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Veterans Administration

Advisory Committee on Health-Related Effects of Herbicides

Transcript of Proceedings

Twenty-Fifth Meeting
June 12, 1986

October 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.

June 12, 1986

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COMMITTEE MEMBERS PRESENT

BARCLAY M. SHEPARD, M.D.
Chairman
Veterans Administration

JOSEPH S. CARRA
Environemtnal Protection Agency

CHARLES F. CONROY, JR.
West Virginia Department of Health

GEORGE T. ESTRY
Veterans of Foreign Wars of the United States

THOMAS J. FITZGERALD, M.D.
The American Legion

DAVID W. GORMAN
Disabled American Veterans

RICHARD A. HODDER, M.D., M.P.H.
Our Lady of Mercy Medical Center

PETER C. KAHN, Ph.D.
Rutgers University

KEITH D. SNYDER
Vietnam Veterans of America, Inc.

HUGH WALKUP
National Veterans Task Force on Agent Orange

SARAH P. WELLS, USAF, RET.
Formerly, Advisory Committee on Women Veterans

ALSO PRESENT:

GENERAL THOMAS K. TURNAGE, USA, RET.
Administrator, VA

HAN K. KANG, M.D., P.H.
Veterans Administration

WAYNE WILSON
New Jersey Agent Orange Committee

HERB MARS
Veterans Administration

WILLIAM TRUE, Ph.D., M.P.H.
Vietnam Experience Twin Study

COL. WILLIAM H. WOLFE, USAF, M.C.
Air Force Health Study (Ranch Hand II)

EDWARD BRANN, M. D., M.P.H.
CDC Epidemiology Study

JOSEPH V. BANGERT
Massachusetts Vietnam Veterans Health Survey

FRANK J. BOVE
Massachusetts Vietnam Veterans Health Survey

ALLEN FALK
New Jersey Agent Orange Commission

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P R O C E E D I N G S

CHAIRMAN SHEPARD: Good morning ladies and gentlemen. I'd like to call the 25th meeting of the VA Advisory Committee on Health-Related Effects of Herbicides to order, and welcome you all to another meeting.

As you know, it's been some time since we met. I think our last meeting was in October, and we're very pleased to follow up. I expect this will be a very interesting meeting for a number of reasons.

A lot has occurred since our last meeting, and we're very pleased to have a number of distinguished guests with us today who will report on various research activities and other activities that are of interest to all of us, I am sure.

We have a very full agenda, and we have a particular treat in store in the person of our new Administrator, the Honorable Thomas Turnage, who will be addressing us shortly.

I will introduce him when he arrives.

Just a few housekeeping notes. As in the past, we ask all attendees to please sign the registry so we'll have your name and a record of your attendance here. We like to keep in touch with all folks interested in our efforts.

We ask again that attendees and committee members refrain from smoking during the proceedings. Please help

yourselves to coffee in the foyer, but I would also ask that you take the pains to pick up your coffee cups and put them in the receptacles provided when you're through.

We have a cafeteria down on the "C" level where you may wish to go during your break. Also there are public telephones down there if you need to make a phone call.

The phone in the foyer is a house phone, and not an outside public phone.

I'd like to announce that since our last meeting we have new telephone numbers so those of you who are interested in keeping in touch with us, please jot these numbers down. Our area code is (202). We have three extensions and we all use the central office exchange number of 389, so these are 389-3886, 3432 and 3774.

Those of you who have FTS, the numbers are the same. We just don't use the area code.

A few recent important developments. As you know, the legislation which mandated the conduct of an epidemiological study, the famous Public Law 96-151, which has been in existence since December of 1979, mandates that we report to Congress on the status of the epidemiological study mandated in that legislation.

We have complied with that and a report has been forwarded to Congress, and members of the committee have a

synopsis of that report in their packages.

Another important law which has been enacted is Public Law 99-272,which has directed the VA to provide for the conduct of an epidemiological study of the long-term adverse health effects which are experienced by women in the armed forces who served in Vietnam.

We're happy to report that progress is moving well on that study. One of the stipulations of the legislation is that the study be designed by contract or by an interagency agreement with another federal agency and that the contract or the request for proposal for the contract is to be published by the first of July, and we're very much in hopes of complying with that deadline.

As a matter of fact we may even beat it by a few days. I'm happy to report that the package for the RFP is currently on the Administrator's desk, or it was yesterday afternoon. Maybe he's even signed it by now. We hope to get it, out on the street, in the Commerce Business Daily very shortly so that we can start working on the design of the study.

Following that, of course, we will have another RFP for the actual conduct of the study. The law also stipulates that the protocol which is the design of the study, must be reviewed and approved by the Office of Technology Assessment and we're already in contact with OTA, explaining

our plans.

One of the mandates or one of the sections of that legislation states that we may look at a number of different types of exposure such as chemicals of various types, medication, other environmental situations that occurred in Southeast Asia.

We have determined previously and have reaffirmed that we do not believe that we can do a scientifically valid study looking at any specific exposure, that is any specific chemicals or medications or whatever, but rather we think that we can do a study of the Vietnam experience, somewhat analogous to the male study of the Vietnam experience which is being done at CDC.

We have expressed this opinion in a letter to the Office of Technology Assessment, requesting their concurrence in our plan and opinion.

There are a number of handouts on the table in the foyer, and we would invite you to avail yourselves of those.

We have been working at publications of various types, and we have now two synopses of our review of the literature. These have been prepared by our contractor, Clement Associates, and I would invite your review of these. These are written primarily for the non-science public, non-scientific individuals for their understanding, and we hope it

will serve this purpose well.

In addition, we have published two monographs, one on birth defects and genetic counseling and another one on Agent Blue or cacodylic acid. As you recall, some expression of concern was made early by some members of this committee about the possible adverse health effects of the use of Agent Blue or cacodylic acid in Vietnam, so we felt it important to develop such a monograph.

This, the Agent Blue monograph, is probably the most detailed, most complete compendium of everything ever written on this subject so I would warn you that it's highly technical. It's not intended for casual reading; however, there are some sections of it which I think would be of interest to non-scientists who are interested in some of the concerns around the use of this herbicide.

We hope to have the monograph on the use of phenoxy herbicides in print later this year. That's nearing completion, and we have that well in hand.

You probably observed in the foyer, as you came in, a display on Agent Orange that was put together by the VA; and Don Rosenblum, our hard-working Executive Secretary, played a key role in the development of that. This exhibit was used at the AMSUS meeting, the Association of Military Surgeons of the United States, at their

meeting last November in Anaheim. It was well received.

It was one of the scientific exhibits at that meeting, and we hope to have it used at other meetings that the VA attends or that the VA sponsors, so we hope that it is useful and informative.

I understand that Mr. Ed Jones who had a hand in developing the exhibit is also in the audience. Mr. Jones?

Fine. Thank you very much for your hard work.

The agenda this morning, as I indicated, will cover a number of topics. After hearing from the Administrator, which I anticipate will be shortly, we will have a rundown of some of the research activities in which the VA is directly involved.

We'll also hear an update of the twin study which we haven't heard about for some time. So we're very happy to have Dr. William True with us today to tell us about that.

We'll also have an update from the Air Force on the status of the Ranch Hand Study from Colonel Wolfe, and also an update on the CDC study from Dr. Edward Brann who is with us, and we'll particularly hear in some detail, I hope, the status of the special cancer studies about which we have not heard very much in detail.

We also welcome the attendance of our various service organization representatives to bring us up to date on their activities.

Good morning, sir.

GEN. TURNAGE: Good morning. How are you.

CHAIRMAN SHEPARD: Welcome. Nice to see you, sir.

It's my distinct privilege and pleasure to now introduce to you our new Administrator, Mr. Thomas K. Turnage, who comes to us from a long and distinguished military career and most recently as Director of the Selective Service of the United States.

General Turnage has a keen interest in the activities if this committee, and I was privileged to brief him the other day an bring him up to date on some of our Agent Orange activities.

At that time I invited him to address our committee, and he very graciously agreed to do so, so I introduce to you the Honorable Thomas K. Turnage.

REMARKS BY THE ADMINISTRATOR

GEN. TURNAGE: Thank you, Dr. Shepard. I'm delighted to be with you this morning. On benalf of the Veterans Administration we welcome you here.

At the outset I want to tell you how pleased I am that you would take of your time to come and participate and be with us. However, I recognize that probably has a greater impact on those of you who are from outside agencies and have scientific backgrounds as opposed to those who are part of the veteran service organizations, because we consider

you part of the family in any event.

You're involved with us in almost everything we do relating to veterans, and you're part of -- we consider you to be part of our infrastructure in any event, and you share the same interests as we.

When I look back at the history of this committee and note the kind of dedication that you have devoted to the project by virtue of 24 previous meetings, and the fact that you started in 1979, and the fact that, I guess, you have been revalidated on two occasions before that in '81 and '83 and then again in '85, notwithstanding the fact that there was another Advisory Committee established by statute relating to environmental hazards for veterans, and the fact that your new charter had to be rather redefined so that we could avoid some of the duplication that would occur between those committees, I'm delighted that you're back in business and you're here.

I think that Mr. Walters, who is my predecessor, made a proper decision in reestablishing, in effect, this committee so that you can continue with your deliberations and take advantage of the expertise that's reflected here and the interest and concern.

The fact that some of you would come all the way -- I guess, Mr. Walkup, all the way from Seattle, and other people from throughout the country -- to come and devote your

time to these deliberations is important.

Sometimes out of sight, out of mind, and the fact that in recent times the Agent Orange issue, which I think is almost synonymous with the term, herbicide, which is the official title of what we're trying to do here, but the Agent Orange issue is, because of it having been delegated to the CDC operation and over a period of time, has become, in some people's minds, less intense.

It hasn't in ours. We recognize the gravity of the issue, and the fact that still a great deal needs to be done in the area, and I guess there are two other issues that have occurred in recent times which give further emphasis to that.

Just recently a public law was passed stating we needed to look into the impact of service in Vietnam on women veterans, and obviously then there's going to be an interface with that that has to be addressed.

Moreover, for example, tomorrow afternoon at 1530 there is a meeting that is to be held or conducted by Don Newman relating to the inter-departmental concerns related to this issue.

Don Newman will be there,and he's the Under Secretary of HHS. I will be participating. Dr. Mayer of the Department of Defense will be there. Dr. Gibbons,I guess, from the Hill -- from OTA, and I guess there's one other from

HHS who will be participating in that.

The issue is there, and people are concerned about it. We have a continuing need for your services and the contribution you can make in this. In addition, to the fact that of the five or six major fields or areas in which you're involved and you will be addressing is the one that, I think, also should not be diminished to some lesser role, and that would be your representation of the individual veteran and his concerns as he expresses them to you and can be addressed by us and by the formulation of procedures by the Administration in addressing their concerns.

Well, I wish you welcome. I hope you have success in your deliberations. I stand ready; my staff stands ready to assist you in any possible way, and please rest assured that those recommendations that you make will be given every thorough consideration within the context of the whole, because we'll be getting input from, as you know, relating to the breadth and the scope of this subject, so we'll be getting input from other people and from other sources.

I thank you for coming. If there is any way that we can make your deliberations more productive, you simply advise, we'll be glad to do that.

CHAIRMAN SHEPARD: Thank you. Would you take a few questions from the members of the committee?

GEN. TURNAGE: Be glad to try.

CHAIRMAN SHEPARD: Yes. Are there any questions from members of the committee?

MR. SNYDER: Keith Snyder from VVA. I am curious as to -- I appreciate your comments this morning about the previous validation of the Committee and the work we've been doing. I am wondering whether during your tenure you expect to further validate and continue the work of the committee so that we can continue meeting.

Is that your intention at this point?

GEN. TURNAGE: I don't know that. My intention is, to be sure, that this subject is accorded, continued and personal as well as full professional broad agency interest. Now the forum in which that's to be conducted, whether or not we continue this one or whether we continue the other one which is statutorily mandated, the effect it will have by virtue of the recent law having to do with the study for women and all of the rest of it, my interface with the other departments who have an interest in this subject, I wouldn't want to make a promise that I wouldn't fulfill.

I don't know that. What I have done, however, based on a meeting with Dr. Ditzler, a meeting with Dr. Shepard, a discussion of the issue in analyzing the decision that Mr. Walters made in '85 when he, in effect, came up with a new charter and new validation of this -- I intend to proceed on that basis for the foreseeable future as far as

I'm concerned.

Everything in the Veterans Administration as far as I'm concerned, however, is subject to review and consideration, and if that answers your question I've been as candid as I can.

MR. SNYDER: Thank you.

GEN. TURNAGE: Yes, general?

GEN. WELLS: Women are newcomers. This is only the second -- we're not newcomers but we are sort of in the importance that we're placed with the VA; this is my second meeting, and I did want to make the point that we really appreciate the strong support that we've gotten from Congress and from the VA, and are looking forward to the study.

GEN. TURNAGE: Well, General Wells, I appreciate that comment. Let me suggest that I have a very great sensitivity both from the standpoint of personal experience of working with women and the influences I have from my staff about the overall role of women in the context of the whole system, not simply in numbers, but in the high mobility positions where they influence the action and have policy influence in the roles that they play.

We'll continue that and I have, well, I guess you'd probably know one of our earliest aquaintances that I knew from about major level up, Elizabeth Hosington, and the support that I received from the women inside the House

in those areas where there's great mutual concern, and this certainly is one of those, you have my full support on a continued basis.

Yes, sir?

Member: I have kind of a personal question, sir. Did you command troops in Vietnam?

GEN. TURNAGE: No, sir, I did not. I appreciate that. I hope I look that young. No, I was in World War II. I served in World War II in Europe. I served in World War II in the Pacific, and then I went back to Korea for the Korean War, and I did not serve in Vietnam; however, I have a sensitivity to any war in which we're involved, and I have a sensitivity to any veteran that we have, and I will assure you that they get that kind of concern.

CHAIRMAN SHEPARD: Colonel De Wire, your Chief of Staff?

GEN. TURNAGE: Colonel De Wire, the Chief of Staff here served twice in Vietnam. He served in a combat arm, and I think he has a greater sensitivity than I perhaps, but we're not without knowledge about that.

Yes, sir?

MR. WALKUP: In reconstituting the committee, the mission statement was revised somewhat and it appeared as if the emphasis shifted from review of research to delivery of services as far as the role of this committee.

Basically, I wanted to find out what you -- is that what you're looking for from us or what are your expectations from us?

GEN. TURNAGE: I recall one of the specific paragraphs in the charter also had to do with this committee's interface with the research issue, so you're not excluded from that whatsoever.

However, I would think that in that role or interface it would still be the impact that would have on the procedures and policies that we should adopt and use in the agency with regard to the overall context of the subject.

I am not concerned about some overlap between this and other committees or input that we receive here. If, in fact, you can come up with something that is innovative or unique or which will make a contribution to the system, it's those constructive type things that I'm interested in, not necessarily the source, so if your deliberations lead you into some area where there's concern, by all means don't let that inhibit you. Do it and then we'll talk about it later.

CHAIRMAN SHEPARD: Are there any other questions?

GEN. TURNAGE: Yes, sir?

MR. SNYDER: Perhaps in conjunction as a followup here of the service orientation of our committee, have you had an opportunity -- I'm not sure that you would have

yet -- to review, in fact, the regulations that are used in the area of granting compensation benefits, persons exposed and that would allege that exposure has led to problems.

GEN. TURNAGE: No, sir. I have not, other than the fact that I recognize now that we have had, what I consider to be the position of a very objective approach to the subject, that is where there's about a -- you try to accommodate the veteran, and worry about the details later.

I think that what we have been trying to do is wait for the outcome of the CDC study before the final determination is made, and the final determination may not be made by the agency from the standpoint of policy. It may be made statutorily by the Congress, so other than that the details are that I've been dependent upon the expertise of the staff who I have great confidence in.

MR. SNYDER: Is my understanding correct that since regulations have been in place or perhaps in the history of the past ten years, no one, in fact, has been granted disability compensation for the alleged exposure and for a health condition that was related to exposure. Is that accurate?

CHAIRMAN SHEPARD: I'm not the expert in that field. We have with us Mr. Herb Mars from the Department of Veterans Benefits. I would just say that there are a number of individuals who have been service connected for illnesses

which might have been related to herbicide exposures. For example, there are some cases that have been service connected for chloracne. Whether that chloracne was, in fact, the result of exposure to Agent Orange, I think is still moot.

The compensation system does not require a direct cause and effect relationship decision. Let me refer you to Mr. Herb Mars who is the real expert in this field.

MR. MARS: Thank you, Barclay. I think at the last meeting we also discussed the fact that we have been service connecting many conditions. For example, skin conditions which usually are claimed as related to the exposure to herbicides in the term, "chloracne".

We have service connected so many skin conditions, but we don't call them necessarily chloracne.

MR. SNYDER: Necessarily or ever.

MR. MARS: Okay.

MR. SNYDER: What I was trying to get to was whether you've ever had an official understanding or actually made a decision in the case which was specifically chloracne which you would say was and was related to service in Vietnam.

MR. MARS: If you remember, Keith, a few years back, they set up a special group within DM&S to review cases where chloracne may have been the cause of the skin condition. They picked a number of cases. They sent them to independent clinics for examinations and reviews to see what their

determinations were.

Most of the conditions came up with non-determinations of chloracne as the cause; however, they are still skin conditions, service connected, and whether we call them chloracne caused or caused by whatever aspect of service was there in Southeast Asia, they're still service connected and payable and treatable the same.

MR. SNYDER: Well, I guess, I just wanted to confirm so there would be no misunderstanding that I have understood that the Agency has not, in fact -- would not officially state that it has granted compensation, service connected benefits based on someone's exposure officially to Agent Orange, or has found either PCT, porphyria cutanea tarda which until I guess September 30th could potentially be service connected. I don't think we found any instance of that either.

Does that --

MR. MARS: We have not found those instances. It still comes down to the basic issue of whether or not the condition that the individual veteran has is related to his military service and we can service connect it, and whether we say that the exposure caused it or what, we don't really know because we're still completing the studies. We still service connect the condition.

That, I think, is the important issue, the fact

that we do recognize the condition was incurred in service, it's service connectible and treatable under our laws.

CHAIRMAN SHEPARD: No other questions? We thank you very much, sir, for being with us.

GEN. TURNAGE: Well, once again, please let me thank you for being with us. We appreciate your coming. We look forward to a successful meeting and some worthwhile recommendations that we can use in determination of policies.

Thank you very much.

CHAIRMAN SHEPARD: I'd now like to turn to our agenda and call on Dr. Kang to give us an update on some of the efforts that he has been personally involved in.

STATUS OF VA RESEARCH EFFORTS*

DR. KANG: I'd like to talk about the research activities concerning Agent Orange and Vietnam, veterans namely the Vietnam veterans namely the Vietnam Veterans Mortality Study, the VA/AFIP Study of Soft-Tissue Sarcoma and the VA/EPA Retrospective Study of Dioxin and Furans in Adipose Tissue and lastly, our planned study, the Women Vietnam Veterans Mortality Study.

Let me start off with the Vietnam Veterans Mortality Study. I have presented a study protocol to you two or three times already so I will not go into detail. But just to refresh your memory, let me describe the outline of the study.

The purpose of study is of course, to compare mortality patterns between Vietnam veterans and non-Vietnam veterans.

* See slides on pages 170-184

We'll are limiting the study in such a way that only ground troops, Army or Marines, are included in the study.

We used the BIRLS, Beneficiary Identification Record Locator Subsystem, that is computerized file that includes most of Vietnam era veteran deaths. Using that as our data source, we identified 185,000 Vietnam era veterans' deaths among the men who served in the Army or Marines or an unknown branch of services.

We excluded from the study veterans who served in branches other than the Army or Marines, whose discharge date was before January 1, 1965 or whose enlistment date was after 1973, and all deaths in the service before 1973.

We excluded active duty personnel deaths before 1973 because combat related, or war related deaths can only happen among Vietnam veterans. Since the study is a proportional mortality study, we have to exclude those individuals who died from war related causes before 1973.

Next one, please.

Okay, this is the status of our mortality study. We have completed collection of military data and cause of death information. Now we're in the process of analyzing that data, and results will be available in the next two or three months.

We did finish our preliminary phase of data analysis concerning suicide, accidental death and homicide. We are doing the analysis of

cause of death related to cancers and others causes of interest.

Okay, we have selected 75,617 out of a possible 186,000 Vietnam era veterans deaths because we know from a pilot test that some of these individuals may not be qualified for the study by virtue of their branch of service not being the Army or Marine or their service date fell outside of our criteria. So knowing the percentage of ineligible cases from a pilot test we oversampled in such a way that we would be ending up with 50,000 eligible cases.

That number, 50,000, is the number we came up with to achieve a certain statistical power for the study. Out of the 75,617 we selected, as expected 22,000 were not eligible because of their branch of service or service date. I'm very pleased to report to you that for only 1.4 percent, or 1.032 individuals, we were not able to locate their military personnel folder. That is, we think, very remarkable.

We have been able to come up with 52,285 individuals who are eligible for the study.

Next one, please?

For cause of death information, out of those 52,285 eligible cases, an we obtained death certificates on 51,423. Again, we are very pleased to report to you that the loss rate because of lack of cause of death information is only 1.6 percent. This is one of the reasons the study

took so long. The person who designed the study at the beginning thought that most of the death certificates would be in records of the VA, but it turns out that for almost 15 percent, or close to 9 or 10,000 individuals, the VA does not have their death certificate in their records. We had to trace them, and identify in which state these individuals died, and request the death certificate from 50 different states. So, it took us a long time to obtain the cause of death information back. I'm very pleased that the loss rate is only 1.6 percent.

Next one, please.

Some of the demographic information of those 52,000 eligible cases is as you expect, most of the Vietnam veterans served in the Army. A very small portion served in the Marines. If you compare Marines, more Marines veterans in Vietnam than elsewhere whereas for the Army personnel, about 47 percent of Army veterans in the study served in Vietnam and about 53 percent served elsewhere.

Next one, please?

Looking at the race distribution, there is not much difference between the proportion of blacks serving in Vietnam and the proportion of blacks serving elsewhere about 18 percent. There are some suggestions that

more black soldiers went to Vietnam but as far as we can tell, looking at the study that we have, the proportion of blacks in the Army -- sorry, the proportion of blacks in the Army and Marines are the same between those who went to Vietnam and those who didn't go to Vietnam.

Next.

Discharge status. More Vietnam veterans were discharged with honorable discharge status than non-Vietnam veterans.

Because we did a comprehensive review of military personnel records we have much information on these veterans. What we do now is to analyze data, not only comparing everyone in Vietnam and not in Vietnam, we'd like to compare by branch Army and Marines who went to Vietnam versus Army and Marines who stayed in the United States or elsewhere. Furthermore, we'd like to compare by rank.

We have length of service information so we'd like to compare the mortality pattern by how long they served in Vietnam. We'd like to compare by proxy combat status. We have MOS information and the service date and unit information on Vietnam veterans so we'll be able to categorize the Vietnam veterans as to veterans with a combat related MOS such

as infantry or artillery or combat engineers, and compare those individuals against the non-combat support individuals. We'll be busy the next two months to do all of this analysis and come back to you within two or three months to report the final results.

Next.

The next study is the case-control study of soft tissue sarcoma that we're doing with the AFIP.

Next one, please?

Again, just to remind you of the purpose of study, the study is to determine whether service in Vietnam is associated with the risk of developing soft tissue sarcoma. The second question is whether there's a dose response based on exposure likelihood and the next is histopathology and anatomic site of soft tissue sarcoma with respect to Vietnam service, and many other environmental risk factors.

Next one, please?

The soft tissue sarcoma cases are selected from the AFIP soft tissue tumor registry and controls are selected from hospitals from which the cases are referred. Originally, we started up with 2:1 matching design, but at the request of the OMB, it became a 3:1 matching study.

Next one, please?

Just a brief review of the literature, as you can tell, there are a lot of studies indicating the relationship

between exposure to herbicide and soft tissue sarcoma. However there's an almost equal number of studies indicating non-positive outcomes. Hopefully, our study will contribute to resolution.

Next one, please?

Some of the host factors, and environmental factors suggested in the literature as possible risk factor are listed up there. Next one, please?

We've designed the questionnaire addressing some of those possible risk factors as well as other medical and environmental factors.

Next one, please?

The selection of controls is completed. Tracing and interviews are also completed. This is the status as of last month. The number expected are 277 for soft tissue sarcoma cases and 811 controls. Out of 277 soft tissue sarcoma cases, we were able to locate 231 cases, that is 83 percent of possible cases; of the 811 controls we were able to find 672, again 83 percent. The interview is completed for 217 cases and 601 controls. That is 78 percent of the total possible cases and 74 percent of controls .

Response rate was 94 percent for cases and 89 percent for controls; that demonstrates that more cases are willing to participate. Next one.

Some of the demographic information much as age, accession year, type of the hospital --

DR. KAHN: Excuse me. Do you intend to estimate the effects of four or five percent difference in response rate?

DR. KANG: We have to take into consideration since the response rate is somewhat different.

The age at accession, 14 percent of cases was less than 25, 13 percent of controls had been 25 or less. We intend to conduct a matched analysis. Since the distributions are similar, we may conduct a non-match analyses as well as a match analyses.

Next one?

This is a statistical power calculation. Having 217 cases so far in the study this is what you will expect. If a true risk is twofold among Vietnam veterans, and if the proportion of Vietnam veterans in our controls is ten percent, we'll expect over 84 percent change of detecting that excess.

The power of the study probably is not that bad. It's adequate

Mr. Feil of my staff is busy helping me in the analysis. Hopefully, within two months we'll be able to come up with a final report.

Next one please?

This is the VA --

MR. CARRA: In one of the overheads you showed the positive studies and negative studies, and I assume that at some point someone would flip this, the results of this study in the context of the other studies?

DR. KANG: Yes.

Mr. CARRA: I might suggest that when we look at negative studies that it gives some indication of the power that was -- that those studies had in them to detect the difference so that we have an idea of whether we really had a negative study or we had a study that we wanted to, in effect, design to be negative.

DR. KANG: Yes. Okay. This is the VA/EPA adipose tissue study. For some time, the last two years, we been working very closely with EPA to answer the question of whether dioxin level in adipose tissue among Vietnam veterans is higher than non-Vietnam veterans. The VA recognized that the EPA collection of adipose tissue going back ten or 15 years can serve that purpose.

The EPA under the National Human Adipose Tissue

Survey Program collected adipose tissue from more or less representative samples of U.S. population. They have collected about 21,000 adipose tissue specimens.

Out of that 21,000 adipose tissue, specimens it was found that only 8,000 had some adipose tissue remaining. In other words 13,000 specimens were already spent for their own purposes, namely measuring chlorinated hydrocarbon pesticide levels. So out of 8,000 possible specimens, the VA set the criteria of eligibility for the study so that only males with birth year between 1937 to 1952 were included. Out of 8,000, only 528 specimens or individuals met this criteria, so the next step was determine of those 528, how many served in Vietnam, how may did not serve in Vietnam and how many did not serve in the military at all.

To determine that we would need social security numbers or names. EPA unfortunately did not collect either names or social security numbers from these individuals. The EPA through their contractor had to go back to individual hospitals and ask them to provide either names or social security numbers or both. Of 494 individuals, the EPA was able to receive either name or social security number.

With that information the VA asked the contractor to research their military records.

Next slide, please?

Out of 495 names or social security numbers given to the VA, the contractor was able to identify that 40 individuals had a record of serving in Vietnam and 94 served in military during the Vietnam era, but not in Vietnam, and for 361, the contractor did not find any record of military service during that time period.

The study is designed in such a way that we will have two veteran controls and two civilian controls for each Vietnam veteran. We have selected 80 out of 94 non-Vietnam veterans and 80 out of 361 civilians.

The list of names was given to the EPA, and the EPA forwarded it to their contractor. They're now pooling the specimen from storage and chemical analysis will be starting in July when their new contract year starts. This will be about a 16 or 18 months project. At the end of 18 months we will be able to come back and present the data in such a way that either yes, indeed, dixoin level in Vietnam veterans' adipose tissue is higher than non-Vietnam veterans, or whether their dioxin level is higher than civilians, or comparing veterans in general against civilians whether veteran's dioxin level is higher lower. We'll get a report back to you after 18 months.

DR. KAHN: Dr. Kang?

DR. KANG: Yes?

DR. KAHN: The analysis would be -- are these just

for 2370 and --

DR. KANG: Well, we will have at least five isomers from dioxin -- and 5 isomers from dibenzofurans

DR. KAHN: Are the isomers chosen to characterize those that are known to the lives of --

DR. KAHN: Yes. We'd hope that the outcomes can somehow suggest the source of that chemcial.

DR. KAHN: Why don't we find the -- MRI capable of doing any good to the multi --

DR. KANG: It is not just limited to five. If they can measure more than five without additional analysis, then we would get that data, but we give them a minimum number of isomers to measure.

DR. KAHN: Could I see a list of those isomers at some time?

DR. KANG: Sure. It's in the interagency agreement.

Next?

Dr. Shepard and our Administrator mentioned the female Vietnam veteran study. Independent of that Congressionally mandated female Vietnam veteran study, we've been planning and implementing female Vietnam veterans mortality study for sometime. Nobody knows for sure how many females Vietnam Veterans

there are, so the initial task will be to -- next one, please -- to identify a study group. Once we identify the female Vietnam veterans and characterize them through a review of their military records, we'll be able to select a control group matching the Vietnam veterans groups.

Once we select controls then we will determine vital status of these individuals through the national death index, Social Security Administration or using the VA's own information, and we will obtain cause of death information for both Vietnam and non-Vietnam female veterans, and we'll do analysis of this data.

Next one, please?

These are the numbers given to us from the Environmental Support Group of the Army. They, reviewed the military morning reports of the units stationed in Vietnam that possibly had female veterans.

That's Army, Navy, Marine, Air Force included.

They gave us the names and whatever information they could gather out of military reports and we computerized that information and tried to eliminate the duplicate names or duplicate individuals because they came from different sources. We came up with roughly 5,000 female Vietnam veterans.

Just to give you an idea of what to expect in terms

of number of Vietnam veterans, according to the VA's own survey of female veterans, only one percent of all female veterans was found to have served in Vietnam.

We look at the column, the first column, total 3,003, reading down the column, Vietnam is one; one percent of 3,003 individuals surveyed indicated that they served in Vietnam.

Next one, please?

All right.

Yes?

Dr. KAHN: There were a great many Red Cross nurses who were technically not military personnel but served in military hospitals out there. These people should be tracking through the Red Cross. There's a great deal of statistics to compile in the study.

It's a little harder to find them than it is to find military personnel.

DR. HODDER: I don't know what your experience was, Dr. Shepard. When we tried to look this up, we could find that they had basically no records on these people that they could effectively access.

CHAIRMAN SHEPARD: That thought has occurred to us many times, and we have approached the Red Cross. Theoretically, it would be possible to do so, but as Dr. Hodder suggests, the ability to identify women who served as Red Cross workers

in Vietnam -- by the way I don't think most of them were nurses -- they were mostly social workers, it's somewhat less central than it is with the military. It's hard enough for the military but it would be --

DR. KAHN: Clear enough. It's no central job, but should identify those people who served with their organization during that time and then track them down and ask if they were in Vietnam.

CHAIRMAN SHEPARD: As I say, we're looking into that. We have not given up on it. There is still that potential. I don't think that we should combine the studies. I think that if we were to do a study we'd want to do it separately as Red Cross isn't the military.

DR. KANG: Okay, the estimated number of female Vietnam era veterans being about 270,000, and follow that column. Next one, please?

The estimated number of female Vietnam veterans can vary depending on what data source you use and what assumption you make. If you use the 1980 census, the 1980 census is the first time that veteran status was asked, there are 1.1 million female veterans overall. If you take a one percent figure based on the VA's own survey, you will come up with 11,000 female Vietnam veterans. Again, that one percent is based on a survey of 3,000 individuals. So if that one percent is not reliable then you would

have different numbers. Another VA survey in 1982 suggestion that there were 742,000 female veterans. Applying the one percent figure you come up with 7,400 female Vietnam veterans.

As I indicated earlier, the ESG come up with roughly 6,000 names. The CDC, based on a review of military records, kept at the NPRC, came up with 7,500 female Vietnam veterans. What they did was that 7 million Army veterans who were discharged between 1964 and 1982, they matched the names by female-sounding first names of about 2,000. They came up with so many Vietnam era veterans and then they actually went back and retrieved a sample of 3,500 personnel records. Based on the pilot test, they estimated approximately 7,500 possible female Vietnam veterans.

We don't know for sure how many female Vietnam veterans there are. We have about 5,000 females veterans' names. We plan to add more names as we can ascertain. I had a phone conversation with the Chairperson of the Women Vietnam Veterans Memorial Committee in Wisconsin. She told me that she had some names of women veterans that I could add to my list. I am expecting to receive a list of female Vietnam veterans from her.

Next one, please?

MR. WALKUP: Dr. Kang, as part of the '80 census, I had a long form where they ask about location of service as well as periods of service. Does that figure from the '80

Census represent responses from the long-term questionnaire or is that the estimate of the one percent?

DR. KANG: It's a response to question 18 or 20. I don't think there was any more information other than that information.

Yes?

MR. SNYDER: Do I understand that you would welcome lists of female veterans?

DR. KANG: Yes.

We will cross match with what we have and if we don't find it, we'll add to our list to complete a roster of female Vietnam veterans.

As Dr. Shepard has said, most of the female veterans are not nurses. If you look at the third line from the bottom, only 16 percent of total female Vietnam era veterans have served as nurses. We had a preconceived notion that most female veterans nurses. Only 16 percent of female Vietnam era veterans was categorized as nurses.

CHAIRMAN SHEPARD: Of those who went to Vietnam, the women who went to Vietnam.

DR. KANG: Yes.

CHAIRMAN SHEPARD: Part of the majority.

DR. KANG: Definitely so.

Okay, I think I have the end of it. I'll take any questions.

CHAIRMAN SHEPARD: Thank you very much, Dr. Kang for a complete, succinct review of our research efforts. Are there any questions from members of the committee for Dr. Kang?

MR. SNYDER: As a part of the packet we have do we have a printout of the slides that were displayed here?

CHAIRMAN SHEPARD: No.

MR. SNYDER: Currently?

DR. KANG: It's not included.

MR. SNYDER: May we get those? Would that be possible to provide, please?

CHAIRMAN SHEPARD: Yes, I think we can do that, yes. We may want to select them.

Any other questions for Dr. Kang?

Thank you very much. Appreciate that.

Next I'd like to call on Dr. William True who will bring you up to date on our Twin Study. Dr. True and Dr. Seth Eisen have been working very hard over the years to continue this exciting effort, and we're looking forward to Dr. True's comments.

VIETNAM EXPERIENCE TWIN STUDY *

DR. TRUE: Thank you very much. It's a particular pleasure to be reporting to you today because the initial source of support for the Twin project was the Agent Orange group under Dr. Shepard's direction. Without their support

* see slides on pages 188-201

we would never have been able to indicate this very exciting project.

The Vietnam Experience Twin Study is a study of 8,000 Twin pairs who both were in service during the Vietnam era from 1965 to 1974. It is a study based on multiple data sources particularly featuring a mail survey concerning current health status of both members of the Twin pair.

The Vietnam experience Twin Study is a Cooperative Study Program of the Veterans Administration begun and planned about at the same time as the other studies you will hear about this morning.

Our collaborators in the cooperative study are from the Cooperative Study Coordinating Center in Hines, Illinois.

I'm reporting for all our team here today.

The research objective is to determine the relationship between Vietnam service and the medical, psychological, and psychosocial aspects of health.

Our methods really are quite simple; to identify and locate a representative sample of twin pairs where both served during the Vietnam era and were born during the years 1939 to 1953.

At this point we are performing a mail survey on the entire registry using the co-twin analysis strategy to detect effects which I described in

our methods an objectives.

An initial question which we received from both scientific and lay audiences about the Twin project is "Are there sufficient twins?" The number of twins available is surprising to us and it emerges from the fact that we determined in pilot work that there are approximately 200,000 twin pairs born during the birth years I described.

Again, through our pilot work, we determined that 46,000 of those were twin pairs where both served in the military during the years of the Vietnam era.

Clearly, there were sufficient twins. The most difficult issue would be to identify them and recruit them. The basic design of the Vietnam Experience Twin Study is portrayed in the slides. We're dealing, of course, with two types of twins, identical twins and fraternal twins, and cells one and four represent the condition where both members of the twin pairs served in Vietnam.

Cells two and five represent the condition where one served in Vietnam and one did not, and cells three and six represent the condition where neither served in Vietnam.

With our 8,000 twin pair samples, we're going to have very full cells in all six of these conditions. The eligibility criteria for the twin pairs I've already alluded to, and the basic element is that they were at risk of going to Vietnam by virtue of being between the ages of 18

and 32 during the years of military service.

These eligibility criteria were dictated by our research objectives and

because our search procedures were predictated on military record system. We also anticipate further clinical studies and followup and are interested that all of our study sample be eligible for care in VA hospitals so that we would have a clinical base from which to work to perform later more refined studies.

The matching system which we employed through a rather complex use of all of the archival data is too involved to describe, but our basic algorithm in searching all these sources was to identify individuals with the same last name, different first names, precise data of birth and social security numbers within 100 digits. This search strategy is based on the assumption that parents of twins to a rather surprising degree apply for Social Security numbers for their offspring at approximately the same time.

I'm not going to go into the pilot work we did to test these assumptions but there was powerful evidence that the criteria caused any relaxation of very low hit rate.

The precise details on all search data are the

subject of an article we're preparing but I thought your eyes could glaze over if I presented it.

The outcome was to decide to that the primary source for twins was the Defense Manpower Data Center Archives, located in Monterey, California, which is quite complete for the war years. We used various computerized records, with the algorithm I described to come up with our sample.

We let a contract to the National Academy of Sciences to perform the labor of assembling the Twin Register. To this date we have about -- and this slide is actually about two weeks out of date -- about 7100 pairs of our 8,000 goal at this time, and we anticipate having our registry completed within, at the outside, two months.

The next question having established that our register is feasible is whether the twins can actually be located. If located, will they respond? This suggests the need for a full-scale pilot study to test the feasibility of our whole approach and to test our research questionnaire.

We have performed our pilot study on the entire registry from the State of Connecticut. Connecticut is a state much valued by twin researchers because they have had a

computerized registry of all twins for many decades. We were able to form a complete registry from that state and test everything on them. What I'm reporting to you today are those pilot results.

The sources of information for our Vietnam Experience Twin Study really are quite ample and this points again to one of the advantages of doing the study within the VA is that we have so much available to us. We have our questionnaire which were mailed. We have the military medical and personnel records which the National Academy of Sciences has already abstracted.

We are seeking non-VA medical records when appropriate requiring direct correspondence with our subjects. There are a variety of VA sources, which are listed providing supplementary information. These records are especially helpful in locating subjects where our contractors have difficulty.

The questionnaire, itself, is, of course, of primary importance. This slide summarizes the main components of the questionnaire. The questionnaire is a short one. It only takes about 23 minutes to fill out, but as we're analyzing it and as you can see here, it contains a surprisingly detailed amount of information.

We're comparing many basic demographic facts

with other documentation to test the validity of all of our different sources of information. These individual's current status of physical and emotional health alcohol and cigarette use, several measures of post-discharge adjustment, and a very important symptom list which approximates but does not duplicate the criteria involved in diagnosing the post-traumatic stress disorder syndrome, which we're looking at a bit more broadly than the precise psychiatric diagnosis.

Then finally there's a section on fertility which we're analyzing separately. The response rate from the pilot survey was really quite remarkable. We got 87 percent of the respondents from our Connecticut pilot to respond. This is an excellent response rate for any survey research, and it's high for this particular topic, so that we had an answer to our question that the subjects could be located and that when approached in an appropriate way by a good contractor, they would respond.

Those of you who are familiar with any kind of research along this line know that in spite of an 87 percent response rate there still is a question about nonresponse. Thirteen percent is small according to some criteria but we were concerned about it, and again because of the strength of having many VA records to resort to, we looked into the aspect of nonresponse in detail

What we learned was that only five percent of the respondents had been hospitalized in VA hospitals, but that 18 percent of nonrespondents had been hospitalized in VA hospitals. The most important aspect of that finding would be a comparison of the diagnoses which would account for their hospitalization.

Here we see that approximately 77 percent of the responders were admitted to the VA hospital for a physical illness whereas approximately 85 percent of the nonresponders were in a VA hospital for a broadly defined psychiatric issue.

We were concerned in an area of research as controversial as this;

this is something that we're going to follow through on with as much precision as we can bring to bear.

Again, I want to point out that most surveys can't do much about nonresponse. As Yogi Berra said if they don't want to come who's going to stop them. Normally you really have no way of finding out about those people; however, we are able to account for nearly 95 percent of our subject population using our multiple sources of information.

Finally, I want to give you just some preliminary findings on our pilot study. This study is on 252 individuals comprising 116 twin pairs and 20 singletons. I want to emphasize that these are pilot data, and because of small

numbers, I'm not even able to apply the kind of statistical tests which we are intending to apply and that really we consider these data preliminary and not publishable at this point.

Merely, we're interested in modeling our analysis and then looking for trends, and whether these trends are retained when we have our full sample of 16,000 individuals.

One of the most important measures we have is what we call our traumatic stress symptomatology scale. This approximates post-traumatic stress disorder.

I believe you can probably see that in the back of the room so I won't read it, but this covers most of the symptoms that have been reported in surveys published and in clinical studies and was put together in consultation with all of the main researchers in the area, so we feel it's pretty complete.

Our second very important scale is a combat exposure scale. This covers most of the combat experiences which have been recorded in all of the literature as being stressful and our form on this was to ask whether a veteran during his time in Vietnam had had any of these experiences. For our purposes today we used the scale in a very simple additive fashion and we're going to get more complicated as we get bigger numbers.

Again, I won't read that because if you have any

questions, we know you will ask.

DR. KAHN: I don't see just straight infantry --

DR. TRUE: Pardon me?

DR. KAHN: Where is straight infantrymen?

DR. TRUE: Well, we have that on their military occupation specialty. It's not included in the combat scale. We have a category of occupation specialty from which we can distinguish infantrymen from clerical. Again, what I am presenting to you today doesn't reflect that. What we found for descriptive purposes was that we were able to distinguish between an in-Vietnam low combat group which includes the value of zero on this scale, a Vietnam high combat group which is greater than six points. Today we're talking gross description and I'm sure that I will be invited back at a later time when we can get more details.

The first result gives us prevalence rates for the post-traumatic stress disorder symptoms and the way this slide should be read is that during the -- for the first row, for example, is that during the six months prior to filling out the questionnaire 42 percent of non-Vietnam veterans reported some sleeping difficulties.

During the six months prior to filling out the questionnaire, 50 percent of the Vietnam veterans under conditions of low combat recorded sleeping problems; In

the last Vietnam high combat group, 67 percent of them reported sleeping problems.

The other items are unpleasant dreams, painful memories, avoided military activity, flashbacks, feeling without military experience, guilt, trouble concentrating, trouble with memory, feeling irritable, angry, loss of interest in every day activities, felt distant from those around, felt life was meaningless and finally easily startled.

Another way of portraying the same data would be to couch them in terms of prevalence odds ratios, and here we'll define, for example, that Vietnam veterans with low combat have a 1.4 percent times of a risk of a non-Vietnam veteran of experience in sleeping difficulties.

Some of these really are remarkably strong such as painful dreams, reported by combat veterans in the previous six months showing 7.8 times prevalence odds ratio. Painful memory is an eight fold prevalence odds ratio. Avoiding military activity presents an 18 fold odds ratio; guilt an 27.8 fold odds ratio. We have low numbers but there's a definite trend here. Whether with large numbers we're going to retain these same numbers, I don't know.

As you can imagine with small cell sizes, two or three more cases will really increase the odds ratio so I am presenting these for what they are worth.

Yes?

MR. CARRA: And I assume what you're doing here is you're not, at this point, taking advantage of the twin status?

DR. TRUE: I'm glad you mentioned that.

MR. CARRA: Just treating it as individual?

DR. TRUE: Just treating them in unpaired analysis, and the reason we haven't done the Twin analysis is that the kind of analysis to do twins is extraordinarily complex and requires larger sample sizes than we now have.

Since you asked that question I'll go ahead and say right now that the set up the formal relationship with the Department of Medical Genetics at Washington University which has some of the premier twin researchers in the country and they're going to be directly collaborating with us on the twin analysis, itself.

It gets into some very sophisticated analysis of covariance modeling that we did not want to tackle on our own.

The next slide parallels the first slide I showed you. These again are prevalence rates and these are the physical conditions that in our first analysis showed some differences. High blood pressure, respiratory, skin and joints and hearing and again I suppose any

us in the room could come up with some story to account for these findings, but I think the more prudent thing is just to hold off and see what we get when we have the bigger numbers and do some medical record reviews.

These are self reports. The precise diagnosis is not given in the questionnaire so these are more provocative, than definitive and we're going to be following up on all of them.

Again, these are prevalence rates and I can portray the same data using the prevalence odds ratios formulation that I did before.

Hearing problems under high combat, show a 4.7 -fold increase in prevalence odds ratio.

MR. WALKUP: Excuse me, doctor, were your tests of significance between the two in-country groups or was it against the non in-country groups?

DR. TRUE: The test was between the distribution between the three conditions. There's a significant difference.

MR. WALKUP: So it's a three-way.

DR. TRUE: Three-way, yes.

MR. WALKUP: Okay.

DR. TRUE: But at least in terms of our preliminary analysis, there certainly is a war effect and that this seems highly related to combat exposure.

Our plans for the future are that within a few weeks or a couple of months at the outside, as I said, our register will be completed, and the survey has been contracted for and will be completed in 13 months. At that time we'll be addressing the final analysis of the study The preliminary results suggest that there is. an effect. that service in Vietnam is associated with emotional symptoms and for some selected reported physical symptoms, and that these are magnified by combat exposure. This follows both common sense and other research that has been done.

These are preliminary results and, of course, we're looking for the sample of 8,000 to validate these findings and perform some more sophisticated analysis.

As the questioner mentioned, we're particularly interested in analyses which will take full advantage of the twin design because we'll be able to answer complex questions which really no other study can address.

Whether there was something in the men, themselves, which predispose them to problems or whether the stress of war was such that virtually anyone would have shown problems. This is the kind of question that really you can only address when you have thousands of identifical twins to analyze.

We're very excited about the unique possibilities

of the twin project and we're looking forward to pursuing this over the next year.

Yes?

MR. CARRA: I'd like to pursue for a moment the way you're doing the study in terms of getting the respondents because it's so critical to success.

How is the -- you are mailing the questionnaire? Is there any contact before the mailing takes place, and what kind of follow-up. Can you give some idea?

DR. TRUE: Yes, it's a very important issue. After a roster of the registry has been developed and delivered to the contractor, a very carefully crafted letter from the contractor and the National Academy of Science describing the purposes of the study and inviting their participation was mailed to all of the participants along with a copy of the questionnaire.

At that point the response rate just to first mailing was in the 40 to 50 -- I don't remember the precise figure, 40 to 50 percent return rate. It took a follow-up card and I believe the sequence was a postcard, another postcard and then a systematic telephone follow-up, and this was done by the National Opinion Research Center who are highly professional in all of this and during the course of the telephone followup the subject was offered a couple of options.

If he said, I've been busy, I'll fill it out and

then we got it, and that would be the end of it. However, if it turned out that really we had somebody who was willing to do it but who just didn't have the time, then the thing was done over the phone.

It's a combined mail response and then a telephone administration of, of course, the same instrument, and through that, now there's a little bit of contrast in methods there which we're going to look at. We don't expect that will contribute to the difference, so that's how we got the response rate so high.

Yes?

MR. CARRA: Also in taking advantage of the twin aspect of this study, are you also doing things to take advantage of that in terms of response like getting one twin to --

DR. TRUE: Okay, I should have mentioned that, too. We have a parallel questionnaire to our main questionniare, and the parallel questionnaire is for the non-responding alive twin and the non-responding dead twin, and we have an order of priority to respond to that. We will only talk to a --

(Simultaneous conversation and laughter.)

If the non-respondent's reason for non-response is that he's dead, then we're going to have different kinds of questions of his survivor than if he were alive. Obviously

you can imagine the grammar on these kinds of things, but we have an algorithm where we're going to go to the twin and then a parent -- a twin, spouse, parent unless the twin is a non-respondent and then we won't go to the spouse.

We're piloting that in Connecticut and we've found really no trouble at all in this. We're very sensitive to offending people, harrassing them but the twins that we have phoned up and said, you know, your brother wasn't able to do this, would you mind telling us a little bit about him. It's just done very smoothly.

Yes?

MR. WALKUP: Doctor, was your criteria for selecting people who were born between '39 and '53, served between '65 to '71 -- appears as if you'd have --

DR. TRUE: '74.

MR. WALKUP: Oh, '74, that you have a couple of confounding variables. One is the time that they would have served in country and then their age that they would have been while they were serving there, that could have some effect on some of the things you're looking at.

Are you doing any kind of a lag design to take that into account?

DR. TRUE: Well, of course, the age issue is controlled within the twin design, itself, because they turned the precise age. The time in service is an important issue.

It turns out that our sample of collection procedures through the Defense Manpower Data Center tends to be later in the war. The very, very early years are less covered. We've examined this very carefully for bias.

The very early years, we've analyzed this sampling strategy for bias and found none. I would say that that would be one of the things we're very aware of. We have that coded, of course, and we'll analyze it, and then we have more information.

CHAIRMAN SHEPARD: Excuse me. I am sorry but I'm going to have to cut off the question period. We're running way behind schedule.

DR. KAHN: Who is the contractor?

DR. TRUE: The National Academy of Science and the Institute for Social Research at Temple is now conducting the main survey.

CHAIRMAN SHEPARD: If you have questions, I am sure Dr. True would be happy to answer them at the time of the break or after the meeting, but I am concerned about our time so I would now ask if Dr. Wolfe would tell us about the status of the Ranch Hand Study.

MR. WALKUP: While he's coming up could we get a copy of the pilot study, the protocol that he was talking about or at least the tables?

CHAIRMAN SHEPARD: You're going to have to ask

Dr. True. I can't --

MR. WALKUP: Okay.

AIR FORCE HEALTH STUDY (RANCH HAND II)*

COL. WOLFE: While we're waiting for the slides, it's a pleasure to be back again with this Committee. I had the privilege to participate in some of the earliest, some of the first couple of meetings, and it's nice to be back. Thank you very much.

Okay, I want to briefly cover a little bit of the background of our study for those of you who may not be totally familiar with some of the details and then go over some of our more recent mortality results, the summary of the results of our 1982 physical examination and then I will bring you up to date on the current activities.

Again, we got direction in 1979 from Congress, got their enthusiastic support and White House direction in early 1980 and we proceeded along those lines to look at the possible health effects in those men who actively handled and sprayed the dioxin containing herbicides over Vietnam.

We developed our protocol between October of 1978 and throughout 1979. By the summer of 1971 we began a five or six-step peer review process including a civilian school public health (University of Texas in Houston), the Armed Forces Epidemiological Board, Scientific Advisory Board of the Air Force, the National Academy of Sciences, the Agent Orange Work Group and various scientific subpanels of that

* see slides on page 203-217

body.

Between '79 and '82 we identified our comparison populations, with intensive hands on review of morning reports, personnel records. We would not have been able to survive it without the great assistance of the folks at St. Louis at the National Personnel Records Center.

We developed our questionnaires and began administering them in late 1981 and throughout 1982. Our physical exams of 2,069 individuals took place in 1982 at the contractor's clinic in Houston.

Our baseline mortality report came out in 1983, and then our morbidity report, the results of that initial physical examination were released in February of '84.

In May of last year we began re-examining the same groups of men out at Scripps Clinic in LaJolla, California, a very nice location, and that contributed to our high participation rates.

In 1982 about 80 to 85 percent of the total group that took part in the physical exam, a two-and-a-half-day exam. Ninety percent or better took part in our questionnaire effort at that time.

Of the group that took part in 1982, 93 percent came back to participate in California. We also picked up 131 individuals who had declined to participate in 1982 and

had changed their mind so we, in fact, did 2309 physicals in '85, an increase of 40 people over what we had initially done in '82.

We had a few dropouts and picked up enough others that had changed their mind to move our numbers up. This slide shows a group that was in Vietnam in 1969. Pictures are great but hard to identify over the years but these were the kinds of folks that we dealt with.

1257 total individuals served the herbicide operation between January of '62 and 1971. We stopped spraying the dioxin containing herbicides in April of 1970 and continued spraying Herbicide Blue and some of the others into 1971.

Forty-two percent of the group of that 1275 were ground enlisted personnel. These were the folks who probably had the dirtiest jobs of all. These were the folks that had to clean the equipment when the spray nozzles would clog and they'd take a coat hanger and unplug it and generally when they'd get the clog released, they'd get their arms and upper parts of their bodies fairly well soaked with the material.

Generally, at least once or twice a year someone would have to crawl inside that thousand-gallon tank to repack the emergency seals. They would go in there with a can of grease and grease the seals to protect them. Generally, there were three or four inches of herbicide left in those

tanks at the time that they never could get it all drained out. Again, one guy would go in and another would stay outside to pull him out if he passed out or had trouble in the tank.

Not a very pleasant job. Generally at that point the most junior enlisted guy in the place was the one that got to do that.

Generally this group, as a whole, would have to replace their combat boots every four to six months because the herbicide that they were walking through puddles of and dripping on themselves would eat up those jungle boots pretty well. About 51 percent of the group were air crew members.

16 percent of the group were enlisted air crew and 35 percent were officer air crew (pilots and navigators).

The remainder were administrative officers. In our study design, we identified our exposed group, and we've identified, we're sure, 100 percent of all individuals that were involved in that effort.

We selected our comparison group using C-130 individuals, folks involved with C-130 operations throughout Southeast Asia during that same period of time. We determined their baseline health status through a continuing and ongoing series of mortality assessments. On an annual basis we review the number of new deaths occurring the past year looking for causes of death and conduct a statistical analysis of that data.

Statisticians have a heyday and we continue to do our follow-ups. Again, just a quick rundown on our strategy. We had our initial match using 1 to 8. Since our comparison group was on the order of 20,000 individuals, we were able to pick and match very closely eight people for every one of our exposed folks.

This gives us flexibility. Downstream, it increases our statistical power and also as individuals, in the comparison group choose not to participate, we can replace them in the physical examination with another very similar individual with the same perception of health.

If one guy drops out because he says, "gee, I am healthy and I don't care about the study", we'll replace him with another equally healthy individual.

If we have a guy who says, "I can't make it because I'm sick", we'll replace him with another equivalently ill individual.

For our mortality efforts thus far, we have used a five to one match -- five comparisons for each exposed person. By next year we will expand that to the entire pool of comparison individuals to totally remove any possibility of bias engendered by this random selection process.

We will then have two total populations and our statistics will be much more powerful.

When it came to the physical exams we couldn't afford the time or money to examine every one, so at that point we went to a one to one match, selecting the first willing living subject in the comparison group who could come to our exam.

Summary counts of death thus far, we have had -- let me get my slide to show it clearly -- this breakdown by rank, Ranch Hand and comparison, again the mortality rates are generally in the range of three to five percent throughout the groups.

Overall we're looking at a 4.4 percent death rate in the Ranch Hand group since they left Vietnam and a 4.6 percent rate in the comparison group.

The U. S. white male general population has a rate much closer to seven or eight percent. I think what we've seen here is a healthy worker effect. These guys were all healthy enough to make it in the military, some as long ago as 40 years. Now they're approaching, on the average 15 to 16 years since they last left Vietnam.

This shows a survival curve of the two groups. There's some separation of the Ranch Hand and comparison groups, in those upper limits of age because there are so very few people in that 60 to 70-year-age group but throughout that cycle you can see the curves overlying very, very closely.

Mortality experience appears to be comparable

We look again at relative risks and statistical P values here on this slide looking not only at the total but within officer, enlisted, flying or ground categories. You find no statistical significance and the relative risks are very close to one or below.

Look at deaths by cause. Total deaths were 55 in the Ranch Hand group and in a group five times as large, 285. They break out into those categories.

The malignancies seem to be tending toward the low side in the Ranch Hand, but this is not statistically significant at this time.

Again, we've compared these groups, both Ranch Hand and comparison to the Department of Defense retirement population and all rank and exposure subgroups are doing better than expected compared to the DOD retired population, age adjusted, of course.

The exposed enlisted group is doing well but not statistically significantly better though. When compared to the active Civil Service personnel we found very much equivalent mortality across the board.

Again, with the U. S. white males, all of our folks are doing significantly better. When we compared our groups to the active Air Force population we found that they were all doing worse. That's reasonable because in the active force when someone develops a life-threatening

illness or following a heart disease, hypertension that's uncontrollable, or diabetes they're no longer in that population. They're medically retired, medically separated and no longer in the population so only healthy folks by and large remain on active duty.

Again, just in summary, 55 exposed, 285 comparison deaths. This was through December 31 of 1984. Again, the relatively small numbers emphasize the preliminary nature of these results. We intend to pursue, and continue these annual exercises indefinitely.

Mortality experience was very nearly identical in the two groups and cause specific analyses were not statistically different. We currently have our data gathered. We're beginning to compile it now and look at deaths that have occurred during calendar year, 1985.

That report should be out and available for public release probably in the early Fall, or early Winter of this year. Now our 1982 physical exams were done again under contract, to a civilian organization of national stature, Kelsey-Seybold Clinic in Houston; the Louis Harris organization did the questionnaire work.

The examiners at the time of the exam were totally unaware of whether an individual was exposed or not. We kept them in the dark so that they would treat everyone and conduct their exams in a consistent, standardized manner.

We concentrated on the skin, neuropsychiatric, hepatic, immunologic, reproductive and these other aspects in a two-and-a-half to three-day examination and I think we ended up with over 5 million items of data to be analyzed, and 2269 people took part.

Again, this is a general list of areas we used in designing our program. We really wanted to focus on specific target areas for dioxin effect. Unfortunately, we weren't very successful at finding specific systems or diseases so we ended up with a very broad, large net that we cast to determine what problems might be in the group.

We found these group differences: self-perception of health, a subjective measure, if you will. More of the Ranch Handers felt that their health was in the fair to poor category as compared to the comparison group.

There was more skin cancer in the Ranch Hand group. When we cut our questionnaire down from five hours to three, one of the questions that we threw out was question on history of geographical residence.

In skin cancer that's a key question because the rate of skin cancer is very much dependent on the latitude of your residence. There's a lot more skin cancer in South Texas than there is in Northern Minnesota, so in our followup round we have very extensively gathered information

on the geographical latitude and duration of residence in various areas.

We found reported birth defects to be slightly higher in the Ranch Hand group. Whether this was an increase in Ranch Hand group or a decrease in the comparison group we're not sure. We're currently in the process of verifying and validating these reports.

There were over 7,000 conceptions and over 6,000 children borne to the men in this study and it's a major effort to locate, retrieve and code the medical records from children, some of whom are now in their late 20s and early 30s.

We're trying to retrieve all those records to very carefully validate and verify the reports, both positive and negative for birth defects.

We expect to complete that task within the next 24 months and will then reanalyze the data using confirmed information.

Neonatal deaths were also increased -- we found some variations in the data there. We're not quite sure what that means. None of these findings were at all related to the level of Dioxin exposure, based on the herbicide used each month and the duration of tours in Southeast Asia.

We had, I believe, about eight or nine people that had Babinski reflex on neurological exam. That reflex generally indicates that there may be a

neurological problem but none of these individuals had other neurological findings to go along with it.

This may have represented a statistical fluke but we've looked very carefully at that again in our follow-up examinations.

We found some subjective psychological differences primarily in the area of anger, depression, some of the subjective sorts of things. We're adjusting the current examination for combat experiences, level of combat experience and post-traumatic stress disorder. We're measuring both of those on our second go around.

We looked at liver function tests. We found three that showed an abnormality or a statistical difference, a GGTP, gamma-glutamyl transferase, a very sensitive liver function test ; however, there are three or four others that showed no group differences.

LDH is another liver function test and cholesterol. In fact, the Ranch Hand group had lower cholesterols to a significant degree than did the comparison group. Again, possibly another statistical fluke -- one test out of 20 that will show up statistically significant when, in fact, it's just purely by chance.

We don't know but are very actively looking into these again. The one finding that was totally unexpected

was a finding of peripheral pulses in the Ranch Hand group.

We found that the exposed individuals had pulse abnormalities when a physician would place his fingers on the pulse and determine whether is it present, absent, strong or weak.

We weren't quite sure what to make of that because cardiograms were perfectly identical in the two groups. Cholesterol values, in fact, were lower for the Ranch Handers. We're not sure whether that was a result of smoking. As you sit out in the examining room and smoke a cigarette and then you go get examined, the effects of nicotine on the small arteries, especially in the feet and legs may have contributed to this finding.

In the followup exam we have gone to the use of ultrasound doppler techniques to very sensitively and carefully measure the pulses. It appears that there may not be much relationship between the physician's feel of the pulse and what the Doppler showed.

The Doppler is the gold standard, I think, as far as we and many other folks are concerned. We have also restricted smoking for four hours prior to the Doppler examination as well as to the cardiogram so you should have a very good picture of that finding.

We looked at thyroid studies and testosterone. There appear to be differences but again these were very small differences in numbers. The difference between 30.1 and 30.3

for a thyroid test is statistically significant when we're looking at a thousand people in each group.

From a clinical standpoint we're very hard-pressed to decide whether that really means anything or not.

Again there were some strange patterns to hepatic function and immunological function, but none that we could tie to herbicide exposures and the relevance of some of these were very unclear.

We did find in our immune studies another unexpected finding that the quality of your immune system is very much dependent on your age, the number of cigarettes you smoke a day and the amount of alcohol that you consume. These were not really recognized factors by immunologists before this study and it has been, I think, a real contribution to that field.

This shows some of the results, the SGOT is a liver function test, 33.0 and 33.1, and you can see that these are very close numbers, and as to whether these represent clinically important difference or merely a statistical difference is open to question.

We're looking into all of these again and if it is statistical fluke, we would not expect to see the same test abnormal the second go around on the same group of men, so we are pursuing all of those.

Again, in summary, we're not able to define a

clinical end point that was attributable to herbicide exposure. We did not see any cases of soft tissue sarcoma, porphyria cutanea tarda or chloracne in the Ranch Hand group.

We did find one case of soft tissue sarcoma in one of our comparison individuals. We did find several clinical and subclinical differences, but we can not, at this point define the significance of those, and we are very actively pursuing those findings in the follow-up examination.

Basically our bottom line from the first exam is a quote stolen from Carl Sagan, "Absence of evidence isn't evidence of absence."

We are not willing to rest at this point and we are firmly committed to follow these men for a good long time with periodic physical exams and annual mortality reviews.

For those of you who are familiar with Southern California, this is on the coast of LaJolla. The golf course is on the right and just off the golf course is Scripps Clinic.

It's a very nice location and I think a real drawing card. We made some modifications in the followinqup exam format. We conducted just a history to just cover the intervening three years, both with the subjects and their spouses. We also went back and did phone interviews with all the additional 7,000 individuals in the comparison qroup who

we had not otherwise contacted. We did baseline questionnaires for new subjects and their wives.

From the first exam we deleted pulmonary function studies because we found no differences at all there. Nerve conduction studies were also deleted and semen studies and IQ testing were deleted this go around. One of the things that was very clear was that people get very tired of the MMPI and all the same old psychological tests so we're trying to modify that psych battery each time to keep the interest up a little bit.

This was the waiting room. We did a lot of work with mark sense forms as far as personal history and medical background went on the individuals. This was a real plus. Some folks had trouble with the bubbles, filling in the right bubbles but it was a new twist and was psychologically stimulating, I think.

Again, while we deleted a few things we had added a lot of others. We are getting an assessment of the skin's reaction to sunlight (again to look at the skin cancer question), geographic residence history, eye color, hair color, complexion and an estimate of the ethnicity of parents because these are all well known factors affecting the incidence of skin cancer.

We improved our alcohol and smoking questionnaires and are looking at combat stress, (PTSD as well as combat

experiences).

In Houston we had four or five people each week get dizzy when we would draw 200 ccs of their blood. We had absolutely no one this time at Scripps get dizzy. We gave them blood bank reclining electrical chairs and they all did absolutely beautifully. Not one problem at all.

There was only one person they couldn't get the full complement of blood on. We also are looking at personality type, (Type A and Type B personality) as it affects heart disease. We're beginning to look at sleep disorders but we'll need to do more of that on the next exam (1987).

Also the parents' assessment of the severity of any birth defects that their children may have had based on prior experience by other researchers in these areas.

Doppler examination of the peripheral pulses. We enhanced our immunological testing. In Houston, we did about 20 percent of the group. In California this time we did full-scale skin testing on 75 percent of the group and immunological B&T cell studies on 50 percent.

Porphrin profiles were done at Mayo Clinic in their laboratory. Very extensive and intensive quality control of the data was added and the data as it's beginning to float in now from the contractor is absolutely pristine. It's really great, very well cared for and properly handled.

Again, this shows the Doppler rather than just

feeling for the pulse. As you can see the screen there, a little TV monitor, you get a real graphic representation of the blood flow through that artery, both the pulse, itself, how extensive or what the amount of blood is and the timing. Is it a long drawn out pulse or is it a short nice peak wave?

Skin testing. These guys ended up with little blue marks on their arms. They went down to one of the local restaurants and one of the Southern California waitresses after about ten minutes came up and asked them if they all belonged to a cult.

It is a nice place.

(Laughter.)

(Slide of Sea World)

DR. KAHN: Looks like they had a whale of a time.

(Laughter.)

COL. WOLFE: I'm looking forward very much to going back. Scripps will be conducting the next follow-up examination in 1987 with the same staff and we're looking very forward to going back.

Are there any questions?

CHAIRMAN SHEPARD: Thank you very much. Very nice and complete follow-up on a very important study. Can we have the lights, please? Any questions of Dr. Wolfe?

DR. KAHN: What do we have by way of particular power and --

COL. WOLFE: I'm not quite sure where we stand right now with the current round of deaths. Each year it gets better. Again, our group now has an average age in the mid-50s, and we should begin to see normal attrition in that group or more -- an increasing accumulation of deaths and as that happens, the statistical power will increase.

DR. KAHN: What's the original --

COL. WOLFE: I'd have to pull that. I'd be able to get that information.

CHAIRMAN SHEPARD: Thank you very much.

I'd like now to call on Dr. Edward Brann who comes to us from CDC. Dr. Brann is a medical epidemiologist who has been with CDC on and off for over ten years and his particular responsibility in the CDC study is that of a special cancer study which I think is of interest because that's an element of the study that we have not heard very much about.

We've known that such a study was ongoing, but it's a pleasure for me to introduce to you Dr. Edward Brann from CDC.

CDC EPIDEMIOLOGY STUDY*

DR. BRANN: Hi. We have no results to report so I apologize to those of you for whom this is a bit more

* See slides on pages 219-236

repetition. The first slide just very briefly tells you the purpose of our study which is to conduct epidemiologic studies.

Next slide. The first of our studies is the Vietnam Experience Study and in this we're comparing the current health status of those serving in Vietnam versus those who did not serve in Vietnam. The eligibility criteria are that they be male Army veterans who entered the service from 1965 to 1971 and that they be draftees or single-term enlistees and that their tours are limited to those sites.

Next slide, please?

We selected 48,000 records randomly at NPRC and of those 17,000 meet the eligibility criteria which were on the previous slide. Of those we chose 8,500 Vietnam veterans and 8,500 comparison veterans.

Next slide. The initial part of the study is the mortality component. This will be the first one that's complete. We're identifying deaths among those 17,000 men from the previous slide through a search of the files of the VA. You know what that acronym stands for. SSA, Social Security, IRS, Internal Revenue and NDI is National Death Index. We're obtaining the death certificates and we're attempting to obtain all medical and other records relevant to the death including police reports for accidental deaths in an attempt

to verify what is on the death certification. You know thereare problems with what gets recorded on death certificates.

We are going to compare the overall and cause specific death rates.

Next slide, please.

All those who can be located who are still alive are interviewed by RTI, Research Triangle Institute of North Carolina. They're locating and interviewing these people. We hope to find about 6,000 out of each group. The telephone interview takes slightly more than 30 minutes. There's a standard computer assisted telephone interview instrument.

A subset of these two groups are then invited to participate in medical examinations which for us are performed at the Lovelace Medical Center, Albuquerque, New Mexico. We expect to examine approximately 2,000 from each of those groups.

The examination takes approximately three days with the medical and lab exam on the first day and a complete day of psychological and neuropsychological tests and exit interviews and discussions with the participant on the third day.

Next slide, please.

This is a listing of the laboratory tests which

we are performing which focuses on those specific systems.

Next slide.

Continuation of the laboratory tests.

Between the time we did our pilot study and our final study, Dr. Wolfe's initial analysis of the Ranch Study Study from Kelsey-Seybold was available to us, and we did some modifications of this study based on his findings of the Ranch Hand group.

Next slide, please?

These are the hematology assays we are performing on the groups. Next slide, please?

These are special medical tests. As you can see from the list, there's a Doppler evaluation of the peripheral vasculature. We added that between our pilot study and our final study based on Dr. Wolfe's findings in the Ranch Hand.

Next slide, please?

These are the psychological and neuropsychological tests which are being performed the second day of their participation at Lovelace, and they do take most of the day completing that list.

Next slide, please?

This tells you approximately how their three days at Lovelace are oriented. The first day that they usually arrive at Lovelace, the day before the exams begin, and

they're given an extensive orientation in the evening and told what to expect.

They are informed that since they're from two different cohorts they are

not to discuss which cohort they're from with any of the examiners and the examiners are also told that

if they feel a veteran is about to launch into anything which might reveal to them whether they served in Vietnam or not, they're to cut them off and remind them not to discuss this.

This is a huge task and most veterans know the rules and follow them well.

Next slide, please.

We've fairly well progressed along in this Vietnam experience and here's where we are today. We have delivered 17,886 names to Research Triangle Institute. They and their subcontractor have successfully traced 92 percent of the names that were given to them. The names are from their NPRC records which are from when they left the service.

They're doing a fairly good job being able to trace these people to their current address. Ninety-two percent of those that they traced agreed to be interviewed. The contractor has completed 15,280 interviews which is an overall response rate of just over 85 percent

We delivered the last list to them. We won't be delivering any more names to them but they are still trying to trace and interview a few people remaining from the last few lists we have delivered so the 15,280 figure should rise slightly over the next two months.

Next slide?

The medical exam component runs a little bit behind the interviewing component because the interviewing is completed before anybody is able to participate in the medical exams and we have completed this through the first 3,756 exams, 534 people are currently scheduled with a definite appointment date at Lovelace. Since all the names have not yet been fed to Lovelace, it takes a little time to contact the men and find a day in which they agree to come. There will be names added to the 534.

Participation rates are about 70 percent. That's 70 percent of those invited show up and participate in the medical exam.

We intend to complete the medical exam component on September 30th. That's when we'll be doing our last exam at Lovelace.

Next slide?

The other part of the study we're doing is the cancer study which is what I am more involved in personally. We're studying those five kinds of cancers. Lymphoma is based on the work done in Sweden, which is the same group that

did the work on soft tissue sarcomas although, as we heard from Dr. Kang, there have been many papers since that time addressing the issue of herbicides and soft tissue sarcomas.

There have been fewer subsequent studies addressing the lymphoma and herbicide issue. Nasal cancer and nasopharyngeal cancer were also addressed by the same groups in Sweden. Primary liver cancer is based more on animal studies than on human studies to date, but we did add that to the list because there was some special concern.

Next slide, please.

We have to change gear for a second in the cancer study from the thinking you've been doing today with I think all the research studies. This is a study which starts with a case of cancer. When the case is identified we know nothing about his veteran status. We are identifying cases of cancer in all males of the United States who fit the rest of our selection criteria.

Only after we interview them do we find out if they are a Vietnam veteran or not. The cancer cases are identified by participating tumor registries. At this point we have eight tumor registries participating. We have the State of Connecticut, State of Iowa, State of Kansas, Dade County, Florida which is Metro Miami, a five-county metro Atlanta area, three-county metro Seattle, five-county

metro San Francisco and three-county metro Detroit. Hope that was eight.

The cancers in the men have to be diagnosed between December 1, 1984 and November 30, 1988. Our study is a concurrent study. We're finding these men and interviewing them very shortly after their cancer is diagnosed so that in most cases we're interviewing the cancer victims, themselves, and also that allows us a fairly long time for the cancer to develop after the potential exposure to herbicides in Vietnam.

The men had to be born between 1929 and 1953. That's just those eligible to serve in Vietnam.

Next slide, please?

The controls -- The main group of controls are living controls identified by random digit dialing. These are men who live in the same geographic area as the cases and have the same birth dates as the cases. They're simply dialed over the telephone. We dial a large selection of people over the telephone and ask if there's a man residing in that household who fits the eligibility criteria.

If they are, then we subselect a sample out of that group, feed their names to the participating tumor registry.

The same person that does our case interviews also does the control interviews.

The interviews for this study are telephone

interviews. Interviews require about 52 minutes on an average to complete.

Next slide, please?

This is where we stand today on the selected cancers study. This is a four-year study and we're only about one year into the data collection. We have eight registries participating which I have mentioned. There are 675 cases identified and 437 controls identified. I need to expand a little on that.

We are not going to analyze this as a study of all types of cancer combined. We're going to analyze this as lymphoma, soft tissue sarcoma, et cetera. Since we have far more cases of lymphoma in the study than any of the other kinds of cancer because it's the most commonly occurring we are planning a one to one match of lymphoma cases with our controls, which gives us a greater than one to one match of controls to the other kinds of cases.

This gets us to about the maximum amount of power we can get out of the number of cases we find in each of the other types of cancer, so we have overall fewer controls than we have cases because we're only matching one to one against the lymphoma cases.

We've completed 461 interviews of cases and 307 interviews of a control, and we're doing a little better

than 80 percent participation rate for both cases and the controls at this time.

That's my last slide.

Any questions?

MR. CARRA: Did you say the controls were interviewed over the phone?

DR. BRANN: Everyone is interviewed over the phone.

MR. CARRA: And it's a 52-minute interview?

DR. BRANN: On the average.

MR. CARRA: Are you getting any -- I see that you have an overall response rate of 80 percent. Are you getting nonresponse toward the end of the interview with some of these people?

DR. BRANN: No.

We were told to expect problems with interviewing that long over the telephone. We had essentially none. I think of the greater than 700 people that completed the interview to date, we've had something on the order of four who have asked to have the interview interrupted and continue it at a different time because they're running out of time or had an obligation at home that they had to tend to and they ran out of time to complete it as a first interview.

Of those, I think all but one has gone on to complete the interview and we're still trying to finish up

the interview on that one. We have almost a -- our rate is very close to zero among people who start the interview and don't finish it. That did not seem to be a big problem.

MR. SNYDER: There's been a lot of publicity recently about the epidemiological studies. I don't recall that you touched particularly on that aspect of the CDC studies that you've been doing. Is that not in an area that you're clear?

DR. BRANN: I can say something. There was a third study. There still is a third study. It's been on hold since December of last year, and I, myself, have nothing to do with a decision on whether and how to proceed with that study.

Dr. Shepard may have something to say on that.

MR. SNYDER: Is there anyone else with you from CDC that is here to address that?

DR. BRANN: Dr. Shepard, I think, could.

CHAIRMAN SHEPARD: Let me say now that I will address that issue at the conclusion of Dr. Brann's comments or answers to questions because that's a separate issue and Dr. Brann is really not prepared to address that.

Are there any questions concerning these studies?

Yes?

DR. HODDER: You addressed a specific block of four years.

DR. BRANN: In the cancer study.

DR. HODDER: What is that adding to Dr. Kang's study. Are you looking more at late in the period or --

DR. BRANN: Well, ours allows for late in the period -- your's starts in 1973 and runs through.

DR. KAHN: '75 through '80?

DR. BRANN: '75 through '80. Ours allows a longer period. We look at four kinds of cancer that Dr. Kang is not looking at. You are finding cases through the VA hospitals?

DR. KANG VA hospitals, no. Armed Forces Institute of Pathology.

DR. BRANN: Ours are all cases diagnosed in a geographic area. Dr. Kang is dealing with referral cases. It's a slightly different study.

DR. HODDER: I guess the concern I have is if you're looking for latency, you're going to get a very clear -- concern from Vietnam from '72 to as early as '61. You've got to have a substantial splay in the data.

DR. BRANN: True. I will address that in our analysis, the date and time certainly. We also are looking at all other possible exposures to herbicides, possible confounders and as research interest in their own right, We ask if there is anyone who has had any contact with farming or forestry work or in the manufacturing of these

herbicides and any other exposure which may have contributed to the development of these cancers.

Dr. Kang?

DR. KANG: What is your expected number of sarcoma cases?

DR. BRANN: About 400. This is at the time they're diagnosed in the field.

We also have four pathology review panels reviewing each of the four types of cancer. The two head and neck cancers are reviewed by the same panel. We expect a certain number not confirmed by pathology review panels so we expect to start with 400 and drop below that after we do our confirmation.

Yes, sir?

DR. HODDER: I have two questions.

CHAIRMAN SHEPARD: Excuse me. Can you speak into the microphone?

DR. HODDER: One is, I believe he said the questionnaire is rather long. Is there any attempt to rotate questions, those that occurred at the end of the interview in some cases and the beginning in others to see if it was an effect of fatigue.

DR. BRANN: No.

DR. HODDER: The second question is there was a 70 percent response rate of the people going to take physical examination. Thirty percent non-responding is a

sufficiently large number and we ought to investigate the reasons for the nonresponse to ensure the absence of the bias.

Is anything being done along those lines?

DR. BRANN: Well, yes, to the extent that we can. Those 30 percent will have completed the interview with the RTI and we will compare everyone -- we will compare the 30 percent who do the interview at RTI and don't show up for their medical exam with the 70 percent who complete the interview with RTI and do show up for the medical exam so there will be a comparison between those two groups and how they answered the questions in the RTI telephone interview.

CHAIRMAN SHEPARD: Any other questions from members of the Committee?

MR. WALKUP: In the experience study, these are all males that you selected? Is that right?

MR. BRANN: Everything was males.

MR. WALKUP: On one of the next slides there was one on FSH and lutenizing hormone. Why are you looking at those?

MR. BRANN: Well, you've hit the person who knows the least about that.

MR. WALKUP: Oh, okay. Mostly out of curiosity. Seemed kind of strange.

MR. BRANN: They're on there and I have to pass.

CHAIRMAN SHEPARD: I believe there is some luteinizing hormone secreted in males.

It isn't just a female hormone. Is that right, Dick?

DR. HODDER: I think that's right.

Yes?

DR. SHEPARD: Any other questions? Thank you very much, Dr. Brann. Let me just now take a minute and then we'll have our break, to give you an update on the status of the deliberations concerning the CDC Agent Orange study. As I'm sure you heard or read, there is some concern about whether or not the military records will reveal a sufficient number of individuals who have a high level of exposure, and this had been an ongoing concern.

A special subcommittee has been established to examine that question. The Committee has met, and has been meeting, has met repeatedly, and has gone to great deal of searching on this question. It's prepared a preliminary report. The report will be submitted shortly to the Science Panel of the Agent Orange Work Group which will meet next week to review the report, comment on the report and then submit their report or their review of the report to the full Agent Orange Working Group which, in turn, will submit its recommendation to the Domestic Policy Council, White House.

We still don't know yet whether or not we will see the Agent Orange component of the CDC study done, but I can assure you that there will be a full disclosure of that determination and, I'm sure, the reasons for the determination however it goes.

I think it's premature at this time to say very much more about that until we have had a chance to review the report of the subpanels in charge of looking into all these details.

Yes?

MR. SNYDER: Can you give us a context, give the members of the Committee a context as to what exactly the Agent Orange Working Group is or what it's relationship is then to the Office of Technology Assessment when they're supposed to have the -- I had thought, by statute, the evaluation of the study.

I'm not sure what the -- the Working Group, as I understand it, is made up of members of various federal agencies, but I thought their responsibility lay with the Office of Technology Assessment and I'm not sure what Dr. Young's role with the AOWG is and what's that got to do with OTA.

Where does the working group get its authority to make recommendations in whether the study should go forward or not.

CHAIRMAN SHEPARD: The authority of the Agent Orange

Working Group comes from the White House, from the President.

It is created by Executive Order. The role of the Office of Technology Assessment, which is a branch of the Congress gets its authority from the legislative mandate directing that OTA review the protocol for the study. The relationship between OTA and Agent Orange Working Group is a cordial one, in which the representatives from the Office of Technology Assessment have been invited to sit in on meetings of the Agent Orange Working Group, so they are an observing member of the Agent Orange Working Group.

MR. SNYDER: And then the VA's role in terms of either the working group or oversight of this study, what, for example, as a committee, if we were to encourage the Administrator to look into all of this and urge the study go forward at a faster pace than it has since it was originally mandated in '79, what -- perhaps do you have a recommendation as to how best we could encourage that things move along and I am kind of surprised that we didn't have the CDC today.

We're on the schedule as epidemiological study. We had to select cancers -- appreciate that information, but given the kind of press we've had and the study being characterized as suspended, as delayed and I think certainly you're very aware of how important to all of us that study is, and I think a lot of veterans organizations have members that are quite concerned that studies go forward and there not be an

appearance of things being delayed by unknown committees and subcommittees chaired by other people.

It's a little frustrating that we don't have as part of our agenda today a more full explanation of what really is going on. You've alluded to next week, I guess, the 17th will be the subpanel presenting its study. We don't have the details of that for us to consider now. We're probably not going to meet -- at least from the Administrator's suggestion -- it's not clear when or if at all we, as a Committee, will meet again.

He wouldn't say this morning that he would go forward with this Committee, so I'm not sure that we're going to get an opportunity to, in fact, see that report, and be able to comment on it ourselves and encourage perhaps some advocacy on behalf of our constituency and to encourage the VA then to push it also.

I'm just a little worried that we're not getting -- we get a lot of information at these meetings. Very nice slides. Very complete. Lots of statistics, but I'd like to get for our committee's use some of the explanation of the internal workings of things that would show up in the press in terms of the conflict with the environmental support group and CDC people and then the working group and subpanels.

I think that's something which we, as members of this committee, and certainly as representatives of veterans

organizations which are the constituency of the VA and these other federal agencies, I think we need to know that kind of information.

I'd like to encourage that if we meet again that we have people that can address those questions and give us some greater insight than what we've gotten, certainly out of today's speakers.

CHAIRMAN SHEPARD: I am not sure exactly what your question is. I share your frustration. I think I did hear you ask what was the relationship between the VA and the Agent Orange Working Group. The VA is a member agency of the Agent Orange Working Group and has played a key role in its deliberations from the outset.

I think it entirely appropriate that this committee address that question. The reason we can't go into it in great detail on the agenda today is that the issue is still on a very much state of flux. This is certainly something that, as I say, I think is entirely legitimate for this committee to address, and I pledge to you as chairman that you will be given information even though we don't meet before the decision is made, that you will be given information as soon as it is available to me to deliver to you.

MR. WALKUP: Excuse me. Could I follow up to that last thing you said? Would that be okay?

CHAIRMAN SHEPARD: Sure.

MR. WALKUP: It seems like that kind of comes to the role of the Committee. If our role is to wait until a decision has been made and then you'll let us know what it is, then I'd just as soon not have to spend my time here. I mean that's a waste of our time.

CHAIRMAN SHEPARD: Excuse me. Let me respond to that.

This is an advisory committee to the Veterans Administration. The Agent Orange Working Group is a White House created body --

MR. WALKUP: I understand.

CHAIRMAN SHEPARD: -- which has been given the mandate or the charter by the President to look into these issues so even if the VA wishes to get involved and it is involved, the authority of the VA to direct that decision is in part, limited. Now that isn't to say that this committee shouldn't address that, and I would encourage you to do so.

I don't want to leave you with the impression that somehow, because you
come up with a piece of advice, that that necessarily will get implemented when we're talking about an interagency group that includes other departments.

MR. WALKUP: I've never been under that misapprehension. The point that I was trying to make is that the VA, as a member of the Agent Orange Working Group does have

some input to that. This is an advisory committee to the VA dealing with that specific issue. If we are to give any advice to the VA on their position with the Agent Orange Working Group, then the time is now.

The time is not after the Agent Orange Working Group has made a decision. The function of this committee is to give advice to the Veterans Administration not to applaud after the Veterans Administration has done something or to gripe about it like I'm doing now.

I think that goes to the part of our role here, and I'm concerned about it.

DR. KAHN: Let me follow up on that. Barclay, the information that we have gotten from Congressional resources is that one of the reasons that the study would stop is for gross violations of the research world. If that is the case, we should know about that. I might add that when I first started in this business I knew very little about epidemiology and even less about survey research.

I've taken the time and trouble in the intervening time to inform myself, going back and looking at the research protocol, and I am horrified. I am afraid that what I am looking at, even if there weren't gross violation of the research program, all this bad science.

Now as an advisory committee we're being asked here by acquiesence to concur in the continued production of what

looks to me like bad science. I try not to do bad science, and I don't want to be associated with bad science.

Moreover, since this is going to cost some numbers of tens of millions of dollars which is the taxpayer's money, I'm really worried about spending taxpayer's dollars on something that is going to fail now because of the way it's set up.

I get even scarier about the pulpit as a scientist because science is my life. I live and breathe every day. If this thing is later shown to be bad science and if it goes bad then science is discredited and scientists are discredited and that is not something that I want to be a party of.

If we're going to provide advice to you, I damn well want to know what the hell is going on.

CHAIRMAN SHEPARD: Let me respond to that.

DR. KAHN: And if I don't find out what's going on, I'm going to walk out of here.

CHAIRMAN SHEPARD: Let me respond to that, Peter, and that's precisely why these deliberations are going on, and you've put your finger on the issue. The one thing that we don't want to do is to subscribe or foster bad science.

There's some real question now as to whether or not some of the assumptions that were initially made when

the protocol was first opposed and put forward, are, in fact, true or are, in fact, supportable, and that is exactly why these deliberations are going on.

We don't want to continue marching down the road of making assumptions that may not be supportable.

Dr. Hodder?

DR. HODDER: Having served one time, both AOWG as well as here, I'd like to make a comment on that.

The CDC study, when it was put forward, had two phases. One which I strongly support and that is answering the question of whether if you survive the experience in Vietnam, did you come back with a disease burden more than those who would not have gone to Vietnam.

That is a very easily answered question and CDC has that study going on. The second study was "was exposure to Agent Orange associated with serious health problems, and could that be demonstrated in Vietnam?"

I know Dr. Keller is here and many of the epidemiologists were not convinced that the data was such that the second question could be validly answered. I think an important point here is that some of the veterans are getting the feeling that the delay means that someone is "sandbagging" them.

We can tell you it's the opposite because if you cannot distinguish those exposed versus those not exposed

effectively, and you let someone go ahead and do the study, is it's going to show no difference and that's against the veteran, not for him. Myself, Dr. Keller and many people have insisted, very strongly, that unless a decent exposure index is found, that is not only reproduceable, but is, in fact, one that convinces the majority of uninvolved scientists who look at this, it is not worth doing. From everything that I've been able to read, that is exactly why a CDC study at this point is on hold.

I think it's important to realize that the fact that it's not going ahead until a group, and I think the people on the AOWG were very good monitors, not disinterested but unbiased. They want to see a good scientific protocol and the fact that it's being held up, in fact, should be reassuring rather than read as an attempt to fool the veteran.

MR. SNYDER: I think that to follow up still, regardless of the time on the agenda alloted for this, veterans are concerned on the status of this study and it going forward. I think the perspective perhaps that the people in the audience and the rest of us perhaps should see or is clear here is there's quite a split between the Executive Branch and the Congressional folks and it's not real clear to me where veterans, people most directly affected, are going to fit in all of that.

Congress says to do a study, get it done. The Executive Branch says, well, let's review the protocol through its various levels of people, and where is Congress' is oversight and then where is the veterans' involvement in all this.

I don't see that the study is progressing very swiftly, and if we're talking about being suspended and recommendations being made in the next week that might suspend it further, I think in dealings with federal agencies when things get suspended, they have a way of staying suspended.

I would like this committee, and I would formally propose that we vote, if need be, and ask our chair to carry a mandate to attend these subpanel meetings and provide input on behalf of veterans, albeit through the VA, and the subpanel understands what any suspensions really mean in terms of veterans who are out there waiting for answers.

I don't think that it's fair, and I think you should express Dr. Shepard, to the subpanels and Agent Orange Working Group that the existing committees such as this, I think, need to be fully apprised of those goings on.

I am chagrined that I've got no more time than I have or have had in the past several weeks to write each of the members of the committee and express what I learned or not learned and try to acquire more information to come in

here with some written reports, for example.

We come here every few months and meet but we don't present things. We don't walk away with a written plan of action or written recommendations to give to you, and then we meet a few more months down the road. I don't think that's really a good role for us as veterans who are given the opportunity to sit on these committees to play. I think we ought to be walking in with resolutions, with recommendations and then have that as the Administrator invited today.

He's looking forward to our recommendations. He is looking forward to our input. What he'll do with that and whether he'll let us meet again, we don't know and he wouldn't give us that assurance, but clearly he said that I look forward to your recommendations.

Let's give him some recommendations. I would say that one of them today that I'd like to formally propose would be that our chair attend the subpanel meeting, I guess it's the 17th of this Agent Orange Working Group, and express that as veterans' organizations and as this committee, that we're concerned about the consequences of any delays or suspensions in the study, and that we would encourage the Congress be fully informed of that subpanels' deliberations and that the Office of Technology Assessment which again by laws -- I'm confused here -- by law OTA, Office of Technology Assessment, the Congressional arm is to have a say in

this study. Instead we have the Executive doing this.

MR. ESTRY: If I may, it was OTA that actually put the hold on this, not the Agent Orange Working Group.

MR. SNYDER: They don't appear to be making the decision at this point.

MR. ESTRY: Well, what they did. We also sit on that panel, members of our organization, and I agree with you. In a way I was expecting more from the CDC report today. We went to a CDC meeting a couple of weeks ago.

The study was put on hold, as Dr. Hodder said, because there was a grave disagreement about the -- exposure index. They supposedly set up a special subcommittee under OTA's jurisdiction to examine this, and I believe they put some people from DOD on that panel.

That was one of the arguments and they brought two people in from DOD, if I am not mistaken, for subcommittee, special subcommittee.

MR. SNYDER: Well, Colonel Young is the chair.

MR. ESTRY: Well, he's on another group. He wasn't on

this one. I didn't get the name, but they mentioned it because that was one of the complaints. They felt there was no military people to help gauge the exposure index.

CHAIRMAN SHEPARD: Excuse me. May I interrupt. Let me just clarify a couple of points just so you're all clear on this.

The Office of Technology Assessment, the branch of Congress and advisor to Congress, has had for some time a special committee composed of a number of fields of expertise including epidemiology statistics, and so forth, to review the progress of this and other studies.

That Committee meets on call of OTA to review protocols, to make recommendations, to make decisions regarding the studies.

Quite separately and appropriately, the Agent Orange Working Group has a Science Panel, a subcommittee of its members who are composed largely of scientists, similar expertise and reviewing protocols and making recommendations to the parent organization.

The current subpanel -- terminology gets a little confusing -- chaired by Colonel Young was established specifically to examine the military records and how they could be used in a scientifically valid manner to set up the process

for selecting the cohorts for study.

In that subpanel there was a request to have an additional military expert, a nonscientist, a nonmedical scientist certainly, to confirm the status and the quality of those records. In addition, an epidemiolgist who was not previously a member of that group was also brought on as a consultant to the Committee.

MR. SNYDER: Who is the military person?

CHAIRMAN SHEPARD: General Murray.

DR. HODDER: Murray.

CHAIRMAN SHEPARD: General John Murray, excuse me.

MR. SNYDER: This is the panel, Barclay, that just formed in February? Is that correct?

CHAIRMAN SHEPARD: Yes.

MR. SNYDER: Okay. That's what I've alluded to.

CHAIRMAN SHEPARD: General John Murray and Dr. Aaron Blair.

MR. SNYDER: Where is Christian in that?

CHAIRMAN SHEPARD: He is attending as the military records expert, yes.

MR. SNYDER: Okay.

CHAIRMAN SHEPARD: So it's a committee that was chaired by Colonel Young and made up of Dr. Keller, General Murray, Dick Christian and Dr. Keller and myself, Dr. Marilyn Fingerhut and Dr. Aaron Blair, the epidemiologist from National

Cancer Institute.

MR. SNYDER: And you have no insights as to what their report on the 17th and five days is going to suggest?

CHAIRMAN SHEPARD: Yes, I do.

MR. SNYDER: You can tell us?

CHAIRMAN SHEPARD: No, I'm afraid I can't. I am sorry. That's privileged information, and I'm not at liberty to disclose that.

MR. SNYDER: Well, I think my original statements still kind of stand, that I think we should ask you as the chair, to give you a mandate from our committee to go to that meeting.

CHAIRMAN SHEPARD: I will be at the meeting.

MR. SNYDER: And to certainly report back to us promptly, but take with you that we want concerns of veterans raised at that panel and hopefully before the conclusion is put on the table.

I think that we would like you to indicate that veterans are concerned the study go forward, certainly that it be a well-constructed study and nonetheless that we want you, as a VA person, and have the agency exercise some over-sight and push the study to get done, not sit idle and not be pushed as diligently as possible

There's at least a consensus that would be the charge or mandate that we give to the chair. I'd like to

see if there's a second to that or something forward.

DR. KAHN: I'll second it.

MR. SNYDER: Thank you.

DR. HODDER: I'd like to suggest, though that rather than pushing for action without necessarily getting critical review, I would say, I'd put a very big "if" clause in there. If the study can be done in a way that will satisfy the veterans, if they're going to get a fair shot, i.e., that a good exposure versus nonexposure index is developed then otherwise as I say, you're working against yourself, but that is --

MR. SNYDER: Well, perhaps that a second motion, a second suggestion is that we find out promptly and perhaps reconvene much sooner than three months or four months or a half year down the road, whatever the recommendation may be.

Give us the opportunity to look at it and if there are people in our communities and organizations that can look at the recommendations or reports, I think we should at least have the text in hand to go do that, and then finally get some more firm analysis by veterans of what this recommendation consists of.

MR. WALKUP: To elaborate that point some more, when I was getting frustrated earlier, part of this probably is my PTSD anger scale, that we were talking about, but part of, it is about the expectation that we have come to assume about how information is going to be

handled.

Going back up on that. I come from a long way out of this town, and I don't understand all the political things you've been talking about, about who does what to whom and how, and most veterans don't. That's not the point.

The point is what's really happening with this study. When we come to a meeting and find out that the most important issue under consideration on Agent Orange is on the agenda but all of a sudden fell off, I have some very worrisome reactions to that.

I think it's very important that however the Agent Orange Working Group and the Veterans Administration handle this decision, it is communicated much differently than it was before this committee.

It's very important to be straight-forward with veterans and have people who can stand up and say, with good backgrounds, good integrity and whom people are going to trust who can say, look, we've got a scale that just doesn't work. We can't find an exposure index here, and the reasons why, and you know, those kinds of things and not just all of a sudden have it disappearing with the bureaucratic hassles with the Congress.

I think there needs to be some straight communication. I feel like we didn't get it here today, and if this is an example of how it's going to be handled next, watch out.

It's going to be difficult.

MR. CARRA: I think I generally agree with what Dr. Hodder said about how to look at this type of thing and to be careful that we don't push something that ends up being detrimental to what many people would like to see.

However, I think the way this whole decision is handled is going to make or give people perceptions that it is not going to be in the best interest of veterans. So that is really what we have to focus on is that however the decision is handled, that people feel that at the end of that decision making that they've had an opportunity to look at it and that the decision is in the best interest of the veterans, number one, and science. So I am kind of sympathetic to what's been said about getting some information back to the people on this committee about what's going on there before all the "i"'s are dotted and the "t"'s are crossed on the decisions.

CHAIRMAN SHEPARD: Let me make a couple of points.

DR. KAHN: Two points and then I am going to shut up. One concerns the function of this committee which you raised also. I don't want to be window dressing. While my acquiescence say the VA is doing a good job and this, that and the other thing which I do not agree with.

We're never given sufficient information to

formulate the recommendation. All this is is a mild discussion group and then we all go away feeling good for having come here. That's not what I want to spend my time on. I have better things to do.

The way these meetings are run gives me the impression that we're here because we feel we have to be here for political reasons not for scientific advice, or advice from veterans which is not always scientific but has other types of information.

I don't want to be political window dressing for anybody. I have more important things to do with my life. Even if we're going to get good information out of you folks with sufficient duration between meetings, communication among ourselves and communication with you that we can actually come to some conclusions about what on earth is going on and then provide some kind of reasonable advice, giving us some time to consult with our members if need be, for certain membership organizations, or this is just a waste of time. It's a debating society who says you're going to listen to what's told to us and some of it is interesting, and some of it is boring and let me go home.

I don't want to do that. I'm not going to do it again. If there isn't something more forthcoming between now and the next meeting, where we can dig our teeth into it and make some sense out of it, I won't come here. I think

there are others here who feel like this.

MR. SNYDER: Indeed.

DR. KAHN: Second point I want to make concerns the study, itself. I have gone back recently and talked with some other folks about a careful look at, this effort survey experts and I have real questions whether the study in its present form, even if you had an exposure index, should go forward.

I raised the question as to whether we shouldn't consider cancelling the whole thing, and reconsider the proper use of $55 million or whatever the number is. It may be possible over the next few years, for example, to develop biological markers in past exposure and with such biological markers and past exposure, it will be possible to select a cohort with greater regard than is now possible.

Should we not consider the research needed to develop such biological markers. That's one possibility. Another possibility would be to take ten percent of that money, 20 percent, take a small fraction and spend that on studies of the mechanism for the dioxin toxicology or some other substandard.

Investigator initiated projects, some of which the VA has come up with, and the Twin Study is a fine example of that -- investigator initiated projects, have the advantage that you have somebody who wants the answers so badly he can

taste it, and from my experience in research, you don't get good research unless you have investigators who want the answers so bad they can taste it. Talk down dictation of research is not research -- always goes wrong. Always goes wrong in my experience, and the CDC study, I think, may be an example of that kind of work, so I would like to see us have open on the table the option of considering things like that.

If we can't do that, we serve no useful function. Now we are serving a window dressing function.

CHAIRMAN SHEPARD: I share your frustrations and concerns. I agree that this committee has not fulfilled to the extent possible its advisory capacity, and I would urge all of you right here and now when you do have recommendations that you communicate with me. I will also pledge to share with you information as it comes out. I think we have done that in the past.

DR. KAHN: You have not, Barclay.

We come here -- in all fairness you have not done that.

CHAIRMAN SHEPARD: Not in the --

DR. KAHN: -- for someone else's, I don't know, but we come here and a subject is raised by the committee and we're told that this will be dealt with or will have an opportunity to consider what has happened at the next meeting

if a subject doesn't come up again or if one of us raises it, enforces it.

In the big meetings there's always no communication except that we get the transcript to correct. Occasionally one of those sorts of documents that's in this comes to us to read, look at, but no specific requests for anything to be done with it. For your information you might want to read this.

What kind of advice is that going to be?

CHAIRMAN SHEPARD: I will not debate that issue further. I accept your comments.

We have something of a disagreement of opinion. I've been with this Committee now for a number of years, longer than you have, Peter, and I have some recollection of some of the efforts that have been put forward in the past.

Suffice it to say, that we will share information. I will personally pledge that I will share information as it develops. It was hoped that prior to this meeting which has to be scheduled sometime in advance -- by regulation, we can't plan a meeting overnight -- it was hoped that this decision would have been made prior to this meeting, and it was on the agenda with that in mind, with that expectation.

Unfortunately, for a variety of reasons the recommendation has not been completed and that's the reason we can't address it. Right at this moment, it's in

a state of limbo. It was hoped to have been made, and it's not been made for a variety of good reasons.

I would also assure you that the concerns of veterans have been foremost in the minds of individuals who serve on that committee, and I can tell you that very honestly and I would include myself in that group. I have always pushed during the deliberations of this to make very sure that the concerns of the veterans are foremost in the logic of how we should proceed.

Are there any comments on that? I would welcome any members of the committee proposing concerns to the Administrator. You've heard him this morning. He is open and receptive to such recommendations, and I would urge and encourage you to put forward any recommendations that you feel you'd like to see presented to him, and I would pledge that he will get them.

Let's now take a -- excuse me.

MR. WALKUP: I think one part of that -- I need some more information, I think, to make it. What you were saying about that you hoped that we would talk about that issue today because the decision would have been made, it sounds like you have a different view of an advisory committee than I do, and I don't understand your view.

What would this advisory committee have done with the information about a decision that had been made by the

Agent Orange Working Group already? What would you expect of us if the schedule had worked out right, if you'd been able to tell us what the Agent Orange Working Group had done?

CHAIRMAN SHEPARD: Maybe I misspoke. The recommendation that would be made by the Agent Orange Working Group to the White House Science Policy -- the Domestic Policy Council concurrently or presumably a recommendation to the Congress, that a certain course of action be followed. I don't think that the final decision as to whether or not a study will be done will be made when that recommendation is filed.

There will obviously be some consideration of that. It is a recommendation. It will be a recommendation, and I think that this Committee has potential for having input into the final decision as to how that recommendation is dealt with.

MR. CONROY: So then, Dr. Shepard, a decision on the 17th will not be cast in stone, and if not, how long will we have? What will the interim be?

CHAIRMAN SHEPARD: If you're asking me for time frames, I can't honestly answer that. All I can tell you is that the steps that I understand will be taken are that the Science Panel will make its recommendation to the full Agent Orange Working Group which, in turn, will make its recommendation to the Domestic Policy Council.

I can't predict what the Domestic Policy Council

will do with that recommendation.

DR. KAHN: At what stage do we get to throw in our oars?

CHAIRMAN SHEPARD: Any time, today forward.

MR. SNYDER: Well, can you provide a copy as of -- provide a copy on the 17th of what the recommendations are and then give us ten days to read and look at and then perhaps a special meeting of the Committee. If we can't be here, telephone conference, that you can give us more details of the timetable of where that subcommittee's recommendation goes and who is looking at it and who are the players that perhaps we as individual organizations should go to.

I really don't want to wait for three or four more months before we come back and find that the recommendations were acted on in the vacuum. I think it would be in the absence of our commenting and our overseeing what the recommendations are.

Would you please get the recommendations to us, not just a executive summary or something, but the full text of whatever is releared on the 17th. Then give us ten days, and call us to either arrange for a meeting here or simply a telephone calling or telephone conference call. I guess that the telephone services still offer that we can all sit on the telephone at the same time and get the benefit of each other's comments, so we'll have some interaction

with each other and not just a polling of us individually.

Would you please do that?

CHAIRMAN SHEPARD: I can't promise to do that because, in addition to chairing this committee, I am an employee of the Veterans Administration. What I will do and would very much like to do is accept a recommendation from the committee, requesting that that be done.

MR. SNYDER: So be it. At least I make such a recommendation and would like concurrence or consensus of the committee that we have that recommendation to present to you, and you accept that.

DR. KAHN: Let's vote on it.

All in favor?

CHORUS: Aye.

CHAIRMAN SHEPARD: We didn't have time for discussion. You have had the discussion, okay. I will infer then that --

DR. HODDER: Just one quick point. All the frustration maybe, I think, particularly among people on this committee for a long time is that at one time we were asked to speak on these issues but we now have a separate committee also with veteran representation that is advising on that.

Is that not correct? Your statutory committee --

MR. SNYDER: Environmental Hazard, but their timetable is that they're not going to meet between now and the

17th. They haven't been given a preliminary report, have they?

CHAIRMAN SHEPARD: That's not his question. His question is what is the conflict between the two committees, I think.

MR. SNYDER: But they're not performing the function that I think you're suggesting maybe they are.

DR. HODDER: That's a question maybe I am asking.

CHAIRMAN SHEPARD: Okay, the statutorily established VA Advisory Committee on Environmental Hazards has a fairly specific function and that is to examine the scientific evidence that would bear on the awarding of compensation to veterans in the area of Agent Orange exposure and radiation exposure.

It is a committee largely of scientists, epidemiologists, statisticians with particular expertise in toxicology related to dioxin and radiation. There are four nonscientists on that committee. They meet on an ad hoc basis when there's evidence to consider that would bear on that issue.

I think their charter is somewhat more narrow than the charter of this committee, which is -- I interpret the charter to bring to the VA concerns of veterans relating to the management of Agent Orange exposure and possible adverse health effects.

MR. SNYDER: When is their next scheduled meeting?

CHAIRMAN SHEPARD: I can't answer that. Mr. Conway can you tell us when the next scheduled meeting of the Environmental Hazards Committee is or has it been scheduled? As I say they meet on an ad hoc basis so they're not scheduled in quite the same way that we are.

MR. CONWAY: I believe the next meeting is tentatively scheduled for November 17 and 18, primarily because there has been some research that has become available since the last meeting. We want them to consider it on a timely basis.

MR. SNYDER: I'd like to propose a third motion then for us.

CHAIRMAN SHEPARD: Do we have these motions written other than the transcript? Okay. The first one that I am aware of was that I provide to the members of the Committee at the earliest time a copy of the report to the Agent Orange Working Group.

Have I summarized your discussion?

MR. SNYDER: Number one was to actually go to that committee meeting prior to its release and conclusions being made, speak to the assemblage and ask that they be conscious of the concerns of veterans, that the study go forward and it be a good study and that we're concerned that suspensions of studies and delays may be terminal.

CHAIRMAN SHEPARD: That is already going on, so you may make that recommendation, but that is occurring. If you wish to put it formally as a recommendation.

MR. SNYDER: On the 17th, somehow that will happen and then prior to a report be --

CHAIRMAN SHEPARD: Make sure that all of what you expect to have happen is a matter of record. I thought you said that I would attend, and I have told you that I am a member of the committee, and I intend to attend part of it.

MR. SNYDER: And we just would like -- I think we would -- there's disagreement with my use of rather loosely of the term "we" here. We would like not only that you attend but that you speak to the Committee as to the concerns we've raised as veterans organizations and veterans, that the study go forward and not be delayed, not be suspended and if suspended, I think perhaps we should try to put a cap on what kind of suspension we're talking about.

Suspended for a month to evaluate something and not let it just be open-ended. That, I think, would be useful for you to present if you're able in your capacity as a VA employee to that committee, that subpanel.

CHAIRMAN SHEPARD: I think, Keith, it would be helpful if you could put something down on paper.

MR. SNYDER: Yes.

CHAIRMAN SHEPARD: So that it is --

MR. SNYDER: Before the meeting I'll do that.

CHAIRMAN SHEPARD: To exchange a little bit each time.

MR. SNYDER: That's right. As I learn a little more or think of other things, yes. Things will change.

CHAIRMAN SHEPARD: I don't want to be placed in an ambiguous position.

MR. SNYDER: Fine.

I will try to draft something and perhaps all of us can look quickly at it and get a consensus on it.

MR. WALKUP: I'd like to get back to the third recommendation.

CHAIRMAN SHEPARD: Could you also pledge to write yours down so that --

MR. WALKUP: Let me see how it works out. If we get the same thing that is in the first place -- same issue then I would like this committee to recommend to the Administrator that we be used for advice on current issues dealing with Agent Orange, that specifically this committee should -- that my recommendation would be that this committee would review the issues before the Agent Orange Working Group and make recommendations to the Administrator regarding the appropriate position of the Veterans Administration, additionally,or for example, that this committee should have

been provided with and had on its agenda review of the GAO report that came out on service delivery to people receiving Agent Orange treatment which is not on the agenda.

Is that on your machine? Is that going to be a transcript? Okay. Succinctly, I think we ought to be giving you advice. There are two examples today of the kind of advice that I think is appropriate for you to have. I would much rather spend my time on those issues than on the very interesting information we're using.

I'd like to hear from other committee members if you share that perspective.

MR. Snyder: Yes, certainly so. The GAO report that again is not on the agenda and which is a little difficult. It's dated in January, GAO report relating to the Agent Orange registry and the examination program, continues some of the criticism that was voiced in '82 and in fact, this report although dated January of 1986 is based on data collected and available to the agency in '84, and there are recommendations that GAO made that the agency has rejected. I'd like to get a status report of perhaps whether there's been some reconsideration of those rejections of recommendations, but again I speak to that briefly.

Here we don't have on the agenda first an overview of what the recommendations in that report were all about because we were not provided with a copy of it. I happen to

be on a mailing list of GAO indexes of publications that have been released and picked it out but there's no press release from VA. There's no distribution to members of the committee and again that's service delivery. That's what is directly affecting our members.

They want to know why they're not hearing back from the VA about their lab results. Here is GAO,same problem. That's something again that we need to have provided for us. I don't think it's fair to rely on GAO circulating to us a list of publications and all of us being able to pick out and order it. Some of us are able to do that. I don't think many of us have the luxury to do that.

I would appreciate that in the future such a function could be provided by this committee, by the chair, and I would hope that yet today we can discuss that report. I think there's some recommendations there that we might also want to make as a committee to the Administrator.

DR. KAHN: Barclay, in that connection until very recently the New Jersey Agent Orange Commission have been recommending that veterans take the Agent Orange screening exam and thereby enter themselves in the registry. To the extent that we were making appointments for men to go, we were actually driving there in our cars and doing everything possible to get them into these VA facilities.

The experience that our veterans have had in New

Jersey, with the exception of those who go to Wilmington Hospital in Delaware, south Jersey veterans go there, the experience has been so uniformly bad that veterans have been getting out to the Commission saying, what did you get us into. This was awful.

They criticize us for having acted as your spokesman, to get people into your registry. We, therefore, are taking the formal position as Commission action a few months ago that we will no longer recommend the veteran take a screening examination. We don't oppose them. If a veteran asks us to make an appointment, we do it, but we do not recommend that they take the screening exam because the program is so full of problems that we see on a daily basis and think it is not remedial.

That's a serious problem. We're seeing that at the grass roots. You people should know about that. I didn't know that GAO report, the second one existed until yesterday.

I should think that one of our functions has to be as soon as it became available we should have had it in the mail to look at.

MR. CONROY: Again, Dr. Shepard, if I could just mention something without being placed in the position of being an apologist for the VA, that particular GAO report was given widespread dissemination in the media. I, myself, saw an article about it about two weeks ago in the Stars and

Stripes, and at that time I called Dr. Shepard asking him if he would provide Committee members with a copy of that. He was more than happy to do that.

It seems every day something is coming out relative to the Agent Orange issue, and I think it's incumbent upon us as Committee members to keep ourself abreast of these publications when they do come out. I think certainly Dr. Shepard has done an adequate job in providing those to us as Committee members.

CHAIRMAN SHEPARD: Thank you. I do recognize that I did not disseminate. I do apologize for it. I will not excuse it. It was an oversight on my part, and I will rededicate my efforts to sending out publications of general committee interest to you in a more timely fashion.

MR. WALKUP: I'd like to reclarify. I think my recommendation got sidetracked in my second example, but what I was trying to speak to was the role and function of the Committee, and I'd really like to clarify what -- to reinforce what Chuck was saying.

I don't think it is you, personally. You end up taking the brunt of most of the things that come here, but what I was trying to phrase was a recommendation to the Administrator about the proper role of this committee,

recognizing that you're going to have to front whatever it is and whoever it is besides what it is that we're going to do and probably going to take more flak about, but what I was trying to say was not personally towards you or to the Veterans Administration or whatever, but just as an interested veteran and citizen, I think it's a waste of our time and money to be here if we're not going to give constructive advice about issues that we can't impact, and there's some issues there that I think you've got some fairly smart folks here who can give some advice.

They might not like to hear it but it's going to be at least some sort of information that they can take into consideration, and my recommendation, again, was around the role of this committee as an advisory body for decisions that are going to impact policy affecting veterans in terms of research on Agent Orange or of herbicides and in terms of service delivery and information programs to veterans about Agent Orange.

I think we ought to have a chance to do that.

CHAIRMAN SHEPARD: Again, as your Chairman, I would encourage all of you, request all of you, plead with all of you and each of you when you do have concerns, please do communicate them to me. I can't always be in your minds and when you have problems or concerns, I would strongly urge you to communicate those to me.

Some of you have been very good about that, and I have tried to respond to those concerns as I have received them. I would encourage you to continue in that role because I do want you all to feel that you're serving a useful purpose.

I think we had better take a quick break. I apologize for the fact that we've gone over our time, but would you please all reassemble at 5 minutes of 12:00 because we still have some important issues to discuss.

(Whereupon, the meeting was recessed at 11:45 a.m. to reconvene at 11:55 a.m.)

CHAIRMAN SHEPARD: Can we please begin. I apologize that we are running late. I think the discussion we had just before the break was a very important one, so I don't regret the time that we took in that area.

I'd now like to call General Wells to give us the report on the Advisory Committee on Women Veterans.

DR. FITZGERALD: Before we do that may I suggest that in view of what's happened just before this break, that we're going to run out of time here this morning, and that we suspend the rest of the agenda in order to settle this point and bring this to a head.

MR. SNYDER: I would think that, in fact, we could do that probably in fairly short order and then move along with the agenda.

DR. FITZGERALD: I don't think we're going to be able to do both as far as time is concerned. What I am saying is let's move the agenda and see whether, indeed, some of this can be suspended in order to get parts of a meaningful discussion within the time frame.

CHAIRMAN SHEPARD: I would ask people who came prepared to make comments, how they feel about that.

General Wells?

Maybe if you have anything written that you could provide me and I would circulate to the committee, you have a short --

GEN. WELLS: I don't have it, but I can do it.
(See page 244)
CHAIRMAN SHEPARD: Okay. That would be very helpful.

Let me ask Mr. Joseph Bangert how he feels about it.

MR. BANGERT: Dr. Shepard, we in Massachusetts are very cost effective, and I'd lose my hide if I can't justify two tickets for myself and our epidemiologist from Harvard who has taken the time off his schedule to come down here and, since it is significant new information, we would like to do the Marine's last stand on at least trying to submit our information because we think it's new and exciting and different from other information that's been presented here today, so we'd like to go ahead.

MR. WILSON: And New Jersey surrenders its time to Massachusetts.

(Laughter.)

CHAIRMAN SHEPARD: Thank you.

Maybe we can then strike a compromise. Let's see. I do want to take some time to address some of the concerns of the Committee in terms of specific recommendations so I think we need to do that, and I also would like to take just a few minutes to discuss the letter I sent all of you concerning the possibility of a workshop.

It may be that we can touch on that very lightly,

and then I can perhaps appoint a subcommittee to work on that and come up with a recommendation.

I think that's probably the way we ought to proceed.

Why don't we now receive the report from Massachusetts, Mr. Bangert, and if you would please introduce yourselves and give us a summary of the study that you're about to discuss.

MASSACHUSETTS VIETNAM VETERANS HEALTH SURVEY*

MR. BANGERT: Good morning. My name is Joe Bangert, and I am the Director of the Commonwealth of Massachusetts Agent Orange Program which is a program under the Office of the Commissioner of Veterans Services.

I am going to be very brief, but in view of the discussion that took place prior to the break, there's no question that we in Massachusetts are very concerned about the recent debate and developments here in Washington concerning the long-awaited study by the Centers for Disease Control which was basically heralded as the independent study that we Vietnam vets hoped for and had waited for. The sentiment, at least out in the field among Vietnam veterans in Massachusetts, was that we should proceed ahead.

As a former Marine, I'm concerned that Marines were also drafted, but none are part of your study. For the record, Marines, not wounded, served 13 months in Vietnam, a month more than Army draftees, and were you to examine

*see slides on pages 238-243

12 Marines, you'd increased the exposure index, regardless of the debate, by at least one year for every 12 Marines studied, either draftee or volunteer personnel, and it's a point that Marines are quite concerned about, at least the former Marines in Massachusetts.

Today we want to report the results of the Health Survey of Massachusetts Vietnam Veterans. The Massachusetts Agent Orange Program was brought into existence in 1983 by the members of the General Court, the Legislature of the Commonwealth of Massachusetts as a line item in the budget signed by Governor Michael S. Dukakis.

Our Legislature reacted to pressure from the veteran community in Massachusetts, quite frankly. We know, on a local level in Massachusetts, if a politician does not respond to the needs of his constituency, and veterans, we really believe are number one, these political considerations are taken very seriously, or else those people find themselves out of office. That's how things work at the local level.

Today, without be laboring it, you will now hear from Massachusetts, Mr. Frank J. Bove who is a doctoral candidate with the Harvard University School Public Health. He is going to basically report the results of the Health Survey of Massachusetts Vietnam Veterans, 1986. I ask you to give him your attention. He does have a few overhead slides, because we learned something a long time ago: Come prepared. So we'd like to have equal time in terms of the slide projection.

tion.

Thank you.

MR. BOVE: First I want to summarize the report. Fifteen hundred male Vietnam veterans from Massachusetts completed health questionnaires in January of 1985. The respondents were those who filed a claim against the $180 million proposed out of court settlement reached by attorneys representing the seven chemical manufacturers of Agent Orange and Vietnam veterans. Although not a random sample of the more than 50,000 Massachusetts Vietnam veterans, the findings indicate a considerable amount of illness among the respondents including tumors, neurobehavioral problems, reproductive difficulties and birth defects among their offspring.

I am going to go into detail. These findings are consistent with the observed symptoms and disease found among those exposed to 2,4-D, 2,4,5-T and 2,3,7,8-TCDD (dioxin) in the workplace or the environment.

Introduction - concern about the long-term effects of exposure to Agent Orange is widespread among Vietnam veterans in the U. S. and Australia as well as among the citizens of Vietnam.

In southern Vietnam, recent studies report a variety of persistent clinical problems including recurring bouts of headaches, depression and anxiety, asthenia, loss of libido, GI disorders and adverse reproductive outcomes.

Studies of workers exposed to dioxin contaminated substances have found elevated rates of lymphomas and soft tissue sarcomas.

Neurologic and liver effects have also been reported. Table 1, slide one, lists the findings of some of these occupational studies taken from the study by Moses, et al.

The next slide includes the findings of other occupational studies, what you see are a number of neurological disorders, fatigue, weight loss, GI symptoms, loss of libido and muscular weakness.

The next slide is a summary of Massachusetts Mortality Study and printed, tendered, I think at the last meeting or meeting before. Here, as you see, is an elevated amount of soft tissue sarcoma, kidney cancer, motor vehicle accidents and estimated suicide.

This is a standardized MOR study. The next slide lists findings from selected studies of Vietnam veterans.

This survey that I am about to show now is part of the ongoing research program sparked by the findings of previous studies as well as the

concern raised by the veterans. The results of this survey are consistent with those in the studies mentioned in the previous slides.

In January of 1985, the Massachusetts Agent Orange Program instituted a large-scale media campaign to alert Vietnam veterans of the court-imposed deadline for filing a claim against the proposed 180 million settlement reached by attorneys for the seven manufacturers of Agent Orange and about 2,000 Vietnam veterans filed claims during a two-day period at the state office of Veterans Services.

The American Legion health questionnaire was distributed to those filing claims. In addition, some 300 questionnaires were mailed to veterans who phoned the Agent Orange Program requesting to participate in the health survey.

Approximately 1800 questionnaires were returned to the Agent Orange Program. Fifteen hundred of these were selected based on the criteria of completeness, actual service in Vietnam and being male.

Staff of the Agent Orange Program as well as trained volunteers, all of whom were Vietnam veterans, assisted respondents with any questions or difficulties they encountered with the questionnaire. Concerning the birth outcome data requested by the questionnaire, if the veterans were not sure of the information being asked, he was provided with a self-addressed envelope and permitted to take the questionnaire home.

The results of the survey was the following: over 404 of the respondents stated that they were diagnosed with some form of tumor, whether cancerous, benign, fatty or other. Nine were diagnosed with Hodgkins Disease. Slide four has the reproductive problems and adverse outcomes. Nearly 22 percent of the respondents indicated that one or more of their children had birth defects. Out of 1907 live births reported in the questionnaire, 462 (24 percent) had at least one birth defect and 160 had more than one defect.

Thirty-seven spina bifida cases, other brain or spine defects were reported. What I've done there is put along side the problems to be found in the questionnaire, birth defects, incidence rate for that.

Nearly one-chird of the respondents indicated a decrease in libido and 22 percent reported fertility problems. Back to defects, you see a lot of spina bifida and cleft lip/palate. Cleft lip/palate was elevated in the CDC study.

You also see -- there are also a lot of hip abnormalities.

Next slide. Nearly two-thirds respondents indicated persistent problems with tiredness. Over half reported persistent headaches and

difficulties with memory or concentration and almost half reported nervous disorders.

There were about 314 or 21 percent of the respondents had problems with all four. They and persistent tiredness, persistent headaches, nervous disorders and difficulty with memory.

Seventy-three percent of the respondents answered yes to the question: "Have you or your family ever noticed a personality change?" Eighty-two percent of the respondents claimed they regularly had at least one of the following problems: depression, violent rage, anxiety and irritability.

Most had more than one problem. Two hundred and 75 respondents reported suffering from mental illness or a breakdown concerning symptoms of peripheral neurophaty: about 526 or 35 percent had symptoms in both the lower and upper extremities.

Also muscle weakness such as difficulty grasping tools, getting out of chairs, climbing stairs or lifting objects above shoulder level, 775 responded that they had a least one of these problems, and 128 said they had all four problems. Many respondents reported GI disorders. Over a third stated they had repeated nausea without flu or other sickness.

Over 25 percent reported repeated bouts of diarrhea. About a third indicated that they regularly experienced loss of appetite and weight loss.

In conclusion, we reemphasize that the questionnaires were not randomly distributed and were completed on a volunteer basis by a self-selected group of Massachusetts veterans. This means that we cannot base a valid, scientific study on the information contained in these questionnaires. However, the questionnaires clearly indicate considerable disease and suffering among a relatively young group of people, most of whom are under 40, and symptoms and disease found are consistent with findings from other studies of people exposed to dioxin, 2,4-D and 2,4,5-T.

CHAIRMAN SHEPARD: Thank you, doctor.

Any questions from members of the Committee?

DR. KAHN: Yes, the last sentence you said that the findings are consistent with what has been seen in dioxin exposed persons. What direction do you intend to take this work? Obviously, this is not a full-scale epidemiology with randomly selected cases and controls. That's perfectly clear.

We make no pretense about it. Where do you want to go with this?

Mr. BOVE: With this survey we don't want to go much further

scientifically. We would use this for health services, but I think Mr. Bangert would like to -- Joe, where are we going?

Mr. BANGERT: Where are we going with the problem? Two areas. Very shortly we're going to be publishing the results of 2,000 interviews that were done on Massachusetts Vietnam veterans looking at the psychoneurological problems of Vietnam veterans that claim exposure to Agent Orange to see if there is at least a causal link or some association or relationship between exposure to Agent Orange and post-traumatic stresses.

That will be forthcoming shortly. Generally, without seeming too flip, what we decided to do in Massachusetts is we usually pick those things that we find certain people in the federal government refuse to do, so in the future we are doing a few things.

We're going ahead with the fat biopsy study, that is 50 fat biopsy samples that we're doing. We're going to be quiet until we get the results on that. We're in the process of a final selection and we've got a great exposure index that we developed on our own, and as they say on Cape Cod, either fish or cut bait. It makes sense that, if you're looking for a criteria, you don't wait three or four years only to change it. But, if one spent four tours of Vietnam, doing four tours of duty in "I" and "III"

corps, chances are the veteran was exposed than a man or woman who served six months in II corps or IV corps. Therefore, you see, we are moving ahead with that, even though there is a problem at the federal level. We have no problems estimating an exposure criteria for our use. Finally, we're decided as a result of the incredible consciousness and the incredible unheralded contributions of female Vietnam veterans, that Massachusetts, in competition with other states and perhaps with the Federal Government, that we want to beat them to the punch and conduct studies on women veterans while everyone else is talking.

We are in the process of developing a protocol to look at morbidity and reproductive outcomes of female Vietnam veterans. We hope to complete that within a year or so. We have a few more secrets, but I can't talk about those yet, but I do welcome this opportunity to come and I'd like to take my state bureaucrat hat off for a moment, perhaps during veteran remarks time, because I've been toying with the idea of Colonel Wolfe's plagiarism of Carl Sagan's quote, and, I think I have a new variation that I'd like to leave you with today as soon as I find it in my bag. In the meantime, please come up to Massachusetts. We have great fun up there, and we're booming while Texas is having some real problems. It's great in the Bay state.

Thank you.

CHAIRMAN SHEPARD: Any other questions?

I have one. In regard to the Massachusetts Mortality Study. Are you involved in the Massachusetts Mortality Study? Mr. Bangert?

MR. BANGERT: Yes.

CHAIRMAN SHEPARD: With regard to the Massachusetts Mortality study, some point it the past I asked and received some assurances that there would be an attempt to do two things that is to validate Vietnam service among those classified in the study as having served in Vietnam through the use of military records and secondly, to have a pathologist's review of the soft-tissue sarcoma to confirm that those were soft-tissue sarcomas because we've had some problems with the classification. I was just wondering if any progress was being made.

MR. BANGERT: There was a pathological review of the soft tissue sarcomas, and you should direct that to Dick Clapp, who is on the Medical Scientific Advisory Board.

In terms of the record search, we'd be willing to do that, but we're kind of in a jam to a certain degree because there's at least two VA institutions in Massachusetts. There is a law in Massachusetts in Cancer Registy, and sometimes it's not applicable to federal institutions, we'd

like to work in cooperation with CDC to track some morbidity, mortality and cancer rates in Massachusetts, and we've got two major VA facilities that have refused to share their soft-tissue sarcoma data and other cancer data with us, and this is a problem that has been addressed to the Regional Director of the VA in Boston, and moreover what we're looking for is a quid pro quo.

We'd love to the records research, and we're coming on line with a computerization, but it would help us, perhaps, if we had a reciprocal agreement with the Environmental Support Group and the VA in terms of -- exposure verification because we need some things too.

We would have a quicker turnover rate, at least for Vietnam veterans in Massachusetts, if we could have access to the data base that Environmental Support Group uses in terms of their exposure index -- you're saying "No way"?

CHAIRMAN SHEPARD: That isn't answering my question.

MR. BANGERT: Generally, I think we're willing to do that, but we want to move ahead in some other areas that haven't been touched on, but we're looking into that question.

CHAIRMAN SHEPARD: My concern is the impression is created by that study that there is a higher risk of developing soft tissue sarcoma as a result of service in Vietnam, and tht is not found in some other studies.

In one study in which we did what I have asked, we found that two of the three individuals who are classified as having been in Vietnam did not, in fact, serve in Vietnam. I am just wondering -- it seems to me that that is a very key element when you're creating the impression that service in Vietnam appears -- does increase the risk of developing soft tissue sarcoma, that you pin down the question of service in Vietnam.

MR. BANGERT: Our criteria was extremely strict as mandated by my Medical/Scientific Advisory Board and we could redouble our efforts, and I have to bring that back to my board. The criteria we used for our mortality study was to determine Vietnam service through the Commonwealth's Department of Military Records, formerly called War Records, but they changed... We're getting very sensitive.

We require a DD-214 showing Vietnam theater of Vietnam service on the DD-214. The commonwealth would not issue a Vietnam Service bonus check for Massachusetts veterans for $300, and that was extremely accurate in 95 percent of those cases which we checked.

We estimate that it's totally accurate. We estimate that in Massachusetts the range of 90 to 95 percent of the Vietnam veterans in Massachusetts who participated in the bonus program are valid, and you ought to know the guy that runs War Records in Massachusetts.

If you don't have a DD-214 that says Vietnam service, you didn't get your $300 check, and we used that data base. If they were not on that

bonus list of having received the $300, they didn't or weren't counted as Vietnam veterans by our criteria.

CHAIRMAN SHEPARD: My point is that the DD-214 is not the definitive document from which one validates Vietnam service.

MR. CONROY: This is the problem I had, Dr. Shepard, as you know, in West Virginia.

We went through every one of those DD-214s. The problem is and we were cognizant of it, and I am sure you are, too, Joe, there were people in Thailand and there were people in Laos that got Vietnam service and Vietnam campaign medals and there's no way to differentiate that just by looking at the 214.

Consequently, as Barclay was saying, we went back and we asked Dick Christian to go through and look at our three soft tissue sarcomas and we found one had been in Thailand and one had been in a ship off the Gulf there in Vietnam and one was in the infantry whom Dick Christian thought was probably exposed to Agent Orange.

Without going back --

MR. BANGERT: There are some contradictions, but I would like to add another controversy, not a controversy per se, but there was a recent CHECO report that was declassified that mentioned that there was Agent

Orange operations in Laos from '65 through '69 so that's another crowd of exposed to Agent Orange. You know, unfortunately, they didn't hand out Laotian and Cambodian campagin medals, and if they did, a lot of us might have a little bit more ribbons on our chest. It is a problem, however, and we're willing to try to resolve it but the problem with us is that these veterans in question are deceased Vietnam veterans, 840 of them, and we have to be very sensitive about contacting those families and asking them: "Will you let us go back and do a Standard Form 180?"

CHAIRMAN SHEPARD: You don't have to contact the families. This can be done by a record search.

MR. BANGERT: We'll talk to you about it, okay?

CHAIRMAN SHEPARD: Okay. Thank you very much. I would like now to ask members of the committee if they would provide comments on the study in terms of what or how you view the applicability of this to solving the question or shedding more light on the question on the risk of exposure.

My concern is, as was indicated, that there is a self-selecting group, and I'd be curious to know what your recommendations might be to the State of Massachusetts regarding its further applicability to our concerns.

Okay, now let's see if we can wind up our agenda.

We'll quickly go around the table and ask if there are members of the committee who would like to further address the concerns of Vietnam veterans and their service organization that they represent.

MR. SNYDER: Briefly, for the Vietnam Veterans of America, I know that at these meetings or the VA typically generally does not mention the Agent Orange law suit, the class action suit that was brought and just so that we know the status of that let me comment briefly about it.

I checked with the special masters' office yesterday to confirm the status of things with that suit. That is the suit that was settled for $180 million that is in a fund earning interest that has to be decided finally how it was to be distributed.

Approximately $150 million of that is to go out in payments to individual veterans; however, prior to that distribution, there has to be a payment application form developed and that's in the stage of being -- a contractor being selected to develop that form. The form is expected to be distributed later this year and checks finally to be written early in 1987 which is about two months beyond what the last court paper suggested that the timetable would be which was November 29th.

In terms of the other $30 million that's available of that fund that is in the -- I guess it's actually $145 and

$40 million but there's a fund -- part of that settlement fund is for funding veterans organizations to provide services or other organizations to provide services to the class, those persons who were in Vietnam and to their families.

The criteria for who would be able to submit requests for funding through that Foundation have not been established yet. There's no real timetable for when that will happen.

There will be a Board of Directors of that foundation and those members haven't been selected yet either. Of course, as a caveat to all of this on April 9th and 10th, the Second Circuit Court of Appeals in New York considered appeals that had been brought to the settlement, and there's no outcome yet from the Second Circuit Court of Appeals, let alone any appeal beyond that, and all of this check writing or anything else can be contingent upon the final outcome of the court case.

That just briefly as to the status of that law suit. We also as an organization continue to have fairly major concerns about the regulations that are currently in place relating to the compensation program. I raised with Dr. Mars as I do each meeting, the numbers of persons who receive compensation from the VA, that the VA officially recognizes were due to exposure to Agent Orange.

We're concerned that perhaps in part the regulations

that the Agency uses and the guidance that has to its adjudicators, may be partly to contribute -- partly at fault in leading to their being, as near as I can tell, zero officially connect or service-connected persons who get compensation due to exposure to Agent Orange.

The GAO report we mentioned earlier, I think later we'll recommend perhaps that it be on our agenda for the next meeting to go through the recommendations and the problems that were raised with the GAO report.

I guess then just to comment that the Center for Disease Control Study that we continued to have concerns about that as an organization and we'll continue to monitor those developments.

I think that is the status of what we have had -- the Vietnam Veterans of America are working on currently.

CHAIRMAN SHEPARD: Thank you, Keith. Any questions of Keith?

Okay. Yes?

MR. WALKUP: Real quickly I'd like to make my semi-annual recommendation that the Committee devote at least half of its agenda each time to considering service issues and information delivery issues to the veterans and that we attempt to focus also on research, recognizing that that is important but at least equally are services to veterans. Specifically, without the time today obviously, I'd like to

recommend at our next meeting we have an opportunity to review the GAO report and have presentations by VA personnel about actions taken by the Veterans Administration to address those problems and whatever other problems there might be and what organizations can do to help overcome the problems that are there and to solicit advice from committee about which of the recommendations in the GAO report are agreed with and which VA responses to the GAO report we agree with and don't agree with.

I'd also like to note that when this meeting was being set up that I had specifically asked that again, that we address those issues, and I really think it's important that those kinds of things get included. Those are -- four out of our five mandates in our mission statement have to do with services to veterans.

The first two aren't about service organizations. They're about things that are going on in the Veterans Administration. We can give advice on those and I think we should.

CHAIRMAN SHEPARD: I appreciate that, and you're absolutely right.

We will circulate the GAO report and ask for comments from each of the members of the committee on that report -- either agree or disagree with the agency's response to the report so that we can have that as a matter

of record.

DR. KAHN: Has the agency formulated a response to the report?

CHAIRMAN SHEPARD: Excuse me?

DR. KAHN: You have formulated a response to that report?

CHAIRMAN SHEPARD: Our responses are part of the report.

DR. KAHN: They are.

CHAIRMAN SHEPARD: That's the standard portion of the report. The report goes out and then before it's finally published, the agency's comments are included.

GEN. WELLS: That brings up something I wasn't going to talk about let me beat a dead horse anyway. It seems like at the meeting of our last committee from looking at the GAO report, at least the preliminary report was under review by the Veterans Administration, and the response to the report by the Veterans Administration occurred in late October, I believe. We met October 22nd.

I don't know what the protocols are but it would seem that that might be an appropriate thing for this committee to be involved in, to review a GAO report on the topic that we're involved in and to make some

recommendations to the Administrator about what responses we feel are appropriate.

As those things come up in the future, at least I hope that that would be considered, I'd like to reinforce and recommend as well as being given copies of this and an opportunity to write back to you that we have this on the agenda for next time and an opportunity to respond to it.

CHAIRMAN SHEPARD: Fine. Thank you.

Any other comments? Yes?

MR. CONROY: Yes, Dr. Shepard. Being cognizant of the time constraints we're under, I just wanted to briefly indicate to the committee that myself and my staff are presently undertaking a comprehensive survey of all states that have ongoing Agent Orange efforts.

West Virginia became the 12th state approximately four years ago to initiate a program of our own and in that interim programs have come and gone by the wayside. It seems like every week we receive an inquiry from a new state that is interested in developing or has been mandated to start up a program, so I would hope that at our next meeting we'll be able to report on a comprehensive basis, what all those states are doing.

In terms of the one thing that you mentioned, information delivery services, there is something that I wanted to make the committee and the audience aware of because I know that a number of Vietnam veterans currently have access

to their own personal computers and/or a modem. There is a subscription informational service known as CompuServe that provides a regular update on the Agent Orange issue.

For those of you who have access to it, I believe, it costs $6 an hour in non-prime time hours and as I said, any veteran with a PC and a modem can log onto the CompuServe system and for that price of $6 an hour be presented with an Agent Orange menu.

Some of the topics on that menu are regular updates on the status of the law suit. A veteran can leave questions regarding the CDC, epidemiological study. There is also an extensive abstract and bibliography that the veteran can access and I just thought that a service such as this might be of interest to veterans with a PC.

CHAIRMAN SHEPARD: Do you know who manages that?

MR. CONROY: I believe the VVA. There was an issue of On-line that had -- Bobby Muller was, I guess, involved in the startup of it.

MR. SNYDER: There was a time that I was providing answers to some of the questions that were being raised on that computer network. I have not been doing that probably in the past eight months. I am not sure who now prepares the answers or provides the material that goes into it.

I don't believe it's currently a -- certainly not an official function of VVA. People within our organization grew

up in Ohio, where CompuServe is based and I'm certain have some continued relations with people that are at CompuServe, but I don't believe it is as in the official capacity that we're providing that information.

CHAIRMAN SHEPARD: Okay. Thank you very much.

GEN. WELLS: I would just like to say one thing not about this, but I just want to say again to the committee, because I'm very sensitive every time that I hear there were only 7500 women, they are Vietnam veterans. Their concerns are the same as the men Vietnam veterans, and they should have equal concern given by the VA and by any studies that are done.

CHAIRMAN SHEPARD: Thank you. I hope we will address those concerns in the coming legislation and the studies.

We will report, by the way, to the members of the Committee by mail as the progress of that study continues. The RFP, as I mentioned earlier, is due to be published by the first of July and we'll circulate copies of the notice to the members of committee for those who don't read the Commerce Business Daily, and also I'll keep you informed in terms of such milestones as when the contract or the design of the study will be anticipated and the OTA review is mandated, and issues of that nature.

MR. SNYDER: Is this the appropriate point to

pick up on our pre-break discussions or did you want to go through the forum --

CHAIRMAN SHEPARD: I just want to see if there are any other members of the committee who had other issues that they wanted to bring up, particularly with regard to concerns of service organizations and Vietnam veterans.

Okay. Why don't we go ahead with them.

MR. SNYDER: Well, if I might, I have made some notes of three recommendations that I have been writing to include, I guess, the fourth item as some agenda items that we've mentioned here that I'd like to leave with you.

If I could read these things to the rest of us and see if we can concur then if I might do that briefly. Number one is we discussed before, we would ask that you attend the subpanel meeting that the Agent Orange Working Group, as you have said you would be anyway, but specifically express the concerns of veterans, the epidemiological study go forward promptly, that any delay or suspension not be open-ended.

I am not sure if we want to add specifics to that, couch it in different language. Does anyone have any suggestions for that point?

Yes? Keith?

DR. KAHN: I am not sure that we should make a recommendation at this point that should go forward. I am not at all convinced that that should be the case.

I think that that question is what should be examined as to whether it should go forward, and if so, in what form.

I have grave reservations that even if a good exposure index could be developed, that the study would be successful in a scientific sense in any case. I think that it is so badly flawed in its design that even with an exposure index, I have serious doubts as to whether it is scientifically adequate, so I would hesitate to see us recommend that the study go forward.

I'd rather reformulate what you said along the lines of the question of whether it should go forward, should be examined rigorously, and we should take part in that examination.

MR. SNYDER: Part of what I had before here of the agenda was to look at the protocol generally at the very next session.

Number two item here was --

CHAIRMAN SHEPARD: Excuse me. He wanted to comment on --

MR. SNYDER: Well, it's related and perhaps, will answer that. Maybe then we don't want to say you don't go forward, but we give you the charge of getting whatever the recommendation is so we can meet on it properly.

That was mostly what number two recommendation was. Dr. FitzGerald?

DR. FITZGERALD: I wanted to express the same opinion that Peter did concerning this. I am not so much concerned about it going immediately forward as to be sure that it is -- that the objection that has been raised is a valid one, and how then to react to it in terms of what or how it would go forward subsequently.

MR. SNYDER: Would that be answered with a cap on the length of time that somebody is going to be deliberating on how long it should be suspended and what else to be done? My concern is that if it doesn't go forward, if we don't urge that it go forward, that's fine but let's back that up by saying let's not deliberate too long, and let's not deliberate for six more years before there's some forward movement on it or some disposition.

DR. FITZGERALD: I understand what you're trying to say. I am concerned about that it serves the purpose of the veteran, and, indeed, if a valid objection has been raised, as to whether it is going to serve those purposes, I think that has to be examined and looked at before we make a blank recommendation that the study go forward regardless.

MR. SNYDER: How do we build ourselves into having an opportunity to look at those recommendations?

MR. CARRA: How about a prompt resolution of the issue -- how you might want to operationalize prompt; two weeks, three weeks? I think there's one other element.

DR. HODDER: Just a suggestion is simply, since Barclay is going to be there on the 17th, perhaps we could ask Barclay to notify us what the decision was. I don't think we're realistically in a position to dictate a cap or anything else.

What we can do is ask for the decision or what information came out so we can quickly respond if necessary.

MR. SNYDER: Yeah, I understand the limits of what we can dictate or recommend or suggest realistically. Maybe then we should simply ask that you express the concerns that we've raised, in that we're especially concerned that although we want the study that is going to be valid, is going to produce results that scientifically are valid, we're very concerned that any delays or suspensions to consider all of that not be open-ended and that, in fact, there be as prompt a resolution whether it's 31 days or six months or something down the road as possible.

Some more general language along those lines rather than promptly go forward.

MR. WALKUP: I think an underlying concern that we're talking about there is more about the questions that that study was intended to address. If the study is flawed, it's not going to answer those questions, so be it. Let's move on to what we need -- but I think what you're looking for is more that if we're going to dump that study, let's get some

alternatives or let's specify how the other studies that have come on line since then address the questions that are being looked at there.

Does that match what you were talking about, Keith?

MR. SNYDER: Yes, I think so. Matter of putting it in fine language .

Let me, if I might --

GEN. WELLS: Would you mind reading number one, please.

MR. SNYDER: One. The first portion is the same. Sure it's in the subcommittee -- expressed concerns of veterans in the epidemiological study go forward if it can properly address the issues mandated by Congress, and then any delay or suspension not be open-ended.

Okay, we'll put it all in favor. Let's do it that way. All in favor?

DR. KAHN: I'd like to offer an amendment, an additional clause that, and alternative studies or sources of information be identified to address the questions of the original study.

MR. SNYDER: Alternative sources of information be developed.

MR. WALKUP: Address the questions of the original study, mandated study.

MR. SNYDER: That's a second "and." First part stays the same and add "and that the alternative sources of information be developed to address the original mandated study." All as part of recommendation one?

CHAIRMAN SHEPARD: I wonder in the interest of time if I might ask Keith to take the lead with you and Peter's help, and General Wells if you care to, to sit down and write these out rather than for us to sit here waiting for -- I am happy to sit here but --

MR. SNYDER: No, I agree.

CHAIRMAN SHEPARD: I think it might be a good idea for maybe a subcommittee of those individuals to sit down and formulate these. In fact, you can give it to us in handwriting.

MR. SNYDER: Well, there are only two more I've written down here that it might not need to be amended or rewritten. Let's go to those briefly and see, and if not then we can all get out of here.

"That the text of any report from the Agent Orange Working Group subpanel be circulated to committee members promptly and that within two weeks a special meeting of the committee be held to consider that report's recommendations, that knowledgeable people be available to the committee to answer our questions and hear our comments."

CHAIRMAN SHEPARD: Realistically, it's a little

difficult to convene this committee because there are certain rules that govern the operation of a federally chartered --

MR. SNYDER: Advisory Committee. We're not --

CHAIRMAN SHEPARD: What I would propose as an alternative, that we circulate those by correspondence and then ask the committee members to respond either in writing or by phone call and we'll collate the responses.

GEN. WELLS: Could you have a subcommittee of people perhaps in this area, and we could do that, and then you could submit it. Then we could get it together and rewrite it as the recommendations and resubmit.

CHAIRMAN SHEPARD: That's an excellent suggestion.

GEN. WELLS: I agree with what you're saying unless it's for the rewording of the --

MR. SNYDER: Special meeting of a subcommittee of the committee.

MR. WALKUP: Could we have a conference call without offending the statute?

MR. SNYDER: I should think so as long as we're not --

CHAIRMAN SHEPARD: Yes, I think that's possible, and we'll get legal advice on that.

DR. KAHN: We'll just do it.

MR. SNYDER: Yes, yes. I mean the principal focus there, I think, was that we not let a couple of months go by

before we actually get the text of whatever we can get out of them.

In following number three, that was more broadly to address kind of what we see as our mandate or what we want to do as a committee in the future and that this committee be provided information in advance in order that we can fairly perform the role of an advisory committee that advises the VA on the role it should take with regard to Agent Orange studies, medical services and compensation, and responses to GAO reports.

Is that acceptable?

DR. KAHN: Yes.

MR. SNYDER: So it's in writing? It's pencil. For an agenda we usually -- I don't know if we talked about that in the past, about what we'd like to see. Certainly again a review of the subpanel or if at that point full panel has considered the subpanel, I think we would like to be able to review whatever the status of that is and actually have someone from those panels that is knowledgeable to talk about that with us and hear again our concerns.

Number two, as Dr. Kahn has suggested, perhaps a review of the protocol generally and not simply the exposure index and with his background, I think that we'd be in a position to have the benefit of that and to walk through and here are the concerns that I think are being raised as to

the basis of the protocol.

Three, GAO report on the Agent Orange medical exams and Agent Orange registry as well as the medical service as a part of that as the medical services that are mandated, Section 102 of the Public Law 97-72. That's a part of the GAO report. Whether the services that are supposed to be provided and the priority of care in medical facilities are being met adequately, that would be within the discussion of the GAO report.

You had asked that we give you comments on the Massachusetts Study, so I think we should all be prepared to do that and have that as an agenda item. Finally, the general issue and solicitation from us of what we see as problems with delivery of services and not certainly, as you have had in the past, our opportunity to, as organizations, describe what we're doing a little bit but I think we should all look within our own organizations at questions that are being raised about individual VA facilities potentially, potentially specific programs that I think were suggested were not being as helpful as other VA offices and be prepared to talk and raise those.

That's what I would propose as an agenda for another meeting. I guess kind of a broad request that you do what you can to encourage the Administrator to have us have another meeting, if not one, a few more.

DR. KAHN: Is there some doubt of that?

MR. SNYDER: I think that the Administrator left it open whether there would be -- this committee would continue. He appears to be concerned that there is an overlap. He said overlap is okay to a certain extent. I think politically that we all need to be conscious of the fact that the Environmental Hazards Committee is largely scientific.

Certainly there are politics and scientists in science. There is much less in terms of voting power of individual veterans or veterans organizations on that committee. There are a couple of veterans that sit on the committee but in terms of numbers they're outweighed.

I think that this committee has a little greater veterans representation and hopefully we would continue to exist, provide that kind of input which in the absence of this committee there is no formal mechanism to provide it.

I would hope that our committee will continue, but I think the Administrator was leaving it open as to whether -- he would not commit himself to revalidating -- use the term "validation" of previous years worth of committee meetings. He did not say that he did, he would, so I think there is some question as to that.

If there are recommendations on how to encourage that, either from yourself or wherever else, we'd like to hear it I think.

CHAIRMAN SHEPARD: Any other recommendations or additions to Keith's list of recommendations?

I know when we've announced meetings in the past, announced the date, even before we put the agenda together, we have asked members of the committee to submit agenda items.

We'll redouble that effort. I know we have on occasion done it in the past. Whether we did it before this meeting I can't remember. We certainly will do that in the future.

MR. SNYDER: Well, certainly we share the responsibility or fault or whatever in having an agenda that turns out to answer our questions. I know that you asked me -- Don called and asked for agenda items, and I at that point didn't give it much thought.

That was a few weeks back and should have, and certainly in the future I'll make every effort to either be prepared to anticipate your phone call or certainly respond quickly in writing with some items.

CHAIRMAN SHEPARD: I apologize for the fact that -- in the sense I apologize for having had so much of the agenda devoted to scientific efforts, but I think it's terribly important that when we're dealing with an issue like this to have some scientific light shed on it, and it's very important to bring

the committee up to date in terms of what's going on and what the expectations are so that we'll have that as part of your advising process, part of your data base, so to speak, when you do advise and make recommendations.

GEN. WELLS: Dr. Shepard, this is my second meeting. Do we never send an advisory report after each meeting? Is not a report -- not just the minutes of the meeting, but is there not a small two-page advisory report sent to the Administrator as to what we discussed?

CHAIRMAN SHEPARD: A summary of the --

GEN. WELLS: Yes, and I don't mean that you do it because I understand your problem, but certainly one or two or three people from this Committee could come in with those things, recommend an agenda for the next time, recommendations of our concerns that goes to the Administrator.

Now maybe that is out of order for this, but it seems to me on any advisory committee I've been on, we have written a report and then --

CHAIRMAN SHEPARD: I would be delighted if it were to happen. It would certainly simplify my role in trying to sift through all of the proceedings and cut out those things which --

DR. FITZGERALD: I think that what has happened in the past is that this has been more of an educational meeting rather than an advisory meeting, and what has been brought

forth here today is the needs of an organization to act in an advisory capacity and how to go about doing that.

I think this has been an appropriate subject that has been brought up and I think the recommendation as I see it right now is to cut down on the amount of time that is spent in reports and to function more as an advisory committee.

CHAIRMAN SHEPARD: I would certainly concur.

DR. FITZGERALD: If, indeed, we'd need some scientific background we can ask for it rather than just sitting here every time to hear anybody who has anything that they want to talk about as far as Agent Orange is concerned, whether it's valid, whether it has any scientific validity or not, has been fed to us rather than acting as an advisor to them.

CHAIRMAN SHEPARD: Good point.

MR. SNYDER: Does somebody has recommendations as to the mechanics for preparing an advisory report? I would be interested in helping with something like that, something that is --

GEN. WELLS: I can only tell you I don't know where you people come from and maybe I should, but if there are two or three people that are willing because it's time consuming. If you are willing, usually they try to get people that can get together. Two or three people are assigned. Usually three to write the report.

People have input to it, but then that report is

written and it goes out to the rest of committees or to the rest of the members, and they have -- and then it's finalized and submitted to Dr. Shepard, I suppose for your final review also. Then it goes to the Administrator.

CHAIRMAN SHEPARD: Since you made that excellent suggestion, General Wells --

MR. SNYDER: And you're in the area, right?

(Laughter.)

GEN. WELLS: I would be glad to assist in that.

CHAIRMAN SHEPARD: Would you take the lead in helping to summarize the report.

GEN. WELLS: Certainly. I would like to know the people that would be interested.

CHAIRMAN SHEPARD: Our staff would be helpful, be happy to help.

GEN. WELLS: But I would need two other people that would be interested.

MR. SNYDER: I would help you with that.

CHAIRMAN SHEPARD: Keith Snyder and anyone else in the Washington area?

GEN. WELLS: Who else here in the Washington area?

CHAIRMAN SHEPARD: You can get together by phone. Hugh, I am sure, would be happy to consult by telephone.

MR. WALKUP: Or you're welcome to come visit Seattle. It's beautiful.

GEN. WELLS: But I will tell you that it takes time and you have to be willing to give your time.

DR. HODDER: I'd be willing to consult by phone.

DR. KAHN: I also -- it's a little hard to get down here to --

CHAIRMAN SHEPARD: That's a very good suggestion and I appreciate that.

MR. SNYDER: Then it sounds like the two of you will end up being stuck with it and if you need to get --

CHAIRMAN SHEPARD: There are other people who had to leave.

GEN. WELLS: I would like three people and I think we should next time, quite frankly, divide up into subgroups and divide up into two and look at some things and report back another time.

I think we might perhaps reach --

MR. SNYDER: We may have an abbreviated report the first time. Expand things down the road.

CHAIRMAN SHEPARD: I'll make myself available to you.

GEN. WELLS: We would meet here, and so if you could get us an office.

CHAIRMAN SHEPARD: Are there any other points from the committee?

I would like to take a few minutes in keeping with

our tradition of soliciting questions from members of the audience who have not spoken to date.

Yes? Would you approach the microphone and identify yourself?

AUDIENCE COMMENTS

MR. FALK: Yes, I am Allen Falk. I'm Chairman of the New Jersey Agent Orange Commission. It's been a very interesting meeting compared to a number I've attended in the past. I think what happened today is extremely important and I think on behalf of the Vietnam veterans, it's in their best interest, and I congratulate the committee and the members of the committee that felt that it is the responsibility of this committee not only to sit here and accept the information and be educated, but to, in fact, put the input back to the director.

We had come down with an entire delegation, specifically to discuss the issue of the CDC Agent Orange study, and we brought Dr. Paul Scipione who is a consultant to the Commission, an expert in the field of surveying techniques and brought Charlie Krause who is the elected member of the veterans who have been chosen to go through our research project and, of course, would have the input of those who are being surveyed and questioned, and we felt the CDC study was quite important.

We are still disappointed that we weren't able to get the full discussion, and we think as Dr. Kahn has

indicated the whole question of the study should be brought forth. There's a lot of money involved with budgetary restraints. There are a lot of other projects that right now are going unfunded and we think it's important that the resources be carefully studied.

We've come down here for many years now and certainly we have no complaints about the presentation that have been made, and I think we were -- I wasn't here for all of them, but I think we were all impressed by the Ranch Hand presentation and the twin study; however, in effect they're packaged so well that we really don't have to come down here. We assume that the personnel and new materials could, by invitation, if we paid the expense, at some point be brought up to New Jersey so the reason we feel this committee is here is the reverse, that not only to get the information out to us and to Vietnam veteran community but it's the only, as Mr. Snyder pointed out, it's really the only opportunity for Vietnam veterans to get back their feelings and their input.

As you pointed out, Barclay, I think there is clearly a distinction between this and the Environmental Hazards committees and that the -- there should not really be any question of overlap. This is where the issue should be brought for discussion and advice and when the questions or answer is resolved clearly enough for that committee, then

to move forward with the question of presumptive ratings and they can pick up from there but certainly not to the exclusion of this committee.

The only problem I see today is perhaps you were too successful, so successful your existence may again be in question.

CHAIRMAN SHEPARD: Thank you, Allen. Appreciate your coming down.

Are there any questions or comments from the floor?

Mr. Bangert?

MR. BANGERT: I just have a short one. This is a very important labor that people have been struggling for about eight or nine years now, and it is all coming to a head. I think we have to do something, somehow, because there is a perception, a common perception out in the field; especially in Massachusetts among its Vietnam veterans that trusting the VA and the Air Force to conduct objective health studies on Vietnam veterans exposed to Agent Orange is tantamount to allowing Dracula to guard the bloodbank. I have thought of my new variation of the quote referenced earlier regarding Col. Wolfe's plagiarism of Carl Sagan's quote: "Absence of evidence is not necessarily evidence of absence." The feeling in the field is what is operating here is: "Presence of evidence is not necessarily evidence of presence". And this is my concern. Maybe it's a psychological concern, but I don't believe that the people out in the field, specifically in Massachusetts, are, I do see them every day, that these people are hysterical. I see them everyday, and many of them are gravely ill and not hysterical.

These are as major concerns among the women Vietnam

veterans in Massachusetts and we're moving ahead. We would like to move in cooperation but if we can't, then we are just going to move ahead, and I would like to thank people because I think that today's meeting was a watershed event, and I look forward to more meetings, and we in Massachusetts would like to come back and participate.

In the meantime we are going to roll up our sleeves and go back and do the research and the testing we think we have to do for our veterans because we in Massachusetts do believe they are number one.

Thank you.

CHAIRMAN SHEPARD: Thank you very much, Joe. I would concur in that wholeheartedly. I think that at the break Dr. FitzGerald mentioned something to me which I think all of us share, and that is essentially as follows: that our first area of concern is: are Vietnam veterans at a higher risk of having health problems? In other words are Vietnam veterans sicker than non-Vietnam veterans or sicker than one would normally expect in this population group of veterans.

If they are, then let's find out what's the cause, if we can, of their illness. I think that whether or not it's due to Agent Orange is an interesting question, but I think the first and more fundamental question is there a health problem in the Vietnam veterans. I think that the Vietnam experience study should not be regarded as a quick and easy answer.

It's a very fundamental question, and I put in that same category a large mortality study that Dr. Kang reported on today. That's a milestone study. It won't tell us very much, at least not now, or preliminarily about Agent Orange.

It will answer much more fundamental question: are Vietnam veterans dying of different diseases than their counterparts who didn't go to Vietnam.

If we find that there doesn't seem to be, and I am not suggesting that we focus on just one study, but if the consortium of studies dealing with the broader question of Vietnam service seem to lead us to the conclusion that there is a different pattern of disease among Vietnam veterans, then we should take the step to find out why.

Is there something we should do about it? Maybe it is too late. If they're to be compensated, they're being compensated whether they served in Vietnam or not. Service connection is not dependent on location of service. It is not dependent on time of service, nor is it dependent on cause of illness.

It's dependent on presence of illness. I think those are the fundamental questions that we need to address ourselves to. If, in fact, it seems that there are different patterns of disease or a higher rate of disease or that sort of thing, then let us address as a scientific curiosity the cause of those diseases. As you know, it's often very

difficult to ascribe causation to many diseases. Some diseases don't have any known causes.

I throw that thought out.

MR. WILSON: Are we still with public comment here?

CHAIRMAN SHEPARD: Yes.

MR. WILSON: Okay. Wayne Wilson. I did want to observe this morning at the onset when the Administrator was here what I perceive to be kind of a walk around the question that Mr. Snyder from the Vietnam Veterans of America asked.

I have not asked him, but I would suggest that I am not satisfied with the response that you were given to your question about how many claims have been granted. I am not so sure that I accept kind of the simple views that the compensation guy gave us.

Let me also say that Chuck mentioned something about -- I found out about this GAO study, like Dr. Kahn and some others in here, yesterday. I read Stars and Stripes. I would not say that that's a publication that a lot of Vietnam veterans read.

I think that we professional veteran people may read it on occasion and let me just say that I commend Vietnam Veterans of America because some of the other veteran organizations, the Veterans of Foreign Wars, for example,

recently mailed to my home an update on Agent Orange that was really not an update on Agent Orange.

The only veteran organization in this country as far as I can tell that really provided me with an update on Agent Orange and an update on where this CDC business was was Mr. Snyder and Vietnam Veterans of America.

In fact, the Stars and Stripes, I believe, in March had an update on Agent Orange, exactly the same as that reported by the Veterans of Foreign Wars that made no mention at all of this situation which has been developing since the end of last year.

I am curious about where the VFW and Stars and Stripes got their update on Agent Orange. In the old days I would have suspected the VA of being a party to that, but I won't go that far.

The fact is that the communications is just going down hill over a period of time, and I just have to stand here and be critical of the lack of communication, particularly with state commissions that represent large numbers of veterans and obviously members of the panel here.

We shouldn't have to come here and learn the day before about information that has been available for months, and so quite frankly we're going to get back on the train, and I can't say -- if this is a watershed, I don't

know, Joe. To me it is a little bit of the same old -- I've danced this tune before, and I always go home from these things a little bit discouraged, not for myself but for Vietnam veterans because I'm not sure that we've moved ahead anywhere, so as my boss said, we don't know what's going to happen here for the future.

CHAIRMAN SHEPARD: Thank you, Wayne. Any other comments, questions?

If not, then I will declare the meeting closed, and thank you all for your attendance and forebearance.

(Whereupon, at 1:10 p.m., the meeting was concluded.)

Slides Presented by Han K. Kang, Dr.P.H., Office of Environmental Epidemiology, Veterans Administration

Status of VA Research Efforts

TABLE 1

THE STUDY SAMPLE - MILITARY RECORDS SEARCH

	NUMBER	PERCENT
ALL NAMES SELECTED	75617	100.0%
RECORDS NOT FOUND	1032	1.4%
RECORDS FOUND, INELIGIBLE	22300	29.5%
RECORDS FOUND, ELIGIBLE	52285	69.1%

Ineligibility was based on
a)wrong branch of service
b)wrong time of service

TABLE 2

RESULT OF DEATH CERTIFICATE SEARCH

	NUMBER	PERCENT
ELIGIBLE CASES	52285	100.0%
NO CAUSE OF DEATH	862	1.6%
CODED CAUSE OF DEATH	51423	98.4%

TABLE 3

BRANCH AND PLACE OF SERVICE

SOUTHEAST ASIA SERVICE

	YES	NO	TOTAL
ARMY	20128	22905	43033
MARINE CORPS	4608	3782	8390
TOTALS	24736	26687	51423

TABLE 4

PLACE OF SERVICE BY RACE

SOUTHEAST ASIA SERVICE

	YES	NO	TOTAL
WHITE	19577	21336	40913
BLACK	4490	4609	9099
OTHER	669	742	1441
TOTAL	24736	26687	51423

TABLE 5

PLACE OF SERVICE AND TYPE OF DISCHARGE

	SOUTHEAST ASIA SERVICE		
	YES	NO	TOTAL
HONORABLE	22538	22363	44901
GENERAL	1394	2637	4031
NOT HONORABLE	779	1646	2425
UNKNOWN	25	41	66
TOTAL	24736	26687	51423

STUDIES ON SOFT-TISSUE SARCOMA AND PHENOXY HERBICIDES OR MILITARY SERVICE IN VIETNAM

Positive Studies		Non-positive Studies	
Authors	Study Type	Authors	Study Type
Hardell (1977)	Case Report	Smith et al. (1982)	Case-control Study
		Smith et al. (1984)	Case-control Study
Hardell & Sandstrom (1979)	Case-control Study	Riikimaki (1982)	Cohort Mortality
Eriksson, Hardell, et. al. (1981)	Case-control Study	Ott et al. (1980)	Cohort Mortality
Honchar & Halprin (1981)	Case Report	Cook et al. (1980)	Cohort Mortality
Cook (1981)	Case Report	Zack & Suskind (1980)	Cohort Mortality
Moses & Selikoff (1981)	Case Report	Zack & Gaffey (1983)	Cohort Mortality
Johnson et al. (1981)	Case Report	University of Sidney (1984)	Cohort Mortality
Sarma & Jacobs (1981)	Case Report	Greenwald et al. (1984)	Case-control Study
		US Air Force (1983, 1985)	Cohort Mortality
Massachusetts State (1985)	PMR	Wisconsin State (1985)	PMR
		New York (1985)	PMR

A. Host Factors

1. Familial Clustering
2. Immunologic Defects
3. Lymphedema

B. Environmental Factors

1. Radiation
2. Chemicals
   a. inorganic arsenic
   b. vinyl chloride
   c. phenoxy herbicides, chlorophenols
   d. asbestos
3. Viruses
4. Trauma

VA/APIP CASE CONTROL STUDY OF SOFT TISSUE SARCOMA STATUS

	Cases	Controls
Number Expected	277	811
Number Located	231	672
Number Remaining	46	139
Number Completed Interview	217	601
Percent Interviewed	78%	74%
Reponse Rate	94%	89%
Found Rate	83%	83%

DISTRIBUTION OF CASES AND CONTROLS
BY AGE, ACCESSION YEAR, HOSPITAL TYPE
AND RESPONDENT

	CASES (N=217)	CONTROLS (N=601)
Age at Accession		
Less than 25	30 (14%)	77 (13%)
26 - 35	165 (76%)	477 (79%)
36 or more	22 (10%)	47 (8%)
Accession Year		
1975 or earlier	37 (16%)	98 (16%)
1976 - 1977	64 (29%)	159 (26%)
1978 - 1979	73 (74%)	205 (34%)
1980 - or later	43 (20%)	139 (23%)
Type of Hospital		
Civilian	163 (75%)	432 (72%)
VA	26 (12%)	87 (14%)
Military	28 (13%)	82 (14%)
Respondent		
Subject	120 (55%)	528 (88%)
NOK	97 (45%)	73 (12%)

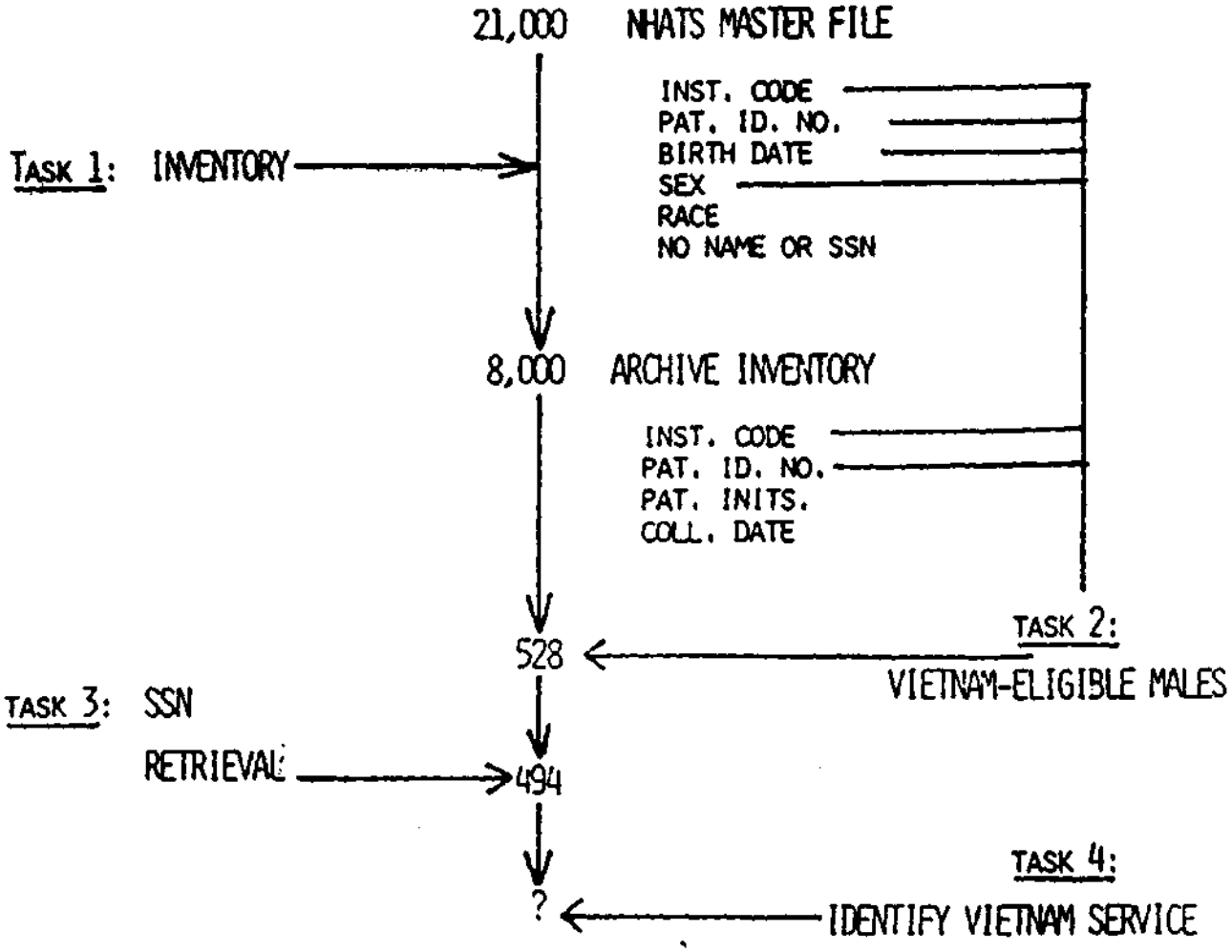
STUDY POWER WITH THREE CONTROLS PER CASE

	100 Cases R			200 Cases R			300 Cases R		
P_o	1.5	2	3	1.5	2	3	1.5	2	3
0.05	16	38	77	25	62	96	34	77	99
0.10	23	57	93	39	84	99	52	95	99
0.15	29	69	98	50	92	99	66	98	99

alpha = 0.05
R = relative risk
P_o = relative frequency of risk factor among controls in the target population

FIG. 2

INFORMATION RETRIEVAL



- DEFINE POTENTIAL VIETNAM VETERAN --MALE, BORN 1937-1952
- MATCH ARCHIVE INVENTORY WITH MASTER FILE TO OBTAIN POTENTIAL VIETNAM VETERANS
- CONTACT INSTITUTIONS TO OBTAIN SOCIAL SECURITY NUMBERS
- CHECK AGAINST VA AND DOD RECORDS TO DETERMINE VIETNAM SERVICE

VA/EPA RETROSPECTIVE STUDY OF
DIOXIN AND FURANS IN HUMAN
ADIPOSE TISSUE

	VIETNAM VETERANS	NON VIETNAM VETERANS	NON VETERANS	TOTAL
Identified	40	94	361	495
Selected	40	80	80*	200

* Matched to Vietnam veterans by birth year and death year

Estimated Number of Female Vietnam Veterans

Sources	Total Female Veterans	Female Vietnam Veterans
1980 Census	1,108,000	11,000*
1982 VA Survey	742,000	7,400*
Preliminary Army RDG	—	5,900
Preliminary CDC		7-7,500

*Assuming 1% of all female veterans served in Vietnam (VA 1985 Survey of female veterans).

Q. 10

Table II-6

PLACES SERVED BY PERIOD OF SERVICE

Q.: In which of these places did you serve while on active duty in the United States Armed Forces?

		Period of Service					
		Wartime				Peacetime	
Base	Total (3003) %	Any Wartime 2040 %	Vietnam 720 %	Korean 270 %	World War II 1107 %	Post Vietnam Only 694 %	Other Peacetime Only 253 %
United States only	72	73	66	66	76	64	90
Europe	18	16	21	19	15	26	6
North Africa	1	2	*	3	3	-	*
Vietnam	1	1	4	-	*	-	-
Laos or Cambodia	-	-	-	-	-	-	-
Thailand	*	*	*	*	-	-	-
South China Sea	*	1	1	1	*	*	-
China, Burma, India	*	*	*	*	1	-	-
Korea	2	2	5	5	1	4	-
Japan	3	4	5	12	3	3	2
South Pacific	4	5	4	5	7	2	*
Indian Ocean	*	-	-	-	-	*	-
Other	3	3	4	6	2	3	1

*Less than .5 percent.

WOMEN IN THE ARMED FORCES IN VIETNAM STUDY

AS OF 7 SEPTEMBER 84

STUDY

1. US ARMY

a. Army Nurse Corps: 3,739

b. Army Medical: 54

c. Medical Corps: 10

d. Army Medical Service Corps: 3

e. Veterinary Corps: 1

f. WAC Officers 204

g. WAC Enlisted: 664

Total Army: 4,675

Army Units Surveyed: 92

Army Units to be Surveyed: Approximately ___ More

2. US Navy. 423

3. US Marine Corps. 36

4. US Air Force 771

Total Armed Forces: 5,905

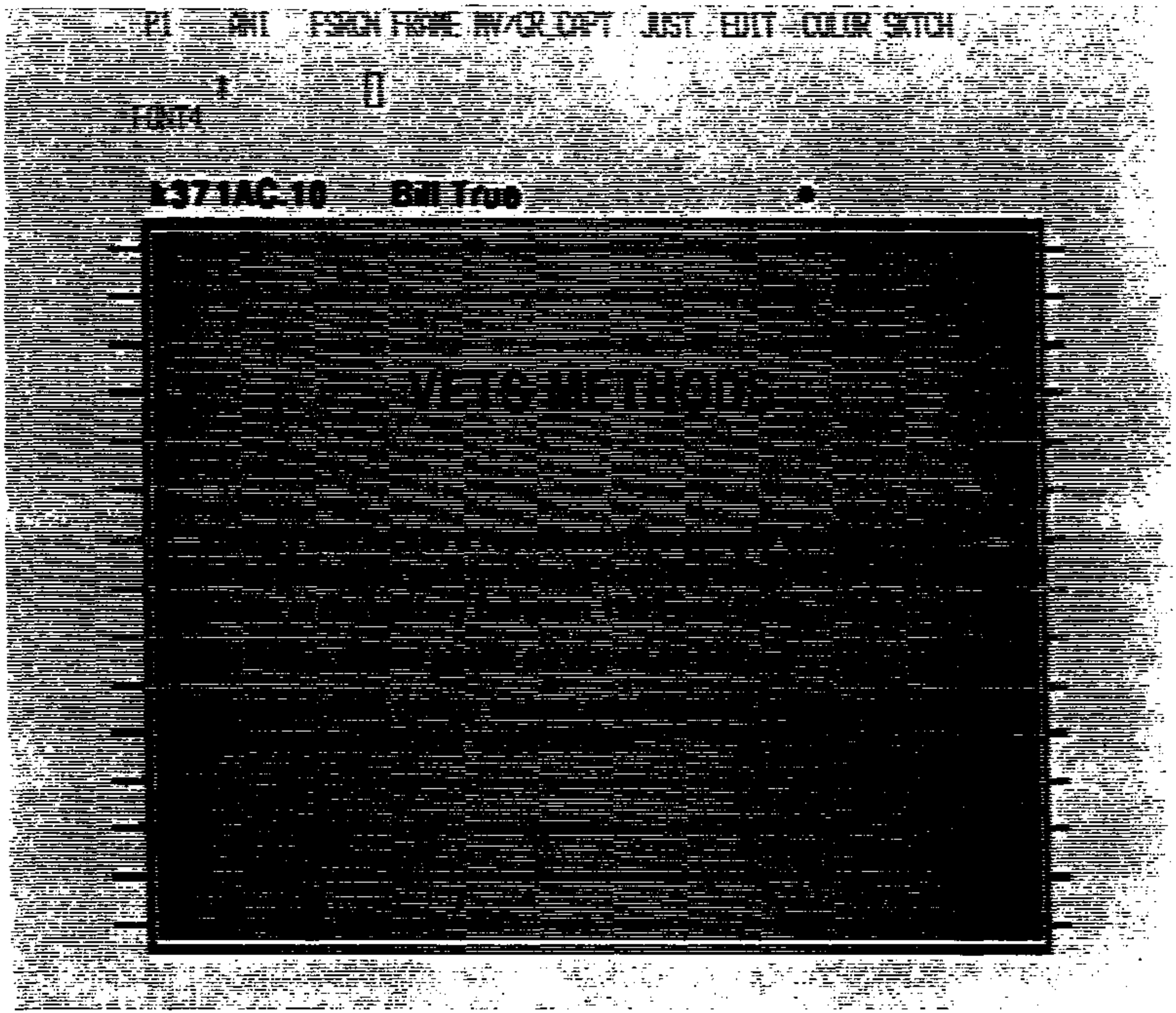
Slides Presented by William True, Ph.D., M.P.H., Veterans Administration Medical Center, St. Louis, MD

Vietnam Experience Twin Study

K304ac.03

RESEARCH OBJECTIVES

To determine the relationship between Vietnam service and the medical, psychological, and psychosocial aspects of health.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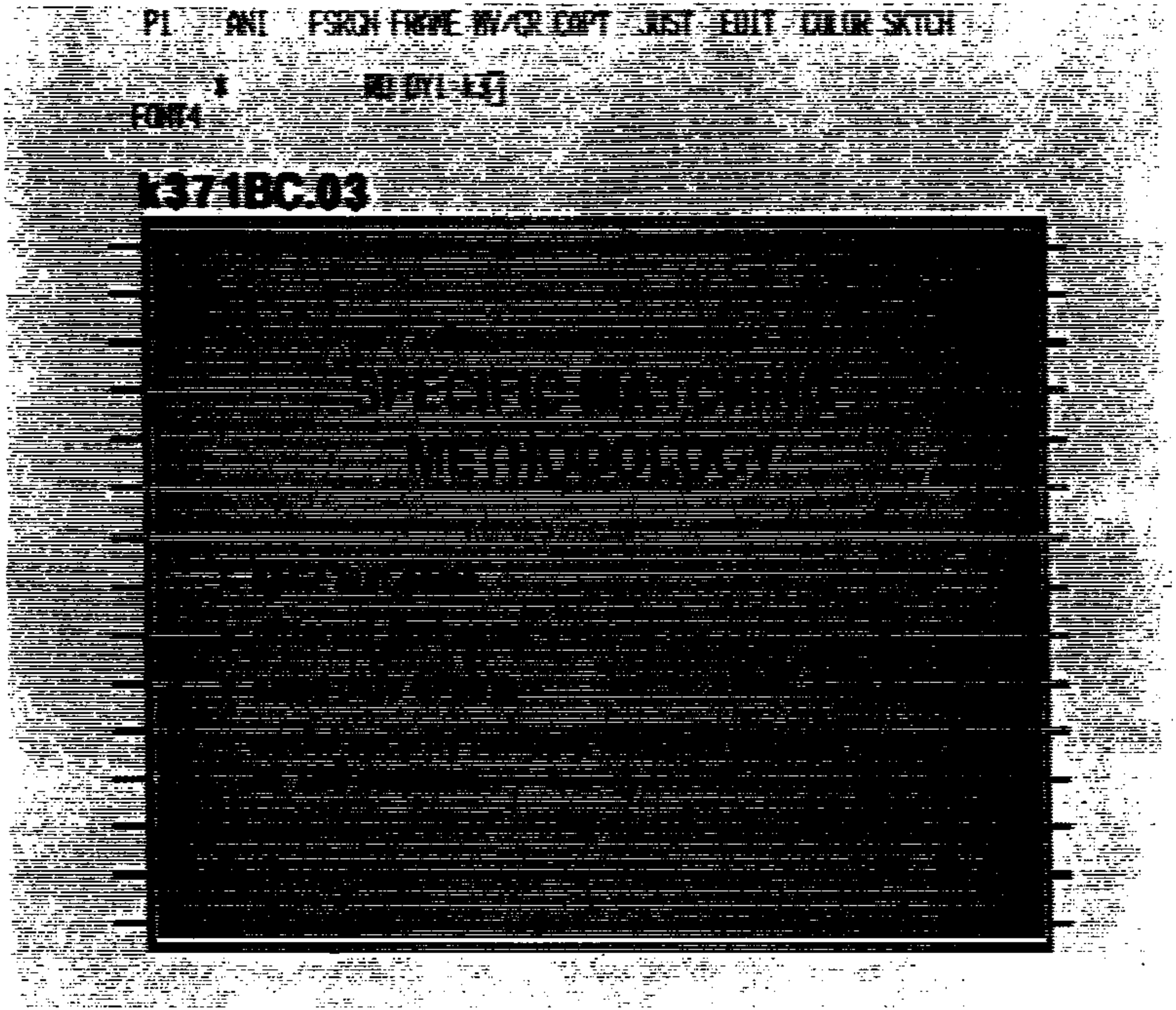
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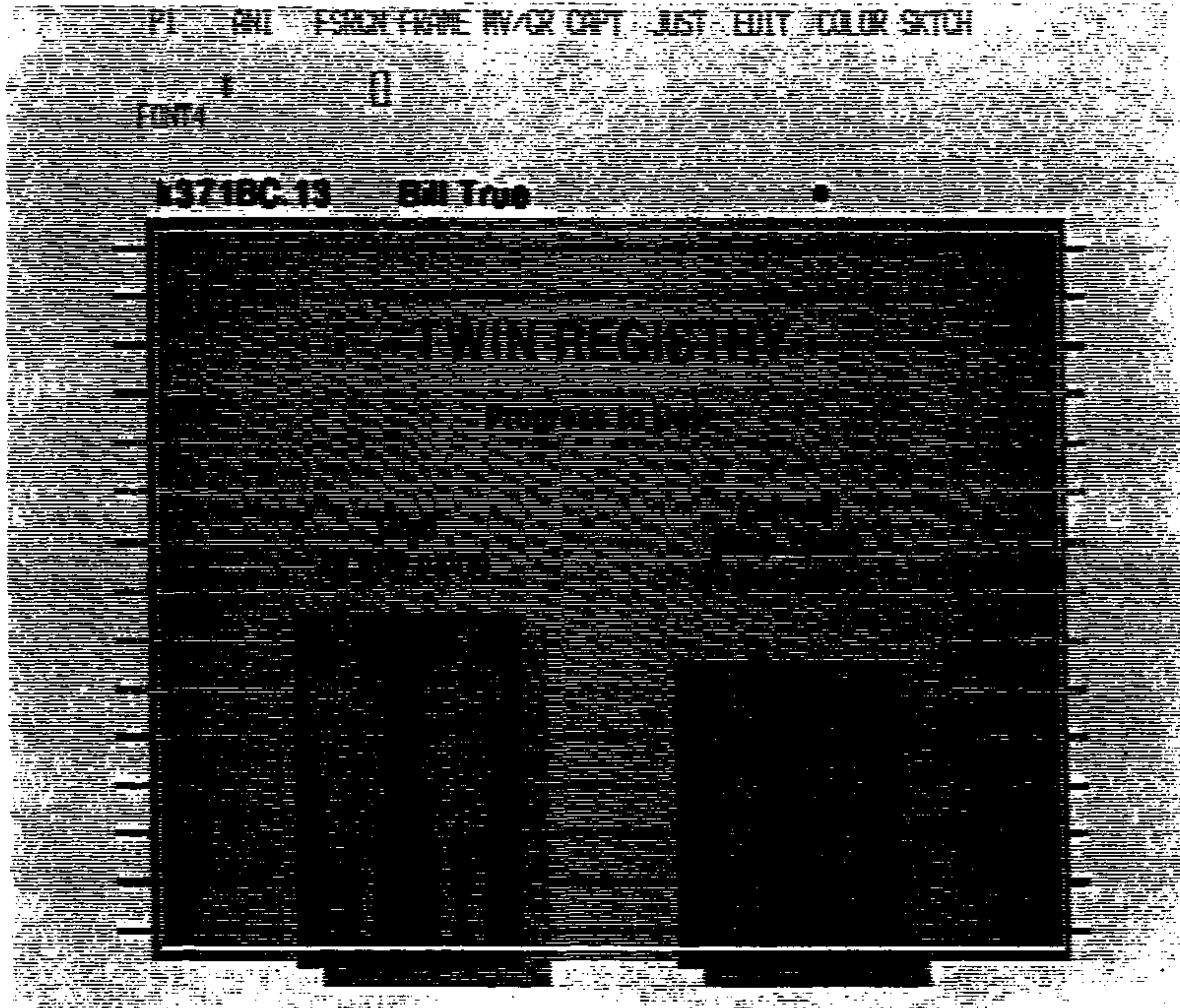
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X371BC-13 Bill True

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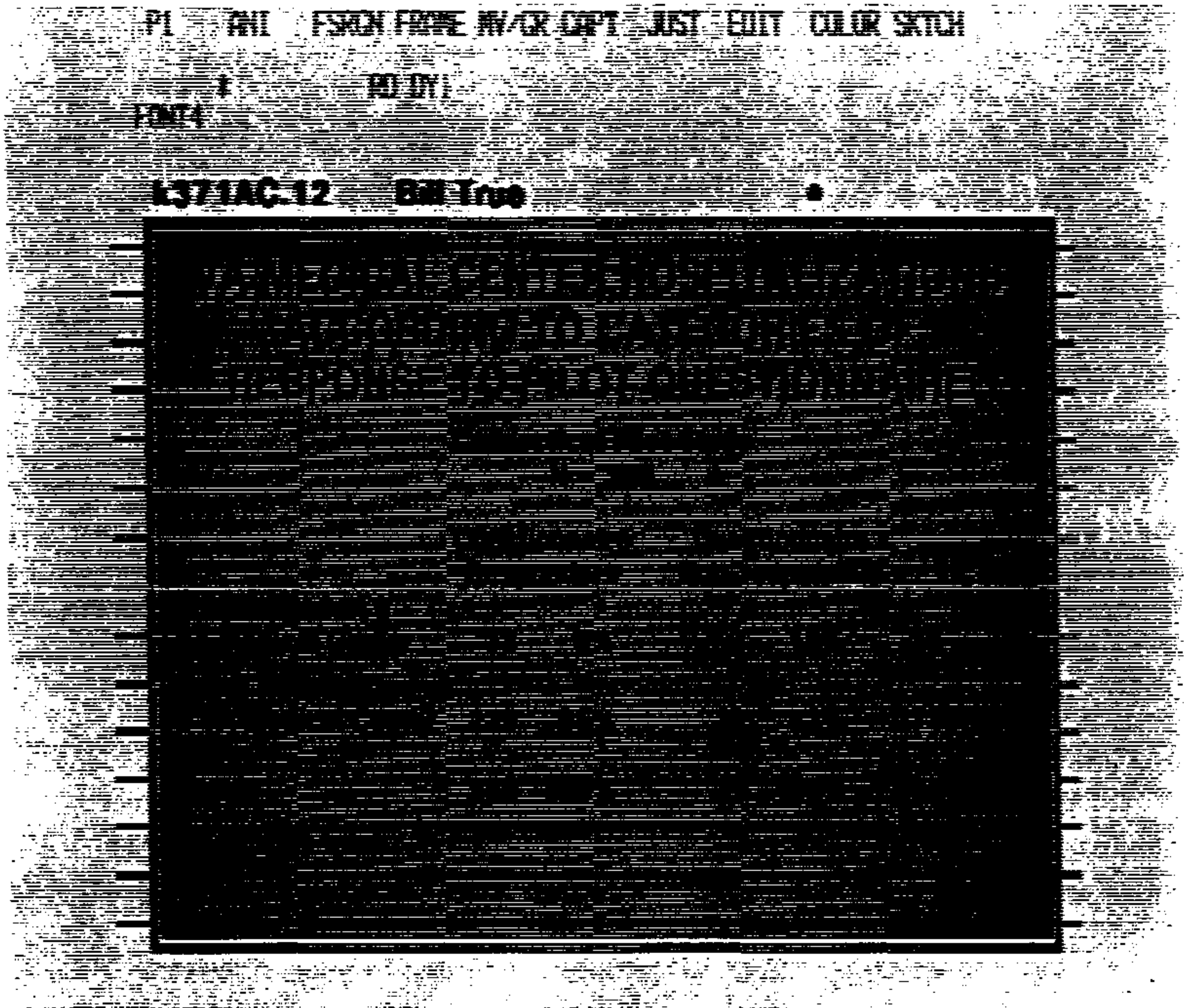
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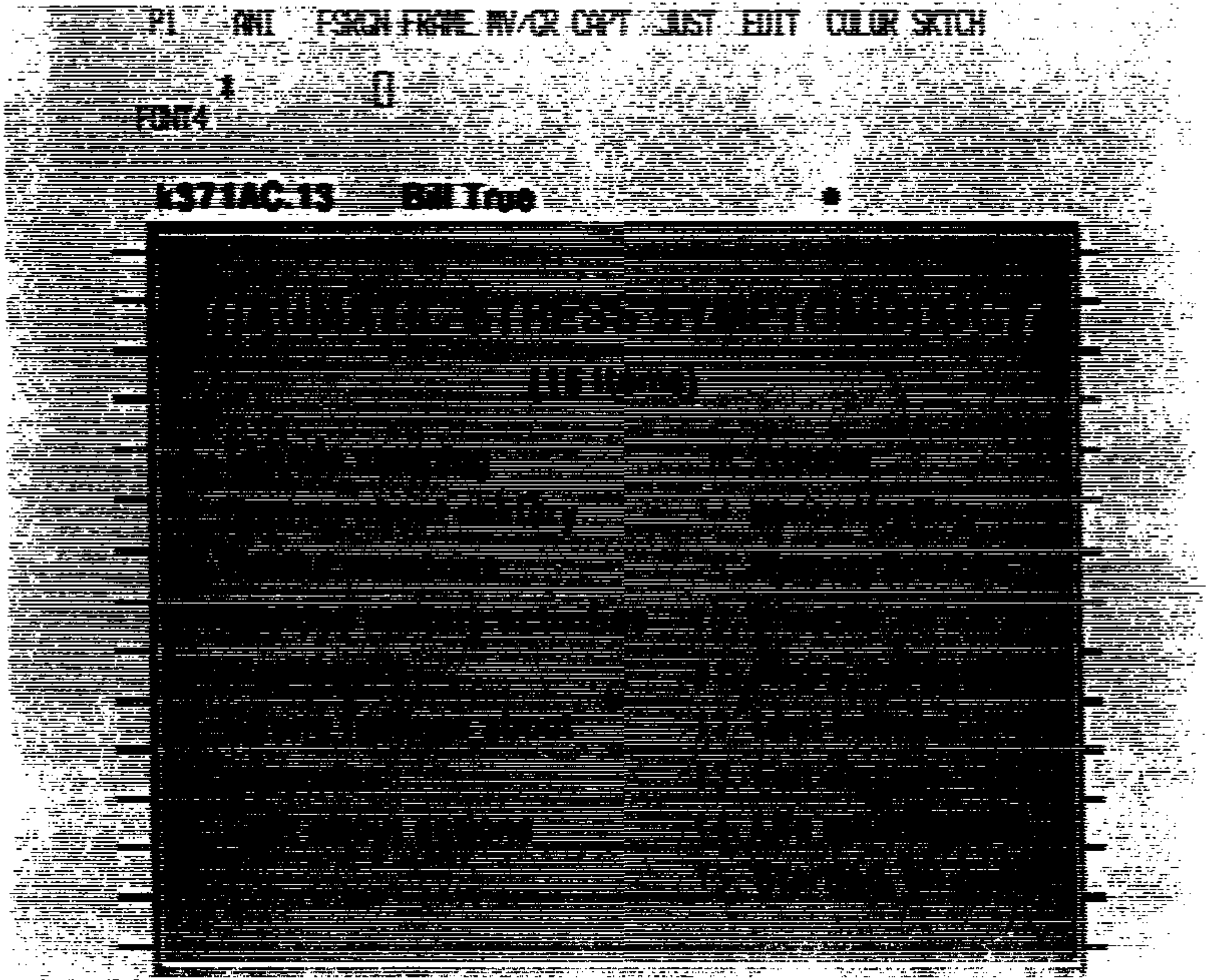
K371AC.12 Bill True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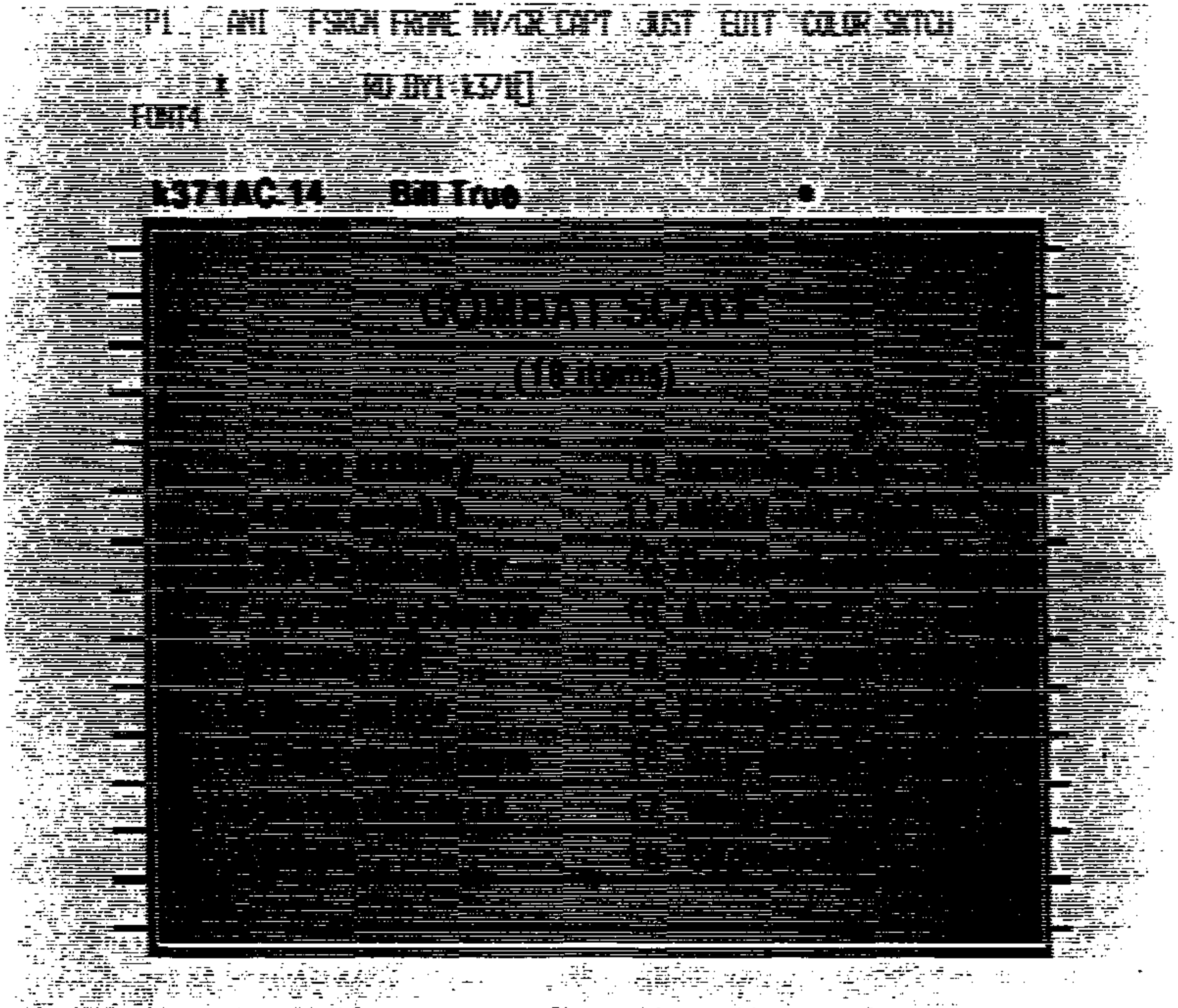
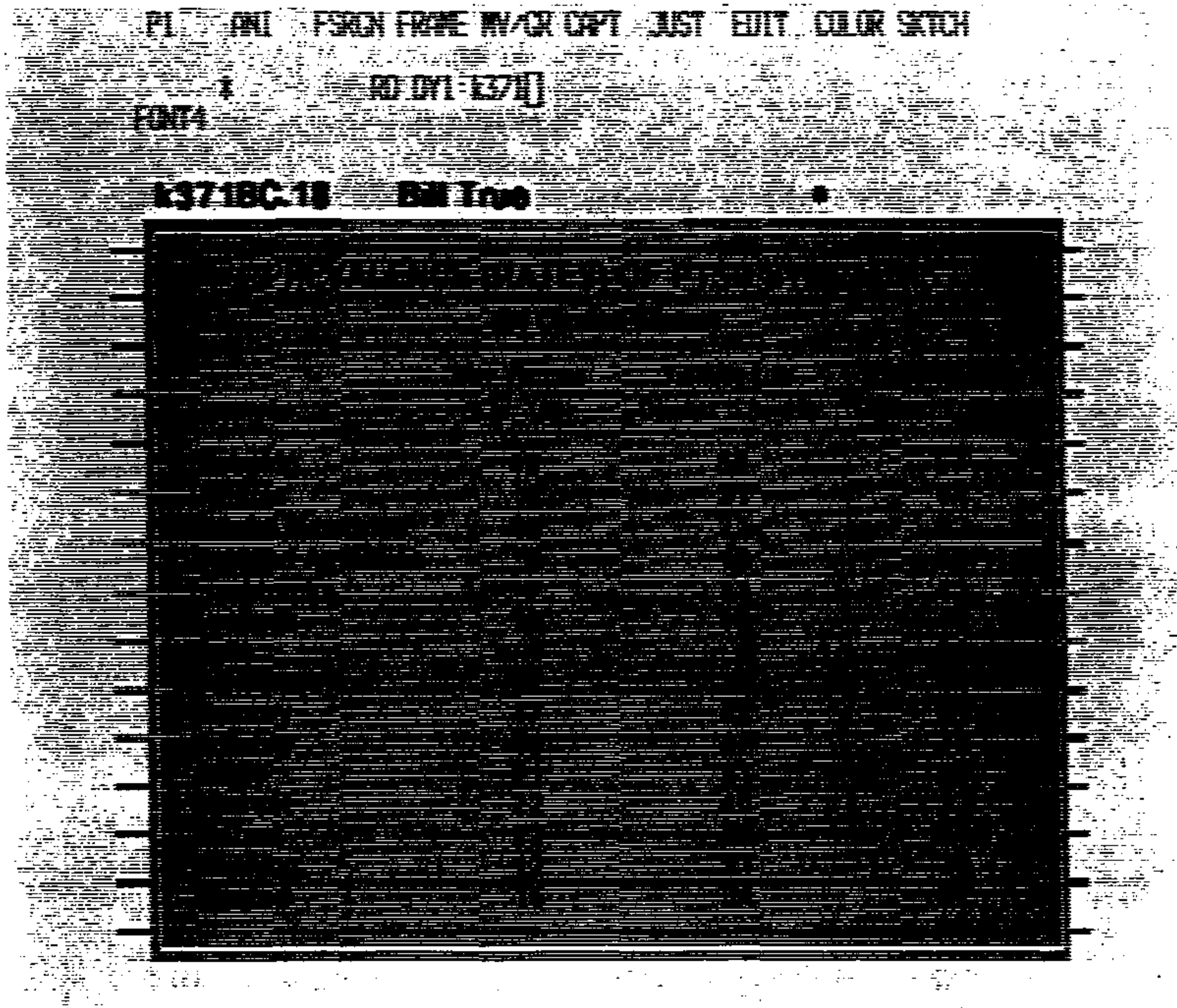

K371AC-14 Bill True



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RELATIVE RISKS
PHYSICAL CONDITIONS BY COMBAT

Slides Presented By Col. William H. Wolfe, USAF, MC

Air Force Health Study
(Ranch Hand II)

AIR FORCE HEALTH STUDY

(RANCH HAND II)

UPDATE

24 JUNE 1986

STUDY DEVELOPMENT

•	1978-79	PROPOSAL DEVELOPED
•	1979	PEER REVIEW AND PROPOSAL REFINEMENT
•	1979-82	EXPOSED AND COMPARISON POPULATIONS IDENTIFIED QUESTIONNAIRES DEVELOPED AND ADMINISTERED
•	1982	PHYSICAL EXAMINATIONS ACCOMPLISHED
•	1983-84	BASELINE MORTALITY REPORT PREPARED AND RELEASED
•	1984	BASELINE MORBIDITY REPORT PREPARED AND RELEASED
•	1985	FIRST FOLLOW-UP BEGUN

STUDY DESIGN

- IDENTIFY EXPOSED POPULATION
- IDENTIFY AND SELECT COMPARISON POPULATION
- DETERMINE BASELINE HEALTH STATUS OF THE TWO GROUPS
  - MORTALITY
  - DISEASE OR ABNORMALITY (MORBIDITY)
- COMPARE FINDINGS STATISTICALLY TO DELINEATE POSSIBLE HERBICIDE EFFECTS
- ACCOMPLISH FOLLOW-UP STUDIES OF POPULATIONS

MATCHING PROCESS

- 8 COMPARISONS SELECTED FOR EACH EXPOSED INDIVIDUAL MATCHED FOR SEX, AGE, AFSC, RACE
- RANDOM COMPARISONS FROM EACH SET USED IN MORTALITY STUDIES
  - PLAN TO USE ALL COMPARISONS IN 1987 REPORT
- 1 RANDOM COMPARISON FROM EACH SET USED IN MORBIDITY STUDY
  - OTHERS AVAILABLE FOR REPLACEMENT

SUMMARY COUNTS OF DEATH BY RANK AND OCCUPATION

	RANCH HAND			COMPARISON		
	AT RISK	DEAD	RATE (%)	AT RISK	DEAD	RATE (%)
RANK						
OFFICERS	466	16	0.034 (3.4)	2278	98	0.043 (4.3)
ENLISTED	791	39	0.049 (4.9)	3893	187	0.048 (4.8)
OCCUPATIONAL						
FLYING	646	24	0.037 (3.7)	3163	161	0.051 (5.1)
GROUND	611	31	0.051 (5.1)	3008	124	0.041 (4.1)
TOTAL	1257	55	0.044 (4.4)	6171	285	0.046 (4.6)

NONCAUSE SPECIFIC STATISTICAL SUMMARY
(DEATHS TO DATE)

GROUP	RELATIVE RISK	P. VALUE	SMR	P. VALUE
OFFICERS	0.715	0.26	0.791	0.37
ENLISTED	0.987	0.94	1.03	0.89
FLYING	0.692	0.12	0.726	0.13
GROUND	1.21	0.35	1.23	0.33
TOTAL	0.915	0.57	0.954	0.73

DEATHS BY CAUSE

	EXPOSED	COMPARISON
ACCIDENTS	19	96
SUICIDE/HOMICIDE	5	23
MALIGNANCY	6	51
CIRCULATORY SYSTEM	18	80
RESPIRATORY SYSTEM	0	7
DIGESTIVE SYSTEM	5	13
OTHER	2	15
TOTAL	55	285

ADDITIONAL MORTALITY CONTRASTS

- DOD-RETIRED POPULATION
  - ALL RANK-EXPOSURE GROUPS DOING BETTER THAN EXPECTED
  - EXPOSED-ENLISTED GROUP NOT SIGNIFICANTLY BETTER
- ACTIVE SERVICE PERSONNEL
  - ALL SUBGROUPS STATISTICALLY EQUIVALENT TO CIVIL SERVICE WORKERS
- 1978 US WHITE MALE POPULATION
  - ALL SUBGROUPS DOING SIGNIFICANTLY BETTER THAN EXPECTED

SUMMARY OF MORTALITY RESULTS

(A/O 31 DEC 84)

- EVALUATION OF 55 EXPOSED AND 285 COMPARISON DEATHS
- RELATIVELY SMALL NUMBERS EMPHASIZE PRELIMINARY NATURE OF THE RESULTS
- MORTALITY EXPERIENCE NEARLY IDENTICAL IN THE EXPOSED AND COMPARISON GROUPS
- CAUSE-SPECIFIC ANALYSES NOT STATISTICALLY DIFFERENT

SIGNIFICANT GROUP DIFFERENCES

- SELF-PERCEPTION OF HEALTH
- SKIN CANCER
- REPORTED BIRTH DEFECTS
- NEONATAL DEATHS
- BABINSKI REFLEXES
- SUBJECTIVE PSYCHOLOGICAL MEASURES (HIGH SCHOOL)
- HEPATIC FUNCTION TESTS (GGTP, LDH, CHOLESTEROL)
- PERIPHERAL PULSES
- THYROID (T_3) AND TESTOSTERONE
- RELEVANCE UNCLEAR

S U M M A R Y

BASELINE MORBIDITY PORTION

- DID NOT DEMONSTRATE DEFINITIVE CLINICAL END POINTS CONCLUSIVELY ATTRIBUTABLE TO HERBICIDE EXPOSURE
- NO STS, PCT, CHLORACNE DIAGNOSED IN RANCH HANDERS
- DID FIND A NUMBER OF CLINICAL AND SUBCLINICAL DIFFERENCES
  - DEFINING SIGNIFICANCE OF SOME DEPENDENT ON ANALYSES OF DATA NOT YET COLLECTED (SUN EXPOSURE, BIRTH RECORDS)
  - MOST VALUES STILL WITHIN NORMAL RANGES
- SCHEDULED FOLLOW UP EXAMINATIONS WILL PROVIDE ESSENTIAL DATA NECESSARY TO DEFINE BOTH FALSE POSITIVE AND ANY FALSE NEGATIVES

PHASE II PARTICIPATION

- 2309 EXAMINATIONS PERFORMED IN 1985-86
  (2269 IN 1982)
  - 93% OF BASELINE PARTICIPANTS RETURNED
  - 160 CONVERTED FROM BASELINE

PROGRAM MODIFICATIONS

- INTERVAL HISTORY (SUBJECT AND SPOUSE)
- PHONE INTERVIEW WITH ENTIRE COMPARISON GROUP
- BASELINE QUESTIONNAIRES TO NEW SUBJECTS AND SPOUSES
- DELETIONS
  - PULMONARY FUNCTIONS
  - NERVE CONDUCTION STUDIES
  - SEMEN STUDIES
  - IQ TESTING

PROGRAM ENHANCEMENTS

- SKIN CANCER EVALUATION
- IMPROVED ALCOHOL AND SMOKING ASSESSMENT
- COMBAT STRESS ASSESSMENT
- PERSONALITY TYPE
- BIRTH DEFECT SEVERITY
- DOPPLER EXAMINATION OF PULSES
- IMMUNOLOGIC STUDIES
- PORPHYRIN PROFILE BY HPLC
- DATA QUALITY CONTROL

MILESTONES

• INITIATION MEETING	4-5 FEB 85
• CONTACT LETTERS MAILED	3-14 FEB 85
• DRAFT QUESTIONNAIRE	4 MAR 85
• FIELD TEST OF PROCEDURES	22-24 APR 85
• PHYSICAL EXAMINATIONS	13 MAY 85 - MAR 86
• 1986 MORTALITY REPORT	SUMMER/FALL 86
• YEAR 5 EXAMINATIONS	SUMMER 87
• YEAR 3 MORBIDITY REPORT	SUMMER/FALL 87
• YEAR 5 MORBIDITY REPORT	SUMMER/FALL 89

Slides Presented by Edward Brann, M.D., M.P.H.,
Agent Orange Projects, Centers for Disease Control

CDC Epidemiology Study

THE CENTERS FOR DISEASE CONTROL
AGENT ORANGE PROJECTS

Purpose: To conduct an epidemiological study of United States veterans to asses the possible health effects of exposure to herbicides and dioxin and other environmental exposures which may have occurred in Vietnam

THE VIETNAM EXPERIENCE STUDY

Eligibility Criteria

Male Army Veterans
Entered service from 1965 to 1971
Draftees or single–term enlistees
Tours limited to Vietnam, CONUS, Germany, and Korea

THE VIETNAM EXPERIENCE STUDY

Sample Selection

48,000 randomly selected records at NPRC
17,000 will meet eligibility criteria:
- 8,500 Vietnam veterans
- 8,500 comparison veterans

THE VIETNAM EXPERIENCE STUDY

Mortality Component

- Deaths identified by search of files of VA, SSA, IRS, NDI
- Death certificates obtained
- Medical and other records reviewed
- Compare overall and cause–specific death rates

THE VIETNAM EXPERIENCE STUDY

Interview Component

- RTI is doing the locating and interviewing
- Telephone and field tracing
- Will locate and interview about 6,000 in each group
- Telephone interviews using a standard questionnaire

THE VIETNAM EXPERIENCE STUDY

Examinations Component

- All examinations being done at Lovelace Medical Center in Albuquerque
- Expect to examine 2,000 from each group
- Comprehensive examination and testing
  - Day 1: Medical and laboratory evaluation
  - Day 2: Psychological and neuropsych tests
  - Day 3: Exit interviews

Laboratory Tests

A. Hematological Indices

B. Blood Chemistries

- Blood Urea Nitrogen
- Creatinine
- Bilirubin (total, conjugated, unconjugated)
- Aspartate Aminotransferase
- Gamma Glutamyl Transferase
- Alkaline Phosphatase
- Creatine Kinase
- Cholesterol (total, HDL)
- Triglycerides
- Total Protein
- Albumin
- Fasting Glucose
- d-Aminolevulinic Acid

C. Hepatitis

- Hepatitis B Surface Antigen
- Hepatitis B Surface Antibody
- Hepatitis B core Antibody

D. Endocrine

- Thyroxine (T4)
- T3 Uptake
- Thyroid Stimulating Hormone
- Cortisol (morning)
- Dehydroepiandrosterone - SO_4
- Luteinizing Hormone
- Follicle Stimulating Hormone
- Testosterone

E. Immunologic

- Ig A
- Ig G
- Ig M
- B-lymphocytes (relative and absolute)
- T-lymphocytes (relative and absolute)
- T4-lymphocytes (relative and absolute)
- T8-lymphocytes (relative and absolute)
- T4/T8 Ratio

Laboratory Tests (cont'd.)

F. Urinalysis

G. 12-hour Urine

Creatinine

Porphobilinogen

D-Glucaric Acid

Uroporphyrins

Heptacarboxyl porphyrins

Hexacarboxyl porphyrins

Pentacarboxyl porphyrins

Coproporphyrin

H. Other

Erythrocyte Sedimentation Rate

Prothrombin Time

RPR (serologic test for syphillis)

Occult blood

Melioidosis Antibody Titer

Breath Alcohol level (day one and two)

HEMATOLOGY ASSAYS FOR THE VIETNAM EXPERIENCE STUDY

HEMOGLOBIN	HEMATOCRIT
RED CELL COUNT	PROTHROMBIN TIME
MEAN CELL VOLUME	MEAN CORPUSCULAR HEMOGLOBIN
MEAN CORP. HEMO. CONC.	LEUKOCYTE COUNT
BAND NEUTROPHILS	SEGMENTED NEUTROPHILS
LYMPHOCYTES	ATYPICAL LYMPHOCYTES
MONOCYTES	EOSINOPHILS
BASOPHILS	OTHER WBC DIFFERENTIALS
ERYTHROCYTE SED. RATE	RETICULOCYTE COUNT
PLATELET COUNT	

Special Medical Tests

A. Chest x-ray
B. Electrocardiogram
C. Pulmonary Function
D. Doppler Evaluation of Peripheral Vasculature
E. Hypersensitivity Skin Test (CMI)
F. Nerve Conduction Velocities
G. Vibratory Sensation
H. Thermal Sensation
I. Audiometry
J. Visual Acuity

Psychological and Neuropsychological Tests

A. Diagnostic Interview Schedule (DIS)
B. Minnesota Multiphasic Personality Inventory (MMPI)
C. Army Classification Battery (same as induction)
D. Combat Exposure Index
E. California Verbal Learning Test
F. Handedness Inventory
G. Grooved Pegboard
H. Paced Auditory Serial Addition Task (PASAT)
I. Rey-Osterreith Complex Figure
J. Wechsler Adult Intelligence Scale - Revised (WAIS-R)
   -Information
   -Block Design
K. Wisconsin Card Sort
L. Word List Generation
M. Test of Reading Level

Overview of Examination Schedule

I. Day 1

Orientation

II. Day 2

A. Medical History

B. Medical Examinations

1. General Physical

2. Neurological

3. Dermatological

C. Laboratory Tests

D. Special Medical Tests

III. Day 3

Psychological and Neuropsychological Testing

IV. Day 4

Exit Interviews

VIETNAM EXPERIENCE STUDY

INTERVIEWING COMPONENT

17,886 names delivered to contractor

92% successfully traced

92% agreed to be interviewed

15,280 interviews completed to date

overall response rate--85%

VIETNAM EXPERIENCE STUDY

MEDICAL EXAM COMPONENT

3,756 exams completed through May 31

534 currently scheduled

scheduling continues

participation rate running about 70%

data collection complete--Sept. 30

SELECTED CANCERS STUDY

Cancers to be Studied

Lymphoma
Soft tissue sarcoma
Nasal cancer
Nasopharyngeal cancer
Primary liver cancer

SELECTED CANCERS STUDY

PERIOD ENDING APRIL 30, 1986

8 registries participating

675 cases identified

437 controls identified

461 case interviews completed

307 control interviews completed

participation rate better than 80%

for both cases and controls

THE SELECTED CANCERS STUDY

Selection of Controls

- Identified by random digit dialing
- Men residing in same geographic areas as cases
- Same birthdate range as cases

SELECTED CANCERS STUDY

Selection of cases

- Cancer cases identified by participating tumor registries
- First diagnosed between Dec. 1, 1984 and Nov. 30, 1988
- Men born between 1929 and 1953

Slides Presented Frank J. Bove

Health Survey of Massachusetts Vietnam Veterans

TABLE 1 Health Survey of Massachusetts Vietnam Veterans, 1986

REPORTED OCCUPATIONAL EXPOSURES TO DIOXIN-CONTAMINATED SUBSTANCES RESULTING IN HUMAN ILLNESS*

Year, place & chemical(s)	Type of exposure & number of cases	Neurological effects	Other effects	References
1949 W.VA TCP, 2,4,5-T	explosion 117 production 111	nervousness, irritability, insomnia, personality change, depression, headache, pain & weakness in lower extremities, peripheral neuropathy	fatigue, weight loss, weakness, decreased libido, impotence	[Ashe & Suskind, 1949, 1950; Suskind, 1953; Suskind, 1977; Moses, et al, 1984]
1949 Germany TCP	production, industrial lab 17	pain & weakness, paresthesia, polyneuritis in lower extremities	fatigue, decreased libido, impotence	[Baader & Bauer, 1951]
1952 Germany TCP	production 31	pain & weakness, paresthesia in lower extremities, memory & concentration deficits, sleep disturbances, apathy, dulled emotional response	fatigue, myocardial damage	[Suskind, 1977]
1953 Germany TCP	explosion 55	hearing impairment, peripheral neuropathy	fatigue, drowsiness, myocardial damage	[Goldman, 1973]
1956 France TCP	production 17	peripheral neuropathy		[Dugois, et.al., 1956]
1964 USSR TCP 2,4,5-T	production 128	headache, memory loss, sleeplessness	fatigue, joint pain	[Telegina & Bikbulatova, 1970]

Health Survey of Massachusetts Vietnam Veterans, 1986

TABLE 1 (continued)

Year,place & chemical(s)	Type of exposure & number of cases	Neurological effects	Other effects	References
1965-68 Czechoslovakia TCP 2,4,5-T	production 80	pain & weakness in lower extremities, somnolence, headache,insomnia,peripheral neuropathy,emotional & psychiatric disorders	fatigue, weight loss	[Pazderova-Vejlupkov, et.al., 1980; 1981]
1969 NJ TCP 2,4,5-T 2,4-D	production 73	weakness in lower extremities,hypomania		[Poland, et.al. 1971]

*adapted from Moses,et.al.,1984

TABLE 2 Health Survey of Massachusetts Vietnam Veterans, 1986

Standardized Proportional Mortality Ratios for Selected Causes of Death for Vietnam Veterans Compared with Either Non-Vietnam Veterans or Non-Veteran Males
[see KOGAN, CLAPP, "Mortality Among Vietnam Veterans in Massachusetts,1972-1983", 1985, OCVS-DPH-Massachusetts Agent Orange Program]

ICD NO*	CAUSE OF DEATH	OBSERVED VIETNAM VETERAN DEATHS	COMPARISON GROUP			
			NON-VIETNAM VETERANS		NON-VETERAN MALES	
			PMR	95% C.I.	PMR	95% C.I.
	All Causes	840				
140-239	All Neoplasms	129	95	(78,115)	112	(94,134)
153-154	Colo-Rectal	8	113	(56,228)	85	(42,172)
162	Lung, Bronchus	25	98	(66,146)	102	(72,145)
171	Connective Tissue	9	880	(513,1510)	473	(262,855)
189	Kidney	9	183	(96,348)	353	(191,651)
390-429 439-459	Circulatory System (except Cerebrovascular)	139	88	(75,103)	87	(74,102)
430-438	Cerebrovascular Disease	28	111	(77,160)	138	(96,199)
571	Cirrhosis of the Liver	29	94	(65,136)	90	(61,132)
E800-E999	All external causes	423	108	(98,119)	113	(103,124)
E810-E825	Motor vehicle accidents	169	110	(95,127)	127	(106,152)
E950-E958	Recorded suicides	102	93	(77,112)	118	(98,143)
799.9, E850-E869, E950-E958, E980-E982	Estimated suicides**	163	113	(96,132)	140	(120,163)
E960-E969	Homicides	31	80	(56,114)	66	(46,94)

*International Classification of Diseases, 9th Revision, code number.
**See reference (6) for discussion of this category. Note that there were 13 deaths in the category 799.9.

TABLE 3 Health Survey of Massachusetts Vietnam Veterans, 1986

REPORTS ON THE HEALTH STATUS OF VIETNAM VETERANS

Reference	Exposed	Health Effects
Steilman & Steilman, 1980	Vietnam Veterans 535	congenital malformations, GI disturbances, pain in joints, sleep and psychological disturbances
Barr, 1982; 1983	Vietnam Veterans Australia, 120	peripheral neuropathy, insomnia, depression, irritability, lassistude, memory loss, headaches, attempted suicides
Erickson, et al, 1984	Vietnam Veterans 696	congenital malformations; spina bifida, cleft lip, impaired hearing, club foot
Reliahan, W, 1985	Vietnam Veterans in Hawaii, 418	weight loss, GI symptoms, neurological symptoms, asthenia, depression, rage, anxiety, irritability
Holmes, AP 1986	Vietnam Veterans in WVA 615 deaths	proportional mortality elevated rates of lymphoma, Hodgkins, testicular cancer, larynx, STS, suicides, ischemic heart disease, motor vehicle accidents
Lang, Van, Viet Duc Huu Nghi Hospital, Hanoi, SRV, 1982 (unpub) [Herbicides in War, Westing, A.H. 1984, p. 126]	Vietnamese Vietnam Veterans 117	fatigue, loss of appetite, eyes sensitive to light, unexplained vomiting, erratic fits of rage, headaches, depression

TABLE 4 Health Survey of Massachusetts Vietnam Veterans, 1986

CONGENITAL MALFORMATIONS

Birth Defect	Total Number	Prevalence *	BDMP[1] Incidence Rate *
Spina Bifida,other brain or spine defects	37	195	18.4
clubfoot	24	126	24.5
cleft lip/palate	17	89	13.4
missing,deformed or extra toes/fingers	31	163	27.2**
Down's Syndrome	11	58	7.9
hip abnormalities	21	111	27.0
heart defect	60		
defect of the digestive system	35		
hearing disorders	63		
cerebral palsy	6		
other skeletal defects	46		
Condition requiring special education or care	122		

* per 10,000 live births
** polydactyly and syndactyly

[1] Birth Defects Monitoring Project,CDC, Atlanta, GA

OTHER REPRODUCTIVE PROBLEMS

Problem	Number	%
Loss of libido	487	32.4%
Infertility	330	22.0%
Infertility and saw physician	246	16.4%
low birth weight children (under 5.5 lbs.)	162	8.1%

TABLE 5 Health Survey of Massachusetts Vietnam Veterans, 1986

Neurobehavioral Dysfunction

Problem	Number	%
persistent tiredness	957	63.7%
(saw physician)	270	18.0%
persistent headaches	773	51.5%
(saw physician)	338	22.5%
nervous disorders	684	45.5%
(saw physician)	356	23.7%
difficulty with memory or concentration	786	52.3%
(saw physician)	165	11.0%
mental illness or breakdown	275	18.3%
(receiving some disability)	132	8.8%
regularly depressed, get into a violent rage, anxious or irritable	1233	82.1%
(more than one behavioral problem)	1015	67.6%
symptoms in the lower & upper extremities (peripheral neuropathy)	526	35.0%
one or more of the following symptoms of muscle weakness (asthenia); can't climb stairs without holding onto railing, unable to do tasks requiring holding arms at shoulder level, difficulty grasping tools)	775	51.6%

REPORT ON THE ADVISORY COMMITTEE ON WOMEN VETERANS

Approximately 7,500 women served in Vietnam. Women Vietnam veterans' concerns, in most respects, mirror those of men. Additionally the women are concerned about the serious female reproductive system problems, such as ovarian cancer, uterine cancer, miscarriage and spontaneous abortion, may also be related to dioxin exposure. The Advisory Committee on Women Veterans strongly supports the need for a study of women who served in Vietnam. The study should examine all aspects of the Vietnam experience, physical and psychological, and should include but not be limited to gender-related diseases and conditions. The Committee has reviewed Subtitle B, Section 19031 of the Consolidated Omnibus Budget Reconciliation Act and fully supports the study of effect of Vietnam experience on health status of women Vietnam veterans.

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