population almost certainly not exposed to Agent Orange. I realize this is a whirlwind overview, and many of you have already heard it. However, some of you have never heard it. If I'm losing both, yell out and I'll be happy to give you more detail about any of the studies.

But, given my limited time, I'll give you the up-date material first. The major components of the Agent Orange study - we've selected a time and place - the III Corps area of Vietnam, (III Corps was. an administrative, geographical area that includes the Saigon area of Vietnam.)

During the years '67 and '68, two years of relatively heavy herbicide use, III Corps was the most heavily sprayed area .

Battalions that: served primarily in the III Corps area, either during the entire time or at least almost all the time, eighteen months or more are included. That is done by obtaining battalion daily journals, and some other documents that I'll outline on the activities list.

Any relevant military documents that will give location information where a given

company attached to the battalions of interest was, is reviewed by ESG. on each day of this two year period/ Searching out all coordinates for each day. Then, once we know where each company size unit was each day, we will match those up with the herbs and services herbs tapes, documents indicating both fixed wing aircraft and other means of spraying, such that we can develop a notion of which battalions were heavily exposed and which were less heavily exposed.

Next, using morning reports, men are documented as being in the battalions of interest. Morning reports, for those not familiar with morning reports, are kind of like a role list of personnel changes. In addition, there are rosters that are which will be more like an entire role call/ included in these reports.

In these first /groups we're looking for 25 battalions in each — one group heavily exposed and the other probably not heavily exposed. To insure that we get men who were almost certainly not exposed,/ that is, to widen that exposure index, we will be using 25 battalions that were located in the areas that were not areas of Agent Orange spraying or use.

We hope that we can get combat units. However,

that's not likely, as combats units were largely mobile and would have been in areas of exposure, so we may be using support units, in that area. For that third cohort.

Once we determine who was in the battalion of interest, we will be extracting information from their personnel files, to determine their qualifications. These qualifications right now, remain preliminary. Once we have identified them, and then begin looking at the files, we will make some more judgements about, for example, whether or not nine months in a unit, is required, and we may want to modify that a bit.

As with the Vietnam experience study, we'll be doing a mortality assessment. The mortality assessments, by the way, are projected to go on at three year intervals from now on. How far "on" will be determined by the longevity of the population, and of course, the of funding a scientific study.

We will locate, interview, and examine these men. We have three populations, the heavy, not so heavy, certainly not, exposed /6 thousand men will be interviewed in each of these three populations. 2 thousand, then, will be chosen at random, from each of these populations, for physical examinations.

Battalion identification has been progressing.

We have identified 48 battalions that were located in the III Corps area for the entire 24 month period, and we are currently tracking them. When I say "we" we CDC are not tracking them. The Department of Defense's Enrironmental support Group is doing the search of the Battalion Daily Journals, etc.

To date, 10 battalion searches are completed. The battalion identification activities are now being directed toward identifying the 25 unexposed battalions. A number of candidates have been chosen, indeed 25 candidates have been chosen for review. However, we've got to determine if they were, indeed, really unexposed battalions, and, also, since many of the support "battalions" were really company size units, we're going to have to determine how many of these units we're going to have to generate in order to get the number of qualified men we would like.

This is not holding our time and effort. It's simply being inserted into the on-going battalion identification and tracking activities.

Quality control. We are developing, I should say, continuing to develope CDC's direct oversight of the battalion tracking activities. That is, in addition to the Department of Defense, CDC personnel are reviewing

the battalion activities for accuracy.

Personnel identification, personnel identification, we have all of the microfilms of the morning reports. We ("we" meaning ESG, and the Department of Defense and CDC) are currently developing the protocol that is going to be used for the abstraction of names, to place men in the individual companies. Whether or not one or another of the two competing protocols will be used, we are testing right now.

The two major methods are one, looking into each and everyday's morning report, and the other using the interim rosters as surrogates for the daily morning reports. We're still kicking that around right now, but for the time being, again, that is no hinderance to our time schedule .

Once, just as is the case with the Vietnam experience study, once identification has taken place, we will locate, interview, and examine these men, examine a portion of these men.

Current activities for these two cohort studies. First, the interviewing portion. The end of August, the interviewing contract was awarded to / Research Triangle Institute. To explain briefly, we plan about a 40 minute to an hour

comprenshensive interview with each of the men that I've described in the two cohort studies. The interviewing will cover demographic information, descriptive information about the man, his occupation, other potential exposures, current health, past health, hospitalizations, etc. It is difficult to explain the content in detail.

We expect that activity to go on for 40 months winding up in November, '87. That will involve the completion of a minimum of 30,000 interviews in this contract. The interview will be conducted by a computer assisted telephone system, meaning that the interviews will be conducted by phone, with the interviewer sitting at a computer screen that will generate the questions and branched questions that will be required for that process.

This has been successfully used in a number of other studies, including Dr. Mulinare's study, just described. A pilotstudy of 300 veterans is already designed and ought to be completed by December of this year. That is the questionnaire and the software for the computer assisted telephone interviewing is undergoing it's final approvals . We expect by the end of the year, to have data to evaluate and make determinations about any problems or additional

questions that we may want to insert.

Medical examination contract is next. For the medical examinations we have completed the initial evaluation of the proposals. The medical examination is a comprehensive examination. It requires bringing ten thousand veterans to a single site for a comprehensive physical, psychological and neuropsychological assessment for approximately a three day period. So, it is a multi-headed contract. The CDC has completed the site visits of all bidders, and also completed site visits on the subcontractors. Negotiations will take place in October, somewhere mid-October. Once the negotiations are completed, we get best and final proposals by late October or the beginning of November.

The selection of the contractor will be made in January, and the pilot study examinations, which will be conducted among those men who were interviewed in the pilot study of the interview contract, will begin around March 1.

At the end of those pilot examinations, we will assess how things are going and make any needed adjustments. The main study should begin June of '85, with completion of

of the ten thousand, (plus approximately 200 pilot) examinations in a 34 month period.

Last study, the selected cancers study. Different than our cohort studies, this is a case control study, which Dr. Mulinare has just described. We begin by identifying men who have a particular disease, in this case, a number of particular diseases, soft tissue sarcoma, lymphoma, nasal, naso-pharyngeal, or primary liver cancer. Once we have identified conditions the men who have these, we then look at these men, we look at a group of controls, men who are free of disease, and determine if there is a greater proportion of Vietnam veterans among those with the disease compared to those without the disease.

We will be getting information from tumor registries, population base tumor registries. We're using birth years 1929 to 1953, which roughly correspond to men who could have been in Vietnam. Once that is complete, we chose our controls. We chose men who are free of disease, in the same geographic area and

from the same age group, using a random digit dial method. We use phone exchanges within that area to see if a male of the appropriate age is there, and is willing to participate in the study. We next locate and interview both cases, and controls. Additionally, we're going to be confirming the diagnoses by histology review panel. I'll explain that in more detail on the contracting parts.

So, the major aspects, or the major tasks in this study, are the tumor registry case identifications, control group identification, pathology panel reviews, and the interviewing phase.

What's happening with each of these? The random digit dialing contract was awarded in August, to Westat. That will be a 58 month duration contract. We are not, unlike the study that Dr. Kang explained earlier, we are not using cases from the past. The CDC selected cancer study is a prospective study. We're going to use cases as they occur from the time of award date of the contract, over the following four years.

We won't take the time right now, but if there are questions, I'll be happy to explain the reasons for that particular design.

Case identification and interviewing. These

activities are currently in the contract negotiation phase. That is, we are speaking now with the tumor registries who have submitted proposals, and we hope to have contracts signed by the end of this month. September 30 is the projected date for those contracts.

Histology review for each of the individual cancers that I have mentioned (soft tissue sarcoma, lymphoma, nasal naso pharyngeal, and primary liver cancer). There will be an individual panel of pathologists, three in each panel, to determine *if* indeed, our cases are correctly diagnosed. Unfortunately, pathological identification of certain of these tumors is a difficult task, and more than a quarter of at least one of these are misdiagnosed. So, these panels are very important.

The contracting process for the histology review panel is similarly in the negotation phase and should be completed during the fall, well in time to correspond with the other portions of this contract.

That wraps up where we are now. Did I make it in time? Okay. Are there questions?

DR. SHEPARD: Are there any questions of

DR. WALKUP: Are copies of this available?

DR. KAFRISSEN: As you can tell from the misspacing, I'm the one that typed up the one copy that you... I'm happy to make a copy and send them out to you. However, certainly everything will be in your report, and I'll make them available to Dr. Shepard, and get them to you. If, for any reason, what you want is not in the report, you're welcome to them. You can also correct that one that is poorly spaced,

DR. SHEPARD: Thank you, Mike. Dr. Kafrissen will be attending our statistics /epidemiology subcommittee so, if there are more detailed questions, I'm sure he would be happy to answer them.

1 think we better now break into our sub-committee meetings. Would you please reconvene promptly, in ten minutes. The science group will meet here, and the information/education group in room 139.

AFTERNOON SESSION

(12:45 p.m.)

DR. SHEPARD: Let me say something that I should have said earlier, and that is, unfortunately, Fred Mullen could not be with us, today, and George Estry very graciously took over his job as Chairing the Subcommittee on Information/Education. I attended part of that meeting, and George handled the situation very well, and we appreciate that, George. Thank you for both me and Fred.

Another issue that I did not discuss this morning, and it relates to the request from Senator Cranston and Congressman Edgar, requesting that this Committee reviewd the CDC birth defects study, as part of our on going effort, and report back to them. The members of the Committee have been provided with the report, not the full report, but the...

DR. MULINARE: I'll be sending you copies so that the Committee can also get a copy of the report.

DR. SHEPARD: That would be very helpful.

DR. MOSES: Yeah, I'd rather see the full report before I comment.

DR. KAHN: The evaluation by Oscar Waite. We'll await that -

DR. SHEPARD: May I just finish my sentence?

We did distribute, I believe, the JAMA article.

As Dr. Mulinare has just indicated, the full report will be distributed as soon as we can get copies to the Committee, and if you would, then, please, make your comments as quickly as possible, and send them back to me.

What we will do, then, is try to synthesize the comments into a consensus document,

and then we'll recirculate that for comments. Fortunately, we don't have any specific time frame in which to accomplish this, but, we'd like to do it as quickly as possible because we know that these issues continue to be of concern the members of Congress.

The same, in a sense, applies, although not to the videotape scripts. requested by Congress, I have circulated copies of the video script which is being prepared for our learning resources center, in St. Louis. Mr. Dan Jones was here to meet with the Information/Education Subcommittee, and some comments were made. I have received some comments in writing. Those of you who wish to comment on that videotape script and have not yet done so, please do so as soon as you can, and we'll go through

the same process with regard to that.

The third similar effort applies to the lay language summary of the volume 3, of the review on the literature on herbicides, and contaminants. We have also circulated that to members of the Committee, and a number of very good comments have come back, and we'll continue to work on that. We'll proceed to try and get that out as soon as possible.

I'd like now to call on the Chairman or the Acting Chairman, George Estry, to give us a summary of the comments, discussions of agenda items that were addressed by his Subcommittee this morning.

REPORTS OF SUBCOMMITTEES

MR. ESTRY: Thank you, Dr. Shepard. You know, we had, the first thing we had to speak of, is a matter I think that has been presented to the whole Committee on numerous occasions. Of course, I think for time it was cut back. You know, when we got in there, of course, again, we've run over this morning, 45 minutes for our Committee, which again, took a lot of time away. And of course, those on the Subcommittee feel that it's a very important aspect of the overall group, here, so we feel that we should be entitled to time.

What we're requesting is, I think, we've

scheduled in the future, more time for our meetings. I think we came to the consensus that we need at least 2½ to 3 hours, rather than the small____this morning. It was also mentioned that we request, that with our guest speakers, if they could kind of stay within the time frames. I understand they have a lot to give out to us, but, it does kind of put, I don't know how the other committee feels, but, it puts a lot on us,a lot of pressure on us when we get in there, and especially with the amount of people we have in our committee, who has a lot of pressing questions to the members, here.

And, of course, within the states, everybody has their own concerns that we're trying to wade through, which, is as you know, an important part of us. So. I think that we would ask again, now, a recommendation that we expand the meeting times a little bit.for our subcommittee, so that we can really fairly deal with each issue that we have. Again, we feel that we're pressed for time in there, and I'll tell you some examples where we got in there and we were running behind, and I'm sure we had a lot more questions of Dr. Mulinare, and he had to rush to another meeting. And other members that came in, as well as the room. That was the first thing.

The second recommendation that we came up

with in our meeting was, a question has come up about the budget that the VA has, dealing with the Agent Orange related affairs. And we were wondering if it's possible if the Committee got a copy, in writing, of course, one of the members asked not to have graphs. If we could get a copy of have some talk on the proposed budget for the last two years, and the up-coming fiscal year budget, in the VA, just to deal with the VA, I mean, excuse me, Agent Orange related affairs. We feel that it's important if we could look at how much of the overall budget really is delegated now for Agent Orange.

And, of course, you've already touched on, we did talk about the video. I've been assured that the members of the Committee would be allowed to see a copy of it before it's put into distribution. And of course, the update on the lay language paper.

The last thing that I think we have is, we've come to the consensus in there, that as an advisory committee, I guess we really haven't been giving too much advise to the VA, meaning our Subcommittee, I guess. And, one of the members had come forward. today, with a resolution we want to bring forth, and have a vote taken by the full Committee. But, as we bantered around realizing that there are different service groups in there

who have different view points on certain issues, and you know, even though we personally may feel one way, we're still bound by what our, I guess most of us are bound, by our directors on what we can and can't do. And so we didn't bring a resolution before you, today, but we would ask, if it's possible to have put on the agenda for the next meeting, some time after our discussion, here, to where we can give our proposal to the Board, and probably get a vote at that time, on the resolution that we would like to submit. Of course, this would be dealing with this as a concern over the latest study on CDC. asking that the VA, perhaps maybe, push the legislation that's pending on Agent Orange issues, through Congress a little faster.

A lot of talk came on this. What our concerns are, I think, is basically the fact, as an advisory committee, sometimes we have to set aside our personal view points on, you know, the restrictions we have placed on, you know, what can or can't be done, and remember the human aspect of the veteran, and I think this concern has come up. That's why I feel a resolution may be necessary at this time, from our Subcommittee, of course, you know, full panel would vote it down. And of course, that would probably be the end of it. But, we would like to have that time, I think..

DR. SHEPARD: Excuse me, George, I'm not quite clear. Did you say, you have..

MR. ESTRY: We don't have it at this meeting..

DR. SHEPARD: ...That you would like to have tine around which you would like to formulate a resolution?

MR. ESTRY: Yes, sir. What was happening is, of course, we couldn't come to an agreement this week, so we're going to work on our own, between now and the December meeting, and at that time, hopefully can come to before, with the resolution. You know, from our Subcommittee, etc. What we're asking for, really, is basically the time to be put on the schedule, to where we can present it to the full Committee, and also have a, take a vote on it. I don't know if that would be done in open meeting or closed meeting.

DR. SHEPARD: As an agenda item, you mean, for the next meeting?

MR. ESTRY: Yes.

DR. SHEPARD: Fine.

MR. ESTRY: I don't know if I expressed that.. any member of our panel have any further comments on that? I told you, between lunch and now I kind of lose a little bit of translation.

MR. WALKUP: I think the only thing they want to make clear is that we needed to do that after our

Subcommittee met, and to have some time on the agenda, after our Subcommittee meeting, for presenting that to the full Committee.

DR. SHEPARD: That's fine.

MR. ESTRY: That's basically all we had in there. We were short of time. Emotion, well, it wasn't emotion, there were also some comments made that, which I think clarifies as far as the agenda goes, as to the amount of scientific discussions we had, in the preliminary meeting, as to why, maybe sometimes some of the, I guess, out of state veterans groups, but I guess that's about the best way to do it, could have some of their people maybe talk on some of the concerns of the veteran community, to enlighten the Board. I think some of the states may feel they would like to have a little time where they could discuss the problems they have within their states, with the VA, concerning Agent Orange, and enlighten the panel. I think we've come to the consensus, that also is kind of necessary.

We hear in our panel, but. since we've split up. we kind of lose sight of that, here, in the main meeting.

DR. SHEPARD: Let me just state, from my position, we are also receptive to ideas. In fact, I think we solicite your recommendations for additional

agenda items. And we do that during the course of the meeting, and any time between meetings. At least, let me just re-emphasize that my office is very open to any suggestions about additional agenda items. It's helpful, obviously, to do that between meetings so we can get them on the agenda, and assign the appropriate time to them. But, certainly we'll accept you comments and do I take that, George, to mean that you would now like to offer as an..

MR. ESTRY: I have no one at this time to offer.

DR. SHEPARD: Is it an agenda item for next time? We'll / specifically set aside some time for reports from the State Commissions? We have done that in the past.

DR. MOSES: Why don't we have it as a permanent part of the agenda?

MR. ESTRY: Yeah, that would probably help.. if we could work that out, I think that may help, because you know, the states do have a lot to say, and of course, we do have Dr. Anderson here, but, sorry, I was pointing the wrong way. Dr. Anderson, but, you know, I realize that his committee takes a lot of his time, also, and... if maybe he could be placed in for the reports or however they would word that. But, I don't think it's so much

even the states, I think it's a lot. of people concerned that you know, we deal with a lot of scientific studies and everything, in the preliminaries, but, we have no time, really, and again, I agree, as they recognize, we haven't asked for it, either. But, time where we can bring people in, and I think again, enlighten the whole panel as to the problems that the Vietnam veterans are having now, rather than just having them discussed in the Subcommittee.

DR. SHEPARD: Okay, fine.

MR. ESTRY: I think I interpreted that right. I'm only acting, remember?

DR. MOSES: In response to something else that he said, with these more scientific type of presentations. Like you sent us quite a bit of stuff before. If we were sent, like from CDC, a little summary ahead of time, that we sort of knew what the basic outline was, and then they wouldn't have to spend so much time with us, but, maybe could go over the highpoints. That might help, too, and then free up more time for the discussion.

MR. ESTRY: That's true. Plus, I think we'd open up for more questions, because it's the first time you've heard it and there are a lot of questions.

DR. MOSES; I, for one, am not for making

the meetings any longer than they all ready are.

DR. SHEPARD: That , of course, was our intent in circulating the CDC birth defects report, and . . .

DR. MOSES: No, no, but I thought he was talking about the CDC presentation about the other study, which we spent a lot of time on.

DR. SHEPARD: Excuse me, I'm sorry.

DR. MOSES: Isn't that what you were talking about?

MR. ESTRY: Not in general, but yes, that's basically, yeah..what happens occasionally, when the run over. .

DR. MOSES: That's what happened this morning.

MR. ESTRY: That's our concern. A lot of them run over and then we can't, you know, we can't do our own subcommittee meetings really justice. No, I didn't want, you know, say it's the CDC's fault.

DR. MOSES: No, no, we were happy to learn it, but if we had had it ahead of time.

DR. ANDERSON: I received your communication last Friday, and I had no way to contact the 22 other states, with such short notice, to get a consensus, as to the study. So, that's why I said very little here, today, is that I did not have a consensus from the

states.

MR. ESTRY: I think they recognized that, Dr. Anderson, because we did mention that. Because that's even happened to us. I was just getting stuff yesterday, even though I'm right across the street, and it's not the VA's problem. It'a just that we're all running around, doing so many things, that I don't get back and get to my mail sometimes. I was fortunate that I made the CDC meeting in August, so I already had the whole full report. Because I think it was, as it was just mentioned earlier was that, really try to comment on just the JAMA article, without seeing the whole report, because, as I was telling our Subcommittee, you know, the full report really is enlightening. I think it was very good very well done.

That's all the comments I have, I think, unless I'm corrected from the floor.

DR. SHEPARD: Any other questions from the other members of the Committee, or comments? Okay... Dr. KANG, would you summarize the meeting that you Chaired for Dr. Hodder?

DR. KANG: Thank you. Since the afternoon meeting is pretty much a continuation of the morning program, we didn't have individual presentations except from people from EPA. We opened the floor for discussion. Dr. Mike Kafrissen from CDC discussed further the material he presented for CDC, Epidemiology study.

The first item we discussed was the physical examination aspects of the study. Whether it is preferable to have a mobile medical unit go around in different regions and conduct the medical examinations, rather than to have the people come to one spot. I think Mike explained adequately that it causes a lot of other constraints that cannot be easly overcome.

One recommendation coming out of that discussion was that, this Committee feels very strongly that CDC should collect biological samples, that is a fat biopsy, for future analysis of dioxins.

Next, Joe Carra and Rick Kutz of the EPA presented the status of the EPA/VA joint study of dioxin levels in human adipose tissues.

The one question that came up was, how can you show the quality of an adipose tissue sample collected many, many years ago? So, the Committee made a recommendation that the chemical analysis should include a surrogate substance, for example PCB, to test the storage stability of chemicals in adipose tissue.

In response to a question on the CDC Epidemiology study, Dr. Mike Kafrissen gave the completion dates for the CDC study. For example, in the Vietnam Experience Study, he foreseesthat by February, '87, the interview phase will be finished. By May, '87, the medical examinations will be completed. By April, '86, the mortality aspects of the study will be completed. For Agent Orange portions of the study, by December, '87, the medical examination will be completed. By May, '88, the interview will be completed, and by July, '88, I have two dates, here. I'm sorry, by July '88, the medical examination will be completed.

DR. SHEPARD: For the Agent Orange portion.

DR. KANG: for the Agent Orange portions. For selective cancer studies that will be completed for years after the beginning of the study. That pretty much sums up the discussion that we had.

DR. SHEPARD: Okay. Thank you. Any questions?

DR. FITZGERALD: Yes. I would like to stress for those that were not in the Committee, something that I think is very vital, and that was the fact that in mentioning CDC, our concerning the conduct of the examinations, that it was brought forth that indeed, the veteran would be given a copy of the findings and that a copy of such findings, by his direction could be sent to anybody that he so desired. And that furthermore, that there would be an advisory session with the veteran, with one of the physicians, following his three day period of examination, in which he would be informed, and allowed to question, in order to get full information, concerning the results of his examination that he had undergone. And I think that was vital from experiences in the past.

DR. SHEPARD: Yes, that's a very good point, Dr. Fitzgerald and I just might remind the group that is precisely what was done during the Ranch Hand study — an interview with the Ranch Hand people so that they got full information that came from the examination. Any other questions or comments from other members of the Committee?

MR. WALKUP: Could you explain to us, who weren't there, some more about the fat biopsy issue? What was that issue about?

DR. KANG: There were two separate ones.

DR. FITZGERALD: The question was, as to whether indeed, they were going to take a fat biopsy, at the time of the examination, and it was explained to us that, at this time, CDC had no plans to take ', such a fat biopsy because one, they weren't sure how to interpret anything they found on it, and how they would use it. In spite of this statement by CDC, it was the expressed opinion of the Subcommittee, that it would, for completeness sake, te desirable while these people were all in one central location, *to* take a fat biopsy for future evaluation.

And that *fat* biopsy would be by aspiration. It wouldn't be a surgical procedure.

DR. KANG: The second part was concerning the cooperative EPA/VA study on existing samples that have already been archived for some time. And the question there, was, there are other substances for which analysis ought to be done. Partly, for reasons of detecting deterioration in their storage, and partly because in the case of the PCB's for example, there are centain PCB isomers that appear to disappear in persons who have been exposed to dibenzofurans which are closely related to the dioxins. A similar thing is likely in the case of dioxins, that might provide a handle on past exposure. Even if the dioxin, itself, is not affected.

MR. WALKUP: Did it sound as if those recommendations were going to be taken or what was the decision?

DR. FITZGERALD: I don't think CDC was in a position at this time, to make any comment in that regard. I'm sure that these will be brought back to their current organization, since they are conducting

the study, and, furthermore, that the Veterans Administration, who is overseeing the CDC study, has seen our recommendations, also.

DR. SHEPARD: Yes. I would just like to point out, and please, Dr. Kafrissen, or anybody else chime in, but, I think it's important to remind ourselves when a study is designed, a protocol is written, that protocol is intensively reviewed, and comments are made, suggestions are made This is an intensive scientific review, and there comes a point at which that protocol, or the design of the study, is accepted.

I think it's difficult, if not inappropriate, to then, during the course of the study, before a study is started, or after a study is started, to alter that protocol. Now, I see no problem, at least conceptually, with harvesting certain tissues, specimens, while an individual is being examined, or at the time that an individual is being examined, so that those specimens are available for future analysis, should the need arise. That seems to be appropriate. In fact, that again, is what the Ranch Hand study did. There are many samples in storage, from the Ranch Hand people, that were not. necessarily the analysis was not necessarily in the original protocol. To say that we

should add *a* whole new segment to an existing approved protocol, at this time, I think might raise some questions on the part *of* the investigators.

I'm not making a value judgement one way or the other. I just want to point out that it is a pretty strong scientific premise that once you have a protocol, you stick with it unless you find something during the course of the study that has made the protocol appear to be faulty in someway, and the correction has to be made. Mike, do you want to comment on that?

DR. KAFRISSEN: This isn't the first time that has come up. Biopsies have been considered in the past on numerous occasions, and indeed, by each of the numerous outside review groups that have looked at this. The question came up, do we want to do an invasive procedure that is not yet well established, the results of which would be difficult to interpret, not knowing whether dioxin levels and/or other chemicals may have been from exposures long ago, not so long ago, two weeks ago. Do we want to get involved with a potentially uninterpretable, rather expensive invasive procedure, that may, indeed, advance science, but not respond to the specific question of a study that is to address to the health affects of Vietnam and/or Agent Orange, on the veteran.

So, the various review committees were hesitant about adding this component. However, technology, hopefully, is and will continue to advance, such that, if we and our advisors are persuaded that the technology has advanced to the point that we would feel it ethically defensible to ask our participants to give us 10 grams of fat, then, we would reconsider it.

So, when you're saying will we consider advice of the Committee, absolutely. We understand there is an interest there to do everything reasonable and in a timely manner. However, until something changes, which is very possible, until something changes from the original reasons that we and the reviewers did not include this procedure, we'll sit tight.

MR. WALKUP: My reaction, and I think that others from the veteran's community, would be that an issue that has come up time and time again, this about the exposure index, you know, how do you determine exposure levels for people? There may be some possibility in looking at dioxin levels, that you can start getting closer to some of those things, and you know, it's all about possibilities, and it sounds like you don't have to waste a test for it. But, that's a really important issue.

DR. KAFRISSEN: Okay. Two things in that area. Number one, we are, indeed, collecting samples already, for the storage, for future analysis of both serum and urine. One of the things that we don't know about right now is, the degradation of these products. A man who was exposed to the Agent Orange 10 or 15 years ago, may no longer have detectable levels of dioxins or changes in their fat, at this point. Does that mean we say, or could feel comfortable in saying no, you weren't exposed at that time. However, let me re-emphasize it is not a closed issue. There are people, indeed, people close by, who are working in this area. And if the data become strong enough, if the argument becomes strong enough that we think it is ethical and reasonable to ask our veterans to participate in such" a study, then absolutely, we would consider it, and advise the various people who have to approve such changes. And then, of course, it would go through all of the layers of review and approval for modification.

But, I don't want you to think that this was something that was overlooked. It has been considered, and there is a reason why we don't feel comfortable right now.

MR. WALKUP: As far as the ethical aspect,

I think that if you ask most of the vets whether it was that much more of a pain in the rear to do that as well as spend the three days, they'd say, well, go ahead and take the tissue. I mean..

DR. KAFRISSEN: I have no doubt that we would get participation. Maybe not from everybody, but certainly from enough and well enough spread around that it could be reasonble to do. However, then we could ask the question, why not collect all sorts of other specimens. Most important among those may be lymphatic tissue, to say, freeze and hold. Until it's something more than a shot in the dark, and something that we could actually, and meaningfully interpret... It's not so much that we think that people are going to drop dead from it. However, it is invasive, and something that we would need good evidence for before we would get involved.

DR. SHEPARD: Okay. Any other questions, comments? Thank you. I'd like to now call on Dr. Anderson, to see if he has any issues to raise, from the various State Commissions. It was not on the agenda. It was an oversight. We usually have it there. But. I don't know if Dr. Anderson has any comments that he

would like to make at this time?

DR. ANDERSON: Well, as I mentioned earlier, I have not had a chance to pulse the various commissions, concerning the study. I will do that in..

DR. SHEPARD: I didn't mean specifically the study, but in any issues that you care to bring forward.

DR. ANDERSON; Not in particular. Things have been rather quiet in the last three months, at the state level. They're all busy, the three or four that I have talked to, going along with their studies, as you know, not all of them have indepth studies. Most of them do have registries, which are rapidly adding names to. But, I might ask that Mr. Bender is here. Mr. Wilson, do you have anything that you would like to say? Any of the other states?

MR. WILSON: Certainly, I'm not sure that the last few months have been quiet for the state. A number of states have been very much involved in the class action litigation. New Jersey, for example, has held a series of public hearings. We've played an active role in information that has been provided to the courts. We are taking an active role, with the veteran organizations, in our state, particularly, in terms of providing notification to veterans relative

to what's happening. They're very interested in this pending Agent Orange legislation in the Congress. The court has imposed some deadlines. relative to filing Agent Orange claims forms, with the court. The veterans need to know about. Are you aware of that, fearclay?

DR. SHEPARD: I'm sorry. Filing claims to the court?

MR. WILSON: Yes.

MR. ANDERSON: The 26th October date, you mean?

MR. WILSON: Yes. Which has been extended. The court, in an order, on June 11th, said that Vietnam veterans must file an Agent Orange claims form, with that court, no later than October 26, 1984, or perhaps be barred from ever recovering monies from a fund, if a fund is established. The judge has, in recent days, given a verbal order extending that deadline to January 2, 1985. Whether the Veterans Administration in it's national outreach effort, through it's vet centers or what have you, I think personally, that the over 100 vet centers around the country, and they are being called by veterans, relative to filing this form, and I think they should play an active role in providing information about this matter, and these court imposed deadlines, to the veterans around the country.

And I think that's a role they can have and if

they haven't had a role to date in that, they better get on the ball, because they're already behind schedule. Okay? So, I'll say that.

New Jersey is conducting research right now. We will be meeting tomorrow evening relative to our dioxin analysis work, as a layman I'll leave it at that point. I'm sure that Dr. Kahn would be more than happy to discuss our research with you and to share whatever protocols he felt were appropriate.

We have asked some of the veteran organizations in the tri-state area, to assist us in finding suitable controls, as well as heavily eaxposed veterans. That effort, I believe is paying tremendous dividends at this point. And it will continue over the next several months.

I think what we're going to be doing in New Jersey, research wise, is going to be significant, I hope, and we have discussed, we may not suffer the problem of credibility that some of the other studies suffered. Which is a real question that perhaps this Committee would want to deal with, at sometime. We've debated it for days on end, in recent days, given the work that CDC has done, Dr. Mulinare.

I wrote something up that I think is important. You know, you spend millions of dollars doing studies.

You try to do them to the very best of your ability, and from what I can see, as a Vietnam veteran, as a layman, I believe you did a good job on that CDC birth defects study.

However, I think scientists must realize that given the unique nature of this issue, Vietnam veterans across this nation have a right to know, other than what they read in the press. Specifically, what transpired in that study. They have a right to be able to ask questions, and I don't think your job is done, coming here. and briefing 30 or 40 people, and saying here's the CDC birth defects study. I think there are a large number of veterans, and their families across this land. that would like to have the privilege that *I* have right now, of catching him in a corner down by the cafeteria, and asking that one question that's important to me and my family.

And when you build in monies for these proposals for these protocols and these studies, what you ought to do is put some monies in, okay? so that folks like Dr. Mulinare, folks like you, folks like members of this committee, can meet with veterans around this nation and say, I will answer questions you have about this study. Because I tell you, I have heard so much misinformation, relative to the size of this study, there

are veterans that think that somehow you slipped this registry down there out of your back pocket or maybe Barclay sent it down from his office, or what have you. Okay? I've heard it all, it's going to continue, and I think it really does a disservice to the fine work that you scientific people do.

But, the reality is, that Vietnam veterans have a right to know, and I think you should, you've got to further than here, in this ivory tower, telling them what it's about. And if you want to leave it to the press, that's okay. But, I would suggest that dosen't always fit the bill, either. Okay?

So, I just don't think, Dr. Anderson, I don't think we've been very inactive. I don't think we've ever been very inactive, and we will maintain our right, at all times, to speak our minds, and have a say. It's much more exciting, it's much more productive, and that's what it's all about, anyway. So, that's all I have to say.

MR. ANDERSON: I might add that Judge Weinstein held a hearing in Houston, which we had a very good turn out for. Our veterans seemed to be satisfied with the hearing .

MR. WILSON: What about the settlement?

MR. ANDERSON: They're not satisfied with the settlement, no. They were satisfied that they had a hearing. Put it that way. They, I did not go to the hearing. This was deliberate on my part. Because being in really two houses at the same time, and one on the research side and studies, and the other representing the veteran in our program, I thought it was smart at that point in time, not to be there. But, rest assured, there was some representation there, because the veteran groups and our program, are very close.

Now, as I understand it, the Judge told us that they had a date to file their claims, but they can add to their file, or claim, additional data as it becomes available.

MR. WILSON: They must do so within a 120 days of their finding out that they've got an additional medical problem or there's been a change or demonstrate to the court any good or special reason why you did not. And if you do not file that form, and we have an attorney here, if you do not file that form, you may be forever barred from making claims for any money, that may come out of that settlement.

And the reality is, we sit here, today, with 2% to 3 million Vietnam veterans in this country and

their families, only about 8 ro 9% have received formal notifications and are participating, and I'm fearful that 90% of the Vietnam veterans will see these court imposed deadlines go by without even having a chance to know what they were supposed to do.

And I would urge the Veterans Administration if you truly are going to be advocates for veterans, providing information is not taking a position pro or con on that settlement. You have a national vet center program, you have other outreach efforts, and I believe it's proper for a your folks to be involved in distributing this information. That's all.

MR. ANDERSON: Mr. Bender would like to say something back there.

MR. BENDER: In the last three months we've been more or less involved in, and Wayne has been involved in, too, is our massive effort to try to get veterans and to sort of notify them of their rights and responsibilities. We no sooner, more or less sat down ---and of course the birth defects study, that is, the CDC birth defects study came down the line and we had to do that, too. I can reiterate what Wayne has said. I think that the Veterans Administration does have an additional responsibility in addition to funding in getting the information out,

But, just as an example, the very day that I returned from Washington after Dr. Mulinare's briefing on the birth defects study, one of the first calls that I got that morning was from a fairly distraught couple, in Minnesota. He was a Vietnam veteran and she was two years younger. And she was, recently learned that she was pregnant. They had made the decision, in the absence of any related problems or any discussions with the doctor, to terminate the pregnancy because of what they consider to be the high risk of birth defects among that crowd.

Well, I first immediately got these people in touch with our own department and also, by the way I dropped of the study with them, the night I came back. And we were able to, you know, get this couple the appropriate genetic counseling, and of course, they changed their mind on that situation. But, I suspect that there are other situations like that occuring right now in the United States. And with, especially a competent and excellent study that has been done by the CDC, I'm a little bit surprised that more information has not been gotten out to the grass roots level.

Now, what Wayne brought up with regard to the Veterans Administration general responsibility to get word out to the veterans, I think the best example of

failure in this regard, deals with notifying veterans of the Agent Orange loss of class action lawsuit. As Wayne mentioned, probably only 8 or 10% of the veterans in the United States have received actual notice, as opposed to the constructive notice or fictional notice in the court system.

Now, 1 started working with the Veterans Administration, on this issue, actually about a year ago, now. Which I attempted to get the VA to go over their list and try to whittle off, for the 9 million veterans, who served in the Vietnam era, certainly there must be a few spare computers around the United States Government, where they could possibly extract out this information. I've been told that that is a fairly difficult proposition, but we've done it in Minnesota. We took our 1973 list of veterans, who had applied for the Vietnam——and presumably we had about 95% coverage there. We then matched them against our current tax records. You know, the computers did their matching on that, and we came up with roughly about 42,000 veterans in Minnesota, who served in Vietnam, and we're going to be sending them notices, through the court. We could use the Veterans Administration, actually, the United States Government. It's not just the VA. It's the Department of Defense, it's the other agencies. We could

use a lot more assistance on trying to reach. not just an 8 or 10% that Wayne has talked about. but 90 or 95 or 100%. It seems to me it was preposterous when I first heard it, that the United States Government did not have a method of finding out who served in Vietnam versus who served in the Vietnam era. And that seems to me absolutely vital. in a project like this, to get underway.

Now, it would be nice to have it underway now, so that we could provide a list of 2.5 million names to the court, so that the court could notify people. But, certainly, by the time that the CDC study, the —— study is done some years down the line, it seems to me we have enough time between now and then. to perform this gigantic task of whittling through some 9 million files, or whatever it takes. That we could put Richard Christian and his army of people in ...

MR. WILSON: You know, the Government went to a lot of trouble to find out where we are, to draft us, and they ought to do the samething now. You know what I'm saying?

MR. BENDER: There's no problem getting the 9 million people in through their physicals, sending you off to whatever training center they had to do, and then another 2½ million on——a surely the amount

of paper work necessary to send me to Vietnam would provide us all with lunch down at your excellent VA cafeteria. But, at any rate, it seems to me, we spent, what, a 150 billion on that war? How much was it, Wayne? It seems to me that it would not be that expensive to acutally whittle out those guys who served in Vietnam from the massive files, have one tape together. So, say, for example, if the CDC, you know, the early stages of the active studies, those reveal that there is some problem about Vietnam veterans that they should be informed about, and there is an easy and convenient way to do that. We could have used it for the lawsuit. Certainly could have used it for the lawsuit. Maybe we still can. And I think that serious consideration should be given to just such a list.

We've got something like that in Minnesota, now. We've probably got 2/3 of the veterans on a list. We're missing the other 1/3 and I'll have to try to find them So, this is clearly a national effort and it's clearly a Federal effort. Not necessarily VA, but DOD. I think serious consideration ought to be given to them.

DR. SHEPARD: I very much wish that such a list of 9 million from which we would winnow the people who served in Vietnam was available. It would have made the job of the epidemiologists infinitely easier if

we had a base list from which to start. But, as far as I'm aware, no list exists of the 9 million, who served in the military, during the Vietnam era. So. your statement, to me, implies that you know, we should spend some time differentiating those who went to Vietnam from those who didn't, and then get in touch with those who did.

But, I'm not sure that we have the starting base to begin that process.

MR. BENDER: Well, the Federal Government has the information. There's no doubt about it- You look at the national personnel record center in St. Louis. You know. it's just a huge structure and they quite literally, carry around the file of the____. So, the information is available, and it's just not in a form which is amenable to automated data processes. It should be in a form like that. The Internal Revenue Service has got that information. If nothing else, you know, we have enough time in the next five years to develop a system like that. It's clearly technically feasible. We can't cure the common cold but we can put a shuttle up, so we can also develop a list. It's just a matter of getting the right technocrats or bureaucrats together and put them to work.

I wouldn't want to do it, but I'm sure there____

This sounds like something for Richard Christian and his people. They seem to enjoy work like that. They're very good at it. The list is quite valuable.

DR. SHEPARD: Any other comments, Dr. Anderson, I think the ball is yours?

DR. ANDERSON: No..

DR, SHEPARD: Any other State Commissions that would like to address their comments, views? Unfortunately, we're going to have to vacate this room. I didn't realize that when we started the meeting but, I would now like to turn over the meeting to questions from the floor. And would you please identify yourselves?

COMMENTS AND DISCUSSION

MR. WALKUP: Excuse me. I want to get one suggestion for an agenda item for next time. That we invite probably the special master or somebody who is connected with the Agent Orange lawsuit, to come and brief us on one, information that they've gleemed from the hearings that they've conducted, relative to Veterans Administration and delivery of service and policies and research. And two, about the mechanisms that they're considering for administering the funds. Hopefully, we could learn from that or at least get some baseline data about how they're going to do something

that we haven't figured out how to do.

MR. WOOSLEY: They don't know.

MR. WALKUP: Maybe by December they will.

MR. PHILLIPS: They're going to schedule hearings for that in September, on the allocation.

DR. KAHN: Get somebody who can update us on what's happening.

MR. FALK: Yes, I'm Allen Falk, I'm Chairman of the New Jersey Commission. I'm not speaking for the Commission, here, because my point is concerning the educational subcommittee. I was present during the discussion this morning, and I think it's very helpful that they do intend to present a resolution before the full Committee. but I'm a little disturbed by the discussion as to the members feelings about their own status and what their responsibility is on the Committee, and I would suggest that they go back to their respective organization, because, and discuss this, because if they are going to be in a position where they will be voting on resolutions, and you only meet quarterly, I think puts, automatically, 6 month delay on everytime something would be brought up before the Committee. We table until the following meeting, until it can be brought back to each of their respective groups tP be discussed, or they can get

instructions from their directors, to come back again, and immediately have one amendment made, and have to go back again, for another three months, and I think it's really appropriate that the Committee members clearly have the autonomy in the responsibility to vote from their feelings and expertise, which they should have developed by now, and I'm sure they have, through all the years of being associated with the Committee.

Dr. Kahn, when he speaks of votes here, does not speak either for the New Jersey Commissions on which he is a member, or for Rutgers University, which he is employed by, and we assume that he does not have to go back and consult with anyone. Simply vote his conscience when something does come up. So, I would hope that it would not be a process of each time something comes before the Committee, it would have to be brough back to each of the organizations.

Secondly, I would like to make a comment on the question of the, whether or n6t CDC will conduct a fatty tissue studies or studies along those lines. We found two trends that are developing, with the Agent Orange issue, now. One, through the courts, and one through the Congress. Both seem to realize that something, has to be done for the veteran, but we're going

to have/finesse the issue of causation because it simply isn't there, the proof, right now. And that's what we heard Judge Weinstein say when we testified before him, and that's what we see is happening with the presumptive bills, that Congress seems to feel that there should be a presumptive bill, but, we seem to be heading towards creation of another advisory committee to discuss what the presumptions would be. because we just don't have the proof of causation. And Judge Weinstein put it right to us when he said, "can you show me right now, one litmus test, that can show whether or not an individual, Vietnam veteran, has the condition caused by Agent Orange? I'm not aware of one."

And he's had all this testimony, and all this expertise availabe to him, and he comes right out and says, I know of no litmus test. Now, that is the problem. If the court is going to approve a fund of 180 million dollars, and Congress is going to say, we will approve some type of structure for receiving compensation, and give us no criteria on how an individual veteran, makes application, and proves his case, clearly we'll need some type of litmus test.

And, from what I can see, all the great studies that are being proposed, and that are being in in progress right now, none of these / answer this

question. We're trying to do that type of work in New Jersey because we see it as a gap. If it isn't done, it's almost acknowledging that the end conclusion of the research that is being taken in advance. There is no causation, therefore, it's silly to even try and come up with a litmus test because they can't possibly prove anything. And I don't think that's the legislative mandate. *I* think the legislative mandate is to, at least investigate every possible area of research that could be beneficial to the individual veteran. and by process of elimination, show that that research *may* not be valuable.

And this is what I'm concerned about is, the CDC study at best. does not seem to present any help towards the litmus test to proving an individual veteran does or does not have a given a condition. And if there isn't consideration for actual subject research, by whatever means is appropriate, either through blood test or fat test, or tissue test, or electronic testing of actual human beings and developing a process for determining whether or not objective procedures could be available, then there still is a big gap.

And the fact that you may have a really great epidemiological study that will be fully accepted by scientific concensus four or fives years down the road.

does not respond to this litmus test issue. And, I'm concerned about that because I don't see the discussions on it.

DR. SHEPARD: Well, if I may just respond. I concur completely with your concern, and I'm very puzzled as to how this is all going to work out, in terms of awarding or making somebody eligible for payment from the trust fund versus somebody not eligible.

Frankly, I think the Judge has a very difficult question on his hands, and I don't know that that can be dealt with, scientifically. I think that the best efforts are being put. forward to do what science can do, but, science may not be able to answer that question. We may not find a litmus test. Certainly we would welcome any suggestions as to what kind of litmus test we use. I'm sure lots of people have been thinking about this, but, it really escapes me, and as to what could be applied in a given case. Yes, Peter?

DR. KAHN: The question of aid to Vietnam veterans is not just a question of money. Whether it's money from the courts or money in compensation. In fact, for a very large number of men, money is not the issue. At least money and compensation. I was in Buffalo, at a meeting in June. One of the things that

was forcefully brought home to me by a great many veterans in Buffalo, is that for a very long time, for whatever reason, post-traumatic stress or poisoning or general mix-up of the head because of the peculiar nature of Vietnam, for a long, long time men did not have their feet on the ground, unable or unwilling to commit themselves to a career or any kind of a long term job. And now, at the age of 30 or 35, they've got their feet on the ground, painfully, but they're there.

Now they've decided that they really ought to be in school, belatedly, but in school. The GI Bill benefits have expired. Even had they not expired, the amount of money that you get on the GI Bill now, is not adequate to put you through school. Compare that to the situations of the veterans of World War 11, where a man would have not only enough to go to school. but to support his wife and children in the process, meagerly, but support them.

So, now you have a unique situation, a peculiar war, where the problems of the veterans are somewhat different from those of previous wars. Compensation is not the issue. And here is something where the Veterans Administration, as advocate for the veterans, could go out and seek the necessary legislation

say, extend the GI Bill, increase the benefits. Vietnam is not quite the same as previous wars this nation has fought. You can go out and ask for that and you would get it tomorrow. Congress would fall all over itself to do that for you. And you would help an enormous number of men, a far larger number, than are ever really going to want compensation.

So, don't think that the aid to Vietnam veterans is a band-aid when he's got a cut or surgery when he's got cancer, or compensation in the pocket. There are other things out there that are just as important.

DR. SHEPARD: I agree with you, Peter. I think it's an issue. I'm not sure it's an issue for this Committee to handle. I think it's a much broader issue, and I'm sure that there are people in Congress and the VA who would like to see benefits extended in a whole variety of ways.

DR. KAHN: Until somebody starts squawking it isn't going to happen.

DR. SHEPARD: Okay. I'm sure there has been a lot of effort focused in those directions, but, as I say, I'm not sure that it is appropriate for this Committee to deal with that. Because this Committee has a fairly focused charter to deal with the health effects, related to herbicide exposure. But, I appreciate

your comments.

DR. SHEPARD: Any other questions or comments? Yes sir?

MR. BURDGE: My name is Janes H. Burdge, Sr., Shore Area Chapter 12, in Monmouth County, New Jersey, and I represent Vietnam Veterans of America. I'm their Agent Orange Chairman. I'm one of the directors, and I'm on the State Council, What I would like to ask you, or somebody of the Committee, to define chloracne for me. And who originally defined chloracne, what it is, what it looks like, and after that, I would like to have a little follow up.

DR. SHEPARD: Okay. We happen to have one of the experts on floor, right here in the audience. Dr. Fischmann, would you like to answer that question? First of all, tell us when it was discovered and by whom, and maybe some of the salient clinical features.

DR. FISCHMANN: It was first described by Herzheimer, a European dermatologist.

DR. SHEPARD: Excuse me, Betty. If you could get to a microphone it would help to make it..

DR. FISCHMANN: It has been, perhaps most clearly defined by the late Kenneth Crow of England, who was the world expert on the subject. The

chloracne task force has set up for chloracne, diagnostic criteria, which were [illegible] to all the consultant dermatologists to the chloracne task force in October of 1983. I'll be happy to supply you with a copy of that. And, what was the rest of your question?

MR. BURDGE: I would like to know what it looks like?

DR. FISCHMANN: what it looks like? It is a special variant of acne. It has large open black comedones, accompanied by pale, straw colored cysts, which actually are now known to be closed comedones. And it occurs, after exposure to chloracnegens, so it has to be correlated with the exposure to a chloracnegen. It usually begins within four weeks of exposure to a chloracnegen. It presents in somewhat atypical areas, which must also be present, such as the crow's foot area beside the eyes, the malar aspects of the cheeks, and behind the ears. It has a compatible histopathology, when you look at the biopsy under the microscope, it must be compatible, it's not a totally specific histology. There are people looking at that. But, there are certain features of histology which must be present. It knocks out the sebaceous glands which produce the oil on the skin. But there may be some recurrence, some small glands coming back at this

time, after the exposure of the Vietnam veterans. You get from histology a hyperplasia or squamous metaplasia of the lining of the hair follicles into which the sebaceous glands drain, and you get that same hyperplasia of the walls of the sebaceous glands before they are completely wiped out. These are the major features which must all be present to be able to make that diagnosis.

MR. BURDGE: Okay. 1961, and I would like to present this report to Dr. Shepard. A herbicide plant in Germany expoded and there was 200 workers exposed to herbicides, and it describes choracne on animals and human life. Which is a reddening, scaling, swelling, skin disease, which does not meet anything that she says. I'm not saying that you're lying. But, if you're telling the truth, then that scientist in Germany, in 1961, is lying. Or, if he's telling the truth, then you're not.

DR. FISCHMANN: That is the acute contact dermatitis, which may be present on the initial exposure to a high dose of the substance. And, indeed, in the veterans that I have examined, at the local Washington VA Hospital, we have five people on our Agent Orange registry, (which is something over a thousand people there on our own registry), five people

who had that particular early manifestation, which is a chemical toxicity on the skin.

That usually clears within a short period, within about a week of the actual accident.

MR. BURDGE: Then what would you call this, ma'am? The Veterans Administration has been denying me disability for this since 1972. What do I have? It matches the report that I just gave Dr. Shepard.

DR. FISCHMANN: The acute dermatitis would not have lasted this long time; from this very remote distance, it looks as if you have some kind of psoriasiform dermatitis; this has not, to date, ever been associated with exposure to Agent Orange, and this is all I can tell you at this point.

MR. BURDGE: What I have on me, and I've taken that report and myself, to a few dermatologists, by a dermatologist, and they say what I have matches that report. It was done in 1961 in Germany. And the Veterans Administration has been denying me disability since 1972, for this___. That's all I have to say. I'd like to have that report investigated.

DR. SHEPARD: Okay, fine.

MR. BURDGE: Find out who is really telling the truth and who isn't.

DR. SHEPARD: Okay, we'll be happy to do that. Do you have any medical reports from dermatologists who think this . . .

MR. BURDGE: My VA file right now is in this office, in Washington, from Newark, New Jersey, awaiting my appeal, at my personal hearing, here. My file number is on each sheet of that, so, if you would like to pull my file and compare it with this report, you're very welcome to.

DR. FISCHMANN: If your disease actually started in Vietnam, and that's recorded in your medical record, then that..

MR. BURDGE: This showed up one year after I came home.

DR. FISCHMANN: One year after you came home?

MR. BURDGE: Exactly one year.

DR. FISCHMANN: On all theevidence from industrial accidents, which is, I'm sure you are aware, the major area from which we have the evidence for effects of dioxin on humans. There are no cases that have started that long after exposure.

MR. BURDGE: This report was done in 1961. What I'm saying is, who is telling the truth in this situation.

DR. SHEPARD: Thank you very much. Are there

any other questions from the members of the audience? Yes?

MR. LATTANZI: Frank Lattanzi, citizen soldier, New York. Just a fast question for Dr. Mulinare on your study. We, as far back as 1980, had appeared before the Inter-Agency Work Group, regarding the study results our medical questionnaire, which had been designed by the Stellmanns at that time, and analyzed by Dr. James Dwyer, Ph.D., Biostatistics and Epidemiology, State University of New York. One of the problems that had been leveled at the study was that it was a self-selected study, but nevertheless, when we evaluated the questionnaire, utilizina a computer evaluation, it did reveal findings similar to fehat CDC noted. Specifically, / that there was a slightly increased incidence of both spina bifida and cleft palate in our study.

I think roughly 108 cases spina bifida out of about 2400 viable pregnancies. T don't know if the Committee would be interested in having us resubmit our study to be reevaluated again, in terms of what was found at CDC, because even though it certainly dosen't approach the complexity of the CDC study, it still did give some indication in some areas relating to an increased incidence of several congenital birth anomolies that should be studied further. I don't believe, after that testimony, we even did meet with anyone to actually evaluate that data. So I don't know if the Committee had ever gotten a copy of that study.

DR. SHEPARD: Would you be willing to take a look at it, Joe, and..

DR. MULINARE: I'm not aware of the report. I'm only aware of an aspect, which was published for the Society for Epidemiology Research meeting 1 June, or around that time. I've ftever seen any of the reports.

MR. LATTANZI: Would it be of any, ...

DR. MULINARE: If you wanted to send one along, I think we could try to look at it, I'm not sure we could promise a formal response to it at this time, but..

MR. LATTANZI: No, I know that. I just thought that since the indications were similar, that it would be beneficial to review our findings again.

DR. SHEPARD: Appreciate it, thank you. Are there any other questions? Yes, sir?

MR. GRAHAM: My name is David Graham. I have a question for Dr. Mnlinare or Dr. Kafrissen,- concerning the CDC study and the control groups. On all of the studies, are you looking at the Vietnam veterans that served in Vietnam, after the cessation of herbicides, or are you just looking up until 1971?

DR. KAFRISSEN: We have a number of different cohort studies. They all, though, are limited to Vietnam

veterans who served up until the end of 1971, although there are different groups, other limitations, and of course, we include men who did not serve in Vietnam at all.

MR. GRAHAM: One of my concerns is that the Veterans Administration presumption is that if a Vietnam veteran served in country, any period, he was exposed to Agent Orange. Is that right?

. DR. SHEPARD: No, not quite. It's my understanding, that for purposes of adjudicating compensation claims, the VA will presume that anybody who served in Vietnam may have been exposed. So, the Vet is relieved of the responsibility of proving exposure. That's one area. T don't think that that would also include the fact that scientifically, we assume that he was exposed.

MR. GRAHAM: I just relocated him from the New .Tersey fire department dioxin all over New Jersey. One of my concerns with the CDC study ,is that, are there any mechanisms to insure that in the control groups, that they are acutally looking at Vietnam veterans that served in country, after the cessation of the use of the herbicides. Where these veterans may be experiencing) either disabilities or had some children with birth defects, where they on the control group that is supposedly hasn't

been exposed to the herbicides. To me it would make the statistics invalid. The way they have them now.

DR. KAFRISSEN: If you're asking, are we paying attention to the dates, as I've stated, yes, we are, and I understand your concern, there. However, just to give you, although I've already been berated once for running over my time. 30 second kind of capsule. The Agent Orange portion, we're looking at three distinct groups that we believe represent, based on our battalion tracking, rather than some of the other possible exposure indexes, but, based on our version of the exposure index, we're looking at three separate groups.

They may have been heavily exposed, probably not heavily exposed, and certainly not heavily exposed groups. If we see differences in those groups, that would give us some associations. However, if each of these groups appears identical to the others, and you can't find one group sicker than the other, that's not going to tell us that just having been in Vietnam was not a problem. For that reason we're conducting the other study, the Vietnam experience study, comparing in-country people, with non in-country military of the same era, to get at those questions.

MR. GRAHAM: Well, my concerns with the fellow

that was in-country making some of the——1971.

DR. KAFRISSEN: They have been excluded from the cohort studies.

MR. GRAHAM: That the guy who wasn't in 1973, but was in a heavily exposed area of Vietnam, is not ...

DR. KAFRISSEN: Yes, they're out because we're limiting our cohort studies to single termers, and we have the 201 files to confirm that. Anyone who has more than one term, in-country or otherwise, is excluded from the study, so that we don't have to worry about that concern. We're equally concerned and that's one of the ways we get around that.

MR. GRAHAM: So, you're not looking at the 1973 guy?

DR. KAFRISSEN: They're out. I promise not to look at anyone from 1973.

DR. SHEPARD: We have time for one more question and then I'm afraid we're going to have to vacate the room because there's another group that has reserved it. Any other questions? If not, thank you very much for your interest and look forward to seeing you all again in December. Thank you.

Dr. Han K. Kang (Veterans Administration), serving as Acting Chairman in the absence of Dr. Richard A. Hodder (Walter Reed Army Institute of Research), convened the meeting at approximately 10:20 a.m., Wednesday, September 12, 1984. Subcommittee members present were Dr. George R. Anderson (Texas Department of Health), Dr. Thomas J. FitzGerald (American Legion), Dr. Marion Moses (National Farm Workers Health Group), and Dr.. Joseph Mulinare (Centers for Disease Control). Dr. Peter Kahn (New, Jersey Agent Orange Commission), a committee alternate, was also in attendance as were many observers at the open meeting.

CDC Epidemiological Study

Dr. Michael Kafrissen (Centers for Disease Control) provided additional information and responded to questions about the CDC Epidemiological Study. Dr. Thomas J. FitzGerald asked about reimbursement of expenses for study participants. Dr. Karfissen indicated that all expenses "door-to-door" would be covered plus a stipend would be provided. Dr. FitzGerald urged that the types of individuals accepting the examination be contrasted with those rejecting the examination. He suggested that economic factors may be a consideration. Dr. Kafrissen assured him that follow-ups of non-participants would pick this up.

Dr. Peter Kahn described his experience in New Jersey which indicated that a letter to possible study participants' employers was helpful in increasing participation. Dr. Kafrissen responded that something very similar will probably take place in the CDC effort.

Dr. Marion Moses questioned whether taking the examinations to the study participants had been considered. Dr. Kafrissen said it had but was not feasible due to the tremendous number of people and equipment involved. The cost and logistical problems were prohibitive.

Dr. FitzGerald noted that the quality of the examination was a major attraction of the Ranch Hand effort and suggested that CDC send information to proposed participants regarding the quality of the examination offered.

Dr. John Levinson of Wilmington, Delaware asked for dates of completion and publication. Dr. Kafrissen said the selected cancer study is projected for four years after it begins (probably four years from the end of October). The medical examination phase will be completed 34 months after June 1, 1985. The interviewing phase about 2-3 months before that. The final reports will depend on what is found and what types of analyses are required, probably 9-12 months following completion of data collection. December 1987 is the report date for the mortality studies of the Agent Orange portion. By May 1988 the Agent Orange interview data should be completed. September 1988, the medical exam data. For the Vietnam experience study: February 1987 for the study interviews, May 1987 for the medical exam data, and April 1986 for the mortality data. He said that these are conservative estimates.

Dr. Moses asked when the protocol is going to be available to the Committee. Dr. Kafrissen estimated February 1. Dr. Moses asked whether CDC expected that the same physicians would be involved for three years. Dr. Karfissen explained that the quality control efforts (standardization, blind repeats, and overlapping) would address this concern.

Dr. Kahn suggested that a protocol of this kind should be applied to current chemical workers. Dr. Moses noted that some veterans may have problems related to current exposures to toxic chemicals and asked how this would be handled. Dr. Kafrissen explained that one of the reasons that CDC chose large populations is to control for occupational and other exposures. He added that the two biggest exposures in this age group that result in health-related effects are smoking and alcohol. If CDC finds someone with a medical problem, they will let him know and recommend treatment. If someone has unusual exposures, CDC will not design separate studies to address the effects of those exposures. Rather, they will control for those exposures, as any other confounders. Dr. Kafrissen said that a board-certified internist would sit down with each study participant to explain the results and when appropriate point out the need for appropriate follow-up care. The contractors have indicated that they will also write letters and will be available for consultations with the veteran's physician. Dr. Moses said she was concerned about what happens to the veteran after the examination. CDC will encourage the veteran to have his reports sent to this physician.

Dr. John Constable of Massachusetts General Hospital asked whether the chemical studies preclude any attempts to test the residual dioxin. Dr. Kafrissen said that fat biopsies are not being solicited but that they will collect extra samples of serum and urine so that if the technology becomes such that judgements or estimations can be made that will be possible. Dr. Levinson inquired as to whether CDC will test for porphyrin and hepatitis. Dr. Kafrissen answered yes to both.

Dr. Kahn asked if he could see the HPLC protocol when available. Dr. Kafrissen responded affirmatively. Dr. Kahn also made a point concerning the limited amount of laboratory equipment to perform dioxin analysis. This precipatated extensive discussion regarding the size of the specimen required to perform the analysis and the desirability of performing fat biopsies. Several meeting participants felt that it would be useful. Dr. Kahn argued that as of last year there has been enough dioxin analytical work on the general population--he cited efforts in Canada and Europe--to draw some conclusions regarding background levels. Drs. Kahn and Moses agreed that knowledge regarding pattern specific isomers is just beginning to emerge. Dr. Kafrissen expressed his view that not enough information is available now to interpret the results. He said that CDC will review methodology after the pilot study is completed. He added that if CDC is then persuaded that something is available that can clearly be interpreted that is sufficiently strong to get a human subject's clearance for an invasive procedure, then any number of possibilities will be entertained. Dr. Moses urged that fat be collected.

Mr. Joseph Carra and Dr. Frederick Kutz both of EPA then described the collaborative study that the VA and EPA have been planning to study the dioxin levels in human adipose tissue. The study will take advantage of adipose specimens collected by EPA for many years. (The study was described during a presentation by Mr. Carra at the most recent meeting, June 6, 1984, of the Advisory Committee). Mr. Carra explained that the objectives of this effort are to (1) determine background levels of dioxin in adipose tissue from the general public; (2) determine the levels in Vietnam veterans; (3) assess potential differences; and (4) assess the feasibility of future prospective studies. He noted that CDC is considering doing a prospective study of some kind. The EPA has met with them to discuss collaborating on such an effort.

While EPA has completed 21,000 analyses over the years from adipose tissue they collected, they have only 8,000 specimens in the archives. A review of these specimens found samples from 528 Vietnam era males in the age group that they are looking at. They found the Social Security numbers for 494 (or 94%) of the 528. In matching the social security numbers with information that the VA has on file 80 of the 424 had been identified to date but many more are expected. Dr. Kutz explained that there are three categories of patients that do not meet the criteria for tissue collection: (1) people suspected of pesticide or chemical poisoning; (2) cachetic patients; and (3) people who have been institutionalized for long periods of time. (Dr. Kutz also described a program that looks at people who died from suspected pesticide poisoning or chemical poisoning.) Mr. Carra discussed the opportunity for multiple matching due to the probability that there will be many more non-Vietnam veterans in the archive. That will increase the statistical power of the study.

Mr. Carra distributed copies of the draft protocol with a request for any comments that committee members thought appropriate. He also noted that the indicated attachment, the proposed analytical protocol, was in fact not attached but would be available from Dr. Kang.

Dr. Kafrissen questioned matching for age and race rather than age and SMSA and asked about the nature and quality of the storage of these specimens over time. Dr. Kutz and Mr. Carra discussed the freezing procedures and responded to concerns regarding these methods. Dr. Kutz expressed his concern, heightened by a recent Canadian study on PCB's in fish, relative to the use of organo-chlorine compounds as surrogate in each one of these tissues. He solicited comments on this problematic area.

With regard to the analytical protocol development, Dr. Kutz noted the complexity and complication encountered and the substantial unforeseen cost. He mentioned the extensive literature reviews and the various meetings of experts in Washington and Kansas City. He defined his terminology and described the protocol development process particularly with regard to this effort. Dr. Moses asked

about quality assurance steps, validating by splitting the sample and sending it to two laboratories. Mr. Carra said that it was too early to develop definitive quality assurance measures but agreed that splitting the sample was worthwhile. He noted that the splitting may be done internally, but blind, because of the limited number of laboratories equipped to do the work.

Dr. Kahn referenced a report out of the Rockefeller symposium about the yusho business in Taiwan where a PCB isomer analysis showed the disappearance of two isomers that were present in controls and people who were exposed to the usual oil. Dr. Kang introduced Dr. Michelle Flicker, who will be a full investigator in the study. She is a VA physician in Kansas City.

CDC Birth Defects Study

Dr. Barclay M. Shepard, chairman of the full committee, apologized for not having noted, during the full committee session, the receipt of letters from Senator Cranston and Congressman Edgar requesting the committee's views on the CDC birth defects study and related matters. Dr. Levinson said the study was well done but wondered about the need for additional research, for instance regarding spina bifida. Dr. Joseph Mulinare responded that CDC thinks that the published study is as thorough as possible with the data sets. He noted that it is possible for other studies to be done but they would be fairly complicated and would require considerable resources. He added that CDC will be looking at some other aspects of adverse reproductive outcomes (possibly miscarriages, infertility, mental retardation) in the Agent Orange study. The recently published case-control effort is probably one of the more sensitive studies with regard to major structural birth defects, noted Dr. Mulinare.

Dr. Moses congratulated CDC on the study. She commented that it supports what has been found in industrial experience and the Australian studies. She asked how the CDC study compares to the Australian birth defects study. (At this point, Dr. Shepard, unsure whether Dr. John Constable of Massachusetts General Hospital had been introduced, made such an introduction.) Dr. Michael Adena, one of the authors of the Australian study, said that while the studies were slightly different, they were comparable and produced similar results. Dr. Moses asked whether any other countries, excluding Vietnam, were looking at this question. Dr. Adena said no.

Dr. Kahn asked about confoundng or potentially confounding variables, specifically alcohol consumption. Dr. Mulinare noted that CDC did not look at minor defects, per se, adding that the resources were invested in looking at major structural defects. Dr. Kahn indicated that he was sure that he would understand better when he sees the full report. Dr. Kahn said that he thinks the study was well done but was concerned about the exposure index. He noted that some of the combat personnel were unexposed while other non-combat troops were probably exposed.

Dr. Jagger from the University ot" Virginia said that she was impressed by the study but asked about comparability of non-respondents. Dr. Mulinare indicated that the basic reason for non-respondents was the inability to locate the individuals. Dr. Jagger asked if there was a difference in severity of birth defects in respondent and non-respondents. Dr. Mulinare responded that it is in the full report, but as far as he recalled the proportions are about the same. Dr. Jagger also asked about stratification on variables and matching. CDC did matching because they felt that matching variables might be potential confounders, that is race and time of birth. They also controlled for hospitals. He noted that there were about 120 strata.

Recommendations

Dr. Kang asked if there are any additional recommendations--he noted that Dr. Moses suggested that CDC collect adipose tissue samples for future analysis--from committee members. Dr. Kahn strongly recommended that in the adipose tissue study the full isomer distribution of all three classes of compounds be done. Dr. Moses supported his recommendation. Dr. Kang noted that each of these recommendations comes with a very high price tag. Dr. Moses felt that it would be worthwhile nevertheless. Dr. Levinson agreed. Dr. Shepard said that while it would be ideal there would be some limitations, for example there may not be enough fat for a multiplicity of analyses. Dr. Moses said that she was referring to the CDC study.

The meeting was adjourned at approximately 12:05.

SUBCOMMITTEE ON VETERANS' EDUCATION/INFORMATION

Mr. George T. Estry (Veterans of Foreign Wars), serving as Acting Chairman of the subcommittee in the absence of Mr. Fredrick Mullen, Sr., (Paralyzed Veterans of America), convened the meeting at approximately 10:23 a.m., Wednesday, September 12, 1984. Other subcommittee members and alternates or substitutes present were Mr. Noel Woosley (AMVETS), Mr. Hugh Walkup for Mr. Jon R. Furst (National Veterans Task Force on Agent Orange), and Mr. Walter Phillips for Mr. Charles Thompson (Disabled American Veterans). Officials from several state Agent Orange commissions and the chair of the VA Advisory Committee on Women Veterans were among those in the audience.

Old Business

Mr. Walkup stated that the minutes of the most recent subcommittee meeting did not reflect the subcommittee's concern about timeliness of the subcommittee meetings, specifically the tendency of the opening full committee meeting to extend beyond the time provided for in the agenda. Mr. Walkup noted that the presentations once again lasted too long and expressed his frustration that his questions were cut off in the interest of time while others were allowed to ask additional questions. Mr. Walkup argued that the agenda for the full committee should be adhered to and that more time should be provided for the subcommittee session. Mr. Estry agreed. Mr. Walkup suggested that the subcommittee meeting continue through lunch or that the next meeting (December 11) have lunch provisions. Mr. Donald J. Rosenblum, Executive Secretary of the Committee, reported that the start of the afternoon session of the committee's meeting had been delayed 15 minutes in recognition of the morning's overrun.

CDC Birth Defects Study Results

Dr. Joseph Mulinare (Centers for Disease Control) provided supplementary information on the recently published birth defects study. (He made a presentation to the full committee earlier in the day.) Dr. Mulinare noted that the full report is now in printed (book) form and will be provided to committee members as soon as possible. Dr. Mulinare explained that the full report is much more detailed than the Journal of the American Medical Association (JAMA) article. (The article appeared in JAMA on August 17 and was circulated to committee members at publication). Mr. Estry commented that he had seen the full report prior to final printing. . He agreed that it was most detailed and would probably answer most if not all of the questions one might have about the study.

Mr. Wayne Wilson, Executive Director, New Jersey Agent Orange Commission, said that he recalled a comment by Dr. J. David Erickson, principal investigator of the study, that if the results pointed in any certain direction consideration would be given to further in-depth study. Mr. Wilson suggested that there might now be further study into the questions surrounding spina bifida, cleft palate and related problems. Dr. Mulinare noted that Dr. Erickson was not here, and he, Dr. Mulinare, was not aware of any suggestion by Dr. Erickson that further study might be necessary. Dr. Mulinare explained that the recently published effort was an in-depth study and that the data set has already been examined as thoroughly as possible. He added that while it is, of course, possible to do other birth defects studies, CDC has no plans to do so in this area.

Mr. Walkup questioned whether it was possible that some of the findings may not be random events while other significant findings may not have been picked up. Dr. Mulinare discounted that possibility citing the large number of study participants which make the results very strong. The statisical power was very strong. Mr. Walkup expressed concern that the small number of non-white participants make conclusions about them suspect. Dr. Mulinare explained that there is very little difference between the races with regard to the incidence of birth defects.

Mr. Woosley observed that political leaders have very different interpretations of the findings. He noted that Senator Cranston was concerned about the statistically significant findings and saw the need for "urgent" legislation, while Congressman Montgomery was reassured by the overall findings. Mr. Woosley was frustrated by the open question as to whether or not the statistically significant findings were chance events.

Mr. Phillips questioned whether there is need for additional study in this area. Dr. Mulinare responded that there is no evidence to warrant further studies. Others may wish to do so, but the information in the CDC data set had already been exhausted/analyzed. He added that there was no documentation in the animal literature that exposure of males to Agent Orange ingredients has caused birth defects. Mr. Wilson questioned whether studies of spontaneous abortions, learning disabilities in children and other matters not directly related to birth defects might not be worthwhile. Dr. Mulinare indicated that there may be an opportunity to examine some of these problems in other CDC studies, but noted that these efforts will not have the statistical power of the CDC birth defects study. Mr. Wilson observed that the VA Agent Orange Registry has a large number of participants. Dr. Mulinare noted the VA's registry is limited to Vietnam veterans who requested the Agent Orange examinations, unlike the Atlanta birth defects registry which contains all birth defects of the children of Vietnam veterans, Vietnam-era veterans, and non-veterans.

Mr. Estry commented that the full report explains the methodology utilized and will no doubt answer many of the questions the subcommittee has. Mr. Estry asked Dr. Mulinare about an NIH study of problems in children and the possible causes of such problems. Dr. Mulinare indicated that he was not acquainted with Such a study, but that it would have to be a long-range effort.

Mr. Walkup said he felt we are near the bottom line scientifically, that the political process was moving, and that we were beginning to respond to the moral questions surrounding the entire Agent Orange issue. He cited the moral questions raised by Dr. Kahn at the last committee meeting. Dr. Mulinare said that based on the CDC study Vietnam veterans should not think that Vietnam service has any effect on their likelihood to have children with birth defects. No additional genetic screening or counseling is required.

Videotapes

Mr. Danny C. Jones of the Regional Learning Resources Center, VAMC St. Louis, Missouri, discussed progress on the Agent Orange videotapes. Mr. Jones mentioned that the script of one of the planned videotapes (the program directed to veterans and non-technical audiences) had been sent to all committee members (and alternates). He indicated that the comments were generally favorable and that he hoped to incorporate as many of the suggested changes as possible. Mr. Jones noted that initial shooting would begin very soon. Next week (September 17-19) some interviews and shots regarding the Ranch Hand Study in San Antonio, Texas were planned. The following week this effort would continue at CDC in Atlanta. Hopefully the project will be completed in December. Mr. Wilson asked whether the states would have an opportunity to provide input. It was explained that Dr. Anderson, who represents the states on the committee, could solicit their views or that any state, organization or individual could obtain a draft script for comment.

Mr. Walkup expressed his interest in seeing the video plans for the script as well as the audio portions. Mr. Jones explained that the video portion is difficult to evaluate without actually seeing it on a screen. Mr. Walkup nevertheless felt it would be desirable to see the video plans, and Mr. Jones said he had no objections.

Mr. Jones reported a second videotape program (the effort directed at MAS staff) was in a rough draft and would be sent to committee members after it was reviewed by VACO staff and cleaned up. The third program (the videotape directed at environmental physicians, researchers, and other health care professionals) was not yet in draft form.

Barclay M. Shepard, M.D., full committee chairman, urged subcommittee members to express themselves on the videotape programs. He invited comments on the concept, asking whether there were any concerns about the focus or general impact of the program or if anyone was aware of any errors of omission or commission. If so, please advise him or his office as soon as possible. Also, if members had not yet submitted comments they should do so without delay.

Lay Language Summary

Dr. Shepard reported that the lay language summary of the literature review update was in the "next to last" draft. He expressed his hope that the summary document would be published in the next couple of months. Mr. Woosley expressed his concern about language on page 7 of the draft document. After some discussion about the meaning of "tentative conclusions" and the difference between an association and a cause/effect relationship, Dr. Shepard requested that any additional written comments be provided to his office as soon as possible. Mr. Woosley indicated that he would provide his comments. Mr. Phillips said that he had reviewed the document and found it to be excellent. He also promised to furnish written comments.

General Discussion

Mr. Chuck Conroy of the West Virginia State Department of Health asked if the American Medical Association Agent Orange/dioxin report update is still on track. Dr. Shepard indicated that it was, as far as he knows.

Comments On Birth Defects Study

Mr. Woosley asked what the procedure was for the committee to comment on the Birth Defects Study. He noted that Senator Cranston and Congressman Edgar had expressed an interest in the committee's views. Dr. Shepard apologized for not bringing this up at the morning committee meeting. He assured the subcommittee that he would do so in the afternoon session. He indicated that he would solicit comments from individual members, circulate such comments, and then try to reach some consensus view. Mr. Walkup urged that the question be brought up today. Dr. Shepard said that it would be but felt a consensus could not be developed today.

Further Discussion

Mr. Wilson commented on the "fairness" of hearings regarding the tentative settlement of the Agent Orange litigation. He said that he heard that government attorneys said that VA was providing medical care (under the provisions of Public Law 97-72) in the cost of $70 million per year. Mr. Wilson questioned the accuracy of this figure and asked if the subcommittee could be notified as to the past two years' and current budget for Agent Orange medical care. Mr. Wilson noted that while the VA provided the court with information on Vietnam veterans who had Agent Orange Registry examinations the VA did not furnish the court with information about Vietnam veterans who were receiving compensation, educational benefits, and other benefits and services. Mr. Wilson argued that the VA should be more forthcoming. Mr. Fred Conway of the VA's General Counsel's Office indicated that the $70 million figure sounded more like a cumulative than annual figure and that the VA did not provide additional information about Vietnam veterans who are receiving benefits for a variety of reasons which he enumerated. Mr. Conway explained that the VA wanted to protect the confidentiality and privacy rights of veterans who apply for benefits and services. He noted that the VA can only release information in accordance with statutes, that this is a private suit (veterans vs. chemical companies) and it may be illegal for the VA to provide this information, and the court has not ordered (or even requested) the information.

Mr. Walkup said he felt it was time that we separate the issue of people (or veterans') concern from the science. He said he thought it was appropriate for the committee to offer a resolution on compensation and service connection. He then presented a draft resolution for consideration. Mr. Estry questioned what weight such a resolution might have. Mr. Ken Satlin of the Board of Veterans Appeals said that claims are adjudicated on the basis of probability not possibility. Mr. Alan Falk, Chairperson, New Jersey Agent Orange Commission, expressed his view that such a resolution was appropriate. Several subcommittee members then voiced their concerns that the various veterans organizations that they were affiliated with have different views on this matter. Some of the subcommittee members were unsure of the exact position of their organizations and were uncomfortable taking a position that may be in conflict with their organization. Gerald Bender, Director, Agent Orange Program for the State of Minnesota, said that this was the wrong time and place for such a resolution, that efforts should be concentrated on getting congressional action. There was a consensus that subcommittee members would work informally (by telephone and correspondence) prior to the next meeting to develop a resolution.

Agenda for Next Meeting

Along with time for the resolution, subcommittee members suggested the next meeting's agenda include the lay language summary, videotapes, Agent Orange budget, and comments on the CDC birth defects study.

The subcommittee adjourned at approximately 12:05 p.m.

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

Twenty-Second Meeting
December 11, 1984

May 1985 Washington DC 20420

VETERANS ADMINISTRATION
ADVISORY COMMITTEE
ON HEALTH-RELATED EFFECTS OF HERBICIDES

Veterans Administration
Central Office, Rm 119
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Tuesday, December 11, 1984

The above item came before the public pursuant to notice at 8:30 a.m.

MEMBERS PRESENT:

DR. SHEPARD, Chairman (VA)
DR. BARNES (EPA)
DR. LINGEMAN (NIH)
MR. GORMAN (DAV)
DR. MULINARE (CDC)
DR. FITZGERALD (AL)
MR. WALKUP (NVTFAO)
DR. HODDER (WRAIR)

CONTENTS

P R O C E E D I N G S

DR. SHEPARD: Good morning ladies and gentlemen. I think we better get started. As usual we have a very full agenda. You are probably getting tired of hearing me say that, I expect. Some of our members unfortunately will not be here today. We just heard of two of them that will not be able to attend for pressing other business reasons.

I would like to welcome you to the 22nd quarterly meeting of the Advisory Committee on the Health-Related Effects of Herbicides, first established in April of 1979. So we are coming up on our sixth anniversary. As usual today's meeting will be open to the public including the scientific session. In order to have a record of attendance, we would like all attendees to sign the attendance book in the lobby. As usual, we have set time aside on the agenda to welcome questions from visitors and guests. If you will please write your questions on cards provided to you by Don Rosenblum that will expedite and smooth the process.

There have been several changes in the committee membership. Mr. Jon Furst has tendered a letter of resignation. For the last

several meetings Mr. Hugh Walkup has been his alternate and has been attending very faithfully. Now that we have Jon's official letter of resignation, we will recommend Mr. Walkup, with his approval, to the Administrator for appointment to the committee.

We have two other letters of resignation. Mr. Noel Woosley and Mr. Fred Mullen both regretfully have tendered their letters of resignation, and that leaves then some openings on the committee. Unfortunately, several members who normally will have attended will not be here today so our committee attendance is somewhat shrunken. That brings me to my next point. Normally we have two subcommittee, concurrent subcommittee meetings. I think under the circumstances we have very few people here who would normally attend the Information/Education Subcommittee so I am going to ask the committee if they would feel okay about having the entire meeting as a plenary session. Let me just poll the committee.

MR. WALKUP: I usually do most of the talking in that subcommittee. Would it be appropriate to ask members of the audience- that might have had their concerns who normally would bring them before our committee and might not have had an opportunity ?

DR. SHEPARD: Well, we'll operate it as though there were two subcommittee meetings. Rather than having separate meetings where there may be only one or two people, in one of the subcommittees, we can all be together. We can do it the other way. We have the other room reserved. I was thinking that it might be just as well to have the entire meeting as a plenary session. We will welcome questions from the floor as we usually do. Does anybody have any objection to that? It will make it a little easier for me personally because I tend to shuttle back and forth between the meetings. It is a little difficult, but I think under the circumstances we might make better use of our time.

We have had a lot of activity since our last meeting in September. First of all the Australian Government has published its mortality study. It is a three-part study, a retrospective cohort study of mortality among Australian National service men of the Vietnam conflict. Several members of the committee have received copies. We didn't have enough copies to send to all committee members, unfortunately, so we decided that we would send the copies of the report that we had to the scientific members of the committee. However, in your packages you will see the

executive summary of that report which we have duplicated and included in the packages, probably the last thing in your packages.

I have asked Dr. Hodder if he would be willing to comment briefly on the report so that we can get it into the record. We are hoping to receive more copies so there will be more copies available for distribution. Early in October we had a meeting of the VA Agent Orange Policy Coordinating Committee chaired by the Deputy Administrator, Mr. Alvarez. This was largely an information sharing meeting and is attended by a number of department heads and senior staff VA personnel. Also, early in October the House subcommittee on Hospitals and Health Care, a Subcommittee of the Committee on Veterans Affairs held a hearing on the birth defects study which was released in August by CDC.

The interagency agreement between the Veterans Administration and the Centers for Disease Control regarding the epidemiology study was revised and updated and signed in October. That study is progressing. Also in October, the National Elucational Conference for Environmental Physicians was approved, that is the budget, for a large educational meeting, a national educational

meeting to be funded by the VA principally for VA employees, but we hope to involve other members of the scientific and veterans communities.

This is scheduled to be held in the third week in August in Washington at the Washington Plaza Hotel, we believe. The agenda for that meeting is being developed currently by our staff with input from other VA departments. We hope very shortly to circulate the draft agenda for that meeting to raaribers of the committee for comment. So, we hope that that will be a successful meeting. I think that we will have a lot to report and we hope to have a number of papers, scientific papers presented at that educational meeting. As I am sure that you all know by now, the president signed Public Law 98-542, known as the Veterans' , Dioxin and Radiation Exposure Compensation Standards Act in October. We are hoping to have a member of the staff of our general counsel here to give you a little more detail on the provisions of that bill and also how the VA is responding. There has been a task force working on various aspects of implementing this very important piece of legislation.

The November issue of the Journal of the National Cancer Institute has two very

important papers dealing with soft tissue sarcoma. The member of the committee have been provided xerox copies of those two articles, one from New Zealand and one from New York state. I recommend those to you. Again, I am hoping Dr. Hodder will have a moment to briefly touch on the details of those two important recent scientific efforts. I am very pleased to report that last week in this room Lt. Col. Alvin Young received one of the highest awards presented by the U.S. Military, that is the Legion of Merit. It was presented by the Administrator and the Air Force Surgeon's generals office was represented by Major General Murphy Chesney. We are very pleased to have a nice turnout, and we all feel that Al Young richly deserves this high award.

Recently the American Medical Association House of Delegates met in Honolulu. On the agenda was a vote on the publication of the update of the Agent Orange review which they published a few years ago. The vote was in favor of publishing it, and members of the committee I believe have been provided copies of that draft, and it should appear sometime in the spring.

Five years ago today, the White House established an interagency group to monitor and

coordinate federal research regarding phenoxy herbicides. on this the fifth anniversary, I would like to call on Dr. Peter Beach, the group's executive secretary for the last several years who has worked diligently at pulling together and monitoring the agencies' efforts, the coordinated efforts of all of the federal agencies that have been working in this area. Dr. Beach. I would just like to announce as Dr. Beach is coming up that at about 9:15 we will have the pleasure of meeting Dr. John Ditzler our new chief medical director who will address the committee. Dr. Beach.

OVERVIEW OF FEDERAL GOVERNMENT ACTIVITIES

DR. BEACH: Thank you. Thank you very much Mr. Chairman. You stole my thunder. Today is the fifth anniversary of the founding of the Inter-agency working group to study the possible long-term health effects of phenoxy herbicides and contaminants shortened to IWG, because it was such an impossibly long name. The IWG was re-established in August 1981 by President Reagan and renamed as the Agent Orange working group of the Cabinet council. The history of the working group is interesting because of the perceived need by the Federal government, by the Carter White House at the time, and reaffirmed by the current Administration, that this important work must go on.

What is the work of the Cabinet Council Agent Orange working group? AOWG was enlarged in August 1981, to include almost all Federal agencies remotely concerned with Veterans. The Department of State was added because of the international aspect and the interest of other governments such as Australia and New Zealand who were involved whose troops and/fought side-by-side with the U. S. troops in Vietnam, because of industrial accidents overseas and the concerns of other scientists such as the research going on in Sweden and Britain. The various other dioxin research activities required that there should be an international contact. Additionally, because of concern over the delicate negotiations with the People's Republic of Vietnam; the international conferences that were scheduled in Ho Chi Minn City the Department of State was added to the cabinet-council working group.

You have I think with you a list of the current federal research activity on humans that is going on, 24 studies. This does not include some 50 plus studies that are currently underway, almost complete or completed by the various federal agencies involving animal research and other types of laboratory activities. I think it

is very important to notice that this is a specifically formed Federal government working group to monitor and to have oversight over Federal government activity; not state government activity; not private activity, but Federal government activity.

The only member of this working group who is non-federal is the representative of the Congressional Office of Technology Assessment. Dr. Michael Gough has been such a member from its inception. He has been invaluable as an observer, but we regard him more as a full member. He is involved with every activity of both the science panel and the full Agent Orange working group at the cabinet level.

Vfe have had a number of chairpersons both chairwomen and chairmen. I note that we have had recently more consistency. Vfe are at Chairman No. 9. Previous occupants were the General Counsel of HEW, the General Counsel of Health and Human Services when it became the Health and Human Services. We have had the Under Secretary of Health and Human Services, the Deputy Under Secretary, HHS, the special assistant to the Deputy Under Secretary of HHS. The Assistant Secretary of Health Dr. Edward Brandt, for the last fourteen months, has been a a very fine chairperson, just resigned from the government

to become the Chancellor of the University of Maryland at Baltimore and we are very sorry to lose . him. He will be replaced by the cabinet with the Uhder-Secretary in HHS, Uhder-Secretary Charles Baker. We will continue to hold monthly sessions. We will continue to meet as sub-groups, which are the scientific panel, the resource panel and the Public and Congressional Affairs Panel.

A frequent question is why do we have so many members? We work very closely with the Veterans Administration. In fact our charter mandates that we are to oversee, coordinate, and set priorities among Federal government research activities designed to relate exposure to phenoxy herbicides to long-term health effects and to design research agendas to assure that

the federal government conducts, comprehensive research of the long-term health effects of these compounds in response to both scientific and policy needs.

When you look at the members I think you realize that working with the VA is a priority. Working with the Environmental Protection Agency is essential. The Department of Agriculture had specific research that we were interested in. In working with the Department of Defense, especially with the Army Agent Orange Task Force / or as it is now known that the Environmental Support Services Group; has such a vast impact upon all of our studies such as the Air Force's long-term studies of the Ranch Handers, making them essential in providing much needed support for Federal Government activity.

Without the Army's Support Group; we all would be in serious trouble. There is absolutely no question that they supply the data and much of the factual data on which we are basing many "of the studies. The Office of Management and Budget has a keen interest upon the impact of the research. They must keep tabs upon the expenditure and when one must consider the millions of dollars spent in research, I presume that was why they were placed upon the

actual membership. The White House Office of Science and Technology Policy is a valued member. This Advisory Committee has frequently heard from Dr. Alvin Young who is an essential member and has given us years of much needed advice, from that perspective and from the Office of the Science Advisor to the President. Their specific involvement shows the President's interest as does the presence of White House Office of Policy Development as another member.

The Department of Health and Human Services, because of the Chairmanship of the Cabinet Council on Human Resources, was asked to chair this federal effort. It is perceived to be a neutral body with the resources of research such as the Centers for Disease Control, the National Institute of Occupational Safety and Health, the National Institute of Environmental Health Sciences, etc.

I believe that because the VA's advisory group is a public body, and is meeting publicly (and I have been attending them since conception) you have the essential contact with the veteran's organizations with the public; with the scientific community that unfortunately the White House working group does not have because we are a closed body, we meet in closed session. We do not make minutes available. However, it is in ourcharter that we must make

available to this body and to the public whenever possible the activities and the research/results. You may find it interesting to look at some of the contact persons. I did not list/all the chairpersons, what I did mention/are the science panel chairs and the other chairs and the contact persons from agencies. I neglected to mention you /Barclay, I'm so sorry. That was a vast oversight.

I do intend to update this as frequently as possible and we will be getting out into the public domain these studies as they become available. I would mention some of the Veterans Administration activities. I think that it is important to notice that we have included the twin studies here because that is one of the VAs activities that is currently under review by the science Panel and by the Cabinet Council Agent Orange Working Group. We are well aware of the other studies and you are kept up to date on them. I think you are aware of CDC because many of the members here are also members of the Cabinet Council Working group. I see Dr. Hodder, Dr. Mulinare, Dr. Shepard of course is the lead from the VA on these studies. You have I think here before you the list of the various activities from the various federal agencies. It is important that these

priorities established by the White House, continue. I believe that the concern expressed both by the Carter White House and by the Reagan White House are real. I believe that the intentions are to follow / research through until there be no shadow of doubt. Unfortunately, so much tine has elapsed; there is no way of speeding up research. I wish it were different. We have reached today the fifth year that we have had such working group activity. All we can hope is that the major studies that /are close to completion will provide the answers that we all so urgently desire. Any questions?

DR. SHEPARD: Thank you Peter. Now, are there any questions from the members of the committee? Okay, thank you very much, Peter, for that comprehensive overview and historical review of the important work of the Agent Orange Working Group. As you say, I think it is very important that we continue our efforts in the energetic way in which I believe we have. *I* have heard it said from various people who are not very close to the issue, that are sort of looking in from the outside that the Agent Orange issue is kind of going away isn't it. After all, the class action suit settlement and the fact that some of the studies have been completed pretty

much puts an end to the Agent Orange issue, and I say vociferously -- certainly not. The issue continues. If there has been a change, I think it is assumed perhaps more rational proportions that there was a time, as you all remember, where veterans justifiably felt that their concerns were not being heard. I think that is less the case now, I hope it is less the case now. I think it is largely the result of the work of the White House group and this committee that has come about. I certainly welcome that because I think it makes our efforts continue in a more measured and balanced way. I think people are listening more eagerly perhaps than they were at one time. Clearly, the research agenda that has been put together by the entire federal government, I think, has gone a long way, is going a long way to answer virtually every major concern at least of the veteran community. We certainly welcome and applaud the work of the White House group in substantially furthering that.

DR. BEACH: Thank you.

DR. SHEPARD: I'm sorry to see. that Dr. Anderson from Texas is not with us. He was next on the agenda. I am wondering if we could jump ahead now and call on Dr. Charles Lawrence. Could we ask you to

present your paper on mortality study from New York State? We are very pleased to have Dr. Charles Lawrence from the Department of Epidemiology, from the Department of Health State of New York. Dr. Lawrence.

DR. LAWRENCE: Can I do it from here? Will that be alright?

DR. SHEPARD: Sure.

DR. LAWRENCE: Should I combine the scientific discussion with the other discussion?

DR. SHEPARD: I think we are doing that, yes.

DR. LAWRENCE: Is it at all possible for me to take my whole 25 minutes in one shot? I can do it either way. It is probably more preferable so it doesn't make it all broken up.

DR. SHEPARD: Sure.

DR. LAWRENCE: Either way is fine. I would prefer the –

DR. SHEPARD: The only hitch to that would be if Dr. Ditzler who is on a very tight schedule will show up. We may have to interrupt you and let him make his comment.

DR. LAWRENCE: I could go after him, or he hasn't come yet?

DR. SHEPARD: Well, he has not yet come, no.

DR. LAWRENCE: Alright, okay. If you have to

interrupt me I understand. I have ten minutes at first, then I will have fifteen minutes later. I will try to make continuity. That's what we are making it in two parts.

NEW YORK STATE PROPORTIONAL MORTALITY STUDY

Okay, a number of years ago the New York State Department of Health began to investigate potential health effects associated with the Vietnam experience. At that time we took really a two-fold approach. One was to say there is some evidence for an apriori hypothesis for one particular disease and that was soft tissue sarcoma. That study was, the result of that study was published in the November issue of the JNCI. I was not an author in that, not particularly involved in that study. That is the first of our, first of the State studies. I think that you will hear about that a little later. The second study said while soft tissue sarcoma has been laid down as a potential hypothesis, there are a number of other potential diseases which we don't know or we don't have a good apriori hypothesis or hypotheses about what may be connected with Vietnam experience or Agent Orange exposure. So, we took what is normally considered a rather broad brush type study, a proportioned mortality study. That proportion's only purpose is to provide information for studies that may

follow it on what are the best causes of death to pursue with further research. You will see as we go on that it is such a broad rush study it can't go beyond that point. The study in particular is proportionate mortality rather than the usual standardized mortality. In standardized mortality, one says I have a large group of individuals who had some exposure and hopefully some non-exposed group to compare. We will follow those forward and see what happens to the death rate.

In a proportioned mortality study when one is stuck in that circumstance as we were in New York state in which we could not identify what we call the cohort of individuals who were exposed, who had had Vietnam service. We couldn't go out and identify all of the men who ever went to Vietnam and were New York State residents. So, the alternative that the methods allow is called the proportioned mortality studies. In that effect, you look to see whether the distribution of the proportions of dying of different causes are or are not in balance with what you see in the general population. So, that study has an important disadvantage. It doesn't give death rates. It could be and indeed there are studies published where the death rates are either high or low for the

group as a whole, but they are out of proportion. So, that could be from a proportional mortality study that the death rates for veterans are low. We have no way of detecting that and out of proportion anything higher we find is not high in terms of death rate, just out of proportion or vice versa. The death rates might be low, they might be high. Anything low we find would not be particularly, would not actually be low. So, has that limitation been a proportional mortality study? The other important limitation is strictly a record linkage study. You will see I am going to combine several sets of records in order to get to the combination of Vietnam experiences and causes of death. The reason that is a limitation is some important variables which we would like to control for but we can't. We have no other sources of information besides what are in those records. You will see we have no way to determine cigarette smoking without controlling for that on any comment we might make like a disease such as lung cancer could easily be compounded or confused by differences in cigarette smoking habits. We have no way to address those issues.

Okay, the methods of the study are basically as follows. We looked as I said at deaths and deaths

only. We looked below all deaths amongst men who were ages 18 to 29 in the years 1965 through 1971. That forms what we call a cohort of individuals who were of the right ages to have likely have had Vietnam experience, Vietnam service. We looked at deaths amongst those individuals from 1965 to 1980 in one case, excluding the years 1968 and 1969 because Veterans service is not contained in New York state vital records for those two years. We found in those years some 4,558 Vietnam era veteran deaths and some 17,936 non-veteran deaths. The New York State vital records contained a question, two questions which relate to veteran and Vietnam service. They asked what if the deceased is a veteran and if they were a veteran what year or years or war did they serve in. From that we have attempted to classify individuals as whether they were veterans or not and given they were veterans did they have Vietnam experience. Given that source of data, we felt that it important to conduct a quality control sample. We picked a stratified random sample of individuals and contacted their next of kin indicated on their death certificates in order to determine the accuracy of the veteran staff of our vital records. I would like to show you a slide on that.

Pardon me for the multi-media presentation tonight. I had a little confusion with the slides so you are going to get all kinds. In this table we have the classification according to vital records of whether they are a non-veteran, a veteran with duty in Vietnam or no duty in Vietnam versus the classification from the quality control sample. As I stated, the quality control sample was done by interviewing next of kin and other individuals about whether or not this deceased individual had been a veteran and if they had been a veteran had they served in Vietnam. You will see that the classification of non-veteran versus veterans is really quite excellent either way you look at it. Ninety-six percent of those who were asserted to be non-veteran were indeed reported that way by their families so there is little mis-classification or confusion between those. On the other hand, if we look at the duty in Vietnam versus duty in the era but not in Vietnam you can see that the mis-classification is quite high. Of those who on the certificates indicated that they had had duty in Vietnam, actually only 56% did. Some 43% did not serve there according to next of kin. Similarly rather high mis-classification the other way around, those who the vital records indicated that had not

been in Vietnam, almost 20% actually did. I hope all of that is clear that we have some reasonable hope of - can I put it this way - that the New York State vital records system may be accurate enough to classify Vietnam era veterans versus non veterans, but clearly the level of mis-classification on Vietnam service versus other veterans of that era is too mis-classified, too error prone to be of much value at all. Actually, we are going to try some statistical method to use that data plus more accurate data. This is so error prone that it was all, that it was essentially of no value to 40% of them or incorrect as to whether they have served in Vietnam. Clearly there is little or no information in there about whether or not they have Vietnam service. So, we have to come up with another way to classify of whether or not they have Vietnam service and we did that with the assistance of the VA. I would like to mention to my co-workers on the study our Dr. Bill Page of the VA, Ms. Amy Kuntz of the VA, and Dr. Andrew Riley who works with me.

In order to get this more accurate information, Bill had been aware of and made contacts with the defense manpower data center, I think it is called. They have on computerized records all of

those who were discharged at fiscal '71 or after. They have Vietnam service on their military records. Unfortunately, New York State Vital Records did not have the critical identifier to match up against those. We didn't have their service number. So we first, the VA had already combined their referral system which contained their service number, with this defense manpower data set. The Burroughs system had enough identifiers, names, addresses, social security numbers, and because those were benefits for individuals who were deceased, enough identifiers to give us good assurance matching with the New York State vital records.

So, in that effect we combined the three of those in order to obtain the simultaneous classification of cause of death and Vietnam service. There were some 1,304 deaths that resulted from that combined match. We elected to add to that digest that we had already obtained through our quality control sample. We interviewed next of kin and that was a random sample of individuals, of death in that call of work. So now there is 192 which left us with 1,496 deaths of which 555 had Vietnam service. The remainder were veterans of that era but with no Vietnam service. Now that, the accuracy of those

records at DMDC were checked again by Bill in the VA against the military's records in St. Louis and found to be 95 or better percent accurate about Vietnam service, all except for the Army in fiscal '71. All 103 Armies in fiscal '71 were checked against St. Louis and this classification was eliminated there at least as to what the military record says which we take as the ultimate classification of Vietnam service.

Okay, now as I said we wish to do what we could about confounding. We did not have cigarette smoking in. Perhaps I will take my usual short digression about confounding. My short digression about confounding. I will have to take a break and we will get back to the results after the break. That is that let's consider the issue. Criminal just for some time ago has shown that people who smoke pipes are not involved in violent crimes not nearly as much as the rest of the population. Does that mean if we stuff pipes in everybody's mouth we are going to have less violent crime? No. It is confounded by socio-economic status. That is to say, people of higher socio-economic status tend to smoke pipes and they do more college stuff, not the violent stuff. Consequently, it is that commonality of the

socio-economic status which is behind both of those. We need to control for those as best we can. In this case we had only age, race, and education as data to control for, and could not control for a set of other important confounded given the record linkage study. With that I will take the requested break and give you a result then.

DR. SHEPARD: Thank you. Could we have the lights please? I would now like to introduce you to Dr. John Ditzler our recently appointed Chief Medical Director. Dr. Ditzler has a long and distinguished career and the specialty of anesthesiology and comes to the job as Chief Medical Director having been for four years the director of the VA medical center in La Hoya Medical Center. Dr. Ditzler.

REMARKS BY THE CHIEF MEDICAL DIRECTOR

DR. DITZLER: Thank you. Good morning ladies and gentlemen. I appreciate the privelege of being asked to speak with you. Let me first of all say that I appreciate, the VA appreciates the many things that you have done for us. We need you, and we wish you to continue to help us. As you might well imagine in the last month I have busily been engaged in transition briefings. I thought that was just a word at first. They scheduled me from seven in the morning until eight or nine at night and when I go home I am even

too tired to eat, which may help my diet.

Let me say that the Agent Orange is not new to me having been a director at our VA Medical Center in San Diego. It had been my observation initially that the greatest number of cries from veterans concerning Agent Orange tended to come from that group who eventually found more compassion and home with our Vietnam Outreach programs than they did with any of our internal health, medical programs. The Vietnam Outreach program became more effective and we had less

concerns expressed about Agent Orange in the hospital center as a whole. I don't know whether that tells us anything, but it seemed significant. It also seems that the number of applications for exams for Agent Orange possibilities greatly diminished as the Outreach program became more effective.

I also remember with great clarity that all of the issues even though quaze emotional did not come from people of lower educational skills. I remember a Health Systems Specialist I had, extremely well educated, an IQ of 190 at least who has still to this moment refused to have children. He and his wife are still afraid of some genetic impact because he was in Vietnam. So, whether we find or do not find we still have people who have great and deeply registered

concerns. I must tell you that you probably have already heard that we have some concerns about our twin study dealing with not so much Agent Orange but at least Vietnam experience. It reached the point where an outside Technical Reviews Committee advised us not to proceed with the second portion, it being scientifically non-valid. This of course as you realized did not go well with some of our Congressional friends. It has now been referred to the Office of Technology Assessment, and I believe just yesterday they fired back with a whole series of demands relating to it. So it would appear in some sense we still will hear of Agent Orange for many years to come. It was interesting therefore this morning just a few moments ago to learn that here yesterday in a District Federal Court a student being dropped by a group of Veterans against Chemical companies relating to Agent Orange was thrown out of court by the Judge on the grounds of absolutely no viable data that Agent Orange had a cause and effect relationship. Now, that's only one District Court, but apparently it was a well-respected Judge. So that the issue will not go away even if the court says it should.

I know very little technically about Agent

Orange, but it will become my responsibility to accept the recommendations and work with them as best we can.

Let me again thank you and assure you that you have an open ear. Thank you very much.

(Applause.)

DR. SHEPARD: Thank you very much sir. I appreciate you coming. I'd like Dr. Lawrence now to finish up his report on the mortality section. I apologize for the interruption.

NEW YORK STATE PROPORTIONAL MORTALITY STUDY

DR. LAWRENCE: Okay, SO we were able to obtain a set of records that allowed us to classific individual's deaths both as to their Vietnam experience and their cause of death. In addition to that, we felt that the original 26,000 deaths amongst our old cohorts, there was no reason not to go ahead with making the comparison between Vietnam era veterans and non-veterans even though 2/3 of those never served in Vietnam. We might shed some useful information about causes of death and veterans in general. So, I will present the results on comparisons of veterans who served in Vietnam versus those who had no such services in Vietnam and Vietnam era veterans versus non-veterans. I known you are more interested in the first one though.

We classified the causes of death into 26

causes of death largely along the lines of the classification of the NIOSH, National Institute of Occupational Safety and Health, with some important exceptions. There were some categories that we did not aggregate for the level they were. They were categories that had apriori interest so all tissues covered and (inaudible) in particular.

Now, a proportioned mortality study in epidemiologist jargon turns out to be *a* multiple what are called case control studies. We select individuals who deny a particular cause, and we compare those to the individuals in that effect to everybody else in that study who died of other causes can look back to see whether or not their Vietnam experience was different. The problem is that I keep rotating into the group that I am comparing the death to, all of the other causes of death. That's intuitively a problem and statistically, I'm the statistician that's really rather a mess but that's the kind of data we have to deal with so it has some influences on the statistical results we will get. In order to partially overcome now that we have filed the recommendations o'f Vietnam all, who say that from the control group one should remove the most extreme other groups, the ones with causes of death that are either

very high or very low for this comparison control group which we did. It turned out in this case that whether we removed them or not it made little difference on the results there. Okay, if I could have my first slide. Can you see that? Could we raise the slide a little please? Other way. Okay, this is the comparison of the Vietnam era veterans to the non-Vietnam veterans of the same era. In this case you will see that the columns are the number of deaths to those who were Vietnam veterns to the number of deaths for non-Vietnam, veterans of that era but did not serve in Vietnam. The MORs, the Mortality Odd Ratio. That's the ratio of the proportion of death to the Vietnam era, to the Vietnam veterans compared to the Vietnam veteran. Our 2.18 there says that non-vehicular injuries of transport are about twice as common in the Vietnam veterans as they are in the veterans of that era who did not serve in Vietnam.

These are ranked, and as I said the purpose of the proportioned mortality study is to provide help to the next scientific group. We ranked these in order that has to do with the involvement of chance and that is to say the highest one is the one that is least likely, that that elevation is least likely to have been just the result of chance variation. What

is non-motor vehicular as injuries of transport. It is everything but automobile deaths that are transport. So, it is water craft, railroad, and airplane. If we look behind what causes that elevation, we find that there is an excess of deaths in accidents of airplanes. To me that makes sense. There were probably more pilots and more airborne troopers who went to Vietnam than the veterans of that era who stayed stateside. So that we should find an excess of air transport type deaths makes sense, and I take it as some positive control. That is to say, something you might have expected to be there is there, and that accounts essentially for all of the elevation in that cateogory.

Other accidents is our next one. You will notice I have these 95% joint conference intervals. That's an effort to say whether or not the 2.8 level of proportion elevation is or is not beyond the realms of just chance alone. It is a fact that the lower confidence intervals are all less than one indicates that you could have had that elevation just out of chance variation alone. The sample size here is relatively small, only 1500 dead. We get down to homicides. Our first disease related, our liver disease including psorosis that had 89% excess but

the .5 in the left column indicates that that's well within the realms of chance although it could be as high as almost seven fold from this data. If we had access of liver disease, especially if that liver disease was not related to alcoholism it would be worthy of note. So we checked into the hospital records of these diseased individuals and we found that for the twenty-one deaths represented there, we were able to get at the record of 20 of the 21, and 19 of those 21 had clear indication of alcohol use in their hospital records. Then we go on down to some other causes of death, drug dependents, suicide. We get down to another — I need to go back now.

Pardon me. He's working on it. Sorry for the delay. Okay, here is the next level. Leukemia which we picked out as a particular cause which ranks about seven, and all digestive system cancers. We come down to lung cancer here. That's about even, just about the proportion you would expect in this case. I'm not having much luck with that.

There is soft tissue sarcomas. In this case there are only five deaths in our cohort of deaths. Consequently, we can't shed much light on that particular cause. Now we are down to the point of which the MORs are going less than one indicating the

excesses amongst the Vietnam era not the Vietnam veterans. Finally we come down where our total was 555 deaths amongst the Vietnam, 941 amongst the Vietnam era veterans, and heart disease was a low excess in this group. Now we go on to the comparison of the, this is of less interest I know. This is Vietnam era veterans against non-veterans. It includes the era veterans who include both those who served in Vietnam and those who did not. Here we find that the excesses, or the first two of them, and the bottom two are statistically significant. You see the confidence it over-exceeds one there. Remember my sample size is much larger, and consequently I have much more ability to detect whether or not chance is playing a role. Here we get more vehicle accidents, other accidents emerge homicides, and so on.

These are not ranked in the same order. If you look at the SLS column one here in the same order that they were before. How do you tell which the highest one is to look at the column. We look at SLM 1. Just let me go back to the first one. In this one we found that motor vehicle accidents were the highest. In that comparison in non-motor vehicle accidents I believe that -transport I believe was second. Here we have those roughly 26,000 deaths in

total that we have studied. So, what do I conclude from that analysis? I conclude that unfortunately we were not much help. Much help, our goal in the study was to compare Vietnam veterans to Vietnam era veterans to give indications to scientists what's the best next thing to study, and what came out to be things that were accidents, non-motor vehicle transport things which appear to be explained by things like excesses of pilots. So I am afraid that our efforts to try to guide future researchers into what causes of death, in particular what diseases might be most useful to study. It didn't turn out that way in our data to identify any diseases that were high on the list or that were elevated beyond the realms of chance.

More details on this study will be available in the March issue of the American Journal of Public Health. That will come out at the end of February, and at that point you can get a written version description of this study. They have a copyright on them and they ask me not to release it until they do. I thank you much and I would be happy to answer questions.*

DR. SHEPARD: Why don't you have a seat there and we will see if there are some questions

* see Am J Public Health 1985;277-279.

from members of the committee on these important studies? I have one. Go ahead, yes, Don.

DR. BARNES: I am just curious as to what plans you have for any additional work.

DR. LAWRENCE: At this point there is no plans to extend the proportioned mortality study given that we do find any of the disease categories particularly high, and given that the soft tissue sarcoma which came apriori as the most interesting. That study has been completed by the health department and you will about it for that, on it at this point, any leads that we see particularly.

DR. SHEPARD: Any other questions? I was just going to ask*. You said that your study did not meet the goals of determining diseases which should be studied further. Is it also accurate to conclude that you didn't show significant differences in the proportion of deaths among the two group studied?

DR. LAWRENCE: Yes, I would say that one could say that our study to the, with us important caveat about a proportioned mortality study right? Its goal is to guide further studies. There are a number of factors we couldn't control or we couldn't look at death rates. To those extent, given those limitations we found no significant excess of disease

causes that were elevated. You an take those limitations then.

DR. SHEPARD: Okay, any other questions? Thank you very much Dr. Lawrence. I see Mr. Conway is here from our General Counsel's office and he is a very busy person. I think I will now ask him to talk a little bit about Public Law 98-542. Thank you.

LITIGATION/LEGISLATIVE REPORT

MR. CONWAY: Good morning. I am going to depart a little bit from the prepared agenda in large measure because Dr. Ditzler made a reference to the court position as of yesterday. He didn't adequately describe what happened in the District Court. So by way of introduction, I will start with that first. The action had been brought by attorneys for Plaintiff veterans, their spouses and their children who had birth defects. It was brought following the settlement of the litigation against the chemical companies last May. The action that was considered by the Judge yesterday was one brought against the United States. At yesterday's hearing, Judge Weinstein who also presided over the settlement of the litigation against the chemical companies, heard arguments by the United States and Plaintiff's counsel on a motion filed by the United States to dismiss the complaint or in the alternative to grant a summary

judgement in favor of the United States. Now at the hearing the counsel for Plaintiffs tried to educate the judge on differences between legal causation and scientific causation. The judge was not too much impressed with that distinction saying in either case, either legal causation or scientific causation I have not seen anything beyond the scintilla of evidence demonstrating cause and effect between the birth defects of a child born to a father who served in Vietnam and that father's service in Vietnam and exposure to Agent Orange. He kept pressuring Plaintiff's counsel to present some evidence that would permit him to allow the case to go forward. They attempted to introduce affidavits of experts in which the experts related birth defects of a child, to the service of the father in Vietnam and the exposure to Agent Orange.

The problem the judge had with that was that the individuals that were the subject of the expert's affidavits were not a party to the litigation. There was no evidence regarding causation with respect to the parties before the Court. He, therefore, granted the United States motion to dismiss. As of yesterday, all veterans' claims were dismissed; veterans' claims for pre-service failure to warn, in-service torts of variety of sorts; and

post-service failure to warn and treat. He held in part those claims were barred by the Feres doctrine which holds that a veteran or a service member may not bring an action against the United States for an injury which is incurred in or incident to military service.

He also held that those claims which were brought by spouses and children that were derived from the veteran's service were similarly barred by the Feres doctrine. As to the remaining cases which would be characterized as independent claims of spouses and children, he dismissed all but about 54 or 55, and granted an additional 45 days to produce additional evidence or additional reasons as to why the case should be allowed to go forward. To give it to them may sound kind of strange, but they were the only ones who had counsel who could identify it and were trying for it. The counsel who were arguing on behalf of the Plaintiffs could not identify by name who their clients were. They argued that they were speaking on behalf of a class of veterans. The judge reminded them that he had never certified a class action and that he had specifically denied certification last week so he wished to know who their clients were. They went into a huddle for thirty minutes, came out,

and tried again to re-raise the issue of class certification. The judge heard nothing of that, and dismissed the case. That was in the United States District Court for the Eastern District of New York, and Judge Weinstein presiding.

I don't know if anybody has any questions or discussion on that particular case, but I thought it necessary to elaborate on it because Dr. Ditzler gave a somewhat shortened and not necessarily totally accurate presentation.

DR. SHEPARD: Are there any questions from the members of the committee on that action? Okay Fred do you want to go ahead now?

MR. CONWAY: Public Law 98-542. It did a number of things. They can be broken down into three basic categories. First it provided a disability allowance for a period of two years between October 1, 1984 and September 30, 1986 for chloracne and porphyria cutanea tarda on a presumptive basis provided they were manifested within one year of the veteran's last departure from Vietnam. Secondly, it set up the requirement that the Veterans Administration promulgate rules that will govern how it will adjudicate claims of veterans who allege exposure to Agent Orange and the subsequent development of

disability. Under the regulations, the Veterans Administration is suppossed to set up the standards by which it will adjudicate those claims. What kinds of evidence we are going to require and how we will handle that evidence in resolving the claim. Those rules are suppossed to be out sometime late January, early February. Final rules are required to be out by sometime in late August, September, 300 days after the law was enacted and that was enacted in October. So, it is about that time frame.

The idea behind that was to ensure that the veteran claimants, or claimants generally, (it may not necessarily be a veteran, it may be a spouse who is trying to claim survivor benefits) would know what is expected of them and would know the process by which the VA would consider their claim. It was also designed to ensure that similar cases would be treated similarly. The focus on that part of it was largely generated with respect to the radiation claims which are also governed by this law. At hearings, there were concerns that some veterans in the radiation area would be allowed benefits with exposures of as low as 1 rem of radiation, whereas other veterans were being denied this with higher exposure and they were

upset by that and they wanted similar claims treated similarly. It was the radiation cases that was pushing the legislation and not the Agent Orange one. The Congress is therefore aware that the agency has been most uniform in its consideration of Agent Orange claims. I don't need to go into what that uniformity is. I think you know.

The last thing that the law did was to establish an Advisory Committee on Environmental Hazards. It will be comprised of fifteen members, eleven scientific members, and four lay members. One of the four lay members must be a disabled veteran. The eleven scientific members would have, and I don't have the exact numbers, but some would have to have expertise for

radiation health effects, and others in dioxin health effects. The balance of the scientific members would be taken from a variety of disciplines that would have some knowledge and expertise that would lend to the resolution of these issues. For example, x-rays and toxicology, pharmocology, epidemiology and so forth.

The law also requires that the advisory committee have two science panels, each with eight members. So you have some overlap in

membership. The scientific panels would be broken into the areas of radiation and Agent Orange. The Chief Benefits Director, the Chief Medical Director are ex-official members and I believe there can't be more than one federal employee as a member. So, it is basically a non-federal membership.

The purpose of the committee is basically to evaluate studies as they come on line, as they become available. They tell us what they mean, whether they have met the three prong test of Dr. Shepard can remind me again. I forget Dr. Custis' definition of what is consensus.

DR. SHEPARD: Consensus is generally achieved when scientific studies are based on statistically valid data, that the study results can withstand peer review and that the study results can be replicated by other investigators.

MR. CONWAY: That is the standard by which this advisory committee is supposed to tell us whether the studies are good or bad, or what areas need to have further development and research done. So far, we have established within the agency what we affectionately call the "542 task force" which has representatives from the Department of Medicine and Surgery, Department of Veterans Benefits, and the

General Counsel's office. We are busily engaged in trying to write the proposed rules that are due to be published in late January or February.

With respect to the Advisory Committee, we have requested recommendations from a variety of professional organizations as to whom they would consider for membership. We also solicited recommendations from the Veterans Service organizations. We requested that they be submitted to us by November 30th. Some of them are still coming in and that was just purely an arbitrary date so we are not hard set about that date. It was not required by the law but was simply an administrative mechanism. We hope to be able to have a package ready to go to the Administrator for his consideration later this month. Hopefully, the establishment of that committee will be occurring sometime early this year. If there are any questions, I would be glad to try to answer them.

DR. SHEPARD: Thank you Fred. Yes, Dr. Hodder.

DR. HODDER: How do you believe in that, it seems that a lot of the things that committee is requested to do really takes over the, at least the evaluation part of this committee will not change the rules.

MR. CONWAY: We really haven't made the decisions on that yet. It is still way up in the air. This committee has played a role, a very active role and useful role for us. Whether the task of this committee would be changed somewhat to meld with the other committee or whether this one should be abolished and taken over the other committee or what. We have not really decided on that. Maybe that's something you may want to give us some information and input on as to what you think. It is still very much up in the air.

DR. SHEPARD: Hugh.

MR. WALKUP: As I understand it the committee has 300 days from the enactment of the law to make recommendations?

MR. CONWAY: The VA has 300 days in which to write the final regulations.

MR. WALKUP: Okay, would that include the committee's input?

MR. CONWAY: We would like very much to have the committee's input on those regulations.

MR. WALKUP: With the time line you were outlining before, it doesn't sound like they are going to have much of a chance to do that unless they meet daily after February, is that right?

MR. CONWAY: We would anticipate having as

many meetings as necessary in order to get the input because it is strongly suggested in the legislative history that they have that function if they participate in the rulemaking process. We would like very much for them to do that and unfortunately the time frames that the Congress gave us are so short that from a realistic managerial point of view it is going to be very difficult to do, but we are going to do our best.

MR. WALKUP: There is a fairly big section at the end about an amendment process for the regulations. Does that involve the advisory committee, or how does that work?

MR. CONWAY: Well to the extent, it would involve it to the extent that if you made any such changes in the regulations based upon changes in the scientific literature. Certainly we would try to involve the committee in that process. If it were simply an administrative change, probably not. Again, that is a very, very fluid situation right now. It is difficult to anticipate what the committee will be able to do for us. Again, what we ask them to do will be dependent on whether we have this committee now. Some questions might be more appropriate if we have this committee.

Other
/questions might *be* more appropriate on the other committee. It might be appropriate for have both committees. You see, one of the problems is that we just don't know what we are going to do yet. We have been so busy trying to meet the deadlines that we have not been able to progress to the rather big question, one which you alluded to, what do you do with this committee and also what does that committee, well what is that committee going to do. MR. WALKUP: After the 300 days, does that committee still stay in effect?

MR. CONWAY: Yes.

MR. WALKUP: Would it be that / they would only be called if there were new research that came up, and if they had not had a - if in their estimation they hadn't had sufficient input on the rules that end up getting promulgated from the first round, they couldn't reconvene? It would be only if the research came up.

MR. CONWAY: Well we are anticipating that they would be meeting on a fairly regular basis.

There is a lot going on on radiation health effects field. There is a lot more literature available so that may be

taking up a lot of time in the initial phase. So, I don't anticipate that they will be sitting around on their hands with nothing to do. Now, if rules need to be written because some study comes out that has a consensus of the scientific community behind it that agent orange or radiation or dioxin causes an indicated condition, we would need to have that input of the committee. So, as I say, I don't anticipate that this will have a low-level job or a low-visibility job. We intend to use them.

MR. WALKUP: And do you expect that they will be formed and starting early in the year next year like January or February?

MR. CONWAY: That is a most optimistic hopeful target.

MR. WALKUP: What's the worst case?

MR. CONWAY: The worst case. The worst case would be that we can't get anybody that wishes to become a member. They just say we are not going to waste our time with this committee. There is nothing to know. That is the worst case.

MR. WALKUP: Okay, what's the latest conceivably that the committee could be formed?

DR. SHEPARD: Excuse me. That's highly

speculative. I don't know how we can answer that. I think you are putting Fred on the spot. Let me just say that I have been involved in the process. Fred was not at a meeting yesterday. Let me just bring you up on a couple of details. We have received now I would say somewhere in the vicinity of 100 nominations. The next step will be to go through these nominations. This is all of the categories, people of various skills and expertise, both radiation and dioxin and so forth. We will go through that list of nominees and sort of categorize them as to what their area of expertise is and also get some sense of the depth of their experience and rank them in terms of what we would recommend to the Administrator. , It would be up to the Administrator ultimately to approve the list. That process is going on and we are moving quickly in that area. So, we expect to have at least a slight of members available for the Administrator within the next three or four weeks at the latest. Part of that process will be contacting these individuals to make sure that they are willing to serve on the committee. Obviously we don't recommend somebody if they are not wanting to serve. I think it is safe to say that we should have a committee in place about the time that the draft regulations are in

the Federal Register. So, that's what we are aiming at. But, at this point to say you know, what's the worst case scenario I don't know that that serves any real purpose.

MR. WALKUP: Thank you. That's the kind of information I was looking for. I have taken a lot of your time and I appreciate the privilege. I think that this is one of the most important things that has been happening on these issues that from the veterans' perspective that we have been raising for quite a while; that there is some chance of at least interim resolution of some of the things that we have been dealing with while the research goes on.

So, we are very concerned about the way in which it gets implemented and that things are going on. I am pleased to hear that there is a group up about the times that the regulations are proposed.

DR. SHEPARD: Thank you. The other thing Fred that I don't think you mentioned is that this would also be constituted under the Federal Advisory Committee Act and therefore the meetings would be open. Is that right?

MR. CONWAY: Yes. There will be open meetings. Now, the meeting process is the notice of the meeting and so forth would be conducted with the

same process of this committee meeting.

MR. WALKUP: One other thing if I could just piggy back. If this committee does go on, which, well if it does go on, it would seem like it would be very useful to members of this committee to meet at the same time as that other committee met so that it would be possible for us to hear what they hear and a chance for conversations back and forth with the other group.

DR. SHEPARD; I have been wrestling with this question obviously as to whether or not we need or should have two committees with overlapping responsibilities, and my gut feeling is, and it is just cay own personal feeling, that obviously we are going to have to make some recommendations to the Administrator because, again, ultimately it would be his decision. I think there may be some built-in problems to having two committees acting independently but addressing some of the same issues. So, at least as far as Agent Orange is concerned, I think there may be some merit to dissolving this committee at the time that the other committee comes on line. As I say, that's just my personal opinion. I haven't had a chance to discuss it. This is all quite new. I haveh't had a chance to discuss it with any members of the committee, but I will do that one way or another

as we are formulating our recommendation to go forward to the Administrator. Any other questions from the committee? I will suspend usual rules for a moment and ask since we are dealing with a rather special issue here are there any member of the audience who would like to address a question to Mr. Conway? Yes, Chuck.

MR. CONROY: Dr. Shepard, Chuck Conroy, West Virginia Agent Orange program director. Do you have any fix yet as to the number of veterans that stand to benefit as a result of this new statute? I think Judge Weinstein memorandum that he had issued September 25th addressing the lawsuit in settlement released some figures that were somewhat surprising to me in terms of how many claims have been filed and approved. The judge had noted that of 20,000 agent orange claims filed, only fifteen had been granted, 2 for P.C.T. and 13 for chloracne. If you have any figures as to the number of those veterans who may be benefitting from this I would like that information. Also something about who will be diagnosing these chloracne problems. Do you have a new mechanism for diagnosing them? Is their a definitive method for diagnosing chloracne? Perhaps you could respond to that.

DR. SHEPARD: Of course. In answer to your

first question, let me take a stab at it. I might ask Mr. Herb Mars who is here from the Department of Veterans Benefit. I think it is very difficult to predict how many new cases, how many new claimants may file claims and how many of those will be adjudicated in favor of the veteran. I just want to point out, however, that there are other aspects to this law that will be, that will hopefully have helped the veterans rather than simply the presumptive service connection. The methodologies, adjudicating claims and so forth will be published and so that hopefully will be of benefit.

In terms of diagnosing chloracne as I think you will recall we went through a process of reviewing a number of claims which had been filed up to a certain point and time about three years ago to look through those claims to see if there were any cases of chloracne. We winmowed those down to some fourteen, twelve or fourteen cases that conceivably might have been, and had those veterans, at least offered to those veterans the opportunity to go to highly respected non-VA medical facilities, say to the Ochsner clinic in New Orleans, the Lee Clinic in Boston, the Scrips clinic in California.

In that group there were no definite cases of chloracne diagnosed.

I think Dr. Fischmann is here. We also have a process underway in which Dr. Fischmann is reviewing any cases that are thought to be, represent chloracne during the course of plans of adjudication. I believe, and I will ask Dr. Fischmann to come up, that there are a couple of cases that look highly suspicious of chloracne. Now whether those are actually the result of exposure to dioxin contained in the herbicides, I think, is an issue which is very difficult to prove one way or the other. I am not sure that for purposes of the claim it is necessary to do that. However, obviously it would be interested epidemiologically to be able to make some judgement in that regard. Dr. Fischmann or Herb Mars, do you care to make any comments?

MR. MARS: I know one of the key words that goes out here is chloracne. As far as our rating procedures, the basic thing that we look for is the relationship between the military service of the Veteran and the condition that exists for which the claim has been filed. We may not be finding that key word chloracne, but we do on a direct basis service connect for skin conditions which may be diagnosed as

any type of acne found, or other condition which generally would arise with service in the Southeast Asia. On the rolls now, the largest group of veterans being service connected for skin conditions are those who served in Vietnam, so that even though our departments may not recognize the conditions as chloracne, we are still recognizing them as a skin condition that are directly related to the service in Vietnam, and we service connect them. We don't know what will happen as the new regulations are promulgated as to how many claims are reopened. They were talking about the figures of 22,000. We are keeping records of claims that are filed where Agent Orange is one of the allegations. Most of these allegations just say Agent Orange. As long as anything in the claim says it is related to Agent Orange, we are keeping records. We can service-connect for disabilities that we find based upon what is in the miltary medical records of the veteran. It doesn't have to have anything to do with Agent Orange, but the fact that there is something in the military medical records is sufficient for us to directly service connect and pay benefits.

We expect there will be more reopened claims. We are keeping these records mainly because

should there be any new information from the various studies we will go out and contact the veterans and advise them of it, and advise them to refile a claim.

DR. SHEPARD: Thank you Herb. Dr. Fischmann.

DR. FISCHMANN: The Chloracne Task Force (CTF) hears of chloracne cases through two sources. Whenever a veteran is rated for chloracne Mr. Mars of Compensation and Pension notifies the CTF and we check out the cases. The CTF offers them an examination at the special

clinics as mentioned by Dr. Shepard. Currently, there are 27 cases service-connected for chloracne in the Veterans Administration. Of those, 22 have accepted the offer to have the special examinations. Of those completed, in four cases, it is neither ruled in or ruled out that their acne is due to exposure to Agent Orange. We also hear through the Agent Orange registry and the same procedure is followed in that case. The Chloracne Task Force has set up criteria for diagnosis of chloracne and these were circulated in or about October 1983 to all of the Veterans Administration Hospital directors.

DR. SHEPARD: Thank you. Any questions for Dr. Fischmann? Yes.

MR. WHITE: Joseph White, president of

Maryland State Chapter, National Association of Concerns Veterans. I am having a problem here. You can recognize chloracne. What about the other skin disorders that the veterans are afflicted with? What are they named, if it is not chloracne?

DR. FISCHMANN: It may be, your question is related to just acne?

DR. SHEPARD: Any skin condition.

DR. FISCHMANN: Okay. The other skin conditions they have are hundreds of conditions known as skin disorders from fungal infections through psoriasis through most any skin disease, any chronic skin disease. These are not related to Agent Orange. The only skin disease which is clearly related to Agent Orange is chloracne.

DR. SHEPARD: Related to dioxin.

DR. FISCHMANN: To dioxin, yes, to dioxin in Agent Orange. Porphyria cutanea tarda is currently accepted as being related to dioxin, and a few acute contact dermatitis problems when the actual chemical contacts exposed areas. The skin may be red and weeping, and that clears up within about a week.

MR. WHITE: What about those that keep returning time after time?

DR. FISCHMANN: Other skin diseases that keep returning, other than chloracne, are not related to exposure to the dioxin in Agent Orange.

MR. WHITE: Then if it is going to be treated then, shouldn't it be made what it does have and compensated for it because it was not encouraged before by the service.

DR. FISCHMANN: Oh yes. Any skin condition, no matter what its name, which developed in service and is recorded in the military record is service connected by the compensation and pension department and the veteran receives whatever is appropriate in disability.

MR. WHITE: Alright, then it is possible that veterans could be compensated for "jungle rot"?

DR. FISCHMANN: Right.

MR. WHITE: Even though they are no longer in the jungle?

DR. FISCHMANN: Correct, if the disease is still a problem, if it developed while you were there, correct.

DR. SHEPARD: Thank you very much Dr. Fischmann. I think we better move on now. I would like to next call on Dr. Hodder to give us a brief word on the two soft tissue sarcoma studies that

appear in the November issue of JNCI.

MR. WALKUP: Excuse me. Dr. Hodder, Dr. Shepard if I may. Since we have adjusted our schedule somewhat, originally we are scheduled to have a recess at 10:00 and we have shifted it some. Could we go ahead and take a recess either now or after Dr. Hodder's statement and then reconvene?

DR. SHEPARD: Yes, yes we could do that.

MR. WALKUP: Which would you prefer?

DR. SHEPARD: I would prefer that we go ahead with Dr. Hodder's brief statement and then we will take a short break. Thank you.

SOFT TISSUE SARCOMA STUDY RESULTS

DR. HODDER: Alright, just briefly two papers in November JNCI. As you all know, there has been a question from the Swedish studies as to the relationship of soft tissue sarcomas with TCCD and chlorophenol exposures of phenoxyherbicide exposures. These two studies attempted to use different mechanisms to look into this. In the first study Dr. Greenwald in New York State took advantage of a state-wide tumor registry. He states that his express purpose was to determine if those men of draftable ages during the Vietnam war who later developed soft tissue sarcomas were more likely to have served in Vietnam than men in an age matched control group. It

is a very simple statement of a fairly complex study. So, using a cancer registry, he looked at all individuals who were diagnosed from 1962 to 1980 with the ICD9 code 171, soft tissue sarcomas. In that group he found ultimately 310 cases to follow. When he subsequently did the study by interviewing these people or a survivor in that family, he had a 91 percent response rate which was rather good. He picked two control groups. One was a live control group which he matched within a five-year period of birth as well as by sex and their zip code of residence. This group, since he found 92% of the people with soft tissue sarcomas had drivers license he felt was a good control to match to the general population.

To be sure that the data collected on individuals who were deceased would be similar to their control he depicted a second control group matched against the New York State Death Certificate by year of death, within a five-year age group. Sex, race, and also to some extent, to correct the socio-economic status I assume, there was a match on user-education and the health systems area that they came from.

The pathology was reviewed to see how accurate the death certificates were. He looked at

108 cases and found 91% agreement which was good, therefore he felt it was not necessary to go through the remainder. The cases and control next of kin were interviewed by telephone. The data gathered included military service experience, work and occupations that might have involved the "herbicides", and then also a list of specifical chemical exposures including Agent Orange as well as some confounding variables to control for such factors as family history, cancer, smoking, and drinking history. The data was coded and entered to screen for events that had occurred after the diagnosis. Now this is not made very clear.

Here I assume it is the Vietnam service after the diagnosis in a control, when he matched, if the control after that date went to Vietnam, I assume it would not be counted. I will come back to that point later. A couple of the points aren't clear here.

What he did find, summarizing, is a slight negative association between soft tissue sarcoma and any military service history which persisted when he looked at Vietnam, and even when he controlled for Vietnam service, for military service. He was not able to find any association between soft tissue sarcomas and any of the study variables including Agent Orange. I might add that this Agent Orange determination was

simply of a question on the questionaire. There was no record verification, etc. So, in looking at his results basically compared to the Swedish study, it would have been really a negative study. If anything, he found the opposite of what he would have expected. It was that individuals with soft tissue sarcoma had a less chance of having been in the military or in Vietnam than one would have expected.

I guess as a general commentary, I think the study was fairly reasonable. At this level of study, which is a retrospective study in which one doesn't invest tremendous amounts of resources such as you would in the prospective study and rely, more or less, on doing multiple studies and having people do repetitive studies like this in different centers using different methods. A study in general I would say, by most standards, would be fairly reasonable. There are some concerns if you look at some of the data of the controls. For example, his dead controls are 35% single, compared to his case, 20% single, and his live control, only 28% single. Which, I guess one bias one could suggest is that people who are killed in accidents, accidental deaths would tend to be a somewhat different population perhaps than these individuals.

There were some other minor differences in education levels and religion.

Now, coming back to the point about controls, we talk about the New Zealand study. The New Zealand study really addresses a similar question. They look at the phenoxyherbicides and chlorophenols. Their mechanism, and this is, by the way, a continuation of the study that has already been partially reported. They mention a phenoxyherbicide spray program having been widely used in New Zealand, and they have a New Zealand cancer registry. What they set out to do in the previous study was analyze occupations of all soft tissue sarcoma patients and compare these with controls who had cancer. They did not find any significant difference in the prior study. This study is a further analysis from that, and concerns phenoxyherbicides and exposure to chlorophenols.

A quick review of the study, they followed people who were diagnosed as cancer between 1955 and 1979. They chose only the people in public hospitals, which represent 95% of the population, for several reasons. They looked at the same code 171; they initially found 112 cases. What they ended with was they interviewed these people or their next of kin over the telephone,

starting out with a series of questions on occupation. Then if there was a yes to any, they would branch to more specific questions on that occupation where they would be more likely to be exposed to herbicides or chlorophenols. The stem question would follow up.

In summary of their findings basically, they again were not able to really show any association with the phenoxyherbicide. The odds ratios were all between 1.1 and 1.6 except for one which was in railway workers but that was .2 and that was a very diverse group. On exposure to chlorophenols, one group, people who worked in meat works, pelt tanneries, etc. had a large ratio of 4.7. They were not able to associate directly with any spraying or with heavy exposures to the herbicides or chlorophenols. What in essence they said was that their study was not consistent with the Swedish study.

The thing they feel that they add is that their study has enough power to test the hypothesis and their results were significant. They said that even if a casual link did exist, taking the extreme likelihood that their study might have missed an association by chance, it still would be unlikely that

the odds ratio would be greater than this 2.93. So, it would be substantially less than the 6 that the Swedish studies showed. They did go down to one or two further discussions of where they found some, apparent association in the meat workers for example, and they talk about the multiple look hypothesis problem. That covers most of the points.

They do spend a fair amount of time discussing one methodological problem and that is the choice of controls with cancer rather than using the general population control. They point out that benefits and the weaknesses of that, the main benefit of doing that is that if the heightened awareness of having cancer affects people's history, using cancer patients helps get a similar level of historical awareness of their exposures. A general population would be a little bit more cavalier because they are not challenged with an illness. In essence, that would compliment the first paper who had stated that the general population. So we really have three different control groups.

Soft tissue sarcoma patients didn't show any difference in these two paper.

DR. SHEPARD: Questions? Yes, Dr. Barnes.

DR. BARNES: Yes, I have a couple. One is,

in the first figure you referred to where they did histological examination of the tissue. You said you found 91% concurrence with the diagnosis. Is that at variance with the experience we have seen in other studies in terms of the difficulty of diagnosing soft tissue sarcoma?

DR. HODDER: That I'm not sure, and in fact Dr. Lamm could probably answer that more specifically. But, just misclassification alone in our pathological diagnosis, as generally recorded, I would be surprised if it would be less than 5%. I would think 10% wouldn't be unreasonable at all.

DR. BARNES: My understanding was that the two of the seven soft tissues reported in the NIOSH study were misclassified. I believe NCI has indicated that particular category is very difficult to classify. To follow up on that in the second study you mentioned, did they examine slides on that one?

DR. HODDER: I believe they did review the slides because they do make a statement here on the second page. Some cases were subsequently found to be ineligible because the pathology report reviewed by a pathologist did not confirm a soft

tissue sarcoma. I don't remember them going specifically into it. That may have been in the earlier paper, the methodology may have been more specifically explored.

DR. SHEPARD: Any other questions for Dr. Hodder? Yes.

DR. LAMM: Dr. Hodder, with respect to the first study. On the 91% of concurrence, what that concurrence said was the soft tissue tumor or some type of a soft tissue tumor that you concurred with?

DR. SHEPARD: I'm not sure I understand the question.

DR. LAMM: Alright. When one said that this 91% agreement on the pathological diagnosis, was that 91% agreement that it was a soft tissue sarcoma or was that 91% as to what type of soft tissue sarcoma?

DR. SHEPARD: I suspect the latter.

DR. HODDER: Again it doesn't specifically say. When he says on the basis of pathology review, ten of the 108 were excluded as not being soft tissue sarcomas. Initially, we reviaw a pathology for all cases and a high 91% agreement with hospital pathology reports is noted. He doesn't say whether it is a specific category or whether it is just the overall class.

DR. SHEPARD: And I would suspect that if it fell into the cateogory of soft tissue sarcoma since the study was not specifically designed to distinguish between various types of soft tissue sarcoma, that it would be considered an agreement if it was one of the soft tissue sarcomas.

DR. LAMM: Second question. Could you discuss the power aspect of the Greenwald study that was in the Swedish hypothesis?

DR. HODDER: I don't remember him making comment on that. It was the other paper that made a comment. I didn't look that up to see. He doesn't say anything here and I didn't look up the tables to look at that.

DR. SHEPARD: Okay, thank you very much Dr. Hodder. I think we will take a fifteen minute break, so if you will all please reconvene promptly at 5 minutes of 11 we will go on with the agenda. Thank you.

(Brief recess.)

AGENT ORANGE VIDEOTAPES

DR. SHEPARD: Okay, I would like to start up again and call first on Mr. Appleman who is on our Office of Public and Consumer Affairs to talk about the videotape program. Strat.

MR. APPLEMAN: Don Jones, the Associate Deputy Administrator for public and consumer affairs asked me to come here today and give you a status report on these things because Don is on travel today. For review, I think most of you know that in the subcommittee on veterans affairs and Veterans Administration, there have been discussions over several months about the use of videotapes to inform veterans groups, the general public and VA personnel on Agent Orange. The proposal that these tapes be produced came to the Deputy Administrator several months ago from Dr. Shepard. The Deputy Administrator approved the concept of doing this with the proviso that suitable scripts be developed first. A script was submitted for the videotape which was designed to go tq veterans organizations and to the public through television. That script has been under consideration by the staff for some month s to six weeks . On December 4, the administrator received a memo from Mr. Jones. I will read it because I think it covers all of tha considerations, and I'll tell you in advance that the Deputy Administrator has concurred in this, and so has the Chief Medical Director.

He (Jones) points out that "Dr. Barclay Shepard

requested that approval for the development and production of several videotapes on Agent Orange. These videotapes were to be used to reach several audiences, including DM & S professional staff at Central office and in the field, veterans groups, and the general public." Mr. Jones continues. "My staff and I have reviewed the proposed script for the general use of videotape for veterans groups and the general public. I have some strong reservations about the VA producing the videotape which is really an update of an existing videotape which in some ways is a duplication of the Agent Orange review which we send by direct mail to all interested parties on a quartlerly basis. I also have strong reservations about the VA being the producer of an informational film on the research, and into the effects of Agent Orange. Since we have turned over the direct research responsibility to the Center for Disease control, I do not believe that our presentation of the facts on the Agent Orange would be viewed as impartial. More importantly, even though we would strive to be so, we are still a party to the law suit and are not viewed as being totally objective concerning Agent Orange.

I do recommend that videotapes for internal DM&S views be produced in order to bring our people up to date on the subject especially as it relates to our responsibilities for treating veterans who may have been exposed to Agent Orange. Therefore, I would recommend that production by the VA of a videotape on Agent Orange for use with veterans groups or the general public be disapproved."

DR. SHEPARD: Thank you. I think if you will permit me, I don't think we ever considered producing a videotape for national television. - I don't know whether you were under the impression that we were producing a video-tape to be used by the media, I mean specifically by the media. That was never our intent. Bits and pieces might be, might be co-opted for that purpose as has happened repeatedly, but it was not designed specifically to be used by the television industry.

MR. APPLEMAN: Okay, we are talking about the general public. It is generally considered videotapes reach the general public through media, through television, not through printing.

But we are not in a debate.

DR. SHEPARD: No no, I didn't want anybody to have the impression that we are producing a videotape to be, you know, given out to the public television media. Any questions from the committee? Yes, Dr. FitzGerald.

DR. FITZGERALD: As I understand, this is going to be just an internal viewing of this tape and it is not going to be open to anybody other than the VA itself?

MR. APPLEMAN: This memo addressed the proposal to produce a specific videotape based on the script that was prepared. The memo accompanying that script says it is designed for the general public and for veterans. As this memo states, the proposal--the additional proposal-that tapes be produced to inform internal audiences was agreed with. Now, I take it that everybody who has ever read the Freedom of Information Act knows that there is no such thing as producing a tape for internal use that could be restricted from anybody else looking at it. This stuff (Conference handouts) was produced for internal use, but obviously it is for everybody's viewing who wants to look at it.

DR. FITZGERALD: Then you are telling me that it is available if we ask for it?

MR. APPLEMAN: That what is available?

DR. FITZGERALD: There is a tape on the —

MR. APPLEMAN: If DM&S chooses to produce tapes for internal use, anybody who wants to request them, obviously, will be able to get them under the authority of the Freedom of Information Act.

DR. FITZGERALD: If they are training the people within the VA by the use of these tapes, it would be helpful to us to know the matter that is being used for training purposes.

MR. APPLEMAN: Exactly, and I don't see any problem in anybody getting to look at that. I think what Mr. Jones was dealing with here and what the Administrator was dealing with is a question of whether or not VA should be involved in producing something that in effect duplicates something that is used in a much more effective way, the Agent Orange review which is sent by direct mail to anybody who asks for it. In fact, it is sent to everybody on the Register plus anybody else who wants it. Now most people in communications feel that the most effective way to communicate is through direct mail, especially if you have the addresses. We do have the addresses. This was viewed as a question of whether or not this effort should be supplemented by

videotape. It was decided that it does not need to be supplemented.

DR. SHEPARD: You had a question, yes. Hugh.

MR. WALKUP: I think then that answers my other question: There is no plan underway then to subcontract it and have another agency produce the video tapes that were being talked about for veterans or the general public. Is that right?

MR. APPLEMAN: Could you address that?

DR. SHEPARD: I'm sorry, another contractor doing? I didn't quite understand your question. I'm sorry.

MR. WALKUP: There are no plans to have a videotape produced independently of the Veterans Administration to address the issues that previously were going to be addressed by the video tape that we are talking about here.

DR. SHEPARD: Not a contract being proposed by the VA.

MR. WALKUP: So that other objective of public information and education for veterans that was part of the videotape would not be met. We have abandoned that and now we are going to have videotape strictly for the employees, but that is going on?

DR. SHEPARD: Yes.

DR. BARNES: And the tape will be different, is that correct?

DR. SHEPARD: Well, let me just bring you up to date as to where we stand on the videotape - was originally being produced for veterans use and now will be for in-house use. When you are updating a body of information, a research agenda, and so forth, if it is factual information, there is not very much that can be altered one way or the other. I mean you are educating a group of individuals be they veterans or VA employees. So, when you say would it be different, the videotape that was being prepared for the Veterans was essentially complete. That is, virtually most of the footage had been taken. The script has gone through some modifications. We were awaiting Mr. Jones' approval of the script for the use of the veterans, and we now have the decision that that will not be produced for veterans. I spoke with Mr. Jones personally on the matter and asked him specifically if he had any objection to our using the script which he was in the process of reviewing for internal VA educational uses. He told me no, that he thought the script was well put together for that purpose.

So, I think that since we have spent, you

know, a good deal of time and money on producing what we now have or virtually have completed, that we will go ahead and use that perhaps with some minor modifications as the basic, underlying, educational videotape for VA employees. We hope to do a second one that will be aimed more specifically toward scientists in the VA dealing with, in perhaps more detail, some of the specific research efforts that are underway. We touch on those research efforts, but not in any scientific depth. So, the film that will next abe available will be aimed at essentially non-science members of the VA staff. We think it is very important that as new VA employees come on line, that they be informed as to what's going on so that they can deal intelligently with questions from veterans as they appear in VA medical centers and also the VA benefits directors. Certainly it is important to keep the Vet center staff informed as to the progress of our efforts.

DR. SHEPARD: Yes, Hugh.

MR. WALKUP: Especially after this last experience we had with videotapes we talked and especially in the subcommittee on educational information, about reviewing that tape and having the assurances that we were going to be reviewing the tape

in each step in its production, and also that there would be review by Vet Center staff of the tape before it was produced. It sounds as though as if it has gone pretty far along, it is about ready to go out. Is that true, and are we going to get a chance to review it before it gets into production?

DR. SHEPARD: Have you discussed that?

MR. APPLEMAN: Those commitments, this office was not involved in. I would rather you comment on that.

DR. SHEPARD: Okay, fine. It would be my hope. As a matter of fact, somebody correct me if I am wrong, have we not circulated one of the versions of the script to the committee?

MR. WALKUP: Yes, we did six months ago.

DR. SHEPARD: Right. I think there is a revised version of that with some minor modifications together with there are some shooting details. I am not sure whether you have received copies of that or not. We can certainly make that available to you.

, Nobody here in Central Office has seen the preliminary footage. I understand it is very good. The folks out in St. Louis who are producing the film are in the final stages of editing

the footage. It will be available for us to look at hopefully in the next few weeks. At our next meeting or maybe even before the next meeting if there are some individuals in the area who would like to come to a preview so to speak, I hope that we can set that up. Certainly at our next meeting we hope to have a reasonably good draft for individuals to look at.

MR. WALKUP: So committee members will be able to look at it before that at least to make comments. Vet center staff will also have a chance to review it?

DR. SHEPARD: I will have to give that some thought. I was not aware that we had made that decision.

MR. WALKUP: I think two meetings ago at our subcommittee meeting, I am not sure that you were there, but people from St. Louis and - I would have to go back to the transcript. There were other people there and that was discussed and that was an assurance that was given.

DR. SHEPARD: I wonder who made the assurance? I was not aware of it. It should be a reasonable request, yes.

MR. WALKUP: I think it's a good idea,

especially after the experience of the last videotape. There were some parts of input, there are some observations that people on this committee could give that would be helpful to the Veterans Administration, and helpful to the people who are using the film. I think the Vet Center staff are qualified in some other ways than people on this committee could help make sure that you have got a videotape that isn't going to create the problems that the last one did, and also give an adequate job of instructing the VA staff, if that's the only people who are going to see it now, on you know, some of the issues. This should help assure that the videotape management/is not going to raise a bunch of problems for the Veterans Administration or the Vets.

DR. SHEPARD: Certainly the idea is good. I was just curious - I wasn't aware that we had made that committment. I think that we can accomplish that. We have a number of people involved in the Vet Center program locally, and there is a practical consideration. The more you review something, the more the delay is in getting it out. So, we want to get this out as quickly as possible but I would like to have some input from the committee for sure.

Are there any questions from the audience

from Mr. Appleman or any other questions related to the videotapes? Okay, thank you very much. I appreciate it.

At a previous meeting, some questions were raised about the budget, the dollar expenditure, the VA committed to research and activities. We made a commitment at that time to share with you some details in that regard. My very able administrative assistant Layne Drash is here to bring you up to date on and be available for some questions about his work in that area.

VA AGENT ORANGE BUDGET REPORT

MR. DRASH: Thank you Dr. Shepard. I hope my voice holds out. I have the Washington area flu. I am sure you all will shortly. Specifically, the origin of my presentation was a very specific question from Mr. Wayne Wilson the director of the New Jersey Agent Orange Commission related to the VA's use of funding of Public Law 97-72 which authorizes s health care for Vietnam Veterans. I thought maybe it would be a good time however, to give a broad-scope presentation on the types of dollars that the VA has committed to various. Agent Orange research and non-research efforts over the past several years. By far, the largest of these commitments . has been the epidemiology study mandated by Public Law 96-151, , which

was enacted on December 20, 1979. During the fiscal year period 1981 to 1984 the VA entered into an inter-agency agreement with the Centers for Disease Control in Atlanta, Georgia . The VA has provided, and/or budgeted approximately $56 million to support this effort. It is currently projected that an additional $5.5 million will be required to support this study in fiscal year 1985. During the period of fiscal year 1981 through 1985, in other words, the VA will have budgeted approximately $62 million to support the development of a research protocol and to provide for the conduct of the major research effort. Additional funding will undoubtedly be required in the outyears and we are relying on the Centers for Disease Control to provide us with statements of their financial need in this regard.

In addition to the epidemiological study however, I might like to point out at this point and time that Mr. Appleman, in the letter previously referred to, stated that research responsibility was transferred to CDC. This statement leaves the impression that the VA is not involved in research. We are. The epidemiology study was the only effort transferred to CDC. In addition to the epidemiology study, the VA has ensured that adequate resources are

available for other research efforts including the Birth Defects Study which was completed by CDC on August 27, 1983 which I think was referred here today, and also, other on-going research now being conducted by the VA.

The major VA research managed efforts coordinated by the DM&S Projects Office headed by Dr. Shepard includes the conduct of Vietnam Veteran Mortality Study, a Soft Tissue sarcoma Study, a Retrospective study of Dioxins and Furans in Adipose Tissue, and start-up resources for the conduct of a cohort mortality study of Vietnam veterans. A Vietnam Veteran Case Control Study, and a Health Surveillance of Vietnam Veterans. For the period of fiscal year 1981 through fiscal year 1985, it is estimated that a little over $3 million will have been expended on Agent Orange related research conducted by the VA. In addition to those dollars, an additional $1,700,000 will have been utilized for thirteen separate investigator-initiated research projects which are sometimes referred to as "specially solicited" research managed by the DMS research and development service, research which is conducted by our field staff. An additional $750,000 has been budgeted for fiscal year 1985 to provide for

the continuing support of this specialized research. I would now like to very briefly address some of our more significant non-research related efforts. These efforts include the preparation of a literature review of the world's scientific literature on Agent Orange and other phenoxy herbicides. We have already produced four volumes related to two specific updates. It also includes the preparation of lay language summaries of these publications, the development of a series of four professional monographs, a review of the patient treatment file indicator, and a review of chloracne by the VAs chloracne passport. Dr. Fischmann spoke a little earlier and related what they are doing. For the period of fiscal year 1981 through 1984, approximately $644,000 would have been expended on these activities.

The VA's Agent Orange Registry program, which some of you are familar with, is another major non-research effort. Approximately 155,000 Vietnam Veterans have received this examination given at each of our VA health care facilities since initiation of the program in May of 1978. It is estimated that each examination cost an average of one hundred dollars for lab tests. That figure varies somewhat. We can reasonably estimate a cost of $15.5

million in resources to support this program through September 30th of 1984.

In addition to research however, and general non-research activities, the VA is providing health care to Vietnam Veterans under the authority of Public Law 97-72 which I mentioned a moment ago, that is, the Veterans Health Care, Training, and small Business Loan Act of 1981, which was enacted on November 3, 1981. Public Law 97-72 authorizes the VA to provide treatment to any eligible Vietnam veteran who feels that his or her condition may have been caused by their exposure to Agent Orange or to a toxic substance in a herbicide or a defoliant used in Vietnam. The VA separates care under Public Law 97-72 into two categories. That is, health care provided during in-patient admissions to our health care facilities, and out-patient visits. Using these categories we were able to arrive at estimated costs of care based on average utilization rates, length of stay, etc.

Based on this categorization, we can reasonably estimate that for the period of the enactment of that legislation through September 30 of this year, that there were 19,151 in-patient admissions representing approximately 15,255 veterans for an estimated cost of §75 million given for in-patient care.

Combining in-patient and out-patient costs, it is estimated that a total of $174 million has been extended on health care under the authority of this legislation. I would like to take the opportunity at this time to respond to the question raised by Mr. Wayne Wilson during our last advisory committee in September.

In response to a question from the special master for the Agent Orange related litigation in New York, the VA advised the Department of Justice that approximately $70 million was spent by the VA on health care in fiscal year 1984 under Public Law 97-72. The actual figure was approximately $69 million rounded off to $70 million. Of that $70 million, $34 million was for in-patient care and $35 million was for out-patient care. That represents 10,900 in-patient admissions and 432,000 outpatient visits.

We have estimated costs using an average calculation rate of $80.00 for out-patient visits, and approximately $208.00 for an in-patient admissions. I should point out that the dollar estimates or expenditures which I have just described to the committee are costs borne by the VA only. As you are aware, research is being monitored by the White House

established Agent Orange Working Group of research being done by other agencies or institutions.

If you are interested in that type of information, this can probably be obtained from the Department of Health and Human Services. That is pretty much my summary of our expenditures. I will be glad to answer any questions anyone wants to ask.

DR. SHEPARD: Wayne.

MR. WILSON: Yes. I would like to do this rather quickly. I have these figures. I would like you to go one step further if you could. That is provide that 68 some million dollars for FY 83, I would really like to see a breakdown by VA facilities, and I am sure if you could compile those figures, you should have those figures and see where those 10,000 visits were geographically and then we could estimate how much was being spent in various parts of the country. Do you understand what I am saying? Can we have that?

MR. DRASH: I understand your question. Our current statistical tracking mechanism doesn't necessarily break it down that way. We would have to generate a special report to obtain that. Generally, our tracking of Public Law 97-72 is for the purpose of providing responses to Congress who is tracking

our utilization of resources. We can look into the matter. If there is a way to do that, we will be glad to provide it to you.

MR. WILSON: Well, when you say at 10,000 and some visits okay, and you know based on $80.00 a visit or something like that, you have got, you've had those 10,000 visits from, I mean you —

MR. DRASH: Yes we do. We get these reports which are generated through the VA's Automated Management Information System (AMIS) which is a report prepared for VA Central Office by each VA health care facility. These reports are sent in to Central Office where they are combined into a general figure. This is the reason that I am saying that the possiblity exists that we can get this for you. We don't currently maintain the breakdown in our office. We would have to go out and, if possible, have it calculated for you.

MR. WILSON: Just for the record, I would like to have an answer whether or not we can have that report. I would not like to wait until the next meeting. I would like at your eariest possible opportunity giving your priorities to know whether or not you would have that data, and if so, anticipate a date of —

MR. DRASH: We'll get it for you as soon as we can generate it, that is, if it is possible to generate it.

That is the only commitment that I can make it to you at this time.

DR. SHEPARD: I would like to ask Wayne, just out of curiosity, what use he plans to make of that data.

MR. WILSON: Well, I yield to Mr. Terzano.

MR. TERZANO: Dr. Shepard, I can think of a number of things that data would be useful for. The way the legislation was written there is a broad discretionary authority given to the local VA facilities whereby treatment may be given. Also when President Reagan signed the bill he also stipulated that no additional monies would be put into the VA to support this program.

In other words, monies to fund the program would have to come out of the existing budget of the local facility. If you have a sympathetic administrator and a sympathetic physician, you will get very good care at a certain hospital, however, if you are in some other area of the country where they might not have the money or the resources committed to do this program, or else you don't have a sympathetic administrator or doctor, veterans in that area might not be getting, as they should be. That to me is one very good reason.

To carry it one step further, I think would be useful if the VA was able to compile a list of what these people are being treated for. That information would be very useful for the existing scientific studies that are going on around the country. If there is a cluster within the 11,000 inpatients, for example, of some type of adverse health effects, that would only be helpful.

DR. SHEPARD: I am glad you asked that latter question because I am prepared to answer that one. Not in light of Public Law 97-72, because the mechanism for tracking patients who have taken advantage of that legislation is not precise. The figures that Layne gave you are estimates. It is very difficult, if not impossible, to produce exact figures. I will just use an example. A veteran comes to the VA hospital for a health problem. Whether or not he gets tallied or tabulated under Public Law 97-72 or whatever, will depend a lot on the kinds of questions he is asked. For example, are you here because you think you were exposed to Agent Orange or do you think that your gall bladder symptoms are related to exposure to Agent Orange? It may be that the Veteran comes in with, you know, a classic case of gall bladder disease and is treated for gall

bladder disease. It might come in as an emergency, it might just not occur to anybody to ask him, do you think your gall bladder or gall stones are related to Agent Orange. I am using an extreme case obviously, but it is very difficult to know exactly in every instance what was a prime motivator for a veteran coming into a VA hospital.

MR. WILSON: Did you tell that to the judge when you gave him that data? Because the judge —

DR. SHEPARD: I was not asked by the judge to give...

MR. WILSON: Well, Fred's not here but I am suggesting to you, and I have not seen the data or the information that you provided via the Justice Department. I would say based on the comments Judge Weinstein said, you did not indicate that there are these disclaimers with this, with these figures, okay. I am certainly willing to look at exactly what you sent over. I think that we are onto something here and if you are going to tell the judge you spent $70 million, I specifically want to know whether you are telling him whether this is a best guess and maybe it is not such a good one. I would like to know whether VA facilities in New Jersey or Philadelphia or Wilmington, the ones we utilize are sympathetic.

Maybe there are councils in our state that should be able to say to a VA hospital director, if you need more money because you are doing Agent Orange well, with those kinds of figures I think we would be able to see where the weak spots are around the country. Now this is the kind of hard data that we are interested in, and I think we ought to be given an opportunity to have it.

DR. SHEPARD: Okay, Layne is going to answer it in more detail, but we have never said that this is hard data. This is our best estimate of what the impact of Public Law 97-72 has been. I don't think that there is any way to generate hard data. By hard data I mean when we are talking about absolute, certifiable data. We have always said that this is our best estimate, and from the best estimate in terms of the workload numbers, we use a factor that we have developed.

MR. WILSON: Well, I'll take your best estimate.

DR. SHEPARD: Well that's what it has been all along. We have never said anything else.

MR. WILSON: I'll settle for that.

MR. DRASH: Wayne, I would just like to point out that the inquiry that came in to us from the

Department of Justice was for estimated costs. That's the spirit in which we replied to the Department of Justice. I would like to note that Mr. Fred Conway was in touch with them who was here on this matter earlier. I think that prior to his transmitting something in writing that he implied this approach to Department of Justice. I would also like to add to what Dr. Shepard was saying that it is true that a lot of our health care facilities are absorbing the costs of care of veterans under Public Law 97-72. This has created, I am sure, some strain on some of our facilities. On the other hand, it hasn't created, I think, as much of a strain as one would think because many of the veterans coming in under the authority of public Law 97-72 were already coming in under the authority of other legislation which provides them with health care if they are eligible veterans.

I think the strain and the stress may be there, but it may not be as significant as it may appear. Your desire to look at it may have some merits. You may find specific hot points where the resources of the center are not able to meet the needs of the veterans. As far as I know, unless anyone in the room can correct me, we have not seen any reports from any health care facilities indicating

that they cannot continue to provide the health care that is required. I think that in estimating the costs, that you also have to look at the many variables involved in trying to calculate what it costs to do an examination. For example, a veteran may come in for an examination and be referred to various clinics. They may or may not receive an x-ray. They may receive a dermatological consult or they may not. They may only see the physician and then walk out. You have to calculate physician time, and also, you have to calculate these and other variables. So, there is really no way that the VA, at at this point and time, can give very specific costs. They are estimates. That is all we have ever claimed that they are. That is probably all that they will ever be.

MR. WILSON: Well, let me say quite frankly, the law says that 97-72 is to provide priority care and treatment equal to that given former POWs okay. That's what the law was intended for by the law of the Congress of the United States. If that's not being done, if we are just molding the treatment and determinations into general treatment that is given on an outpatient basis, I am not sure if that's the intent of the Congress, and I'm not sure if that then

is for priority care and treatment even for that given point.

MR. DRASH: I agree with you wholeheartedly. Are you aware of any specific examples?

MR. WILSON: of course. I will tell you quite frankly and I will say it for the record right here and now. Okay, I'm critical and I have said so to the judge. I will continue to say so. I am critical of the quality of care given under 97-72, and quite frankly I don't believe that you are following the intent of the United States Congress.

MR. DRASH: I don't think we agree with you.

MR. WILSON: Well, of course. I am telling you Layne, I think I may talk to more Vietnam Veterans out there in the real world than you do.

MR. DRASH: I'm not here to argue with you Wayne, I am telling you some very basic facts and I am also a Vietnam Veteran. I have no cause to give you less than the truth.

MR. WILSON: Please don't take it personal.

(Laughter.)

MR. DRASH: I appreciate that. We will give you the answers we can give you. We can do no more than that.

MR. WILSON: Thank you very much. If I had known you were a Vietnam veteran I would have perhaps been a little bit easier.

(Laughter.)

MR. WALKUP: I think Mr. Terzano has raised a point about management information. Is it something that is available to the Veterans Adminstration or to this committee, either in this form or in some other form? A way to look at how, how people have changed their uses of the VA facilities before and after this all was enacted and to look at the distribution of usage of facilities before and after the law among different places so that if by looking at those numbers that indicates, again, like everything else that we deal with in this committee, there may be conceivably some viable cause of effect somewhere down the road. At least we would have a trigger that we could go back and look at particular facilities and see if there is a problem there. Is that information available in this form or in any other form, and is any of that information available to this committee?

DR. SHEPARD: Are you specifically asking about the workload at individual facilties? Are you talking about clinical information?

MR. WALKUP: More, there are a number of ways that you can look *at* it, so it is a large area. One would be the portion of visits that are related to Agent Orange.

DR. SHEPARD: Excuse me. Best estimates are all based on visits that our best judgement can be related to Agent Orange, because that's what the law was written for. So, the figures we are giving you, and by the way it is now over a million outpatient visits and about 22,000 in-patient admissions since the law was enacted. So, it is a large body of work. As far as we know, these are all related to Agent Orange. As I said earlier, sometimes it is difficult to distinguish what is in the mind of a veteran, whether he comes in for an Agent Orange related problem, or whether or not it is another problem that might conceivably be related to Agent Orange. There is no breakout of that distinction.

MR. WALKUP: Right. What *I* was meaning was the proportion of these visits that were identified to the total number of visits to the facility. By facility, that might be a way of seeing if you have got one where 5% of the visits are related to Agent Orange, and another one where .5 percent. Then, maybe it would be a good idea to go look at the 5%

facility and what they are doing and look at the .5 facility and see what they are doing and maybe make some management decisions around that.

DR. SHEPARD: What you are saying is express as a percent these figures/of the total workload of a given facility?

MR. WALKUP: Right, or some other way of looking at it to address Mr. Terzano's question about if you've got uniform implementation at them all.

DR. SHEPARD: Okay, I can shed a little light on that perhaps. We know that it is not uniform and this is one of the reasons. The law specifically states that this is a benefit to non-service connected veterans. It puts them at the same priority level as non-service connected POWs. I think that is an important decision to make. Some hospitals have a fairly large non-service connected workload. Other hospitals have a relatively low non-service connected workload simply because the service-connected workload has pretty much filled up all of their capability or comes close. So, there is a built-in non-uniformity. The VA health care delivery system itself is not uniform in that sense. I mean, the percentage of non-service connected veterans will vary from one facility to another. So, without even looking at the

figures, I can predict that it will not be uniform in the sense that the percentages will be the same across the country.

MR. WALKUP: Well again, I think every other piece of research we talked about here there are those things that effect us. We can correct for the socio-economic status of the facility or those other sorts of things in looking at those kinds of figures. It would be possible to compare that data, wouldn't it?

DR. SHEPARD: I would, I would —

MR. WALKUP: The real question I am looking for, I don't know that it needs to come up here, but is that something that the Veterans Administration looks at? You try to deal with, you collect that kind of information so you can decide whether you need to go someplace and work with the Administrator of the facility and say you have got some problems in this.

MR. DRASH: Hugh, I can really appreciate what you are saying. Each medical center does an annual review of their budget. They do five-year projections and what have you. They are generating the report from the out-patient admissions and in-patient visits related to Public Law 97-72. The management does routinely review at the local level, the type of

expenditures, or the type of resources that they project are needed for their area. This is all part of a bigger package of planning which the VA has, I won't get into the details. Budget projections are submitted to VA central office and it is reviewed by the appropriate VA DM&S region.

Maybe not in the same sense that you are speaking in terms of, but I am sure they are looking at it in terms of resources and making sure they are available because obviously if you don't have the resources you can't run your hospital. I appreciate where you are coming from in that regard. I don't know how specific the report might get the answer that you are looking for.

MR. WALKUP: I think that answers my question in another way too. That's not a function of the Agent Orange Project office, if you are not consulted on those kinds of things or get involved in those kinds of things.

MR. DRASH: We monitor Public Law 97-72 as far as the overall statistics of what health care is being provided. We also work with our Systematic Internal Review (SIR) program and our Systematic External Review Program (SERP) staff to give them guidelines about what we think they ought to be looking at when they go out to

visit our health care facilities in order to make sure that veterans are being provided, in accordance with VA policy, examinations in the Agent Orange registry program or other services related to Agent Orange. We do get reports back from those programs. We monitor those. we ask for input as to what is happening in regards to the Agent Orange Registry or public Law 97-72 We are involved in the registry more directly, but we do track the general data on Public Law 97-72. You can be sure that the VA DM&S regions track the statistics Very closely because they realize that health care under the authority of PL 97-72 is a priority. I feel very confident that they are trying to do this in compliance with the spirit of the legislation.

But we are involved. We do look at the data. There are different pieces of the pie obviously that different people are responsible for.

MR. WALKUP: Would it be possible at our next meeting for you to bring to us whatever information you do have that relates to the uniformity of provisions of care under 97-72?

DR. SHEPARD: That would be a mammoth task I think. Let me just point out that there are appropriate avenues for research, and I think there are

inappropriate avenues for research. Once again, I am just expressing my own opinion. I think the Agent Orange Registry and the P>ublic Law 97-72 data are not appropriate tool for epidemiological research. The data is not gathered that way, and there is very limited use that you can make of this kind of estimated workload. What we have done, and the closest thing that I think we can come to doing that is with the use of our patient treatment file. That's what I was going to answer in John's question. He asked what kind of clinical information is being generated as a result of Public Law 97-72. It was never our intent to do that, because we saw a lot of problems in terms of trying to analyze it, trying to judge the significance of the clinical information if we got it. It would be a mammoth task to gather it, and like everything else if you don't have a good use for it, you probably oughtn't to be gathering it.

MR. WILSON: But would —

DR. SHEPARD: I'm not through Wayne. Please don't interrupt me. What we are doing is I think a more reasoned approach to a review of our existing clinical data bases. That is, the review of our patient treatment file. As I think I have reported to you on a number of previous occasions, we have

randomly selected some, we started out with about 14,000 Vietnam era veterans who have come to VA medical centers for treatment and have been admitted to VA centers for treatment. We went through a process of distinguishing who in that group of the Vietnam era group actually served in Vietnam and who served elsewhere here in the Vietnam era.

Having that information, then we did an analysis of the various disease categories for which these people were being treated. We came up with some interesting figures. First of all, I think it is close to 14,000 Vietnam era veterans on whom we have valid Vietnam service status information. Forty percent of those in the patient treatment file of the Vietnam era group actually served in Vietnam and 60% served elsewhere. When we look at that same proportion in disease categories such as soft tissue sarcoma and a whole range of disease categories we broke them out using the ICD~9 coding system which is information that appears in the patient's file. We found that almost without exception that same proportion, that 40 - 60 proportion exists for all disease categories. Now, there are some minor variations, but it is remarkably consistent that the 40% of people with the disease category. You can pick

any of them, served in Vietnam and 60% did not. So, looking at that, and it is not an epidemiological study, but it is a survey of existing health data. There does not appear to be a disproportionate survey of who served in Vietnam as compared to those who did not serve in Vietnam. So, that I think is a reasonable approach to a health survey and probably is more valid than trying to make some connection between the data, the workload data Public Law 97-72 and even the registry. Remember the registry is a totally self-selected group of individuals who come in for a specific worry.

MR. WALKUP: I understand where we are going with this but I want to say one thing. Veterans who served in Vietam/and are concerned come in because they have Agent Orange. There are concerns about that because of the way the whole issue has been handled for a long time, and that doesn't mean whether, if you can eat Agent Orange on your breakfast or not. We are concerned about it. The way in which they are treated is very important because at least the veterans get some sympathy for other people. We have seen ways in which people can be treated. It is important that whether or not Agent Orange is related to any of the diseases that people might be coming in for, that there be some

conscious effort the local facility to address the concerns as well as the disease entities of the person who is coming in. The issues that people are trying to raise is about how can we look at, how can we deal with the issues of some uniformity of treatment of veterans in VA facilities across the country. We hear from a lot of people that, at least we have heard of an experience a couple of times, that there is some discontinuity in service. In one place somebody is up on what's going on, and in another place we hear presentations. It is, maybe, it doesn't look like it is uniform. Most veterans don't believe that it is uniform. We believe that it would be in the best interest of the VA to try to make it as uniform as possible, and I think it would be very useful for members of this committee and for members of the audience to be reassured that there were some things being done to ensure that uniformity of service.

Again, I would encourage that if there is any way for you to look for that information and get a handle on those kind of things for this group or those groups is something I think would be very useful to everybody we are trying to help out.

DR. SHEPARD: Okay, any other comments or questions?

DR. BARNES: If I understood this correctly, you said between FY 81 and 85 some $3 million was spent on VA research. During that same period of time $62 million was spent on what?

MR. DRASH: The epidemiological study. That would be dollars that we have either identified or obligated.

DR. BARNES: That's Vietnam ground troops study?

MR. DRASH: Yes, that's the three-part study, the Vietnam Agent Orange Study, the Vietnam Experience Study, and the selected Cancers study.

DR. LAMM: Is there a figure of $80 for outpatient visits and $206 or so for in-patient visits?

MR. DRASH: $208.

DR. LAMM: Do you mean that per hospital day rather than per hospitalization?

MR. DRASH: Yes.

DR. SHEPARD: Yes, John.

MR. TERZANO: I would like to add just one more question that is related to I guess the first question. I assume it was, I hope it was an omission, but I didn't hear any mention of money being allocated for the Twin Study. It is my understanding that money is

has been allocated for the study.

DR. SHEPARD: On the matter of the twin study, the protocol one — the twin study. That is, the study to identify a large pool of twins from which a random selection would have been made of the twins to actually come in for the examination. The National Academy of Science's follow-up agency has been given a contract amounting to about $2 million give or take a few thousand. To establish a large pool of twins, twin veterans of the Vietnam era. So, to that extent, the money has been obligated for that effort. Obviously, some money has already been spent in the development of the protocol, the review process that has gone on. I don't have that figure in front of me, but I suspect several hundred thousand dollars has already been expended on the development of protocol 2 and additional monies were allocated for protocol 2 in FY 85. Again, I don't have those figures in front of me. To answer your question has that money been pulled, as far as I know, no. Since it is not my program, I really can't answer that question.

MR. TERZANO: So we can go on the assumption that the resources are there to complete the study.

DR. SHEPARD: Excuse me, no. I don't think that it would be accurate to assume that the resources are there to complete the study. The study is, was projected to go on into FY 86 and I don't think the FY 86 research budget has been developed as far as the twin study is concerned, completely. I am not certain of that again.

MR. TERZANO: Correct me if I am wrong, but I think the chief medical director was incorrect when he said an outside agency recommended that they pull the Twin VA/study. Was that not an internal group that did that review? That is/an internal VA group he was referring to?

DR. SHEPARD: It was a merit review panel that was put together by the ACMD for Research and Development, Dr. Boren, Dr. Greene. Dr. Greene, I think, actually empaneled the group. When you say outside, there were no VA employees on that review panel. So, in that sense they were not employees of the VA. They were outside, there were some government members on the panel and I think mostly non-government members.

MR. TERZANO:

As a representative of a Vietnam Veteran organization, I feel that there is a tremendous utility

in proceeding with the twin studies. The Vietnam veterans have put a lot of faith in the federal government's research efforts/for people to be trying to holdback research/ and is a breach of that faith. But, I think it even goes beyond that, and you can correct me if I am wrong. Does not the twin study have validity outside the Vietnam Veteran/ community area to the health community in general, that it has some applicability outside of our issues?

DR. SHEPARD: Well, I think any research when you are dealing with a large number of individuals and for this kind of a study, 600 pairs of twins is a large group ;/ does have some applicability. Plus, the larger registry and some information on those individuals is also going to be collected. Yes, I think that any time you are studying a large group of individuals there is useful information that the general scientific community that can be drawn on. So, I would expect yes, that they would be, for example in the area of some of the innovative things that were being contemplated in twin studies. It is my understanding that psychological testing between identical twins is one of great interest in on-going efforts.

People are interested,in that aspect,whether

identical twins do, in fact, behave very much alike even when they are reared apart. There is some evidence to suggest that identical twins reared apart have very much the same kind of behavior patterns and behavioral problems. So, that, of course, is very interesting, whether it has anything to do with service in Vietnam.

MR. TERZANO: I have another question. You mentioned earlier that OTA, Office of Technology Assessment, has been invited into the process. What do you view their roles as? Are they going to do another review of the protocol?

DR. SHEPARD: It is my understanding that the members of the Veterans Affairs committee has asked that the OTA review the protocol. I am not sure exactly how they plan to do that. I spoke with Dr. Gough, and he has told me that he plans to have a committee. They have had a standing comittee, I believe, in OTA to review various protocols related to the Vietnam experience in Agent Orange and so forth. So, it is my understanding that he is planning to convene a meeting of that panel to review the protocol.

MR. TERZANO: If I might, do you have any

suggestions for veterans organization on how we can help ensure that this study gets back on track and it ultimately gets completed? I don't mean to put you on the spot.

(Laughter.)

DR. SHEPARD: I would be presumptuous if I were to advise service organizations how they can best use their persuasive techniques for accomplishing things that they would like to see done.

MR. TERZANO: Thank you.

DR. SHEPARD: Any other questions for Layne? Okay, thank you very much. We are approaching the noon hour, and I think what I would like to do is to ask now for Dr. James Woods. Is Jim Woods here? Yes. Dr. Woods is here to tell us about the NCI supported research effort on the subject of cancer and phenoxyherbicide exposure. Dr. Woods.

CANCER AND PHENOXY HERBICIDE EXPOSURE

DR. WOODS: Now, let me first give a brief overview of what this study is all about. The study first of all began in March of 1983. It is a three-year study and due for completion hopefully by mid-1986. A method of assessment is a case control study, where study subjects with specific cancers have been linked to T.C. D.D. exposure from other human studies are compared with non-cancer control subjects

with respect to previous exposure to dioxin-containing chemicals. The cancers that we are concerned about in this study are soft-tissue sarcomas and non-Hodgkins lymphomas, as these are the cancers that have been identified in the studies that have come out of Sweden and elsewhere to be most likely associated with exposure to dioxin-containing chemicals.

About 200 soft tissue sarcomas and about 500 non-Hodgkins lymphoma cases are involved in the study all together. Diagnosis years are 1981 to 1984. Study subjects are restricted to males between the ages of 20 and 79. Cancer cases are identified from the Cancer Surveillance System tumor registry, which is located at the Fred Hutchinson Cancer Research Center in Seattle. This is part of the NCI's SEER system. The Cancer Surveillance System has a rapid reporting system, which allows us to identify essentially 100% of all of the cases which arise in the study area. The controls for this study are selected from the same area from which the cases arise, and are group-matched to the cases by age and by vital status, whether living or dead. We are matching them on the basis of 1.5 controls per non-Hodgkins lymphoma case, which means that the study will have about 750 controls all together. A

random digit dialing procedure has been implemented to identify control subjects, and these are being treated in exactly the same manner as are the cases. Could I have the next slide?

This next chart shows a map, the cross hatched area, where it looks like it is raining, shows you the counties in which the study is being conducted. This is the area which comprises the Cancer surveillance System tumor registry. This is an area of about 2.8 million people, and where, largely because of the heavy concentration of forestry and wood products industries, there has been considerable usage of phenoxy herbicides, particularly 2,4,5-T and silvex over the past 35 to 40 years. Chlorinated phenols have also been widely utilized in this area, and pentachlorophenol is manufactured there. We estimate that approximately 3.5 to 5% of the population in this area, or about 100,000 people, currently hold jobs that have historically involved prolonged exposure to dioxin containing chemicals during the past 40 years or so. Could I have the next graph please?

Information about past exposure to dioxin-containing chemicals and other risk factors is being acquired through face-to-face, very extensive I can

say, interviews with each subject. The most extensive aspect of the interview deals with employment history. That includes in-depth questions about the specific jobs held, specific chemicals used and worked around, and occupationally-related diseases that the subject might have had. The employment history of any subject who indicates or even suggests that he may have had exposure to dioxin-containing chemicals is followed up through a follow-up confirmation with his employer on that job if it is possible to get in touch with that person. In some cases, a considerable time has elapsed since the person was employed. In this case, it is difficult to obtain employer confirmation, but we are doing is in every instance where it is possible. In additibn to occupational information, details about the subjects' residential and medical histories, military experiences, and demographic characteristics are being acquired to allow us to evaluate a number of questions about dioxin exposure and its possible health effects that have been suggested from clinical and toxicoligical studies. Some of the principal questions that we hope to be able to evaluate in this study are indicated in the next chart.

First of all, if an increase, a risk of

cancer for either one site, or both can be demonstrated in relation to dioxin exposure, we want to know if that risk is dose-and duration-related.

Secondly, can we determine a latency period for the onset of cancer if a relationship is observed? Third, does the carcinogenic action of the dioxin require or involve the inter-action of other risk factors for those cancers? This is a particularly important issue. Finally, are there symptoms or biological sequelae of dioxin exposure that might have clinical utility in confirming such exposure or in predicting adverse health effects? The next one please.

To evalute the question of dose responsiveness with respect to dioxin exposure, we have identified approximately 40 specific job types or titles associated with work activities in the study area that involve potential exposure to dioxin containing chemicals. We have used exposure data taken from EPA's Carcinogen Assessment Group (GAG) 1981 estimates to calculate daily doses of TCDD received by workers in each of these job types. We have then divided these job types into three exposure categories: high, medium, and low exposure, respectively. We expect to have sufficient numbers of

subjects falling within each category so that stratification in the analysis will allow us to determine whether cancer or other health effects that we might observe in relationship to dioxin exposure is dose-and duration-related. The next one please.

The question of a latency period, how long it takes from time of exposure until diagnosis of cancer, is a matter which has not been yet possible to evaluate from the animal studies that have been conducted of this issue. But, of course, it is of considerable importance in light of the health risks that are perceived by veterans and other human populations which have been exposed to this substance. If a positive association exists between dioxin exposure and cancer, our studies should allow us to estimate a latency period for this effect, because of the fairly accurate temporal information that we have collected with regard to when exposure began, and when it ended, and the dignosis date for cancer.

We also anticipate that we may be able to estimate an induction period for this effect if in fact a direct-acting type of carcinogenesis is involved. The next one please.

Now, many of the alternate risk factors for the

cancers that we are evaluating are listed here. There are obviously numerous of these. Immune diseases and disorders are of particular concern because these are common risk factors for both soft tissue sarcomas and non-Hotchkins lymphomas. The drugs that are listed here on the right hand side are known to effect the immune system, and so we are assessing past exposure, especially continuing use of these substances.

Many of the occupations where dioxin-containing chemical exposure occurs in our population also involve exposure to other classes of chemicals, especially those that are listed in the center of this chart. So, we are very interested in assessing past exposure to these, especially the chlorinated organic aromatic halogenated hydrocarbons. Trichlorethylene and perchlorethylene are widely used in the area as well as a number of other organic chemicals. Many of the occupations which I indicated involve dioxin-containing chemical exposure also involve exposure to these. We are also assessing life style and demographic factors to see if any of these are associated with the cancers that we are evaluating here or may pre-dispose to an increased risk of cancer in concert with exposure to dioxin-containing chemicals. The next one please.

Finally, one most particularly interesting aspects of the study aside from the assessment of possible association between dioxin and cancer per se, is the evaluation of other biological sequelae of dioxin exposure and their correlation with past exposure episodes and overt health effects. Some of these are listed here. Chloracne of course has been subject of much discussion this morning and is well recognized as a long-lasting symptom of high level dioxin exposure. We have had several cases of chloracne reported so far, although without clinical confirmation. While we don't attribute any biological or statistical significance to these findings so far, it is interesting that a number of them are associated with the dioxin exposure. There is no particular division between cancer cases and non-cancer cases. But, in essentially every other case, there is some exposure to either a dioxin-containing chemical or other type of halogenated aromatic hydrocarbon . One case involved exposure to chlorine-containing cleaning solutions.

With regard to porphyria, of course we know that T.C.D.D. is a well known porphyrinogen and an inhibitor of your uroporphyrinogen decarboxylase. The direct mechanism of this effect is not known

and the manifestations of this condition are either elevated porphyrins in the urine, especially 8-carboxyl porphyrin, or particular skin conditions. In our study, no cases of porphyria have as yet been reported among any of the subjects. However, we have reported quite a number of skin rashes, blotches, other types of skin conditions in association with occupational exposures to dioxin-containing chemicals, which could possibly represent a porphyrinogenic response.

Guillain-Barre Syndrome or peripheral neuropathy are conditions that have been reported more in association with phenoxy herbicides than with dioxin containing chemicals per se. We have had a couple of cases of peripheral neuropathy that haven't really been diagnosed as Guillain-Barre syndrome and could be, and certainly further follow up on this condition is going to be required.

Finally, immune disfunction, this is both a sequela of dioxin exposure, and an independent risk factor for the cancers that we are evaluating. I mentioned before, we are assessing the existence of this condition in great detail. We are seeing some considerable excess of immune-related disorders among cancer cases as anticipated, but we haven't yet

determined whether this is associated in any way with dioxin exposure. These are issues that we definitely plan to be evaluating in some considerable detail. The last one then please.

This is just a very brief summary of where we are to date. We are approximately 2/3, I would say 3/4 of the way through the interview process. We have completed 998 interviews. The total expected number is 1450, which we expect to complete by spring of 1985. The completion rates for these interviews are extremely good. There is a slightly greater subject refusal among the controls, and the reasons for these are documented very carefully. The age distribution for all subjects, as you can see, are largely tending towards the older ages, which would be expected on the basis of these cancers. This may have some implications with regard to a latency period, or how long cancer takes to develop if in fact we do observe an association. With regard to viable status, about 3/4 of our subjects are living. Thank you.

DR. SHEPARD: Thank you very much, Dr. Woods. I apologize. I think it might be fitting if you could give us a little bit of information regarding your background and your current position. I know that you are with Battelle. I am wondering if you could give us a little bit of

description as to your scientific background, and I apologize for not doing my homework and introducing you properly.

DR. WOODS: Sure. Well, I have somewhat of a checkered background. My doctorate is in pharmacology. I have about seven or eight years of experience as a biochemical toxicologist. I was at the NIEHS doing biochemical toxicology on substances such as T.C.C.D. for six or seven years during the 1970s. I then at the same time acquired a masters in the public health in epidemiology, and decided to orient my research activities more towards human toxicology.

Now I consider myself to be more of a biochemical epidemiologist. I have an appointment in the Department of Environmental Health at the University of Washington, which is right next to the Battelle campus in Seattle. We largely orient our research toward the types of activities and the types of studies that I described this morning. We have this study sponsored by the NCI, which is largely an epidemiologic study but we hope to bring in more laboratory-based components as issues that I mentioned during my presentation arise and present themselves for laboratory analysis.

DR. SHEPARD: Did you say, when you plan to publish the study? Roughly when do you hope to do that?

DR. WOODS: As I mentioned, we are about 2/3 of the way through and are entering the data from the questionnaires into computer file at this time. We anticipate that we will probably commence analysis of the data towards the middle of 1985, although that is probably an optimistic estimate. It probably will take maybe a little bit longer than that, and I think probably will extend into 1986 before we have something that we can start presenting as hard data.

DR. LINGEMAN: Dr. Woods, I was surprised to see the term Guillain-Barre/peripheral neuropathy on your list, on the next to the last slide. Correct me if I am wrong, but, I never was aware that the Guillain-Barre syndrome had been associated with exposure to dioxin. I don't think that peripheral neuropathy and Guillain-Barre syndrome are synonymous.

DR. WOODS: It is not quite synonymous. They are largely confused, although the initial manifestations of Guillain-Barre do involve peripheral neurapothy, and if you assess the literature on this you will find that cases reported with this condition are largely associated with the exposure to

phenoxy herbicides, rather than to TCDD per se. In particular, 2,4-D doesn't contain dioxin, but some cases associated with both 2,4-D and 2,4,5-T have been reported. So, our study isn't restricted entirely to the dioxin issue. We have sufficient number of cases with association with 2,4-D alone on which we hope to be able to do some independent analyses for health effects that may be associated with exposure to that particular herbicide. While dioxin of course is a principal culprit here, I don't think that we can completely exonorate the phenoxys per se from any of the adverse health effects that might have been associated with exposure to Agent Orange. There are at least a dozen cases of peripheral neuropathy syndrome recorded in the literature. Guillain-Barre, as you may know, is a syndrome of extremely ambiguous symptoms and causality. It usually starts out with a peripheral neuropathy and lasts perhaps much longer, with a question of complete or incomplete recovery. But, it involves axonal degeneration and denervation of the axonal bodies and problems that are very, very similar to those that involve peripheral neuropathy even though there has been no demonstration that these herbicides or dioxins can destroy the axion.

DR. LINGEMAN: Guillain-Barre is a polyneuritis, often associated with viruses.

It was most recently associated with the swine vaccine a few years ago. I believe it is a fairly specific syndrome.

DR. HODDER: I agree with you in the early stage, particularly the initial presentation. The patient is being sent home or diagnosed is missed because of it. But, in the natural evolution of the case, I don't think you would call it ambiguous it all. I think it is typical and there is at least two stages, one in the journal that is pretty specific criteria for the diagnosis I think. I can't remember them now, but I think it was 12 criteria that would be used.

DR. FITZGERALD: Phenobaria (phonetic) is primarily a motive involvement isn't it rather than sensory though?

DR. HODDER: Yeah, the other area, again, the array can go all the way to the brain stem level in the most severe ones. I have worked with 129 cases of this myself in the swine flu type of thing. Most of them, it was not an ambiguous problem past the emergency room in terms of making the diagnosis. I do agree with you in the characterization, even in the I.C.D.A. code was such a way that would open a lot of

confusion.

DR. WOODS: I would suggest then that there should be some considerable analysis by those who are expert on this issue with respect to the cases that have been reported and the association of the phenoxy herbicide exposure because I assure you considerable confusion still exists in that particular situation. In our study we are using it merely as an indicator as to follow up with regard to past exposure to the chemicals of concern , not as a cause. I don't suggest at this point that exposure to these substances causes the peripheral neuropathy or Guillain-Barre but rather as an indicator of where we should looking for potential exposure.

DR. SHEPARD: Certainly I think we would all agree in terms of causation it is very ambiguous. I don't think anybody has come up with a - Dick, do you have any ideas? Does anybody think they have a handle on the causation of Guillain-Barre?

DR. HODDER: Not that I know of.

DR. SHEPARD: So that's certainly up in the air. We have seen it, and it does have some relationship if I am not mistaken with immune, some immune diseases or immune active diseases.

DR. HODDER: Certainly the question in

relation to a viral infection certainly would be.

DR. SHEPARD: Yes.

DR. LAMM: One I think you will find Guillain-Barre is an ascending motor neuron disease, rather than a polyneuropathy, without a combination of the motor and the sensory involvement. I think that would be a clear separation of those two diagnosis. But my question to you is on the definition of latency period, introduction period. Prom your definition, I couldn't understand the difference between them.

DR. WOODS: By latency period we are talking about the time between the onset of exposure and the diagnosis of cancer. As far as an induction period is concerned largely about duration of exposure period between the initiation of exposure and how long exposure had to ensue before cancer is induced.

DR. LAMM: Your definition —

DR. WOODS: The definition was not clear. I confess.

DR. LAMM: Your definition looked at the end point as when the carcinogenic event has occurred and I wasn't quite sure how you documented that time period.

DR. WOODS: By the fact that if a person has short-term exposure and doesn't get cancer even after

t an appropriate latency period, we would assume that exposure
2 / would preclude an induction period. However, if a
3 longer duration of exposure is required, even after a
4 latency period, we should be able to distinguish those
5 two in our study because we have such precise
6 information on duration of exposure. So, the
7 induction period really pertains to how long exposure
8 is necessary.
9 DR. LAMM: I think the concept you are
10 working towards is the comparison between latency and
11 recency.
12 DR. WOODS: I have never heard of
13 recency."
14 DR. LAMM: Where what you are looking at is
15 the time interval between the time of the diagnosis of
16 cancer and the last date of exposure as opposed to the
17 first date of exposure. You see that for instance in
18 the benzene leukemia, that 90, 80% of the benzene
19 leukemias occur with the recency of less than 2 years.
20 DR. WOODS: Thank you. That's an important distinction.
21 MS. MARINELLI: My question was, when you
22 look to your studies, what do you consider a
23 "appropriate" latency?
24 DR. WOODS: Appropriate?
25 MS. MARINELLI: I believe it is the term

latency. What is your definition of a latency period of, and appropriate I think you used?

DR. WOODS: I'm confused with the –

MS. MARINELLI: Do you have any working hypothesis?

DR. WOODS: With regard to how long? No, at the present time, no.

MS. MARINELLI: Thank you.

DR. WOODS: Dr. Schulz ,

DR. SCHULZ: Jim, could you tell us what the smallest increase in the two types of cancer you are able to detect?

DR. WOODS: Yes, I had a table from our study, but I didn't make a chart of it. However, we should be able to detect for each type of tumor approximately the same. We anticipate that we will review some percentage of exposures and then/what determine the risks are that we should be able to detect. For 25% of the population exposed, we should be able to detect a relative risk of 1.5 for soft tissue sarcoma and 1.4 for non-Hodgkins. For 10% exposed, they are approximately 1.7 and 1.5. For 5% exposed, 1.9 and 1.7. We anticipate that the percentage of exposure will lie greater than 5%, so we anticipate that we will able to detect with a power of 0.8 or 0.9

a relative risk of 1.5 for soft tissue sarcomas and about 1.6 for non-Hodgkins at a level of significance of $P < 0.05$.

DR. SHEPARD: Yes, Dr. Keller.

DR. KELLER: Sir would you —

DR. WOODS: Relative risk, I am sorry.

DR. KELLER: Would you briefly go over the criteria you are using for heavy, moderate, light exposure?

DR. WOODS: Criteria for exposure?

DR. KELLER: Yeah. You mentioned the heavys as being, the heavys being the —

DR. WOODS: It is largely based on an analysis of the exposure that a person gets in a specific job category. So, we sat down with occupational experts in the particular types of industries where exposure occurs and went down every single job title or category within that industry and assigned a high, medium or low exposure with regard to potential for direct exposure to the chemicals, or working with products that involved exposure to the chemicals, or worked in areas where chemicals had been sprayed or used, in order to come up with an admittedly subjective, but I think fairly reliable estimation as to the kind of exposure a person would have received based on proximity to the

chemicals and duration of time on a daily job activity.

DR. KELLER: Well I noticed that you had mentioned on your slide you mentioned an applicator would be heavy exposure.

DR. WOODS: Yes.

DR. KELLER: I also recall an earlier version of the study which included people who resided in areas where they had sprayed along the road or something like that. Is that to be included in this version?

DR. WOODS: No. Residential exposure is not, while it is being assessed in the study, the original study design was revised significantly to include for exposure-category assessments. only occupational based exposures/ The residential exposure and home use / are two other categories which are being assessed separately from occupational exposure are being evaluated completely separately and they do not enter into the determination of occupational exposure category.

DR. SHEPARD: Alright, are there any other questions for Dr. Woods? Okay, if not I think we will stop at this point and take a lunch break. I would like us to reconvene at 1:15 for the completion of our agenda which will be the presentation of three of our

specially solicited research projects being conducted by the VA. So, we will reconvene promptly at 1:15 please. Thank you.

(Recess for lunch.)

DR. SHEPARD: I'd like to introduce Dr. Matthew Kinnard who is a staff person in our Department of Research and Development in the Department of Medical Research. He has been coordinating the efforts of the investigators who are doing a number of studies under the program we call specially solicited studies. That is a term of convenience. It has no specific significance other than these are studies that were proposed as a result of a solicitation that went out from central office here several years ago encouraging VA scientists and investigators to submit proposals for Agent Orange and herbicide related projects. Dr. Kinnard has been heading up that section now, and we have three of the investigators with us today and we are delighted that they are here and Dr. Kinnard will introduce them. Thank you.

VA IN-HOUSE SPECIALLY SOLICITED AGENT ORANGE RESEARCH

DR. KINNARD: Thank you Dr. Shepard. My supervisor, Dr. Richard Greene sends his regrets and wishes he could have been here today but he is tied up with another important meeting / somewhere in the

confines of Washington D.C.

But, at any rate, in keeping with past tradition, the Medical Research Service (MRS) has arranged for the last of the three investigators who were awarded research dollars via a special solicitation to conduct Agent Orange research to make scientific presentations today. You heard four of them last December, and another three presented in June.

The first investigator who will present today is Dr. Raj Lakshman, who is a biochemist by training, and is currently an investigator at the VA Medical center, Washington, D.C. The title of his research is "Mechanism of TCDD Absorption and Toxicity of Lipid and Lipoprotein Metabolism." I would like to say that Dr. Lakshman adds an international flavor to our group of researchers here today in that he has held positions in his native India, Thailand, Canada, as well as here in the continental United States. He has applied his biochemical expertise to the understanding of another problem critical to the VA, namely alcoholism and has published extensively on the topics of Lipid metabolism and alcoholism.

In addition to his VA appointment, Dr. Lakshman currently serves as an associate professor in the Department of Medicine at George Washington

University. Dr. Lakshman.

DR. SHEPARD: While Dr. Lakshman is coming up to the podium, I just want to remind members of the committee that abstracts of all three papers that are being presented are in their folders.

MECH. OF TCDD ABSORB. AND TOXICITY ON LIPID AND LIPOPROTEIN METABOLISM

DR. LAKSHMAN: I am really privileged and honored to have been invited to speak to this very distinguished audience. The work I am going to present today is the result of our research efforts in the past several months. As you are all aware, we had to take care of a lot of safety measures to make our lab fully functional. Finally everything is in order including the hood and the lab is HEPA-charcoal. filter for the special/ rolling. We have got some very interesting findings. May I have the first, slide please?

Here is our culprit-TCDD which is 2,3, 7, 8, tetrachlorodibenzo-p-dioxin, the major toxic contaminant of Agent Orange and other herbicides used in Vietnam war as a defoliant. Exposure to TCDD caused a number of abnormalities; to name a few; the Chloracne which all of us know very well, hepatotoxicity, carcinogenicity, Porphyria Cutanea Tarda, etc.

Most of the human exposure has been with industrial workers working with the production of trichlorphenol or trichlorphenoxy acetic. Other than

this, the other major one which all of us are aware of is the industrial accident in Seveso, Italy resulting in exposure of the general population. In the next slide I have given the toxicities of the known potent toxins. You can see that the Botulinum toxin works at 10^{-17} M. TCDD is not very far off. It is fourth on the list with a lethal dose of 10^{-9} M. This amounts to one microgram per kilogram. I might add that this was tested in a guinea pig which is a very sensitive animal. But, it seems to vary depending on the species as shown in the next slide. Here, as you can see, guinea pig is the most sensitive species with an LD_{50} dose of 0.6 to 2.1 micrograms per kilograms, whereas in the rat the LD_{50} was 22-45 mg/kg. Again, the females are more refractory than the males. The rabbit is the most resistant species with a LD_{50} of 115-272 mg/kg. I don't know where the human population would fall in this toxicity scale. Perhaps Dr. Shepard might want to comment. Now, coming back to t'he structure of TCDD, the thing that we are struck by is its highly hydrophobic nature. Because of its complex aromatic ring structure with chlorine atoms it behaves like a lipid and therefore must be transported by lipoproteins. Thus, TCDD molecule should behave like other lipid molecules in terras of absorption, transport, distribution, and perhaps this may even be important in the

manifestation of its toxicity. Furthermore, as you can see in the next slide, the solubility of this compound in water is extremely low. It is .2 parts per billion; so naturally the TCDD molecule needs to be attached to some protein or any hydrophilic compound to be transported in the plasma compartment so as to be compatible with the aqueous environment of the body. Lipoproteins are ideally suited to serve this function. They play an important role in the transport of lipids. So, the lipoproteins would definitely have an important role in the absorption, uptake, transport and metabolism of TCDD. If I may briefly summarize the current status of the lipoprotein metabolism given in the next slide which depicts chylomicron metabolism, but this would apply for other triglyceride-rich lipoprotein like (VLDL) very low density lipoprotein.

The lipid molecules, when they come through the the thoracic duct during active intestinal absorption, are assembled to form what we call the nascent chylomicrons. At this point, they have 98% lipids, 2% protein. The major apoproteins of chylomicrons are the Apo B and Apo A. When these nascent chylomicrons enter the system circulation, they pick up a Apo C particle as well as Apo E from circulating HDL2 lipoprotein to form what we call as remnants. The Apo C II peptide of this molecule activates

the lipoprotein lipase which is present in the heart muscle and other extrahepatic tissues. They attack this molecule, and partially hydrolyses the triglyceride so that the molecule is shrunk inside. It is depleted of the triglyceride and therefore the molecule becomes richer in chloresterol. At the same time, the Apo C proteins also leave the molecule, and what we end up is called the remnant. The remnant particle then is transported to the liver, where it is picked up and metabolized efficiently. We have published extensively in this area, and now we can ask the question where and how TCDD fits into this overall scheme with respect to its absorption and transport As far as the methodology is concerned we work with albino rats, but as we go along we may be changing to other species depending on our protocol. The thoracic duct cannulation is done in our laboratory routinely. This helps to completely dissociate the lymphatic system from the systemic circulation. Plasma turnover studies are carried out in fully conscious rats where we cannulate the jugular vein and coronary artery so we can infuse the compound through the venous side and periodically sample the blood on the arterial side. The liver profusions were carried out according to Professor Knebs' method and is a standard part of our laboratory procedure. I was fortunate to be trained with his system which will do everything that

a normal liver in vivo will do. As for quantitative anlaysis of TCDD, it is extracted quantitatively from tissues with 20 volumes of chloroform; methanol (2:1V/V) and the lipid extracts are analyzed in a Beckman 9800 liquid, scintillation spectrometer.

Now, let's look at the results: In the first of these experiments, what we did was to give intraduodenally a tracer amount of [3_H] TCCD to thoracic duct cannulated rats and after 24 hours look at the distribution in various fractions. About 58% of the compound was unabsorbed and was therefore excreted in the feces. More importantly, 31% of the administered dose was recovered in the lymph, and even more crucial was 90% of that was associated with the chylomicron fraction. As you can see, the other tissues had extremely low radioactivity; so the TCCD is transported by the lymphatic system and essentially by chylomicron. Okay, the next question is what is the fate of this compo.und when it is entering the systemic circulation as chylomicron? As shown in the next slide the TCDD turnover curve in the blood compartment, exhibited first order decay Kinetics with two exponential components. The faster component had a half life of 4.4 minutes while the slower component had a $T_{½}$ of 24.5 minutes. Just for comparison, we also have been doing, studies in relation to my other project on alcoholism where we labelled the chylomicrons

in the lipid components and have looked at the decay characteristics of the triglyceride and the cholesterol moieties. As shown in the next slide, the half life of triglyeeride label was about 3.3 minutes, whereas that of the cholesterol label was 5.1 minutes. These values agree very closely with the half life of the faster component of the decay curve for TCCD in this study. The slower component quite possibly is due to a partial transfer of TCDD to other lipoproteins in the plasma compartment. We are currently working in this area.

The next approach was, what happens to this TCCD component of the chylomicrons once it is being metabolized in the plasma compartment. Just to look at that, we gave intravenous infusion of the chylomicron labeled TCCD and analyzed the radioactivity in various tissues as a function of time up to 24 hours. May I draw your attention to the two yellow vertical columns, the adipose tissue and the liver, which together accounted for 80% of the TCCD radioactivity distributed throughout the body.

The other interesting thing was that the •intraperitoncal route was as effective as the oral route for the absorption and uptake of [?H.] TCDD within 24 hours while the subcutaneous route was less effective. To get further idea of what is happening to the TCDD label from chylomicrons in various tissues,

we plotted the decay curves for each organ as a function of time, and as shown in the next slide the two major organs which has most of the TCDD label within 1 hour were adipose tissue and liver. The adipose tissue decay curve showed a negligible rate of disappearance with a poor correlation coefficient (-0.17). In contrast, the liver exhibited a fast rate of disappearance with a $T_{1/2}$ of 14.4h (correlation coefficient -.97). All other tissues had very little TCDD radioactivity to start with and the decay curves were almost parallel indicating that it was remaining in the body for a long period.

All of these data imply that liver probably was the major site at which the TCDD undergoes any metabolism. So, the obvious question was what happened to TCDD in the liver? To answer this, we set up the liver perfusion system where we incubated the liver with chylomicron remnant labeled with [^{3}H] TCDD and determined the uptake in 3 hours. It was found that over 83% of the TCDD label added to the profusate was picked up by the liver. When we looked at the subcellular distribution of TCDD radioactivity we found that the nucleus had the maximum amount of radioactivity. The next highest one was in the microsomal fraction followed by the mitochondia and the cytosal fractions. This is somewhat at variance with the findings of a long term study in guinea pigs by Gasiewicz and Neal who found that most of it was in the microsomal fraction 7 days after TCDD administration.

This indicates that possibly TCDD is initially concentrating in the nucleus and then transferred to the microsomes where it undergoes metabolism. To look at excretion in the bile, as you can see in the slide 15% of the label that was present after three hours in the liver was recovered in the bile. It seems likely that TCDD's oxidized and excreted as glucuronides in the bile. We are currently trying to identify these metabolites of TCDD in the bile.

In the summary therefore, I might say that TCDD is absorbed in the lymphatic system and carried essentially by the chylomicrons. When the chylomicrons enter the systemic circulation the lipoprotein lipose attacks this molecule. Part of the TCCD is transported along with hydrolyzed fatty acids to the extrahepatic tissues and stored. The remaining TCDD associated with the remnant particle is carried to the liver where it is picked up efficiently and initially concentrated in the nucleus. Thereafter, it is transferred to the microsomes where it undergoes its metabolism and finally the metabolites are excreted in the file. Thank you very much.

MR. KINNARD: Are there members of the committee or persons in the audience that have any questions? We have allotted a few minutes for Dr. Lakshman to respond to those questions.

DR. BARNES: Can you speculate as to the transport mechanism by which it appears in the nucleus?

Dr. LAKSHMAN: Well, I believe that there is a nuclear binding protein specific for TCDD which carries it to the Ah locus which is responsible for the induction of the P-450 mono-oxygeneses.

DR. BARNES: Do you find any evidence of binding in the nucleus?

DR. LAKSHMAN: We are currently looking into that and have some evidence to support it.

MR. KINNARD: Thank you very much. The next investigator is currently at the VA medical center, Lexington, Kentucky, Dr. John Dougherty. Dr. Dougherty's research is entitled "Behavioral Toxicity of an Agent Orange Component" namely 2,4-D. Dr. Dougherty has held key positions in both clinical medicine and in academia, and in his present position at the VA Lexington, Dr. Dougherty also currently serves as an adjunct associate professor in

of the Departments/Psychiatry and Pharmacology at the University of Kentucky. One additional sidelight regarding Dr. Dougherty is that he is the first of the ten specially solicited Agent Orange investigators to come up for subsequent review. In other words, these projects as you may recall were reviewed by a specially constituted panel. However, the decision was made that when they come up for renewal that they would be reviewed by our traditional peer review system. Dr. Dougherty's proposal has already been reviewed and I can say that scientifically the study has been approved for continuation. Final approval rests with the MRS council which meets later this week. So, without further adieu, I would like to introduce to you Dr. John Dougherty.

BEHAVORIAL TOXICITY OF AN AGENT ORANGE COMPOUND (2,4-D)

DR. DOUGHERTY: Thanks Dr. Kinnard. Well, 2,4-D or dichloro phenoxy acetic acid is a herbicide that is chemically related to plant growth hormones and was a component, along with 2,4,5-T and TCDD and a number of other substances, in Agent Orange. To date, 155,000 Vietnam Veterans have come to the VA for examination and treatment in the Belief that they have suffered continuing problems from exposure to Agent Orange or similar herbicides. Problems that have been attributed to herbicide effects include a number of

physical problems, but also numerous phychological problems as well, such as weakness, lack of energy, anxiety, depressed mood, violent behavior, fear of crowds, and sleep disturbances just to name a few. The scientific bases for these claims, especially the psychological symptoms, have not been well established. We have therefore started to characterize the neurobehavioral toxicity of herbicides contained in Agent Orange. The work reported today is limited to the effects of 2,4-D butyl ester, the form of 2,4-D that was used in Vietnam. Could I have the first slide please?

There were three basic goals of these experiments. First we wanted to determine if 2,4-D exerted behaviorally toxic effects and, if so, at what doses. We have defined a behaviorally toxic effect as one that impairs the animal's ability to successfully meet environmental challenges. Secondly, we wanted to find out if the effects were reversible or if they persisted. We also wanted to look for tolerance [which could be defined as an adaptation to the herbicide that is reflected as a decreased effect with repeated exposure] or sensitization, which is an increase in effect with repeated injections. Thirdly, we wanted to evaluate for

possible latent CNS impairment. It is possible that 2,4-D produces a long-term insult to the central nervous system, but that the impairment may not be reflected in our choice of behavioral measures. By making extreme demands on the central nervous system, we might be able to elucidate the impairment, and we have done so by "stressing" the central nervous system with injections of amphetamine.

In our studies, we used the n-butyl ester form of 2,4-D which was diluted in a castor oil vehicle and injected subcutaneously at doses of 3 to 300 milligrams per kilogram of the animal's body weight. We have used two kinds of general dosing procedures. The first was an intermittent injection procedure in which single injections were given about once or twice per week. Behaviorally toxic effects resulting from these injections were allowed to dissipate and pre-injection conditions recovered before the next injection was given. This intermittent dosing method allowed us to determine the dose-response relationship for 2,4-D and vehicle within individual animals while minimizing the development of tolerance. The second procedure involved daily injections of 2,4-D for two-week periods at different dosage levels in order to look for tolerance

or sensitization. We are using Wistar albino rats in these experiments.

The data presented today are based upon four behavioral methods. In the first method, the rats are reinforced with sugar pellets for pressing a small lever continuously for one hour per day in a ventilated chamber. The rate and temporal pattern of this responding are very reproducible and are sensitive to the effects of chemicals. Sugar reinforcement availability periodically and briefly interrupted by what are called "time-out" periods. When the time-out period begins, the lights in the chambers go out and sugar pellets are withheld for four minutes. Understandably, responding becomes much lower during time-out periods than during reinforcement periods. The rats therefore detect and appropriately adapt to the relevant environmental change which is the availability or non-availability of the reinforcing sugar pellet.

A second method utilizes photocells to measure the amount of movement in the rats for five-minute periods. This method is sensitive to drug-induced sedation, motor impairment, or motor stimulation.

We have measured grip strength in these animals because other investigators have reported increases in

t grip strength with chronic 2,4-D exposure. Finally,
2 landing foot splay provided us with a measure of
3 motor coordination. We have observed motor incoordination in
4 rats treated with 2,4-D.
5 The next slide shows the effects of single
6 intermittent injections of 2,4-D given six hours
7 before the daily lever pressing sessions. The decline
8 in lever pressing response rate is expressed as a
9 percent of the castor oil vehicle control effect, which
10 essentially was zero. 2,4-D produced behaviorally
11 toxic effects at 100, 200, and 300 milligrams per kilogram doses.
12 The doses of 2,4-D that producedthis acute toxicity
13 are relatively large because the literature indicates
14 that 400 to 600 milligrams per kilogram can be a lethal dose to 50%
15 of the rats so exposed. In comparison, 2,4-D was 100 times less
16
17 potent in decreasing response rates than d-amphetamine
18 in these rats. (I will illustrate this point in a later
19 slide.) Motor activity in the photo
20 cell chambers and neuromuscular coordination
21 (foot splay) was also decreased at these doses.
22
23
24 The next slide shows effects of the vehicle injections.
25 The volume that we used for injection of 2,4-D was one

milliliter per kilogram, but we also studied other volumes of the vehicle to see if we could get a dose /volume response for this substance. We found no effect with six hours pre-treatment or with zero hours pre-treatment. At a volume of 3 milliliters per kilogram, we did see some transcient diarrhea in these rats which is not unexpected since it is a castor oil derivative that we are injecting.

found no behavioral effect, but

The next figure shows the duration of effect of single injections of 2,4-D at a dose of 100 milligrams per kilograms. Because the lever pressing session was only 1 hour long, we actually varied the pre-session injection time to assess the duration of action of this chemical. The peak effect occurred about 6 to 9 hours after exposure, and then gradually dissipated over the next 12 hours. The dependent variable that we are using here is the rate of 2,4-D responding expressed as a percent of the vehicle control rate of responding. The effect of 300 milligrams per kilogram was more severe, but like 100 milligrams per kilograms, the effects dissipated within 24 to 36 hours after the injection.

With repeated injections of 100 to 300 milligrams per kilogram once or twice weekly over a 20 month period, the peak effect of 2,4-D and the

duration of that 2,4-D effect/did not significantly change , This indicates that we have not seen any sensitization to the effects of 2,4-D with repeated intermittent injections. This rapid decline in effect that we see with 2,4-D is consistent with the urinary excretion studies we have performed in collaboration with Jerry Blake , Ph.D., of the College of Veterinary of Science at the University of Kentucky. The next slide shows that 95% of the injected 2,4-D ester was excreted in the urine within / 48 hours, and 100% was excreted in 96 hours. Most of the 2,4-D was excreted in the polar acid form; about 97% of what we injected was excreted as the hydrolyzed acid.

Although we found that the neurobehavioral . toxicity of intermittently injected 2,4-D dissipated within a day and a half, it is possible that long-term CNS impairment might not have any influence on lever pressing, but might be evident under other conditions where the demands on the central nervous system might be somewhat greater. We therefore chose to evaluate the effects of amphetamines a drug with potent and well-studied effects on the central nervous system,both before and then again after one year of intermittent injections of 2,4-D in one group and in a group that

intermittant
received /vehicle injections over that same one-year period.

The next two slides show these results. The first slide shows the individual amphetamine dose response curves from pre- and post- 2,4-D exposure. The filled circles are the amphetamine dose response curves from before 2,4-D was injected and / the open circles are the amphetamine response curves one year later after the series of intermittent 2,4-D injections. The dose response curves are the same in four of the rats and slightly different in two of the rats. The post- 2,4-D amphetamine was less effective in those two rats as the dose response curves are shifted slightly to the right. However, when we compare / the 2,4-D group with the vehicle control group / in the second slide, we see similar decreases in amphetamine effect in some rats. Therefore, I interpret these changes as being related to aging or some other variable and not related to 2,4-D exposure. Therefore, we haven't found any latent CNS changes with this procedure. Note that amphetamine completely suppressed lever pressing at 1 and 3 milligrams per kilogram. To achieve the same effect with 2,4-D required about 300 milligrams per kilogram.

The next slide is a bit complicated, and

shows some new data that we have just collected within the past three or four weeks. This graph illustrates the effect of the two-week daily dosing procedure on lever pressing rate, photo cell activity, and landing foot splay.

Looking just at the response rate curve, this portion of the curve is the stable pre-2,4-D baseline. After the baseline period, we injected 2,4-D everyday at a dose of 150 milligrams per kilogram for two weeks. After injections were stopped, there was a 7-day recovery period during which behavioral chancres were observed. Immediately upon dosing, there was a decrease in the response rate in these animals which peaked on about the third day. By the sixth or seventh day, the effect had lessened, although the effect did not completely disappear as response rates were still below the pre- 2,4-D baseline. The tolerance was therefore incomplete.

When we discontinued the 2,4-D, the effect of 2,4-D dissipated with a day and a half and again we find response rates that were identical to those occurring during the 2,4-D baseline.

The open circles at the bottom of the graph show the very low response rates that occurred during the time-out period when sugar pellets were not delivered. The unreinforced response rates here did not increase when 2,4-D decreased reinforced rates. If anything, time-out rates decreased slightly at higher 2,4-D doses.

This is a clear indication that 2,4-D, even though it had a pronounced behavioral effect did not effect the animal's ability to discriminate between periods of reinforcement and non-reinforcement.

The solid triangles on the figure show changes in photocell activity. Activity decreased with continued dosing with a peak effect on day 3. There was tolerance by the sixth or seventh day and similar to response rate, tolerance was incomplete. When we discontinued 2,4-D, the levels of activity bounced up within 2 days to just slightly higher levels than on the first 2,4-D day.

Landing foot splay has been graphed on the right vertical axis and we have inverted the scale so that the direction < .7 of the effect would be on the figure the same as the activity and the rate effects. As we can see, 2,4-D increased hindlimb and fore limb foot splay, with a peak effect on the 3rd dosing day. By day six, complete tolerance to 2,4-D effects had developed. When we discontinued 2,4-D there was no- further change.

Since we have conducted this 150 milligram per kilogram study, we have

experiment
replicated this/in the same animals at a dose of 175 milligrams per kilogram and found very similar effects except that the degree of tolerance was somewhat lower. As of a few days ago, we began the study of 200 per kilogram
milligrams /and we'll know next week what effect that dose will have had.

effect and
The time course of/tolerance development in these 3 behavioral measures are almost identical with a peak effect at and
three days /tolerance by day 6 or 7. This similarity single
suggests a/mechanism of tolerance, but before I can be interpretation
sure about that/I need to more closely examine the data from individual animals to insure that the similarity isn't an artifact of averaging across animals.

The next slide shows what happened to grip strength with two weeks of daily 2,4-D/a dose of 150 at
milligrams per kilogram. There were no significant changes in hind limb grip strength, however fore limb grip strength increased gradually over the period of the 2,4-D injections and continued to climb after 2, 4-D was stopped. We have exposed the same rats to 175 and are now exposing them to 200 milligrams per kilograms. Forelimb strength has climbed from a pre-2,4-D baseline at 1.1 kilograms to 1.6 kilograms, which
/ is the upper limit of our strain gauge.
7-day
Even during the/wash out period between 150 and 175 mg/kg

and between 175 to 200 mg/kg, grip strength remained elevated.

We haven't had the opportunity to determine if or how long the increase in grip strength will take to decline, but Squibb, Tilson , and Mitchell at the National Institute of Environmental Health Sciences have also published a report finding an increase in grip strength after chronic 2,4-D exposure. They found that grip strength returned to normal about two weeks after the cessation of dosing.

These changes in grip may be related to the muscle myotonia that has been previously reported by other investigators and reported to this committee by Bernard et. al. It is quite clear that whatever the mechanism accounting for the increased grip strength, the temporal pattern of grip strength change is as radically different from that of the other behavioral changes (response rate, activity, splay). The differences in time course strongly suggest that the central nervous system or peripheral mechanisms underlying lever pressing and activity and splay changes on one hand, and grip strength on the other hand, are perhaps quite different.

In summary, we found that 2,4-D is behaviorally toxic in doaes of 100 to 300 milligrams per kilogram. Most toxic effects disappear within 48

hours after single doses or two weeks of daily dosing. The decline of effects are correlated with rapid urinary excretion of the herbicide.

Considerable tolerance was found with daily dosing. complete tolerance was observed to one effect, and partial tolerance to two other effects. In contrast, fore limb, but not hind limb, grip strength actually increased during daily dosing. No changes in the effects of amphetamine could be attributed to latent CNS impairment, and lastly, the animal's ability to detect and appropriately respond to environmental changes (the time-out periods) was not impaired at any dose.

Even though our studies indicated that 2,4-D produced transient behavioral toxicity, we used the animals that had learned/lever pressing task before exposure to 2,4-D. The acquisition of new behavior is known to be more sensitive to drug and chemical effects. Therefore, it will be important to evaluate the effects of 2,4-D • and Agent Orange on the acquisition of new behavior in order to more fully understand its toxicity. In addition, our understanding of the neurobehavioral toxicity of these herbicides will be incomplete until we evaluate the actual commercial formulation of Agent Orange that is

contaminated with TCDD. Thank you.

MR. KINNARD: Thank you. Questions? Dr. Lingeman.

DR. LINGEMAN: I am very impressed with what you have presented. This study seems to confirm the few case reports in the literature concerning people who have been accidentally poisoned with 2,4-D. I don't know the long-term follow up on these people, but the acute effects seemed to be reversible. My question concerns the purity of your 2,4-D preparation. In the past, some preparations of 2,4-D have contained some relatively non-toxic dioxins.

DR. DOUGHERTY: In the studies that were done in cooperation with Dr. Blake, we did analyze the purity of 2,4-D, and I hate to tell you that I don't have that information with me right now. I know that the purity was enough to detect a very small amount of metabolite that was not the 2,4-D acid and the graduate student who did that particular aspect of the study and Dr. Blake were satisfied with the purity of the compound that we were giving to them. But, I can't right now answer your question about whether there

were any other dioxins that were in the 2,4-D. I assume there probably were, but not TCDD.

DR. BARNES: I think what we would expect to be some TCDDs but not 2, 3, 7, 8.

DR. DOUGHERTY: Right.

DR. BARNES: Would you say that your data showed a dose response effect?

DR. DOUGHERTY: Yes.

DR. BARNES: Does the area that you are finding the response similar to what NIEHS found?

DR. DOUGHERTY: They only went up to 80 milligrams per kilogram and they dosed 5 days per week. In our subchronic studies, we have done fourteen days straight, starting off at higher doses (150 mg/kg), I think they also noted the changes in the animal such as lethargy and some ataxia, but their testing schedule was such that not a lot of that showed up on their objective behavioral measures; they saw changes in the home cage but not in the behavioral measures. We have sometimes seen behavioral changes at 30 milligrams per kilogram acute doses, which is slightly lower than some of the doses that they have used.

DR. BARNES: Given that you areas close to the LD 50 as you are, have you tried to determine whether

or not what you are seeing here is a primary effect or a secondary?

DR. DOUGHERTY: No, we haven't.

The literature suggests that 2,4-D -- like compounds may reversibly change blood-brain barrier permeability. The time course of BBB changes is very consistent with the time course of changes in ataxia, activity, and schedules-controlled behavior in our studies. It would be very unusual if these neurobehavioral effects were related to a peripheral rather than a central nervous system effect. The spectrum of effects of 2,4-D look more similar to a centrally-acting drug than a local irritant or something producing a systemic toxicity.

DR. MULINARE: Were there any other evidence or signs of physical deterioration like weight loss. I mean, metabolic changes. Did you monitor any metabolic changes?

DR. DOUGHERTY: The animals that we have been studying have been food restricted so that they would learn to press the lever for sugar pellets. So, we have been keeping them at . 85 to 95 percent of their free-feeding weight. We haven't noticed any weight loss in those animals. But, on the other hand, we might not expect to see weight loss under those kind of conditions. We have injected 2,4-D in animals that were not involved in any behavioral

200 mg/kg of 2,4-D, we found
studies and were not food-restricted. After a single dose of/
in body weight
an initial drop /in the first couple of days, and then
curiously a week or so later a greatly enhanced rate of
food consumption and a temporary weight gain. If you
NIEHS,
look at Tilson's data from/ they also show some
weight gains that were statistically significant in
2,4-D
some of their / animals. So, there were some transient
weight changes that were observed.

DR. KINNARD: Thank you very much Dr. Dougherty. Let me, just before we introduce our last investigator, say that the results that you are witnessing and hearing here today are still considered preliminary.

Therefore, for discussion purposes, we would like to keep discussions of the results as they are, simply as preliminary information because none of the results to date are definitive. These studies will be on-going for some time yet so we would just like to make that request.

One other thing that I would like to observe
is as
and that /you can see that the studies run the gamut scientifically from Dr. Dougherty's behavioral studies to Dr. Lakshman's very biochemically oriented studies.
geographically
They also run the gamut/ from the East Coast to the West Coast. As we can see, Dr. Lakshman is from
D.C.
Washington, /and Dr. Siegel is from California. Now,

the final speaker here today is Dr. Jerome Siegel. He is an investigator at the VA Medical Center Sepulveda, California. The title of his research is "Effects of Agent Orange on Sleep." Dr. Siegel also has had several responsible teaching and research appointments during his relatively youthful career. In addition, he has numerous publications in refereed journals related to the topic of sleep. Coupled with his VA appointment, Dr. Siegel currently serves as an to Associate Professor of Psychiatry at the University of California, Los Angeles Medical School. Dr. Siegel.

EFFECTS OF AGENT ORANGE ON SLEEP

DR. SIEGEL: One of the most common complaints of Vietnam veterans claiming exposure to Agent Orange is disturbance of sleep. People who have been exposed to Agent Orange or Agent Orange constituents in industrial accidents and where there is documented evidence of Agent Orange ingestion, , also almost invariably complain of sleep disturbance. However, sleep disturbance is a side effect of many kinds of behavioral problems. Stress itself of course causes sleep disorders, and many psychiatric disorders are associated with sleep disturbance, perhaps most psychiatric disorders.

Therefore, it is difficult to evaluate the significance of reported sleep changes.

Furthermore, the reports have indicated both increases and decreases in sleep in subject self reports, Lethargy, hypersominas and insomnia. We now know that there are several different kinds of sleep and differences could be quite significant in evaluating sleep disturbance.

There have been no animal studies of sleep disturbance after Agent Orange. If we could have the first slide. Okay, these are the sort of variables you can record to quantify sleep state in animals. Basically ail animals, human included , are in one of three states, waking, slowed sleep, and REM sleep. This is the record in which EEG or brain wave activity, eye movement activity and activity of the lateral geniculate a thalamic structure as well as muscle activity recorded along with particular neuronal activity which we won't get into. During waking the EEG is flat or desynchronized, eyes are moving and there is muscle activity of course. The first stage of sleep can be called slow-wave sleep or non-REM sleep or in human stages 2, 3, and 4 sleep. It is identified by the presence of slow waves in the EEG and also by sleep spindles. ., It can be subdivided into slow-wave sleep stages 1 and 2. The third state,

is REM sleep which is an acronym for rapid eye movement sleep. In this state, the brain activity looks exactly like waking in terms of the EEG/is desynchronized, unlike the synchronized state of slow-wave sleep. The eyes move also just like waking, but the muscle activity is completely absent. This is the way REM sleep is identified. Essentially, the animal is paralyzed in this state while his brain looks like it is awake, but the animal is in fact asleep.

If you have deep electrodes in the brain you can see paroxysmal like activity in the lateral geniculate nucleus which occurs only in REM sleep or in transition to REM sleep. These states can be readily recognized and quantified. You can quantify the duration of each state, the percentage of daytime spent in each state. These percentages are similar, grossly similar in cats and in humans. You can measure changes in the periodicity of these states.

Now, to explore the cause of the reports of sleep disturbance resulting from Agent Orange, we have concentrated initially on doing longitudinal studies in a small number of animals, measuring them continuously over a period now as long as a year after exposure to see if there is

any sleep disturbance if it is maintained and for how long and of course the most important thing is to determine what stages are disturbed, because disturbances in REM sleep would have a different significance from disturbances in nonREM sleep.

Clinically, slow-wave sleep and REM sleep disturbances are associated with different disorders. Slow-wave sleep very often is associated with respiratory problems including sleep apnea. REM sleep disturbance has long been known to be associated with irritability, overeating, hypersexuality, and depression. The depression in humans is associated with increased REM sleep and particular short REM latency. Depressives go into REM sleep shortly after they go to sleep which is abnormal, they seem to have a greater REM sleep pressure and in fact all effective anti-depressent drugs depress REM sleep and that's how they apparently achieve relief from depression.

Okay, if we could have the next slide. So this is the effect of a very high dose of Agent Orange on sleep in cats.

I have additional slides related to non-REM sleep. But, everything I will be showing you relates to REM sleep because that's where we have seen all of the changes. We are giving a high dose of Agent Orange, 385 milligrams per kilogram. But, just a single dose. So, this dose is given right before the period of data that is displayed here. It causes weight loss. The animals stop eating, and there is weight loss that stops at about 21 days and the animal gradually recovers his ad-lib weight.

What's interesting is that there is also a decline in REM sleep which does not happen immediately or at least it is not maximal until a couple of weeks after the injection. This is maintained for at least a week and then gradually gets back the baseline. In fact, as you can see here, the REM sleep then increases to beyond baseline levels.

Now, this next slide is part of the same data showing the entire period that we had monitored for 270 days after the Agent Orange adminstration. This shows REM sleep time / Agent Orange adminstration. What you can see is that there is an initial decrease in REM sleep and then REM sleep increases above the baseline level which is indicated here, and stays up throughout the period of recording. - Weight increases to baseline

values, then there was a fall and weight again returns to baseline, but this second decrease did not seem to be associated with a great reduction of REM sleep. This is data from another animal also monitored for 270 days, and again you see the initial dip in REM sleep, not quite as severe as in the first animal, along with the dip in weight resulting from reduced food intake. Again, the REM sleep remains elevated throughout the period of observation.

The obvious explanation for the initial decrease in REM sleep is that the animal isn't eating. Food intake itself might have an effect on REM sleep, and while that still would not negate the fact that the loss of REM sleep can have behavioral effects, it would explain the mechanism. So, we did some food deprivation studies where we prevented food intake by reducing food intake for a period of a week, so the animal of course lost weight. But, under these conditions REM sleep was not decreased. It was not really significantly changed from baseline. It does not appear that the changes in food intake are causing the change in REM sleep after the Agent Orange administration. This slide is from another animal, also after food deprivation and the REM sleep is, if anything, elevated above baseline levels.

Now, the "long-term increase in REM sleep which could be quite important is a finding that is very tenative and I certainly would be not ready to publish. But it is possibly significant. However, one confound might be that as the animal runs for longer and longer periods, they adapt through our experimental situation, and that is causing the long-term increase in REM sleep rather than this being an effect of Agent Orange.

Now, in this case we run an animal at a much lower dosage, a tenth of the previous dose. It looks like there might be some of the intial dip in the REM percentage that we saw in the previous animals. But, even though these are in the same exact situation, there was no long term increase in REM level above baseline values. These animals were not very severely effected. There was also no change in weight.

This is from another cat showing REM values right around baseline. This particular animal had a greater variability, but nevertheless you can see that the trend is certainly not toward this persistent increase in the REM seen after the Agent Orange. So, to summarize our findings at the high dose, we have seen a significant decrease in REM sleep lasting for at least 21 days after a single administration of Agent

Orange. Non-REM sleep, both non-REM stages 1 and non-REM stages 2 were not significantly changed. The increase in REM sleep that we have seen beyond the initial 21 day period was also statistically quite signficant although I think it is still a little early to attribute that to Agent Orange. We have to control for additional experimental variables and mostly we have to run more animals to be sure of this. At the lower dose, we didn't see any signficant effect on REM sleep although as we bring in more animals, we perhaps will be able to detect a similar decrease in REM sleep early on. Total food deprivation was not seen to account for any of these effects.

So, if the changes in REM sleep hold up with further studies, they could be signfiicant in relation to the depression. The increased REM sleep animals is analogous to the

change in sleep patterns that are shown in human depressives. What we intend to do is run baselines as long as a year on animals before dosing them so we can be sure that any long-term shifts in REM sleep are not due to any sort of adaptation. We now have animals that we have that very long baseline on.

We of course want to determine the dose threshold for these

effects. We have recently dosed animals with dioxin, (all of what , I have shown you so far is from dioxin free Agent Orange). We now are finally equipped to study dioxin and we are studying animals who have been drugged. We intend to study repeated doses, and also use more sensitive measures of sleep disturbance such as spectral analysis of the periodicity in REM sleep. Thank you.

(Applause.)

MR. KINNARD: Comments or questions? Dr. Barnes.

DR. BARNES; What is your definition for dioxin?

DR. SIEGEL: Well, this is Agent Orange that was shipped , to us by Dr. Young and we didn't indepently ask for a dioxin assay but is supposed to be under .02 parts/million.

DR. BARNES: In your abstract you talk about the change in the REM sleep with a decrease in the frequency of the REM events as opposed to any change in the duration of the events when they did occur. Do you have any comment on that as to how to interpret that?

DR. SIEGEL: Well, I think this is the most common way in which the change in REM sleep are seen

after a variety of drugs and toxins although there are situations in which REM duration is changed, like sleep apnea, where maintenance of the state is disrupted. But, you do see both patterns, and while it is easy to distinguish which is happening.

I don't know what more to say about the clinical signficance.

DR. BARNES: In your comments in the abstract about the 38.5 milligrams per killogram, you comment that there was no change seen in the sleep state duration. Is the implication, that there was no change in the frequency either?

DR. SIEGEL: Right. There was no statistically significant change in either, although there does seem to be a tendency in the same direction as the higher dose. But, it is just not significant.

DR. BARNES: Okay, so the frequency is reduced.

DR. SIEGEL: Right.

DR. BARNES: Would you, say that would be a no-effect level?

DR. SIEGEL: Right.

MR. KINNARD: Any further comments or questions from either of the three investigators? If not, thank you very much. Dr. Shepard.

(Applause.)

DR. SHEPARD: Now, these are very interesting studies, all of them, and we are certainly looking forward to their publication because they will materially add to the basic science understanding of these compounds which still have a great deal of mystery around them and their effects certainly on humans. Hopefully in the process of presenting the animal data, there will be some attempt at our ability to correlate or extrapolate animal data to humans. Dr. Kinnard will be interested in knowing when we anticipate publication of any of these studies so that we can, as they come on line, we will be able to share them with members of the committee.

I would like, now I would like to open the floor for comments, questions, from members of the audience. Yes. If you will come forward please.

COMMENTS AND DISCUSSION

MR. FALK: I am Allen Falk, chairman of the New Jersey Agent Orange Commission. I would like to address my remarks to the issue that was brought up this morning concerning the future role of this advisory committee. I am quite concerned about the discussion that indicates that the committee may dissolve itself, or recommend that it be dissolved in light of the creation by Congress, or the mandating of

the creation of the Advisory Committee on Environmental Hazards. Now, at first flush, it appears as if this, the Advisory Committee on health related effects of herbicides may certainly in some ways be redundant with an advisory committee on environmental hazards. However, speaking on behalf of the Vietnam veterans, the structure that I see in the new law seems to clearly indicate a further dilution of the ability of the Vietnam veterans to have a direct input into the issue of Agent Orange research if this committee is dissolved and the functions are absorbed into the new committee on environmental hazards. I see two key reasons why that would happen. One is simply the dilution that would occur by merging the issue of Agent Orange with the issue of radiation explosion in the atomic veterans. We as laymen have been coming to these meetings for a long time and we see how complex the issue of Agent Orange has become, and how difficult it is to present scientific papers at the quarterly meetings and still have the Vietnam veterans have some input. I think that it is clear that once this issue is merged with a second scientific issue, such as the hazardous effects of explosion to atomic tests, that there has to be a dilution of the efforts.

Now, I see that there will be separate panels in the revision, one for radiation and one for Agent Orange. But, again that is creating a lower level where the Agent Orange issue would be discussed exclusively. Whatever the panels recommend, I assume would have to go back up to the committee. The committee would then be made up of partially of Agent Orange experts so to speak and partially of radiation experts and with a small input of veterans. As it exists now, we have apparently a 33% representation on this body of Vietnam veterans as Vietnam veterans and with no scientific background necessary as a qualification. Of the new body, apparently there will be fifteen members, eleven of whom must be scientists, and four of whom must be veterans although it doesn't say whether they are Vietnam veterans or veterans exposed to radiation. So, if an attempt was made to keep those numbers even, the Vietnam veterans now would become two of fifteen as opposed to three of nine. So, clearly there the numbers are decreased and the input of the Vietnam veteran as a Vietnam veteran is further diminished.

As a Vietnam veteran, I am quite concerned about that. If the discussions that we had in the hallway between the Vietnam veterans who were present,

and the small number that were there seemed unanimous among us that we felt the same way. I would like to go on record as opposing this body considering recommending that it be dissolved because of the fact that if we don't, the Vietnam veteran input couldn't be anything other than greatly diminished if there is only the new body.

Now, my recommendation based on our experience in New Jersey would actually be to go further in the other direction with this body once the new committee which is mandated is created. That is, to increase the number of Vietnam veteran representatives without necessarily having the scientific background. That was the legislative mandate that we were given in New Jersey. We created an Agent Orange Commission with nine members, appointed by the Governor, six of whom are mandated to be Vietnam veterans but no other qualifications, and only three of whom are mandated to be scientists. We have been able to conduct scientific research programs. We have had not problems attracting very well qualified, excellent, good qualified scientific people, medical doctors to work with us under that type of a structure. Yet, we have been able to keep the credibility of the Vietnam veteran in the research

because in effect *it* is the Vietnam veterans who do control the commission. Sometimes I think we get the feeling that there is a fear of allowing the Vietnam veteran, as a Vietnam veteran any control and voice in any body involving the scientific research. From our experience, the Vietnam vet is very concerned in seeing that the research is being done with top credibility. Most in the veteran community understand that that must be done even when they have the ability to out-vote scientific panel members. So, that is simply my recommendation that this body not in effect go out of business, but request that even more Vietnam veterans be appointed there is the second-side to the committee. Thank you.

DR. SHEPARD: Thank you. We will certainly take the points under consideration. A thought that has been occuring to me is that we may want to structure a separate committee to deal specifically with veterans concerns, Vietnam veterans concerns and not necessarily the scientific efforts, but other concerns of Vietnam veterans which may not be being addressed by the scientists. Maybe an information exchange kind of thing similar to what the education/ information subcommittee has been doing.

So, we certainly will take that under advisory. Thank you very much for your comment. Are there any other questions or comments? Yes.

Would you please identify yourself for the reporter?

MR. BURDGE: My names is James H. Burdge, Sr. I am the Agent Orange Chairman for Vietnam Veterans of America, Chapter 12 in Monmouth County New Jersey. I have a couple of things for you Mr. Shepard. On October 23, I received a letter from you telling me that you would send me transcripts of the last two years of the advisory committee meetings. As of this date, I have not received any of the transcripts. I would like to know why. A little follow up with what Mr. Falk was saying. The veterans representatives on this committee today was George Estry, Veterans of Foreign Wars. No one was here. Thomas FitzGerald from the American Legion. He was here as a doctor. There was no veteran representatives here except for this gentlemen here. There should be more Vietnam veterans representing this committee.

MR. WILSON: Let the record show they are pointing to an empty chair.

DR. SHEPARD: Mr. Gorman was here this

morning.

MR. BURDGE: And, let's see what else. Also, a report that I presented to you at the September meeting entitled occupational intoxication and the manufacture of chlorophenol compounds. I think in the transcript it said that you would investigate that report and that you would make a report at the next meeting. This is the next meeting and no one has made a report on that yet.

DR. SHEPARDs Okay, first of all I apologize for not sending you transcripts. There is no problem with that, it is just an oversight on our part.

MR. BURDGE: Also I had written a letter to you, to the Advisory Committee if I could sit on this Committee as a Vietnam veteran representing Vietnam veterans and I was written a letter back and told that, I will read the letter, part of it.

"At present, the committee includes officials from a number of traditional veterans service organizations, American Legion, Veterans of Foreign Wars, Disabled American Veterans, AMVETS, and Paralyzed Veterans of America as well as a non-traditional non-veterans group, National Veterans Task porce on Agent Orange." Coming to the end of it,

you turned me down. I am a member of the Vietnam Veterans of America. I have been very active in this Agent Orange issue since 1978. Basically, you were not recognizing Vietnam Veterans of America as a traditional organization, but then again the Veterans Administration recognizes Vietnam Veterans of America as a service organization. I would like to know who we are. I think the Vietnam Veterans of America should be represented on this committee.

DR. SHEPARD: Okay, good point. We, the committee was not organized specifically to have service organization representatives per se. Okay, in the early formation of the committee a number of Veterans organizations did in fact request that an individual be a member of the organization and that has occurred. I think that the concept has evolved of that a number of service organizations are in fact represented officially as service organization representatives. That has always been a touchy point. That's really not the case. We have obviously veterans on the committee. They do belong to service organizations, but they are there as individuals not necessarily representing the organization in any kind of official capacity.

MR. WILSON: That's not what they said by the

way.

DR. SHEPARD: Excuse me, I think you are interrupting me.

MR. WILSON: Yes.

DR. SHEPARD: So, also we have the fixed number of members on the committee and as vacancies occur, we entertain replacements recommending those replacements be filled to the Administrator who has the ultimate decision as to who sits on the committee. An example of how that has worked in the past as you recall the state organizations felt that they should have a representative on the committee and a request was made to the Administrator. The number of representatives from the state organizations actually met with the Administrator and voiced their concerns and interests in serving on the committee. That effort in fact did result, as you know, in the appointment of Dr. Anderson to represent the various state organizations which he has done, and also Dr. Peter Kahn from the New Jersey Agent Orange Commission as his alternate. There is nothing to preclude anyone requesting membership on the committee. There is a process that has gone on over the years to help people to become members of the committee. So, I don't think there was any intention of slighting you in your

request to be on the committee. We have to consider a number of factors when we ask people to serve on the committee or people ask to serve and then their requests are considered.

MR. BURDGE: But as it is today there are no veteran's organizations here representing except this gentlemen.

DR. SHEPARD: Now at the moment that's true. There were some members earlier today who had to leave for various reasons. I obviously can't coerce members of the committee to come to meetings. You have attended past meetings in which there —

MR. BURDGE: I have attended almost every meeting in the past five years.

DR. SHEPARD: I know you have, and I think you will recall that this meeting today is rather exceptional in that we have few representatives here from the veterans groups. Normally we have many more. As I indicated earlier, two members have resigned because of pressure from other duties, so that creates a couple of vacancies on the committee and we will be looking at people to fill those vacancies.

MR. BURDGE: Well, I would like to go on record and ask for permission to sit on this committee

to represent the Vietnam Veterans of America.

DR. SHEPARD: Okay, as I indicated, I cannot as chairman appoint you to the committee. There has to be a process.

MR. BURDGE: You should be able to put me in touch with the proper people that could?

DR. SHEPARD: Yes, you're, if you wish to serve as a member of this committee, then I would suggest that you write me a letter requesting –

MR. BURDGE: I did sir, and this was your answer saying no.

DR. SHEPARD: Okay, at that time there were not, I don't believe - I am not sure. I would have to check the records. But, at the time my recollection is that there were no vacancies on the committee. There are now some vacancies, and if you wish to submit your name as a nominee for serving on the committee *I* surely will be happy to entertain that.

MR. BURDGE: I will send you a letter tomorrow morning.

DR. SHEPARD: Do you have another question? You mentioned something about a report.

MR. BURDGE: A report that was done in 1961 in Germany. You were supposed to check into that to

find out if it was true or it was not true. It was on chloracne.

DR. SHEPARD: Can you refresh my memory on what the report was? I am sorry.

MR. BURDGE: Occupational intoxication in the manufacture of chlorophenol compounds. It was transcribed at Technical Services Division, School of Aerospace Medicine, Brooks Air Force Base in Texas in 1961 defining chloracne as superficial dermatitis with reddening, swelling, and scaling.

DR. SHEPARD: I'm still not clear what it is that you had asked me to review.

MR. BURDGE: You were supposed to find out if that report was true or not and you were supposed to report to the committee and to the audience.

DR. SHEPARD: Dr. Fischmann, yes, are you aware of this?

DR. FISCHMANN: Yes, you did send it to me and asked me to check on the report. Dr. Shultz was one of the authors and I had the privilege of speaking with him in Germany. The question in particular was whether the dermatitis, which was mentioned in the report with the redness and scaling, whether this was the chloracne that is related to Agent Orange. The dermatitis in the report was the early acute

contact dermatitis that is frequently seen after acute exposure and which is not a chronic problem. Therefore, it is the acute toxic reaction, which may be sometimes followed by development of chloracne.

MR. BURDGE: Did you say it is acute ma'am. I would like to the committee to look at this and tell me if that is not acute.

DR. FISCHMANN: No, that is chronic, because of the duration.

MR. BURDGE: Because it has been there since 1972.

DR. SHEPARD: That's what makes it chronic. A condition which persists over a period of time is generally referred to as a chronic condition as opposed to an acute condition which develops immediately and does not persist.

MR. BURDGE: This showed up in 1972, one year after I came back from Vietnam. In 1980, I filed a serivce-connected disability claim. I am rated at 0% pending since 1980. I can't understand why. I cannot work because of this, and the Veterans Administration is denying me disability. Myself, I don't feel it's right and there are a lot of other Vietnam veterans out there in the same situation. Something should be done and this committee should look into it to find

out why.

DR. SHEPARD: Okay, this committee is really not constituted to review compensation claims or disability claims.

MR. BURDGE: I realize that, but it is here for Vietnam Veterans and Agent Orange.

DR. SHEPARD: Well, in terms of claims and disability claims, there is a structure and a process which the VA has and I am sure you are aware. The first tier of review, and then if that is not satisfactory to the veteran then the Board of Veterans Appeals that re-reviews that case. I don't think that this committee can influence or should influence the process by which the VA deals with claims for disability. There is a very carefully structured mechanism to do that, and I don't see that it is the role of this committee to get itself involved in that process. Now, recently the past legislation that was referred to and discussed this morning does bear on that. That legislation was discussed, its purpose and also many of its effects.

That does set up a process for rule making or regulations for how the VA conducts its claims review process or to that extent there is some new effort being intitiated. Again, I do not feel that it is

really the purview or the responsibility of this committee to get into that area. We are primarily looking at scientific research and to address the concern. It is perfectly legitimate that you should raise the concern to this committee, but I think the committee is not really constituted to address the process of adjudicating claims.

MR. BURDGE: But the new law is going to cover chloracne right?

DR. SHEPARD: Yes.

MR. BURDGEs Okay, they had me listed as service-connected psoriasis. I would not fall into that category.

DR. SHEPARD: That's correct. What you show us now is clearly not chloracne .

I am not a dermatologist, Dr. Fischmann can check you out. It looks much more like psoriasis than chloracne,and I am not aware of any relationship that has ever been suggested between herbicide exposure and psoriasis.

MR. BURDGE: I just can't understand why it takes the VA four years to give someone a rating when in 1980 I was listed service connected. It is now 1984, almost 1985. I still have not gotten a rating yet. I can't understand why with all of the people

that are employed by the VA why it should take them almost 5 years.

DR. SHEPARD: Well, I understand your concerns. I would suggest that you address it to the people who are in charge of that department.

MR. BURDGE: I have and I get no answers. I address everybody in writing, and I get no answers from anybody. My file has been here in this office in Washington since July.

DR. SHEPARD: At the regional office?

MR. BURDGE: At the regional office, since July.

DR. SHEPARD: Well, again, I wish I could help you but I really don't see how I can other than -

Yes.

MR. WHITE: My name is Joseph White. I am the National Director for Minority Affairs and the Maryland State President of the National Association of Concerned Veterans. In 1981 I also submitted a letter to be an alternative for Jon Furst who represents the National Veterans Task Force on Agent Orange. I got a letter from you saying that you received my letter, but no other letters saying whether I could be accepted or denied, and as far as that is concerned, no more information as far as when

this group would be meeting again. I would like to know what happened in that time, that I had to go through other methods to find out what's going on for my behalf and also all the veterans that I represent.

DR. SHEPARD: Well, I'm sorry if we didn't keep you informed as to the availability of membership on the committee. You apparently were aware that there is a committee, and I gather that we are aware that I am a chairman of the committee. I am a phone call away. You could have called me and asked me when the next meeting was. I guess I had no way of knowing that you wanted to be kept informed as to the various meetings. If you did in fact request that and we didn't do it, I apologize. Until very recently, the, Mr. Hugh Walkup has been Jon Furst's alternate. Jon Furst has just very recently resigned from the committee. As you may have heard this morning, we will consider the application for Hugh Walkup to replace Jon. Mr. Walkup has been a very faithful alternate attending all of the meetings. So, I think that he might be a very good candidate for replacing Jon Furst as a full member of the committee. If you, again as I said earlier, if you have interest in being a member of this committee, then I think you ought to make that known to us and we will consider your name

along with others.

MR. WHITE: Well, by being a Vietnam veteran I am 100% involved in this committee because I too have filed suit for Agent Orange poisoning along with the other members of my organization. So, we are very much concerned with what goes on here.

DR. SHEPARD: Good. I am glad.

MR. WHITE: It has a lot to be said about what is going to have to go up in the future.

DR. SHEPARD: I'm sorry, I didn't understand.

MR. WHITE: It has a lot to do with what is going to happen to us in the future, and I think that there may be some more Vietnam veterans should be involved than there are, since we are the ones with the problem and we know more about what's wrong with us than you do.

DR. SHEPARD: I'm sure that's true.

MR. WHITE: Because it is very easy for us to tell you the symptoms, but it is very hard for you to tell us what the problem is. You know, Mr. White he has got a rash, or you say this is psorasis. It doesn't look like psorasis to me. I don't know how you can tell from sitting all the way over there looking at it. I run into this at the VA hospital. The doctor will sit over there. He will put on rubber

gloves, he won't touch me, yet he will tell me what I have got. There is no skin graft. When did medicine become so good that you can from a glance tell what is wrong with someone?

DR. SHEPARD: In the case of Mr. Burdge, I said that from this distance it appeared that his condition looked like psoriasis. I didn't make the diagnosis, I just gave the impression that that's what it appeared to be. He was asking if his condition was related to Agent Orange and I said to my knowledge psoriasis has not been implicated in a matter of Agent Orange exposure.

MR. WHITE: For the record, give us a definition of chloracne.

DR. SHEPARD: That is a matter of record. I am sure Dr. Fischmann would be happy to talk to you after the meeting and give you the benefit of her expertise. She is the chairman of the VA Chloracne Task Force, and I am sure she would be happy to discuss the particulars of chloracne with you.

MR. WHITE: Also photographs of chloracne?

DR. SHEPARD: Photographs?

Yes, I think she has some photographs. We have some slides. I don't know that she has them with her.

DR. FISCHMANN: I don't have those with me.

DR. SHEPARD: We are still working on the monograph. It has been a long, slow process because we have been trying to get authors for the various chapters of the monograph. But, we will be publishing a monograph on chloracne, so that will hopefully give you some pictures.

MR. WHITE: A very, very slow process. I have been out of Vietnam now for fifteen years, and it seems like it is going to take fifteen more years before you all can come to a decision on anything conclusive. Maybe about fifteen years after I die you all will come up with an answer.

DR. SHEPARD: I hope it won't be that long. Yes, Wayne.

MR. WILSON: I raised my hand. Two points, and I raised the issue about these veteran representatives. We went through this business in a subcommittee meeting, Mr. Walkup, as you will recall not too long ago, when we pressed them for an answer and their response was that they are representatives of the Veteran organizations and one of the things that they had to do was run down the block and check with their people before they in fact could take positions on the issues that might be raised. Clearly, they are

representatives of other Veteran organizations and I think that when we replace people to serve the terms of Mr. Woolsey and Mr. Mullen perhaps maybe we should take some veterans on there that may in fact belong to the Veterans of Foreign Wars or another Veteran organization that is not an employee of that particular veteran organization, okay. I am sure that there are a number of Vietnam veterans in this room that belong to any one of those other veteran organizations. Also, I wrote you on November 19th and asked you, I think everyone may have seen a copy of that out there about the issue of the dogs, the sentry dogs.

I haven't been satisfied with the response to that business going back to 1929. I know I gave you short notice since I wrote this on November 19th, but as to cut you a little slack as the saying goes, do you intend to send me a report in response to my request or will it be scheduled at the next meeting or what?

DR. SHEPARD: Okay, we did get your letter. I spoke to Dr. Lingeman and she refreshed my memory on the matter of the dogs. That, by the way that issue,was brought up before I became chairman of the committee,but I did look into the

matter. We had discussed it at a couple of previous meetings. I wonder if Dr. Lingeman could just bring us, or could refresh our memories about the situation first with the dogs and the pathology that was done, and the determination of the illness that those dogs were found to have. Then, we can go on from there. Dr. Lingeman.

DR. LINGEMAN: I do recall that we discussed these dogs prior to Dr. Shepard's assuming the chairmanship of the Committee. Dr. Haber was chairman at the time. I do recall that you or someone else (a representative of a veterans group) brought up the issue originally.

It so happened that I was working in the Armed Forces Institute of Pathology, in the Dept. of Veterinary Pathology during the Vietnam war. I went to work there in about 1967 and I was aware that there were, many military veterinarians stationed in Vietnam. The military working dogs (sentry dogs) were cared for very, very well. All dogs that died received a complete necropsy and all of their tissues were sent to the Armed Forces Institute of Pathology where they were examined thoroughly.

MR. WILSON: Is that examined for the presence of dioxins too?

DR. LINGEMAN: No. At that time

dioxin was not an issue. I was not aware and I don't think anyone else was at that time aware of dioxin as an issue. However, there were reports of a hemorrhogic disease in dogs, breaking out all over the far east including dogs in Vietnam. The dogs hemorhaged from the nasal cavities and elsewhere. This disease was studied at the Walter Reed Army Institute of Research (WRAIR). Some work was done in attempting to transmit this disease from one dog to another by means of a cell-free filtrate. The disease was a transmittal by a rickettsia – a small microorganism. It was proven that this hemographic disease (ehrlichiosis) in dogs was caused by an infectious microorganism, Ehrlichia Canis.

Now, most of the dogs that served in Vietnam were killed in Vietnam. No dogs as far as I know returned to the United States alive. I think there were several reasons, but one of them was the fear of transmitting this disease to dogs in the United States. But, the dogs that died in Vietnam received thorough necropsies. There were pathologists stationed in Saigon and elsewhere. They were well-trained veterinary pathologists. As I said, at the time, no one was aware of dioxin.

There was a discussion in 1979 and in 1980 with a veterinary epdemiologist at the National Cancer Institute of the possibility of doing ah epidemiologic study on these dogs. It is a matter of priority. As you know, there are many so/other projects that need to be done. It is a matter of funding, but there was a man who was willing to do this -- Dr. Hayes at the National Cancer Institute. Now, where do we stand in priorities? In ray opinion it does not appear that this Study is a high priority item but other people could have other opinions. So, if anybody is interested, we can look into it again and find out if NCI is still interested in doing the Study. We have only tissues that were collected ten or fifteen years ago and they may or may not give us any information.

MR. WILSON: The reason I raise this issue is from the old transcripts that in reading the transcript, clearly there was discussion that day, particularly by some of the Vietnam veterans who had reason to believe that there may be a connection between dioxin exposure and what happened to these

dogs.

DR. LINGEMAN: Many of these sentry dogs were used to guard the peripheries of compounds and of course dogs do sniff the ground. They could very well have sniffed some dioxin-containing soil -- there was great interest at one time in following through on this. As I said, it is a matter of priorities. What do you think? Is that a high priority item with you? If the funds are available, should they be spent on these studies, or caring for the veterans who are ill or should they be spent on something else?

MR. WILSON: If there is any possibility at all of a connection, and clearly the fact that these dogs were used in perimeters. I am not a scientist or a doctor okay. Perhaps Dr. Mulinare or one of the other doctors could talk to that. But, I think that at that time in 1979 I think any stone that was moved even the smallest amount should be picked up and looked at. It is one thing to talk about priorities five years later, but I think given what little we knew in 1979, I am very much surprised that someone didn't pursue this and that if a veterinary epidemiologist offered to do something with it, I think he should have been encouraged to do that. That is hindsight now, but I am wondering if we will be

sitting here five years from now having the same discussion on some other area. I am fearful that that may in fact be the case. So, I am not qualified to make the determination of whether that is a priority versus something else, but it is on the record and I think that I will ask people that may be much more qualified to answer that. Given what we didn't know, it may have well have been a very high priority and I am sure the doctors and the scientific people. I think that's the basis for their profession anyway. So, I will let it go at that and I am satisfied to some extent with the response that I got here today, but I may bring it up on another occassion.

DR. LINGEMAN: I will be willing to contact Dr. Hayes to see if he is still interested in doing the Study. It would require funding, and that is going to be government money.

It will be an expensive study to do.

I think we need to set the priorities. Again, I think this is somewhat down on the list of priorities because I am not certain what it's going to tell us.

MR. WILSON: Well, I think I could scratch off a few things around here that aren't as high a priority as that. So, okay, we will discuss

that.

DR. SHEPARD: I think, you know, that was a concern to determine whether or not there was evidence to suggest that these dogs had died of some toxic poison a kin to herbicides. I think Dr. Lingeman very fairly pointed out that it was determined that this was a virus which was endemic in the area, and therefore it is reasonable to conclude that this was not a result of exposure to a chemical toxin. So, I think the only thing that would be gained is to re-review that and reinforce that initial impression. In terms of doing dioxin analysis, I don't think that would be good. I am not sure that the specimens are suitable to do that.

MR. WILSON: But you are not sure of that?

DR. LINGEMAN: Well, they probably are not. The material that was sent back from Vietnam was only a limited amount, fixed in formaldehyde. I don't know how much tissue was sent back, but it is a very small amount. With a fixed tissue we are not certain whether the formaldehyde interferes with the

dioxin or any other chemical that would be in the

tissue. There would be only a very small amount of adipose tissue which is where we would want to look for dioxin. We would have only small amounts of tissues like liver and kidney, and we wouldn't expect to find too much there. So, again, at that time, the dioxin issue had not been raised and hindsight is so good, but at that time no one thought of the possibility of herbicides. I Will be glad to look into it and try to find some answers for you if I can.

MR. WILSON: Thank you.

DR. SHEPARD: Yes.

MR. WHITE: Did I hear you correctly when you said all of those dogs were destroyed?

DR. LINGEMAN: As far as I know, all the dogs were killed then. No dogs returned from Vietnam.

MR. WHITE: I think that's enough reason right there. All of these dogs are not allowed to return to the continental United States.

DR. LINGEMAN: There were several reasons, but one was the possibility of transmitting this infectious disease to the dogs in the United States.

MR. WHITE: But it is not an infectious disease that possibly a man could get or possibly get

from dealing with the dogs?

DR. LINGEMAN: Most micro-organisms, except for rabies, are fairly species limited. There is no evidence that any human became infected with this disease.

MR. WHITE: Then this virus has been labeled?

DR. LINGEMAN: Yes, Dr. Paul Hildebrandt did this study and published three papers. I gave copies to Dr. Haber. 3 will have to look them up. I see Dr. Hildebrandt every day and will let you know. The possibility was raised at the time of whether there was any human syndrome similar to this hemorragic disease. There was concern that this might be a disease infectious to man but it has never been known to occur in man.

MR. WHITE: I am feeling lots of concern right now.

DR. SHEPARD: Are there any other questions, comments? Yes.

MR. WALKUP: I have one on priorities and another on roles of the committee. This morning, the twin study was briefly touched on, and I understand

that it is being, it is under review because a merit review committee recommended that it not be continued, is that correct?

DR. SHEPARD: That's correct.

MR. WALK-UP: Was that merit review panel a part of the protocol? Was that intended from the beginning that that be a stage in the review?

DR. SHEPARD: No, not from the very beginning no.

MR. WALKUP: Then that isn't something that has happened with most of the studies that have gone on before has it? Let me, this is kind of a new concept that I hadn't heard before. This was going on, but I just hadn't heard about it.

DR. SHEPARD: To the best of my recollection, this is sort of the way that it went. There was a request that the twin study be reviewed by an outside merit review panel. At one point we were anxious to have the Office of Technology Assessment review, be that outside review panel and for reasons not entirely clear to me the decision at the time was that the OTA would not review the protocol in a merit review process. Actually OTA, that is really not the role of OTA to merit review Agency protocols. They are an arm of the Congress and they respond to

questions posed to them on scientific issues by members of Congress. So, I can understand their perhaps reluctance to be cast in the mode of a merit review panel at the request of the VA. So, then since they declined or seemed reluctant at the time in the merit review mode, another merit review panel was constituted, some members of which had been on a previous review panel. There were several new members added to the previous oversight committee, and after some deliberation that review panel met on the 30th of August and after a long meeting recommended that the part 2 of protocol 2 not go forward.

MR. WALKUP: Was this oversight committee a --

DR. SHEPARD: It wasn't really an oversight committee. Excuse me, the original oversight? I am sorry.

MR. WALKUP: An oversight committee with some people added to for this. Had that oversight committee reviewed it before?

DR. SHEPARD: Yes.

MR. WALKUP: What was their recommendation?

DR. SHEPARD: There recommendation was that it proceed.

MR. WALKUP: Did the members of that

committee change their minds or was it the new people who came in who changed that outcome of it?

DR. SHEPARD: I honestly can't answer that Hugh. I was not at that meeting. I think that some of the newer members seemed to be able to persuade the existing members that the study should not proceed. But, I can't tell you exactly how that happened because I wasn't there.

MR. WALKUP: In other studies that I have heard up here, there have been peer review panels. Were there, was there also one of those as well as an oversight committee on this?

DR. SHEPARD: On the twin study?

MR. WALKUP: Yes.

DR. SHEPARD: Well, the peer review panel was the one that met in August. That was a group that was supplemented by people added to the previous oversight group.

MR. WALKUP: So there was only one oversight group and one peer. Which was the peer review, which was then added to —

DR. SHEPARD: An augmented committee, yes.

MR. WALKUP: Who decided to augment? I guess who decided to augment the committee and who chose the people who were added to it?

DR. SHEPARD: It is my understanding that Dr. Boren's staff, Dr. Boren is the Assistant Chief Medical Director for Research and Development, and Dr. Green is the director of the Medical service. I believe it was he, or it was under his sponsorship or control that that was done.

MR. WALKUP: I guess I was kind of afraid that was what I was going to learn by asking those questions. I want to say strongly, and I would encourage the scientific members of the panel, if you can't publicly, to talk privately about what looks like happened here at least on the surface of it. I don't know much about what's going on and perhaps you do. But, it seems to reflect what happened was that there was a peer review that was in accordance with how other things had happened here and then that was overridden and I can see a number of reasons why that would be overridden when we are trying to pick up budgets and when this was a fairly comprehensive study that we can ask a whole bunch more questions that we are going to have to research through. But, this process I think raises some real significant concerns about the conduct of research and the conduct of science under the auspices of the Veterans Administration. If something is going to cost too

much or you don't like the answers that it might give you, then you just add some more people who are going to vote the way that you want to vote. Maybe that isn't what happened, but on the surface it certainly appears that way.

DR. SHEPARD: Dr. Hodder.

DR. HODDER: I am just curious, I keep hearing about the staffing the Twin Study. It was presented here and was pretty well received. I was just curious about what I missed that made it turn bad or Mr. Walkup is suggesting that there is other things in the decision perhaps. But, I would be curious however, if we can't get a direct answer perhaps we could get an answer at the next meeting as to exactly why. There were at least three or four scientists sitting here who felt that the study was not only a very good one but should go forward. I would just be curious to see why it was stopped, what, as you say, the other merit panel felt was wrong with it.

DR. SHEPARD: That escapes me too. I have a hard time understanding why that was turned around. I think it would be appropriate for members of this committee if they are concerned to address that question either separately or collectively to Dr.

Boren. I know that there has been considerable interest on the Hill. As *I* say, they are the ones now who will officially ask that the Office of Technology Assessment review the protocol, and that I presume will happen. It has also been requested that the Science Panel on the Agent Orange Working Group review the protocol. That, I believe, is in the process. There are members of this committee that also serve on that committee, and so there may be a more direct way in which you can make your wishes known.

DR. BARNES: Is there any, is there anything that is confidential about the merit review process or what the outcome of it was? The deliberations?

DR. SHEPARD: Not that I am aware of.

DR. BARNES: Well then could we request here that at the next meeting we have that as an item on the agenda to review?

DR. SHEPARD: Yes, I don't see why not we couldn't do that.

DR. BARNES: I would recommend that.

DR. SHEPARD: Or before.

MR. WALKUP: Could we also ask Dr. Boren to come and tell us about that? Would that be appropriate for us?

DR. SHEPARD: Sure, that would be entirely

appropriate.

MR. WALKUP: I would like to suggest that we do that then.

DR. SHEPARD: Your wish is known. Any other questions or comments?

MR. WALKUP: I did have another, although my previous suggestion may bear on it about the role of the committee and whether we are going to continue. I think that some of the statements that were made earlier I want to reinforce. I think all of us have wondered about how effective we have been and what contributions we have been able to give, especially after input from a number of veterans those appealing that this is one of the, this is a forum that is available that would go away if this committee were abandoned and the other committee assume the same role. More than that, I think the functions of the other committee are quite different from those that we have. We have not had input into the regulations, into compensation, into the issues that are outlined in the legislation even though sometimes some of us wish that we could have, we haven't had that function. But, and at the same time, this new panel isn't going to have the functions that this group has had of reviewing and planning research or making recommendations for

avenues for research or dealing with issues such as information, education, and implementation of systems within the Veterans Administration to carry out the legislation. The law defines a very restrictive role for this other group, and as uncomfortable as maybe sometimes we make it for you and the Veterans Administration, I think that's a useful thing for us all to have, the Veterans Administration as well as the veterans, so that there is an avenue for letting some of these issues out and hopefully for getting to some sort of resolution. I think a group like this is limited at best. There is a way that there is an avenue for that kind of information to flow out both to get some, some dialogue across the two or three cultures that are here, and two, to get help, get some outside input into the decisions that the VA has to struggle with and make it a fairly sensitive area. I don't think that other group is going to provide that. I think that many of us who were on that group, we would be very busy dealing with what the research of this specific body of knowledge tell us about these specific things that could be compensated and whatever recommendations when things are to happen. That would be very different here from what we have done here to date.

I would encourage other members of the committee to recommend that we or some group, probably all of us would prefer not to leave, but as a group continue to do some of the functions that we have, if there is this other group coming up.

DR. SHEPARD: Those are good points Hugh, and as I said. First of all, I would encourage any members of this committee, either through me or directly to the Administrator with a copy to me so that *I* know your thoughts voice your opinions on this subject. I know, it is going to be a difficult question. I certainly understand your point, and I think it has merit. This committee has provided an opportunity for Vietnam veterans to voice their concerns, to bring their concerns to the VA. I think it would be reasonably fair discussion of the concerns.

The new mandated committee is not really mandated to do that. Now, that isn't to say that it couldn't be directed or chartered to do that. So, what you see in the law does not necessarily restrict the committeee in any way. I mean, it mandates that the committee will do certain things, but I think that the case could be made for the fact that additional duties will

be placed on that committee. Now, whether it is unreasonable to expect the committee to deal with all of the scientific issues concerning radiation and dioxins, herbicides, and also be responsive to the concerns of veterans -- that may be too much for one committee to handle appropriately. So, it may be that this committee should continue in some form, maybe with more emphasis on veterans concerns and less emphasis on the science other than translating the science and bringing the results forward.

I would encourage all of you to put down on paper what your thoughts are on the subject and probably do it fairly soon because I am sure that the Administrator and the Chief Medical Director will be asking some of these same questions. I would encourage your early response.

Any other questions, comments? Well, thank you very much. I appreciate all of you being here.

(Whereupon, at 2:00 p.m. on December 11, 1984, the meeting adjourned.)

*U.S. GOVERNMENT PRINTING OFFICE: 1985-461-890/35615

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

Twenty-Third Meeting
March 26, 1985

June 1985 Washington DC 20420

VETERANS ADMINISTRATION

Advisory Committee

on

Health-Related Effects of Herbicides

Veterans Administration
Central office
Room 119
810 Vermont Avenue, Northwest
Washington, D. C.

March 26, 1985

ADVISORY COMMITTEE PRESENT

BARCLAY M. SHEPARD, M.D., Chairman
Director
Agent Orange Projects Office
Veterans Administration
Washington, D. C.

GEORGE R. ANDERSON, M.D.
Occupational Medicine and Toxicology
Texas Department of Health
Austin, Texas

DONALD BARNES, Ph.D.
Senior Science Advisor
Office of the Assistant Administrator for
Pesticides and Toxic Substances
U. S. Environmental Protection Agency
Washington, D. C.

GEORGE T. ESTRY
Appeals Consultant
Veterans of Foreign Wars of the United states
Washington, D. C.

THOMAS J. FITZGERALD, M.D.
Medical Consultant
National Veterans Affairs and Rehabilitation Commission
The American Legion
Washington, D, C.

RICHARD A. HODDER, M.D., M.P.H.
Colonel, US Army
Deputy Director, Division of Medicine
Walter Reed Army Institute of Research
Washington, D. C.

CAROLYN H. LINGEMAN, M.D.
Office of Hazardous Substances Information
National Toxicology Program
Bethesda, Maryland

JOSEPH MULINARE, M.D.
Centers for Disease Control
Atlanta, Georgia

WALTER PHILLIPS, representing
CHARLES A. THOMPSON
Administrative Assistant
National Service and Legislative Headquarters
Disabled American Veterans
Washington, D. C.

HUGH WALKUP
Department of Human Resources
City of Seattle
Seattle, Washington

ALTERNATE

PETER C. KAHN, Ph.D.
Associate Professor of biochemistry
Department of Biochemistry ana Microbiology
Rutgers University
New Brunswick, New Jersey

OTHERS PRESENT

JAMES BURDGE
Vietnam Veterans
State of New Jersey

FREDERIC L. CONWAY III
General Counsel's Office

CHUCK CONROY
Coordinator, West Virginia Agent orange Assistance Program

ALAN FALK
Chairman, New Jersey Agent Orange Commission

MR. TERRY HERTZLER
State of Pennsylvania

ALAN HOLMES, M.B.A.
Director, Health Statistics Center
State of West Virginia

JEFF STANTON
Vietnam Veterans' Consumer Health Representative
Oregon Public Health Advisory Board

JOSEPH WHITE
National Association for Concerned Veterans

A G E N D A

P R O C E E D I N G S

CHAIRMAN, DR. BARCLAY M. SHEPARD: I think we better get started.

As usual, we have a fairly full agenda and unlike recent meetings, however, we hope to get through the agenda by noon today. That's an ambitious goal.

Unlike some of the recent meetings, we will have only a plenary group. We will not divide into subcommittees today because we thought that the items on the agenda were of sufficient general interest that we would not break up into separate subcommittee sessions.

So I'd like to welcome everybody to the 23rd quarterly meeting of the VA Advisory Committee on the Health-Related Effects of Herbicides. As in past meetings, this meeting is open to the public under the terms of the Federal Advisory Committee Act.

We ask that audience attendees please sign the register in the outer lobby, if you have not already done so, so that we may keep a record of people interested in our program.

As usual, we'll have a time to solicit questions from the audience. If you have questions, please write them out and give them to Don Rosenblum so that we can handle them in an orderly fashion.

OPENING REMARKS BY THE CHAIRMAN

CHAIRMAN SHEPARD: There have been a number of recent activities. The Air Force Health Study, Ranch Hand *II,* mortality update is included in the members' folders. We're also very interested in two recent developments; that is, a study that has been reported *by* the State of Massachusetts, a mortality study, and we're looking forward to a more detailed report on that study later on in the program.

We're also interested in the fact that the State of West Virginia is conducting a very similar study based on Vietnam era veterans who were eligible for and received a state bonus.

The comparison of these two studies obviously will be very interesting.

We've just received the first draft of the ongoing effort to update the analysis of the world's literature on phenoxy herbicides and related compounds. Clement Associates have just submitted drafts of Volumes V and VI and we will be reviewing those shortly.

The lay language summary of Volumes 1 through IV, at long last, is about ready to go to print. It's been a fairly long drawn out process, but I think we have the makings of a good document and we'll look forward to the appearance of that.

You may recall that, from time to time, we've discussed the possibility of conducting an educational conference primarily designed for VA employees to deal with new issues and information relating to Agent Orange. We had originally hoped to have something on the scale of a conference that was last held in May of 1980.

Unfortunately, budget situations being what they are, we've had to cut back a little bit on the extent of that conference in terms of the content as well as the number of attendees that we had hoped to bring to the conference.

However, we have been approved for funds for a conference which we plan to hold the third week in August here in Washington, which will deal primarily with the issue of chloracne. Chloracne still remains an issue of concern, in part because it's not a very frequently seen disease and, therefore, there's some question as to its diagnostic criteria; and, of course, it has great relevance to the matter of claims adjudication.

So we hope to have this conference the third week in August dealing primarily with the issue of chloracne, and I think I'm right in saying that this will probably be the world's first conference on chloracne. We're very happy to sponsor that.

We are looking at the possibility of listing other professional organizations and societies to cosponsor that

with us. Because of its unique topic 1 think it may attract a good deal of attention ana hopefully will result in a successful conference.

The Agent Orange Registry Program continues apace and we still are experiencing a very high level ot requests for the examinations. We've been sort of looking tor a peaking effect, but we haven't really reached that.

We think that, in part, this has been related to the class action suit. However, I think that explanation is beginning to wear thin, now, because that class action suit has been settled now tor some time, but we continue to experience a high level of requests for the examination.

So I'm sure there must be some other explanations that go along with that.

However, we report that the initial examinations are ranging between 4400 and 4700 a month, during tne last few months of calendar year '84. In January ot '85 initial examinations performed were 7500. That's an increase trom 4700 to 7500 during the month ot January and similar increases have been seen in the requests tor follow up examinations.

So I thought you'd be interested that that effort is still ongoing and seems to be fulfilling a real need.

FUTURE OF COMMITTEE

At the last meeting ot this committee, there was a

discussion about the future of this committee. Considerable thought and effort has gone into resolving that issue.

As I think I pointed out at our last meeting, the charter for this committee expires in April – that is, next month. There was, at one time, some consideration tor merging the nonscientific aspects of this committee with another committee which addresses concerns of Vietnam veterans; namely the Readjustment Counselling Committee. I may not have the name quite right.

That committee is also planning to nave its charter renewed. Their charter expires in May.

So the current plans call tor a rechartering or this committee and a rechartering of the otner committee, ana the process for that is currently underway ana is in tne final stages of internal VA review – tnat is, the charter for this committee.

So depending on the outcome ot that a aecision will be made as to the future of this committee. it is a little bit early to, I think, speculate on all the various possibilities.

It seems that, in the near term at least, there's a real likelihood that this committee will continue in some form in the year ahead,

I was hoping Dr. Arthur Blank would be here to discuss the other aspect of that. He's a very busy man. he

may be able to be here a little later.

I'd like now to call on Dr. George Imes, a Colonel in the Army Veterinary Corps, to respond to some concerns that have been expressed from time to time in this committee on the role of military working dogs in Vietnam.

We're very please to have Colonel Imes with us this morning.

MILITARY WORKING DOGS IN VIETNAM

George Imes, D.V.M.

DR. IMES: Good morning.

I spent from October 1970 until October '71 in Vietnam. I was in the United States Air force at that time.

I just want to give you a briet idea ot what we were seeing. I was assigned at Cam Ranh Bay. That was the Air Force referral center for Air force military working dogs. The Army center was down at Long Binh.

The Air Force had very tew problems with their military working dogs, at least problems not requiring special shipment and treatment to the center where 1 was stationed. The Army, on the other hand, had many aogs in tneir special treatment facilities.

The primary reason for this was there were basically two different populations of dogs in Vietnam. There were sentry dogs, which served for perimeter security at night, and there were patrol dogs and tracker dogs that

were daytime working dogs and they were out in the field with the Army platoons.

The biggest problem that was encountered, disease wise with the dogs, was the Richettsial disease caused by Ehrlichia canis. The disease accounted for deaths of many dogs, and treatment, and dogs out of service.

It was a very serious thing and a lot of work was put into it, and eventually it was determined that it was an infectious disease caused by this Rickettsial and that it treatment was instituted on the basis of some clinical pathology findings that many times the disease could be controlled, be cured and controlled.

The disease early on was known as the Idiopathic Hemorrhagic Syndrome. That's before we had any idea what was causing it. Dogs would just start to bleed, for no reason at all, from the nose.

Then as more information came in, as far as the clinical pathology, we found that the dogs suffered from a decrease in all the circulating blood cells or blood cellular elements; and the reason for the bleeding, then, was related back to the decrease in platelets.

We found that if dogs dropped a white count down to 7,000 and hematocrit (HCT) -- the hematocrit being a measure of the actual cells in the blood; it'll give you an idea of the red cell count, which normally runs around 50%. It (HCT) got

per cubic milimeter
down to 37 and, as I said, the white count down to 7,000 we automatically would put these dogs on a two week treatment or an antibiotic.

Usually they would then respond and be all right.

Other problems were just routine things that are seen in almost any dog population . Conditions that are seen often in the summer here in the States we would tend to see year around there because it was like summer year around; those being some of the dermatitis problems.

At Cam Ranh we felt we were fortunate. We didn't have as many problems with dermatitis. We always had the handlers take the dogs down to the South China Sea about once a week and just play with them there in the water and groom them and work with them, and it seemed to have the desired results as far as dermatological problems were concerned.

I primarily would like to answer questions that anyone has; any questions about the dogs, the symptoms or other lesions seen in the Rickettsial

CHAIRMAN SHEPARD: Let me, just for your sake, Dr. Imes, suggest that one of the concerns that was expressed — and this was some time ago at one of the early meetings of this committee — was that the hemorrhagic diathisis that you have described was in some way related to toxic chemical exposure, and that that might indicate several things.

First of all, that the handlers of those dogs

might have been exposed to the same toxic substance ana, therefore, might lend themselves to some kind ot epidemiological research. That was one point.

The other point was that this was some kina ot indication that there was a toxin, whether it was a herbicide or some other toxin, that might have affected larger numbers of ground troops or other military personnel serving in those areas.

I was just wondering if you would comment, because I'm sure there would be some questions in this area, on your thoughts and what consideration, it any, was given to that possibility.

DR. IMES: At the time, 1 don't think anyone considered such a thing. I don't think anybody was thinking about toxins in the environment.

One thing 1 should point out aDout the disease and one reason that we saw it so much in the patrol dogs is because it is a tick borne disease and these doys were out in the bush, in the country. It was a tremendous problem keeping ticks off of these dogs.

The handlers could just practically work 24 hours a day and they could not keep the ticks off.

Whereas in these sentry dog facilities, the second population — the dogs that were the security tor the Dases at night — they were in fixed kennel facilities with

concrete runs and chain link fences. They were amenable to spraying with tick sprays to keep the tick populations down and we could deal with the problem much better.

So that's one of the things 1 meant to point out, the reason I think that there was such a difference in the two populations of dogs? primarily kenneling facilities.

No one ever had any concerns about toxic products or seeing dogs they thought had been poisoned in any means. We had dogs die of heat stroke; dogs die ot gunshot wounds and other trauma.

But I can think of no instances where anyone suspected anything such as a toxin.

CHAIRMAN SHEPARD: Let me just ask one other question that may be in the minds ot others. Was there any attempt to look for human health problems that might nave been traced to this same or similar conditions among the handlers that were most closely exposed to these animals?

DR. IMES: Not to my knowledge. AS far as 1 know, this is a very host specific disease. I have never known ot a case being reported, a human case, of this particular Rickettsial disease.

CHAIRMAN SHEPARD: Fine. Thank you.

Are there any questions from members ot tne committee for Dr. Imes?

Yes. Dr. Lingeman.

DR. LINGEMAN: Colonel imes, what specific chemicals were used to control the ticks ana fleas. 1 presume these dogs had fleas.

DR. IMES: Some fleas; but ticks were the big problem.

Now, as I recall it was malothion. We sprayed the kennels and the dogs.

DR. LINGEMAN: Is malothion known to damage or injure the dogs in any way, or is it pretty safe?

DR. IMES: Well, you know, it's pretty safe or we wouldn't use it.

It's a pretty expensive product we were using up there. At that time, we figured it probably cost around $5,000. Each dog was probably worth about $5,000 to get it to Vietnam.

CHAIRMAN SHEPARD: Any other questions from members of the committee?

[No response.]

CHAIRMAN SHEPARD: Well, because Colonel Imes has opened up this interesting topic, I think we'll deviate from our plan and entertain questions from the floor.

Dr. Kahn?

For those people who are not at the table, would you please come up to the table and take this microphone so that your comments and questions can be recorded? Thank you.

DR. KAHN: There's one report ot a metabolic study of dioxin in dogs that's been publisned, 1 think in 1981. It was mentioned there that the animals seemed to nave a severe problem of renal clearance. This was a laboratory study.

Were there any kidney problems that might have cropped in the animals that might suggest that they were having renal clearance problems ot something that they might have gotten?

DR. IMES: The dogs with ehrlichiosis did develop kidney problems, but —

DR. KAHN: That would be contingent on tne disease.

DR. IMES: Right.

But other than that I'm not aware ot any.

DR. KAHN: Yes. Would you come up, please?

MR. WILSON: Wayne Wilson trom New jersey.

Doctor, would it be possible at tnis time, given the passage of a number of years, to perhaps nave some copies of some of the autopsies that were done on those dogs?

DR. IMES: I'm sure they would be available. Those records are all held at Lackland. All tne aog medical records on all the military working dogs are neld at the center down at Lackland and they're busy now putting them all in computers.

I'm sure that they should be available there.

MR. WILSON: Do I have to make a Freedom of Information request, or can I just ask that we be provided with a sampling of those?

DR. IMES: Oh, excuse me.

In our accession folders at AFIP there is a copy of the veterinarian's necropsy record.

MR. WILSON: I'm a layman doctor, so —

DR. IMES: Well, the autopsy.

MR. WILSON: okay.

DR. IMES: There's a copy of the record held in each dog's file.

They're there and there's approximately 1300 dogs for which tissues were sent from Vietnam. By regulation for all military working dogs the tissues are to be sent to the AFIP where we examine them microscopically and then the tissues are stored at the AFIP.

We have around 1300 dogs represented there. Around 400 were from the era of '64 to '69 and about 800 or so from '70 to '74.

MR. WILSON: Okay. I think we would be very interested in, if we could having a cross section, a small number of autopsies or whatever you call them covering those spans of years, perhaps like from '65 up through '71 or '72.

Also, let me ask you this: Would it be reasonable to assume that — I know someone is here from DOD and base

perimeters were routinely sprayed throughout Vietnam — ammunition dumps, places where Air force sentry dogs would go at night and so forth, it seemed to me from having served in Vietnam.

Isn't it possible that these dogs would have been exposed to one or more of the different herbicides? Is that reasonable to assume that?

DR. IMES: Well, I would think so. 1 don't know where the herbicides were sprayed, 1 was never in an area or knew of an area where they were being sprayed; but 1 suppose, certainly.

MR. WILSON: Okay.

You never saw any real differences between the Air Force dogs and the Army flogswhen you did an autopsy on the two?

DR. IMES: Well, it was the Army dogs that were having all the trouble with the Rickettsial disease. There was a tremendous difference there.

MR. WILSON: But nothing unique with the Air Force sentry dogs. I mean, they just died of normal causes?

DR. IMES: We had the rare case of the Rickettsial disease; but usually they were put to sleep — The Air Force had a lot of older dogs in Vietnam and, as you know, military working dogs are all put to sleep at the end of their careers.

When they are unable to perform their duty anymore, they're euthanized. A lot of the Air force dogs were the older dogs.

The Army? Since their dogs were out in the field they were getting young fresh dogs from the states and we had the older dogs, eight-, nine-, ten-year-old dogs, some as old as 11 and 12.

MR. WILSON: One more question. Are there figures available of now many — particular the Air force doys, just the Air Force dogs — dogs died per year? Do you think that might be available?

Could you look into that?

DR. IMES: I'm not sure. 1 suppose.

There's very few dogs in the Air force dogs that died of natural causes. They usually were put to sleep.

MR, WILSON: I would like to know how many were put to sleep in the course of a year.

DR. IMES: Well, you should be able to yet that through Lackland. That information probably is available at Lackland.

MR. WILSON: Do I have to make a separate request or can I make it through you?

DR. IMES: It probably would be better to go directly through the military working dog people. They're very protective of that program and I'm not sure 1 would nave

any more luck getting the information —

You won't have any problem getting the information, don't get me wrong; but I don't think it would be any easier for me to get it than it would be tor you to get it.

CHAIRMAN SHEPARD: Yes. Other questions?

DR. LAMM: Dr. Lamm.

Dr. Imes, has the Rickettsia been isolated trom the tick observed there, and have any antibody studies been done on the dog handlers?

DR. IMES: I'm not sure whether the Rickettsia has been seen in the tick, itselt. It's been isolated trom ticks. I'm pretty certain of that.

This disease is widespread. It's throughout the world. In fact, it was first recorded, I think, in Tunisia or South Africa. Back in the early '60s the british were seeing this disease in Singapore, but they didn't have a handle on it. They didn't realize it was Rickettsial disease when they had these dogs start bleeding.

In all instances, it's been tick associated.

As far as serology on handlers, I don't know of any that has been done.

CHAIRMAN SHEPARD: Are there any other questions for Dr. lines?

[No response.]

CHAIRMAN SHEPARD: If not, thank you very much, sir. We appreciate your coming down.

DR. IMES: Thank you.

CHAIRMAN SHEPARD: Very interesting.

I'd like now to call on Dr. George Anderson to give us a report on various state government activities.

Dr. Anderson?

STATE GOVERNMENT ACTIVITIES

George R. Anderson, M. D.

Accompanied By: Jeff Stanton, Chuck Conroy and Terry Hertzler

DR. ANDERSON: Make sure that you get this down.

Dealing with the 19 or 21 states which have Agent Orange programs is a little bit like the 13 original states getting together. Sometimes you hear from them; sometimes you don't.

Prior to these meetings, usually a month or two ahead, I attempt to go out to the states with a little memo and ask them if they have anything that tney'd like to say. I am glad to report that Oregon is getting the Agent Orange program going.

I had a very interesting phone call with Mr. Jeff Stanton from out there. He said he was going to be here at the meeting.

Is Jeff here?

MR. STANTON: Yes. I'm here.

DR. ANDERSON: There he is; from the State of Oregon.

He didn't have too much to say, unless he'd have something to say now, other than the fact that they were getting going. With your permission, may he come up?

CHAIRMAN SHEPARD: Yes. That would be great.

Happy to have you here.

MR. STANTON: My name is Jeff Stanton, and I'm the Vietnam Veterans' Consumer Health Representative for the Oregon Public Health Advisory Board.

Our program was started in 1983 by the state legislature and, in June of '84, we officially got off the ground and started releasing our health questionnaires, in December, we had 506 questionnaires returned. As of this month we have 1800.

So in a four month period we've doubled.

We have some things that I don't know if any of the other states are doing. We are checking into the use of Dapsone - this is on the questionnaire - and also cigarettes being issued by the military and whether they smoked; okay?

What we're trying to do is look to see if there's any correlation between a multiple exposure.

One thing that we just found from our printout which looks very interesting is it seems that there is an

upswing, starting in '67 and going to about '70, and then it's coming back down. We're now cross checking with the use of Dapsone and being exposed to Agent Orange.

We don't know if there's any correlation, but that's presently what we're doing.

VOICE: Upswing in what?

MR. STANTON: Major health problems; specifically liver problems. We also find a large increase of liver and chloracne in problems with multiple tours.

CHAIRMAN SHEPARD: Excuse me. I was distracted for a minute.

Maybe you clarified it, but could you go over that again? These results are on the basis of questionnaire responses, or is there going to be any attempt to follow up with medical examinations?

MR. STANTON: Okay. Right now, we've received 1800 questionnaires. We went through and we pulled out all of those that have been rated by the Veterans Administration, all those that had had liver biopsies and fat tissue.

We had, I think it was, 44 liver biopsies submitted and 28 fat tissues biopsies. We're following those first. Then we're taking the multiple tours and we're in the process of verifying those, and we're checking with the Veterans Administration to see exactly what the test results

are.

There was a position presented to the Health Advisory Board which is now being considered ana it was just submitted to the state legislature last Friday that we ao limited testing doing a 24-hour urine test — I don't know exactly what it is since I'm a layman — looking tor PCT, porphyria cutanea tarda.

Basically, that's where we are in tne process.

CHAIRMAN SHEPARD: You said looking at the VA test. It this the Agent Orange Registry, or is this claim results?

MR. STANTON: Okay. We have 33 veterans that are rates by the VA. The State of Oregon has one Agent Orange case that is recognized by the Veterans' Administration and that was from chloracne and it's zero percent.

We have 33 that were listed ratings anywhere from o percent through 100 percent. There were six of them rated at 100 percent. Of the six, four of them had liver biopsies, four of them had multiple tours, five of them are Marine or Army in the jungle, four of them were issued Dapsone, ana they were all serving between '67 and '70.

It also does the same thing as you go down? but ot the six that are rated 100 percent an additional three ot those also reported cancer. So we were just surprisea to see this many that were rated by the Veterans Administration ana

all of them having liver and chloracne problems.

They may not be recognized as Agent Orange, but they are rated.

CHAIRMAN SHEPARD: Okay. Thank you.

Are there any questions from members ot the committee?

DR. FITZGERALD: Yes.

You say they have been rated as having chioracne problems. How many have been diagnosed as chloracne?

MR. STANTON: In the State of Oregon recognized Dy the Veterans Administration there was one, and that was rated at zero percent. We have, I believe it was, 44 cases that were reported as chloracne.

DR. FITZGERALD: Reported by whom?

MR. STANTON: by the veterans ana listed on the Agent Orange health survey as rated by the Veterans Administration. Right now, what we're aoiny is going back through and verifyiny those diagnoses. Those are our top priorities right now.

DR. FITZGERALD: So what you're saying is that there have been cases that claim to have chloracne, but this has not been definitely established?

MR. STANTON: out of the 44 there's one that's been verified by the VA.

DR. FITZGERALD: Okay. You also saia that there were a significant number of fat biopsies done.

MR. STANTON: Yes.

DR. FITZGERALD: Who were they done by?

MR. STANTON: There was a total of 23 biopsies. Some were done by the Veterans Administration, ana some were done by the — If you wait a minute, I've got a chart here. I'll bring it up.

[Pause]

MR. STANTON: oh, another thing that I forgot. Going back through our death certificates in the state ana the deaths due to drugs, we received one private physician secondary cause of death due to 2,4,5-T exposure; 35-year-old male and he did serve in Vietnam. So he was listed by a private physician, and we're obtaining those records, also.

DR. BARNES: What was the cause ot death?

MR. STANTON: What they listed was 'Death due to Drugs'. Secondary cause of death was 2,4,5-T exposure.

Now, the health division has pulled the death certificate (*) and they're in contact with the physician to get a full report of what the primary cause was, and also if there was an autopsy performed. So they're verifying all that.

Now, the question you had, Dr. FitzGerald?

DR. FITZGERALD: I'm interested in the tat biopsies; where they're being done.

MR. STANTON: There were 23 liver biopsies and, of the 23 liver biopsies, b of these were — they also had the

(*MR. STANTON subsequently provided a copy of the death certificate which indicates: immediate cause; pulmonary embolus; due to or as a consequence of; hypercoaguable state; due to or a consequence of; carcinoma of pancreas; other significant conditions-conditions contributing to death but not related to cause given above; hemocardium, 2, 4, 5-T exposure.)

fat biopsy. Right now, the health division is in the process --

We just got our report last Thursday and the health division is talking with the Veterans Administration on getting the health records from them.

DR. FITZGERALD: Who was doing the tat biopsies.

MR. STANTON: Of the 23, 18 ot them were done Dy the Veterans Administration and the remaining were done by private physicians,

DR. BARNES: That's the liver, then.

DR. FITZGERALD: The liver.

DR. BARNES: What about the tat?

DR. FITZGERALD: The fat.

We're not aware that the Veterans Administration is doing any fat biopsies.

MR. STANTON: At this time, I don't Know that; but we should have some answers within the next week.

MR. WALKUP: Is this what the veterans are telling you? This is self reported information?

MR. STANTON: These are all the ones that were reported by the veterans, came out on the questionnaire, and we are obtaining preliminary physician reports back confirming that they had biopsies done,

MR. WALKUP: so those reports about the tests are from the physician, not from the veteran.

MR. STANTON: They're from both.

MR. WALKUP: From both.

MR. STANTON: Right.

And, again, we're finding that there's a large number of multiple exposures and all of the serious ones that are coming in, that were being verified, there's multiple tours, Dapsone exposure, Agent orange exposure, and smoking.

yy percent of these are all Marine and Army units with the serious problems. We can see that there's an upswing in '67 starting to come back down in '70.

So that's what they're going through right now is pulling all of those that submitted questionnaires between 1967 and 1970 to find out if, in tact, they tail into the segment,

CHAIRMAN SHEPARD: Dr. Lingeman, did you have a question?

DR. LINGEMAN: Oh, I was going to ask about the 35-year-old man. You said he died of a drug overdose?

MR. STANTON: Under the State ot Oregon, they consider 2,4,5-T a drug and they list it in the official — Health Division deaths due to drugs report 1982.

DR. LINGEMAN: But you said that was listed as a secondary cause of death. What was the primary cause ot death?

MR. STANTON: Right now, J don't know. The health division is pulling all that information.

DR. LINGEMAN: It wasn't recreational drug use.

MR. STANTON: No.

DR. LINGEMAN: Not heroin or any other drug.

MR. STANTON: No. There was no association to that.

I know he had some type ot cancer, but whether that was the primary cause ot death I don't know.

CHAIRMAN SHEPARD: Do you have point or contact in the state health department whom we could contact for the follow up on these?

MR. STANTON: Yes, I do. 1 can provide all tnat for you.

CHAIRMAN SHEPARD: Okay. I'd appreciate that.

Dr. Hodder?

DR. HODDER: Are you having support trom an epidemiologist or you getting consultative advice?

MR. STANTON: Yes. We have a Dr. Campbell with the health division who is doing all that. In tact, we have two epidemiologists. We also have an Agent Orange Advisory Committee which is made up of five physicians. Two ot tnem are with the Veterans Administration; two ot them are epidemiologists/dermatologists.

There are five physicians on the panel.

DR. HODDER: The reason I asked is because 1 think it's very important if you're going to be doing a lot ot work

with, a lot of information, it doesn't come as a surprise that a group of men will have a certain incidence ot liver disease.

The real question is compared to a normal — or, not to use the word 'normal', compared to a group, say, that didn't go to Vietnam, who are veterans — is there more disease and is it associated with exposure the veterans had specifically? I Vietnam

CHAIRMAN SHEPARD: Any other questions?

MR. WALKUP: Do you h ave a time line tor this project or for a report coming out of it?

MR. STANTON: Originally the program was to end this year and the legislature has extended it. There is appropriated to the Health Division for the biennium beginning July 1, 1985, $83,000, and $20,000 to reimburse the Attorney General for expenses incurred by the Department of Justice.

We expect the first initial full report in about September or October.

DR. BARNES: Could 1 ask how many Vietnam veterans you think there are in the state?

MR. STANTON: We have received estimates somewhere between 40,000 and 50,000, and we've received almost 2,000 questionnaires in.

CHAIRMAN SHEPARD: Very good.

Thank you very much, Jeff. We appreciate your

coming.

Dr. Anderson?

DR. ANDERSON: I thought you might tind it ot interest to hear from the State of Oregon since tnis is tne first time they have paid a visit here.

CHAIRMAN SHEPARD: Yes, indeed. Thank you.

DR. ANDERSON: The state of Hawaii. We received a letter from Dr. Rellahan. He states that they now have 418 Vietnam veterans in their program, on which tney have, of course, gotten the questionnaires completed.

They are planning on bringing these individuals into their offices for interviews and to nave them point out on maps where they served in Vietnam, and get some kind of an index of exposure on them.

In the State of Iowa, tne Registry lists 45,000 Vietnam veterans. A preliminary analysis ot survey information to date reveals no statistically significant information compared to Iowa or national standards.

Their's is a survey, a study looking at disease instances and so forth as to what is present among their veterans. I have a copy of their questionnaire here which is designed for computer use.

Pennsylvania? I received from them a tine rundown on their Registry, their case control study ot sott tissue sarcomas, lymphomas, selected cancers and so forth. They

also sent me a copy of their tape which they send to physicians in the state as a part of their educational effort.

I have listened to it several times. It's very good; straightforward, lays it on the line tor the physicians.

Did you get a copy ot this?

CHAIRMAN SHEPARD: Yes, 1 did. Thank you.

DR. ANDERSON: Yes. I'm sure you've listened to it.

CHAIRMAN SHEPARD: Yes, I ayree.

DR. ANDERSON: It's very good.

They also have an excellent small manual, a brochure which they put out to the physicians in the state which is very good. It's on very tine paper, smooth. It's very readable and they're doing a good JOD in bringing tne story of Agent Orange to the physicians in tne State ot Pennsylvania.

I heard from Ohio. 1 believe John Gaeuman is nere today. I believe he was going to come in at your request and be at the meeting.

I'm not going to cover what he wanted to talk about it he is here.

CHAIRMAN SHEPARD: Is the gentleman trom Ohio present?

[No response.)

CHAIRMAN SHEPARD: Maybe he'll come in later; we'll call on him at that time.

DR. ANDERSON: All right. Fine.

Chuck Conroy, of course, is here trom the state ot West Virginia. He always has a good rundown on their program.

As you know, the West Virginia program is very similar to the Texas program in many respects. They're moving along beautifully.

With your permission, could Chuck say something it he wants to?

CHAIRMAN SHEPARD: Yes. Sure.

Why don't you come up, Chuck, it you'd like to.

There's going to be a discussion ot tne West Virginia Mortality Study later on on the agenda.

DR. ANDERSON: Yes, we know.

CHAIRMAN SHEPARD: But, fine. Maybe you'd like to address some of the other issues?

MR. CONROY: Thank you, Dr. Shepard.

Chuck Conroy, Coordinator tor the West Virginia Agent Orange Assistance Program.

To date, the West Virginia Department ot health has received requests for medical testing tor possible health related effects of Agent Orange exposure trom 4800 state

Vietnam veterans. This represents approximately 12 percent of West Virginia's Vietnam veterans.

In order to register for medical testing services available under our program, a veteran simply completes and returns a postage paid portion of an informational brochure. We have provided these brochures to all state Vietnam veterans.

If the veteran objects to being tested by the Veterans' Administration, which is phase one of our testing protocol, they so indicate on the informational brochure and arrangements are then made to test these veterans from start to finish within the state system.

To date, 107 veterans – or approximately only 2 percent of our respondents – have refused to be tested by the Veterans' Administration; and this figure has remained relatively constant throughout the life of our program.

Upon receipt of this request for testing, provided the veteran has no objections, an appointment is arranged for that veteran to receive an Agent Orange screening examination from the Veterans' Administration Medical Center closest to them. In West Virginia, we have four VA centers.

Over the past 24 months, over 3,000 of these VA examinations have been scheduled. Our office makes every attempt to make these appointments as convenient as possible for the veteran and this quite often involves making

appointments around work schedules, et cetera; ana the VA has been most cooperative in making these appointments as convenient as they could for the veterans enrolled in our program,

After receiving the VA examination, the veteran is then forwarded a consent form enabling the VA to release copies of their examination results to the West Virginia Department of Health. The veteran is also asked at that time to complete a comprehensive medical questionnaire and provide copies of medical records from any private physician the veteran may have visited over the past three years.

Once all these medical records ana medical questionnaires have been received, they are then forwarded to our health department epidemiologist to assure that all required exams, lab work, x-rays have been performed ana are included with the veteran's medical records.

After all these medical records are gathered, they are abstracted by the health department epidemiologist noting abnormal test results and symptoms which can possibly relate to Agent Orange exposure. All this information is then coded, as is the questionnaire the veteran completes, and entered into a computer so it's easily retrievable.

Upon completion of this review and evaluation, the health department epidemiologist then forwards the veteran's records to a physician who the health department has placed

on contract at one of the state's three medical schools; at Morgantown, Huntington and Lewisburg.

To date, 27 percent of our applicants reside in the Morgantown area, 46 percent in the Huntington/Charleston area, and 22 percent in the Lewisburg area.

The physician then determines what additional testing may be required from our medical testing protocol. Some of the examinations we have in our protocol are electromyelographs for veterans experiencing peripheral neuropathies, genetic counselling, and a battery ot neuropsych' tests.

All the physicians that conduct our examination have an expertise in environmental and occupational medicine.

Subsequent to the veterans' examination and testing by our state physician, they are afforded an opportunity to discuss the results of the testing with the physician. A final report with diagnoses and test results are then sent to the veteran and to the west Virginia Department of Health.

To date we have completed approximately 200 examinations and have received diagnostic summary letters on the first 53 examinations. Of course, the confidentiality or the veterans' medical records is maintained at. all times ana the veteran is advised that both VA and health department medical testing is totally free ot charge.

As Dr. Shepard has indicated, we have commenced a mortality study to determine how many West Virginia Vietnam veterans have died since the conclusion of the war, specifically the cause of death; and that study should be completed in the near future.

Finally, the program in recent months has been extremely active in providing information and assistance to Vietnam veterans wishing to file a claim form with the court in New York. This activity has involved the dissemination of claim forms, instruction booklets and informational updates on the state of that settlement to veterans.

As a direct result of this activity, West Virginia now ranks 14th in the nation in the number of claim forms returned to the court. West Virginia has returned 5,273 claim forms to the court in New York.

It's somewhat interesting, really. I have asked the court to provide a breakdown. Keep in mind the caveat here is that, at this juncture, these are all self reported medical problems.

Of the 5,273 claim forms returned to the court, 182 report that they are currently suffering from cancer; 1,535 reported that they have a birth defected child; and 811 have reported that their wives experienced a miscarriage.

As I say, this is all self reported. At this point in time, there's no medical verification for those

claims forms that have been returned to the court.

CHAIRMAN SHEPARD: Thank you very much, Chuck.

Are there any questions tor Mr. Conroy trom members of the committee?

(No response.]

CHAIRMAN SHEPARD: West Virginia should be complimented on its fine program and we appreciate the good words concerning the cooperativeness of the VA.

Thank you very much, Chuck.

Will Mr. Holmes give a more aetailea report on the workup?

MR. CONROY: Yes.

CHAIRMAN SHEPARD: Okay. We'll call on Mr. Holmes in a minute.

Dr. Anderson?

DR. ANDERSON: Yes. The State ot California. They now have an active program that's getting started.

They sent me a copy of their legislation, which is dated September 25, 1984, which states that "Under the existing law the Department of Veterans' Affairs assists Vietnam veterans and their dependents in pursuing possiDie claims against the United States arising out ot exposure to herbicides, including Agent Orange; and provides an outreach program to inform those veterans of the possible detrimental effects of herbicide exposure in Vietnam."

Under existing law, this program will terminate on June 30, 1985. I understand it has been extended until June 30, 1987. So California is now in business.

I have no further details as to how they set up their program or how they are going to function.

I know we have Wayne Wilson here from New Jersey. His communication with me in January was rather short. In fact, you didn't leave me anything to say, Wayne.

MR. WILSON: We're not saying anything at this point.

DR. ANDERSON: You're not saying anything. Well, that's very good because I'd like to take a little time now and talk about the great State of Texas, and what we're doing to try to solve all the problems of the world, including the border along Mexico.

A little over a year ago, we received from the VA a list of names and addresses of veterans in Texas who had received the Agent Orange physical and were in your Registry; some 4500 at that time. I realize it's larger now.

We sent out to these veterans a questionnaire asking five simple questions to see what the response would be because it wasn't that we didn't appreciate the physicals that the VA was doing — and the cooperation in Texas has been excellent.

We have no difficulty at all. We yet everything

we ask for.

We thought it might be ot interest to near trom veterans what they thought about the physical examinations.

The first question, of course, does not apply to you but it does to us. "Is this the first time you have heard of the Texas Veterans' Agent orange Assistance Program?" 1510 responses, out of 4500. bo about a third responded to our questionnaire.

1,010 said yes and 500 said no. We asked this question to see if our outreach program was getting to the veterans of the state. It appeared it was not to our satisfaction.

The second question is: Where do you live? Urban areas over 100,000 and nearly 700 ot the respondents lived in large cities, which was primarily, of course, ban Antonio, Dallas, Fort Worth area and Houston.

Urban? 25,000 to 100,000; 300. Urban, less than 25,232 and rural areas 267. So we teit a little better realizing that perhaps we were getting to the rural areas.

As you know, in Texas we have difficulty getting to the rural areas because it is a rather large state.

Question 3: Has your health changed since you had the Veterans Administration's Agent Orange physical examination? Now I'm getting to things you have an interest in.

766 said their health is the same; 35 said they

were better; 530 said they were worse. tio of the 1,510, 1,490 responded. 20 gave no answers or had not taken Agent Orange physicals, which is an interesting point.

You had some names on the list in the Registry who had never had a physical. We found this of interest.

Question number 4: Did the VA find a medical problem as a result of the examination? 539 said yes; 837 said no; of 1,376 respondents. So a goodly number said, yes, something was found.

If yes, were you treated or followed up for this medical problem by one of the following: Veterans Administration, b27 said they had gone back to the VA; a state hospital, 20; private or public hospitals, 85; private or clinic physicians, 189; or none, 311.

This was 1,132 respondents.

It's interesting that the majority went Dack to the VA hospital for follow up treatment or their medical problems. The next largest group didn't do anything. They just accepted it as it was.

CHAIRMAN SHEPARD: Let me ask. Those figures you gave going back, were they the same that said they reported some kind of a health problem, or was it the whole group?

DR. ANDERSON: The way we asked the question and the way we tabulated it, I can't answer your question. 1 think when I get back I'm going to look at that; but we didn't tabulate —

We don't have this in our computer. We had to work from raw data.

The sixth question was; What is your usual occupation, job or kind of work today? We wanted to know what the veterans are doing today and we used the international classification of job descriptions, of which, of course there is 1 through 9. Large groups, we used the large groups.

Professional, technical and management, 228; clerical and sales, 236; service occupations, 229; agriculture, fishery, forestry and so forth, 24; processing, 50; machine trades, 155; bench work, 70; structural work, 163; miscellaneous, 104; retired, disabled, unemployed or no answer, 201.

Most of our veterans are employed working every day, enjoying we hope **fairly** good health. I'll give you a copy of this so you can have it.

I was recently asked by our state legislature, which is now in its session -- You may or may not know that the Texas legislature goes into session once every two years for a period of time that varies from a few weeks to as much as 2-1/2 months.

They asked the question: What about the Agent Orange program since the legislative Bureau of the budget had recommended that the program not be funded? The Texas Department of Health, which now houses the program, was up

for sunset legislation this year.

Therefore, they were kind ot like a zero budgeting system. You go back *to* zero and then you add to it on a priority basis the various programs.

It would appear that we will most likely De funded next year. It's just a matter of proper legislators getting into the act.

The individual, Mr. Shaw, Larry Shaw, who came to one of the meetings here three years ago, proposed the Dill back in '81 and is still in our legislature and will be working toward getting proper funding.

We have been very busy. We have modified our University of Texas research programs somewhat. We nave completed the sperm study in which we were looking at f lourescent Y bodies in sperm to see if they were an indicator of some toxic exposure.

It would appear that it would De a negative report. We're hoping that the medical branch in Galveston will be able to get this published within the next tew months. That study is *completed.*

The UT cytogenitic study should complete by August of this year. We're hoping to continue it. However, there's a question as to whether or not it's showing enough to where we should continue it.

We feel we probably have enough subjects in that study; several hundred at this time.

The University of Texas immune suppression study? We will continue that enlarging the number ot subjects, which you probably are very much aware is a difficult problem to get control subjects for immune studies. Nobody has a standard that you can compare anything against.

We're hoping that that will be continued.

We have a new study in which we are looking at liver enzymes — P-450 and AHH enzymes — the induction ot which causes certain changes in cultured lymphocytes which we are looking at. That's a new study.

We are also doing uroporphyrins on selected veterans, particularly those of which we suspect they've had some liver disease, so we correlate the medical records with our selections committee in attempting to see it we can find some porphyrin problems.

The Texas veterans' Agent Orange program is a viable and active program.

We have nearly 2,000 Agent Orange tiles on our veterans in the program now. Our file consists ot the following information:

We have registration, ot course. We have completed a questionnaire which includes military occupational and family medical histories. We have signed medical records release forms, signed program participation forms, military personnel records which we get from St. Louis, a DD Form 214 for discharge.

We have a considerable number now with the overlay maps from the Army showing their correlation between location of their unit and the herb tapes on spray missions. Those that we don't have I have worked out from experience now working with the maps I've gotten from the Army.

So I can pretty well, now, do my own as to exposure time and place.

We have the individual's military medical records, the Veterans Administration medical records, civilian hospital records, physician medical records, spouse and children's medical records, copies of correspondence and telephone call records with the veterans, and University ot Texas study reports from those individuals who have been selected for study.

We're attempting now to get all this into our computer to see what it's going to tell us. These tiles are invaluable to the veterans as they file their claims in New York District Court.

We can give him, in most cases, a tile which is about an inch to two inches thick, which contains all the following information, which gives a good medical background on the individual for the use of the court.

I think that pretty well winds up what 1 have to say today. Would there be any questions on the Texas program?

CHAIRMAN SHEPARD: Are there any questions trom

members of the committee?

[No response.]

CHAIRMAN SHEPARD: I would congratulate the State of Texas. It seems like they've done a fantastic job.

I was going to ask you, Dr. Anderson: Have you attempted to get any kind of data base on veterans who did not serve in Vietnam for purposes of comparison? I presume that the 2,000 you mentioned are all presumed to be in country veterans.

DR. ANDERSON: Those are veterans.

We have not, as such. Now, in the control group that we have selected, we have a considerable number of non-Vietnam veterans in that group because we're dealing with the same age group.

Now, our controls are all matched by age and area, occupation as close as possible, medical background, smoking, drinking, income index; as many variables as we could to try to get a good control. We didn't attempt to make a non-Vietnam era veteran, as such. A large number did come in, though.

CHAIRMAN SHEPARD: So your controls then are males of the same age, —

DR. ANDERSON; Same age.

CHAIRMAN SHEPARD: — But not necessary veterans.

DR. ANDERSON: Within five years of the same age.

CHAIRMAN SHEPAKD: But not necessarily veterans.

DR. ANDERSON: Not necessarily veterans, no.

CHAIRMAN SHEPARD: To the 2,000, though, are Vietnam veterans —

DR. ANDERSON: Yes.

CHAIRMAN SHEPARD: — and then you have an additional number of controls. Is that right?

DR. ANDERSON: We have an additional number tor those veterans that were selected tor study in the University of Texas system. We have matched controls tor those ana there are about *200* that we have studied so tar.

We'll be selecting another 50 later on this month or next month under the new protocols. We have dropped the old protocol on sperm and so forth and gone into new protocols.

Then that means, of course, we'd have to yo back and contact some of the previous veterans ana controls to gather blood on them for. the new studies. We don't Know how successful we're going to be because, as you know, people tend to move around and you begin to lose track ot them.

One of our big problems in our studies is just keeping track of the individuals and keep a current address.

CHAIRMAN SHEPARD: Thank you very much, Dr. Anderson, for that complete report.

Yes, Mr. Walkup?

MR. WALKUP: Dr. Anderson, if I were able to persuade Dr. Shepard to include copies ot the state

reports in our minutes each time, would you have any problems with that?

DR. ANDERSON: No. I would have no problem with that.

MR. WALKUP: I think it might be helpful to the committee and other people who are here to have the complete information that's coming from each of the yroups. It the rest of the committee agrees, I'd like to see tnat.

CHAIRMAN SHEPARD: I think it's a yreat idea. 1 don't want to put too mucn of a burden on Dr. Anderson, though.

Are they in such a form that they can be submitted to us?

DR. ANDERSON: Well, most of them are just in a letter form in which they are letting me know what's yoiny on.

Now, occasionally they'll nave an attachment. for instance, West Virginia, they have a group ot attachments, Pennsylvania does, which we could just take ana reproduce.

I'm sure the states wouldn't object at ail because it was sent to me with the purpose of bringing it to this committee. So I think it's a good idea.

CHAIRMAN SHEPARD: fine. Well, let's work on that. (See State Reports beginning on page 146)

Any other questions or comments trom members ot the committee?

DR. BARNES: Is the State or Texas planning to review anything special as these studies come to fruition in the way of putting out a publication on them or just whether they go into the scientific literature one by one?

DR. ANDERSON: You have heard of the university system in which you publish or perish?

DR. BARNES: Yes.

DR. ANDERSON: The individuals who are doing these studies are university professors and the reason that we are very slow in getting reports out is that I cannot release information, even if I have it right now, on these studies in detail until they've had an opportunity to publish.

If you've ever had to deal with the university, you know what I'm talking about.

They own the data although we paid for it out of our funding. I think the privilege should go to them to have the right to publish.

CHAIRMAN SHEPARD: Yes.

DR. LINGEMAN: These studies will be peer-reviewed before publication, which is a very valuable safeguard. The results are thus subjected to the scrutiny of their scientific peers.

DR. ANDERSON: Oh, yes. Of course, the university system has the review system with its own architecture to approve all their research programs before they start. Then, of course, anything that they publish they must approve of.

CHAIRMAN SHEPARD: Thank you.

Any other questions for Dr. Anderson?

[No response.]

CHAIRMAN SHEPARD: I'm pleased to recognize Mr. Terry Hertzler, who just walked in, from the State ot Pennsylvania. It's too bad you just missed the nice comments that Dr. Anderson just made about your efforts.

I'm wondering, Terry, it you have any comments that you'd care to make? The various states have been reporting on their activities and if you have anything you'd like to share with us we'd be happy to have you do so at this time.

I don't mean to put you on the spot.

While he's taking his chair, let me just say that I had the distinct pleasure of Deiny in Philadelphia a tew weeks ago at the request of the state Agent Orange Commission and the multiservice center in Philadelphia, along with Congressman Bob Edgar and some other individuals.

We had, I think, a very useful symposium on the whole issue of Agent orange which was well attended by a number of Philadelphia area Vietnam veterans. 1 was very appreciative of that opportunity to address veterans in the Philadelphia area.

Terry?

MR. HERTZLER: Thank you, Dr. Shepard. Sorry 1 missed the presentation, Dr. Anderson. We weren't able to

get a report out lately because we've been very busy.

As Dr. Anderson probably reported, our Registry program is picking up. We're trying to contact all ot Pennsylvania's Vietnam veterans.

We know of approximately 200,000 that served from Pennsylvania and so forth. We've been able to at least make contact with 47,000 of than.

We're cleaning up our list right now ana trying to get further information from them so that we can determine exactly what Pennsylvania's role should be ana how we can best support the federal effort as well as taking care ot our veterans within the state, itself.

Dr. Shepard alluded to the seminar we've run. We've run three of them in Pennsylvania so tar,ana we have two more to go. We're hitting five major areas ot Pennsylvania in order to try ana contact ail the Vietnam veterans, find out exactly what their problems are it tney haven't contacted us and also bring a better working relationship with them and any of the groups or organizations that are currently sponsoring programs for Vietnam veterans and Agent Orange, in particular.

Our physicians' educational piece, we're hoping to update that a bit. There was a minor error which we've corrected on that and it's been fairly well received by those that have received it, and we're hoping to expand that because the physicians in Pennsylvania have been grateful to

at least learn something about what's going on other than what they've read.

We're continuing our efforts. Right now, legislatively we go out of business June 30th of this year. Legislation is being introduced this week that would continue us for another two years with increased funding.

We've only been operating at $150,000 a year. We're hoping for at least $230,000 or more next year.

That's all we have at this time. Vve hope to have you back again for the next step.

CHAIRMAN SHEPARD: Thank you very much, Terry.

Are there any questions tor Mr. Hertzler?

[No response.]

CHAIRMAN SHEPARD: Fine. Thank you very much tor coming.

We had hoped to have two individuals trom the State of Massachusetts report on their recently released mortality study, but I just got word that one was called suddenly for jury duty so he's not available and I'm not sure about the other individual.

Am I correct, neither Chris Gregory nor Dr. Richard Clapp are available?

[No response.]

CHAIRMAN SHEPARD: Well, I'm sorry. 1 was looking forward to their report because the members of the committee also have in their folders copies of the Massachusetts

Mortality Report.

MORTALITY AMONG VIETNAM VETERANS IN MASSACHUSETTS

CHAIRMAN SHEPARD: What I'd like to do at this time is to call on members of the committee to review that report and get back to me, hopefully by the end of the third week in April, the comments on their review of that report.

Some of you, I think, we provided copies earlier and if there are any of you on the committee who would like to comment on the report at this time I would like you to do so.

It's also been made available to the member of the Agent Orange Working Group for their review.

DR. BARNES: Barclay?

CHAIRMAN SHEPARD: Yes, Dr. Barnes.

DR. BARNES: People who have looked at this have had additional questions about it. This material has been made available to people over the past month or so and people who have looked at it have raised certain questions more or less as factual matters.

My understanding was that people were going to be getting back to the State of Massachusetts and making inquiries on this.

Do you happen to know if anyone has gotten answers to those kinds of questions?

CHAIRMAN SHEPARD: No, not to my knowledge, Dr.

Barnes.

I was in hopes that we have had that opportunity today. I'm very disappointed that the members from Massachusetts weren't able to show up.

I have had one meeting with Dr. John Constable, a surgeon on the staff of Massachusetts General Hospital, who has had a keen interest in this whole issue, has visited Vietnam a number of times, and has kept very closely abreast of the activities of the state as well as the government in general.

He and I met a couple of weeks ago when he was here in Washington on another matter and we went over some of the details in the study. It's my understanding that the study reflects data which was available from death certificates and from the veterans' bonus list; both those who served in Vietnam and those who did not.

At the time the report was published, there had been no attempt to confirm various diagnoses or review medical records other than information that appeared on the death certificate. So I think that it's accurate and fair to say that this report is a first step.

In fact, in the introduction, I believe, there are words to that effect; that this is not a definitive study in the sense that firm epidemiological conclusions could be drawn, but certain hypotheses have been raised that deserve further evaluation and analysis.

One of the disturbing findings of the report is that there seems to be a significantly increased incidence of soft tissue sarcoma, or proportion of soft tissue sarcoma, among disease Vietnam veterans as compared to those who did not serve in Vietnam.

So that's something that clearly we have a keen interest in and want to follow up on further or have the state follow up on further.

It's my understanding that they are now considering having the tissues from these soft tissue sarcoma cases reviewed by a competent pathologist in this area. I took the liberty of visiting Dr. Enzinger • out at the AFIP to see if he had any recommendations and I got some names of individuals and provided those names to Dr. Constable.

So hopefully they will be in the process now of reviewing some of the pathologic materials from those soft tissue sarcoma cases, at least.

DR. BARNES: So that will be looking at the cases of false positives.

CHAIRMAN SHEPARD: Yes; or to confirm the diagnosis. Possibly false positives.

DR. BARNES: Yes. People might raise questions then about a equally rigorous look at the false negative possibilities. Is there any thought of addressing that?

CHAIRMAN SHEPARD: Well, as I say, this was just a discussion I had with Dr. Constable, who was not directly

responsible for the study. He's been acting in the capacity of an advisor.

So, as I say, I was hoping that we'd yet some answers to those questions today that I think are very important. But we will attempt to contact the folks in Massachusetts to see what their ongoing plans are because I think this is a very important question that they've raised.

Dr. Lingeman?

DR. LINGEMAN: The importance of histologic verification of diagnoses can't be overemphasized; I see the list here is quite heterogeneous except for the fibrous sarcomas. Hemangiopericytoma is an extremely rare neoplasm and it's particularly rare in males. It tends to be more frequent in females. I think the histopathologic verification is very important.

Dr. Shepard, I have a question concerning a previous study or studies that might illustrate this point. Some of the people from NIOSH had collected intormation trom several different industrial plants in which individuals were exposed to dioxin and related compounds.

At first it appeared that there was an excess ot soft tissue neoplasms if you counted several plants togetner. Then I understand that later these were all subject to histologic review.

I've not heard the final outcome ot that. Do you

know what finally came of that?

CHAIRMAN SHEPARD: I think what you're referring to, Dr. Lingeman, is not the NIOSH Registry, but a collection of reports that NIOSH made and submitted, I think in the form of a letter to the editor, suggesting that there seemed to be an increase in the number of soft tissue sarcomas when one put together, I think, three or four studies.

I think there were seven of those cases. They were all reviewed by Dr. Enzinger out at AFIP, as you suggested.

It's my recollection that at least two of the seven, in his opinion, did no fit the criteria for sort tissue sarcoma. I think NIOSH is now republishing that data.

DR. BARNES: It's published.

CHAIRMAN SHEPARD: Is it published?

DR. BARNES: Yes. It was distributed —

CHAIRMAN SHEPARD: That's right. You're right. Right.

But I don't have that information in front of me. We'll be happy to share it with you.

Does anybody else remember the results of that?

VOICE: The seven reports, NIOSH looked at them and what they did was to determine that for three of them they could not document exposure to dioxin situations. The fellow said he worked there and was a truck driver, something like that; but they could not actually document

they had been exposed to dioxin containing materials.

So those three were set aside. That left four and of those four Dr. Shepard pointed out two on his pathological reexamination two were determined not to be soft tissue sarcomas.

CHAIRMAN SHEPARD: Are there any other questions from members of the committee? Dr. Kahn?

DR. KAHN: Two comments.

First of all, on the NIOSH business in which some of the men are initially included, there is a rather large dispute as to the exposure of some of them. I know of one case in which the man was a maintenance worker and was all over the plant, but because no records are made on a daily basis of where maintenance workers go he was therefore disqualified as having been exposed, and yet he was in virtually every part of the plant.

They're using as the exposure information solely material from the company files, and the company files are very patchy; sometimes complete, frequently not. So that's a matter of some considerable dispute as to whether all of those men should have been tossed out.

I think that dispute is still going on.

Now, on the point that you just raised on the gap of time between induction into the service and the appearance of soft tissue sarcoma, the median latent period in the Swedish soft tissue sarcoma studies was 15 years between

exposure ana the onset of symptoms.

CHAIRMAN SHEPARD: I was aware of that, ana that's why I brought this up.

DR. KAHN: Yes, so that's right on the ball park.

DR. LINGEMAN: But it could be as short as six years, as I remember.

DR. KAHN: Yes, it couia. The spreaa on that is quite large. So that it's right on the money today.

CHAIRMAN SHEPARD: Thank you, Dr. Kahn.

Are there any other comments or questions concerning the Massachusetts stuay, given that we haven't naa very much time to review it?

[No response.]

CHAIRMAN SHEPARD: Okay. If you would, kinaly review that and get back to me with your comments by the middle of April I would really appreciate that because I'm sure we're going to be asked to comment on it. So I'a like to get that process started.

CHAIRMAN SHEPARD: Yes, Mr. Walkup.

MR. WALKUP: A couple of things, Dr. Sheparo.

First, since the people from Massachusetts weren't able to be here today, assuming that this committee still exists next time, could we invite them back again ana maybe bribe them or something so they come?

Then, also, I see that we have a letter from Senator Cranston asking for review ot the Project Ranch hand

mortality update and maybe it would be appropriate tor members of the committee to review the Massachusetts study and the other information that we received to date, together with the Ranch Hand update in responding to the letter.

CHAIRMAN SHEPARDs Yes. That's one ot the reasons I suggested that we'd like to have that review; so in case Senator Cranston asks us for review of the Massachusetts study, we could have that processed.

Thank you.

Now I'd like to call on Mr. Alan Holmes from tne State of West Virginia to give us a status report on their mortality study.

Mr. Holmes?

WEST VIRGINIA MORTALITY STUDY

Alan Holmes, M.B.A.

MR. HOLMES: I am Alan Holmes, Director ot tne Health Statistics Center for the State of West Virginia.

We were asked approximately a year ago to take a look at doing a mortality study of our West Virginia veterans. Our study has been going on, I guess now, tor about five months and we are not ready to release data.

We are just now getting to the pnase where we nave data coming up and we are going through the statistical analysis. So I do not have any data to release, but 1 thought I would go through a little bit about our methodology.

Our methodology is quite similar to the Massachusetts study, but since we didn't talk about that I'll maybe talk a little bit more about it.

There is a three page handout with little boxes on it which we've put together. (See pages 176-178)

Basically, we're doing a study from 1968 to 1983 and we had the luxury of starting with a bonus tape. In 1974, the State of West Virginia provided a bonus for our veterans. So we have a computer tape of some 83,736 individuals who did qualify for the bonus.

This was a starting point for our study. From this tape, we were able to separate those individuals into three groups: those veterans who were not in the country, or era veterans, of which there were 41,783; those that did serve in country, of which there were 41,064; and those that had died in service, and there was 889.

One of the unique things at this point that we found in West Virginia compared to the other states is that when you look at the veterans in country versus not in country we're splitting on a 50/50 split. I think in other states or across the nation it's about a two to one split with twice as many veterans in the era as opposed to in country.

So we are somewhat unique there, although West Virginia has always been unique when it comes to the proportion of its population that has served in all the wars

clear back to the Civil War.

At this point, we attempted to cross match these individuals from this bonus tape with our mortality data. We have all of our mortality data from 1947 to present on computer tape.

The mortality data is split into two groups. from 1979 to '83, we had social security numbers on our mortality data. Of course, we have social security numbers also on the bonus tape.

From 1968 to '78, our mortality data aid not have the social security on computer tape although it is on the death record.

So from the period ot 1979 to '83 we took a look and we cross matched on social security numbers, the first match, from our bonus tape to our mortality tapes ana for the 1968 to '78 period we first came up with possible name matches which generated approximately ten names tor every one that we finally found.

As we generated possible matches, we then went in and pulled the death records and were then able to do a social security match as well as further checks on the name.

What we found, then, in these two groups, in the era group we match 614 death records ana in the in country group we matched 620 records.

Of the era, group, which was the 614, there were four females who had died. Again, none ot these females had

served in country. There were 610 males. In the in country group, as I said there were no females. So all 620 were males.

We then broke down the two groups of males into nonwhite and white males, and we found in the era group 3u nonwhite males and 480 white males, ana in the in country group 36 nonwhite males and 584 white males.

The second two pages basically just show the aye groupings of these two groups. They are very similar.

The in country group averaged about 35 years at death and the era group I think was about 33. It was tairly close. Those are rather gross numbers, but —

Basically, then, what we are doing, we're doiny a standardized porportional mortality study where we have now isolated — As I said, we only had four remales and we're not going to be doing any more with them, but we are working with two groups in country and out of country, both whites and nonwhites and all males as a group.

We also are looking at what I call our general population; all individuals, all males who haa aiea between 1968 and '83. We took all individuals who aiea in this period and excluded from that file the veterans that we have matched.

So we have a control group trom our general population which, to the best of our knowledge, are males, white and nonwhite, who did not serve in country or in the

service during this era.

So what we are doing is a proportional mortality between our in country, comparing those to our era veterans, and our in country compared to our general population. We'll also be looking at our era veterans compared to general population and we'll be looking at both in country ana era veterans compared to the general population.

As I said, the methodology is very similar to Massachusetts in that we started with the bonus tape. we are looking at both males in terms of white and nonwhite; Dut because we have a rather small sample size tor nonwhites I think we're going to focus on the white males, as a group, and the combined males as a group.

Of course, we'll be looking at these same groups in our general population.

I would hope that within the next two montns we would have the data to be published. We have a new health director coming on within the next month and so we'll have a little transition period until we can bring him up to date on the results of the study.

We had one request from our veterans concerning suicides, and that was another reason that we decided to go in and do this study. So I think that when we are done we will have a pretty good feel for what our in country veterans are dying of and be able to compare them to our control group of era veterans and then to compare them to our general

population.

CHAIRMAN SHEPARD: Thank you very much. That was a very interesting report.

I congratulate you on the thoroughness of this. i was struck by something that is not the case in the Massachusetts study, and that is the similarity in West Virginia between those who served in Vietnam and those who did not.

Am I correct in assuming that there was a differential bonus paid and that's how the distinction was made?

MR. HOLMES: Yes. There was a differential bonus.

CHAIRMAN SHEPARD: Is there going to be any attempt to verify the service records on a sample of those?

MR, HOLMES: Yes. We have pulled a sample or rive percent, a random sample of five percent, and are looking at those to make sure that they were initially put in the right grouping.

CHAIRMAN SHEPARD: Any questions?

DR. FITZGERALD: I don't know if I missed it. What is the timeframe for your study?

MR. HOLMES: 1968 to '83.

DR. FITZGERALD: No. I mean, when is the study going to be completed?

MR. HOLMES: When is it going to be completed? I would say within the next two months we will be releasing it.

DR. FITZGERALD: Any other questions? Yes, Dr. Mulinare.

DR. MULINARE: What proportion of veterans are on your bonus tape from all sections in West Virginia?

MR. HOLMES: I can't answer that. I don't know of any way that we can determine that.

Now, one thing we did look at — I don't have the numbers in front of me — is that of the individuals who had died in service, which we're not including in this study, we did find that we had a list of those veterans who had died in combat.

Of some 500 and some veterans that had died in combat 100 of those were not on the bonus tape. That is the only figure we have to get at that.

DR. MULINARE: Were survivors of veterans also eligible for applying for the bonus?

MR. HOLMES: Yes, they were.

There were things that we didn't know when we first started the study, That was the first question: how many veterans did not get into the bonus? The second part was, of course, the problem that every state will run into — there were residents of the state as of 1974 — is: Where have they gone?

Many of them have moved out of state. There's no way that we will ever be able to track them.

of course, so what we in essence have are matches of our West Virginia residents who were on the bonus tapes in '74 and who died in the state or who died out ot state ana were still residents and the records were sent back.

DR. MULINARE: What procedures were used in 1974 to make corrections as to the availability ot the bonus?

MR. HOLMES: I'm not sure.

Chuck, do you know?

MR. CONROY: Yes.

They used pretty much conventional methods. They went to all the veterans' organizations, let tne veterans' organizations fill out the bonus forms for them. They aia a number of PSAs, Public Service Announcements.

We thought that they had a fairly adequate coverage of the fact that the bonus was available; but, as Alan has mentioned, I have received phone calls from veterans that did not receive the bonus.

As far as actually capturing that number, I think it's going to be almost impossible.

MR. HOLMES: Of course, since this is a proportional study, you'd have to assume that tor those wno did not apply and those that did in terms ot mortality perhaps it would be similar, except for the fact that there could have been some that had died.

That is one bias that could be introduced, that it an individual had died before the '74 period you would

presume that their next of kin would be less likely to apply. So those could possibly be missed.

But we're assuming that an equal number would be missed in both the in country and the era groups; ana in the proportional study that will factor out.

CHAIRMAN SHEPARD: Yes. Dr. Hodder?

DR. HODDER: I was curious about how you could look into some methods of validating that. There has always been a veterans' death benefit and I believe that's centrally recorded.

I don't know whether that's only burials or not, but if that has the address of the veteran at death you should be able to see those who have filed a death claim ana then see who are from West Virginia; and pernaps you can yet an idea of proportional reporting.

CHAIRMAN SHEPARD: Good point. Yes.

I was just going to suggest that we'd be happy to work with you. As Dr. Hodder has indicated, the VA has a fairly complete file of fact of death since virtually all veterans are eligible for some form of burial benefit; and that requires the filing ot a death certificate and a claim usually by the funeral service personnel.

Somewhere in the Massachusetts report it says

that they think that approximately 98 percent ot the eligible veterans actually did apply for the bonus; and you might ask them how they arrived at that figure because I was wonaeriny the same thing.

I was wondering how they got that fact.

Yes, Dr. Mulinare?

DR. MULINARE: One other question for you.

Exactly how did you determine Vietnam veteran status from the bonus? Was it based on their DD-214?

MR. HOLMES: Yes. There's a DD-214 in the file ot each of them.

DR. MULINARE: Does the DD-214, on it, specifically say 'Vietnam service' for every veteran.

MR. CONROY: What the 214 has is that the individual received a Vietnam service medal or Vietnam campaign medal. That's what's on the 214.

DR. MULINARE: So it's based on the service medal.

MR. CONROY: That's correct.

DR. MULINARE: But the service medal awards were limited to a certain number of years. I don't know tor sure what it is, but there's an interval for this service meaal.

MR. CONROY: That's correct.

DR. MULINARE: I'm wondering if you're getting everyone just based on that interval.

MR. CONROY: Well, the problem with that is we know that there are individuals that received Vietnam service

medals who were, in fact, stationed in Thailand and Laos, ana things of this nature. That's why, you know, it's always desirable *to go back and actually look at the military records in those cases.

CHAIRMAN SHEPARD: Yes. Mr. Walkup.

MR. WALKUP: Did people get the bonus based on residence before and after service, or just after service. Or how did that work in West Virginia?

MR. CONROY: It you went into the service ana were a West Virginia resident, you were eligible for the bonus.

MR. WALKUP! So before goiny into the service was what determined it.

MR. CONROY: Residency before yoiny in; correct.

CHAIRMAN SHEPARL): You didn't necessarily have to be *a* West Virginia resident at the time you applied for the bonus.

MR. CONROY: That is correct.

DR. MULINARE: That's another limiter in most states.

MR. WALKUP: Another question, too, is about: Have you compared these figures with 1980 Census data or DOL estimates on Vietnam veteran population in West Virginia?

MR. HOLMES: Yes, we have. I don't have the figures here, but it looked pretty fairly comparable, yes.

CHAIRMAN SHEPARD: Dr. Kahn?

DR. KAHN: What about people who went TDY Vietnam, who would not be listed on a DD-214 and wouldn't yet a service medal? There are a considerable number of those.

CHAIRMAN SHEPARD: I believe that people on TDY were eligible for the service medal.

DR. ANDERSON: Not necessarily; not all ot them.

CHAIRMAN SHEPARD: Well, certainly some *ot* tnem were.

DR. ANDERSON: Yes, some were.

CHAIRMAN SHEPARD: I assume the majority ot tnem. Yes, do you have a comment?

MR. WHITE: Joseph White, National Association tor Concerned Veterans.

Your DD-214, will it tell you the year down to month and day that you spent in Vietnam. It you were TDY to Vietnam, you did not get Vietnam service or the campaign ribbon. One requires three months service, the other one requires six months service.

Navy personnel who were outside ot Vietnam in the waters did not receive the ribbon, neither did the veterans in Thailand or Guam.

CHAIRMAN SHEPARD: I beg to difter. Navy personnel off the coast of Vietnam did get the service medal, and I'm one.

[Laughter]

CHAIRMAN SHEPARD: I know ot other people who were

TDY. I think you had to be a TDY for at least three months to get the medal; but there were many people who were TDY for a lot more than that who didn't get the medal.

DR. MULINARE: I think it's important to just state that these are some of the concerns that everyone will have with the proportional mortality study that perhaps some of us already have with the Massachusetts study and any study that's done with proportional mortality.

That's why we're asking these questions, and not to set up conflicts of who was there and who was not there. So I think you're going to find that these questions are going to be very important in terms of classification of your veterans and ascertainment of your veterans.

CHAIRMAN SHEPARD: Dr. Anderson?

DR. ANDERSON: Having reviewed at least 2,000 214s, it's seldom that the dates of service in Vietnam are on that form, very seldom.

Now, the Navy offshore, they got the medals. The guys in Thailand that flew over and came back, they got them. Those who went in there, many times TDY, on a rotational basis, the 214 doesn't show Vietnam service but you'll see they got a medal.

In many cases, the individuals were smart enough to keep a copy of their TDY order that sent them in and out of there so that we can confirm this. They're not always in their personnel records, all this information; but if you

will take the time to go to St. Louis and get the personnel records, and then check against military organizational records, you then have it.

Now, we have it in our files. We don't consider a file complete until we have identified his unit, its location, the time he was there and reviewed his personnel record to make sure that he was there.

So unless you do this I am going to challenge every study that comes up until you have looked at that man's personal records and his organizational records because we're finding that at least 50 percent ot the veterans ao not know where they were. In fact, a high percentage don't even Know the unit they belonged to.

When we get their records, I call him up ana i say, "You were not with Company B of the 38th Infantry. You were with Charlie Company of the 7th Infantry." And the guy will come right back and say, "You know, you're right. i get those numbers all mixed up; it's been a lot of years."

So until you validate on an individual basis, a high percentage of the veterans that received bonuses in the various states never set foot in Vietnam. A high percentage of the Navy and Air Force veterans never set toot in that country.

DR. MULINARE: That may be another interesting question in terms of people trying to determine what the meaning *is* of these mortality studies, to break it down by

service and perhaps give an idea of what proportion ot these men were in the Army, the Navy, the Marines or the Air Force.

You might consider that as just a look at the distribution of the men who died and were part ot the Vietnam era.

DR. ANDERSON: I might also add that in reviewing these records the best records of all are Marine records. They give you campaign; they give you place; they give you time; everything you need to know.

The second best, ot course, are Army combat unit records. When you get into support units, forget about it. Something happens.

Air Force? You don't know where the yuy was at, if he was even there many times. And the Navy, ot course, I don't really bother too much looking their personnel records over because it's so hard to interpret.

How the Marines and the Navy can have such a close association and have their records so screwed up and so different, I don't know.

CHAIRMAN SHEPARD: Okay. I think it's time tor a break. Could we please reconvene promptly at 20 minutes or 11?

[A brief recess was taken.]

CHAIRMAN SHEPARD: Back to order, please.

Next on our agenda is a discussion by myself or the VA/EPA Adipose Tissue Study.

VA/EPA ADIPOSE TISSUE STUDY

Barclay M. Shepard, M.D.

DR. SHEPARD: I would just like to report that the plans for that study are moving along. We had a recent meeting of the Science Panel of the Agent Orange Working Group at which the protocol for the study was reviewed, and I think we're coming close to a resolution of some of the issues.

The recommendation at the time of that review was that we concentrate on developing the analytical protocol for the interlaboratory validation by a number of analytical chemical laboratories in the country to analyze a batch of reference human adipose tissue that will be both unspiked and spiked with various compounds, to include TCDD and some others in varying amounts.

One of the interesting points that was brought up was that the detection limit for TCDD — and I presume other compounds — has a close relationship to the amount of adipose tissue available for analysis. That was a point that had not been particularly stressed before, but I guess to analytical chemists that's self evident.

So that in order to test, so to speak, the ability of certain laboratories' capabilities in the area of low detection limits, laboratories will be provided with not only samples that have been variously spiked but also varying quantities of the material so that they can test the lower

limits of their detection limits.

Then based on that a more precise analytical methodology or protocol for an analytical methodology tor the actual specimens that are stored in the EPA tissue bank can be developed with a better and more precise sense or what range of detection limits we can expect to see.

Now, I'm not an analytical chemist, and I would ask now for Dr. Barnes and other members of the committee to comment on this. I know Dr. Barnes has been following this very closely because of his position in EPA and he may have some additional comments resulting from that meeting.

DR. BARNES: Yes.

At the Agent Orange Work Group Science Panel when this was presented -- I think it's fair to say it was generally favorably received – the concern that we've had at EPA and in the Veterans Administration is that we hear, periodically, reports of analyses being done by government agencies, by universities, by private individuals.

The question often is: Well, what do those results mean? Who did the analyses? What was the protocol being used? And do we know that the results are, quote, any good?

Following up on a decision that the Science Panel had made, actually back in 1981, we are now moving forward to set up an interlab validation where people with different competing methodologies – We're not trying to say there's

only one methodology that would work, but at least everyone's methodology ought to be put forward as some kind of a test.

By comparing comparable methodologies in an interlab validation method, it will be useful tor the analytical chemist to determine how their method and approacn stacks up to other people's methods and approaches.

Then once having established that certain people can do this and, quote, get the right answer, then it would be appropriate to look at applying this to the tissues that are stored.

Everyone seems to recognize that this is something of a national treasure and there are relatively small amounts of this material available. Therefore, when we do go to start the analyses of these, we had better be very sure about the methods which are going to be used,

CHAIRMAN SHEPARD: Thank you, Dr. Barnes.

Any questions on this study trom members of the committee? Yes, Dr. Anderson?

DR. ANDERSON: Back in ly«l in Texas, when we developed our protocol, we did develop what they called the biopsy analysis, which really was an analysis for dioxin ot fatty tissues. We wrote it up to look at deep tat tissues, omentum and deeper.

At that time, I talked to Dr. Gross out at Nebraska and he told me that it would be necessary to have at least 60 grams of fat for proper analysis with the technique

they had at that point in time.

So we went to the surgeons within the University of Texas system who will be doing the biopsy work and, of course, they were appalled at this and said that with the problems of informed consent and other things that would be involved they just couldn't participate in it. So we dropped our study.

Now, since that time we have collected, at autopsy, specimens from two of our veterans who have died. One was a Navy man who was with the Riverine Force down in the Delta and, as best we could determine, he did not have at least heavy exposure, if any exposure at all, to Agent Orange during the time he was there.

The other veteran was one from whom I recently sent some specimens to Kansas City for analysis along with the study. He recently died, within the last month or two, and we gathered a considerable amount of deep tat which we sent forward.

He was with the 1st Division in the Iron Triangle area and was an infantry soldier. That's really what we're looking for, someone that definitely had a high probability of exposure.

So taking what you're doing now into consideration. I think we're heading in the right direction because the conversations I had four years ago were very

disappointing and we dropped our study rather quickly when we found out the facts.

CHAIRMAN SHEPARD: Peter Kahn from New Jersey.

DR. KAHN: One of the questions about the interlaboratory studies: Are they going to be looking tor isomers other than the 2,3,7,8-dioxin? Because one ot the questions that you really want to ask is to what extent is any 2,3,7,8 present due to exposure either in Vietnam or trom any other specific source, and to what extent does it arise from what we now know to be the natural background ot various dioxins ana and furides that are present in the general population?

There is now accumulating evidence that there is a background and the isomer distribution pattern seems to be characteristic of what you would see trom municipal incinerators in that background.

If you fail to do an isomer distribution pattern, you could very well miss something which might stand out as either Vietnam related or occupational related as opposed to background, even if the total amount ot 2,3,7,8 is not unusual.

DR. BARNES: The answer to that question is yes, we're going to do that.

DR. KAHN: You are going to do that.

DR. BARNES! Yes.

DR. KAHN: With a whole bunch of the dioxins the furides or selected isomers, or is that decided?

DR. BARNES: That has not yet been decided. I think in terms of interlab validation it would be a select number. But then when the analyses are actually done, depending upon what our skill level is at that time, we would try to figure out as much of the profile as possible.

DR. KAHN: What about availability ot standards for each of the isomers?

DR. BARNES: We are looking into that. The Centers for Disease Control have -- EPA has fairly large amounts of all the tetras and CDC has indicated their willingness to get involved, at least to some degree.

DR. KAHN; Because you should probably want to distribute the same batch of standards to each of the laboratories to be sure they work with the same thing.

DR. BARNES: Correct.

Purity of standards is an important feature ot any interlab study and we want to have one central laboratory prepare all the samples, do all the spiking, prepare the coded materials, send them out and decode the results when they come back in.

DR. KAHN: Better take good care of the people who do that. That's a tough one.

CHAIRMAN SHEPARD: While you're here, Peter, —

DR. KAHN: Yes

CHAIRMAN SHEPARD: — I'm sorry to do *it* without warning — I wonder if you'd be willing to give us a little brief status report on your study because we're all very interested in it.

DR. KAHN: Very briefly — I explained the stuay -- the prior meeting so I won't go into that since time is short here — we've had 12 men go through our hospital protocol thus far. Of those 12 samples, some are in Sweden and some are about to go through analysis.

We have added to the protocol something which we did no previously have. We now take ten grams or more of subcutaneous fat by lucosuction, the procedure that John Constable mentioned. That's been added to it.

We're busily getting out reports to the individual veterans. We're deliberately refraining from trying to make any conclusions from the preliminary data until we have our first 30 men in. At that point, we'll attempt an analysis.

CHAIRMAN SHEPARD: What are you doing in way or, A, quality and, B, interlaboratory validation or the method?

DR. KAHN: Well, Chris Rappe is doing all the analyses, the complete isomer specific dioxin and furan analysis, and we're just leaving it at that.

CHAIRMAN SHEPARD: Okay. Fine. Well, he's certainly a reputable source.

DR. BARNES: What sort of time line is there on the study?

DR. KAHN: The total study is 150 men; 50 exposed and 100 matched controls, half of whom are Vietnam service who were not exposed or minimally and the other half of the control is era veterans who never went to southeast Asia.

We divided into two stages; 30 men and then the remaining one 20. After the first *20,* we'll stop and do no more hospitalizations or examinations until we receive all the dioxin results from the first 30. At that point, we'll make a decision as to whether we go on to the full 120 of the protocol, drop it; who knows.

We plan to have our full 30 men through *by* the beginning of the summer and we hope to get back some of the results at least by end of the summer, perhaps all of the results by then. I don't really know.

At that point, the group will have to make a decision as to what we publish, if anything, at that time. If the results are not sufficient to make a case one way OF the other and we must go on to the other 120, there will be no publication.

As George mentioned, we're subject to peer review. There will be no public mention until we've been peer reviewed. So with luck by the end of the summer we'll have the first 30.

CHAIRMAN SHEPARD: Dr. Lingeman?

DR. LINGEMAN: My question is both to you ana Peter, and to Don, too. It concerns the method or spiking these adipose specimens with dioxin because the storage of dioxin or any other chemical in fat is a dynamic living process ana it involves the cell membranes and what's transported across them.

If you just pour some dioxin over a piece of fat, / this is not really going to mimic the biologic situation at all. The dioxin may remain only on the cell surfaces. I think might be misleading.

I think some thought really should be given to this process.

CHAIRMAN SHEPARD: Yes. Let me take a crack at that.

You're absolutely right and it has been an ongoing concern that what happens when you spike a specimen is not necessarily analogous to what happens when that specimen is bioincurred, the TCDD is bioincurrea.

We think -- at least I think the consensus ot scientists is — that for the purpose of detection — that is, for the purpose of validating the method — whether the spiked material gets there biologically or mechanically, artificially, in the homogenized specimen probably doesn't make a lot of difference.

There probably will be differences in terms of extraction methods and that sort of thing, purification. but in terms of being able to detect through the standard analytical methods how the substance got there may not make that much difference.

Now, in terms of interpretation, it's very important, obviously, to make some estimate of what happens to TCDD when it goes through the skin or the lungs or is swallowed through the GI tract, so forth, and what happens to it between then and the time it gets to the tat in which it's deposited.

We have started exploring methods in which we could take a look at the whole issue of the bioincurred effects and that will obviously be something that we'll be looking at before any final conclusion is drawn in terms of the significance of the TCDD and related isomers, and the patterns and so forth, so on.

DR. LINGEMAN: Who is doing this? It wasn't clear from your comments.

CHAIRMAN SHEPARD: So far the VA has convened a number of analytical chemists to discuss the methodology and there's been a pretty good identification of chemists who would be willing to cooperate in the intervalidation process.

We have not yet identified a specific laboratory to do this bioincurred study, but we're working on that. We

thought we had somebody, but he recently backed down. so we're going to have to start looking tor somebody else.

But we certainly are aware of the problem. When I say 'we', I mean VA working with the scientists at EPA.

Don, did you have anything else you wanted to add?

DR. BARNES: I would just say that as a result ot the meeting of the Agent Orange Work Group again we were given positive indications and encouraged to go ott and do this interlab validation work, and then go back to the Agent Orange Work Group when we went on to the next stage ot looking at the storage samples themselves.

So there are several agencies that are interested.

DR. KAHN: The storage question ot samples that are going to be analyzed for dioxin is a serious one. It sticks to plastic and depending on what kind ot plastic it may or may not be possible to get it oft.

Extreme care has to be taken in how you handle fresh specimens. We solvent wash everything with hexane at least six times after it's thoroughly washed with laboratory and rinsed with distilled water, the whole nine yards; and then the samples are stored at minus 80 centigrade to prevent any migration.

for autopsy specimens, if kept at room temperature, glass containers that solvent washed with metal lids with Teflon inserts are about the only thing you can do.

You know, if the archival samples have been stored in some other way, then that has to be taken into account. It is possible to get the dioxin off some kinds of plastic containers but not others. This has not been fully explored.

It's a tough one.

CHAIRMAN SHEPARD: It's my understanding that these are stored in glass.

Other comments?

DR. LAMM! Yes.

Thank you, Dr. Kahn, for raising the issue ot now these things are stored and how they are kept. 1 think those are very important issues.

One other issue I would like vivid discussion trom Dr. Barnes: What is the sampling arrangement as to now things got into your treasure house and now representative these specimens are of what.

DR. BARNES: There's a report that's, I think, probably available now that goes into that in some detail. Let me just basically say it's a network that was set up obviously not for this particular issue, but trom our perspective to try to get a sense as to the tissue loadings of pesticides and other chemicals in the general population.

There's an overall statistical design that is laid out to be representative of the country down to a certain level; and you get down to a certain level and you have to,

then, look for cooperative pathologists or people who would actually supply the tissue.

It seems as though the numbers of samples in there the number of Vietnam veterans that are in that repository are representative of one might hope to be in terms ot based upon the statistically general population. AS people have mentioned, storage is a question that has been raised on that group of samples as well in terms of what has been their rate over the past 10 years or 15 years, whatever the case may be.

Again, it has not been ideal by what we would like to have designed for this study, and yet it's the only game in town. I would think it's probably not that bad.

CHAIRMAN SHEPARD: Thank you, Dr. barnes.

I think we better move on. Let me 3ust very briefly tell you what little I know about the twin study process.

TWIN STUDY REPORT

Barclay M. shepard, M.D.

DR. SHEPARD: The protocol tor the VETS II, or the physical examination, has been reviewed by both the Office of Technology Assessment and the Science Panel of the Agent Orange Working Group.

To the best of my knowledge, those reports have not yet been submitted. Just to summarize, I think there is going to be some recommendation in terms ot some modification

of the VETS II protocol in order to focus more on specitic hypotheses that might be generated as a result ot the interview process, the questionnaire process of the larger group of veterans that will be developed by the National Academy follow-up agency and so called twin registry.

That's about the extent of my information on the subject at the present time.

Yes, Hugh?

MR. WALKUP: Last time when I had asked tnat this be put on the agenda for this time we were going to have, hopefully, some of the people who were involved in the decision to revise the peer review panel or, you know, whatever happened to the study. I see that those people aren't here.

Could you tell us what happened in terms ot tne process by which the original recommendations ot the review panel were overturned and now what's going on?

CHAIRMAN SHEPARD: Yes. I would prefer not to. The study is not under my area of responsibility.

The individuals who are in charge of the study were invited to come to this meeting and, tor various reasons, were not able to. so things are a little bit up in the air.

For me to speculate, I don't think, would be appropriate. Just suffice it to say that I think that there

will be -- I hope, and this purely my own opinion – an attempt to revise the protocol such that there will be some elements of what was suggested in the VETS *II* protocol, will proceed after an analysis of the information on the VETS I effort and twin registry effort.

MR. WALKUP: So after reviewing the first pnase, they are going to look at testing specific hypotheses it the data from the first phase indicate that some of those questions can be answered?

CHAIRMAN SHEPARD: Something like that, yes.

MR. WALKUP: This is an advisory committee ana 1 would imagine it's fairly difficult for scientitic panel, ana especially I know for nonscientific panel members, to give much advice when we don't know what's going on.

It sounds like that's intentional and, you know, 1 have some real concerns about that ana question the ability of our committee to give any kind of aavice if we don't know what's going on.

I would imagine that the White House Working Group is probably very well informed of what's going on here ana it's probably making a fair number of decisions about that. It seemed, last time, that OMb probably had some input into the decisions that were being made on this.

That gives me some serious concerns since this is a public forum, the White House working group is not.

My advice to the Veterans Administration, I guess, in whatever role I have as an advisor here, is that we be more open with what's going on with these kinds of things and that we attempt to address the issues that are important to Vietnam veterans and not those that are politically expedient either to the Administration or the Veterans Administration.

Maybe it makes perfect sense that this has been changed; but personally I'm really concerned about the way in which it's been changed, the lack of public information about what's going on with it, and the loss is that we'd eventually have to find something out that's going on.

Before, we were told that this was a really important study that's going to tell us some things that we couldn't have known before, Finally, we've got some clues that are going to give us some controls that we keep saying don't exist with the studies that tell us anything; and now we're going to crash this study.

I've got real concerns about all ot that, and I hope that's your conclusion, anyway.

CHAIRMAN SHEPARD: 1 think -- ana I'll let anybody speak who is also involved in the process — it would be premature to assume that this study is going to be scrapped. I have not heard any results of any of the reviews that I have been aware of that say that the study should not *be*

done.

I think what I have heard is that the study should not be done in its present form; that some modification should be undertaken to focus on health outcomes which can be more easily attributed to specific causes rather than a, quote, fishing expedition.

It's hoped that some of that information will come out as a result of the review of the questionnaire that will be sent to all members in the twin registry.

I have also recommended that as that twin registry is developed we determine how many of those individuals have come to the VA either for treatment and are, therefore, in the patient treatment file — which is a computerized data based of all veterans admitted to the VA hospitals and to the Agent Orange Registry. That would give us a ready access to already documented health information on any of the twins that may, in fact, have come to the VA.

So that process will go on. That proposal has been approved by the medical research service and that is underway.

MR. WALKUP: I'm pleased to hear that part of it.

I do have concerns about what you're talking about. I think that, specifically, the way we got to this place with Agent Orange is that there were some general health problems that Vietnam veterans had.

We ended up with two things that we looked at in all that. One was Agent Orange and the other was post traumatic stress disorder. We've invested a whole lot in researching both of those things because they were identifiable and they sold newspapers,

I can see the study being limited to those specific things for which we've constructed categories before.

It seems like one of the values ot the twin study was that we could detect differences in health among veterans based on Vietnam service without having artificial constructs that have directed most of our other research.

It seems like we're limiting what could have been an expansive study to maybe a minor replication or wnat it is that we've been fishing in already.

CHAIRMAN SHEPARD: Dick, do you have any comments?

Dr. Hodder was at one ot the review sessions. He might want to shed some more light on or amplify no what I attempted to summarize.

DR. HODDER: Unfortunately, I didn't review this before coming.

As I recall, the phase one part, the initial part of forming the registry and mortality and the basic, it you want, studies of the Vietnam experience will still be done. What the overview committee, in August, and what the,

committee at AOWG's concern was, was more on metholog; that a fishing expedition looking at, again, several hundred variables, would, just by chance, find a certain proportion "significant" and the real difference might be lost because it would be difficult to see the forest for the trees.

As I got the sense of the committee it was not that this was not worth doing, but rather that they should go back, do their homework, and focus in on the questions generated by Ranch Hand, by the CDC study and by occupational studies that have already suggested hypotheses so that the effort is appropriately directed.

One of the difficulties, I know, in myself getting involved in studies that looked at every possible variable is that the analysis is an unknown, and people simply get lost in the huge volume of data whereas what everyone is suggesting is that we focus now and that this is an appropriate time to be looking at specific hypotheses and not adding just another fishing expedition to the study.

So I also was concerned that the study not be dropped only because of fear of how much would be spent on it or, say, a quarrel as to where it should be done or who should do it, et cetera.

I looked at that fairly carefully myself and it really is a method problem. A, that the study has not been

trashed, that the investigators have just been sent back saying, "DO you homework; come up with a more focused study." I also got the feeling that no one wanted to just drop the issue.

It's moved along, but it's saying, "Let's get it appropriate to where we are."

A fishing expedition tour to five years ago would have been quite appropriate. We've had enough of those ana now if we want to spend the money we want to spend it so that it gets done what we have to.

CHAIRMAN SHEPARD: Thank you, Dick.

Don, you were there. Do you have any comments?

DR. BARNES: I agree.

CHAIRMAN SHEPARD: All right. I'd like now to call on Mr. Fred Conway of our General Counsel's office to give us a report on the status of activities relating to Public Law 98-542 and anything else he wants to talk about.

REPORT FROM GENERAL COUNSEL'S OFFICE

Mr. Frederic L. Conway III

MR. CONWAY: Thank you.

As you may remember, Public Law 98-542 requires the VA to promulgate regulations that would set forth guidelines and, where appropriate, standards and criteria for the adjudication of claims relating to exposures to Agent Orange and ionizing radiation.

We have put together a task force which has

written a proposal which will be presented to the Administrator of Veterans Affairs this week for his consideration.

If he approves them, they will then go to the Office of Management and Budget for their regulatory review process. We are hoping to have them published by April 22nd, which is the deadline for publication in the Federal Register under the law.

We would invite your consideration ot those proposals and whatever comments you wish to make you can please provide them to Dr. Shepard, and I'm sure we'll De able to work that out.

In addition to that process, Public Law 98-542 also mandated the establishment of a Veterans' Advisory Committee on Environmental Hazards. AS I indicated at the last meeting, we solicited recommendations for membership on that committee from a variety of professional societies ana associations, and a number of veterans' organizations, botn the traditional organizations and those that are more narrowly focused.

Those recommendations were considered by individuals in the Department of Medicine and surgery ana tne Department of Veterans' Benefits and the General Counsel's office, and a recommended list went to the Administrator tor his approval. That was concluded at the end ot January. He

had made a determination of the membership.

They have all been notified and invited to attend the first meeting which is " ' ' scheduled for April 22nd, coincidentally the same date that is the deadline tor the registrations. It's purely a coincidence.

There's nothing more I can say about that right now other than that the first meeting of the Advisory Committee on Environmental Hazards will be basically an introductory meeting; an overview of Agent Orange and an overview of the Atomic Energy Testing Program in the 1950s, what the problem is that the agency is faced with and what the task is for the committee to address.

We then anticipate a second meeting being held in June at which they will specifically focus in on the regulations that we have proposed. The reason tor that is the Congress has mandated that they review the proposed regulations prior to their final implementation.

Any questions?

CHAIRMAN SHEPARD: Thank you, Fred.

Yes. Hugh?

MR. WALKUP: Could you tell us who the members or the committee are?

MR. CONWAY: Not off the top of my head. i will make a listing available.

MR. WALKUP: Are any members of our group on that

committee?

MR. CONWAY: I don't believe so, no.

MR. WALKUP: If this group continues to meet, could we schedule our meetings — which I think would come up some time in June — to happen at the same time as this committee meets so that we could have some interaction with those people?

MR. CONWAY: I can't make a commitment on that at this point because I don't know where this new committee wants to meet. Traditionally, we're meeting in Wasnington. That's not required.

The other committee may feel it's more appropriate, would be easier to have a meeting in a midwestern city, on a university campus for example.

I don't know where they're going to want to meet so I can't make any commitments on behalf of that committee until the committee has a chance to have their first meeting and decide where they want to have their meetings.

It will be an open meeting, by the way. It's an advisory committee. Anybody who wishes to attend can attend. Transcripts of the meeting, such as this one, will be prepared. We'll be glad to disseminate whatever information we have to this committee to the extent that the committee would like to have that.

MR. WALKUP: Maybe if that committee decides where

and when it wants to meet, this committee could have that same privilege. I'd like to recommend that our committee propose that we meet at the place and time that this other committee meets for our next meeting.

MR. CONWAY: One other point. I'm not sure you're aware of this.

The other committee is not intended, as it's currently planned, to meet more than twice a year. The tun committee would probably meet once a year and the Science Panel would meet twice a year simply because their focus is different than the focus of this committee.

The focus of that committee is to evaluate studies and provide advice and recommendation to the Administrator as to what they mean. Now, I suppose you could say that that is part of the focus of this committee; but it's only part ot this focus whereas it's the total focus of that committee.

I can't anticipate that they would meet more than twice a year given the more narrow focus; but maybe we can work something out in terms of overlapping dates or maybe having a delegation meet with that committee, or something ot that nature.

MR. WALKUP: Do other members ot the committee see a value of meeting together with this committee, or have you had a chance to talk to them? Or is that just me?

DR. BARNES: I guess my reaction will be, until we

know more clearly what their agenda looks like -- The first one doesn't sound very exciting for us and I'm not sure what the second agenda is going to be. I'd hate to go ahead and make special arrangements to meet with them not knowing what we're going to chew over.

CHAIRMAN SHEPARD: Any other comments from the committee?

[No response.]

CHAIRMAN SHEPARD: Fred didn't mention this, I don't think, but it might be of interest to this committee. It's that the composition of that 15 member congressionally mandated committee will be 11 scientists, three ot whom will have particular expertise in the area of the effect ot ionizing radiation, three of which will have particular expertise in the health effects of exposure to dioxins, and the remaining, five will have *general* expertise in the areas of epidemiology, biostatistics, toxicology and so forth.

Considerable effort was expended to make sure that we covered these various mandates of the legislation because the legislation is fairly specific in terms ot the make up ot the committee.

The remaining four members are to be non-scientists. There are to be no employees ot the Veterans Administration or the Department of Defense and I think only

one government employee is allowed.

MR. CONWAY: Who we have for lay members - I do know that one -- one of the lay members is a former staff director of the House Veterans' Affairs Committee. He's had a long career involved in veterans' affairs.

A second lay member is a Supreme Court Justice in the State of Utah who has been very heavily involved with the downwind population problem. For those of you who don't know, 'downwind' means people who lived in areas south of the shot sights where radioactive fallout may have fallen down on them.

A third person is a retired officer and nurse, and is I believe President of the Retired Officers' Association, Colonel Bonner and she's been active in veterans' affairs.

The fourth is a representative of the State of Minnesota Agent Orange program, Mr. Bender, who is seated here today.

We tried to get a cross section of individuals that would have some interest in and experience with the problems that this committee is supposed to address. Hopefully, we've achieved that.

. CHAIRMAN SHEPARD: Yes. I think you'll De very pleased with the membership of the committee. It has some outstanding people.

Dr. Leonard Kurland, for example, the well know epidemiologist from the Mayo Clinic, will Chair the Scientific Council, as it's called – the 11 member group, again mandated in the legislation – to review the scientific evidence.

Any other questions tor Mr. Conway?

[No response.]

CHAIRMAN SHEPARD: Thank you, Fred.

I'd like now to call on Dr. Kang of our department to bring you a quick overview of the Australian Mortality Study and also bring you up to date on our own VA Mortality Study.

Dr. Kang.

AUSTRALIAN MORTALITY STUDY AND
OVERVIEW OF VIETNAM VETERANS MORTALITY STUDIES

Han K. Kang, Dr. P.H.

DR. KANG: During the last one year or so several Vietnam veteran mortality studies have been published or reported to and discussed at this meeting. bo 1 ' thought it beneficial for everyone concerned to look at these studies and quickly go over the strengths and limitations of these studies.

The fourth one here* Vietnam Veterans' Mortality Study – we presented protocol and progress to this meeting the last couple of times – briefly it is a comparison

*see charts, tables beginning on page 171

of mortality patterns between Vietnam veterans and non-Vietnam veterans limited to ground troops, being Army and Marines.

Data collection is completed. We have now about 50,000 plus matched cases; namely, we have all the information on the military side and all the information on the medical side.

The preliminary data show that we have over 5,000 suicides among the 50,000 plus Vietnam veterans there.

This is a nationwide study of a sample of all eligible Vietnam Era veterans.

The next study here is an Air Force health study. The baseline report, in 1983, shows us that there are 15 deaths among Ranch Hand and 250 deaths among comparison populations. The update just published last month shows 54 deaths among Ranch Hand and 265 deaths among the comparison group.

There were 3 suicides in Ranch Hand and 14 in the comparison group and there was no soft tissue sarcoma; but the last report shows : one cancer case, not in soft tissue sarcoma, in 171 to 17b category. I don't know whether that one individual has soft tissue sarcoma or skin cancer or any other category, but there was one cancer.

DR. LINGEMAN: In which group?

DR. KANG: Comparison group.

PR. LINGEMAN: The first group?

DR. KANG: Right.

In the New York State study, the investigator or that study gave us a report at the last meeting that showed 555 deaths among Vietnam veterans and 941 among non Vietnam veterans. There were 80 suicides among the Vietnam veterans and 125 suicides in non-Vietnam veterans death. Statistically, there was no difference.

There were two soft tissue sarcomas among Vietnam veterans and three among non-Vietnam veterans.

The reason I'm presenting this tiyure is to give you an overview of what you can expect from each study, tne strengths of each study.

The Massachusetts study. It is unfortunate that the investigators cannot come to this meeting and answer some questions. I, for one, have several questions on this study.

For example, according to that report over 95 percent of all eligible Vietnam era veterans received tne bonus. Looking at the 1980 Census, the number ot Vietnam era veterans in the State of Massachusetts, was estimated to be 171,000.

The number ot reported deaths among Vietnam and non-Vietnam veterans is much smaller than what you would expect from the number of eligible Vietnam era veterans who reside in the state of Massachusetts.

One other concern I have was that this 840 and 2,515 represent 98 percent of all eligible Vietnam era veterans who received the bonus, which means there are only 2 percent non-white bonus recipients and that's very hard to believe. In fact, the West Virginia data show something like a 5 to 6 non-white population.

So it's hard to expect that the Massachusetts Vietnam era veterans are almost all white; that there's very little non-white population.

Another concern is that they include the veterans who served in the military some time between 1958 and 1972, which means there are a lot of non-Vietnam era veterans who are not comparable to Vietnam veterans in many respects. In our VA mortality study, the Vietnam era veterans were defined as somebody who served in the military at least sometime between 1965 and 1972.

So almost half of the non-Vietnam veterans in the State of Massachusetts study, according to our definition, had no chance of going to Vietnam. So in the strict sense they are not a true control group or comparison group.

Their study shows that reported suicide was not statistically higher among Vietnam veterans but if they throw in possible suicide categories like accident or poisoning cases — the results show that there is a higher proportion of, quote/unquote, suicide among Vietnam veterans than non-Vietnam veterans.

The Australian veterans' health study; I'll go into that later/a little more in detail. The CDC study, the study or 30,000 veterans will yield about 1,100 deaths after they finish with the study. That will produce approximately 100 suicides.

So the CDC study has very little statistical power in terms of making any kind of a conclusive statement as to whether a certain group of Vietnam veterans commit suicide more often than non-Vietnam veterans.

Soft tissue sarcoma.

If the rate of soft tissue sarcoma development among Vietnam veterans is similar to the general population, there will be about five or six soft tissue sarcomas among the CDC study.

So the CDC study, although it's a very comprehensive study, cannot conclusively answer two important issues: number one, the high frequency of suicide among Vietnam veterans; and two, the issue of soft tissue sarcoma among Vietnam veterans.

Let me spend a few minutes on the Australian veterans study. Before that, I'd like just to show this graph to show you what to expect from each study.

. For example, the CDC study, if there are 100 suicides and if the suicide cases are split into Vietnam and non Vietnam equally, you would expect

about 50 suicide cases which means if actually suicide among Vietnam veterans is not moire than 50 percent higher than non-Vietnam veterans, you have less than a 50 percent chance of detecting that. In other words, the power of detection is about 50.

Not to mention that if the number ot sott tissue sarcomas among your comparison population is less than 10, the power of detection is just about nothing. bo what I'm trying to say is the mortality study being conducted by the state or being conducted by other groups, by virtue ot the small number of deaths available for analysis, cannot give you a conclusive statement as to whether Vietnam veterans die trom sott tissue sarcomas moire often than non Vietnam veterans.

I will spend a couple ot minutes on the Australian Vietnam veterans' study. This is a stuay ot all Australian Vietnam Era veterans, what they call 'National Servicemen'.

Through their military records they identity 19,450 veterans who served in Vietnam and 44,295 they say non veterans; but that means non Vietnam veterans according to their definition. After eliminating the various individuals with different characteristics, they end up with 19,029 available from those Vietnam veterans and 26,957 trom non-Vietnam veterans for mortality analysis.

CHAIRMAN SHEPARD: Is everybody clear on that point? The Australians use a different set of terms. In

Australia, a veteran is somebody who served overseas in a combat situation.

The National Serviceman is somebody who served in the military and, in this case, during the Vietnam era. So as we use the term 'Vietnam era veteran' they would use the term 'National Servicemen'.

DR. KANG: Okay. This is the crux of the whole analysis. There were 260 deaths among Vietnam veterans and the expected number of deaths in the Australian male was 311.8, yielding the mortality ratio was .83. In other words, the number of deaths among Vietnam veterans was less than what you expect from the general Australian male population.

The confidence interval was .74 to .94. It was statistically significant in the sense that the veterans' mortality rate is less than what you expect in the general population.

For non Vietnam veterans there were 263 deaths and the expected number was 407. Again, that was less than what you expect from the general population and this is not unusual for other veterans' studied. The mortality rate for veterans is less than the general population for various reasons.

Comparing the mortality rates between Vietnam and non Vietnam

veterans, there was an excess, high rate of mortality among Vietnam veterans. The mortality ratio was 1.29; the 95 percent confidence interval was 1.08 to 1.54. But after adjustment for various pre enlistment confounding factors and then for the Corps, the difference was not statistically significant.

This is a final table." It's kind of a busy table.

Okay. Looking at different Corps – infantry, engineers and other specialties in the military – one striking data is among the Army Engineers, the person who served in Vietnam had higher mortality than the person who did not serve in Vietnam.

The relative mortality rate is 2.48, right here. That was statistically significant. Even after making adjustments, that was still significant.

The Australian mortality study has a three volume report. I read page to page and they tried to explain – and they couldn't explain or I couldn't explain – why the Army Engineer who served in Vietnam showed a high rate of mortality.

With that, I'll conclude. Thank you.

CHAIRMAN SHEPARD: Do you remember in the cause of death analysis among the engineers that there was anything that emerged as a striking –

DR. KANG: No. Most of the excess from the

engineer group, Vietnam group, is from external causes; suicides, accidents, things of that nature.

CHAIRMAN SHEPARD: Thank you.

Are there any questions tor Dr. Kang trom members of the committee?

[No response.]

CHAIRMAN SHEPARD: Thank you very much tor summarizing that so completely and briefly.

DR. BARNES: Would it be possible tor us to yet copies of those overlays?

CHAIRMAN SHEPARD: Yes. I don't know why not. Surely. Yes. Be happy to. (see pages 171-175)

Dr. Barnes would like a set ot your nice overlays.

Okay. Any other questions or comments?

[No response.]

CHAIRMAN SHEPARD: All right.

In just a moment, we'll start taking questions from the audience, but I did want to make sure, while I had it on my mind, that in response to Senator Cranston's letter, a copy of which the members of the committee nave in their folders, I would like in addition to the review of tne Massachusetts Mortality Study if you would Kindly look at tne Ranch Hand Study, a copy of which you also have in your folders, and provide me with comments on your review ot that so that I can answer Senator Cranston's letter.

So if you could accomplish that within the next three to four weeks, I'd be very much appreciative.

All right. We're now ready to take questions from the audience.

COMMENTS AND DISCUSSION

Does anybody have any written questions, first of all, that you've given to Don Rosenblum?

Yes. Mr. Falk.

MR. FALK: I'm Alan Falk, Chairman of the New Jersey Agent Orange Commission.

Rather than a question, I do have a comment on what transpired today concerning the future of the committee. I was pleased to hear the decision that has been made so far, at least the decision that has not been made. There may still be more in the decision making process.

On the New Jersey Commission, though, had formally discussed this matter after the last meeting and we had passed a resolution formally addressed to the committee and to the Administrator requesting that the committee be retained in its present form; that we feel that this is a valuable institution, that it does allow the Vietnam veterans of the country the opportunity to be present during the important discussion of the research work that's going on; and that none of the new committees being proposed will provide as much detailed information, as much of an

opportunity for the veterans to see what's going on in the area of research.

In addition to the formal vote of our commission, we ask that a copy of our resolution be attached to your record.

I also was provided today with a copy ot a letter that a member of our congressional delegation, who is also a member of the House Veterans' Administration Committee, had just sent to the Administrator, Mr. Walters – and that is Congressman James Florio from the State of New Jersey – also requesting that the advisory committee be retained in its present form.

We were happy to see that a member of our delegation from the Veterans' Service Committee has taken this position.

So, again, on behalf ot our state commission, we do want to go on record as urging that the committee be retained. Obviously, there are some de facto changes in the format that have occurred and there may be further discussion as to the format, but we feel it's very valuable.

It's very important that the veterans and the representatives of the state commissions and programs be able to come here, see what's going on, hear the scientists who present the papers, be able to ask questions, to hear the reports of the other state committees.

Again, although sometimes we may not present ail the information that we have because of the type of restraints Dr. Anderson indicated – that it may not always be possible to give scientific reports in the middle ot what's going on – we do think it's valuable to hear what everyone is doing and tell you what we are doing.

So again I did want to make that point for the record.

CHAIRMAN SHEPARD: Thank you very much, Ai. 1 appreciate your comments. I think that will be very helptul and *I* appreciate your sharing with us Congressman Florio's concern.

I hope that gets transmitted to the Administrator promptly so he'll be aware of that.

Are there any other comments or questions trom the floor? Yes, sir.

MR. BURDGE: Good morning, Barclay.

CHAIRMAN SHEPARD: Good morning. How are you this morning?

: I'm James Burdge, Sr. I'm the Agent Orange Chapter #12, Chairman for Veterans of America, in the State of New Jersey.

In September I came here and I raised a little stink about my own particular problem. The chloracne task force made an appointment for me to go to Philadelphia VA to be examined.

I went to that appointment and I was taken there by a state agency in New Jersey. I was supposed to see a Dr. Jegasaffe [ph] that day. The man was on vacation for that week and I was not able to see him. I was seen by a Dr. Barton, who I find out now is no longer at the VA in Philadelphia. Nobody can find out where he is.

I walked into the room to be examined and I didn't mention the word 'Agent Orange' whatsoever. The doctor said my skin condition has nothing to do with Agent Orange; and I told him, "I didn't say it did; you did."

I have sent a VA 413b two times since I was there in November. It's been returned to me and I have a copy of a letter from a Denise in Philadelphia saying they have no record of me being at that VA facility.

I would like you, Doctor, to check on this and find out why this is going on, not only to me but other veterans. There are many veterans in New Jersey that are having specific problems with the Veterans' Administration; getting treatment, getting compensation.

It seems to me it's a big runaround.

CHAIRMAN SHEPARD: Okay. If you would allow me to make a copy of that I will certainly look into it. I know that Dr.Fischmann at one point, was making an attempt to set up an examination for you.

I wonder, Betty, would you be willing to share

with us your recollections of that process?

DR. FISCHMANN : We did that after a meeting seeing about him getting checked out. He wasn't able to keep the first appointment — we had to arrange a transport — and so we made a subsequent appointment, which is the one he kept.

I don't have any more information at this point.

CHAIRMAN SHEPARD: Fine. Thank you.

We'll look into that. Don Rosenblum, would you make sure we get a copy of this; if you're willing to share it with us.

MR. BURDGE: Sure.

CHAIRMAN SHEPARD: We'll look into it then.

MR. BURDGE: The problem isn't only mine. It's maybe 1,000 Vietnam veterans at least in New Jersey. They go to the Veterans Administration for an examination; they're treated; and when they go to try to get copies of their medical records, they can't find their files.

This has been going on with me since 1972.

CHAIRMAN SHEPARD: Well, as I say we'll certainly make an attempt to locate your records or at least find out what the problem seems to be.

MR. BURDGE : Thank you, Doctor.

CHAIRMAN SHEPARD: Thank you.

Are there any other questions or comments? Yes, Jeff? Mr. Jeff stanton from Oregon.

MR. STANTON: Thank you, Dr. Shepard.

We have two concerns in Oregon. One, is there any way that we could get a VA specialist in Southeast Asian diseases to visit Oregon and give a seminar on what kina ot diseases were prevalent in Southeast Asia.

Number two, how do we go about seeing to it that part of the Oregon Agent Orange testing that they do, the 24 hour urine test when you specifically have veterans with liver problems.

Those are the two problems that we have in oreyon.

CHAIRMAN SHEPARD: I'm sorry. I missed your second question. I got your first one.

MR. STANTON: The second question is the 24 hour urine test for PCT. Some of the veterans that we have have definite liver problems and they're not given the 24 hours urine test. They're just given a regular urinalysis.

The second part of that is it they come up with a positive, do they recheck for high iron blood count?

CHAIRMAN SHEPARD: Okay. I'm not an internist. Dr. FitzGerald may want to take a crack at it.

I don't think there's necessarily a relationship between all liver disease and the necessity for aoing a 24 hour urine collection. One does 24 hour urine collections for specific problems, but not every liver disease would require or suggest that a 24 hour urine specimen is

necessary.

Certainly not every liver disease or every liver condition has anything to do with with PCT, or porphria cutanea tarda. That's a rather special limited, relative rare liver condition that has a number of features to it.

So I hope that's answering your question. I think that in general, if I may say this, that laboratory studies out the general baseline laboratory studies are requested or ordered based on what the medical history and the physical examination and other laboratory studies may show.

so it's very difficult to generalize and it would be inappropriate, I think, to do a complete screen for all possible liver diseases or certain porphria cutanea tarda on every Vietnam veteran.

First of all, it would show up relatively infrequently; and, secondly, there are probably more important studies to be done than that particular one.

MR. STANTON: We at the health division have approximately 38, I believe is the count ot liver problem veterans. It's my understanding that to do the 24 hour urine test it would be approximately -- the cost of it is approximately $35 to do that. That's the figures that I received just before I left.

So it seems like it's an inexpensive thing to do. I'm not saying give it to every vet that comes in for Agent

Orange screening. What we're saying is that if they have the liver problem, I can't see what the harm is with doing it; and if it comes out positive, the ones that have had it they've called them in to redo the tests two or three times.

If it comes out positive each time, then they're checking into high iron count.

Now, I know of five where the VA has done this because the veterans have gone in and specifically demanded that they do it, and they're now being sent to Sacramento for some special study.

CHAIRMAN SHEPARD: Dr. FitzGerald, do you have any thoughts on that?

DR. FITZGERALD: I think I'd agree with Dr. Shepard.

The purpose of the screening and examination is to determine what further tests should be done. Certainly our experience with the veterans has been that those who have liver disease, the liver disease is most frequently accountable by the doctors during the screening examination.

Any doctor who has any suspicion of porphria cutanea tarda and they're looking for this specifically in the examination would certain pursue it rather than to have it a routine urinalysis being done.

You could clog up the laboratories by routine screening examinations unless there was some specific

indication to do it.

CHAIRMAN SHEPARD: Dr. Hodder?

DR. HODDER: I guess I'm having trouble with ray first impression. *I* thought you were asking, why would you ao a urine test for liver disease.

I would agree with Dr. Shepard that I don't think you want to screen everyone coining to an Agent Orange exam for porphria cutanea tarda. I do agree that it a person has evidence of liver disease, as part of the workup I would look for not only, post hepatitis or chronic alcoholism, which is certainly the most common reason, but I would want to look for hemochromatosis and PCT.

So if they were not doing this on people who definitely showed signs of liver disease, then probably the quality assurance at the VA, at that point, might add it. That happens at any hospital. I don't think that's something that's improper.

MR. STANTON: That's basically what I'm saying, is the ones that definitely have liver problems they're not doing this on them and we think it would be appropriate that they do it.

DR. HODDER: Well, that could be put into DRG, then.

CHAIRMAN SHEPARD: Right.

Do you have an idea ot which hospital you're talking about?

MR. STANTON: It's not being done at the Portland VA and it's not being done at White City. We have a very good person who is running the Agent orange program in Roseburg named Nancy Walgemont.

She is extremely helpful. She does everything sne possibly can. So I want go give her a pat on the back for that.

CHAIRMAN SHEPARD: I'll contact our physician in Portland and see if they have a plan.

Let me answer your first questions, specialists in diseases in Southeast Asia.

Well, there are a number of specialists and lot of them have been in the military.

So there are probably physicians in the Portland area that have been in the military and have some expertise in diseases that were prevalent in Southeast Asia. I can't give you the name of anyone off the top of my head; Dut, Dick, maybe you know in your research community if there are people who specialize in tropical diseases.

DR. HODDER: I don't know specific people because I've just been on the east coast most ot the time, mostly in New York. But as you say there are certainly people who have written on this area.

In fact, there are people who have written on the Vietnam experience themself. Dr. Ognibene " wrote, tor example, on the FUOs in Vietnam. So there certainly would be people.

I think the best source would *tie* to get them out of the literature. A good contact person would be at the Uniformed Services University; Colonel Lou Legters, who is interested in tropical diseases. In fact, he might be a good resource person for it either himself or —

CHAIRMAN SHEPARD: Would you get together afterwards and maybe give him his name?

The other thing that comes to mind is Madigan Army Hospital, although it's not in Oregon. It's not too tar away from you. The chief of medicine or medical service there in communicable diseases may be able to give you some help in that regard.

MR. STANTON: Thank you very much.

CHAIRMAN SHEPARD: And the local VA. It you contact the chief of medicine at Portland VA, ftemay be able to give you some hints.

MR. STANTON: We've checked the VA statt in all the hospitals in Oregon and there isn't anybody that has the background.

CHAIRMAN SHEPARD: But they may be able to give you some references of people that do have that —

MR. STANTON: Well, the closest one was LOS Angeles and they said that we'd have to see about getting them sent up.

Okay. Thank you very much.

CHAIRMAN SHEPARD: Wayne, aid you have something?

MR. WILSON: I'm not a professional service officer, but I have attended the DAV and the VFW school.

When you have 38 Vietnam veterans that believe they have liver disorders that they believe are connected to their service in Vietnam regardless of whether it's Ayent Orange or whatever, what we do in New Jersey is we contact the veteran organizations and we ask these veterans to tile service connected claims listing their symptoms.

The VA handles the compensation business very routinely and quite well over many years, as you gentlemen will agree. Let the Veterans Administration provide a diagnosis based on a compensation exam.

I mean, it's really so basic. A physician will examine the veteran, work up that veteran and decide based on evaluation whether specific tests for PCT are warranted. They're not going to miss those kinds of things, including 24 hour analysis.

So you have to understand, and veterans should know, the Agent Orange screening exam is just that. It's a basic screening exam.

But when you file a claim tor compensation, one or the things that the law provides is that you will get *a* diagnosis; the Veterans Administration will clearly set forth the basis for that diagnosis andcite the law that they either compensate you or deny your claim for it.

So, you know, if these 38 veterans want an answer and they want, I think, a good battery ot tests to determine whether they have PCT, just tell them to file a claim. GO see their service organizations and they'll get it all in writing; it will all be done quite well; and you'll nave the answers.

And you won't need anyone from Washington to come in and do that?

CHAIRMAN SHEPARD: Thank you, Wayne.

DR. FitzGERALD: I think Wayne has a point there as far as that's concerned. Too many veterans think that having *a* screening examination for Agent Orange is the same thing as filing the claim.

We have to repetitively advise the veterans to ao both.

Now, on the examination that would be done tor compensation purposes if, indeed, the veteran disagreed at that point then that case would be remanded and specifically, at that point, require the individual hospital to do that specific test.

CHAIRMAN SHEPARD: Yes. Do you have a question?

MR. WALKUP: Excuse me. Let me say one thing about what they just said, if you don't mind.

MR. WHITE: I just want to answer him.

CHAIRMAN SHEPARD: Come on up.

MR. WALKUP: While you're coming up, let me say i think it's been pointed out by the gentleman from Oregon that, yes, that's the way the system works. Why does it work that way?

Why shouldn't someone coming in tor an Agent Orange screening examination have whatever tests are appropriate, or why aren't they told by the examining physician that they need to file a claim for compensation it they're going to get something more?

MR. WHITE: Exactly. Why not just file tor Agent Orange and double with the screening because you get better service by filing for compensation.

DR.FITZGERALD: Where there are several reasons for filing for Agent Orange. One of them is that it, indeed, at a future time it is determined that there is a cause and effect with Agent Orange — and that's what we're all working towards — that veteran is protected at that point because he has filed after he has gone through an Agent Orange screening examination as to what is the status of that veteran.

MR. WHITE: But the Agent Orange screening does so

little when if he would go ahead and just file for compensation the gain would be more extensive.

DR. FITZGERALD: Again, let me reiterate, they are two distinct things. He should file for compensation so that he has an effective date for his disease entity that he is claiming for.

CHAIRMAN SHEPARD: If I may just add, not all people going in for the registry examination have a problem for which they want to file a claim.

In other words – in fact, in our analysis – at least a third of the veterans going in for the Agent Orange examination are totally asymptomatic. They're going in just to get a good physical examination to determine it they have any problems; not that they're going in with any preconceived notion that they have a problem.

so that would account for a fair number of cases in which they don't necessarily need or want to file a claim. Of course, there are a number of people who do have problems and if they think those problems are related to service in Vietnam, then obviously they should file a claim to get to the bottom of that.

MR. WHITE: That's not the information I'm getting from my veterans. They don't want to file because they know that the Agent Orange screening test is a nothing; that you can really find nothing from the screening test.

But if they would file for compensation you get better service.

MR. ESTRY: If I could clarify one thing.

MR. WHITE: It's is a difference between the service.

MR. ESTRY: I understand what you're saying, but in any claim that's filed you have two problems.

If you're filing a claim tor Agent orange, the first thing the man is going to do – especially it he hasn't had the screening exam -- we're going to remand it to tne regional office and demand that the screening exam be done; partially for due process and for other reasons.

But you have to have the screening exam.

The second thing is they're going to be very, very specific. Mr. Wilson said it great. I don't usually agree with Wayne, but I will today. He's been very good.

[Laughter]

MR. ESTRY: But what he said was true. One, you want the screening exam so you're on the register, et cetera, et cetera. But if you're filing a claim and you say "I'm filing a claim for Agent orange," it's going to get bounced right back and all you've wasted is maybe eight, nine months of this veteran's time because you have to be specific. What are you claiming?

The first thing the adjudication section will say is: What are you claiming? What residual are you claiming was caused by that exposure to Agent orange?

This is where the screening and the exam will narrow it down; and hopefully sitting with the service officer you'll also narrow it down saying, "Well, are we talking about PCT? Are we talking about sarcomas, chloracne? Or what? The numbness of the hand?"

But you have to be specific. AS I said, in my dealings with the Board, for many that's the tragedy I see. By the time it comes to the Board, of course, you're talking about 18 months out of this guy's life. He's waiting tor a decision.

The first thing we do is we bounce it back another six, seven, eight months because he bypassed that initial step of taking that Agent orange exam.

So that's the reason why you'll probably hear most of us say you should take that Agent Orange exam, especially if you're going to file for compensation.

I agree with you, you're going to get better service once you go in for comp' and pen' and we're trying to clarify this; but you have to be specific what you're asking for. If you just go in and say, "I want to tile tor Agent Orange," you know, it may slip through by the time it gets to us, to the Board, because they're going to deny it, or

course, you know, until this liberalized legislation comes out.

MR. WHITE: Usually my veterans know what to complain about.

MR. ESTRY: Well, I understand. As long as they are being specific, then you might have a claim. But they're still going to remand.

As soon as it's Agent Orange or related to it, or even has a hint of it, it's going to be sent back tor the Agent Orange screening exam. They put them on a register for due process purposes.

The man can't squawk, "Well, 1 never had the special exam." For some reason, they think it's a specialized examination that's going to do more than the comp' and pen' in some areas; but I think they're botn basically the same.

CHAIRMAN SHEPARD: Dr. Anderson?

DR. ANDERSON: I believe if you will remember the report of the survey we did in Texas that I reported on earlier today that of the 1500 that responded to the survey — he has a copy of it, I don't have it here; I'll just try to remember the numbers — some 800 of them had a medical problem filed.

Of those 800 over 500 went back to the VA tor subsequent treatment of that condition, and some of those —

I don't have the statistic ana never will because we didn't ask the question: How many of them then tiled the claim? We don't have that.

But this does say something tor the screening examination; that they are finding things ana that the veteran is going back and subsequently he is getting treatment.

Now, how good the treatment is ana so forth 1 certainly didn't cover.

DR. FITZGERALD : I think that's an important distinction, that when they got for an Agent Orange examination they are asking for an examination to tind out it there's anything wrong with them ana specifically, it they do find anything wrong with them, then if it can be taken care of in the Veterans Administration they are set up to take care of it in the Veterans Administration.

If it is something to be found at that time not related to the service or to Agent Orange they're notitiea ot that and advised to go their private physician.

This is treatment oriented. It is diagnostically oriented. But what we're also advising at the same time is for the veteran — if, indeed, he thinks he has something that is related to service — to take the other step ana to go ahead and file simultaneously for compensation purposes.

They are really overlapping, but they are designed

for two different purposes.

CHAIRMAN SHEPARD: Thank you, Dr. FitzGerald.

Any other questions? Yes, Mr. Burdge.

MR. BURDGE: I would like to add to the Agent Orange; since 1980 I have had four Agent Orange/ screenings. Each one ot them, the results came back different. They were ail done at the same facility at East Orange, and the third one I had said *I* did not have any kind of a skin condition at all.

My skin condition has been there since 1972.

So you cannot believe what the results are on these exams, in my opinion and in the opinion ot the veterans that *I* deal with every day.

The veterans in New Jersey are not happy witn tne results that they are getting from the exams and the way it is handled. Some of them are getting results; some aren't. Some are getting results that there's nothing wrong with them and two years later they drop dead.

You can't believe, you know, the results that are coming from the exams. I think this committee snould check into the Agent Orange exam and find out if the doctors are diagnosing the illnesses the way they see them.

CHAIRMAN SHEPARD: It's very difficult to deal with a broad guestion of that type. The only way we can deal is to have, you know, specific names and cases so we can help you look into them.

I can't answer your question. I appreciate your concern, but until we have specifics it's very difficult for us to do very much about it.

MR. BURDGE: I'll get you names.

CHAIRMAN SHEPARD: Okay.

Yes, Chuck.

MR. CONROY: I was just wondering, along this same vein, we had mentioned in prior meetings the fact that the GAO would possibly be conducting another evaluation or these screenings and if you had any information on that.

CHAIRMAN SHEPARD: Well, I know that they have completed their field work. They have completed their data gathering.

We met with them, I guess, about three weeks or so ago at which time they had some, I think, final questions. It's my understanding that they are now in the process of preparing their report.

So I can't give you a specific time when we expect that, but they are working on it and they should be submitting it.

MR. CONROY: Hopefully results from that survey will address some of these things we've cited here this morning.

CHAIRMAN SHEPARD: Yes. I hope so.

One of the issues they are dealing with is the

matter of sending biopsy specimen to the AFIP. That process has changed a little bit in that we are no longer encouraging VA hospitals to send specimens ot Vietnam veterans into the AFIP to be included in their registry since they have over 1200 now, which don't seem to be showing anything.

So we're trying to wrap that up.

Dr. Nelson Irey is interested in getting tissues from non Vietnam veterans — that is veterans ot the Vietnam Era who didn't go to Vietnam — in order to draw some comparison. So he is engaged in that phase of nis effort.

Any other questions or comments?

[No response.]

CLOSING REMARKS BY MEMBERS

CHAIRMAN SHEPARD: There's one piece o± business that I haven't dealt with, and I think I'd like to get on the record, and that is we've Deen talking about the future of this committee in various contexts.

I would like to have an expression or the membership here as to their thoughts about the future ot the committee as it's presently constituted. We've nad some input from the state of New Jersey and other concerned individuals and groups.

Most of them that I've seen have urged that the committee continue in its present form. I think that, as an

advisory committee, the members of the committee should be solicited for an expression of their feelings on the subject of the future of this committee.

So I'd just like to quickly go around the table and poll you. If you want to abstain and prefer to communicate that to me in writing, I'd be very happy with that.

But could we just quickly go around the committee and get a sense of the committee as to whether or not you feel that the committee should continue; ana if you think it should continue in some other form or whatever, please feel free to say so.

Dr. FitzGerald, we'll start with you.

DR. FITZGERALD: I think the committee has served a useful purpose. I think there's some question as to the frequency of meetings of this committee since, at the present time, the information that is coming forth as tar as Agent Orange is concerned seems to have reached a plateau.

I would be perfectly willing to serve on the committee. I would be perfectly receptive to the suggestion of the Chair as to the frequency of the future meetings.

CHAIRMAN SHEPARD: Thank you.

Mr. Walkup, would you care to express your feelings?

MR. WALKUP: I sent a letter to you after the last

meeting and conveyed most of my concerns. I think the bottom line that I came down to was: for all the limitations or the effectiveness of our committee, I think it's useful at least for communication across the cultures among those in the Veterans Administration, those in the scientific community, those in the veterans' organizations and Vietnam veterans who may not belong to an organization.

It's a place where we can come together around a fairly sensitive issue. If we do continue I would hope that we could focus on issues perhaps beyond Agent orange or studies of dioxin specifically, but look at some of the confounding variables in the Vietnam experience that may interact or have something to do with Agent Orange and to begin looking at some of those kinds of issues; and also that we look to some better extent than we have at the service delivery system that's there for Vietnam veterans to deal with concerns about Agent orange as well as about physical examinations for Agent Orange.

CHAIRMAN SHEPARD: Do I infer from that, then, Hugh, that you would not be opposed to merging this committee with the Readjustment Counselling Committee?

MR. WALKUP: No, I wouldn't.

I think in some form or another what we're doing here ought to go on, is what I'm saying.

CHAIRMAN SHEPARD: Okay. So as long as there's some committee that continues in terms of addressing concerns of Vietnam veterans you'd be happy with that form of committee.

MR. WALKUP: Right. I think it would be good to have some device so that there's a scientific as well as a veterans' based input into that.

CHAIRMAN SHEPARD: Okay. Fine.

Dr. Anderson, do you have any thoughts on the subject?

DR. ANDERSON: over the past year, a little better, we've been breaking up into subcommittees. Having an interest in the activities of both committees, I, of course, attend to the scientific part of it.

I think I missed something by not attending the other half. Today I feel much more comfortable as the meeting comes to an end because everything has been in front of me. Perhaps some other people have a different feelings.

I'm not saying that the Chairmen of the two subcommittees didn't do a good job of bringing the word back; but it's nice to hear from the individuals themselves, their thoughts and their feelings.

If we do continue, I would rather see us continue as a committee of the whole and not break up because there is no other representation from my state on the other committee.

Now, as far as state representation is concerned, I feel it is very important that the states, particularly those states in which the legislatures have put out considerable amounts of money to look at a problem which definitely is a federal mandate — it's not a state mandate.

The state legislatures have been concerned enough to take their tax money to put it into these endeavors and i feel that — I know I am privileged to be able to sit on this committee and to let you know what the states are doiny and how they feel, and to report back to the states that we do have a voice at a federal level.

Beyond that, I have nothing more, Dr. Shepard.

CHAIRMAN SHEPARD: How do you feel on the subject of merging this committee with the Readjustment Counselling Committee? Do you have any position on that?

DR. ANDERSON: Well, we're talking about two different things entirely.

I think that this committee is basically probably more scientific in its endeavors that have been going along over the last 3, 3-1/2 years that I have been here. I think that group — I don't know what the life of it's going to be.

This group, I hope within the next two or three years, will have an answer to a lot of the problems and perhaps its life expectancy will be shortened. The other

one I have no feel for.

I have no objections to working with them or even combining.

CHAIRMAN SHEPARD: Fine. Thank you.

Dr. Hodder?

DR. HODDER: I have found the committee very useful from my own perspective. I also serve . on the Agent Orange Working Group. Of the committees I've served on, this one is the only one where I feel that the states' and the veterans' opinions are coming to us.

I don't know how Dr. Barnes feels, but it gives me a perspective when I go back to the cabinet council level committee in terms of what we are working toward.

I don't know enough about the other committee to give a valid sense of whether I think we should join, but something Mr. Walkup said before I think is important; that the link of a lot of the illnesses that have been suggested for Agent Orange, with Agent Orange itself is based on some fairly weak data.

I think there are really two questions that keep coming to my mind. Is there, in fact, a large amount ot disease in the veteran due to having been in Vietnam? Ana, secondly, is it due to Agent Orange?

Normally, in epidemiologic studies we would answer the first question — Is there an excess? — and then yo and

look at the cause. This is sort of an inversion.

We're looking at the cause first.

If I were, tomorrow, present a definitive study and say, "Guess what. There's no effect of Agent Orange," I'm not sure we've still answered the question of the veterans who have sat here with their complaints.

So if going with the other committee would, in fact, expand or allow more of that concern to be voiced, that might be a very beneficial consideration.

If I might take a few more seconds, on the question that Mr. Walkup also raised about relating to the other committee on adjudication of claims. For the same reason that I've mentioned about this committee's effect on myself, I think I would like to see at least somehow the committee to have some kind ot a tormai liaison; if not meeting together at least have someone who represents the feeling; not a voting member since the Congress has decided the composition of that, but some tormai liaison ought to be there.

CHAIRMAN SHEPARD: Yes. 1 think that will take place. There's been an informal suggestion that 1 serve in that capacity; but, there may be other ways to approach that issue.

I would agree very strongly that there certainly needs to be a definite liaison between that committee and any

other committee dealing with concerns and issues around Vietnam veterans.

Mr. Estry.

MR. ESTRY: It gets around to me. Thank you.

What's good about being on this side ot the table is I can just echo what's been said to the right. It does a lot for me.

My feelings really are, of course, that first ot all I agree with Dr. FitzGerald. I think with the progress that's been made over the past few years sometimes we yet the feeling that we're meeting too often and a lot ot the information, I think, is almost redundant.

You know, it comes to mind, if we're talking about the scientific data, with most of the studies that we needed time then to understand how they're being made up and all the other problems with them. They are now underway.

Now it becomes almost, "Well, we shouldn't meet until we have something we can really talk about it we're in an advisory capacity"; but that's just one aspect, I think.

I agree with Hugh strongly that as more and more problems are being viewed branching out from the Agent Orange issue — Of course, when we formed Agent Orange I think it was a catchall term. We didn't really know what we were looking at. Now it's expanded a lot.

We almost have to either merge or somehow combine

with these other committees because these problems, I think, we've taken upon ourselves. I sometimes believe those committees were really an outbranching from this committee, itself,

So, you know, of course it's up in the air what's going to happen with the charter and everything else.

Dr. Anderson made a good point that I've always felt; that it's hard to be in two places at one time. When you're representing an organization and you're put on one committee – of course, it was very important to hear what was going on out in the outer stations -- you miss out on some of the scientific data and it's hard to get someone else to come with you to some of these meetings.

So I agree. I have really enjoyed today. Of course, I missed the last meeting because of a conflict in scheduling, but I enjoy it when we can sit down and we can interact all together; we can hear what's going on from the actual person.

So basically, I guess, I can only echo what they said and I'm going to leave it at that; stay noncommittal.

CHAIRMAN SHEPARD: Well, let me just paraphrase what I think you said.

I think you think there needs to be some committee of this type. Whether or not it merged with the other committee, you don't have any strong feelings about.

Then the other thing that I heard you sayiny is that you question whether or not it's necessary to meet with the same degree of frequency.

MR. ESTRY: I believe so, yes, because the scientific aspects, I think, we can't take from the expertise that's shown here at this table. So even if we were to combine with the Readjustment Counselling Committee,

if it was a total combining we would lose that aspect. *I* really believe that.

The logistics of that, I'm g,lad 1 aon't have to worry about that. You know, it's not ray tunction tnere.

But, yes. I believe we need the committee, but I'm in that void area where we also have to combine, I think, now and to expand a little bit with the other problems which are manifested from this issue.

So I'm staying noncommittal.

CHAIRMAN SHEPARD: Dr. Mulinare?

DR. MULINARE: I think the history ot this committee reflects the enthusiasm that people have had tor having a forum for dealing with issues that are both scientific and non scientific; and that the types ot people, at least the short time I have been with this committee, who have come and participated also reflects the enthusiasm that people had for participating here.

I think something along these lines and in this

framework must continue. I'm not sure how it should be done because obviously there's this new committee that seems to be a subset of what we've been doing over the last several years; and that is to look at adjudication of claims.

But, as well, it's broadening its prospective by also including radiation. I'm not sure I know how our committee can interrelate to those aspects.

But I'm all for having a continuation of the kind of forum that we've had here and with consideration tor the amount of scientific input that those of us that are interested in these sorts of things can put into it.

CHAIRMAN SHEPARD: Very good. Thank you very much.

Mr. Phillips?

MR. PHILLIPS: I would have to concur with what's been said in terms of the committee. I believe there is a genuine purpose for this committee.

The Agent Orange issue is very complicated, as you know. There are questions out there that haven't really been answered. Until we have the answers to the Agent Orange questions, I don't think this committee should dissolve itself.

As I understand it the charter expires in April but there was, within the Administration, consideration to extend that charter. I certainly hope that they favorably

entertain that.

It's a tough issue, but it's one that has to be addressed. The radiation issue is a tough issue that has to be addressed.

Again, I believe there is a purpose for this committee and that the committee should continue.

CHAIRMAN SHEPARD: All right. Thank you very much.

Dr. Lingeman, I think you're a charter member of this committee. You were here before I got here.

DR. LINGEMAN: I think I'm the oldest one on the committee.

I think the committee has served a very useful purpose in its almost five years. I have certainly learned a lot such as the way that the VA operates. I have also learned much I didn't know before about dioxin. I can take this information back to my agency with mutual benefit for all.

I would like to see the committee continue. If it's going to be discontinued, I would like to see it phased out gradually because the new committee will be composed of entirely different people.

Some of these people will be coming in cola, so to speak. I think to just suddenly drop this committee and replace it with another comprehensive group would cause delays. It took a while for members of this committee to become familiar with the issues.

In the early days of this committee, we were all very naive, I think, in many ways. I think hearing wnat the veterans themselves had to say and what their concerns were has had the effect of stimulating our efforts in ways that we might not have thought of.

One other that has occurred is the decrease in attendance by members from academia. I think we had more people from academia, to start with. Now the greatest proportion of scientists are from government agencies.

I really would like to see an effort made to yet more people from outside government on tne committee.

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

I might also point out that to the best ot my recollection Dr. Lingeman, in the 4-1/2 years *at* least tnat I've chaired this committee, has only missed one meeting. So i think we owe her a round of applause for faithful duty.

[Applause]

CHAIRMAN SHEPARD: Dr. Barnes.

DR. BARNES: As the choir director says, it you want to be heard and noticed in a chorus of things, sometimes you sing off key. So since I'm the last let me siny a little off key from what I've heard.

That is that I have not been a member of this

group for very long; however, my sense is the committee sort of 'growed up' when nobody else was on the block. It was put in of necessity.

' of the committees that deal with this issue around it seems to be the oldest. When it got started I sensed that it was trying to fill a broad spectrum of needs all the way from communicating with individuals who have problems and providing something of a forum to the other end of perhaps suggesting scientific research that ought to be done, which is very broad span to try to cover.

It might not be inappropriate at this time in the committee's history to reassess what its purpose ought to be for the next five years, let's say. My suggestion would be it should not be for the same purpose that it had for the first five years.

In the same way that the churches were involved in setting up higher education in this country and in many ways have moved off into other endeavors, leaving a church related aspect in that endeavor, I think this committee ought to see that there might be new fields to plough or new ways to approach it.

So first of all I think that, to some degree, we are a tad redundant; at least so far as the scientific aspects are concerned.

Now, this is strictly the scientific regard. I

think the Agent orange science panel is able to focus on areas in greater detail. Perhaps because of its constitution, maybe because it's not open to the public it can get in there and thrash things out in a different way.

The new committee which is coming forward is, again, trying to plough the same kind of turf. 1 would question whether or not, on a strictly scientific basis, this group ought to focus on that.

However, it seems to me the unique aspect that this group does have is that it is open to the public ana it encourages communication. It seems – picking up on theme, anyhow, that was mentioned on the other side of the table – was that that is what this committee seems to be able to do; is to provide an avenue of communication in a relatively non-technical way.

The presentations that we hear, the more technical they get I think the less effective the meeting becomes in some regards. Yet the meetings don't seem to get technical enough to really deal with some of the nitty gritty science issues; and I'm not sure this is the form in which that ought to be.

So my suggestion would be to see it we couia not reconstitute this group in some way which would engage in transferring of scientific information. Perhaps it's a level that we hear from the states.

For example, as Dr. Hodder says, this is the only avenue that we have from hearing about what the states do and I think the presentations are very accurate and appropriate. We enjoy hearing about what New Jersey is doing and Oregon.

I know this fellow who died of 2,4,5-T is a secondary case. I mean, all these things are very intriguing.

So I would encourage that level of scientific communication as opposed to the formal presentations that sometimes we've had.

Also, I would encourage the committee to consider perhaps drafting a status report; not necessarily going over in detail its first five years, but just giving an overview of where we've come from, where are we now, where is it we need to go?

Committees and organizations have a tendency to just go on as a part of their own momentum. New situaies can always be thought of. New things can always be funded.

It's a question of where it is all leading? Do we have a direction?

To echo what Dr. Hodder said a little while ago on this, twin study — one of the suggestions that the Agent Orange Science Panel makes — is, look, it's time that we not just let the momentum carry itself. We ought to say that we've come to a demarcation point.

We have a certain amount of information now. This is what we know from that. And, from this point on, we're going to require or at least encourage this sort of activity.

I think on the basis of this committee's being the longest standing one in town and on this issue, the whole country could benefit by such a report from this committee.

CHAIRMAN SHEPARD: Thank you, Dr. Barnes, and all of you.

DR. FITZGERALD: May I have one more minute?

CHAIRMAN SHEPARD: Yes, certainly. Please.

DR. FITZGERALD: I think that one of the guidelines to show the effectiveness of this committee would be a comparison of today's meeting versus the first two meetings of this committee. I think Dr. Lingeman will bear me out in this.

What has come forth here is that this has served a need with the public as well as with the Veterans Administration. In the first two committee meetings the hostility that was present in the rooms was overwhelming to the extent that many of you may not notice it, but there's still a guard outside the door.

Well, the guard is outside the door because of the hostility that was present in the first two meetings in which physical violence was actually threatened.

I think that this is an indication of some of the

purposes that this committee has served; and I would second Dr. Barnes' statement that since the situation has changed since the original onset of this committee, again guidelines as to our approach in the future are definitely indicated.

CHAIRMAN SHEPARD: Fine. Thank you very much, all of you.

CLOSING REMARKS OF CHAIRMAN

CHAIRMAN SHEPARD: If I might just sort of summarize my sense of the committee is that there seems to be a strong sense that the committee should continue. The question of whether it should be merged with the other committee is a little bit ambiguous, I think largely due to the fact that this committee has had no direct interaction and doesn't have any firsthand experience dealing with the other committee so there may be a little bit of uncertainty.

But certainly Dr. Barnes and Dr. FitzGerald's comments about taking a quick look backwards to see where we come from and then redefining our charter seems to me to make a lot of sense.

As a matter of fact, we at One point had somebody engaged that was going to do precisely that; to go over all the proceedings of the previous thing and pull them together and highlight it as an interesting historical document it nothing else; but then hopefully to perhaps point the way to the future.

That initiative has gone on the back burner, so to speak; but I think it's a good one and we'll try ana revitalize it.

Are there any other comments, questions?

[No response.]

CHAIRMAN SHEPARD: If now, thank you very much. i think it's been a very worthwhile session and we'll look forward to getting back to you in terms of any decisions about the charter.

[Whereupon, at 12:35 p.m., the meeting was concluded.]

STATE OF CALIFORNIA – STATE AND CONSUMER SERVICES AGENCY GEORGE DEUKMEJIAN, Governor

DEPARTMENT OF VETERANS AFFAIRS
DIVISION OF VETERAN SERVICES
P. 0. Box 1660, Sacramento, California 95807
Telephone: (916) 445–2334

December 6, 1984

George R. Anderson, M.D.
Texas Agent Orange Program
Texas Department of Health
1100 West 49th Street
Austin, Texas 78756

Dear Dr. Anderson:

Thank you for your letter announcing the V. A. Advisory Committee on Health-Related effects on Herbicides on December 11, 1984 in Washington, D.C.

As we understand the American Medical Association is preparing an article on Agent Orange/Dioxin for publication in its journal and you would like to include California's Program. Since our program is in developmental stages – we are enclosing a copy pf our new legislation AB 3443. Again, thank you for this opportunity.

Sincerely,

Kenneth A. Kronen

KENNETH A. KRONEN, M.P.A.
Agent Orange Coordinator

KAK:sc

Enclosures

Rcd 10-10-84 PASSED

Assembly Bill No. 3443

CHAPTER 1480

An act to amend Section 698 of the Military and Veterans Code, relating to public health, and making an appropriation therefor.

[Approved by Governor September 25, 1984. Filed with Secretary of State September 26, 1984.]

LEGISLATIVE COUNSEL'S DIGEST

AB 3443, Hayden. Department of Veterans Affairs: herbicide exposure: assistance to civilians.

Under existing law, the Department of Veterans Affairs assists Vietnam veterans and their dependents in pursuing possible claims against the United States arising out of exposure to herbicides, including Agent Orange, as defined, and provides an outreach program to inform those veterans of the possible detrimental effects of herbicide exposure in Vietnam. Under existing law, this program will terminate on June 30, 1985.

This bill would do all of the following:

(1) Direct the department to provide referral for administrative, medical, and compensation services of the United States Veterans' Administration.

(2) Direct the department to follow up its referrals of veterans to the VA for medical assistance and claims for compensation and maintain contact with veterans referred to the VA to establish a record of their degree of satisfaction with the VA's Agent Orange services in accordance with the findings and recommendations contained in a specified United States General Accounting Office report. It would direct the department to report on the record so compiled to the VA headquarters and the appropriate committees of the Legislature.

(3) Require the department to similarly assist American civilians who served in Vietnam in obtaining information regarding herbicide exposure, and to conduct an outreach program to contact these civilians and furnish them information on herbicide exposure. It would direct the department to prepare and submit to the Legislature on or before January 1, 1987, a report on the results of its activities in this regard.

(4) Require the Board of Medical Quality Assurance, in cooperation with the department, to provide a program for the dissemination of information through physicians on the Agent Orange and herbicide exposure health care and compensation services of the VA and assistance provided by the department.

(5) Extend the termination date of this program to June 30, 1987.

(6) Appropriate $50,000 to the department for purposes of the bill.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares as follows:

(a) Vietnam veterans in California have no alternative to the United States Veterans' Administration in seeking help with health problems and concerns related to exposure to herbicides such as Agent Orange, while some other states, by contrast, maintain screening and diagnostic services or assistance to veterans in obtaining necessary health services from the Veterans' Administration together with followup monitoring of the performance of the Veterans' Administration facilities in those states.

(b) There are 14 Veterans' Administration facilities within California, and the Veterans' Administration is under congressional mandate to provide a range of health care services, examinations, and information to Vietnam veterans possibly exposed to herbicides while serving in Vietnam.

(c) The United States General Accounting Office has recently published a report, designated GAO/MRD 83-6 dated October 25, 1982, and titled "The Veterans' Administration's Agent Orange Examination Program: Actions Needed to More Effectively Address Veterans' Health Concerns," which concluded that health care facilities of the Veterans* Administration nationwide were significantly deficient in carrying out federal law regarding services to Vietnam veterans potentially exposed to Agent Orange. This report concluded, among other things, that, overall, the Veterans' Administration provides Vietnam veterans with complete physical examinations in only a minority of cases. The sample of Veterans' Administration facilities investigated by the General Accounting Office in its study included two of the 14 in California.

SEC. 2. Section 698 of the Military and Veterans Code is amended to read:

698. (a) The department shall assist Vietnam veterans, and the dependents of those veterans, in presenting and pursuing claims that a veteran or dependent asserts that he or she may have against the United States arising out of exposure to herbicides, including Agent Orange. As part of the department's assistance in the preparation and filing of claims for damages alleged to be due to herbicide exposure, the department shall do all of the following:

(1) Cooperate with the State Department of Health Services and other state, federal, and private agencies to organize and distribute the information on the effects of Agent Orange and other herbicides on Vietnam veterans, as identified pursuant to subdivision (b).

(2) Provide an outreach program to inform California Vietnam veterans of the possible detrimental effects of herbicide exposure in Vietnam. This program shall include, but not be limited to, dissemination of information to county veteran service officers and other California veteran agencies and organizations.

(3) Retain information on those Vietnam veterans responding to

the outreach program.

(4) Provide referral for administrative, medical, and compensation services administered by the Veterans' Administration.

(5) Follow up on its referrals of veterans to the United States Veterans' Administration for purposes of assisting Vietnam veterans in securing medical assistance or pursuing claims for compensation.

(6) Maintain contact with veterans referred to the United States Veterans' Administration to establish a record of their degree of satisfaction with Agent Orange services provided by the Veterans* Administration. The findings and recommendations contained in the United States General Accounting Office report GAO/MRD 83-6, dated October 25, 1982, entitled "The Veterans' Administration's Agent Orange Examination Program: Actions Needed to More Effectively Address Veterans' Health Concerns" shall be used as a guide in compiling this record. The department shall make a report of the record so compiled to both of the following:

(A) The proper administrators at the headquarters of the Veterans' Administration.

(B) The appropriate committees of the Legislature,

(7) Report to the Legislature on or before January 1, 1985, on the Agent Orange Program. The report shall include, but not be limited to, the following:

(A) The number of California veterans identified as having been exposed to Agent Orange and other defoliants.

(B) The number of California veterans filing claims for compensation for service-related exposure to Agent Orange and other defoliants.

(C) A categorization of symptoms reported by the veterans.

(D) A summary of medical test results from exposed veterans.

(E) The availability of federal and private funds to offset state expenses incurred in assisting veterans in filing defoliant-related claims.

(b) The department shall also assist American civilians who served in Vietnam in obtaining information concerning their possible exposure to herbicides, including Agent Orange. As part of the department's assistance in this regard, the department shall conduct an outreach program to do all of the following:

(1) Contact civilians who served in Vietnam.

(2) Furnish these civilians with information on the possible detrimental effects of exposure to herbicides employed in Vietnam and on possible sources of information relative to securing medical services and assistance in pursuing claims for compensation.

(3) Prepare and submit to the Legislature on or before January 1, 1987, a report on the results of its assistance to civilians.

(c) The Board of Medical Quality Assurance, in cooperation with the department, shall provide a program for the dissemination of information through physicians on the Agent Orange and herbicide

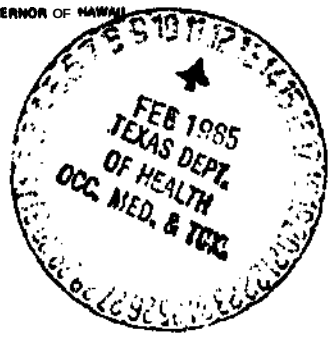
exposure health care and compensation services administered by the Veterans' Administration and assistance provided by the department.

(d) As used in this section, "Agent Orange" means the herbicide composed primarily of trichlorophenoxy acetic acid and dichlorophenoxy acetic acid.

(e) This section shall remain in effect only until June 30, 1987, and as of that date is repealed, unless a later enacted statute, which is enacted before June 30, 1987, deletes or extends that date.

SEC. 3. The sum of fifty thousand dollars ($50,000) is hereby appropriated from the General Fund to the Department of Veterans Affairs for expenditure during the 1984–85 fiscal year for purposes of this act.

GEORGE R. ARIY08HI
GOVERNOR OF HAWAII



LESLIE S. MATSUBARA
DIRECTOR OF HEALTH

STATE OP HAWAII
DEPARTMENT OF HEALTH
P. O. BOX 3378
HONOLULU, HAWAII 96801

In reply, please refer to:
File:

February 6, 1985

George R. Anderson, M.D.
Occupational Medicine and Toxicology
Texas Department of Health
1100 West 49th Street
Austin, Texas 78756

Dear Dr. Anderson:

Thank you for your letter of January 24 requesting Information about State Agent Orange activities which you are Intending to present to the VA Advisory Committee on Health Related Effects of Herbicides.

The Hawaii Agent Orange Program will terminate dune 30, 1985. At that time we will Have completed a brief survey of reported adverse affects of exposure to herbicides in Southeast Asia by Vietnam Veterans and Southeast Asia nationals who currently reside in Hawaii. I am enclosing a copy of that report. A large caveat 1s attached to the report, since we solicited responses, and the population studied 1n the report 1s a voluntary group, probably consisting of both 111 people and the "worried-well" population. As might be expected, we found more Illness reported by persons who felt they were exposed to herbicides than Illness reported by persons who felt they were NOT exposed to herbicides 1n Southeast Asia.

Our Hawaii Legislature authorized a continuation of the health survey, but restricted the survey to male veterans of the Vietnam era who could be contacted in a random way for telephone Interviews. We have now a sample of 418 Vietnam-era veterans, about one-third of whom did not serve in Vietnam and consequently could not have been exposed to herbicides. We will contrast the reported health status of both the "in-Vietnam" and "out-of-Vietnam" groups. Me will thus have a small sample of data to describe the effect of Vietnam service on the health of Vietnam Veterans, but will not attempt to attribute to herbicide exposure any Impact of that service on current health status.

We had planned to have the Vietnam Veterans come 1n to the office to show on a map where they had served and use the HERBS tape to try to assign an exposure Index to their area of service. Our funds may not suffice to complete the second half of this study.

The first half of the current project is entitled "The effect of Vietnam service on the reported health status of veterans". We will publish the study before June, 1985. I will send you a copy of the paper when it appears, probably as a publication of the Research and Statistics Office of the Department of Health.

Thank you for the Information about the AMA article, "Health Effects of Agent Orange, etc., etc." I'll look forward to reading it.

Sincerely yours,

William L. Rellahan, Ph.D.
Agent Orange Program

IOWA
HEALTH
DEPARTMENT

HON. TERRY E. BRANSTAD
GOVERNOR

NORMAN L. PAWLEWSKI
COMMISSIONER Of PUBLIC HEALTH

March 5, 1985

George R. Anderson, M.D.
Occupational Medicine and Toxicology
Texas Department of Health
1100 W. 49th Street
Austin, TX 78756

Dear Dr. Anderson:

Re: Meeting of the V.A. Advisory Committee, Iowa Update

The Iowa State Department of Health will have completed it's Agent Orange Program responsibilities as mandated, June 30, 1985. The life of the Program was not extended beyond that termination date.

The Iowa State Department of Veterans Affairs has proposed and presented a funding request to the State Legislature for consideration to maintain and continue Agent Orange program activities and veteran services. If approved the Department of Health would transfer it's records and information compiled to Veterans Affairs with a final report.

Presently our registry lists 45,000 Iowa Vietnam veterans. Preliminary analysis of survey information to date reveals no statistically significant information compared to Iowa or national standards.

I will continue to keep you informed of future developments.

Sincerely,

Al Wendt

Al Wendt
Agent Orange Program Coordinator
Division of Disease Prevention
515/281-8220

AW/lcb

153

OSU

The Ohio State University

Department of
Preventive Medicine

Starling Loving Hall
Columbus, Ohio 43210-1228

January 8, 1985

Mr. Barclay Shepard, M.D.
Agent Orange Projects Office (10A7)
VA Central Office
810 Vermont Avenue, NW
Washington, DC 20420

Dear Mr. Shepard:

This communication is to apprise you of the status of the Ohio Veterans Agent Orange Program.

The period of active solicitation of information initiated in April of 1983 and originally scheduled for a one year period and to be concluded at the end of June 1984, was extended until the end of August. At this time no further data is being collected, so that the Health Forms are no longer available.

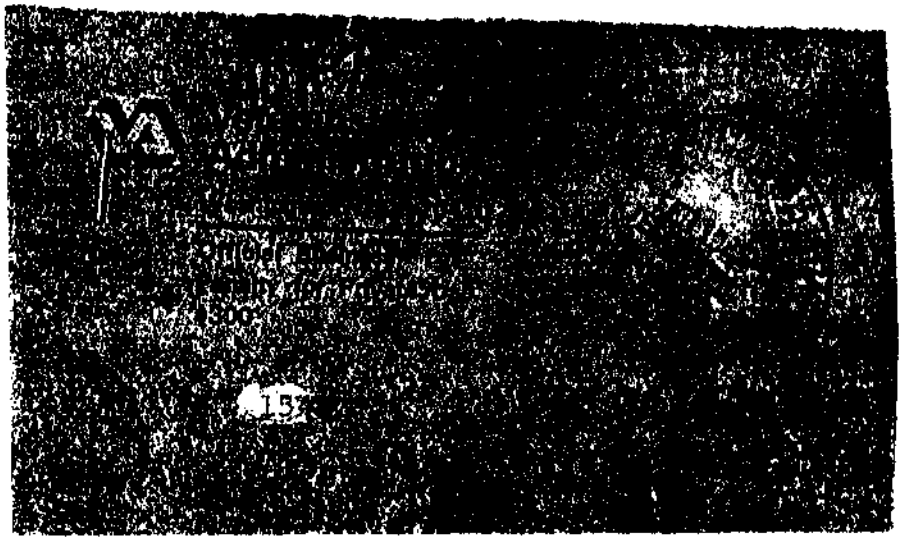
The future of this program will be decided by recommendations of the Ohio Board of Regents to the State Legislature.

It should be noted that the Federal Government, through the Center for Disease Control in Atlanta, has initiated a very extensive program to study the health effects of Viet Nam service on veterans, which should be considerably more revealing than any effort an individual state could support. This will definitely influence the direction which we feel the Ohio program can best serve its veterans.

Sincerely,

John V. Gaeuman, M.D.
Assistant Professor of Preventive Medicine
Director, Personnel Health, OSU Hospitals & Clinics

JVG/pap



AGENT ORANGE

JAN 15 1985

RECEIVED - (10A7)

VIETNAM HERBICIDES INFORMATION COMMISSION

P.O. BOX 8380 • ROOM 912A - HEALTH AND WELFARE BUILDING • HARRISBURG, PA 17105 • PHONE: (717) 787-1708

December 4, 1984

George R. Anderson, M.D.
Texas Agent Orange Program
1100 West 49th Street
Austin, Texas 78756

Dear Dr. Anderson:

Enclosed is information that you requested concerning Pennsylvania's Agent Orange Program.

I expect to attend the Veterans Administration's meeting on December 11, 1984 if my schedule permits. I look forward to seeing you there.

If you have any questions, don't hesitate to contact me.

Sincerely,

Terry L. Hertzler
Executive Director

TLH:rkj

Enclosures

On June 29, 1984, the Pennsylvania Vietnam Herbicides Information Commission (VHIC) was extended for Fiscal Year 1984-85 in an effort to complete its mission. The two major components that are currently being addressed are: 1) the Pennsylvania Vietnam Veteran Registry and 2) a Case Control Study on Soft Tissue Sarcoma, Lymphoma and Selected Cancers.

Pennsylvania Vietnam Veteran Registry

The Registry consists of three major components. They are: 1) a mailing list of the names and addresses of PA Vietnam veterans; 2) the Herbicide Exposure and Health History Questionnaire data; and 3) the Physician's Medical Report Form data.

The VHIC has developed a mailing list *of* over 200,000 names and addresses of Vietnam veterans who are curently residing in Pennsylvania or had residence in Pennsylvania during the time of their service in Vietnam. The major portion of this list (196,000) was based on the applications for the PA Vietnam Bonus. The remaining names and addresses were received by inquiries on the VHIC toll free information telephone number, returned VHIC post cards and various other responses from interested Vietnam veterans.

The PA Department of Revenue assisted in updating 127,000 addresses on the bonus list. Currently, efforts to update the remaining 69,000 addresses on the bonus list are being pursued with the Social Security Administration so that all of Pennsylvania's Vietnam veterans will have the opportunity to participate in the VHIC Program.

On October 2, 1984, Governor Thornburgh kicked off the mailing of questionnaire components. The mailing has been conducted in three phases: 1) Southeast; 2) Northeast; 3) Central, West and out-of-State veterans. Questionnaires for Vietnam veterans not on the VHIC mailing list are also available from the Governor's Veterans Outreach and Assistance Centers, Veterans Administration Vet Centers, County Directors of Veterans Affairs, the Adjutant General's Service Officers in the Bureau of Veterans Affairs, and VHIC members. To date, over 130,577 questionnaires have been mailed to PA Vietnam veterans. As of December 3, 1984, 25,882 completed questionnaires have been returned. Various methods of processing and analyzing the questionnaire data are currently being explored.

In June of 1984, over 9,200 booklets entitled "Toxic Herbicide Exposure (Agent Orange) the Physician's Resource" were sent to physicians (general practitioners, family practitioners, internists and osteopaths) in Pennsylvania. This booklet is intended to provide physicians with a reference resource that may be useful in their practice. Included in each booklet was a Physician's Medical Report form. This form is to be completed at the request of the Vietnam veteran by the physician who has been treating him. The information received from these reports will supplement the information supplied by the Vietnam veteran on his questionnaire. The use of the medical report form will provide an insight to the accuracy of the information on the veterans' questionnaire.

The compilation and analysis of the Registry information will be the basis for recommendations to the Governor and State legislature as to what social, administrative and medical assistance is needed by Pennsylvania Vietnam veterans and how Pennsylvania can best serve her sons and daughters who served in Vietnam.

Case Control Study of Soft Tissue Sarcoma, Lymphoma and Selected Cancers

The purpose of this epidemiologic case control investigation is to determine whether male Pennsylvania Vietnam veterans are over-represented in the cohort of Pennsylvania males dying of soft tissue sarcomas, lymphomas, and other selected cancers. These cancers have been suggested by some researchers to be causally related to dioxin exposure. Specific aims of this study include:

1. To determine if male Pennsylvania residents of draftable age during the Vietnam war, who died between 1968 and 1982 of soft tissue sarcoma, lymphoma, and other selected cancers as reported on their death certificates, were more likely to have served in Vietnam.

2. To determine if any unusual trends or patterns of soft tissue sarcoma, lymphoma and other selected cancers can be noted in Pennsylvania death certificate data for the years 1968 through 1982 in regard to temporal trends, geography, clustering, occupations, or other demographic factors.

A major strong point of this study is that it could be completed in a short time-frame. The study would review available Pennsylvania mortality data and ascertain if an excess proportion of those who have died of soft tissue sarcomas and lymphomas were Vietnam veterans. If a positive association was seen this would be strong evidence for the need for a more comprehensive morbidity study. A morbidity study, rather than a mortality study, would be preferred, but these data are not currently available statewide for Pennsylvania. It is noteworthy that quantitative exposure information would not be available in any retrospective mortality or morbidity study of Vietnam herbicide exposure. The study might suffer from standard problems of mortality studies: validity and reliability of cause of death (COD), as well as occupation, would be unknown. Possible problems of this study might include difficulty in ascertaining information of military and Vietnam service, and difficulty in tracing next-of-kin.

Benefits of the proposed study will include its timely analysis of the potential association of soft tissue sarcomas and lymphomas and Vietnam military service. The Commonwealth's general populace, as well as the approximately 196,000 Vietnam era veterans of the Commonwealth, will potentially be served by the proposed study as phenoxy herbicides are known to have been used extensively within the United States for clearing brush along highways, power lines, and railroad tracks.

Other VHIC Programs

The Commission has a toll free information telephone number for veterans or for the public to call from within the Commonwealth of Pennsylvania if they need assistance or have any questions concerning herbicides exposure and services that are available to veterans.

The Commission has also developed a newsletter that will be distributed periodically to inform the veterans as to what is happening in the herbicides problem,

Texas Department of Health

Robert Bernstein, M.D., F.A.C.P.
Commissioner

1100 West 49th Street
Austin, Texas 78756
(512) 458-7111 - 7251

Robert A. MacLean, M.D,
Deputy Commissioner
Professional Services

Hermas L. Miller
Deputy Commissioner
Management and Administration

DATE: February 7, 1985

TO: AGENT ORANGE ADVISORY COMMITTEE
AGENT ORANGE SUBJECT SELECTION COMMITTEE
VETERANS' ORGANIZATIONS AND OTHER INTERESTED INDIVIDUALS

FROM: Harriet Franson, Program Manager
Agent Orange Program

RE: STATUS REPORT FOR PERIOD ENDING JANUARY 31, 1985

Enclosed for your information is a cumulative status report reflecting Texas Veterans Agent Orange Assistance Program activities through January 31, 1985.

Enclosure

TEXAS DEPARTMENT OF HEALTH

AUSTIN TEXAS

INTER-OFFICE

THROUGH: CHIEF, BUREAU OF EPIDEMIOLOGY
THROUGH: ASSOCIATE COMMISSIONER FOR PREVENTABLE DISEASES

THROUGH: DEPUTY COMMISSIONER FOR PROFESSIONAL SERVICES

FROM George R. Anderson, M.D.
Occupational Medicine and Toxicology
Agent Orange Program

TO Robert Bernstein, M.D., F.A.C.P.
Commissioner of Health

SUBJECT TEXAS VETERANS AGENT ORANGE ASSISTANCE PROGRAM
STATUS REPORT FOR PERIOD ENDING JANUARY 31, 1985

REFERRALS	TOTAL	TO DATE
No. of veterans referred into the program this reporting period (No. of deceased veterans--4: TOTAL 20)	80	1,911
Military and medical records have been requested for all referred veterans:		
Medical records reviewed to date: (Include VA and civilian records-- 166 reviewed this reporting period)		1,731
Military records reviewed to date: (include combat history, DD214, and/or medical--141 reviewed this reporting period)		1,278
No. of veterans referred into program and not in compliance with residency requirements--ineligible	2	14

CONTACTS

Direct contacts from veterans this reporting period	91	1,280
By phone--65 (total to date: 925)		
By letter-21 (total to date: 311)		
By visit--11 (total to date: 17)		
Contact from News Media: Herb Preminger, Free Lance Writer, New York City; Odessa American (John Watkins)	2	110
Contact from or with other states/countries:	5	257
Connecticut (1)		
Massachusetts (1)		
Minnesota (1)		
Washington, D.C. (1)		
West Virginia (1)		

160

-Continued-

SIGNED

DATE February 5, 1985

TEXAS DEPARTMENT OF HEALTH

AUSTIN TEXAS

INTER-OFFICE

FROM George R. Anderson. M.D. TO Robert Bernstein. M.D., F.A.C.P.

SUBJECT TEXAS VETERANS AGENT ORANGE ASSISTANCE PROGRAM Page 2
STATUS REPORT FOR PERIOD ENDING JANUARY 31, 1985

Continuing contact with Legislative offices (Congressman Mickey Leland and State Representative Larry Don Shaw), Office of the Governor, Office of the Attorney General, Texas Department of Corrections, Texas Veterans Affairs Commission, Texas Land Commission, University of System, Veteran's Administration, Vet Centers, Military Personnel Records Center, County Veteran Services Officers, Local Health Departments/Clinics, Other State Agent Orange offices, counseling services/physicians/hospitals, veterans' organizations, Dow Chemical Company, and law firms.

54 followup letters were sent this reporting period to veterans who previously inquired about the program but not yet participating. (TOTAL TO DATE: 627)

Made/mailed 103 followup. phone calls/letters to check on military/medical records requested but not yet received. (TOTAL TO DATE: 1,554)

34 feedback letters were sent this reporting period to veterans in our program to apprise them of the status of their case (military/medical records received, pending, etc.). This method of feedback had not been accomplished since June 1983. (TOTAL TO DATE: 539)

10 veterans in the program requested or were placed on inactive status this reporting period, primarily due to individuals moving with no forwarding addressess available (TOTAL TO DATE: 110) However, four (4) inactive veterans have resumed participation in the program. (TOTAL TO DATE: 6)

In response to our mailing to Texas veterans on the VA Agent Orange Registry received 10 completed questionnaires (TOTAL TO DATE: 1,505) of which 7 asked to be registered with the Texas Agent Orange Program (TOTAL TO DATE: 1,212).

3 veterans requested and were sent copies of case file records, in preparation for filing a claim: (TOTAL TO DATE: 18)

-Continued-

SIGNED

Februarv 5, 1985

TEXAS DEPARTMENT OF HEALTH

AUSTIN TEXAS

INTER-OFFICE

FROM George R. Anderson, M.D. TO Robert Bernstein, M.D., F.A.C.P.

SUBJECT TEXAS VETERANS AGENT ORANGE ASSISTANCE PROGRAM Page 3
STATUS REPORT FOR PERIOD ENDING JANUARY 31, 1985

PROTOCOL STUDIES

The second phase of the clinical studies has begun, with the following studies to be conducted this fiscal year:

Cytogenetics at UTS CANCER CENTER, Houston, by Dr. Hsu
Bleomycin Test at UTS, CANCER CENTER, Houston, by Dr. Hsu
Immune Profile at UT HEALTH SCIENCE CENTER, Houston, by Dr. Kerman
Uroporphyrins at UT HEALTH SCIENCE CENTER, Houston, by Dr. Kerman
Aryl Hydrocarbon Hydroxylase Induction at UT MEDICAL BRANCH, Galveston, by Dr. Ward

The protocols were published in summary and complete format.

Questionnaires received from selected veterans and proposed controls continue to be reviewed to establish proper matching of veterans with controls.

Two volunteer controls for the Agent Orange clinical studies submitted a study questionnaire. (TOTAL TO DATE: 123, of which 21 are TDH employees.

Telephone contacts made with selected veterans and controls to make appointments for the collection of specimens.

Contacts made by telephone with the clinics/laboratories where specimens are to be collected/delivered.

36 appointments arranged for the collection of specimens (TOTAL TO DATE: 222). Arrangements made with 3 individuals for the 2nd/3rd collection of specimens for the Sperm Study (TOTAL TO DATE: 231). 6 reminder letters were sent re. collection of specimens for Sperm Study (TOTAL TO DATE: 20).

SIGNED -Continued-

DATE February 5, 1985

FROM George R. Anderson, M.D. TO Robert Bernstein, M.D., F.A.C.P.

SUBJECT TEXAS VETERANS AGENT ORANGE ASSISTANCE PROGRAM STATUS REPORT FOR PERIOD ENDING JANUARY 31, 1985

26 letters were mailed to veterans concerning their participation in the clinical studies (TOTAL TO DATE: 341) and 72 to proposed controls (TOTAL TO DATE: 146).

Number of specimens collected and shipped to UTS:

		TOTAL TO DATE
CYTOGENETICS STUDY	26	196
IMMUNE SUPPRESSION STUDY	26	193
UROPORPHYRIN	26	26
AHH (Enzymes)	26	26
SPERM STUDY	0	126
SPECIMEN NO. 2	0	99
SPECIMEN NO. 3	8	94
FAT TISSUE SPECIMEN	1	2

2 veteran/controls requested and were given results of individual study specimens analyses. (TOTAL TO DATE: 19)

SELECTION PROCESS FOR REFERRAL TO THE UTS SYSTEM

Review of cases is an ongoing process for eventual referral to the Agent Orange Selection Committee--450 were reviewed this period for referral to the committee.

To date the Selection Committee has reviewed 590 cases (147 being reviewed more than once), of which 155 have been selected for the clinical studies (of which 33 are for inclusion in the second study phase).

BROCHURES/POSTERS

To date approximately 34,448 brochures and 7,720 posters have been mailed. In addition to individual requests, brochures and posters have been provided to veterans' organizations, county service officers, clinics/hospitals, and other states.

SIGNED -Continued-

DATE February 5, 1985

TtXAS DEPARTMENT OF HEALTH

AUSTIN TEXAS

INTER-OFFICE

FROM George R. Anderson, M.D. TO Robert Bernstein, M.D., F.A.C.P.

SUBJECT TEXAS VETERANS AGENT ORANGE ASSISTANCE PROGRAM Page 5

STATUS REPORT FOR PERIOD ENDING JANUARY 31, 1985

MAINTAINING STATISTICAL INFORMATION

Information is compiled each month from case files concerning the following medical conditions reported and substantiated by medical records. This information is provided to the Agent Orange Selection Committee and becomes part of our data information. Such information will be compiled for other medical conditions as the need arises.

Cancer in Veterans Under Age 36	Current Rashes
Cancer in Veterans Over Age 36	Children with Leg Deformities
Tingling/Numbness in Extremities	Miscarriages/Stillbirths
Post Traumatic stress Disorder (PTSD)	Schizophrenia

Diagnoses continue to be coded with International Code for computer entry.

AGENT ORANGE ADVISORY COMHITEE

Meeting is scheduled to be held on February 13, in Austin.

Two vacancies in representation of Vietnam veterans on the Advisory Committee were filled with the appointments of Billy O'Dell and Roland Nichols.

SPECIAL ACTIVITIES

Continue review of available literature for research on Agent Orange and related topics.

Continue to purchase publications for reference library.

Extraction of statistical data from case files concerning specific military data and medical conditions, etc.

Utilize word processor for the storage/retrieval of data and for multiple reproduction of originally-typed letters when form letters are not warranted.

In-house training on use of computer equipment for Richard Smith and Harriet Franson (d-Base and Software Users Group) will continue.

SIGNED -Continued-

DATE February 5, 1985

FROM George R. Anderson, M.D. TO Robert Bernstein, M.D., F.A.C.P.

SUBJECT TEXAS VETERANS AGENT ORANGE ASSISTANCE PROGRAM STATUS REPORT FOR PERIOD ENDING JANUARY 31, 1985 Page 6

Provided article on State Agent Orange Programs for American Medical Association technical report on "Health Effects of Agent Orange and Polychlorinated Dioxin Contaminants: An Update, 1981."

Ongoing communication with other state Agent Orange Commissions/Programs as their representative on the VA Advisory Committee on Health-Related Effects of Herbicides.

Reviewed and prepared comments on Veterans Administration Agent Orange videotape script designed for VA employees.

MAJOR ACCOMPLISHMENTS

1. Number of veterans in the program has increased to 1,911-- an increase of 1,508 since the beginning of FY 84.

2. To date 590 cases have been reviewed by the Subject Selection Committee, of which 155 have been selected for referral to the University of Texas clinical studies. A total of 761 blood/sperm specimens have been collected and shipped to the University of Texas System laboratories and one fat tissue shipped for analysis in the V.A./E.P.A. Study of Dioxin Levels in Human Adipose Tissue.

MEETINGS ATTENDED

November 1981	Technical Report Writing Class, TDH, Austin (Riohard Smith)
November 14, 1981	Agent Orange Advisory Committee, Houston (Dr. Anderson, Harriet Franson)
December 4-5, 1984	Achieve Your Potential II Training Course, TDH, Austin (Richard Smith)

SIGNED -Continued-

TEXAS DEPARTMENT OF HEALTH

AUSTIN TEXAS

INTER-OFFICE

FROM George R. Anderson, M.D. TO Robert Bernstein, M.D., F.A.C.P.

SUBJECT TEXAS VETERANS AGENT ORANGE ASSISTANCE PROGRAM Page 7
STATUS REPORT FOR PERIOD ENDING JANUARY 31, 1985

FORTHCOMING MEETINGS

February 13, 1985	Agent Orange Advisory Committee, Austin (Dr. Anderson, Harriet Franson, Richard Smith)
March 13-15, 1985	Texas Public Health Association, Houston (Dr. Anderson, Harriet Franson)
March 26, 1985	VA Advisory Committee on Health-Related Effects of Herbicides, Washington, D.C. (Dr. Anderson)

Attachment--Data Sheet

cc: Agent Orange Selection Committee
Agent Orange Advisory Committee
Veterans' Organizations and other interested individuals

SIGNED George R Anderson

DATE February 5, 1985

Arch A. Moore, Jr.

L. Clark Hansberger, M.D.
Director

State of West Virginia

DEPARTMENT Of HEALTH
CHARLESTON 25305

March 7, 1985

George R. Anderson, M.D.
Occupational Medicine and Toxicology
Texan Department of Health
1100 West 49th Street
Austin, Texas 78756

Dear George:

As per our discussion, please find enclosed an informational update on our program, a summary of the medical conditions reported in our first 53 examinations and a claim tally from the court (which I have ranked according to number of forms returned and self-reported medical problems indicated on the claim form). I've also enclosed an article on soft tissue sarcomas and the New York mortality study which may be of some interest to you.

Regarding our West Virginia mortality study I think you will concur that, because of the media coverage which these studies invariably generate, it is imperative that they be as methodologically sound as is humanly possible. Consequently, I have advised Dr. Shepard that because of our need to secure the necessary clearances from newly-elected and appointed state officials and, more importantly, our desire to assure a strong peer review of the study, we will be unable to present our findings to his committee as we tentatively scheduled. However, I did indicate that the study will be ready for publication shortly, and that at that time we would, of course, be delighted to address either his committee, or whatever VA Scientific Committee might be in operation.

I plan to be at the meeting on the 26th and would be happy to present this update to the committee on that occasion.

Thank you for your invaluable advice and assistance and I look forward to seeing you in Washington.

Sincerely,

Chuck Conroy, Coordinator
Agent Orange Assistance Program

CC/em

Enclosure

UPDATE ON THE WEST VIRGINIA AGENT ORANGE ASSISTANCE PROGRAM

To date, the West Virginia Department of Health has received requests for medical testing for possible health related effects of Agent Orange exposure from 4,800 State Vietnam Veterans. This represents approximately 12% of West Virginia's Vietnam Veterans.

In order to register for medical testing services available under the program, a veteran simply completes and returns the postage paid portion of an informational brochure (these brochures have been mailed out to all 41,000 State Vietnam Veterans). If the veteran objects to being tested by the Veterans Administration, which is phase one of the testing protocol, they so indicate on the card, and arrangements are made to have them tested at an alternate facility. To date, 107 veterans, or approximately 2% of the respondents have refused to be tested by the Veterans Administration.

Upon receipt of their request for testing, providing they have no objections, an appointment is arranged for the veteran to receive an Agent Orange Screening Examination from the Veterans Administration Medical Center closest to them. Over the past twenty-four months, over 3,000 of these exams have been scheduled. Every effort is made to make these appointments as convenient as possible for the veteran, and this quite often requires making appointments around work schedules, etc....

After receiving the VA exam, the veteran is then forwarded a consent form, enabling the VA to release copies of their examination results to the West Virginia Department of Health. The veteran is also asked to complete a comprehensive medical questionnaire and copies of medical records from private physicians the veteran has visited (over the past three years) are also solicited.

Once all the medical records and the medical questionnaire have been received, these documents are then forwarded to the Health Department Epidemiologist who assures that all required exams, lab work, x-rays, etc., have been performed and are included with the veteran's medical records.

After all these medical records are gathered, they are abstracted by the Health Department Epidemiologist, noting abnormal test results and symptoms which may possibly relate to Agent Orange exposure. All this information is then coded, as is the questionnaire which the veteran completed, and entered into a computer so that it is easily retrievable.

Upon completion of this review and evaluation, the Health Department Epidemiologist then forwards the veteran's records to a physician, who the Health Department has placed on contract, at one of the State's three medical schools (at Morgantown, Huntington or Lewisburg). To date, 27% of our applicants reside in the Morgantown area, 46% in the Huntington area, and 22% in the Lewisburg area.

The physician then determines what additional testing may be required from our medical testing protocol (e.g. electromyography, genetic counseling, neurophychiatric testing and perhaps, in rare cases fat tissue biopsies) and contacts the veteran regarding an appointment. All the physicians have an expertise in environmental and occupational medicine.

Subsequent to the veteran's examination and testing by the State Physician, they are afforded an opportunity to discuss the results of the testing with the physician. A final report with diagnoses and test results are then sent to the veteran and to the West Virginia Department of Health. A summary of the medical conditions reported in the first 53 examinations, is attached to this report.

The confidentiality of the veteran's medical records are maintained at all times, and the veteran is advised that both VA and Health Department medical testing is totally free of charge.

A mortality study to determine how many West Virginia Vietnam Veterans have died since the conclusion of that war, the cause of death, etc., has also been commenced, and should be completed in the near future.

The program has also been extremely active in providing information and assistance to State Vietnam Veterans who wish to file a claim form for a portion of the $180 million settlement fund established as a result of an out of court settlement in New York. This activity has involved the dissemination of claim forms, instruction booklets and informational updates to all interested veterans. As a direct result of this activity, West Virginia ranks eleventh in the nation in the number of claim forms returned to the court. Of the 4,351 claim returned to the court by West Virginia Vietnam Veterans, 168 reported that they are currently suffering from cancer, 819 reported that they have a defective child, 466 reported that they have a child born with multiple birth s, and 668 reported that their wives experienced a miscarriage.

ted by: Charles Conroy, Coordinator
Agent Orange Assistance Program
State Department of Health

PHYSICIAN RECOMMENDATIONS FOR FOLLOW-UP*

Dermatology	12
Genetic Counseling	2
Lab Studies (e.g. thyroid, sed. rate, trigly., chol.)	9
Medical Follow-Up:	
-Vets (e.g. audiometric, ophthal., pulm.fx)	14
-Children (e.g. birth defects/congenital defects)	2
Nerve Conduction Studies	22
Neuro Psychiatric Testing	25
No Follow-Up Necessary	5
Urology	
-Semen Analysis	6
-Urine Porphyrins	1

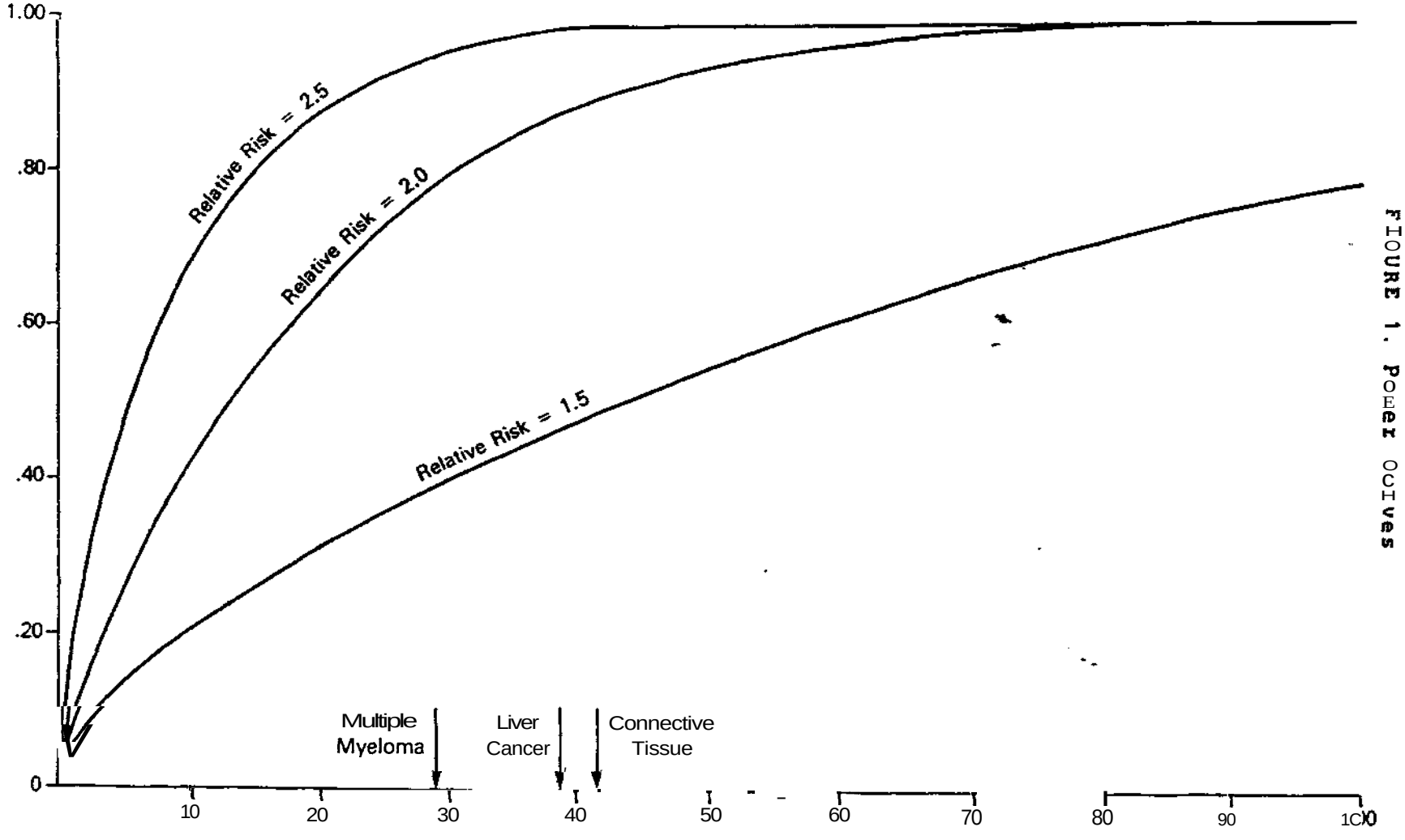
*Reflecting 53 summary letters received as of February 15, 1985.

Mortality Studies of Vietnam-era Veterans

Study	Total Deaths Vietnam	Non-Vietnam	Suicide Vietnam	Non-Vietnam	STS Vietnam	Non-Vietnam
VA Vietnam Veterans Mortality Study	60,000		*		*	
Air Force Health Study	54	265	3	14	0	0
New York State Study	555	941	80	125	2	3
Massachusetts State Study	840	2,515	102	*	9	*
Australian Veterans Health Study	260	263	40	36	2	0
CDC Epidemiology Study	1,100 (expected)		*		*	

*Not available

FIGURE 1. POWER AND EXPECTED NUMBER OF DEATHS IN NON-EXPOSED GROUP (SEE TEXT FOR ASSUMPTIONS)



172

FIGURE 1. POWER OBJECTIVES

Australian Vietnam Veterans Mortality Study.

Table 2.1 Number of National Servicemen excluded from the Mortality Study, classified by reason and veteran status.

Reasons for excluding National Servicemen	Veterans	Non-veterans
Total National Service records	19480	44295
Less those who enlisted after February 1971	(28)	(14686)
Less those who served less than 90 days	(0)	(2527)
Less those who died in service within two years of enlistment (730 days)	(200)	(121)
Less Vietnam combat deaths (after two years of Army service)	(14)	(0)
Less those aged less than 18 at time of first enlistment	(0)	(1)
National Servicemen eligible to be Mortality Study subjects	19216	26960
Less those not selected due to incomplete data at time of sample selection	(7)	(3)
Mortality Study subjects	19209	26957

The number of National Servicemen excluded from the Mortality Study is shown in Table 2.1, together with the reasons for exclusion. After the cohort of study subjects was selected and data collection commenced, incorrect dates of enlistment and discharge were found among the records of ten National Servicemen who were previously ineligible to be subjects. These individuals were not included in the study population, since it was not practicable to determine their vital status (Section 2.5). A National Serviceman is excluded only once in Table 2.1, although he may be ineligible to be a subject for a number of reasons (e.g. enlisted after February 1971 and served 90 days or less). The application of these criteria left 46166 former National Servicemen as study subjects. The corps grouping (see Section 3.5.2) and cause of death of National Servicemen excluded from the study due to death in the first two years of Army service are shown in Tables 2.2 and 2.3. Also shown in Table 2.3 are the corps groupings of the 14 veterans who died in combat more than two years after enlistment.

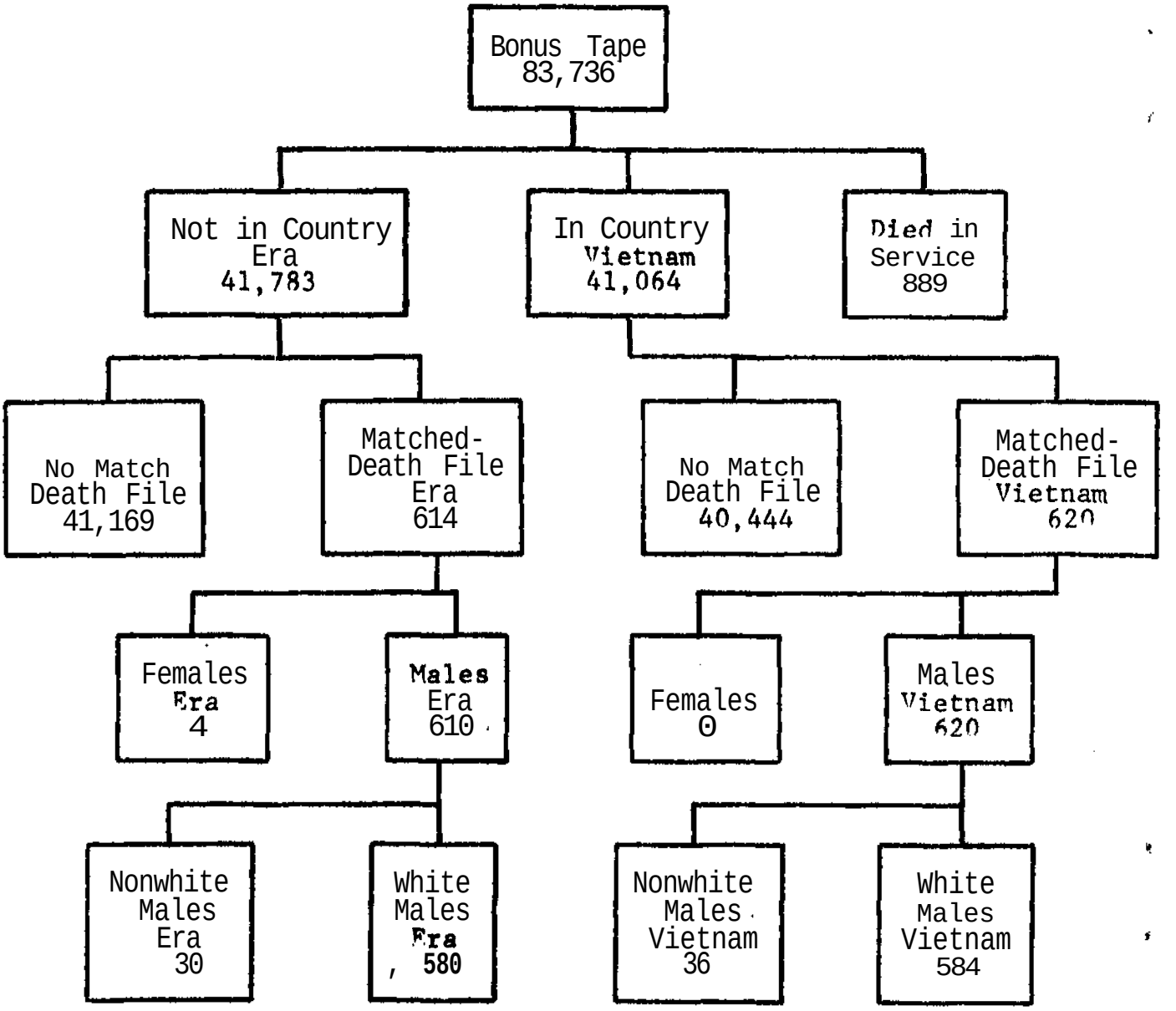
Observed and Expected Number of Deaths by Veteran Status

Veterans Status	Observed	Expected	Ratio (95% CI)
Veteran	260	311.8	0.83 (0.74-0.94)
Non-veteran	263	407.3	0.65 (0.57-0.73)
Ratio			1.29 (1.08-1.54)

Table 3.10 Number of subjects, number of deaths observed and expected, estimated death rate and estimated relative mortality rate of veterans and non-veterans (with 95 per cent confidence intervals in brackets), classified by corps grouping and veteran status.

Corps grouping	Percentage of study subjects who were veterans	Veterans				Non-veterans				Total	Relative mortality rate	95 per cent confidence interval
		Total	Deaths Obs.	Deaths Exp.	Rate ($\times 10^4$)	Total	Deaths Obs.	Deaths Exp.	Rate ($\times 10^4$)	Rate ($\times 10^4$)		
Infantry	61	8270	122	135.2	12.5	5382	80	85.6	13.0	12.7	0.96	(0.7,1.3)
Engineers (RAE)	52	2758	45	44.2	14.1	2568	17	41.3	5.7	10.0	2.48	(1.4,4)
Armour and Artillery	48	2487	34	-40.1	11.7	2742	35	44.0	11.1	11.4	1.06	(0.7,1.7)
Minor field presence	28	2288	23	37.1	8.6	5894	38	93.1	5.6	6.5	1.52	(0.9,2.6)
Non-field corps	27	3404	36	55.1	9.0	9091	93	143.1	9.0	9.0	1.01	(0.7,1.5)
Total	43	19205	260	311.8	11.6	25677	263	407.3	8.9	10.1	1.29	(1.1,1.5)

WV VIETNAM VETERAN MORTALITY STUDY
SELECTION OF STUDY POPULATION
1968-83



VIETNAM VETERANS - IN COUNTRY - **MALES**
MATCHED WITH 1968-83 WV DEATH TAPE
AGE DISTRIBUTION BY RACE

AGE GROUPS	WHITE		**NONWHITE**		TOTAL	
	#	%	#	%	#	%
<19	0	0.0	1	2.8	1	0.2
20-24	87	14.9	5	13.8	92	14.8
25-29	118	20.2	11	**30.5**	129	**20.8**
30-34	138	23.6	8	22.2	146	23.6
35-39	57	9.8	2	5.6	59	9.5
40-44	51	8.7	2	5.6	53	8.5
45-49	59	10.1	1	2.8	60	9.7
50-54	29	5.0	4	11.1	33	5.3
55-59	30	5.1	2	5.6	32	5.2
60-64	12	2.1	0	0.0	12	1.9
65-69	3	0.5	0	0.0	3	0.5
70-74	0	0.0	0	0.0	0	0.0
TOTAL	584	100.0	36	100.0	620	100.0

VIETNAM-ERA VETERANS - MALES
MATCHED WITH 1968-83 WV DEATH TAPE
AGE DISTRIBUTION BY RACE

AGE GROUPS	WHITE		NONWHITE		TOTAL	
	*	%	#	%	#	%
<19	4	0.7	0	0.0	4	0.7
20-24	77	13.3	5	16.7	82	13.4
25-29	130	22.4	8	26.7	138	22.6
30-34	126	21.7	10	33.3	136	22.3
35-39	81	14.0	4	13.3	85	13.9
40-44	42	7.2	0	0.0	42	6.9
45-49	33	5.7	3	10.0	36	5.9
50-54	39	6.7	0	0.0	39	6.4
55-59	24	4.2	0	0.0	24	3.9
60-64	12	2.1	0	0.0	12	2.0
65-69	10	1.7	0	0.0	10	1.7
70-74	2	0.3	0	0.0	2	0.3
TOTAL	580	100.0	30	100.0	610	100.0

Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

Twenty-Fourth Meeting
October 22, 1985

March 1986 Washington DC 20420

VETERANS ADMINISTRATION

Advisory Committee on Health-Related Effects of Herbicides

Veterans Administration
Central Office
Room 119
810 Vermont Avenue, Northwest
Washington, D.C.

October 22, 1985

COMMITTEE MEMBERS PRESENT

BARCLAY M. SHEPARD, M.D.
Chairman
VeteransAdministration

JOSEPH S. CARRA
Environmental Protection Agency

CHARLES F. CONROY, JR.
West Virginia Department of Health

GEORGE T. ESTRY
Veterans of Foreign Wars

THOMAS J. FITZGERALD, M.D.
American Legion

DAVID W. GORMAN
Disabled American Veterans

RICHARD A. HODDER, M.D., M.P.H.
Our Lady of Mercy Medical Center

KEITH D. SNYDER
Vietnam Veterans of America

HUGH WALKUP ,
National Veterans Task Force on Agent Orange

SARAH P. WELLS, USAF, RET.
Formerly Advisory Committee on Women Veterans

ALSO PRESENT:

CARL KELLER, M.D.
Agent Orange Working Group

HAN KANG, Dr. P.H.
Veterans Administration

ALVIN YOUNG, Ph.D
Office of Science and Technology Policy

RALPH TIMPERI
Masssachusetts Advisory Committee

RICHARD CLAPP
Massachusetts Department of Health

WAYNE WILSON
New Jersey Agent Orange Committee

JERRY BENDER
Minnesota Department of Health

TERRY HERTZLER
State of Pennsylvania

ARTHUR BLANK, M.D.
Veterans Administration

JOSEPH WHITE
National Association for Concerned Veterans

HERB MARS
Veterans Administration

INDEX

P R O C E E D I N G S

CHAIRMAN SHEPARD: It is my pleasure and privilege to welcome you to the 24th meeting of the VA Advisory Committee on Health-Related Effects of Herbicides. We have not met for quite a period of time for a variety of reasons, some of which I will touch on. But, I do want to recognize the newly reconstituted committee and particularly recognize the new membership.

Some, as you will note, have been serving faithfully for some time. But, we are very delighted to have some new faces on our committee.

Mr. Joseph Carra comes to us from the Environmental Protection Agency. Mr. Carra and we have been working closely on the VA/EPA adipose tissue study. So, we're very happy to have Mr. Carra as a member of our committee.

Charles Conroy has been a faithful attender at many of our meetings, and now he is officially established as a member of the committee. We welcome you, Chuck, and are very pleased to have you serve with us.

George Estry has been here a number of times before and is no stranger to the committee. We're happy to have George back on the Committee.

Dr. Tom FitzGerald from the American Legion has been

a faithful member for a number of years now. Tom, it is good to see you again.

Mr. David Gorman from the Assistant National Legislative Director for Medical Affairs of the Disabled American Veterans is on our committee again. Nice to see you again, Dave.

Dr. Richard Hodder, who has been serving as a member of the committee for some time has recently moved to New York City, where he is the Director of Medicine at Our Lady of Mercy Medical Center in the Bronx. We are very happy to have you back, Dick. Thank you for coming.

Dr. Peter Kahn, I understand, will not be here today. unfortunately, he had other commitments and could not make it, but Peter will serve as a member of the committee.

Mr. Keith Snyder will be serving from the Vietnam Veterans of America, and Hugh Walkup is with us again. Hugh, good to see you again.

General Sarah Wells, an Air Force retired Brigadier General is a member of the committee and hopefully will be joining us soon.

We were to have had Dr. Earl Brown, who is

my immediate boss, with us this morning to make some opening remarks, but, unfortunately, he will not be able to be with us. He sent word this morning that he has a conflict, but he wanted to send greetings to the committee and wish the new members well. And congratulate them, and thank the committee for its on-going efforts on behalf of Vietnam veterans and the Veterans Administration.

I'd like to briefly review for you the agenda so you'll all be aware of what v/e plan to accomplish this morning and early afternoon. We'll be hearing from Dr. Kang, who is director of our research section, who will review our research efforts for you.

Dr. Carl Keller, who is the Chairman of the Agent Orange Working Group Science Panel will bring us up to date on some of the activities of the Agent Orange Working Group.

Colonel Alvin Young will talk to us about some of the interesting events that are occurring around the world. Particularly some of the highlights, I hope, of our recent meeting in Bayreuth, Germany.

We will have a report from the Massachusetts Mortality Study, which has been of great interest to all of us.

Mr. Conroy will bring us up to date on what is going on at the state level, and then we'll hear from a number of representatives of service organizations bringing us up to date on their various activities.

We also will have a report from three other advisory committees with which we stay in touch.

General Wells, we hope, will bring us up to date on the activities of the Women's Advisory Committee, Dr. Arthur Blank on the Readjustment Counseling Advisory Committee, and Mr. Fred Conway on the Advisory Committee on Environmental Hazards.

And then of course we'll have our usual open discussion from members of the committee and also our audience.

I'd just like to ask all of those who have not signed our guest book, please do so during the break so we will have a record of your attendance.

RECENT VA ACTIVITIES

Just a few highlights of events that have occurred since our last meeting. During the week of August 26 we were privileged to have visiting us the Secretary of Veterans Affairs from Australia, Mr. Derek Volker and his first assistant secretary, Mr. Mick Letts. They spent the better part of that week here in Washington visiting a number of departments here in the VA and other agencies with whom we deal on the whole

Agent Orange issue. And at that time he extended an invitation to our Administrator to visit Australia. That did occur during the first week in October. Mr. Walters and Colonel Fred Bidgood visited Australia, and I was very privileged to accompany them on that trip. It was a very worthwhile visit. We had the opportunity to visit the largest VA hospital in their system in Sydney and also *a* readjustment counseling center in Sydney or in one *of* the adjacent towns.

We then went to Canberra, where I spoke with some *of* the senior members of their Department *of* Veterans Affairs, bringing them up to date in terms of research and other activities that are on-going in this country. And we visited a number of offices in the Canberra area. Canberra, as you know, is their national capital. And I think on the whole it was a very worthwhile and, I think, meaningful visit.

I mentioned the international symposium, the 5th international symposium held in Bayreuth during the week of the 16th and I'm hoping that Colonel Young will give us some of the highlights of that important meeting.

I'd like to announce to you that our research section under the directorship of Dr. Han Kang has been moved to the Armed Forces Institute of Pathology

on the grounds of Walter Reed Army Medical Center. That move has been talked about for some time and has now been completed. Hopefully, they are comfortably settled in in suitable space out at AFIP. For those of you who need to know, his telephone number is 576-0366.

Dr. Kang's office is in a building adjacent to the main AFIP building, immediately in back of it.

Our office has been moved from the Shoreham building to the Cafritz building, which is just the other side of 16th Street. We're currently in the turmoil of settling in over there, and, unfortunately, our phones are not hooked up, so we're not very easy to reach. But, we can be reached, hopefully most of the time, through the number 389-5301. We're assured that our telephones will be hooked up in the next few days.*

During the week of August 19 we held, here in Washington, an educational conference on Agent Orange, which I thought went very well. It was a one and a half day meeting attended by approximately 100 VA personnel. It was primarily designed for two purposes. One, to provide an in-depth overview of the whole issue of chloracne, from the point of view of its toxicology as well as the clinical aspects of chloracne.

* The new telephone numbers are 389-3432, 3886, 3774.

We had a number of excellent speakers with expertise in various aspects of chloracne provide us with a very good overview of that whole question. In addition, we reviewed, for the attendees, virtually all of the major activities on-going both here in the VA and in our sister agencies.

As I indicated earlier the charter for this, committee has been rewritten. The reason, principal reason for that is that Congress, as you probably know, mandated the establishment of an advisory committee on environmental hazards. Mr. Fred Conway will tell us a little bit more about the activities of that committee since he is its executive secretary. That committee is charged with many of the same responsibilities that had existed in this committee. Therefore, we thought it prudent to make some changes to the charter of this committee so there would not be an overlap of responsibility between the two committees. Many of you will recall that we discussed this at a couple of previous meetings. The Administrator himself decided that this committee

should continue, albeit under a somewhat revised charter. We will provide to members of the committee a copy of the charter before you leave today. But, let me just read for you one paragraph which outlines the objectives and the scope of the committee.

"The committee will one, review and make appropriate recommendations relative to the Veterans Administraton's programs to assist Vietnam veterans who are exposed to herbicides. Such recommendations may concern the information delivery system and outreach efforts, scheduling of Agent Orange related examinations, essential follow-up activities and other related matters.

"Two, advise the Administrator on VAAgent Orange related programs, programs of the Federal Government and State programs which are designed to assist veterans exposed to herbicides and simultaneously will minimize duplication of VA and other Federal programs concerned with Agent Orange issues.

"Three, receive and review information from the Veterans service organizations regarding services provided by the Veterans Administration to Vietnam veterans concerned about the possibly adverse health effects of exposure to herbicides.

"Four, review and comment on proposals for research on the possible health effects of exposure to herbicides.

"And five, serve as a forum for individual veterans to inform VA of their views on policy issues and on the operation of Agency programs designed to assist veterans exposed to herbicides and dioxins in Vietnam."

I think the charter is fairly broad in its scope. However, it minimizes to some extent the role that had been here previously, and that is to actually review scientific efforts, that is to review protocols and comment on those. Albeit, we still have some scientists on the committee and we're very grateful for their presence. The role has shifted a little bit in that we will not be primarily charged with reviewing the scientific merit of certain scientific efforts which are either underway or proposed.

Are there any questions from members of the committee so far about what we've gone over? Any comments?

MR. SNYDER: Yes. Dr. Shepard. I had a question as to whether we -- you had laid out here a time to describe the various adjudication status claims. How many have been received that have alleged Agent

Orange association and health effects related to that, the appeals status or whatever else has happened there?

CHAIRMAN SHEPARD: In terms of the actual claims being filed by veterans to the VA?

MR. SNYDER: Right.

CHAIRMAN SHEPARD: We don't have that on the agenda, but I see Mr. Herb Mars is here and maybe during the discussion time we can deal with that issue.

MR. SNYDER: Herb Mars?

CHAIRMAN SHEPARD: Mr. Herb Mars, yes. Prom the Department of Veterans Benefits. Any other questions or comments? If not, then let's proceed on with our prepared agenda. We're a little bit ahead of schedule although Dr. FitzGerald accurately reminds me that clock is five minutes slow. Dr. Kang should be here momentarily. I see Dr. Keller is here. Maybe I could now call on Dr. Keller to bring us up to date on some of the efforts of the Science Panel and related issues. Dr. Keller is the chairman of the Agent Orange Working Group Science Panel. Good to see you, Carl.

DR. KELLER: I will go over some of the studies that have been completed and are being done that are sponsored by the Federal Government. I think that's what Mr. Rosenblum asked me to do. And a couple of comments about activities of the Agent Orange Working Group as well.

I will not talk about studies that the Veterans Administration is doing, since those are covered independently, although I may mention some of the international work that Dr. Young will undoubtedly talk about or allude to.

First of all, I would like to say I'm picking and choosing amongst studies to report, and I'm not going to report on most of the laboratory or any of the laboratory studies specifically except in general terms. And I'm dividing this approach up into what has been done in the past and what is on-going. Furthermore, I'm dividing it into studies that focus on veterans versus — as well as studies that focus on humans that aren't veterans, or at least their exposure was not as a veterans. They might be veterans, but that isn't the reason their study is being done.

The studies which have been

completed give us a background of what we know about the subject at this point. One of the best known ones was the Australian series. The birth defect study, which essentially found no increase in birth defects among veterans in their group. They completed a mortality study, which found no increase among Vietnam veterans in mortality rates, although there were some differential service-connected -- possibly service-connected groups within the veterans group. Some had higher rates than others. The most recent Australian release is the Royal Commission Report, which focused on exposure and found essentially that among Australian veterans there seemed to be little connection between problems that were being experienced and exposure to Herbicide Orange in Vietnam.

Now, the major domestic study which has been completed, one of the major ones has been the birth defect study by CDC, which again found no increase in major birth defects among Vietnam veterans in the Atlanta birth defects registry area as compared to other veterans.

And finally, the Ranch Hand preliminary report, which as you all know focuses on the Ranch Hand group, which was responsible for maintaining the planes and spraying the fixed wing applications of herbicides in

Vietnam The researchers found in their preliminary or the first phase of the mortality report no differences in mortality between the Ranch Hand group and the comparison group and that there were still no differences after the second year.

And the morbidity phase, the first phase, they found no major problems, although they did find an increase in skin cancer among Ranch Handers. This is being investigated at this point because the known major cause of skin cancer in this country is sun, exposure to sunlight. And so that will have to be examined to see whether there is any differential exposure to sunlight among the Ranch Hand group.

That will be done during the second morbidity phase because they did not have the information the first time. And that is on-going. The second morbility phase is being — I'm not sure what stage it's in, but it's being --

CHAIRMAN SHEPARD: It's underway.

DR. KELLER: It's either underway or will be very shortly. So, we'll hear from that in probably another year and a half, I presume, before they get their — it takes a long time to examine all the folks and then to write up their report.

And they will focus on some things that were suggestive in the first study. A few little things.

The other thing that they found was some unverified increase in certain reproductive outcomes. Primarily minor birth defects. And they have gone back and are examining that question at this point. And I don't know what the status of that is. I know they've done some examination, but the question is then have they examined all of the records for all of the people and that's a question that has to be resolved over the next several months, I'm sure.

Those are the major veterans-focused studies that have been completed, for which we have some information. And unfortunately, it doesn't give us a whole lot of leads about what to look for. I know we had all hoped that this would be able to generate some hypothesis. They still may, but they haven't so far.

There have been several studies not focusing on veterans, but focusing on exposed individuals. They have tended to look at people involved with application of pesticides in one form or another. A completed study done in Florida on pesticide applicators found an increase in lung cancer, which was — I don't know, from my experience an increase in lung cancer in an occupational group is never a

surprise because they always find an increase in lung cancer for some reason. I don't really know why. However, there was no way to tease out and separate the effect of one form of pesticide from another. In other words, these applicators were using herbicides and insecticides and so forth. And they were unable to separate out and determine whether this was more likely an increase in herbicide exposed versus pesticide exposed people.

There are a number of international studies which you're all familiar with, which have generated a good deal of the concerns. The Swedish studies, a couple of studies in Sweden on essentially people who have worked with herbicides or with other chemicals in the woods and railroads found an increase in soft-tissue sarcomas, a rather significant increase. A rather sizable increase up to two, four times, six times as common among these workers. However, there are questions about whether, how well the exposures were documented and so as a result several studies have been documented in other parts of the world, which so far have not confirmed the original findings, but they have not been as large either. They just haven't confirmed it. They haven't refuted the original finding. So,

that is a question that is still up in the air. And the U.S. data of workers exposed industrially to the components of the herbicides, particularly dioxin have suggested there *is* some increase in soft-tissue sarcoma. But, the numbers are too small. The number of verified cases is too small, at this point, to make any assessment.

Now, with these studies there is some concerns although, as I say, except for soft-tissue sarcomas and the known connection with chloracne -- and the possible connection with prophyria, there aren't any good hypothesis. Now, there are concerns about immunological problems. There is concern about liver damage, and perhaps neurological damage and those are usually, always incorporated, at least some examination for those factors in these other studies. But, so far no definitive information.

Now, the major studies on-going that focus on Vietnam veterans of course are CDC co-sponsored -- well, actually by the Veterans Administration. I don't know if Dr. Kang is going to cover those or not.

CHAIRMAN SHEPARD: I don't think so. But, if you have something to say please feel free to address

that.

DR. KELLER: Well, I think you all undoubtedly known about those studies. There is a Vietnam experience study, which is essentially halfway done, I think, at this point. The veterans are being examined and the interview phase has already been completed, and

cohorts have been selected, and that's all completed. That's on-going. This will involve 6,000 Vietnam veterans and 6,000 non-Vietnam veterans for a telephone interview, plus 2,000 of each group for examination, which is being conducted by the Lovelace Clinic in Albuquerque, New Mexico under contract. That, as I say, is on-going.

Another component of that study, the Agent Orange Study, is designed to compare three groups of veterans. All Vietnam veterans, group of 6,000 combat veterans known to be at least in the proximity of -- to some extent — of herbicide application. A group that are less likely to have been in proximity to herbicide application and a third group who were stationed in an area where herbicides were known not to have been used. So, they are unlikely to have been proximal to a herbicide application.

Now, that study is

scheduled to go into the field in January. The

selection of cohorts is on-going. It is not completed. The determination of who is in which cohort has not been finally made at this point. The Agent Orange Working Group, as well as other review agencies will be looking at this process over the next two or three months. So, we'll have to see there what is going on.

The third study that the CDC is doing is a selected cancer study, which contains about 2,000 cases of cancer of various kinds. Soft-tissue sarcoma, non-Hodqkins lymphoma, I think, liver cancer is some and perhaps some others. And a group of controls chosen who do not have cancer who are living in the community. Cases to start accruing as of 1985. So, they will be sufficiently long after the Vietnam conflict – or return from Vietnam – to have at least touched into what should be a minimal or reasonable incubation or latent period. There is a possibility of induction of certain kinds of cancer. The major hypothesis of interest in that study is, in fact, service in Vietnam, will be compared.

The cases will be assessed from the SEER, the Surveillance Epidemiology End Results of the National Cancer institute, which has been maintaining several registries, population-based registries over the last -- most of them have been going

since 1969 — most of them since earlier than that and a few later than that. The third National Cancer Survey in '69, '70 and '71. The advantages of that kind of a study are that they take all of the cases of cancer in a given population group. Therefore, they assume they have all of the cases of cancer. And so they can compute rates and so forth there.

The way the selected cancer study is utilizing that population is to obtain cases for comparison with controls. But, the SEER registries are population based. The advantage being that you won't be selective. You won't have just some. You'll have all that occur in a given population.

And as I said, the other on-going study, Vietnam veteran study, is the second phase of the Ranch Hand Study at this point.

Now, there are a number of studies that are not focused on veterans that are nearing completion that again focus on such things as pesticide applicators. The National Cancer Institute has three or four. And I say three or four because they're doing a study in Kansas, Iowa, Minnesota and Washington State. And I'm not sure that the Iowa and Minnesota are separate or

the same study. And their focus is on exposure to pesticides. Now, the Kansas study, the data is completed and those were all case controlled type studies focusing on soft-tissue sarcomas, non-Hodgkin's lymphomas, leukemias, primarily those. In Kansas, it is soft-tissue sarcoma and non-Hodgkin's lymphoma and the reason that Kansas was chosen as a good site for a study like this is because in the agricultural practices of the State of Kansas there is a tendency to use herbicides without insecticides. Or whereas herbicides are used in this country in enormous quantities in the modern no-tillage type of agriculture that's being practiced, which means that you don't use plow, you use herbicides to keep the weeds down. And there are problems, of course, in the corn fields of a lot of insects too, so they tend to use a lot of insecticides along with it. So, the applicators are involved in both. Whereas, in Kansas there is a little more ability apparently to separate. I talked to the principal investigators, and they say they feel they have been able to separate effects of herbicides from insecticides in the Kansas study.

That data is being prepared. I am told that it will be imminently submitted for publication. It's already past the time when they originally thought it

would be, *so* I've tried to keep up on that.

Now, there is another study going on in Washington State -- this is a similar type of a study. It happens to be based on a population based tumor registry, also looking at soft-tissue sarcomas and non-Hodgkin's lymphoma. This study is being done by Batelle Corporation with funding through the National Cancer Institute. You had a report on that study in this meeting last year, a few months ago, I recall that. And as I recall, it is another couple ot years before we can expect results from that study. However, there is a lot of herbicide used in the State of Washington, and in the forestry divisions. That's one of the reasons that was a good place to try and do a study like that.

The other two states, the Iowa and Minnesota studies, there is a lot insecticide used and so the investigators aren't really convinced they can separate out the effects of insecticides from herbicides in those studies. And also in some parts of the mid-West in this country there seems to be an increase in what we call blood cancers anyway, particularly leukemia. So, that's one of the reasons that that group is being looked at. It is not totally directed by concerns over

herbicide and cancer.

Another group that's doing studies is the National Institute of Occupational Safety and Health (NIOSH) has completed a dioxin registry of all roughly 6,000 workers in the history of the United States who have been involved in those chemicals likely to be contaminated with dioxins in the manufacture and processes. They are doinq a mortality study in this group. They are also doing a morbidity study or planning a morbidity study. I'm not sure whether that has been started or not.

And there is an international dioxin registry, which is being funded jointly by the National Institute of Environmental Health Sciences. Some inputs from NIOSH and the International Agency for Research on cancer in Leon.

They plan to conduct a mortality study as well. That's one of the initial efforts through the International Dioxin Registry.

Now, those are all of the major human studies and veteran studies that I am familiar with, that are under the sponsorship of either the Federal Government, ours or someone else's. There are, of course, a number

of State supported studies which you've heard about and will hear more about. We have not been involved in those. There are a few industrial studies which have been done. Dow, I understand has completed a study, although I'm not familiar with the results.

Dr. Young may report on that as it was reported at the Fifth Symposium.

There are also a large number of laboratory studies done by several" agencies in addition to the Veterans Administration. There are some done by EPA, a large number, that focuses on each of the agency's general charge.

They have to be concerned a lot about how to destroy this stuff. How to handle it. And so a lot of their focus is going to be in that direction. The National Institute of Environmental Health Sciences has done a lot on the metabolism, the distribution of dioxins, mechanisms for action, which is important work to try to determine where one might look for problems, health problems — if we have some notions about what tissues that it affects.

CDC does some of this work primarily in the determination of amounts and detection and concerns with exposure, since that's part of what their

responsibilities are.

And the U.S. Department of Agriculture has been involved in some of this work because they are concerned with how long the stuff lasts in the environment, how good it is, what is the possible — along with OSHA, what are the concerns with workers that might get exposed and so forth. The Labor Department gets involved.

So, a lot of the federal agencies get involved with dioxin research, which all impinges on our interests but for the various reasons they have to be involved.

As far as the Agent Orange Working Group recent activities, we have recently submitted a status report, which contains a listing of all of the projects that we know about that are being done under Federal sponsorship by agencies and roughly how much is being spent over the last six, seven years or projected to be spent in the next year or two. There *is* some write-up about the findings, what we know about, what one can say at this point, which isn't a lot, and where we're going with that type of research at this point.

Other activities of the Agent Orange Working Group were that we -- the working group has been able

to report fairly recently to Congress on the current status of proposals to study female Vietnam veterans exposed to Agent Orange. And the general gist of what they said was that there is the evidence for Agent Orange exposure on female veterans is not only unlikely, but more importantly, it is undeterminable. That one can't really tell what might be going on there. Therefore, the general recommendation was that studies focusing on Agent Orange would not be very productive among female veterans. And what will happen about that we don't know. Perhaps other types of studies will be generated.

I think that's about it.

CHAIRMAN SHEPARD: Thank you very much, Dr. Keller, for that very complete and lucid presentation. Are there any members of the committee who have questions or comments for Dr. Keller? Yes, Hugh.

MR. WALKUP: I appreciate your overview. I think, in detail, it gets hard for the uninitiated to figure out what is going on. Could you tell us basically what you know and when will you know it, what, from all these studies and from that is projected to come out in the next few years, do we know about Agent Orange and what kinds of implications might that have

on the kind of work that the VA and the committee here should be doing?

DR. KELLER: Well, I think we don't know much. The studies that have been completed haven't really revealed a lot of problems. They were partly done to see if we could even get a suggestion of what was going on. And it doesn't appear that that has happened at this point. In fact, one of the recommendations from the Agent Orange Working Group, at this point, is let's examine what we have to get a better idea of where we're going.

we don't have anything to hold onto. We look at this, and there is nothing there. We look at that, and there is nothing there. Like birth defects was something that there was a lot of interest in and several people looking at it and many millions of dollars were spent.

But, there wasn't anything there when we got through. So, that's what I mean.

The intention was to say, maybe we can find something that we can focus in on. But, when you didn't find anything, then you back off and you start doing something else. So, that's kind of the status we're at now. Mortality studies haven't revealed any suggestive things to make one want to go on.

MR. WALKUP: One of the things that's been discussed in this committee several times *is* that maybe we picked a specific causal agent and didn't look at what was maybe *a* complex different environmental factors that could have lead to some of the problems. The research that you've reviewed, does it shed any light on that, whether it is the chemical set or the chemical/psychological set?

DR. KELLER: I think that most of us who have been involved in this issue are concerned that there are some things that haven't been looked at that are not necessarily related to the chemical set that we think may be important. And in fact, many of us have encouraged such studies as the Vietnam experience study to be conducted. And you might go back in the history, before there was an Agent Orange Working Group, there was a thought at that time that that was what was being fostered.

The pressures, however, came and the concerns, and a few little research things, like the soft tissue sarcoma, have stimulated the continuation of searches for Agent Orange related problems. And so far we haven't really found anything like this. We haven't found enough to get all excited about at this time. So, *I* agree with you that -- although this has not been our charge.

I mean the Agent Orange Working Group is not in the business of looking at the whole war experience of Vietnam veterans. It's not that we're not concerned about it, but that's not what we spend our time doing. It's not our charter. It's not our business. Although I think all of us encouraged those activities because, you know, the closer we get to it the more we realize that that is certainly something very well worth looking at.

CHAIRMAN SHEPARD: I think we'd better move on. We certainly want –

MR. SNYDER: Can I ask just a quick question. You had mentioned the status report that you prepared recently and submitted. Are copies of that available to us?

DR. KELLER: They either are or will be. It's – it will be a public document. It has to go through the secretary of something first. I think it is probably available. It has to be released by the Cabinet Council But, I can't imagine it won't be. Do you? Mr. Meese's decision.

MR. SNYDER: You had also mentioned a problem with the women's study that you couldn't -- something you can't tell. What were you alluding to there?

DR. KELLER: Agent Orange exposures. The

charge was to do an Agent Orange study of women veterans, and this was what we focused on primarily --

MR. SNYDER: You didn't have enough women to study to tell –

DR. KELLER: There are enough women to study. The question is if we want to do an Agent Orange Study, we've got to study those who were exposed to Agent Orange and those who weren't, and we can't tell. And furthermore, the data isn't there to support very much exposure. And even what is there we can't decide that this one was and this one wasn't. There is no way to do that.

MR. SNYDER: So you decided that such a study would not go forward?

DR. KELLER: An Agent Orange study. I want to be very careful about that, because nobody is recommending that a women's study not be done. That is another issue. It's that the focus has often been, particularly from Congress, to focus on Agent Orange. And we have been responsive to trying to address that question. And our determination, at this point, is that it doesn't seem to be evidence to select participants for a study of Agent Orange among female Vietnam veterans.

MR. SNYDER: You mentioned the third study, the case controlled study, the third CDC study and that the cases were going to come from the SEER network.

DR. KELLER: Right.

MR. SNYDER: Do they come from particular areas of the country?

DR. KELLER: The SEER network covers roughly 10 percent of the United States.

MR. SNYDER: So they're getting it from the entire SEER network?

DR. KELLER: I think so. But, I won't say the entire SEER network is cooperating. I'm not sure that they are all cooperating. And furthermore, there are some other problems. For example, if you were to pick up soft-tissue sarcomas, for example, and you do this in some of the big cities, part of the SEER network includes San Francisco, we have a problem with AIDS. We have a problem with Kaposis sarcoma, which is a soft-tissue sarcoma.

You're going to include some people who clearly aren't relevant to this study. So, they are not chosing soft-tissue sarcomas from that. They will try to include some other registries to make up for that difference. So, it is intended to be all of the SEER registries for which the data is sound and

for which the data will be complete.

MR. CARRA: Has CDC made any estimate as to how long it would take to get 2,000 from the --

DR. KELLER: I think their study is planned to be completed in 1989.

MR. CARRA: Thank you.

DR. KELLER: But there has been pressure now to release earlier results.

Do you need to do all 2,000 of them to release anything. Or 1,200 or whatever exact number they had planned. And you know, there is going to be pressure to say what have you done with the first 500 or something like that.

CHAIRMAN SHEPARD: I think we'd better move on. We're slipping a little on our timetable. There will be adequate time for questions later on. I'd like now to ask Dr. Kang to bring you up to date on some of our in-house and cooperative studies. Dr. Kang?

DR. KANG: This is a listing of research activities on-going now within the research section of tne Agent Orange projects Office. I don't know whether Dr. Shepard mentioned it earlier, but because of the reorganization within the Department of Medicine and Surgery, the research section has been redesignated as tne Office of Environmental Epidemiology, and has moved out to AP1P, Armed Forces Institute of Pathology, located at Walter Reed Army Medical Center.

Because of the limited time I will try to cover two items: Number two, the BIRLS Validation Study and Item number five, the VA PTF Survey of Soft Tissue Sarcoma.

If you recall, the large Vietnam veterans mortality study is based on the records the VA maintained. We sampled 75,000 deaths among Vietnam era veterans from BIRLS. That is the Beneficiary Identification Record locating Sub-system. The question that has been asked is of what percentage of Vietnam veterans era deaths VA actually has some knowledge. Since we sample our study subjects from the VA record, if only half of Vietnam era veterans have been recorded in the VA record then we're missing the second half or 50 percent from our sampling.

So, we commissioned HAS Medical Follow-up Agency and asked them to ascertain the completeness of our BIRLS system.

The way NAS approached this problem is that they contact several large states vital statistics offices and asked them to provide death tapes – death tapes of men with a certain characteristics. Namely, birth year 1936 to 1955. That would pretty much cover all the Vietnam era veterans. So they contacted eight states, New York and New York City being one state, and selected 4,001 study subjects. These are men with the birth year 1936 to 1955 and who died in the various states.

With that death tape they went to the National Personnel Record Center and matched that record. I'm sorry I have to go back and reintroduce the samples. Okay, it you look down there are 203,870 men with the birth year 1936 to '55. And they went to NPRC and computer matched those individuals to NPRC record and came up with 4,001 veterans.

As you can see from this table (Table 2)* ascertainment of the BIRLS record of death by state, there seems to be no dramatic difference. In other words whether veterans died in New York City or New York State or Michigan State, the percentage of reporting, the frequency of reporting to the VA is pretty much around 85, 87.

Now, this is I think a very important table (Table 6). Looking by Vietnam service status, 97.6 percent of Vietnam veterans deaths were reported to VA, whereas 82.5 percent of non-Vietnam

* see tables on pages 154-158.

veterans deaths were reported to VA. So, contrary to what we heard that, for one reason or another, Vietnam veterans or their families are more likely to stay away from tne VA system, the percentage of death reporting was higher in this group.

Looking at by race (Table 7), for those who served in Vietnam there is no difference between the white and non-white. 98.1 percent whites and 96.5 percent non-whites deatns were reported to the VA, whereas of those who didn't serve in Vietnam, 78.6 percent of whites and 85.6 percent of non-whites deaths have been reported to VA.

The next important question is what about those deaths not reported to VA. Is there any differential reporting by cause of death? So we looked at cause of death and frequency of reporting (Table 8). Again not much difference: Cancer 87.1 percent, whereas overall rate is 87 percent; All other diseases 35.2; Motor vehicle accident 88.6; suicide 90.9. The homocide is underreported, 78.8 percent. All other trauma is 87.1. So, there is no differential reported to the VA because of the cause of death except homocide.

Looking at by branch of service (Table 12) is there any possibility, by virtue of serving in one branch of service,

one veteran's death is more likely to be reported to VA then otners? That was the case. If you look at the far right hand column, 91.4 percent of Navy personnel or Coast Guard deaths are reported. The lowest one was Army, 85.6 percent. If you look at the table by the length of active duty by months, for the veteran who complete at least a two year service, their reporting frequency is over 90 percent: 93.3 percent for Army; 94.0 percent for Air Force; 90 percent for Marine; and 95 for Navy. So those who completed at least two year tours, their deaths were reported over 90 percent of the time.

The final table (Table 16) shows frequency of death reporting by discharge status. Among the veterans with an honorable discharge, 89.2 percent was reported to VA. For those other than honorable status 43.8 percent was reported. And that is understandable because the requirement for receiving VA burial benefits, either reimbursement of burial expenses or headstone of any kind, one has to be discharged under conditions other than dishonorable.

So the conclusion we can draw from the NAS BIRLS validation study is that yes, it is justifiable to sample from BIRLS death records. About 87 to 90 percent of all Vietnam era veterans deaths are reported to VA. We are not missing a large number of Vietnam veterans from our sampling scheme.

The next study is the VA PTF, Patient Treatment Files survey

for soft tissue sarcoma. I remember reporting to you about a year ago our survey of soft-tissue sarcoma in patient treatment files. At that time I reported the results through the second phase of our survey. The first phase of efforts was identifying the Vietnam era veterans who were treated in VA hospital with ICD 171. That is the presence of malignant neoplasm of connective tissue and other soft tissue. Just to give you some background, from Patient Treatment Piles (1969-1982) we identified a total of 418 cases with ICD 171. After we identified individuals, we asked each treating VA hospital to submit pathology report. We received 394 pathology reports and asked a VA pathologist to review the path report in the absence of military service information on each case. His conclusion was that out of 394, 234, in his opinion, should be classified as soft-tissue sarcoma. At the same time we sent a list of 418 ICD 171 cases to National Personnel Record Center for military service information.

Simultaneously, we made a systematic sampling from the same Vietnam era veterans population from which the STS cases were identified. We sampled 14,931 patients and determined their Vietnam service status. Of the sample of 13,469, 59 percent did not serve in Vietnam and about 41 percent served in Vietnam. That's the background population of Vietnam veteran patient population in VA hospitals. Among those 234 STS cases 36.8 percent of soft tissue sarcoma patients did serve in Vietnam and 63.2

percent did not serve in Vietnam. Comparing the proportions to the background rates, 41 percent of Vietnam era veterans population in VA hospitals served in Vietnam, whereas 37 percent of soft tissue sarcoma patients served in Vietnam. Using the chi square (X^2) test there wasn't any association between sarcoma cases diagnosed in VA hospitals and previous military service in Vietnam.

The last phase of this exercise was to answer the question, how sure we are about the soft tissue sarcoma diagnosis made by the VA hospitals. We asked the VA hospitals to send in the actual tissue specimen to us so that we could send it over to AFIP for tneir review. This is the outcome of that exercise. There are 104 cases that VA determined yes, soft tissue sarcoma. At AFIP, Dr. Enzinger looked at these and he determined *92* cases are soft tissue sarcoma and 6 are not soft tissue sarcoma. If we use the AFIP diagnosis for a reference 6 percent of VA diagnoses was false-positive. Of the 77 cases that the VA say no-soft tissue sarcoma, Dr. Enzinger determined 4 cases as soft tissue sarcoma. So, we have 5 percent false negative.

But even if we decide to use those 92 cases that both AFIP and VA agreed on diagnosis of soft tissue sarcoma the proportion of Vietnan service did not change significantly. So tnis exercise did not change the outcome of our earlier evaluation. We didn't find any significant positive association between STS and previous military service in Vietnam.

Finally, this is the status of our VA/AFIP case-control study of soft tissue sarcoma. I've reported this study to you a couple of times, so I'm not going to give you the background. The study is progressing very well. As of October 1985, 274 cases and 795 controls are in the study. And looking down the table, 176 of 274 cases are finalized and 98 cases still need tracing and interview. That gives us 64 percent completion. Response rate is 92 percent and found rate is 67 percent for cases.

Similar proportions are shown for controls. We still have about 340 subjects to locate and complete the telephone interview. Our current estimate is that by next February we'll be able to find most of these cases and controls and complete the interviews. We hope we'll be able to report to you by next June the findings of the study.

Thank you.

CHAIRMAN SHEPARD: Thank you. Are there any questions from members of the Committee at this time?

MR. SNYDER: Will he be able to provide copies of those charts and tables?

CHAIRMAN SHEPARD: Yes. We will ask that they be included in the transcript.

MR. SNYDER: But, the transcript doesn't show for several months. Would this not be available perhaps in the next couple of weeks. What was shown here?

CHAIRMAN SHEPARD: I'll have to give that some thought. I'm a little reluctant to release tables without the accompanying explanatory material. We'll see what we can do. Dr. Kang has some of this material written up, so we can probably share that with you. Any other questions? If not, thank you very much, Dr. Kang. I'd just like to say that in the discussion that follows I know we've gone into a fair amount of scientific detail and to the non-scientists among you I apologize for that, but I think it is important to review this whole issue. What I hope will come up during the course of this discussion is to what extent are or will Vietnam veterans be persuaded by this data. And that really is the bottom line. It would be very unfortunate if we, the Federal Government, you, as taxpayers, all of us as taxpayers, have expended a significant amount of Federal resources to conduct this research if it isn't then translated into some mechanism

whereby Vietnam veterans are told of the results and hopefully will respond in a way that the results will tend to direct.

Okay. I'd now like to call on Colonel Alvin Young, who will talk to us a little bit about some of the activities of countries around the world who have been working with us on this issue. Good morning, Al.

DR. YOUNG: I've prepared a handout in anticipation of some of your needs* I'll go into that handout in just a moment. This is some material that I presented at the International Symposium in Bayreuth in September. Much of it is self explanatory, but we'll go through it just to give you some idea of what kind of literature has been released in the past ten years in this subject area. As a matter of fact, let me start with that first.

The Veterans Administration and other agencies and individuals have been collecting the literature in the subject area for many years and I had an opportunity to take a look prior to the Bayreuth sumposium as to what does the world-wide literature base look like on the subject area, and the first viewgraph, (first handout page) shows that in fact we were able locate some 6,800 published articles. These were scientific articles. Of that, 3,700 were in fact related to the 2,3,7,8-TCDD. That gives us a sizable data base from which to draw some conclusions as to some of the scientific material. If you 11 notice that indeed the interest in the Agent Orange controversy and the Agent Orange issue, beginning in the late 1960's,

* See pages 159-170.

early 1970's triggered the investigations. Our first analysis for 2,3,7,8-TCDD in a human situation was 1957. Very little, over the next few years; and then once the Vietnam veteran issue and Agent Orange surfaced, tremendous effort began to appear in terms of research. And so we see the peak of this is about 1983 right now. Much of what's being reported now is lot of summary articles, some orginial investigations, and I'll talk a little bit about that with regard to the Bayreuth symposium.

If you take a look at the major key words that I searched the literature on. For example "toxicology"; the most of the published results, some 2,190 publications in the area of toxicology. However, the human articles were not rare. 19 percent of the published articles related to the human. And you can see the percentage for environment and analytical and then the reviews. Much of the reviews were the most recent material.

In the human arena, of the 1,055 articles, Agent Orange in fact is mentioned as a primary key word for 381 of those. Chloracne, some 355; epidemiology, some 292; and industrial accidents, 222. The last is a very important component, because we've had 24 major industrial accidents throughout the world.

As you look at the dioxin literature for the

environment there is 980 articles cited. That will give you some idea of the kind of work that's been going on in the environmental arena. Obviously concern over fate, bioconcentration, is quite high. A lot of effort is being put into that. As you go into the toxicology, the LD-50 kind of work, the issues are how toxic is the material? What kind of effects? One sees that animals are mentioned some 1,600 times and then you can look at work on into enzymes, cancer, teratology, birth defects, reproductive problems, mutagenesis and impact on the immune system. Much of your most recent literature has been on the immune system. So, most of those immune articles (178) are within the last few years.

As you take a look at the episodic events, you can see that the Italians by far have been the most productive in terms of publications. Some 394 published on Seveso alone as of 1985. Articles on Vietnam are coming rapidly up (232). Information on Missouri and the Missouri episode is widely distributed now in terms of publications. YUSHO, the Japanese episode, involving the 2378-TCDF, the Furans. Coalite is the English accident of 1968. The Binghamton accident, the fire in Binghamton, New York, is a 1981 episode. Love Canal, 1979, and we put the Eglin, Air Force Base research, some of the first ecological researched published as early as 1973.

lights please. I'll come back to the NATO project in a few minutes and pick up on that. Let me just give you some highlights of the Fifth International Symposium in Bayreuth, Germany, the Federal Republic of Germany. That was October — excuse me, September 14 through the 20th in Beyreuth. Some 500 in attendance. More than 100 papers presented. When that literature comes out, which will be in a volume of Chemisphere, 1986, probably July of 1986, that will further add to our 1985-86 literature. Much of it again, material previously presented or added on to the previous material. Dr. Shepard, for example, had a chance to give the final paper on the PTF soft-tissue sarcoma study. And that was a paper well received.

A lot of interest in the soft-tissue sarcoma work. But most of that work is going on in the United States. A great deal of it going on right here. And I think you could — if you recall Dr. Keller's comments — probably the bulk of the world's work in the human arena is occurring right here in the United States. Much of it by the Federal Government of the United States.

In terms of some of the recent analytical work, the entire direction of the analytical chemist today is in an area we call pattern recognition. We are now capable of looking in the sub-parts per

trillion in human tissue for the dibenzo-para-dioxin and dibenzofurans. At those incredibly low rates we are finding human tissue with significant residue levels for a variety of dioxins and furans. More than a dozen papers focued on the issue of human tissue with dioxins and furans in it. The analytical chemists are pursuing this patterned recognition as trying to figure out what the source is; because certain dibenzo-para-dioxins and dibenzofurans are generated from incineration of municipal waste containing chlorine. Humans exposed to that incineration product have unusual peaks that can be identified now by the chemist. If a person was only exposed to Agent Orange one might see a only a significant peak of 2,3,7,8-TCDD and probably three other tetra-chloro-dibenzo-para-dioxins.

What we are finding is that the bulk of the tissue has a variety of larger chlorinated dibenzofurans and dibenzo-para-dioxins and very low levels of the tetras. This suggests that most of the tetra is probably a consequence of being exposed to such things as incineration sources. One extraodinarily interesting paper, however, was presented that brings us a word of caution. Dr. Poiger and Dr. Schlatter from Switzerland have been involved in the study of human intact and metabolism of 2,3,7,8- TCDD. This was the talk

of the symposium. It was about a single paper. The paper by Schlatter and Poiger was a paper where Dr. Poiger, a research toxicologist, consumed a quantity of 2,3,7,8-TCDD. Now, prior to the consumption of the dioxin he fasted. Reduced his body fat almost to a bare minimum. Took the dioxin in a capsule form (he says he ate it with a bologna sandwich but it was a tridiated form of 2,3,7,8-TCDD. Six times over a period of four months Dr. Poiger gave up adipose tissue. All of the feces and all of the urine was collected during that time period. He reported on his results of some six months of monitoring at the time of the meeting. So, we've got just preliminary data. The problem is he has seen no disappearance of the 2,3,7,8-TCDD. He indicates that he can account for the bulk of it. We've still got some concerns on the results, but he is suggesting that if in fact this stuff is not disappearing very rapidly, so that he can detect it's disappearance that the half life of 2,3,7,8-TCDD in human tissue may be as much as ten years.

All of a sudden we have an individual coming forth that says this stuff may exist a lot longer in human tissue than we ever dreamed. Well, I'm not sure how good the data are yet. There is still a lot of work going on. All the feces analysis aren't complete

yet, so we've got to wait and see a little longer. But, if his data are correct we have certainly some value in the monitoring of human tissue for 2,3,7,8-TCDD. And the Veterans Administration study, which has been reported on before, of 2,3,7,8-TCDD in tissue collected from Vietnam veterans and others many years ago in fact may be a very valid study and we should get on with it. That's a very large study and you may want to address this later.

Well, that study, as I indicated, was the talk of the town. The second study that was the talk of the town was a study by Dr. Arnold Schecter and Dr. Michael Ryan, Ryan from Canada, Schecter from Binghamton, New York. Dr. Schecter had been to Vietnam and had collected tissue from South Vietnamese. Tissues provided by the Government. Ten tissues from individuals in the South and ten tissues from individuals in the North. Unfortunately, he couldn't give us much as to the sampling scheme. The sampling was done by the Vietnamese. The tissue was provided to Dr. Schecter at his request. "So, none of us really know very much about the history of the tissue except upon analysis by Dr. Ryan, who is probably one of the foremost analytical chemist in the world in this arena, the positive samples were those from the South with levels

averaging as 22 parts per trillion. There were a couple of outliers of the ten. I think one had more than 150 parts per trillion in it. However, most of them contained 10 to 15 parts per trillion.

Now, the samples from the North, of the ten samples, the average was about two parts per trillion. Dr. Schecter concluded that all of this was probably associated potentially with exposure from Agent Orange by those in the South of Vietnam.

The problem with that, and Dr. Ryan pointed it out to Dr. Schecter, was that other dibenzo-para-dioxins were found in the human tissue. Some very high chlorinated congeners of 2,3,7,8- suggesting that other sources, perhaps exposure to pentachlorophenal may have been responsible for much of the dioxin in the tissue. That does not eliminate the fact that Agent Orange may have also been a contributing factor.

Needless to say, the sample numbers are very small and we don't have enough history yet on the samples but a very, very interesting observation has been made. Dr. Schecter has returned to Vietnam this week and, as I understand it, is collecting more tissues and this time participating in fact in the sampling protocol.

The Dow Chemical Company provided another report on the epidemiological studies of the Dow workers.

They've gone back now and enlarged their sample size to about 2,200 men who have been exposed to 2.3,7.8-TCDD since Dow foeqan the manufacture of chlorophenol herbicides. At this point Dow finds nothing of great significance. The paper has not yet been published. The presentation that was given indicated nothing in terms of increase in mortality. At this point the issue regarding soft tissue sarcomas is still up in the air. There were a couple of soft-tissue sarcomas found in the Dow population. The significance of that, because of sample size, has not been concluded yet.

As for toxicology, very little new material being presented in the area of toxicology. A few efforts on mode of action. However, a lot of controversy occurred at the meeting because of Dr. Ellen Silbergeld of the Environmental Defense Fund. She presented a view of much of the toxicology trying to point out some concerns that she has. She has done one study looking at female animals, primarily rodents, who were subjected to small quantities of 2,3,7,8-TCDD and she has seen some problems with in fact the production of oocytes. So there may be some fertility issues here that need to be resolved. She went back and gathered a lot of the literature and used that to point out that there is some concern about fertility in female

animals exposed to 2,3,7,8-TCDD. Needless to say, that was controversial because many of the studies have been done by government and industry scientists, and they certainly were willing to argue with her on her conclusion. Nevertheless, I think her papers do mean we've got to take a look at this issue a little more carefully.

Two special symposia finished up that week. The symposia, as was the entire program, were designed primarily by the Germans. They have a lot of concern right now about hazardous waste and a lot of dioxin waste has been found in Germany and so much of the agenda focused on the German concerns. A lot of legal actions occurring in Europe and as a consequence, one of the symposiums was in fact about dioxin and the law. It was well attended. The highlight of that was the Judge from Seveso who came in and talked about the resolution of the Seveso cases. The legal resolution of Seveso.

The last symposium that was presented was on chemophobia and the problem of communicating results of studies to a population that is quite concerned over the whole issue of chemical exposure. Again one that the Germans has sponsored.

will publish the results of this symposium in 1986. You can look for it about July of 1986. The fourth international symposium, which was held in Ottawa has just been released. It's in the August, the July/August issue of Chemisphere 1985, and I had worked those articles up in the total numbers that you saw a few moments ago.

The sixth international symposium is scheduled for Japan in October of 1986 and much of that is going to be the issues related to the dibenzofurans and PCB's and it is going to focus on the accidents that occurred in Japan, primarily Yusho and the episode in Taiwan. So, that's going to be a very interesting one.

Following the Bayreuth symposium, there was a short symposium in Italy. Dr. Betty Fischmann of the Veterans Administration participated as one of about six speakers. She presented much of the work that she has been doing with the chloracne task force.

The Italians have essentially completed the Seveso episode. They are maintaining a birth defects registry, a soft-tissue sarcoma registry and a mortality registry. But, those registries will yield very little at the present time. It's going to take many years before those registries become valuable because of the population base. The numbers are much too small. There is just too small a population. So, it will be many

years before those registries are significant in terras of results.

The other international activity that has been of significance has been the nine volume report of the Royal Commission, released in August from Australia. The Royal Commissioner will be in the United States to present a capsulation of that report on February 19, 1986. He's going to be here in Washington at the toxicology forum.

A very controversial report, but one that has received world-wide coverage outside of the United States. To my knowledge, only two or three reports in the United States of that nine volume effort. Significant coverage in Europe and in the Far East, but very little coverage in the United States. That report focused primarily on exposure and looking at a whole variety of pesticides that the veterans could have been exposed to. The Judge concluded, in his report, that the likelihood of exposure to a concentration that would cause a health effect was almost nil for the Australian veteran. Very controversial. He then follows up with a statement and says Agent Orange is a myth. Needless to say that did not bring him the kind of support from the veteran community that he was hoping for. So, it is very controversial in Australia. The

report, however, is a very, very comprehensive document and it deserves the study of the community, the scientific community and the veteran community. He called witnesses from all over the world to present data on the issues. Chemical exposure, potential chemical exposure and health effects as a consequence of chemical exposures. He looked at a variety of pesticides, including the herbicides 2,4-D and 2,4,5-T.

The last effort that I would like to talk about, going back to the handout now, is the NATO project. Over the last 15 years the dioxin issues have continued to attract world-wide attention. And in Europe because of the concerns now by many of the NATO countries, eg., they have found dump sites where there are high concentrations of 2,3,7,8-TCDD. and I would point out that we are talking about concentrations at least comparable to Missouri and in some sites the dioxin concentrations of soils, residues coming out of dump sites, make the Missouri levels look even small. We're talking about really high concentrations of residues and in many sites around Germany, (West Germany) and Holland and even in England.

As a consequence, NATO was approached and asked to put together a project on coordinating research and findings related to the dioxins and the furans. It is an international information exchange involving

primarily the NATO countries, but observer nations have been asked to participate. For example, Sweden, France, and Finland. It is a three year project. There are three working groups. One on exposure and hazard assessment chaired by the United States, EPA's Bretthauer. Dr. Bretthauer is the chair of that. The technology assessment group is chaired from West Germany and the investigation of management of environmental accidents, the third working group, chaired by the Italians.

I point out on the next page some of the challenges that have been identified in terms of research. Some of the concerns the NATO group will have. Continuing to look at the mode of action of dioxins and furans, identifying sources of contamination. The issue of bioavailability is very, very high on the research agenda. It may well be that the dioxins are so quickly tied up in the environmental matrixes, soils, plants, animal tissue, that they do not become available to the digestive system readily. So, although we may be exposed to a great many dioxins the total quantity that's being picked up by our tissue, as a consequence of the digestive juices working on the matrixes, environmental matrixes, may actually be very low. We're finding from some studies that have been conducted

that the bioavailability of the dioxin in the soil may be less than two percent, although there was one study done on some of the Times Beach soils that had a lot of oil in it, that indicated the bioavailability may be as high as 50 percent.

Food chain contamination appears to *be* another area of concern. The extent of human exposure of course is important.

Going on with research challenges, determining the significance of trace quanitities and contaminates in human tissue. It looks like about 95 percent of the human tissues examined do contain 2,3,7,8-TCDD and other dioxins and furans. What the significance of that is remains to be seen. You can take a look at the rest of them. The last one, the conduct of risk assessments that are comprehensive and realistic is a major concern for all of the nations that were there.

I have one last piece of information I will share with you. Dr. Keller was here from the Agent Orange Working Group and Dr. Beach is here also from the Agent Orange Working Group. In that effort, we were asked by the White House to take *a* look at some of the Federal expenditures and I have prepared for you some information I presented, in Europe through the Agent Orange Working Group. The Federal Government

has expended for research, and you can see what it is.

The Veterans Administration, $81.1 million. The Department of Defense, some $34 million primarily in the Ranch Hand epidemioloqical study and the work by Dick Christian of the environmental support group over at the Army. HHS, $19.3 million. Remember that his does not include the Centers for Disease Control studies because that is funded from the Veterans Administration. The $80.1 million includes the funding from the VA to CDC. Environmental Protection Agency, some $15.8 million. Department of Agriculture, $.6 million. Agriculture was one of the early investigators in this arena and then got out of it essentially. Other agencies picked up the responsibility. So, that tallies up about $155 million.

This is 1981 to FY '87 dollars projected at this point.

CHAIRMAN SHEPARD: Thank you. Are there any questions, for Dr. Young at this time?

MR. CONROY: Yes, Dr. Young, I have a publication here. I don't know if you've seen it. The publication is- Indochina Issues, "Agent Orange in Vietnam: America' Shared Legacy." Dr. Jim Rogers is the author. Dr. Jim Rogers is a member of the Vietnam Veterans of America

and also a member of our West Virginia Agent Orange Advisory Committee. I thought this might be of some interest to you because he speaks to the methodology employed for sample selection. And if I could just impose upon the Committee to read it briefly. "All tissue samples were obtained at hospitals in Hanoi and Ho Chi Minn City. Human fat was obtained by Vietnamese surgeons during operations on the surgical schedule or during autopsies of random patients who died in the hospital during the days we were there." Dr. Rogers was with Dr. Schecter on his trip to Vietnam. "One patient volunteered to undergo the procedure even though he was not scheduled for surgery after the purpose of the minor operation was explained to him by his physicians. Tissue from North Vietnamese patients were regarded as the control group. Tissues from South Vietnamese was the potentially exposed group. All specimens were cooled with ice and refrigerated. They were returned to the United States and transported to an Ontario laboratory with the requisite analytical capabilities. No specimens left Schecter's custody after they were received."

"Of the seven specimens analyzed from North Vietnam, none contained any detectible 2,3,7,8-TCDD. 1 of the 13 specimens obtained from South Vietnam were positive for 2,3,7,8-TCDD. The range of positive specimens.

was 3.6 parts per trillion to 79.4 parts per trillion." The average dioxin level was, as you pointed out, 22.1 parts per trillion.

The average South Vietnamese dioxin level was 300 to 400 percent higher than the average levels obtained among exposed groups in North America. This finding suggests that the Vietnamese exposed to Agent Orange in the South are probably the most heavily dioxin exposed people in the world." I wonder if you just might comment on that.

DR. YOUNG: Well, I haven't seen the report. There is some discrepancy with what Dr. Schecter presented in Bayreuth. I guess my comment would be I think we need to see more sampling yet.

Dr. Schecter did not talk about those sources. Now, that's very interesting to me because upon question he indicated that he did not know how the samples had been obtained. There is already a discrepancy that concerns me. I think we need to find out why Schecter and Rogers are not communicating. Something doesn't fit. Again, remember that Dr. Ryan pointed out that the tissues from the South also contained higher levels of other dibenzo paradioxins and dibenzo furans.

Now, that was presented at the Bayreuth symposium. I don't know if it's in here.

CHAIRMAN SHEPARD: Dr. Hodder?

DR. HODDER: Al, do we have any information on the differences in either the cultural practices between the North and the South or uses of dioxins before military use?

DR. YOUNG: No, we don't. Recognize this. We did meet and talk about pentachlorophenol. A tremendous quantity of pentachlorophenol went to the South during the Vietnam conflict. The Navy, for example, used a large quantity of pentachlorophenol for the treatment of wood around docks.

The Army treated all of the ammunition boxes that went to Vietnam with pentachlorophenol. We know that the incineration of plastics with municipal wastes undoubtedly generates dibenzo-para-dioxins and dibenzofurans If, in fact, one sees higher concentrations of waste containing chlorine in the South being incinerated versus the North, one could account for some of that discrepancy. Certainly I think you'd have to take a look and find out where the tissues came from in the North and the purity of the sample. I mean it would appear to me that incineration in North -- the North part of Vietnam must be almost of low chlorine material. Recognize that the VA study that was done, the small VA study

that was done a few years ago indicated that the levels were five to 10 parts per trillion in our own Vietnam vets and non-Vietnam vets. So, again those levels are quite comparable to that being reported in the South. Why the North should be so clean, I don't know. Why those samples could be so clean, I don't know.

DR. HODDER: Didn't the North originally -- I can't remember the name of the North Vietnamese doctor, he claimed a lot of exposure up in the North, did he not?

DR YOUNG: Dr. Tung claims --

DR. HODDER: Dr. Tung, right.

DR. YOUNG: Dr. Tung claims that the Agent Orange had - that the dioxin had drifted North. He made quite an argument about that at one time. These tissues suggest otherwise.

MR. FITZGERALD: Al, the researcher that utilized the material in his own body, has he shown any physiological effects of it?

DR. YOUNG: No, he showed no health effects. No enzyme changes. He did calculate the concentration of TCCD that he felt would present little or no hazard to him. I think the total concentration of dioxin he consumed was 10 nanograms. I'm not absolutely certain of that, but with that kind of concentration he felt

he should be able to detect it in the fat tissue if it went there. And apparently it did. It's triated TCDD,.

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

DR. YOUNG: Thank you.

CHAIRMAN SHEPARD: I think we'd better move on. I've been informed that our colleagues from Massachusetts are here. They will be reporting on their mortality study and other efforts. Mr. Ralph Timperi is a member of the Scientific Advisory Board of the Massachusetts Agent Orange Program.

MR. TIMPERI: My name is Ralph Timperi. I'm a member of the Scientific Advisory Board to the Massachusetts Agent Orange Program. I'm going to very briefly just list the projects we have in progress in Massachusetts. One being a behavioral effects study looking at Vietnam veterans. That's being performed in McLean Hospital in Cambridge. We also have a study looking at the cancer registry in Massachusetts specifically for Vietnam veterans. We'll follow those over time. A third study, which is an analysis of self-reported health problems by Vietnam veterans, 1,800 questionaires. And a fourth project, which is in the stage of negotiations. We're attempting to contract for the analysis of adipose samples for quantitive levels of 2,3,7,8-TCDD in a group of highly exposed Marines in Massachusetts.

I might mention here that the Massachusetts Board was disappointed and surprised at the fact that the CDC study would not -- at least does not at this time plan to measure 2,3,7,8-TCDD levels in fat of veterans in their study. The major reason why we're here today is for Richard Clapp, one of the co-authors of the study that we've completed, to present the proportional mortality study.

of Vietnam veterans in Massachusetts. Richard Clapp, who is here with me, will present his findings to you now.

MR. CLAPP: Thank you. Let me start with just a little more background about how we initiated this study, where the idea came from, and why we limited its scope. I work in the Department of Public Health in Massachusetts, in the Health statistics and Research Division, and we keep track of mortality through a centralized records registry in our office with computerized records going back to 1969 — death certificate information. So, we had this enormous back-log of mortality information against which to examine the mortality experience of Vietnam veterans and we also, as you probably know, are a State that had paid bonuses to people who had served in the military during the period 1958 to 1973. And it was a differential bonus. If the honorably discharged veteran could show evidence that he or she had served in Vietnam, then they got a $300 bonus. And if they were in the service during that time period, but not having proof of service in Vietnam, their bonus was $200. And this was also on a computerized list, which was produced by the State Treasurer's office, which paid the bonuses. And so we could easily distinguish between bonus 02 and bonus 03, who were decedents; once we linked

that computerized list of bonus recipients to our death files we could identify which decedents had received a bonus for service in Vietnam versus Vietnam era.

Now, at no point did we anticipate that we would have exposure information. In the design of this study we used Vietnam service as the exposure of interest. And I think the most important comparison was to other Veterans who were in the service; we age adjusted and compared Vietnam veterans to other veterans who were in the service at the same time, but did not show proof sufficient to get a Vietnam bonus.

So, when I presented the study plan to the advisory committee, which Mr. Timperi and others are part of, we had in mind a very exploratory look at data that were already in hand. We did not anticipate any interviews with next of kin. We did not anticipate any lengthy attempt to establish the accuracy of the Vietnam bonus information or, as it turns out, the discharge data--the discharge papers were the basis on which the veteran showed proof of Vietnam service. We did not expect to do a lot with validating that or from that anticipating any kind of analysis of exposure history. It was an exploratory study. I want to make that point again. We expected to take a quick look at the mortality status over

the previous 12 years to give program guidance to the office of Commissioner of Veterans services in Massachusetts and specifically its Agent Orange program tor further studies, or for further service programs. We actually thought that the mortality data might give guidance for program activities that are already underway in the office of Veterans Services. So, we really had those very practical goals in mind. It was in no sense a comprehensive or gold standard type study that we had in mind. It was an exploratory study, mainly to generate further work. And, needless to say, that has happened.

Let me just now briefly summarize. *I* assume all of you have gotten a copy of the study report that came out last January. Let me just review for you the methods and results and I'm actually going to summarize for you a table that's in an article that we've prepared and submitted for publication. It's in the process of revision and will be resubmitted, so I can't give that out to you today, but I think that the article is a much more succinct treatment of the study, so I'll summarize data from that article.

The methods as I've indicated, were the record linkage from two computerized files on the Department of Public Health main frame, from which we identified

840 Vietnam bonus recipients who had died in the period 1972 to 1983 and 2,515 Vietnam era veterans who had not served in Vietnam or had not gotten a bonus from having served in Vietnam. And from that we calculated standardized proportional mortality ratios on all causes of death where there were at least seven deaths or more. And in those instances where there was a statistically significant finding either comparing Vietnam veteran decedents to other veterans or Vietnam veteran decedents to other white males, (This was a white male study since there were so few females and non-white males in the list of decedents.) where we found a significant excess in either of those two comparisons we did an auxiliary analytic approach, which is called a standardized mortality odds ratio; this is akin to a case control study using the death certificates, all deaths, in other words, as the case pool.

We produced a draft report, which was reviewed internally within our Department through our normal mechanism by epidemiologically trained individuals in the department. We also got an external review by four people from Yale University, NIOSH incincinnati the University of Massachusetts School of Public Health and Harvard University School of Health where we had colleagues who were willing to do a review for us.

And we incoporated those comments into the final draft of the report, which you received.

And subsequent to the release of the report and in some ways in response to questions that were raised I think here in March, (I'm sorry we weren't able to attend that meeting.) we decided that we would take the steps of calling all the hospitals where the soft tissue sarcoma patients cases had died. On the death certificate we can identify the hospital of death, so we were able to contact the -- actually in my case I'm the director of the tumor registry, the cancer registry in the State Health Department, so I called up the tumor registars in those hospitals where the patient had died with a diagnosis of soft-tissue sarcoma in Massachusetts and in one instance in Rhode Island. And I asked them to look up the pathologic records in that patient's record and verify the diagnosis that was on the death certificate. And in five of the nine soft-tissue sarcoma Vietnam veteran decedents records were available in hospitals. The tumor registar looked those records up and reported back to me that the cause of death, as reported on the death certificate, was accurate. In the other four cases either the patient did not die in a hospital or one of those four was a patient who died in the VA hospital in Rhode Island,

in Providence, Rhode Island, but the path records were not available there. And the tumor registar was not able, without a lot of work, to find out where the patient had been referred from prior to death. So, in that particular case, although she felt that it was clear from whatever records that she had, that it was soft-tissue sarcoma death, we were not able to track back to the Rhode Island hospital that had the path report.

In every case of the soft tissue sarcoma deaths we did look up to verify at least the information that was on the DD 214 as to the accuracy of the Vietnam service designation.

Now, the limitations of this approach are basically twofold or threefold. One is, as I've said at the outset, we have no information on exposure other than Vietnam service or actually Vietnam bonus. So, there is — that requires that we be very constrained in any conclusions that we draw, and I think if you read the report you'll find that we are very constrained on that issue. We claim -- we make no claims that this was an Agent Orange exposure effects study.

Secondly, and maybe more importantly, this was a death certificate study. And so by definition we're left with that — we analyzed only deaths. Only

the Vietnam or Vietnam era veterans who have died in that 12 year period. We know nothing about their medical care. We know really very little about their social history other than what is called their usual occupation on the death certificate. And so we have very limited information other than the cause of death and even the cause of death, as you probably know, on death certificates, especially with malignancies is not all that accurate. Maybe all malignancies are accurate to a level of 90 percent on death certificates, but for specific malignancies the percent of accuracy compared to hospital record information is quite low. And although we did verify those hospital records where the soft tissue, sarcoma decedents had died, and those were accurate to the best of our information available, we're still left with the overall problem of death certificate information being not the best. Not what we would like. And also I think our report makes it very clear, we did not have denominator data. We did not know either how many veterans there were in either category in specific age groups, because that would require hand searching. That was not on the computer tapes, so that would have required hand searching 250,000 records, and we had no plans for that and actually can't imagine how it could be done in the room where these

records are kept without stretching it out over months or years. So, we used the PMR approach or the SMOR approach, neither of which requires denominator data. But, — and in that sense they are not the gold standard in some sort of methodological sense among the types of mortality studies.

So, with all those limitations we worked the data a little bit further for publication — we actually liked the standardized mortality odds ratio statistic or risk estimator for a number of methodological reasons, which I won't go into. We calculated confidence intervals. 95 percent confidence intervals for the odds ratios. And the two — looking at the comparison I think is the most cogent, the comparison between Vietnam veteran decedents and other veterans who were in the service at the same time a comparison which is age-adjusted. Looking at that comparison there really are only two causes of death which the Vietnam veterans were significantly, statistically elevated over the non-Vietnam veterans. And those are connective tissue cancer, all of which were soft tissue sarcoma. The odds ratio is 5.16. The 95 percent confidence interval is 2.39 to 11.14. It is a wide confidence interval because it is based on only nine deaths.

And the second cause for which there was statisically significant elevation comparing just the Vietnam decedents to the Vietnam era decedents was motor vehicle accidents, where the odds ratio is 1.5 with a 95 percent confidence interval of 1.20 to 1.87. And that's a narrow confidence interval because it's based on many more deaths.

There is border line significance for suicides. Comparing again, Vietnam to Vietnam era veterans. So, those are the findings that we will emphasize in the article that has been submitted for publication and which we will happily share with you once it has been accepted. And those are the results that lead us to further studies. One of which - Mr. Timperi has already alluded to, which is the behavioral study, which is being conducted at McLean Hospital and another of which I'm personally involved with with the cancer registry. This is to look at, in an on-going way, cancer incidence experience in the Vietnam veterans and the Vietnam era veterans by linking the same computerized tape of veterans to our incidents tape. Our registry began in 1982, so we only have state-wide cancer incidence data available in Massachusetts from 1982 forward. And so we have linked the two tapes for the period 1982 and 1983 and we have gotten already

matches on 160 Vietnam era veterans who have been diagnosed with cancer in those two years and about 50 Vietnam veterans — of those two each were soft-tissue sarcoma. Two in the Vietnam veterans and two in the Vietnam era veterans. So, there is not sufficient data there to do any kind of a statistically stable analysis and we'll have to accumulate more years of data. We are almost ready to link a third year, the 1984 incidence data with that tape.

We're also looking at females and non-white veterans as part of this analysis. We expect to do -- again without denominator data we 11 probably do something which we call *a* morbility odds ratio, the same technique as the mortality odds ratio using cases of incidence cases, whether they have died or not as the case — as the disease of interest and then an auxiliary cause, which would probably be all other cancers or some selected group of all other cancers. And then calculate the odds of exposure in the form of Vietnam service and then go from there to more detailed information about length of service, area of service, as best we can determine it, and potentially at least at least with the soft tissue sarcoma cases, possibly some other data. Fat biopsies if the patient is willing and other possible information from questionnaires.

So, that's an on-going project and perhaps if this committee exists and we exist in a couple of more years we'll come back and report some more data from that. I really don't have any more to present right now. If people have questions I'll be happy to take them.

CHAIRMAN SHEPARD: Thank you. Are there any questions from the committee? Yes.

MR. FITZGERALD: One suggestion, and that is because of the interest in the soft tissue sarcoma cases you verified, as far as going back to pathology reports, I think the next step would be to have the slides verified as to the diagnosis of another pathologist.

MR. CLAPP: That's a good suggestion. I think we will do that.

MR. FITZGERALD: Because there is a great deal of difficulty in the diagnosis. Second question. When will the McLean study be anticipated as being ready?

MR. TIMPERI: I would expect sometime in the summer of 1986 we should have a preliminary report.

CHAIRMAN SHEPARD: Dr. Hodder?

DR. HODDER: You have a reversal as it were where Vietnam service shows a significantly lower instance of malignancies in a category.

And how many comparisons did you actually do of that kind?

MR. CLAPP: In the mortality report we did 14 comparisons. There was significantly lower homicide in the Vietnam veterans and I really have no explantion for that. That's compared to other white males. Not compared to non-Vietnam vets. It was not significantly lower compared to non-Vietnam vets. And significantly lower cardiovascular disease.

DR. HODDER: So, you did quite a few comparisons?

MR. CLAPP: 14. It was only those comparisons where we had at least seven deaths amongst the Vietnam decedents. So, that eliminated a lot of the rarer causes. And again these are young men, so basically – mainly young men, so cancer is not a big cause of death yet. It s – the incidence data would indicate it is getting there. And there will be a lot of incidence data to analyze. We have a hundred or over 200 cases to analyze already and I think in the entire ten years we only had 129 decedents. So, we have 60 Vietnam service incidence cases in two years, whereas we had 120 over the previous 12 years as decedents.

DR. HODDER: In the patients with the connective tissue malignancies were they fairly evenly

distributed or did you see a bunching together. I'm looking here for a possibility that once an association is established, people start reporting it; or if you suggest something, where the reading of these tissues is very difficult, one might, because of an association in Vietnam, tend to read it as a sarcoma than to say something else.

MR. CLAPP: Well, we started the study in 1972, so if Dr. Young's slide is right the literature may have started around that time or even earlier, or the concern in the public media may have started around that time, So I think we may have already started by the time public concern was heightened or maybe medical concern was heightened. And the pattern is fairly evenly distributed throughout the 12 years.

DR. HODDER: It is even?

MR. CLAPP: Right. I think the first one was a death in 1972.

CHAIRMAN SHEPARD: Any other questions for Mr. Clapp? Yes.

MR. CONROY: At any time did you attempt to actually take a look at the DD 214's for any of the deceased veterans or were you satisfied that because of their numerical amount they were assigned on the bonus tape that they were in fact – did in fact have

Vietnam service?

MR. CLAPP: No, we looked at them. We looked very closely at the soft tissue sarcoma decedents, as I indicated, and we looked at a sample to – I forgot, I think it was a one out of 20 sample of Vietnam decedents to make sure that the – the bonus tape was right.

MR. CONROY: Five percent is your sample size then?

MR. CLAPP: Yes right. And I think we found that the bonus data was 99 percent accurate on that sample.

MR. CONROY: The reason I inquire, we're doing a similar study in West Virginia and we were initially going to do the same thing, take a representative sample, and decided to actually look at all the decedents DD 214's.

CHAIRMAN SHEPARD: With your permission, Chuck, I think we'll take our break now. And if we could all be back in 15 minutes, a quarter of by this clock here.

(Whereupon, a brief recess was taken.)

CHAIRMAN SHEPARD: I'd like to call on Chuck Conroy from West Virginia, who has taken over the role of being the coordinator for various state Agent Orange related activities following the retirement

of Dr. George Anderson. So, Chuck is taking over his role as the coordinator for various state activities. Mr. Conroy.

MR. CONROY: Thank you very much, Dr. Shepard. I'm pleased to be with this committee. I'm rather chargined at the departure, as you mentioned, of Dr. Anderson, who has taken an early retirement, I understand.

Today I'd like to inform the committee of recent Agent Orange related projects conducted by several states. Myself and some of my colleagues from the other states I notice are here in the audience, particularly Pennsylvania, New Jersey and Minnesota, so I would like to yield some of my time at the end of my presentation to each of them to update us on their respective activities.

The first state I'd like to report on is Texas. Most of the people on this committee are aware that this past legislative session the Texas legislature recommended that the Agent Orange program not receive further funding, and so consequently as of August 31 the Texas Agent Orange program went out of existence. The Texas program has published their final anuual report. I would be happy to provide anybody who is interested with a copy of that annual report. They mention in the report that there are no final conclusions drawn

within this particular report and that that is going to have to await the accumulation and the analysis of their data.

Again I think the State of Texas did a remarkable service in laying the ground work for a lot of the states that came on board later and as I said I'm rather saddened to see the departure of Texas. Although it seems to be the trend in terms of states that have their own programs. In addition to Texas a few other states, Hawaii, Iowa, Ohio are also in the process of or have already concluded their respective activities and are waiting on the completion of the CDC epidemiological study.

I would like to also share with the committee two studies that were concluded this summer. Basically what they were were surveys that came up with remarkably different conclusions. One is titled "Agent Orange, an Iowa Survey of Vietnam Veterans." This particular survey looked at 10,846 Iowans and provided them with a medical questionnaire, much as a number of other states have done, (e.g., Georgia and Pennsylvania) and tallied the results of those. I'd just like to read the final concluding paragraph on the Iowa study. And that is that based on the preliminary data that has been accumulated in Iowa "no definitive

evidence exists to establish any link between exposure to Agent Orange and subsequent long-term adverse health effects. At present there is no convincing evidence that the rates of birth abnormalities, physical disorders and mortality are significantly increased among Vietnam veterans." As I say that particular conclusion is in stark contrast to the Hawaii report. The Hawaii sample, the survey sample was significantly smaller than the Iowa sample. There were 418 veterans sampled in the Hawaii sample. Of the 418 approximately 232 were actually stationed in Vietnam and 186 were not stationed in Vietnam. And again going to the conclusion section of the Hawaii survey and reading "The Vietnam service group of veterans can be said to have currently a greater incident of digestive, emotional, skeletal and neurological problems of the type specified in the health survey. The results of the survey are not decisive enough to delineate specific medical problems that might be addressed, but the total picture is one of non-specific malaise in that group when compared to the control group."

So, again two surveys with two different conclusions. It should be pointed out again, of course, that since these were surveys, neither the Iowa survey, nor the Hawaii survey provided any clinical confirmation of the medical problems that

were cited by veterans. These were self reported.

I would also like to provide the committee with a report of our on-going activities in West Virginia. To date in West Virginia we have tested 152 Vietnam veterans. We are testing these veterans at the state's three medical schools as mandated by the state legislation and are really underway now and are providing, on a monthly basis, a monthly report, much as the Texas program had before they went out of business, indicating the medical problems that have been confirmed. These are as confirmed and reported by the physicians during the course of a physical examination. what we are finding in West Virginia, again, based on those first 152 examinations, and again you have to preface this with the caveat that we have a self-selected population. We also have a provision in our program whereby if a veteran would like to be tested because they think they have some sort of pressing medical problem we put them on what is known as our priority testing list and we can move them to the head of our testing line. So, we would expect that these initial medical conditions would be skewed somewhat because of that proviso.

But what we are finding in terms of the physical maladies that are reported by the physicians,

skin problems are ubiquitous. Out of the first 152 examinations, approximately 75 of the 152 were diagnosed by a physician as having dermatitis. There were eight possible diagnoses of chloracne. Again this is extremely difficult because it is very difficult in getting a definitive diagnosis of chloracne. But, at this point in time, afflictions seems to be one at the major problems that West Virginia veterans are experiencing.

One of the most important things that we've been involved with for over the past year and a half is the conduct of a West Virginia Vietnam era mortality study. That mortality study is in its final phases of peer review now and we are committed to a publication data of mid January on that study. We have done, since our last meeting in March here we -- myself and Mr. Holmes, who is the principal investigator of the study, have taken some of the suggestions we had from this committee this past March and incorporated them into our study and as a result it's taken a great deal of time really.

One of the suggestions that the committee had is that we actually pull a representative sample of the DD 214's to ascertain Vietnam service. Rather than pool a representative sample we decided to pull DD 214 s on every deceased veteran in our mortality

study. We did that and find remarkably, as Massachusetts did, that approximately 99 percent of the deceased veterans were accurately coded as to their Vietnam service status. So, we pulled everyone of those DD 214's and in the process of doing that we gleaned some information that we think may be of interest to the committee. And that is we broke down every one of those deceased veterans in terms of service. How many of them were in the Army. How many were in the Air Force, Navy, Marines. And as you might expect from a state like West Virginia the vast majority of our veterans were in the United States Army. Very few were in the Navy, the Coast Guard. The Marines had, again, a significant portion. But, we think that will increase the utility of our study.

So, again we are committed to the publication of that mortality study and hopefully at our next meeting I will be able to share the results of that study with the committee and with the group.

That is all I have, Dr. Shepard on the several states that I have. As I said I see three other states out there that might like to come up and address the committee.

CHAIRMAN SHEPARD: Please. Why don't you call on them.

MR. CONROY: Sure. Let's start with Wayne Wilson from New Jersey.

CHAIRMAN SHEPARD: Mr. Wayne Wilson from the New Jersey Agent Orange Commission.

STATEMENT OF WAYNE WILSON, THE NEW JERSEY AGENT ORANGE PROGRAM

MR. WILSON: I'll be very brief. I recognize we're on a tight schedule today with this new format. Dr. Kahn, from our commission, was unable to join us today because of a previous commitment, and I'm not prepared to say a whole lot, but I will make some comments, and I appreciate the chance, Chuck, and my sister says hello, by the way.

The State of New Jersey, as you know, has a dioxin analysis study underway. We are, at this point, about two thirds of the way through that study and as we get further into the study I think that the feeling or the mood of the medical or research people, as well as myself and my boss is that we should make every effort to — we're being very cautious to quote the bottom line. We are anxious to complete phase I of our dioxin analysis study and I think as we get close to the end there is a feeling of excitement or anticipation of completing the work arid of results coming back in.

The chairman of the Commission, Mr. Falk, received a letter two weeks ago from Dr. Rappe at the University of Umea indicating that the work is progressing quite well at this point. If we're able

to complete the selection of participants in the study we may have the analysis back around the first of the year. One of the reasons we're down here this week is to look as closely as we can at some of the possible participants in our study and quite frankly, having been attending these meetings for, I guess four or five years now, the selection of people to participate in this study is a complicated and complex process. I'm an administrator, basically, and not a medical or research person,but it is difficult and I can certainly appreciate some of the problems you've had in finding people to participate in your studies. So, I guess the watchword for us now is that we're being very, very careful. It's kind of dragging it out a little bit because we are anxious to do everything right, to dot all the i's and cross all the t's. That's the best way to go. I've been convinced of that. That's the charge I have from our people and that's they way we're going to do it. Although given that significant effort and obviously that is the first priority in the New Jersey Agent Orange Commission, nevertheless I know I don't have to remind my colleagues from other states that the providing of services, outreach and information, factual updated information to Vietnam veterans and still going out there and talking with them on their

block and as I always say we're out there in the trenches in the very real world. I think that's still a very necessary part of what this issue is about. And I hope that as the committee has been rechartered, we will not lose sight of that aspect of this issue. Remember those Vietnam veterans pay most of our pay-checks. Those are the people that we're out there to serve and they still have, even today, many questions, and even though there may be a tendency, at this point, to hone in on studies and research and literature reviews or analysis there are still real people to deal with out there and I would just ask everyone to be as equally sensitive to that as we are about choosing the prospective people to participate in studies. So, we always enjoy coming here. And as I said out in the hall, I hope in the months ahead it gets a little bit more lively here. We've got to get it back where there is some excitement generated. It's always nice to have the room full, so when you come to the next meeting, which I hope will be not too far down the road, bring 10 Vietnam veterans with you, and let's have a good lively meeting. Thank you.

MR. CONROY: I wonder if we might hear from Jerry Bender now, Dr. Shepard, from Minnesota.

STATEMENT OF JERRY BENDER, MINNESOTA DEPARTMENT OF HEALTH

MR. BENDER: Thank you very much. Minnesota, unlike other states such as West Virginia, Iowa, New Jersey, Hawaii, is not conducting any research. The legislative charge we have is merely to identify those Vietnam veterans who served in Vietnam, provide them assistance with any problems they might have with Agent Orange, and most importantly, I think, provide them with information on Agent Orange. To that end, over the last several years we have refined our computer list and as far as I can determine we've been able to personally send out to over two thirds of the Vietnam veterans who served in Vietnam from Minnesota, two thirds of them have received direct information from us. As soon as the Court

sends out its next mailing in October, we're going to be contacting all those veterans again and providing them with the most recent information on Agent Orange.

Now, one thing you mentioned, Dr. Shepard, earlier in the meeting here, was the difficulty in convincing some of the veterans as to the accuracy or the credibility of some of the scientific research that has been going on. Now, I – just as Wayne, I get out in the State of Minnesota quite a bit. I don't get

out in New Jersey, but I am put in the trenches, I'm out in the Legion clubs and the VFW clubs and the BVA chapters, the local Lions clubs, FFA, anybody who want to listen to me I'll go out and talk to. And I am surprised at some of the questions that people ask this far down the line with regard to Agent Orange or with regard to some of the studies that have come up. Some very sophisticated people, and by that I mean people who are not easily fooled, will believe, I think, some quite incorrect and in some cases preposterous things with regard to Agent Orange simply because they have seen it in the newspapers or they've seen it on TV or something like that.

And I found that a lot of this is due to the fact that it is the – with all due respect, the Veterans Administration that is putting hte information out. For some reason some very good, some very bad, a lot of Vietnam veterans tend not to trust the Veterans Administration or trust the United States Government. I think a lot of this obviously has to do with the conduct of the Vietnam war.

So, I ran into a problem. How was I going to get the veterans in Minnesota to believe some of the information that I was putting out. Well, Minnesotans, I think, are as ethnocentric as West

Virginians, Californians or anyone like that. They tend to trust other Minnesotans and especially they tend to trust our Minnesota Department of Health and also the Mayo Clinic. So, what I'm going is I've put together a small committee of medical professionals, including all of the specialists we need be on call or just toxicologists, the epidemiologists, all the other ologists, including a few number crunchers, and we're putting them together into a committee and essentially they're going to be performing a review function of the review function. I have hired a graduate research assistant. A very competent woman with a Bachelor's in biochemisty. She is working now on her Master's in public heath. She will be reviewing all of these documents, submitting them to the committee. They will make their own independent review as to the credibility of the study and then we'll take that information and we'll get it out. Now, I anticipate that I will run into some opposition from some members of the Agent Orange committee, some people who are involved with the Agent Orange with some of these conclusions. But, I think now in 1985 we're some really six or seven years down the road and it is possible, at least about this point, anyway, to make some statements with regard to the dangers facing Vietnam

veterans from Agent Orange, the relative danger. How high should they place Agent Orange worries in their life. I assure you that there are veterans out there who are, we might say mortally afraid of their exposure in Vietnam to Agent Orange. I have talked to couples who made a decision not to have any children because they were afraid of Agent Orange birth defects.

I know veterans who are quite worried about developing cancer from Agent Orange. I especially see this in Legion and VFW clubs, where I'm talking to a group of two dozen, maybe three dozen, four dozen veterans. They're worried about cancer from Agent Orange while they're smoking cigars arid cigarettes and drinking alcohol. I think that some of this has to be put in to perspective and I hope the efforts of our committee can do that.

CHAIRMAN SHEPARD: Thank you very much.

MR. CONROY: Can we hear from Terry Hertzler from the State of Pennsylvania.

STATEMENT OF TERRY HERTZLER, STATE OF PENNSYLVANIA

MR. HERTZLER: Pennsylvania is continuing, we just got a two-year extension from the Administration and legislature this past June and will be continuing our program through June of 1987. We were also happy enough to get funding level increases, which unlike some of the other states, which have gone out of business in their activities and have problems with funding, we are enjoying a slight increase to try and carry out our project.

For most of you that don't know we are a Vietnam herbicides information commission. Our primary legislative charge is to contact all the Vietnam veterans who either lived in Pennsylvania at the time of their service or who now reside in the State of Pennsylvania and served in Vietnam. We are to ascertain from them just exactly what their medical, administrative and social problems might be since their service in Vietnam and whether or not they believe it may be related to Agent Orange exposure. We're doing this by means of a Survey questionnaire that was sent out to 134,000 that we were able to obtain addresses from. To date we've received back approximately 48,000 and just this week we've been able to get them on the computer and we're starting to look over some of the specific

demographic information to show us how successful we've been in our contact efforts. We are going to have a second mailing in the next two weeks to go out and try to reach the 76,000 who have not responded as of this time to find out whether or not there is something we can do to get them in the registry and to create this line of communication with them. Out of the list that we've been using, Pennsylvania was a bonus state and paid a bonus to Vietnam veterans, so we have learned that there are over 200,000 Vietnam veterans in Pennsylvania.

We hope to create a large enough data base to give us information as to whether or not our State should be doing more in this area and also to give the information to our legislators and Congressional delegation here in Washington, since it is a Federal issue, to let them know exactly where Pennsylvania stands and what we've been able to do.

The basic bit of research that we are involved in is a small soft-tissue sarcoma study that is being done in cooperation with our cancer advisory board in Pennsylvania, and is being conducted by contract with the Graduate School of Public Health, the University of Pittsburgh. It was originally scheduled to be completed in December of this year, but due to some difficulty in getting some of the live controls we are

going to extend that contract and we expect to have the final report and completion of that June of 1986.

We did start an education program for the health professionals in Pennsylvania because it was perceived that many of the Vietnam veterans, for whatever reasons, weren't going to the Veterans Administration to obtain whatever help may be necessary for them. So, in cooperation with the Educational and Scientific Trust of the Pennsylvania Medical Society we put out a small booklet to try and inform physicians in Pennsylvania exactly what the Agent Orange problem was and what they may be seeing in Vietnam veterans that were coming to them and they could then explain to them exactly where their problems came from or what and try to put it in perspective for the physicians. We did produce about 15,000 copies of the booklet. We have distributed, 13,000 to general practitioners, internists, family practice and osteopaths within Pennsylvania.

The booklet was distributed about a year ago, we've received numerous requests from other states and groups asking to receive copies of it, so we have set up a licensing agreement with the Educational and Scientific Trust to reproduce the booklet and we had a cassette tape that ran 17 minutes, which was like an interview process of exactly how a physician may have

a Vietnam veteran come into his office and some of the questions he may ask. They were also distributing that.

We expect to complete our program within the next two years and then it will be reevaluated whether or not we should continue along with this line of work or just turn it over to the Federal Government and see where we can go from there, but things are coming along very well and we expect the some results of our questionnaire, which is self-reported general information, possibly to be available around February or March of 1986.

There are 68,000 Vietnam veterans we have not been able to get good addresses on at this time. We are currently going over the death certificates and also other mechanisms to see if we can get a viable address to give all of Pennsylvania's Vietnam veterans an opportunity to participate in our program if they wish.

Thank you.

CHAIRMAN SHEPARD: Thank you very much. I might just add that Pennsylvania has graciously invited me to several meetings there, and I did address one of the groups of physicians, and on two occasions have addressed veterans groups put together by Terry Hertzler and his organization. I highly

commend the State of Pennsylvania for the very thorough work that they have been doing. That isn't to detract from any others, but I've had perhaps more personal contact with Pennsylvania than any other single state. I hasten to add that Chuck Conroy has been trying hard to get me down to West Virginia, and I had to back out from the last invitation because the Administrator wanted me to go to Australia with him. So, anyway, I hope that invitation will be forthcoming.

MR. CONROY: I'm sure it was a tough decision.

CHAIRMAN SHEPARD: It was a tough decision, seriously. I requested, at that time, not to go to Australia because it came at a very impropitious time, and part of that was the fact that I had made a commitment to go to West Virginia, so I was very reluctant to go to Australia, but nevertheless that happened.

I think the folks who have spoken from the states have brought up a very important point. I'd just like to take a minute to stress and amplify that. I think now as the research studies, the results are coming in, that the States have a particularly vital role to play. That has been touched on by Jerry Bender and I hope will be shared by other states. I would view that network to be particularly important

in communicating the results of various studies to veterans at the State level. Because as Jerry so accurately pointed out, I think oftentimes folks within the state have a higher level of credibility than the Federal bureaucracy might enjoy at the local level.

So, I think it would be very important for those state commissions, which are still in existence and maybe even rejuvenate some of those which are not, to play this very important role. I don't think it would be one that would require huge amounts of state funding, but I think that those two have established certainly address lists of veterans that it would be very important to maintain that contact and I hope that that will occur.

Okay. Now I'd like to now call on the various service organization representatives to bring us up to date on some of their respective activities. And I'd like us first to call on Dr. Tom Fitzgerald from the Legion.

STATEMENT OF THOMAS FITZGERALD FROM THE AMERICAN LEGION

DR. FITZGERALD: Since our last meeting the American Legion has published a study that they sponsored with A Dr. Jean Stellman and her husband Dr. Steven Stellman. It is identified as the Columbia University / American Legion Vietnam Veterans Study. A copy of this is in each one of your folders. This is the first of three reports that will be put out on this subject. I stress the fact that this study was a self-assessment study.

Within the study it was designed for 7,000 veterans, equally split between those who had service in Vietnam and those who did not.

The initial study or report has several interesting facts in it. One is that the educational attainment of these veterans was not related to the exposure to combat conditions. And as general population income and educational attainment are highly correlated. That is those who have the higher education had the higher income, as might be anticipated.

However, there was one other factor that came out of here that seems to be quite remarkable. And that is that those with the highest intensive combat

experience have fared more poorly subsequently. From an income level the group in the age group born in 1944 to 1949, which have -- would have borne the brunt of the combat, they report a difference of three to four thousand dollars by people in the same age group without the combat exposure.

In addition they are reporting an increased amount of social and health problems. The social problems are manifested by an increase divorce rate and general health conditions. The survey in the subsequent two reports will address the findings concerning post traumatic stress disorder and Agent Orange exposure, as seen by the respondents. As I said, this is the initial study, report. There will be two others. And I think that it brings out some very significant potentials.

CHAIRMAN SHEPARD: Thank you very much, Dr. FitzGerald. Any questions from members of the committee for Dr. FitzGerald? Okay. Now, next I'd like to call on Mr. George Estry from the Veterans of Foreign Wars.

STATEMENT OF GEORGE ESTRY PROM VETERANS OF FOREIGN WARS

MR. ESTRY:

The Veterans of Foreign Wars, unlike the American Legion, doesn't have any Agent Orange studies going on. Since most of the phone calls we get are disbursed among the 54 service offices we have out in the field, I don't have exact figures on how many calls we're getting. I would say that from my expertise, which is at the Board of Veterans Appeals assisting veterans in their appeal cases on Agent Orange, responding to the VA's calls and also the veterans' calls informing them of the Agent Orange problems regarding the taking of exams and again our service aspects, the difficulty in getting a claim allowed by the VA and seeking out other avenues, must be working because the Agent Orange claims, the number – the physical number of claims is drastically reduced from what it was say two years ago.

Ken Eaton talked at our training conference a week before last in Atlanta and he used a figure of approximately 10 percent allowance rate on Agent Orange figures at the Board of Veterans Appeals. But, as anyone knows when they're reviewing the VA's statistics dealing with Agent Orange cases, that system was a catch-all category. The majority of claims that are

won are not, in fact, for Agent Orange, but some of the residual disabilities that have been claimed, and as we instruct our people you really must ask for direct service occurrence rather than Agent Orange exposure. The VA only conceded Agent Orange.

But, other than that let me say that I think the information network that we're using now is working. I will get with Chuck afterwards and give him a card. I really think we may be able to assist the states in finding their people through our magazines and our network also if we know what states are going to contact people. But, other than that we're just going to stand strong here at the advisory committee and everytime we get some viable information we'll get it out to the veteran community. That's about all we're doing.

CHAIRMAN SHEPARD: Thank you, George. Any questions for Mr. Estry from members of the Committee? Okay. Next I'd like to call on Mr. David Gorman from the Disabled American Veterans.

STATEMENT OF DAVID GORMAN FROM THE DISABLED AMERICAN VETERANS

MR. GORMAN: Thank you, Dr. Shepard. I'll say this at the beginning, I haven't had the opportunity to come to these meetings very often, primarily because I served an alternate and not a committee member. But, from what I've heard this morning, the format, I've found very interesting and very helpful to me in trying to, at this point in time, gain abetter understanding of what this committee has done in the past and the role its going to be taking in the future. I'd also make one request of the individuals from the states, if I may. I know we get in the office a copy of a newsletter from the New Jersey Agent Orange commission, which we find helpful and interesting to read. And if the other states do put out that kind of a newsletter or a publication, whether it be monthly or quarterly or whatever I would sure appreciate being furnished a copy of it to try to keep us up on what the states are doing.

In the same vein as what was being talked about from the representatives of the states I think outreach is an important part and aspect of this whole issue, as well as all the other issues that go into what the VA does and what they try to do.

The DAV is embarking on a number of new projects. And although — they weren't directly prompted by the issue of Agent Orange, that issue certainly will be incorporated into these programs. And one -- two of them are specific outreach programs where we're going to be using our national service offices, which now number about 260 all across the country. They're going to be going out in those parts of the country where they can to the Indian reservations, and we're going to be having outreach programs to the native Americans. That might be one group of Vietnam veterans that have been neglected, not only with respect to Agent Orange and information pertaining to it, but the whole gambit of services the VA provides.

We're also going to embark on an outreach program in prisons. Again with a whole range of VA benefits, but certainly Agent Orange information will be contained in our visits to those — to both the reservations and the prisons.

We've also, as a means of trying to further our ability to filter down information from our national level to the — both the states and the local chapters that we have, have initiated what we call a DAV news service, which is simply a random selection of topics that we think are of interest on a monthly basis that

we sendout to all chapters. Basically so they can incorporate that into their monthly chapter newsletters. Again we think it is going to be a good vehicle for information, sharing of information and the Agent Orange issue, I'm sure, will be brought up as appropriate.

We have found, as I think most of the other service organizations have, that since the passage of Public Law 98-542 there hasn't been a whole lot of interest or activity legislatively on the Hill with respect to Agent Orange, with the exception of probably a proposed study in the House and a lot of interest from Senator Cranston on female veterans. We think it's time to do something like that, and we certainly would support something like that.

I'm taking most of the inquiries now as far as Agent Orange is concerned and somewhat to my surprise I find that we're getting an increased number of inquiries in our office. A lot of inquiries on the lawsuit, but still a lot of inquiries are coming in as to what the VA is doing and how they're progressing. I have this problem, is there a relationship and so on, and there are both letters and phone calls. We try to answer them as best we can by the personal nature of the inquiry, plus whatever information we have provided us by the VA, we try to send out to the veterans

as they come in. Other than that I don't have anything else.

CHAIRMAN SHEPARD: Thank you very much, Mr. Gorman. Are there any questions to Mr. Gorman from members of the committee? Thank you.

Next I'd like to call on Mr. Keith Snyder from the Vietnam Veterans of America.

STATEMENT OF KEITH SNYDER FROM THE VIETNAM VETERANS OF AMERICA

MR. SNYDER: Thank you. The VVA continues to be concerned about the implementation of the latest Public Law 98-542. Particularly its phase of regulations which were recently finalized. We had commented on those regulations, and I have copies of those comments here that I would like to distribute to members of the committee.

As I had asked earlier, and as I think you still suggested, Dr. Shepard, to use the opportunity during the forum period to ask about how claims are going — Claims for service connection, as well as claims for interim benefits. We'd still like to get those questions answered so we can see what progress is being made on that field.

The VVA, in addition to the regulatory scheme and its interest in that, is also very interested in the Agent Orange lawsuit of New York, the class action suit there. And we're awaiting, as are others, the publication by the Court of its application for payment and anticipate then developing written materials to help individuals fill out that application for payment to take advantage of that settlement fund.

We also have other publications, what we call

self-help guides, one of which is on Agent Orange, which we are in the midst of revising to take into account the new regulations.

That's what VVA has been working on and anticipates continuing to monitor -- both the VA and the lawsuit activities around this issue.

CHAIRMAN SHEPARD: Thank you. Would you like to say anything about what I understand is an upcoming Agent Orange — excuse me, not just Agent Orange, a VVA program which I think is being scheduled for -- in Chicago. I got a call from Ginny Richards about that.

MR. SYNDER: The VVA has it's bi-annual convention scheduled this year in Detroit. November 20 to 24. And I believe that the Administrator is going to speak at that session. That's our, as I say, bi-annual convention. We intend to have workshops on Agent Orange that would be put on by the subdivision of WA, of which I'm a part of, which is the legal services aspect. We would have a workshop on a claims process and in particular on the lawsuit and what developments there are on that.

CHAIRMAN SHEPARD: Thank you very much. Now, I'd like to call on Mr. Hugh Walkup, who comes to us from the National Veterans Task Force on Agent Orange.

STATEMENT OF HUGH WALKUP, THE NATIONAL VETERANS TASK FORCE ON AGENT ORANGE

MR. WALKUP: Thank you. The task force is a fairly loose coalition of community based organizations including the recently independent Vietnam Veterans Leadership Programs which were formally sponsored by Action in a number of states. The major focus of the organizations that make up the task force has been on individual service. And primarily around the lawsuit recently and also in working with veterans to get that sort of physical examination, whether through the Veterans Administration or private physicians, that they need to solve some of their issues, and also assistance in claims. We've been able to work with four states so far who do not have commissions to set up hotlines for information on issues of concern to Vietnam veterans, in particular where they can get services.

Again our focus has been primarily on an individual basis and there are a number of individual concerns that other people have talked about this morning which I think bring to bear on an issue which you've raised, Dr. Shepard, several times this morning, and Dr. Young did also, about the point of view of the individual Vietnam veteran versus some of the conclusions that appear to be coming through the Veterans

Administration and other parts of the Government about the results of the Agent Orange studies.

As Mr. Bender said I think many times Vietnam veterans have already made their decision about Agent Orange. They know that it did something to them. They don't know what it is. And they don't really particularly trust what anybody is going to say to them about it. I think in a lot of ways the time has passed for being able to communicate very effectively, especially from the Veterans Administation, anything contradicting that. But, at the same time I think most Vietnam veterans have moved on and have accepted that as part of their lives and are trying to deal with other issues that are of more concern.

But, I think that in any approach that we take it is really important to understand that that's the bottom line understanding of many veterans. And that also because of that Agent Orange has impacted their life very significantly even though it may not have physically affected their health. For instance people who have chosen not to have children, as was mentioned here today. People who've had significant concerns about their health which may or may not be based on what the studies have been finding. But, also what appears to be a large instance of people who do

have problems with their health that maybe doesn't have a base in dioxin, but has a base somewhere else and is somehow related to the experience of a Vietnam vet coming back from Vietnam or maybe being concerned about Agent Orange.

When I was in Vietnam one of the things that was close to "Kilroy was here" that was on many of the latrines that I saw was very close to a comment earlier that Agent Orange was a myth. What many latrines said was that "Gravity is a myth. The Earth sucks." And I think that that represents many Vietnam veterans' perception of the Agent Orange issue. It may be a myth, but it's a myth in an older sense in that it represents many of the things that came from the Vietnam experience. And the parallel extends to the second part of the phrase that it was not a pleasant experience and it has had significant impact on the lives of many Vietnam veterans. So, in whatever ways we try to move on from the Agent Orange issue and give people reassurances about the effect on their lives, I think that we have to be very sensitive to the impact that Vietnam has had on their lives and attempt to deal more effectively with those kinds of things than we have in the past, and definitely much more affectively than we have in dealing with the Agent Orange issue from the original

time it came up.

CHAIRMAN SHEPARD: All right. Thank you very much, Hugh. I certainly agree with that. Are there any questions for either — excuse me, I didn't ask for questions for either Mr. Snyder or Mr. Walkup from members of the committee. All right. Thank you very much.

General Wells, I wonder if you would mind my asking Dr. Blank, to go on ahead of you.

Thank you.

Dr. Arthur Blank, here in Central Office, heads up our readjustment counseling program. He's also in touch with an advisory committee not too dissimilar to this one, dealing with concerns of Vietnam veterans and readjustment issues. Dr. Blank.

STATEMENT OF DR. ARTHUR BLANK, VETERANS ADMINISTRATION

DR. BLANK: Thank you. I appreciate the opportunity to be here. Thank you very much for deferring. I wanted to give you just a few minutes of orientation on an advisory committee, which relates to your concerns. Specifically, the Agency advisory committee on Vietnam veterans. The full name of is The Advisory Committee on the Readjustment of Vietnam Veterans. I am the responsible federal official for this committee on behalf of DM&S and the Readjustment Counseling Service, which operates the vet center program.

This committee is now beginning its third year of operation. It is not a legally mandated committee but was established at the initiative of the agency. It has a number of new members this year. The chairman is James Bouries, the National Service Director of AMVETS. He has been the chairman of the committee for the past year as well. It contains a number of individuals concerned with the readjustment of Vietnam veterans both in the psychological sense and in a broader social, including employment, sense. The committee also includes members from the major service organizations. In general, it has taken a focus in the three years to date, which undoubtedly will

continue, in the areas of the Vietnam veterans counseling centers, the treatment of post traumatic stress disorder and the medical facilities, a related item, the matter of disability from DVB for post traumatic stress disorder (PTSD). A focus has also been placed on the employment difficulties and advances of Vietnam veterans generally in our society as well as the employment of Vietnam veterans by the Veterans Administration and other Government agencies. We recently, for example, had an interesting presentation from 0PM about the advances being made in the employment of Vietnam veterans throughout the entire Federal Government.

The committee is, I might say, relatively convivial and usually has two-day meetings where we engage in in-depth discussions of a number of issues. The meetings sometimes continue to the point of exhaustion, and I think that is partly because of the complexity and the richness and the psychosocial implications of the various issues that we have dealt with. I would say that the committee, it is very interesting in what has happened over the past year. The committee was previously established in an atmosphere, with respect to the public, the Veterans organizations and the Congress of some tension and discontent about what the Agency was doing in the various program areas. One of the reasons we had to revise the membership

of the committee is because so many members became employees of the Veterans Administration over the past three years, doing expert v/ork in this area.

The committee's charter is now renewed for two years, and we expect to continue. I will be happy to entertain any questoins about the work of this group.

CHAIRMAN SHEPARD: Are there any questions for Dr. Blank? I have a question. Could you give us a word about the status of your study? Your readjustment counseling study?

DR. BLANK: Yes. The Congress directed the Agency to carry out a nationwide study on the readjustment of Vietnam veterans with an emphasis on determining on an epidemiological basis the prevalance of post-traumatic stress disorder and other key post-war readjustment problems. There has been significant over sampling to provide for generalization to certain special populations, namely Black, Hispanic and Women veterans. This is an approximately $4.5 million dollar study, which is fully contracted out to the Research Triangle Institute in North Carolina and is overseen by our office. It is moving right along thanks to the help from many people. We are, at the moment, carrying out in the field a validation pre-test to try to arrive

at an instrument which will diagnose PTSD accurately on an epidemiologic basis in the hands of lay interviewers. We are expecting some first results from this study in the autumn of 1986, which will, we hope, have a holographic relationship to the final results. That is, the first results will be based on one-third of the samples, and the final results of the study will not be presented until late 1987 or early 1988.

CHAIRMAN SHEPARD: Any further questions of Dr. Blank. Yes, Hugh?

MR. WALKUP: I wonder if you could comment on the kind of perceptual space that you see Vietnam veterans coming from vis-a-vis Agent Orange and addressing some of the issues that we've been dealing with around — no. Let me ask it this way. If the available scientific evidence says that you can eat Agent Orange on your breakfast cereal, what are Vietnam veterans reactions going to be to that?

DR. BLANK: That's a good question and good for at least a one-week seminar. I appreciate the comments which you made a few moments ago, which I heard. Over the last six years clients coming to vet centers have expresed concern about Agent Orange. Around eight or ten percent of our clients have expressed such

concern. We have an interesting report from a special study that was done on the program somewhat more recently, which suggests that that number may be higher in the last year or two. In general, our experience is much in line with what you were discussing a bit ago, that along with the medical and scientific technical issues this problem is very much a metaphor for individual veterans' feelings about the Vietnam experience. It is a very powerful metaphor. I think it has become a very powerful and important myth in the Greek sense and we are very much concerned with it in our daily work. Our impression is that veterans can sometimes express larger concerns about the Vietnam experience and what happened there through the modality of concern about Agent Orange. And that this accounts, in part, for the great emotional power of this issue.

A little difficult for me to say much more than that about it now. As I say that is good for a one-week seminar.

MR. FITZGERALD: Dr. Blank, did DVB have any input into your committee? Specifically, what I'm thinking about is if you're trying to get an easy method of evaluation of PTSD that this be one that is acceptable to DVB in their determinations for compensation.

DR. BLANK: Yes, the realms are somewhat

different although we try to take an account of clinical experience. We're concerned with the diagnosis of PTSD in an epidemiologic study. In the context of a five-hour interview on 3,000 persons conducted by Lou Harris lay interviewers It's a very different situation than the clinical diagnosis and assessment of post traumatic stress disorder.

However, in the national study we do have an interesting twist. We are going to have expert follow-up on about 300 out of the 3,000 total subjects. These will be mostly subjects that have been diagnosed as PTSD in the main household survey for the purpose of seeing whether we can validate our epidemiologic diagnosis with a clinical diagnosis.

MR. FITZGERALD: Why I brought this up is that we have experienced a reluctance on the part of DVB to accept a diagnosis of PTSD that is established within a VA hospital after a period of hospitalization. So that I think that there is an area between the two departments of the Veterans Administration to work together in getting this done.

DR. BLANK: Yes. Our committee is very concerned with specifically this issue. And the problems that interface between the treating clinicians and the

examining clinicians, which are two very different roles. It is appropriate to keep them separate. It's very important for treating clinicians programmatically not to have the responsibilityfor making recommendations about disability. Because being in that role grossly interferes with treatment. Since we have this appropriate separation we also have to deal with the discrepancies and that kind of thing.

CHAIRMAN SHEPARD: Are there any other questions? Thank you very much Dr. Blank. I really appreciate your being here. I think it points up, along with what Hugh was saying, the importance of dealing with not just the Agent Orange issue as the research comes in, but the more global concerns of veterans and the extent to which Agent Orange may be a portion of that. So, I think it's very important to have people like Dr. Blank working with us and we really appreciate his being here.

I'm sorry, we're not quite at the point in our agenda to request questions from the floor.

THE VOICE: But he will be gone.

CHAIRMAN SHEPARD: No. He's here. He's just got another meeting to go to. General Wells, can we hear from you. Very pleased to have you as a member of our committee.

STATEMENT OF BRIGADIER GENERAL SARAH WELLS, FORMERLY ADVISORY COMMITTEE ON WOMEN VETERANS

GEN. WELLS: Thank you. I'm delighted to be here, and I'm sorry I was late. I'm not used to the traffic anymore. I did not intend to go into the history of the advisory committee because I think most of you are familiar with it and most of you have representatives.

But, approximately 7,500 women served in South Vietnam. Mostly, they were Army nurses. And until 1983 I don't think any of the studies concerning Vietnam veterans included women. In fact, I think it was the VA study of the patient treatment files, that that was the first time that any women were included. I think that people have to understand that the concerns of the women Vietnam veterans mirror those of the men Vietnam veterans. And so the advisory committee has always supported a study of women Vietnam veterans possible exposure to Agent Orange.

As we get into this and talk more and more to women veterans — and more and more to the experts, the committee recommended that the study be construed in such a matter that it includes all issues of the Vietnam experiences, physical as well as the post traumatic stress disorder. And that

it should not focus only on gender specific diseases.

And those were the things that I wanted to say today. But, I would like to emphasize what New Jersey and what Minnesota and what you said, Dr. Shepard. When you go out and talk to veterans there are women veterans, and there are women veterans who served in Vietnam, and they do not like to be ignored.

CHAIRMAN SHEPARD: Well, I hope that we will redouble our efforts. We've tried to be sensitive to that issue, and I hope we will never lose sight of the fact that many of us who were in Vietnam worked side by side with women too.

GEN. WELLS: But, I think it should be pointed out that women don't use their benefits as much as men do, and that they have not really enrolled in the Agent Orange registry, have they Dr. Shepard?

CHAIRMAN SHEPARD: We're trying to get a handle on that. Is Dr. Kang here? Yes, do we have any figures on the number of women in the registry.

DR. KANG: We don't have a firm count.

CHAIRMAN SHEPARD: The question was the number of women in the Agent Orange registry. I think we had a figure of about 60 at one point out of over 200,000. So, obviously it is not a lot. But, we are continuing to look at that.

GEN. WELLS: I think that that is one way that the states and the organizations can help the women veterans.

CHAIRMAN SHEPARD: Yes. Very good. We also are continuing our efforts in reviewing the patient treatment file, especially as it applies to Vietnam era women who have been treated in VA hospitals. And we'll use that as one of the important data bases in doing our review of the patient treatment files of women who served in Vietnam, as opposed to those who did not, to get a handle on the health problems of those two groups and to compare them one with the other. Any other questions, for General Wells?

MR. FITZGERALD: General Wells, do you have any reason as to why women are not taking the Agent Orange exam? Is it because of their distrust of VA hospitals or is it because of their feeling of isolation as a female within the VA hospital atmosphere?

GEN. WELLS: There may be two reasons. But, in the beginning they did not put down the gender of people who enrolled, did they, Dr. Shepard?

CHAIRMAN SHEPARD: No.

GEN. WELLS: So that there may well be women that we don't know about. And then when they did start

to identify sex, gender of it that maybe the majority of women who intended to enroll already had.

Secondly, we think there needs to be more of an outreach program for the women. To get out there and let them know and encourage them to enroll.

MR FITZGERALD: It's not then, in your opinion because they're afraid to go to a VA hospital?

GEN . WELLS: That could well be. That could be an assumption, but I don't know that that – in a recent study that was done by Lou Harris those people who have gone to the VA hospital have been happy with their treatment at the VA hospital.

MR. FITZGERALD: That's been true in both sexes?

GEN. WELLS: I'm trying to figure out exactly what they told us about those people who did not go. And I'd have to look that up, but I do not get the impression it was fear of going to the VA hospital.

MR. SNYDER: Was there any suggestion that – from members of your committee, that there are any continuing privacy concerns about the VA facilities where people have to – the clinics they go to to report tor exams. I know they had an issue raised in the GAO report a couple of years ago for treatment purposes. I'm not sure if that would have any applicability to

the Agent Orange exam.

GEN. WELLS: I can't answer that right now because I'm not sure that I have read recently of that toeing a problem. It has been said. We have heard that time and time again. There has been a great deal done by the VA to solve that problem of privacy. And they recently had a national conference of all of their women coordinators at their facilities, and I can check that to see. When I was there that was not something that they broached, but I can check that to see.

MR. SNYDER: Thank you.

CHAIRMAN SHEPARD: I think if I may, another possible explanation is the majority of women who served in Vietnam, certainly not all by any means, but the majority were nurses. And therefore, I think when compared with the majority of Vietnam veterans who were not nurses and the majority of them were males, we're dealing with a group of individuals who are probably medically more sophisticated than the average. Therefore, they have their own mechanisms for dealing with their health issues and their problems and maybe have the—

MR. FITZGERALD: They probably have outlets — medical outlets that don't include the Veterans Administration. That's probably true.

GEN WELL: That's true.

CHAIRMAN SHEPARD: Thank you very much, General Wells.

I would like now to call on Mr. Fred Conway from our General Counsel's office to bring us up to date on the status of the Advisory Committee on Environmental Hazards as established by Public Law 98-542.

STATEMENT OP FRED CONWAY, VETERANS ADMINISTRATION

MS. CONWAY: Thank you, Dr. Shepard. I'm going to exercise my prerogative and reverse the order of my talk because the Environmental Hazard Advisory Committee was created by public Law 98-542. It is in a sense a 98-542 issue. By way of background, Public Law 98-542 mandated that the Veterans Administration promulgate rules, guidelines and appropriate standards and criteria governing the adjudication of claims for benefits based upon exposure to Agent Orange or to radiation. The primary emphasis for the development of guidelines and criteria and standards and so forth came about largely because of criticisms of the Agency's handling of radiation claims and not Agent Orange claims. The agency has been rather consistent in its handling of Agent Orange claims, far less so in its handling of radiation claims. At least that was the perception of the Congress.

In order to ensure that the guidelines that were prepared by the Agency were consistent with sound medical and scientific evidence the Congress felt it appropriate to mandate the establishment of an Advisory Committee on Environmental Hazards, which would be charged with reviewing the existing scientific literature and making appropriate recommendations to the agency

as to whether changes or modification need to be made in its rulemaking and its adjudication of claims or benefits.

The membership of the Advisory Committee was selected the after soliciting recommendations of veterans organizations, scientific groups and so forth to ensure that we would have a widely respected group that was representative of variety of disciplines. I think we achieved that goal very well. I think we have a good membership.

The first meeting they had was in March of this year – excuse me, April of this year after the last meeting of this committee. And they had basically an introduction to the issues. There was an overview provided as to the background of radiation related claims and the disputes by veterans about that issue and also with respect to Agent Orange. They were provided, at that time, with the proposed regulations that the Agency had promulgated, which was developed by a task force of agency personnel from General Counsel's office, Department of Veterans Benefits and the Department of Medicine and Surgery. They were brought back in June to review those proposed regulations and to take into account whatever public comment the Agency had received by that date.

At the meeting in June they reviewed the regulations and made some recommendations for changes that were primarily directed toward the radiation side. With respect to Agent Orange they concurred in the Agency's position that there did not seem to be a sound scientific basis for awarding benefits on a presumptive basis for porphyria cutanea tarda. They also concurred in the agency proposal of a three months presumptive period for chloracne following departure from Vietnam They felt that was a reasonable timeframe given what we know about the nature of the disease. They were concerned, somewhat, about the possibility of a diagnosis not occurring within that timeframe and we tried to assure them we're not concerned with a diagnosis within that three month period, but rather a manifestation of a skin disorder somehow being noted.

With respect to soft-tissue sarcoma the committee made a recommendation that as far as they could tell the jury was still out. They were somewhat intrigued – that's not the right word, maybe concerned by the Massachusetts Mortality Study that they felt is just one more little question mark there. It didn't resolve it one way or the other and they felt that more work was necessary. In any event they did feel that our approach of not awarding on a presumptive basis

service connection for soft-tissue sarcoma was an appropriate one. The meeting next scheduled for the committee will be sometime in March of '86. At that time they will be asked to consider whatever -- what other additional scientific studies might have become available since their meeting in June. They will also be asked to take a look at all the public comments that we received on the proposed regulations before they were implemented, so as to have their findings as to whether they felt we made appropriate final regulations. And to decide at that point whether any changes need to be made in the regulations as we have them based upon experience and the comments and the science.

So, we have a full agenda ahead of us already on that meeting. And you are all welcome to attend.

CHAIRMAN SHEPARD: Thank you, Fred. Are there any questions for Mr. Conway?

MR. SNYDER: Yes. I understand as part of the VA's regulatory process that the Office of Management and Budget does comment on, and in some cases more than just comments, as to the nature and substance of Agency regulations. Can you tell us what OMB input there was as to the decision to drop PCT.

MR. CONWAY: About PCT?

MR. SNYDER: Yes.

MR. CONWAY: As I recall there was none. they made no changes or made any comments regarding our position on PCT. They did review the regulations as part of the overall regulatory analysis process, which is applicable to all regulations promulgated by all agencies.

MR. WALKUP: We discussed at our last meeting about the possibility of having a joint meeting of this committee with the other committee or having representatives go back and forth. I appreciate the invitation to the March meeting. I don't know, at least some of us didn't know, about the other two meetings that had happened there. Are there any mechanisms set up to get communication between the two committees to have, you know, actual members to come and sit with us or for people here to go and communicate to them?

MR. CONWAY: I don't think -- there's no formal process right now. If this committee feels that that is the recommendation they want to make I'm sure we would certainly consider it and if it can be logistically worked out I'm sure we would be glad to work something out. We do have one member of our advisory committee present here today, Mr. Bender, who has already spoken to you. He is one of the lay members of our advisory committee, so to that extent we do have representation

here at this meeting. I am here. At the other -- at the meeting of the Environmental Hazards Committee anyone who wishes to attend is free to attend. Dr. Shepard does attend as a representative of the Department of Medicine and Surgery. And so I think there is an overlap and I don't mean in any way, shape or form to intimate that your idea is not a good one. I think it deserves consideration. But, we do have some avenues for overlap and making sure that people are aware of what is going on in each of the committees.

CHAIRMAN SHEPARD: I might suggest that we will be happy to share the dates, as a minimum share the dates of the meetings and the agenda perhaps. And also similar to this committee that committee has a transcript and –

MR. CONWAY: That committee did not have transcripts. We have summary minutes.

CHAIRMAN SHEPARD: Summary minutes. I'm sorry, yes.

MR. CONWAY: Mainly because it gets to be – the words that they use are too complex it seems for a stenographer. And the transcript came out rather garbled and I decided – I made the decision, I take the blame or responsibility. I decided that perhaps summary minutes would be adequate. And no one seemed

to have complained with that. They seem to be satisfied with it. I will defer to Mr. Bender as a committee member here.

MR. BENDER: Scientists tend to have their own language that doesn't translate very well to lay people, especially when they use words of over 12 syllables or so.

But, I tend to agree with Fred that summary minutes, with regard to the notion of merging the two committees. At first I thought that was an excellent idea, but after spending several hours listening to the scientists I don't think it would be a very good idea at all. I think under those circumstances it is best to let the scientists get together and get that free flowing exchange of information that I think can only take place in a small type group like that. And then you have the lay members, me and the other lay members, can effectively then try to translate that and put it in laymen's language out to the veterans' population in general. With regard to your access to the veterans – to the environmental hazards committee, I received and reviewed, read and recorded all of the comments that were sent in and if any of you have any comments now, by all means send them to me or send them to Fred. Fred will send them out to all the members.

Or if you want to call and talk to me and discuss any agreements or disagreements by all means do that. And then on our next scheduled meeting on March 22, I believe it is. It's in March, sometime in March, I can bring those comments up to the committee or submit them in writing. And I'm sure that there will be — I know that there is going to be some vigorous disagreement going on between now and March with regard to the content of the rules. So, if you want to take part in that just either bring it through me or through Fred. The committee is open. I had quite a few nasty conversations. By that I mean unfriendly conversations with people from all over the country who were in disagreement with the rules. I can see that, but one thing the committee not, which it was charged by some people with — meetings were not held in secret and we're not trying to keep anybody out of the process. We want all of the comments and all of the opinions in. So, please send them in. I've got a cast iron ear for most of the nasty comments anyway, so --

MR. CONWAY: I've gotten a few of them.

MR. BENDER: I send them to you and I don't like them.

MR. WALKUP: So, it will be possible to get notes of the meeting and the summary minutes and the

agenda for the next meeting to the members of the committee here.

CHAIRMAN SHEPARD: Okay. One thing I think Fred did not say, if he did I apologize, but the committee is made up and chartered specifically to look at the scientific evidence that exists for adjudicating claims related to Agent Orange exposure and ionized radiation. It is made up of 11 scientists and four lay members for a total of 15. Approximately half of the scientific members are experts in the area of ionizing radiation exposure and another half in the Agent Orange exposure. Well, actually there is a mix. Some of them are toxicologists and epidemiologists. So, there are people with broad experience in research, and the chairman of the science panel is Dr. Leonard Kurland, who is the senior epidemiologist at the Mayo Clinic. So, I think you can tell that it is a very high caliber committee. It's been very interesting attending the meetings.

MR. CONWAY: I might also mention that the chairman is Mr. Oliver Meadows, former staff director at the House Veteran Affairs Committee and former National Commander, Disabled American veterans and very active still in veterans affairs. So, I think

we have a good, as I indicated earlier, a good membership. And if you want I can make available to this committee the biographical sketch of all of the members. I think I've already done that, but I will be glad to do it again if you wish another copy.

CHAIRMAN SHEPARD: Any further questions of Mr. Conway. Thank you very much, Fred.

MS. WELLS: Dr. Shepard, I'm sorry. Before we go on I want to get an answer for that privacy issue. And I have made some telephone calls because now at each of the VA facilities there is a women's coordinator. So, if a woman does have some concerns she has someone to go to. They just had a meeting and I tried to see if that had come out as one of the concerns that they were having privacy problems. Additionally, I will cheek again when they publish the study, the Lou Harris study and I will get that information to you.

CHAIRMAN SHEPARD: Thank you very much. We now come to the time on our agenda that we throw the meeting open to questions from the floor. We solicit any of your questions to the committee. If you have an specific person on the committee that you would like to address your questions to please feel free to do so. If not, I will field the question. And if you have questions written clown that's always

helpful. If not please feel free to raise your hand and we will recognize you. Yes.

CHAIRMAN SHEPARD: Could you come up here and identify yourself? We want to be sure that your comments and suggestions are included in our transcript.

MR. WHITE: My name is Joseph White. I'm the National Director of Minority Affairs for the National Association of Concerned Veterans. And my question is for Dr. Blank. With his study I would like to know if they have taken into consideration those veterans who belonged to specialized units in Vietnam. Such as Re-con and Kag.

CHAIRMAN SHEPARD: In the selection process, in selecting the study subjects, I believe not. However, I believe that there are questions that will identify those individuals regarding specific kinds of combat experience that they had. But, I will pass that question on to Dr. Blank and get an answer for you.

MR. WHITE: It is important, because there is a difference between those members who were in combined action groups who lived with the Vietnamese everyday and those who were in front units who stayed with their own kind every day and only saw Vietnamese when they engaged the enemy. That's a very important question.

CHAIRMAN SHEPARD: It is a very important question. I would agree, and I will try to get an accurate answer for you. In fact, if you'll leave your name and phone number with Don Rosenblum, I'll see if I can get Dr. Blank to give you a call and answer that question. He had to go out for another meeting. I'm sorry. He isn't here. Okay. Are there any other questions?

MR. WILSON: Art Blank.

CHAIRMAN SHEPARD: Yes.

MR. WILSON: This is for Art Blank. You know that I've never quite been able to resolve the results of that 1978 presidential commission that suggested that there were something on the order of 500,000 plus Vietnam veterans suffering the effects of post traumatic stress disorder. And certainly I think everyone realizes that this large number of Vietnam veterans, men and women, suffer these effects in varying degrees. Someone like myself who is rated 30 percent PTSD, I think my problem is survival guilt, although the VA sent me a letter saying I was service connected, they never told me specifically where I fell in that disorder. And I think that is a problem. But, what occurs to me, given this large number. And you know, if you want to just take it along a little bit let's just say for example that

10 percent of this 500,000 plus. Let's say 10 percent of those suffer some serious readjustment problems. Or serious enough that they warrant some medical attention or emotional counseling or what have you. And we come up with about 50,000 in that number. And I see that and I see these numbers and I look at New Jersey, for example, where a report to our legislature identified about 20,000 Vietnam veterans in our state who suffer these varying degrees of readjustment problems. And I look at our VA facilities to see how many beds we have to deal with this. And I see a ten bed special PTSD unit at Lyons VA hospital in New Jersey. And I have to wonder in my mind, we're going to study this problem through 1987 or 1988. We've got these tens of thousands of veterans who need help that we see everyday as well as the other organizations in our state and I just, you know, even us folks from South Jersey, as I said, we can do some math, and I'm trying to figure how you can take — let's be generous. Let's say 10 percent of the 20,000 in our state. That's 2,000. In fact if you want to cut it in half let's say five percent and so you can see. I still haven't figured out how we take this larger number and press that into ten beds. There are, as I understand it, 294 beds nationwide for PTSD. Special units to deal with the

special problems of this readjustment disorder, this problem. 294 beds in the 50,000 or 5,000. Somehow it just doesn't -- and I have to wonder where the VA is going. Now, the DAV, with its forgotten warrior project really began identifying PTSD as a significant problem in 1976. This is 1985. So, we've got nine years since that landmark report. The VA is going to study it for another two or three years. That's 12 or 15 years. That's a long time for a Vietnam veteran to live with the alcoholism or other problems that may plague him or her. And so I've got to wonder where we're going with this PTSD program and I think that the American Legion report was very revealing in a sense that it indicated that most Vietnam veterans, a great number of Vietnam veterans aren't familiar with vet centers or what their role is. You know I don't know how many of you folks here have crossed the threshold of a VA Vet Center in the last several weeks. I mean go through the door. See those three people inside trying to stem the tide of urban and minority veterans for the most part that are really overworking them to the point where there is a big turnover because of burnout. But, most Vietnam veterans don't go to the vet centers. Most veterans aren't familiar with the vet center program, according to the

American Legion study and so I have to agree with that, and so I have to wonder about 294 beds and thousand of veterans having problems and I just have to wonder where we're going with this business.

I think that PTSD is a significant problem. I don't think that it is an area that is confined to this business of well there are always that number of Vietnam veterans who are going to have problems anyway. I think that's -- the numbers are too large to categorize it in that way. I wish Art Blank had stayed here and I wonder sometimes when we're going to get to the real issues.

The thing is that next week more than ten veterans will call our office with significant enough problems where they should be seen by a physician. And you know, some of you folks should call Steve Silver up at Coatsville VA. Vietnam veterans, very non-descript looking type of combat guy. And he's got a waiting list of eight to nine months up there. It would be much larger, but veterans know that there is an eight or nine month waiting list and so again I wonder, you Know, Art Blank is a physician and he talks about what is it, validation verification and Lou Harris lay lanquage surveys and all of that. I think that's all well and nice. I talk about things like

I'm telling you, I'm going up in some tower and I'm going to just start taking some pot shots. Or Mr. Wilson, my husband has been abusing me and beating me up and terrorizing the kids and all of that business. Those are the real kinds of problems that you can't talk about in validation verification or Lou Harris surveys polls. So, if you haven't crossed the threshold of a VA vet center and you haven't taken those kinds of phone calls. You know, there is an old saying, if you ain't been there, you ain't been there. And I think that's the real world. And I still — I'll maintain that a bunch of us Vietnam veterans in the American Legion Post were gathered in our post and we've got a new saying. The American Legion used 50,000 dollars to Columbia University for that study. We'd have done it for a tenth. Because a lot of things that are in that study are things that if you put 20 Vietnam veterans together in a room they'll save you 50,000 dollars because that's what they'll talk about. And that's the real world. And I may be wrong, but I doubt it. And I'll maintain that and we'll see about the final outcome, but pass that on to Art Blank. Maybe they'd better stop studying this thing to death and get on with more beds and more people in Vet Centers and get the word out and start dealing with some of the real problems. So, I want

the record to reflect that.

And I know there are some Vietnam veterans in the room that aren't professional veterans.

And if I asked them about what I just said they would agree with me.

CHAIRMAN SHEPARD: Thank you Wayne. You never cease to liven things up, and I appreciate that sincerely.

MR. WILSON: And I mean it from my heart.

CHAIRMAN SHEPARD: That's one of the resons we're here, and I really appreciate your comments. I'd like to respond just briefly, if I may. First of all, and I'm not refuting anything that you said. First of all not all PTSD treatment requires in-patient treatment, number one. Not all PTSD is treated in PTSD designated beds. There are many hundreds of beds that are general purpose psychiatric, long-term care, whatever. And I think I'm accurate in this, maybe I'm a little off base, the beds that are designated are designated specifically for research in the area of PTSD and there is for the first time established a PTSD research center. And I think it's in Cleveland.

MR. WILSON: It is in Cleveland.

CHAIRMAN SHEPARD: Yes. And Art is the one to talk to you. And by the way his committee is also

open. It's chartered under the same set of laws that this committee is chartered under, so I strongly urge anybody who is concerned about this issue to attend those meetings and raise those issues with the experts in this area.

Keith Snyder has just reminded me that he would like to discuss the status of the claims, so I wonder if Herb Mars could come up and take some questions on that. Keith.

MR. SNYDER: Yes. I wanted to start with a number of claims, perhaps that have been —

CHAIRMAN SHEPARD: Excuse me.

MR. SNYDER: I wanted to start with, if we may, the number of claims that have been filed for the interim benefits that are currently available through 98-542.

MR. MARS: It's too early for us to have a record of those. We've just finalized the regulations and these claims will be coming in over the next few months.

MR. SNYDER: So, let's back up to the service-connected claims that have been available over the past several years.

MR. MARS: Over the past several years we've

had, as of the begining of September, 23,139 claims. These are claims where the veterans indicate some relationship to Agent Orange, whether the disability is claimed as Agent Orange incurred or just exposure to Agent Orange. In about 28 percent of these claims the veteran made no claim of a specific disability. He just claimed Agent Orange exposure and went through our rating process.

About 47 percent had the diagnosis that was claimed confirmed on medical examination and through the medical records.

MR. SNYDER: And that diagnosis was?

MR. MARS: The diagnosis varied. It could be almost anything claimed as a disability.

MR. SYNDER: But, did you have any confirmed diagnosis of chloracne, for example?

MR. MARS: No.

MR. SYNDER: Or PCT?

MR. MARS: No, but I will say that of the veterans who served in South East Asis the major disability that we have found were skin conditions. Just as Chuck said, determine. Chloracne is very difficult to identify. But, a skin condition can be service connected if it shows up in the service medical

records.

MR. SNYDER: The rating for chloracne versus dermatitus or a skin condition --

MR. MARS: Would not be different. The name may be different, but the percentages that would be assigned the disability would be the same.

MR. SNYDER: Okay, but just to summarize you actually have seen nothing that confirmed the diagnosis or ever allowed a service connected claim specifically because of Agent Orange exposure.

MR. MARS: What the agency has done over the last half dozen years is have a review of all of the ratings that have come in alleging skin conditions. A special group was set up under the Department of Medicine and Surgery under Dr. Fischmann, and they were a special chloracne task force. They went through all of these files. They went through the folders to see whether or not there would be anyone that would have chloracne. They picked out a number of the cases where it looked like there was the possibility of chloracne. These cases were sent to independent clinics who were asked to conduct full examinations of the veterans and to make their recommendations. And I believe that of that whole group she did not find any with chloracne. She is still over-seeing any cases where there is a potential of chloracne.

MR. SYNDER: In terms of *the* establishment of the specific percent of disability you rate by analogy I understand, since under the rating schedule you don't have the words chloracne or PCT.

MR. MARS: We don't have chloracne, but we do have the various types of skin conditions.

MR. SNYDER: And then PCT falls under --

MR. MARS: PCT we don't have a direct name for, but --

MR. SNYDER: But by analogy —

MR. MARS: By analogy to other diseases.

MR. SNYDER: Such as whatever it's manifested?

MR. MARS: Yes. Right.

MR. SNYDER: Would you — I'm not sure your DVB would be responsible for generating publicity as to the availability of the interim benefits. If not, maybe Dr. Shepard, you would answer whether public affairs has done any outreach, any press releases to indicate that VA regulations have been finalized and that interim benefits for chloracne are currently available. People are invited to take advantage of that opportunity. Has any of that been done or is planned?

CHAIRMAN SHEPARD: Correct me if I'm wrong, but the regulations were publicized in the Federal

Register, and I agree that is not an outreach effort. certainly, I would be the first to admit that. I don't know, Fred, if anything has been suggested in terms of any public awareness effort to publicize those regulations. Is that your question?

MR. SNYDER: Yes.

CHAIRMAN SHEPARD: I believe the usual mechanisms, that is the VA publishes annually, I think, a veterans benefits booklet. I presume that the service organizations have picked up on this. That's a presumption on my part.

MR. MARS: They generally have. They come out in the major service organizations monthly magazines for their members. They've been covering that.

MR. SNYDER: But there is no ether sort of outreach planned by the Agency to try and reach the targeted population generally?

MR. MARS: I don't know because we do get out a quarterly Agent Orange report. I don't know what will be contained in the next one. The Agency gets out —

MR. SNYDER: Is that being issued to persons who are a part of the Agent Orange registry?

MR. MARS: Eight.

MR. SNYDER: To whom does that go regularly?

MR. MARS: It goes to everybody who has been on the Agent Orange registry.

MR. SNYDER: I guess the next set of questions, unless someone else had a follow up on that, is about the Agent Orange registry. I'm not sure that that's your ballywick. How many names of persons do we now have of persons who've come and asked for exams?

CHAIRMAN SHEPARD: We have examined over 202,000 veterans for initial examinations. In addition, there are a number of veterans who have come in for follow-up examinations.

MR. SYNDER: Do you have current addresses of all 202,000 so that you send the report to those? Your quarterly publication or not?

CHAIRMAN SHEPARD: I'm sure we don't have current addresses on all of them. By the nature of the situation. We have attempted — we try and encourage both VA hospitals and veterans themselves to keep their addresses updated and current in their respective VA medical centers. At one point we sent out a brief questionnaire or mailback asking if veterans wanted to have information sent to them and the majority of them did. There were some that did not. So, there is an on-going process by which this information is

sent to those veterans who have indicated a wish to know. Then that is supplemented by people coming in since that initial quiry was made.

MR. SYNDER: Records of treatment for persons who present themselves pursuant to 97-72 asking for treatement of a condition, alleging exposure, what sorts of figures do you have on that to date?

CHAIRMAN SHEPARD: These are not recent figures. We have not done a recent analysis, but the last time we did it, and I think it is almost a year ago now, we estiamted that approximately 1.25 million outpatient visits had been made and approximately 22,000 to 25,000 inpatient admission.

MR. SNYDER: You have no subsequent breakdown, though, as to what the nature of the treatment was.

CHAIRMAN SHEPARD: No.

MR. SNYDER: Visits that are charted as being pursuant to 97-72, but not specified as to what the diagnosis was or the nature of the treatment.

CHAIRMAN SHEPARD: That's correct.

MR. WILSON: Isn't that figure really a guesstimate rather than hard data?

CHAIRMAN SHEPARD: Well, it's, we think, a reasonably good guesstimate. It is very difficult,

on an unit basis to determine whether or not that individual is there specifically because of public Law 97-72. Many veterans, if you were to ask them, are you here because of Public Law 97-72 wouldn't know what you're talking about.

MR. SNYDER: Sure.

CHAIRMAN SHEPARD: Are you here because you're worried about Agent Orange? Yes. And that may or may not constitute a public Law 97-72 admission or visit because they may be there for the Agent Orange Registry examination. So, it's difficult to be very specific and we tried to be as precise as possible in counting those visits and those in-patient admissions, but we found very soon that it is very difficult to set up hard and fast guidelines that would, in every case, sort out whether the individual was there because of Public Law 97-72.

MR. SNYDER: In terms of the availability of the Agent Orange registry exam, is any special effort being made to contact the various state Department of Corrections to make arrangements with correctional facilities to transport inmates, Vietnam veterans who are incarcerated, to a VA facility or in turn shipping perhaps an environmental physician to the facility for an exam?

CHAIRMAN SHEPARD: The policy has been that in the event that incarcerated veterans wish an Agent Orange examination they communicate that to the institutions' medical department or whatever institutional leadership there is there. The VA, in turn, will provide the applicable instructions to the penal institution. When the penal institution sends the completed forms back to the VA medical center, they would be included in the Agent Orange registry.

MR. SNYDER: Does that, though, have any applicability to requests for service-connected disabilities? Providing the sort of medical protocol for an exam for PTSD?

CHAIRMAN SHEPARD: There is no direct formal link between the Agent Orange Registry process and the claims adjudication process. If a veteran — well, let me let Herb speak about that.

MR. MARS: The veterans who come in for the formal examination, you can see with 200,000 of them and only about 28,000 or about 10 percent applying for benefits, there is no direct link. But, a veteran who will thereafter apply for benefits and advise us he has been examined, we get that full examination to handle as part of our rating process because we do require a VA

examination.

MR. SNYDER: Are necessarily these 28,000 persons those who had previously had an Agent Orange registry exam?

MR. MARS: No.

MR. SNYDER: You don't know how many of the 202,000 actually – what percent of that figure actually filed a claim?

MR, MARS: No we wouldn't.

CHAIRMAN SHEPARD: What about the incarcerated? He asked about -

MR. SNYDER: You suggest with the Agent Orange registry exam *I* would think something that is perhaps appropriate for the PTSD advisory committee to look at, perhaps make some recommendations on, *a* mechanism by which protocol for the Agent Orange exam was given to the prison physicians to do an exam pursuant to that protocol. It comes back and it is filed with the Agent Orange registry. That would suggest that perhaps protocol, in the physicians Guide, for example, for PTSD, the three pages there in chapter 20, could be used perhaps by the prison physician, provided to the rating people, rating side of the VA for – in support of a PTSD service connected claim. Is any consideration being given to that currently or perhaps to whom should

such a request be directed?

MR. MARS: I don't know. Normally we don't request exams unless we have a claim filed. Whether or not we visit every prison, although we do have some liaison with some of the state prisons as to veterans needs and some of the service organizations do contact them as to veterans needs. As to whether or not the protocol should be set up, that should be no problem because when we have outside examination, basic examinations we advise them of the basic necessities for the exam. *But,* to set up a national procedure for prisons is some other question that I can't answer. It's not within our department.

MR. SNYDER: I appreciate the responses.

CHAIRMAN SHEPARD: Are there any questions from anybody to anybody?

(No response.)

CHAIRMAN SHEPARD: If not, thank you very much. Before you leave the room will you please pick up around your chairs and take empty coke bottles and coffee cups and deposit them in the appropriate recepticle. Thank you.

(Whereupon, at 12:40 p.m. this meeting was adjourned.)

Table 2

BIRLS Results by State of Reported Death

State	BIRLS death shown	No death shown	No BIRLS record	Total
California	934 87.5*	62 5.8*	72 6.7*	1,068
Colorado	116 88.5	4 3.1	11 8.4	131
Florida	372 89.9	24 5.8	18 4.3	414
Michigan	385 88.7	24 5.5	25 5.8	434
New York	306 85.0	17 4.7	37 10.3	360
New York City	229 84.5	25 9.2	17 6.3	271
Ohio	421 85.6	37 7.5	34 6.9	492
Tennessee	171 83.8	12 5.9	21 10.3	204
Texas	548 87.4	43 6.9	36 5.7	627
Total	3,482 87.0	248 6.2	271 6.8	4,001

*Second row of numbers are percentages of all deaths for that state
x2 - 21.42 (8 d.f.), P - 0.19

Table 6

BIRLS Result by Vietnam Service by Period of Military Service

Served in Vietnam?	Served during Vietnam era? Yes: BIRLS death shown	Yes: No death shown	Yes: No BIRLS record	No: BIRLS death shown	No: No death shown	No: No BIRLS record	Total: BIRLS death shown	Total: No death shown	Total: No BIRLS record
Yes	1,036	21	4	0	0	0	1,036	21	4
	97.6	2.0	0.4	-	-	-	97.6	2.0	0.4
No	1,594	150	189	218	49	50	1,812	199	239
	82.5	7.7	9.8	68.8	15.5	15.7	84.3	9.3	11.1
Unknown	553	19	17	77	9	5	630	28	22
	93.9	3.2	2.9	84.6	9.9	5.5	92.6	1.3	6.1
Total	3,183	190	210	295	58	55	3,478	248	265
	88.8	5.3	5.9	72.3	14.2	13.5	87.1	6.2	6.7

Table 7

BIRLS Result by Vietnam Service by Race

Served in Vietnam?	Race: White — BIRLS death shown	White — No death shown	White — No BIRLS record	Nonwhite — BIRLS death shown	Nonwhite — No death shown	Nonwhite — No BIRLS record	Total — BIRLS death shown	Total — No death shown	Total — No BIRLS record
Yes	762 98.1	12 1.5	3 0.4	274 96.5	9 3.2	1 0.4	1,036 97.6	21 2.0	4 0.4
No	1,331 78.6	147 8.7	216 12.8	481 85.6	52 9.3	29 5.2	1,812 80.3	199 8.8	245 10.9
Unknown	544 92.5	24 4.1	20 3.4	90 93.8	4 4.2	2 2.1	634 92.7	28 4.1	22 3.2
Total	2,637 86.2	183 6.0	239 7.8	845 89.7	65 6.9	32 3.4	3,482 87.0	248 6.2	271 6.8

(1) White vs. nonwhite, BIRLS death ascertained (Yes vs. No): $X^2 = 7.807$ (1 d.f.), P = .005.

(2) White vs. nonwhite, BIRLS death ascertained for service in Vietnam (Yes vs. No): $X^2 = 2.287$ (1 d.f.), P - .130.

(3) White vs. nonwhite, BIRLS death ascertained for no service in Vietnam (Yes vs. No): $X^2 = 13.14$ (1 d.f.), P - .00028.

Table 12

BIRLS Result by Branch of Service by Length of Active Duty Service

Branch	Length of period of active duty in months* 0-5 BIRLS death shown	0-5 No death shown	6-12 BIRLS death shown	6-12 No death shown	13-22 BIRLS death shown	13-22 No death shown	23+ BIRLS death shown	23+ No death shown	Total BIRLS death shown	Total No death shown
Army	136	143	95	45	395	50	1,389	100	2,015	338
	48.7	51.3	67.9	32.1	88.8	11.2	93.3	6.7	85.6	14.4
Air Force	20	37	25	5	44	4	451	29	540	75
	35.1	64.9	83.3	16.7	91.7	8.3	94.0	6.0	87.8	12.2
Marine Corps	26	23	11	7	58	11	243	27	338	68
	53.1	46.9	61.1	38.9	84.1	15.9	90.0	10.0	83.3	16.7
Navy or Coast Guard	14	19	36	3	85	8	418	22	553	52
	42.4	57.6	92.3	7.7	91.4	8.6	95.0	5.0	91.4	8.6
Total	196	222	167	60	582	73	2,501	178	3,446	533
	46.9	53.1	73.6	26.4	88.9	11.1	93.4	6.6	86.5	13.5
Chi-square	X^2 = 4.59		X^2 = 12.30		X^2 = 2.60		X^2 = 7.11			
P value	P = .205		P = .006		P = .458		P = .07			

*There are 22 veterans for whom complete data on service dates could not be obtained.

Table 16

BIRLS Result by Type of Discharge by Period of Military Service by Race

Character of discharge	Served during Vietnam era?							
	Yes				No			
	White		Nonwhite		White		Nonwhite	
	BIRLS death shown	No death shown	BIRLS death shown	No death shown	BIRLS death shown	No death shown	BIRLS death shown	No death shown
Honorable	2,350	284	748	59	253	96	73	17
	89.2	10.8	92.7	7.3	72.5	27.5	81.1	18.9
Other than honorable	28	36	23	20	2	0	1	1
	43.8	56.2	53.5	46.5	100.0	0.0	50,0	50.0
Total	2,378	320	771	79	255	96	74	18
	88.1	11.9	90.7	9.3	72.6	12.8	80.4	19.6

CHLORINATED DIOXINS AND FURANS

CHALLENGES TO MODERN SOCIETY

ALVIN L. YOUNG. LTCOL, USAF, PH.D.
SENIOR POLICY ANALYST FOR LIFE SCIENCES
EXECUTIVE OFFICE OF THE PRESIDENT

OFFICE OF SCIENCE AND TECHNOLOGY POLICY
ROOM 5005. NEW EXECUTIVE OFFICE BUILDING
WASHINGTON, D. C 20506
TELEPHONE (202) 395-3125

LITERATURE ASSESSMENT

DIOXIN AND RELATED COMPOUNDS

TOTAL = 6,800

2, 3, 7, 8-TCDD = 3,700

MAJOR KEY WORDS - DIOXIN LITERATURE

TOXICOLOGY	=	2,191	=	38%
HUMAN	=	1.055	-	19%
ENVIRONMENT	=	980	=	17%
ANALYTICAL '	=	950	=	16%
REVIEWS	-	508	=	9%

KEY WORDS - DIOXIN LITERATURE

TOXICOLOGY (2,191)

ANIMAL	=	1619
ENZYMES	=	646
CANCER	=	536
TERATOLOGY	=	410
REPRODUCTION	=	304
MUTAGENIC	-	216
IMMUNE	=	178

KEY WORDS - DIOXIN LITERATURE

HUMAN (1055)

AGENT ORANGE	=	381
CHLORACNE	-	355
EPIDEMIOLOGY	=	292
INDUSTRIAL ACCIDENTS	-	222

KEY WORDS — DIOXIN LITERATURE

EPISODIC EVENTS

SEVESO	=	394
VIETNAM	=	222
MISSOURI	=	115
YUSHO	=	38
COALITE	=	21
BINGHAMTON	=	21
LOVE CANAL	=	20
EGLIN AFB	=	11

KEY WORDS - DIOXIN LITERATURE

ENVIRONMENT (980)

FATE	-	343
SOIL	=	338
FLY ASH	=	191
BIOCONCENTRATION	-	179
PHOTOCHEMISTRY	»	158
AIR	=	145
MICROBIAL	=	45

NATO PROJECT
COMMITTEE ON THE CHALLENGES OP MODERN SOCIETY

- INTERNATIONAL INFORMATION EXCHANGE
- THREE-YEAR PROJECT
- THREE WORKING GROUPS
  - EXPOSURE AND HAZARD ASSESSMENT (USA)
  - TECHNOLOGY ASSESSMENT (FRG)
  - INVESTIGATION AND MANAGEMENT OF ENVIRONMENTAL ACCIDENTS (ITALY)

RESEARCH **CHALLENGES**

- **DETERMINE** MODE OF ACTION OF **DIOXINS** AND FURANS

- **IDENTIFY** SOURCES OF CONTAMINATION

- ASSESS **BIOAVAILABILITY** AND ROLE OF MATRIX

- EVALUATE FOOD CHAIN CONTAMINATION

- DETERMINE EXTENT OF HUMAN EXPOSURE

RESEARCH CHALLENGES
(CONTINUED)

- DETERMINE SIGNIFICANCE OF TRACE QUANTITIES OF CONTAMINANTS IN HUMAN TISSUE
- EVALUATE METHODS FOR HANDLING AND MANAGING CONTAMINATED MATERIALS
- EVALUATE DESTRUCTION AND DETOXIFICATION TECHNOLOGIES
- CONDUCT RISK ASSESSMENTS THAT ARE COMPREHENSIVE AND REALISTIC

FOR THE PAST FIVE YEARS, THE UNITED STATES GOVERNMENT, THROUGH THE AGENT ORANGE WORK GROUP, A CABINET COUNCIL WORKING GROUP COMPOSED OF REPRESENTATIVES FROM 12 DIFFERENT FEDERAL AGENCIES, HAS BEEN COORDINATING THE GOVERNMENT'S SCIENTIFIC RESEARCH INTO AGENT ORANGE AND ITS ASSOCIATED DIOX1N.

FEDERAL GOVERNMENT RESEARCH EXPENDITURES

VETERANS ADMINISTRATION	=	$81.1 MILLION	64%
DEPARTMENT OF DEFENSE	=	$34.0 MILLION	23%
DEPARTMENT OF HEALTH AND HUMAN SERVICES	=	$19.3 MILLION	12%
ENVIRONMENTAL PROTECTION AGENCY	=	$15.8 MILLION	10%
DEPARTMENT OF AGRICULTURE	=	$ .6 MILLION	1%