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**OVERSIGHT ON ISSUES RELATED TO AGENT ORANGE
AND OTHER HERBICIDES**

HEARING
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE
NINETY-SEVENTH CONGRESS
FIRST SESSION
ON
AGENT ORANGE AND OTHER HERBICIDES

NOVEMBER 18, 1981

Printed for the use of the Committee on Veterans' Affairs



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OVERSIGHT ON ISSUES RELATED TO AGENT ORANGE AND OTHER HERBICIDES

WEDNESDAY, NOVEMBER 18, 1981

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, D.C.

The committee met, pursuant to notice, at 9:37 a.m., in room 1224, Dirksen Office Building, Hon. Alan K. Simpson (chairman of the committee) presiding.

Present: Chairman Alan K. Simpson, Senators Jeremiah Denton, Frank H. Murkowski, Arlen Specter, Alan Cranston, and George J. Mitchell.

OPENING STATEMENT OF HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Chairman SIMPSON. Good morning. I welcome you all to today's oversight hearing on agent orange. Our purpose this morning is to provide oversight on the Federal Government's efforts to determine the adverse health effects which may result from exposure to agent orange and other herbicides.

I think there is an important determination to be made with respect to the outcome of the protocol and the study which will follow. Because of the emotion and the controversy which surround this subject, it is imperative that the credibility of the study and of those involved with the study be clearly established. Therefore, I would wish to emphasize the importance of adequate communication between the Congress and the VA on this matter.

This committee wishes to be advised of the progress of this decision making process and should be advised of the progress of the criteria used by the VA to determine whether or not the protocol is acceptable.

This stage in the study process is crucial because it is now that it must be demonstrated to concerned veterans, and all other citizens, that the VA, the Congress and leading epidemiologists are working seriously to uncover all possible scientific evidence about agent orange.

And I think it is crucial that we not underestimate the importance of the timing and the timeliness of the effort. It has already taken us more than 10 years to get to the point where we are in 1981. The veterans who are experiencing health difficulties do not have the time to wait another 10 years for answers to their medical problems.

Public Law 97-72, the "Veterans' Health Care, Training, and Small Business Loan Act of 1981," contains a very important provision that provides a new health-care eligibility for Vietnam veterans who may have been exposed to agent orange. Under this provision, eligibility for basic VA health-care services is granted for a veteran's disability if it is found that the veteran, during active duty in Vietnam, "may have been exposed" to dioxin or was exposed to any toxic substance in an herbicide or a defoliant used in connection with military purposes there.

Only those veterans with disabilities that result from specified exposure, according to guidelines issued by the chief medical director, will be eligible for this health-care benefit.

It is my firm belief that this provision should be an interim effort, and Public Law 97-72 does provide that this health care that will terminate 1 year following the submission of the first report on the VA's epidemiological study of the health effects of agent orange. As we know, the first report on that study is due within 2 years after the protocol for the study is approved.

However, this is only one way of attempting to respond to the concerns of veterans who may have been exposed to agent orange. It is also my firm belief that we need to get cracking on the actual epidemiological study mandated by Public Law 96-151 in 1979.

We would wish to have assurances that provide actual timetables and details of what is going to occur, with respect to the study of agent orange, in order to meet the guidelines set out by the provisions of Public Law 96-151.

So, this morning we will hear testimony on the protocol. We will hear about the status of the protocol and the problems that have been experienced by the VA and the DOD, and Dr. Detels and Dr. Spivey, the coauthors of the protocol in developing what is called an "exposure index," we will also hear comments from those groups who have reviewed the protocol to date.

And then we shall also hear status reports on other continuing studies which deal with agent orange exposure, and we shall then hear comments from veterans' groups and others concerned with this complex issue.

So, the hearing is intended to be quite comprehensive. It is intended to raise important questions about current status and the future course of the agent orange protocol and study. I think it is important that we ask those serious questions and that we have the answers as part of the public record, along with the views of those who are involved with the study. It is not a hearing to attempt to embarrass, cajole, or get things to a high pitch. That is not what I am up to. We need some information, some data, some background, and some commentary from you as to where we are. I want to reemphasize my commitment to a credible and timely study.

The limited health care that is provided under the new law is only an interim measure, to meet the needs of the veterans who are ill and who may have been exposed to agent orange. It was never intended to be anything more. So, if we find that some tough decisions need to be made concerning what happens next with the protocol, then we will strongly urge that the VA be decisive and do just that.

This hearing will provide us the first opportunity for public presentation of peer reviews of the protocol, DOD reviews on what can or cannot be accomplished to develop an exposure index, and reviews of current and continuing studies that address the health effects of exposure to agent orange.

Before we proceed with the first witness, there may be opening remarks from my good friend and colleague from California, Senator Cranston.

Senator CRANSTON. Thank you very much, Mr. Chairman. I am pleased to welcome the various witnesses today, including my good friend from California, Bob Nimmo.

Today we are seeking updates and general status reports on the many efforts, both inside and outside the VA, that are planned or are underway to help address the serious questions that exist with respect to the current health of Vietnam veterans, especially as their health may have been affected by exposure to agent orange.

Congressional interest in the possible adverse effects of exposure to agent orange has been strong since the subject first rose to national attention in 1978. This interest and concern has promoted many hearings—this committee alone held four on the subject last year—and generated considerable legislative activity.

In the last Congress, section 307 of Public Law 96-151 mandated two research initiatives on agent orange: A scientific review of the literature relating to the effects in humans of exposure to dioxins and an epidemiological study on the health effects of exposure to dioxin, the contaminant in agent orange, on Vietnam veterans.

The literature review has recently been completed and will, I believe, prove useful in revealing the current status scientific knowledge and the gaps in that knowledge relating to the health effects of exposure to dioxin. I am pleased to note the high quality of this report.

More recently, on November 3, a provision I authored in the Senate was enacted in Public Law 97-72 that establishes new health care eligibility for Vietnam veterans for the treatment of disabilities that may be related to exposure to agent orange or other herbicides. Another provision in that law authorizes the expansion of the scope of the epidemiological study mandated by Congress in Public Law 96-151.

Today the committee will hear testimony on the current status of this epidemiological study, as well as the status of other ongoing studies such as the Air Force's Ranch Hand Study in which the health of the 1,200 participants in the agent orange aerial spraying missions is being examined, the Center for Disease Control's Birth Defect Study, and the Armed Forces Institute of Pathology's Tumor Registry Review.

As a result of this hearing, the committee should learn just how much closer we are today to some sound, scientific findings on the health effects of agent orange than we were 1 year ago, how much closer we can get, and what the best means are for doing so.

After numerous delays, including a legal challenge to the VA's efforts to get the epidemiological study underway in 1980, a contract was finally let in May of this year for the design of the study. Now, nearly 2 years after the study was mandated, a proposed

design for the study—the so-called draft protocol—has finally been submitted to the VA by the contractor.

Several peer groups, including the Agent Orange Working Group, the VA Advisory Committee on Health Related Effects of Herbicides and, as required by Public Law 96-151, the Congressional Office of Technology Assessment have each undertaken a review of the draft protocol.

Although I am reserving judgment until I receive more information, both from today's witnesses and in further formal reports from reviewers, the early evaluations of the draft protocol are, unfortunately and quite frankly, not encouraging. My understanding of the reviewers' comments thus far is that they believe the protocol in its present condition is inadequate.

The Agent Orange Working Group's Science Panel has asserted that the submission is not even a protocol. Serious questions have also been raised about the effectiveness of the coordination between the work of the investigators and Department of Defense and VA activities.

Other questions that warrant our full exploration include: What should be the next step in the epidemiological study? How can this step be taken in a responsible manner and how long might it take? Is the epidemiological study as presently conceived with emphasis on the possible effects on Vietnam veterans of exposure to agent orange a feasible one in light of the state of information available on who was exposed to what levels of dioxin, or even desirable? What should be the VA's direct role and what should be the role of the contractor in present and future efforts relating to the epidemiological study?

Finally, I would note that the American public is understandably growing impatient with what are perceived as the Government's plodding efforts to resolve the many difficult issues involved and get on with the study.

I sincerely hope that an appropriate strategy can be found and pursued with the necessary single-mindedness of purpose and urgency.

I pledge my continued best efforts to achieve that goal.

Mr. Chairman, I regret that, due to an unavoidable conflict in my schedule, I will not be able to remain for the full hearing. I must attend another committee meeting at 10:30. I have written questions, however, for each of the witnesses.

This is a very important oversight hearing and I congratulate you, Mr. Chairman, for holding it. Finally, I want to note that the committee is scheduled to hear from Mr. James Stockdale of HHS, the Chair of the Agent Orange Working Group. I have already had some constructive correspondence with Mr. Stockdale and fully support the efforts of the coordinating group he heads.

Let me say that despite all the technical difficulties relating to this issue—and the human difficulties, and there are many—we must make plain that we are determined to do all that humans can do to solve this very, very difficult problem. I am committed to doing that. I know that you are, Mr. Chairman, and we will do our utmost to fulfill our obligations.

Chairman SIMPSON. Thank you very much, Al, and certainly if there was a pattern set as to being productive and responsible in

this area, you certainly set it when you were chairman of this committee. I remember well the hearings that you held. They were quite productive, and I would thank you.

I would recognize Senator Denton, also a member of the committee. It is good to have you here this morning, Senator Denton.

Senator DENTON. Thank you, Mr. Chairman.

I have reviewed the evidence on this subject to date and share the interest of the chairman and Senator Cranston in the matter in spite of some of the economy's efforts to make more effective the veterans programs. I want the veterans to know that my basic position was and remains that George Washington was correct when he said that we must not, he effectively said, ever see as a pool of means of effecting economies cutting into veterans benefits.

Of all the people in this country who deserve not to have that which was sort of contractually viewed by them when they signed up in this country's armed services, the veterans should be least, in fact, they should be immune from any taking away from them. And I will fight for that.

Agent orange is a shocking thing to me. I wasn't aware, I got a lot of communist propaganda about agent orange, but now to learn that there are many who have suffered from it has been a shock. It's a subject which obviously requires careful analysis and some fair solution for taking care of those and their dependents who were harmed by this agent orange thing.

As the chairman knows, and as Senator Cranston indicated, it is a tragedy but it's true, we, like this chairman of this committee can be here this morning, because this is his committee and he has to conduct this hearing. I must go to a meeting at 10 o'clock because I have four amendments to offer to the rewrite of our code, our Criminal Code. So, I will have to be there, and as much as I hate to leave, I will have to.

I want to express my confidence and admiration for our chairman. He is a man who has the most basic honesty of any whom I have met in this Senate and I strongly commend him for your total trust and tell him the why nots as well as the whys as you proceed with the causes for benefits, because he needs to know. If he gets caught in a boobytrap, he is going to have the bottom fall out from under him and he won't be able to do as good a job as his talents would otherwise permit.

That's all I have to say, Mr. Chairman.

Chairman SIMPSON. Thank you very much, and I would like to welcome Senator Murkowski to the panel this morning. Nice to have you here, Senator.

Senator MURKOWSKI. Mr. Chairman, I appreciate that and I look forward to testimony that's going to be given this morning. And I will just submit my opening statement for the record.

Chairman SIMPSON. I thank you very much.

[The prepared statement of Hon. Frank H. Murkowski, a U.S. Senator from the State of Alaska, follows:]

PREPARED STATEMENT OF HON. FRANK H. MURKOWSKI, A U.S. SENATOR
FROM THE STATE OF ALASKA

In December of 1979, Congress passed the Veterans Health Programs Extension and Improvement Act which the President subsequently signed into law as P.L. 96-151. This law directed the Veterans Administration to prepare a plan for the study of Vietnam veterans who may have suffered adverse health effects as a result of exposure to Agent Orange. The law also required the Director of the Office of Technology Assessment to review the study, and in the case of disapproval to periodically report to Congress on the progress of the study. Finally, in August of this year, a draft protocol for Epidemiologic Studies of Agent Orange was submitted by Dr. Spivey and Dr. Detels, both of the School of Public Health at UCLA.

This draft protocol has been the subject of some criticism both by the Office of Technology Assessment and the National Veterans Task Force on Agent Orange, among others. While I am not a scientist nor a specialist in epidemiologic studies, I do feel that many of the criticisms by the OTA and the National Veterans Task Force on Agent Orange of the draft protocol may be valid. At the very least, these criticisms deserve full exploration by this committee.

Fortunately, the study mandated by P.L. 96-151 is not the only study currently being conducted on the possible adverse health effects of agent orange on humans. I look forward to the testimony of those involved in the Ranch Hand Study and the

study currently being conducted at the Center for Disease Control in Atlanta. The search for answers to the Agent Orange question is not a quick or easy one.

The veterans who served in Vietnam and who know or fear they were exposed to Agent Orange deserve nothing less than the best efforts of the Veterans Administration and any independent groups doing studies on the possible health effects of Agent Orange.

I look forward to the testimony of the many distinguished guests here today as a guide to the difficult decisions which this committee must take regarding the involvement of the federal government in Agent Orange studies.

Chairman SIMPSON. Before we begin, you will notice this curious array of electronic equipment here. I would ask the witnesses to make every effort to remain within the 5-minute time limit when they testify. We have a great deal of important material to cover and we want to be certain that we hear from everyone. And so, we will enforce this 5-minute time limit with these lights. Thank you.

And, Bob Nimmo, I really appreciate your coming here today to testify on this issue. I know that the VA will be responsive to the concerns that are raised by the witnesses here today, just as you have been responsive to all issues since you have taken on this tough job. Certainly, we are going to be very interested in your reactions to the views that are expressed today. We would appreciate your furnishing the information that you would care to share with us after you hear the testimony of the various witnesses today. It would be very helpful if you could keep us informed at each step of the decision process on the protocol. We will look forward to your written reactions to this hearing at a separate, and hopefully, early time.

Bob Nimmo, please.

TESTIMONY OF ROBERT P. NIMMO, ADMINISTRATOR, VETERANS' ADMINISTRATION; ACCOMPANIED BY JOHN P. MURPHY, GENERAL COUNSEL; DR. BARCLAY M. SHEPARD, SPECIAL ASSISTANT TO THE CHIEF MEDICAL DIRECTOR FOR ENVIRONMENTAL MEDICINE; AND DR. LAWRENCE B. HOBSON, CLINICAL ASSISTANT TO THE SPECIAL ASSISTANT TO THE CHIEF MEDICAL DIRECTOR FOR ENVIRONMENTAL MEDICINE

Mr. NIMMO. Mr. Chairman and distinguished members of the committee, good morning. I am pleased to appear before you this morning as we address this troublesome matter. Accompanying me are Mr. John Murphy, the VA General Counsel; Dr. Barclay Shepard, Special Assistant to the Chief Medical Director; and Dr. Larry Hobson, clinical assistant.

With the committee's permission, I ask that my full testimony be entered into the record and that I will provide this morning a summary of its content.

Chairman SIMPSON. Without objection.

Mr. NIMMO. And I will do my best, Mr. Chairman, to stay within that 5-minute limit. So, I will go rapidly.

When I appeared before the committee during my confirmation hearing in July, I told you of my concern and support for the members of our Armed Forces who served in Vietnam. I also indicated my strong desire to resolve questions regarding the possible health effect on American service personnel of exposure to agent orange and other herbicides used in Vietnam. And I want to say at the very outset, Mr. Chairman, that I share the frustration experienced by this committee and the Congress as a whole in attempting to deal effectively with this issue. It is a frustration with progress that has been too slow. It is a frustration that urgently needed answers to the scientific questions are mired in the complex processes of scientific research.

It is my conviction, based on the agency's rate of progress to date, that the Veterans' Administration must move more aggressively in addressing this issue. And toward that end, I have formed a policy coordinating committee on agent orange and have directed that it move aggressively to expedite all pending actions. The committee will be under the leadership of the Deputy Administrator-designate, Mr. Charles Hagel, who is himself a twice wounded, combat veteran of the Vietnam war.

Let me state briefly the progress that has been made in some key areas and what is being done to accelerate the program.

The newly reconstituted agent orange working group with cabinet counsel status will significantly expand VA's ability to work with and consult other Federal agencies concerned with policy and research. We participated as a member in the group's first meeting on August 28 and were assured of the President's full support for Governmentwide cooperation in resolving the agent orange issue.

Within our own agency, several organizations regularly meet to receive the views of a variety of interest. The VA Advisory Committee on Health Related Effects of Herbicides meets quarterly and consists of distinguished representatives from the scientific community and from major veterans' organizations. Its meetings are proving to be an effective means for individuals and groups to communicate their concerns.

VA has been cooperating with several States which have adopted or are considering adoption of agent orange legislation. Representatives of the agency have appeared at various State legislative hearings and we have also had State participation in our advisory committee meetings.

Let me turn briefly to the status of several studies that have either been mandated by law or which we have initiated.

Recently, in accordance with Public Law 96-151, the VA completed a comprehensive review of the scientific literature on various phenoxy herbicides. This two-volume report contains an analysis of some 1,200 published scientific papers that will aid in further research. The report is being distributed widely through an array of Federal and private scientific and policy organizations.

Our own Department of Medicine and Surgery is encouraging additional agent orange research proposals, and our hope is that this report will inspire additional scientific inquiry.

Public Laws 96-151 and 97-72 directed the VA to design and conduct an epidemiological study of veterans exposed to herbicides and other chemicals.

Following delays invoked by legal challenges, scientific proposals, and bids were received and on May 1 of this year a contract award was made to the UCLA School of Public Health for an epidemiological study design.

The VA received a draft design on August 5. It was forwarded for comments to various review groups, including the U.S. Office of Technology Assessment. It is the opinion of the VA, and of the review groups, that the design was inadequate.

Comments from the review groups have been given to UCLA for appropriate response. UCLA has been given until late December to submit an additional draft study design adequate for peer group review as required by the contract.

In the meantime, the VA on its own is going forward with a study of mortality among veterans who served in Vietnam during fiscal years 1968 through 1973. Our plans have been submitted to the Science Panel of the Agent Orange Working Group and the American Public Health Association. I will keep you informed of our progress on this effort.

In another study area, VA continues to cooperate with the Armed Forces Institute of Pathology in its study of biopsy and autopsy materials from persons who served in Vietnam. The Institute's research is aimed at seeking the presence in these materials of significant pathology patterns among these individuals.

Mr. Chairman, since the issue of agent orange first surfaced, it seems that the dilemma evolves into two fundamental questions. The first is whether a veteran was exposed to agent orange, and second, what are the effects, if any, of that exposure?

The VA in April of 1980 resolved the first question by presuming that a veteran who served in Vietnam was exposed to agent orange. This was prompted by the lack of any practical method of distinguishing between individuals who were exposed and those who were not.

Unfortunately, the second question is not so easily answered. I believe, however, that the various activities that I have described today will enable us to bridge some of the knowledge gap which has thus far frustrated our efforts to resolve this question.

In closing, Mr. Chairman, I want to respond to the committee's interest in future VA activity concerned with the examination and treatment of herbicide exposed veterans.

As we know, the President signed into law Public Law 97-72, which gives the VA broad latitude in providing direct priority medical care to veterans with health conditions that may be related to herbicide or chemical exposure. The interim guidelines implementing this law are being released to the field today. They will be published in the Federal Register and comments received will be considered before the guidelines are issued in their final form.

They will call for examination and treatment in all cases except those clearly due to specific and identifiable causes other than chemical or herbicidal exposure.

Mr. Chairman, since 1978 when VA began conducting and registering exams for agent orange health effects, more than 67,000 veterans have come to our medical centers and clinics.

Chairman SIMPSON. If you could, Bob, I hate to be rude, but we must stay within the guidelines and I have allowed you to run about 3 minutes over.

Mr. NIMMO. Thank you, Mr. Chairman.

Chairman SIMPSON. If you could summarize in just a few seconds, I would appreciate it.

Mr. NIMMO. I would just simply conclude by reiterating that I am committed to the resolution of this issue. I intend to insure that the VA aggressively pursues this troublesome matter to a satisfactory conclusion.

Thank you, Mr. Chairman.

Chairman SIMPSON. I believe your personal commitment there, I really do. I say that myself so that you will have a sense of the true spirit of fairness here.

[The prepared statement of Robert P. Nimmo, Administrator of Veterans' Affairs, follows:]

PREPARED STATEMENT OF ROBERT P. NIMMO, ADMINISTRATOR OF VETERANS'
AFFAIRS

Good morning. I am pleased to be here today to discuss with you the Veterans Administration's Agent Orange program. Accompanying me are Mr. John Murphy, the General Counsel, and Dr. Barclay M. Shepard, Special Assistant to the Chief Medical Director, and Dr. Lawrence B. Hobson, Clinical Assistant.

Mr. Chairman, in my testimony today, I will provide you with an update on a number of Agent Orange-related activities. I will also report to you the progress we have made in various research activities since this Committee last held hearings on the issue of Agent Orange on April 30, 1981.

I wish to state at the very outset that I am frustrated by the fact that more progress has not been made towards finding answers regarding the possible adverse health effects on American service personnel of Agent Orange or other herbicides used in Vietnam.

I firmly believe that the Veterans Administration must take a more aggressive stance in addressing this issue. It is my intention to acquaint Vietnam veterans with the programs now available to address their concerns. I encourage VA researchers to respond positively to the recent request of the Department of Medicine and Surgery for research proposals relating to Agent Orange.

While we have made some progress in resolving this complex health care issue, nevertheless, I also realize that much more needs to be done. Towards that end I have directed the

Deputy Administrator Designate, Mr. Charles T. Hagel, who is a combat Vietnam veteran, to assume an active leadership role and to report directly to me the recommendations of the Agency's Policy Coordinating Committee which he is now chairing. Further, I have asked the Assistant Deputy Administrator for Consumer and Public Affairs to develop an action plan specifically designed to enhance the ability of the Veterans Administration to effectively maintain full communication with Vietnam veterans, Congress, and the general public.

I will continue to support and cooperate with the key research efforts being conducted in other quarters. The more important of these research efforts are the U.S. Air Force's "Operation Ranch Hand" study and the Centers for Disease Control birth defects study.

COMMITTEE ACTIVITIES

Fully cognizant that we cannot proceed alone in our search for answers, we have viewed our close and continued cooperation and participation in key Agent Orange related committees as vital to a systematic, integrated approach to the sharing of significant information within the VA and with other concerned Federal agencies. We are particularly pleased to have the opportunity to continue our membership in the newly formed Agent Orange Working Group established at the Cabinet Council level. This reconstituted committee, formerly designated as the Interagency Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (IWG), was

established on July 7, 1981, by the Human Resources Cabinet Council. The lead agency for the working group is the Department of Health and Human Services (DHHS). Other member agencies, in addition to DHHS and the VA, include the Departments of Defense, Agriculture, and Labor, the Environmental Protection Agency, Office of Management and Budget, ACTION, Council of Economic Advisors, Office of Science and Technology and the Office of Policy Development. We believe that the newly reconstituted committee will significantly expand our ability to carry out the statutory responsibilities of Section 307(c) of Public Law 96-151 which calls for the VA to consult and coordinate with other Federal entities in conjunction with the conduct of our epidemiological study.

The first meeting of the Agent Orange Working Group was held on August 28. The working group and its Science Panel have met on several occasions since that date to address the issues and to share information of equal concern to all participants. We view our participation as absolutely vital to the scientific process and as fully consistent with President Ronald Reagan's expressed goal of ensuring "... that the full resources of the federal government are available to support the working group's continuing efforts." The establishment of this Committee at the White House level signals the President's personal interest in resolving this issue.

The VA Advisory Committee on Health-Related Effects of Herbicides continues to meet quarterly at VA Central Office. This VA Advisory Committee, which consists of distinguished

scientific representatives and representatives from major veterans' organizations, is continuing its primary role of advising me on appropriate Agency policy as it relates to research on Agent Orange and other phenoxy herbicides. Recently, the Committee has been serving as one of the groups reviewing the preliminary design of the epidemiological study. It has proven to be an effective instrument for receiving suggestions from concerned veterans and other individuals who participate in the "open" meetings.

The VA Agent Orange Policy Coordinating Committee has continued its important role of overseeing the Agent Orange related activities of the various departments of the Veterans Administration. The Committee, as I stated previously, is currently chaired by the Deputy Administrator Designate (Attachment A). I expect this Committee to play a more active role in the development of policy initiatives and in making recommendations to me on future agency Agent Orange-related programs.

STATE COOPERATION

The Agent Orange issue has become a matter of concern not only at the national level but also at the state level. Agent Orange-related legislation has been introduced in several state legislatures in response to the growing public concern over the possible adverse health effects of this defoliant upon their Vietnam veterans.

The Veterans Administration has made every effort to cooperate with the states as they undertake their various activities. We have offered to provide an historical perspective on the use of phenoxy herbicides in Vietnam and to advise on what is known about the effects of exposure and what research initiatives are currently underway or in planning.

State representatives have met with VA officials on several occasions at VA Central Office. On August 21, 1981, representatives from the States of New York, Texas, California, and New Jersey participated in the quarterly meeting of the VA's advisory Committee on the Health-Related Effects of Herbicides. Additionally, representatives of the Veterans Administration have appeared at various state legislative hearings and meetings of state commissions. We believe that we have learned from these contacts and have found them to be very worthwhile. We have received indications that they have been welcomed by the various states also. It is our intent to continue this spirit of cooperation.

INTERNATIONAL ACTIVITIES

The Agent Orange controversy has not been limited to the United States. It is of concern to the government of Australia which also had troops who may have been exposed to herbicides during their service in Vietnam. In June of this year, the Veterans Administration was honored by a visit by the Australian Minister of Veterans Affairs, Senator Anthony Messner. Senator Messner met with a number of officials from the Veterans Administration and other Federal agencies to discuss the

actions of his government in responding to the Agent Orange controversy. Of particular interest are the efforts of the Australian government to conduct an epidemiological study of its Vietnam veteran population. We have provided them with periodic updates on the status of various undertakings of this government, particularly the Centers for Disease Control's birth defects study and the Air Force's Ranch Hand study. We are currently exploring the possibility of sending American scientists to Australia to participate in a number of activities of the Australian government now ongoing or in the planning stage.

Mr. Chairman, I believe these contacts have been especially helpful and fruitful. The exchanges we have had have been open and frank. This spirit of cooperation that we have established will allow both governments to benefit from the actions of the other and can help avoid unnecessary false starts or delays.

LITERATURE ANALYSIS

Mr. Chairman, I am pleased to report that the comprehensive literature review of worldwide scientific literature on Agent Orange and other phenoxy herbicides used in Vietnam, has been completed in accordance with the provisions of Public Law 96-151. The two-volume report which includes an annotated bibliography and analysis of 1,200 scientific papers, was submitted to the Veterans Administration by J.R.B. Associates, Inc., of McLean, Virginia, on October 1, 1981. Copies of this literature research effort have been provided to

the Chairmen of the Senate and House Veterans' Affairs Committees. We are distributing this document widely within the VA. Copies have been provided to the Environmental Physician and the Library Service at each of our 180 health care facility locations. Distribution of the review to the 130 VA Research and Development Services located in the field is also underway.

We are also providing copies to members of the White House-established Agent Orange Working Group, the Advisory Committee on Health-Related Effects of Herbicides, the National Academy of Sciences, the Office of Technology Assessment, the Departments of Agriculture and Defense, Surgeon General of the U.S. Air Force, Library of Congress, the Centers for Disease Control and other individuals, organizations, or scientific research groups. We realize that the concern about the possible health effects of Agent Orange and other selected herbicides is not solely limited to that of the United States, and we will be sharing this research effort with the governments of Canada, Australia, and New Zealand. The successful completion of this review represents a step forward on the long road to understanding the complex health issues related to the use of herbicides. It will undoubtedly serve as an invaluable scientific resource which will assist scientists and others in identifying areas suitable for additional research.

EDUCATIONAL ACTIVITIES

As part of our continuing effort to keep abreast of scientific developments in the area of dioxin research, members of our VA staff played a major role in the planning and organizing of the recent International Symposium on Chlorinated Dioxins and Related Compounds which was held here in Arlington, Virginia, on October 25-29, 1981.

The primary objective of the meeting was to present new information, summarize existing data, and recommend research efforts for the future. The importance of the conference to the Veterans Administration was that it provided a strong scientific information base to the VA as a whole and especially to 42 Environmental Physicians of the VA who were able to attend.

The program consisted of presentations by a number of eminent scientists from the United States and abroad to address the topics of animal and environmental toxicology, analytical and environmental chemistry, biochemistry, metabolism, laboratory safety and waste management, human observations and risk assessment.

Panels consisting of experts in each area met to deliberate upon such problems as the validity of data, identification of data gaps and future research need. The conclusions of these panels were presented to the entire group on the final day of the meeting. In addition to VA physicians the conference was attended by approximately 250 scientists from many parts of the world.

AGENT ORANGE REGISTRY

We are continuing our program of examining Vietnam veterans who are concerned about the possible health effects of Agent Orange. The results of these examinations are entered into the Agent Orange Registry. Since it began in 1978, over 67,000 veterans have participated in this program. I encourage Vietnam veterans to request an examination at their nearest VA health care facility. A veteran who participates will receive a comprehensive physical examination and be asked to complete a questionnaire about his service in Vietnam. Following the examination, the veteran is advised of its results. A special follow-up letter will be sent outlining the findings and the need for follow-up, if indicated.

We have shortened waiting times for veterans requesting examinations. To accomplish this, a special monthly statistical report is prepared utilizing registry data forwarded to VA Central Office. The monthly and cumulative totals of examinations performed and the number of pending examinations, that is, examinations scheduled but not completed, are analyzed within the Office of Environmental Medicine. Stations evidencing "out-of-line" situations, that is, those stations with examinations pending more than three work-weeks or having more than 50 examinations pending during any reporting period are contacted by program officials at VA Central Office and directed to take immediate action to reduce the number of pending examinations to comply with Central Office guidelines. These statistical reports and action plans on out-of-line stations are forwarded to the Chief Medical Director and the Associate Deputy Chief Medical Director. I believe that this "tracking" system is working and will serve to reduce the number of complaints from veterans regarding excessive waiting times.

The Data Analysis Task Force continues to meet bi-monthly to review registry activities and make recommendations for improving the registry process. Among the activities being undertaken is the preparation of an address update form and questionnaire to be sent to all registry participants. Every effort is being made to expedite this activity. Following internal VA review, it will be sent to the Office of Management and Budget for approval. Distribution will be made as soon as possible thereafter.

The Task Force is also reviewing the examination process. In this regard, I have asked that recommendations for improvements in the registry process be provided to the Chief Medical Director by the end of this year.

EPIDEMIOLOGY STUDY

Public Law 96-151, section 307, directed the Veterans Administration to design a protocol for and conduct an epidemiological study of persons who were exposed to the class of chemicals known as the dioxins produced during the manufacture of various phenoxy herbicides, including Agent Orange, to determine if there may be long-term adverse health effects resulting from that exposure. Recently, Public Law 97-72 was enacted. Public Law 97-72 amended section 307 of Public Law 96-151. The amendment directs the Veterans Administration to design a protocol for and conduct an epidemiological study of any long-term adverse health effects among Vietnam veterans which may be the result of exposure to phenoxy herbicides, including Agent Orange, and the class of chemicals known as the dioxins. Under Public Law 97-72, the effects of exposure to other herbicides and chemicals may also be included in the mandated study.

In March 1980 the Veterans Administration issued a Request for Proposals (RFP) for the design of the epidemiologic study (Attachment B). In May, the National Veterans Law Center initiated legal action attempting to obtain a temporary restraining order to preclude VA from opening any proposals received for the contract for the design of the study. Although the court subsequently denied the temporary restraining order, it referred the matter to the GAO. On advice of attorneys from both the Justice Department and VA General Counsel, action was deferred on awarding a contract pending the GAO ruling. Following the February 1981 ruling by the GAO in favor of the VA, the VA contacted the bidders and sought updated information about continued interest in and capability to design the study protocol.

In April 1981, a panel of experts reconvened to review the revised bids and subsequently to recommend that the School of Public Health, University of California at Los Angeles, be awarded the contract for the design protocol. The contract, awarded in May 1981, required U.C.L.A. to submit a draft of the study protocol to the VA within 60 days. Following a 30-day extension, requested by U.C.L.A., a preliminary design was received by the VA in early August and forwarded to the Agent Orange Working Group, the VA Advisory Committee on Health-Related Effects of Herbicides, and to the Office of Technology Assessment and to others for review and comment. The U.C.L.A. School of Public Health has been provided the comments from reviews of the draft. On November 3, 1981, Public Law 97-72 amended section 307 of Public Law 96-151. We are presently considering what changes, if any, should be made to accommodate the development of the protocol to the amendment of section 307, Public Law 96-151.

VIETNAM VETERAN MORTALITY STUDY

As a result of a suggestion from members of the Science Panel of the former Interagency Working Group on Phenoxy Herbicides and Contaminants (IWG), now reconstituted as the Agent Orange Working Group, the VA began a study of mortality among Vietnam veterans. The study concentrates on veterans who were in service during FY 68-73, a group chosen because reasonably accurate demographic, service and mortality data are available for it. The focus of the study will be to see if there are differences in mortality rates between those servicemen who served in Vietnam and those servicemen who did not.

In brief the study plan is: first, to gather the data, check its accuracy and completeness and take whatever actions necessary to assure its quality; then to compare the overall mortality rate for those who served in Vietnam and those who did not; and then study the causes of death for those two groups.

Members of the VA staff prepared a draft of a preliminary study protocol, a copy of which was originally given to the Science Panel of the former Interagency Work Group. Recently a brief oral summary of these plans were given to the Science Panel of the newly constituted Agent Orange Working Group. The VA presented this same summary to the American Public Health Association earlier this month.

A positive factor concerning the Vietnam Veterans Mortality Study is that it shall provide us with some statistical indicators of the total Vietnam experience rather than narrowly focusing only on those factors relating to exposure to Agent Orange.

The Vietnam Veteran Mortality Study should provide the first large-scale analysis of deaths among Vietnam Era Veterans. It will gather useful information on the level and causes of death among Vietnam-service veterans and non-Vietnam service veterans within ten years of exposure. As the study continues, we will inform the Committee of its progress.

ARMED FORCES INSTITUTE OF PATHOLOGY (AFIP)

The Veterans Administration is continuing to cooperate with the Armed Forces Institute of Pathology (AFIP) in providing biopsy and autopsy materials to the Institute for analysis. The purpose of this analysis is to determine what diseases Vietnam veterans are currently suffering from, as reflected in biopsies removed during surgical operations and/or autopsy examinations.

Both VA and Armed Forces hospitals have been directed to submit tissue materials to the AFIP through their respective pathologists. The sole criterion for the selection of submitting cases is "service in Vietnam." The purpose of using this single criterion is to obtain as complete a sampling as possible of the current medical problems of Vietnam veterans, as reflected by analysis of their diseased tissues.

If, in the initial phase of this effort, clustering, peaks or trends are found, these indicators will assist us in determining the nature of subsequent epidemiologic studies. Cases in the Agent Orange Registry are being specifically monitored to identify clustering or peaks in specific organ-diagnosis combinations, clustering of any pathologic changes that are unusual for particular sites and finally, clustering of unusual ages for particular diagnoses. The assessment of causability of diseases found in Vietnam veterans, in relation to their exposure to Agent Orange, is in the initial phase of collection and pathologic evaluation.

For general orientation, it has been found in diseases caused by chemical agents that a particular chemical or drug will tend to affect primarily or predominantly one organ, site, or tissue. While a given chemical or drug may affect more than one part of the body, it tends to exhibit its most serious consequence on one "critical organ," or at most, several "critical organs."

We will continue our close cooperation with the AFIP in order to ensure that the sampling base is adequate to meet the goals of this research.

PUBLIC LAW 97-72

Mr. Chairman, the President recently signed into law authorization for the Veterans Administration to provide certain health care services to Vietnam veterans for conditions which may be due to exposure to herbicides of other chemical agents used in Vietnam. For purposes of this authorization all conditions will be treated other than those which, under guidelines issued by the Chief Medical Director, are found to have resulted from a cause other than the exposure. The Enactment of Public Law 97-72 signals a new approach to medically assisting Vietnam veterans claiming symptoms or illnesses as a consequence of possible exposure to Agent Orange. This legislation will provide immediate assistance to Vietnam veterans in need of examination or treatment by the Veterans Administration. I believe that our guidelines will be in keeping with the spirit and intent of this legislation. We are prepared, consistent with those guidelines, to receive and treat all Vietnam veterans reporting for care at our health care facilities. Recognizing that there is a high degree of public interest in this area, we are preparing the guidelines for publication in the Federal Register and will be soliciting comments from the public on their content. We have also asked the VA's Advisory Committee to review the guidelines and offer us the benefit of their recommendations.

SUMMARY

Mr. Chairman, since the problem of Agent Orange first surfaced for the Veterans Administration in early 1978, we have pursued in a forthright manner the resolution of this most complex health care issue. During all of this time, Agent Orange has remained a highly emotional, volatile and perplexing issue for Vietnam veterans as well as the general population. I believe that the Agent Orange controversy devolves into two basic questions: 1) whether a veteran was exposed to Agent Orange, and 2) what are the effects of that exposure. The Veterans Administration in April 1980, resolved the first question by presuming that a veteran who served in Vietnam was exposed to Agent Orange (Attachment C). This was prompted by the lack of any definitive method of identifying individuals who were exposed. Recognizing this, and consistent with our policy to resolve reasonable doubt in the favor of the veteran, the Veterans Administration decided to remove any requirement that a veteran prove exposure.

Unfortunately, the second question is not so easily answered. I am confident that the various activities that I have described today will enable us to bridge some of the knowledge gap which has thus far frustrated our most concerted efforts to resolve this question.

Let me reiterate that I am committed to the resolution of this issue. Vietnam veterans have every right to question what actions are being taken on their behalf and "where are we going next?" I am determined to set this agency on the path which will lead us to a scientific resolution of the possible health impact of Agent Orange on the Vietnam veteran population.

AGENT ORANGE

POLICY COORDINATING COMMITTEE

Membership

Deputy Administrator, Chair

Associate Deputy Administrator for
Congressional and Public Affairs

Associate Deputy Administrator
for Planning and Finance

General Counsel

Chief Medical Director

Chief Benefits Director

Assistant Deputy Administrator
for Public and Consumer Affairs

Assistant Deputy Administrator
for Program Planning and Evaluation

or

Designated Representatives

ATTACHMENT A

EPIDEMIOLOGICAL STUDY - CHRONOLOGY

- December, 1979 - Congress passes the "Veterans Health Programs Extension and Improvement Act of 1979." Section 307 of the Act directs the Administrator to design a protocol for and conduct an epidemiological study of Vietnam veterans who were exposed to dioxins contained in herbicides (Agent Orange).
- December 20, 1979 - President signs the Act into law.
- January 8, 1980 - Decision made to use the competitive procurement method to obtain the required services for the design of the protocol.
- February 4, 1980 - Announcement of intent to let contract for the design of the protocol published in Commerce Business Daily.
- March 19, 1980 - Request for proposals issued.
- April 11, 1980 - Pre-bid conference conducted by VA at VACO.
- May 6, 1980 - National Veterans Law Center initiates legal action attempting to obtain a temporary restraining order to preclude VA from opening any proposals received for the contract for the design of the study.
- May 7, 1980 - Court denies motion for temporary restraining order.
- May 8, 1980 - Last day for receipt of bids.
- May 1980 - A selection panel of government experts (including a representative from OTA) reviews bids received and makes tentative ranking. On advice of U.S. attorney no further action is taken because of litigation and pending referral of bid protest to GAO.

ATTACHMENT B

- June 13, 1980 - Judge Green refers matter to GAO to rule on bid protest.
- December 23, 1980 - Letter from Elmer B. Statts, Comptroller General to Congressman Ray Roberts, describing GAO review and recommendation that VA not proceed with award of contract until completion of that review.
- February 2, 1981 - GAO rules entirely in favor of VA.
- February/March 1981 - VA contacts bidders and seeks updated information about continued interest in and capability to design study protocol.
- April 1981 - Panel of experts reconvened to review revised bids.
- May 1, 1981 - School of Public Health, U.C.L.A., selected to design study protocol.
- May 1, 1981 - U.C.L.A. receives notice of award. Has 60 days to submit draft of study protocol.
- June 1981 - U.C.L.A. granted 30 day extension for submission due to difficulty experienced in working with DoD records.
- August 6, 1981 - Preliminary design submitted by U.C.L.A.
- August 1981 - VA submits design for review.
- November 12, 1981 - Comments received provided to U.C.L.A.

Department of Veterans Benefits
 Veterans Administration
 Washington, D. C. 20420

DVB Circular 21-80-1
 Change 1
 (Confirming Teletype Trans.)
 April 3, 1980

REVIEW OF AGENT ORANGE EXPOSURE CLAIMANTS

1. Purpose: This change provides additional criteria for review and reconsideration of claims.

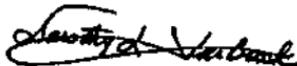
2. DVB Circular 21-80-1 is changed as follows:

Page 2, following paragraph 3e insert:

*4. Policy Regarding Allegation of Exposure. It is VA policy to resolve any reasonable doubt in favor of the claimant. Consistent with this policy, given the considerable uncertainties as to the deposition of defoliants in Southeast Asia and troop positions at pertinent times, we will accept in the absence of positive evidence to the contrary a Vietnam veteran's contention of exposure.

a. In the course of the review being conducted under this circular, claims should be identified where the policy cited above was not applied. If there is positive evidence that veteran could not have been exposed, such as a headquarters assignment in Saigon or a desk job at the Da Nang Air Force Base, such facts should be cited. Otherwise it will be assumed that veteran was exposed to defoliants as alleged and the claim for service connection will be resolved on the basis of the relationship of the disability in question to such exposure.

b. Copies of favorably amended rating decisions will be submitted to Director, Compensation and Pension Service (211C).*



DOROTHY L. STARBUCK
 Chief Benefits Director

Distribution: CO: RPC 2901
 FU: RPC 2068 plus VUC and VRUC, 1 each
 EX: ASO and AR (included in RPC 2068)

804625

ATTACHMENT C,

Chairman SIMPSON. I want to ask you, so that we might understand clearly, who is responsible for the final decision on the protocol? I want to understand fully the timetable that is involved in reacting to the peer group comments on Dr. Spivey's and Dr. Detel's protocol. Would you share that, please?

Mr. NIMMO. Well, I guess, Mr. Chairman, in the final analysis that decision is mine and I, of course, in making that decision will be guided by the Policy Coordinating Committee which I mentioned in my earlier testimony.

We have given UCLA a period of 35 days to give us an acceptable design study for further review. As soon as we get that and, again, we have given them 35 days, we will again submit that design to the scientific technical groups for study and we certainly hope, and expect, that that will be an acceptable product.

Chairman SIMPSON. Dr. Shepard, I would like to address this to you; how much responsibility should you have in making the decision on whether or not to accept the protocol? Has the VA adopted guidelines by which to determine whether that protocol is acceptable?

Could you draw that microphone over closer, Dr. Shepard, please?

Dr. SHEPARD. Mr. Chairman, I think that as Mr. Nimmo has indicated, we will have the ultimate responsibility, but we will certainly be guided by our own VA advisory committee, which has reviewed the protocol, the product to date, as well as the efforts of the Agent Orange Working Group and the Office of Technology Assessment.

So, I think that it will be a joint decision, but ultimately that responsibility lies with the Veterans' Administration.

Chairman SIMPSON. Would you please share for the record a definition, under this present administration and in the VA, of a protocol and a request for a protocol, the so-called RFP?

Dr. SHEPARD. Sure.

Chairman SIMPSON. Request for proposal, excuse me, as we refer to it.

Dr. SHEPARD. I think it's accurate to say, Mr. Chairman, that if you were to ask that question to a number of scientists you might get slightly different answers. In other words, the definition of the word "protocol" might be open to some interpretation.

However, I would like to give you a broad definition: Essentially a protocol is a design for the conduct of a study. It outlines the essential steps to be taken in order to arrive at a conclusion.

As I say, the details of exactly what is included in a protocol might be open to debate. But that's essentially what a protocol is supposed to be.

As to your second question, the "request for proposal" is simply a solicitation to any scientific group for submission of a proposal for the conduct of such an effort.

Chairman SIMPSON. How would the VA characterize the UCLA product? Is it, in your professional opinion, a protocol? Does it comply with the contract? I would like your views on that.

Dr. SHEPARD. As Mr. Nimmo indicated, we have decided that the submission that was presented does not satisfy the terms of the contract. We do not consider that it was an adequate protocol, ade-

quate for review. And in that light, we plan to give the UCLA group an additional 35 days to come up with a satisfactory design proposal that will be satisfactory for review.

Chairman SIMPSON. At what point in time did the VA realize that the submission would not be a full or an adequate protocol?

Dr. SHEPARD. We did not realize that, sir, until we had the submission of the initial product, which has undergone review and the comments are in hand.

Chairman SIMPSON. Based on your decision to give UCLA 35 more days at this time, will the National Academy of Sciences not review the same draft protocol as the OTA and the working group?

Dr. SHEPARD. Sir, we have submitted that initial product to the National Academy of Sciences and the VA is currently negotiating with the Academy of Sciences for that review process.

Chairman SIMPSON. Do you believe that UCLA can improve the protocol sufficiently if given this additional opportunity? Would consideration be given to rewriting the contract demands?

Dr. SHEPARD. I would certainly hope that the UCLA team would improve and modify their product based on the comments that have been submitted. I have every hope and expectation that they will, in fact, be able to develop an acceptable protocol.

Chairman SIMPSON. What weight is going to be given to the recommendations made by the OTA, the working group, and others, for changes in the protocol or in the contract with UCLA?

Dr. SHEPARD. That's a little difficult for me to answer. What we will do, and have done, is provide these comments from various review groups to the UCLA team. It is our expectation and our understanding that those comments will be utilized in their modification.

Chairman SIMPSON. The document submitted by UCLA does not explain how an exposure index will be established. The law center stated that this effort is not a protocol because in the cohort study, a major focus of the design is based on an exposure index, and exposure is very hard to estimate. That fact has been known since 1979 and has been discussed repeatedly by the Agent Orange Working Group.

Did the VA anticipate that UCLA's submission would present these difficulties because of the exposure problems? Where are we with that?

Dr. SHEPARD. I think it would be more helpful to await Dr. Detels' comments, but I would say in general terms that establishing a detailed exposure index is technically a rather complex process, and that we cannot reasonably expect to have a detailed exposure index at the time of the next submission.

We are hopeful, however, that the methodology for establishing an exposure index will be provided to us. But I doubt that we will have all of the details available to us at that time.

Chairman SIMPSON. What did the VA do in the period between 1979 and 1981 in order to get its data and the DOD data in the form that would enable UCLA to proceed with the protocol in as efficient manner as possible?

Dr. SHEPARD. Well, I think, again, the details of that answer probably will more appropriately come from the members of the Department of Defense who will be testifying. But certainly we

have been working very closely with those individuals and it's my perception that they have been working very diligently.

I think it's important to point out to the committee that the whole question of military records is an ongoing evolving process. In other words, there isn't a body of records in one place, at any one point in time, that tell the whole story. These records are widely distributed, many of them are classified, and I think it's important to point out that this is an extremely complicated process. A lot of record review has to be done by hand. Most of the information contained in these records is not computerized.

Chairman SIMPSON. That is something we are going to discuss today. In light of the tremendous amount of manual effort required here, I would like to know if we can speed up the process in some way.

Let me ask you, is there an established communication channel in place between the VA research scientists and scientists who do research on a contract basis for the VA? Do the parties generally share their findings? I ask that question because Dr. Spivey's proposed mortality study seems to demonstrate no knowledge of the VA mortality study that was presented recently to the Agent Orange Working Group and originally prepared for the American Public Health Association. Would the UCLA mortality study overlap with the VA mortality study? Would it not have been possible for the working group to have been made aware of the study at an earlier date? Did the VA inform Dr. Spivey of the problems it had experienced earlier with interpreting the agent orange registry? I would be interested in your comments on those questions.

Dr. SHEPARD. First of all, let me just point out that the VA's mortality study was initially recommended and suggested by the Science Panel of the previous Agent Orange Working Group. And our biostatisticians have been working at trying to identify data bases; in other words, data sources.

Not very much has really happened except that a broad outline of a potential methodology has been worked out.

It's my understanding that Dr. Spivey's proposal is a more specific mortality study that would look at the causes of death of exposed individuals. The VA's initial efforts to date are simply looking at the methodology by which a broad mortality study might be developed.

Chairman SIMPSON. My time has expired. Senator Cranston, please.

Senator CRANSTON. Thank you very much, Mr. Chairman.

I want to welcome you, John Murphy, the VA's new General Counsel to this hearing. I am delighted that another Californian holds a very important position in the VA.

Mr. MURPHY. Thank you very much.

Senator CRANSTON. Bob, as you know, section 401 of Public Law 97-72 was enacted on November 3, authorizes the expansion of the epidemiological study to include evaluation of the health effects on Vietnam veterans of exposure to elements other than dioxin in Vietnam.

What are your plans in that regard?

Mr. NIMMO. We have no immediate plans, Senator, to broaden that project. I think we have to take a very close look and see

whether it would be advisable to broaden the survey to issues or problems other than agent orange. If we can do that without burdening the entire survey with additional time, it might be wise to do that. But I would be most reluctant, absent some compelling reason, to broaden the survey if it would have an adverse effect on the resolution of the agent orange issue.

Senator CRANSTON. If the study is not expanded, how do you believe the possible effects of exposure to other elements in Vietnam such as agent blue or the antimalarial drugs or other possibly toxic substances can be distinguished so as not to confound and confuse the study results?

Mr. NIMMO. It may well be that we will have to include those issues in the study. As I say, we have made no decision. After we get an acceptable protocol, we then can examine those issues and see whether or not we want to expand the study.

Senator CRANSTON. Do you have any thoughts as to how the effects of exposure to these other elements should be investigated, if the study is not expanded?

Mr. NIMMO. No, I do not, Senator.

Senator CRANSTON. I realize the expansion question is a complicated matter.

Mr. NIMMO. Yes, it is.

Senator CRANSTON. With reference to the agent orange registry, what analysis has been done of the data in the registry up to this point?

Mr. NIMMO. If I may, Senator, I would like to defer to Dr. Shepard on that.

Senator CRANSTON. Certainly. Doctor.

Dr. SHEPARD. As we have testified before, we have been collecting this data. One of the really burning questions has been whether there is a higher than expected incidence of malignancy in this group. In other words, does agent orange exposure tend to lead to malignancies?

We looked at the first 20,000 individuals who were examined in our agent orange registry and sought to get specific information on the numbers of those individuals who have reported malignancies and the types of malignancies.

Of the first 20,000, we discovered that 234 of those individuals reported malignancy. We can provide you with the details of what malignancies those consisted of.

We are now in the process of updating that to include as close to the some 68,000 that we have currently examined as we can. We should be able to provide you with that information fairly soon.

We are looking at a number of other illnesses and conditions which have been reported and we have some information that we can provide the committee for the record.

Senator CRANSTON. You agree that the registry is a valuable source of information and should be used as much as possible and reasonable?

Dr. SHEPARD. I think it's a valuable source of information, but I would caution the registry participants consist of a self-selected group of individuals. Therefore, one cannot readily use the registry data as an epidemiological tool because the principal factor that

this group has in common is that they are worried about exposure to agent orange.

It would be difficult to establish a control group against which to compare this group of individuals. We certainly can provide descriptive materials as to what the problems are and what complaints these veterans have registered.

Senator CRANSTON. Bob, I recognize the self-selected group aspect to the registry. Nonetheless, a great deal of money has been spent developing it, some 60,000 individuals have been entered into the registry and that would seem to make it a pretty valuable resource, that could demonstrate groupings of symptoms and possible trends. Isn't that so?

Mr. NIMMO. I think that's probably true, yes.

Senator CRANSTON. In your discussion of the registry, Bob, you mentioned the ongoing physical exam process. With reference to those exams, what guidance is provided to VA physicians on what exactly to look for in an exam? And are you satisfied that the examinations are now being sufficiently standardized?

Mr. NIMMO. May I again, Senator, defer to Dr. Shepard?

Senator CRANSTON. Sure.

Dr. SHEPARD. It is our hope that the examinations are being conducted in a thorough manner bearing in mind that these examinations are being conducted in some 180 different VA facilities by a number of different physicians. I think that in the eyes of most physicians a physical examination is a fairly standard procedure.

We have not given any specific guidance as to exactly what a physical examination should include. But the guidance is that it will be a complete physical examination.

The laboratory studies are reasonably standardized.

Senator CRANSTON. Bob, before you assumed the job as Administrator, as you know there was a lot of feeling that the agent orange physical examinations were not standardized. Do you feel that this year adequate progress has been made in getting them standardized?

Mr. NIMMO. Well, I would have to say, Senator, that I don't think we have had adequate procedures in this entire matter. But whether or not there should be instructions from VA Central Office to the medical centers establishing, administrative rules for physical examinations, for example, is a question I just am not competent to answer.

Senator CRANSTON. Yes.

Mr. NIMMO. I think that's a medical issue that Dr. Shepard or the Chief Medical Director would have to answer.

Senator CRANSTON. Yes. In your statement you address the agency's attempts to increase research efforts relating to agent orange. What's been the response of the recent D.M. & S. request, or to the recent D.M. & S. request, for more such research proposals from VA investigators?

Mr. NIMMO. Again, if I may defer to Dr. Shepard.

Senator CRANSTON. Fine.

Dr. SHEPARD. As you know, a number of months ago the Department of Research and Development in the Department of Medicine and Surgery requested that VA physicians and other researchers

in the Veterans' Administration submit proposals for research related to agent orange.

Initially a deadline of November 15 was given for submission of those proposals.

Senator CRANSTON. How many have you gotten back?

Dr. SHEPARD. I can't give you that answer, sir. We have had somewhere in excess of 70 contacts requesting information. The process is such that the initial proposals will be submitted to the local research committee at each hospital for—

Senator CRANSTON. I just wanted to know how much was happening.

Dr. SHEPARD. We have had a high level of interest and we expect a number of good proposals to be forthcoming.

Senator CRANSTON. How much money will be available for these proposals and how will the level of the research appropriation for fiscal 1982 affect the effort?

Dr. SHEPARD. I really am not able to answer that. If we may provide that for the record, sir.

[Subsequently, the Veterans' Administration submitted the following information:]

It is not possible to determine at this time the amount of funding which will be required for additional research efforts until all proposals have been received and reviewed. Our projected funding will be contingent upon the various structures of such proposals, the time period required for the research and the nature of resources which will be required to initiate and complete them.

Senator CRANSTON. Bob, are you intending to see to it that some money is earmarked for this purpose?

Mr. NIMMO. There is no money specifically earmarked for this purpose; no, sir.

Senator CRANSTON. But will you be able to find funds in the budget for them?

Mr. NIMMO. I am sure we can; yes, sir.

Senator CRANSTON. With reference to your efforts to implement section 102 of Public Law 97-72 which establishes new eligibility for VA health care for Vietnam veterans who may have been exposed to agent orange, when will you publish the proposed guidelines in the Federal Register?

Mr. NIMMO. Maybe I can defer if I may, Senator, to Mr. Murphy.

Senator CRANSTON. Fine.

Mr. MURPHY. The Administrator mentioned that the guidelines were sent out to VA field facilities today; they will be published in the Federal Register very shortly. We will attempt to submit them to the Federal Register within a week or so, as fast as possible, for publication.

Senator CRANSTON. Thank you.

When will the guidelines for radiation related treatment be published?

Mr. MURPHY. I believe that the radiation guidelines would be published together with those addressing agent orange.

Senator CRANSTON. Has guidance been sent to the field offices on radiation-related care?

Dr. SHEPARD. Yes, sir. It was sent out at the same time as the other guidelines.

Senator CRANSTON. There seems to be some confusion about the costs associated with this new eligibility. There were some VA officials suggesting significant new costs. In a statement to time of the signing of Public Law 97-72 the President recognized the intent of Congress; that is, that any care provided under this new authority is to come from existing resources through adjustments in priority categories when he stated that he expects the new eligibility to "be implemented in a manner that will not add to budgetary costs of Veterans' Administration medical care and treatment."

Is it safe to presume that this statement by the President supersedes any statements by a VA official regarding cost implications?

Mr. NIMMO. Well, Senator, I expect the President's statement was based on an opinion of the Office of Management and Budget, and it is not unusual for people to disagree with Office of Management and Budget estimates I suppose.

We are hopeful that it can be done without increased costs. I have a personal view that there will be some costs in connection with it. I doubt that they will be exorbitant or of any tremendous magnitude. But there are some differences of opinion.

Senator CRANSTON. Thank you very much. I have more questions but I guess we will have to submit them in writing. My time has expired, not only in asking the questions, but in the time I can be here today.

Thank you very much.

Chairman SIMPSON. Thank you, Senator Cranston.

[The Veterans' Administration response to written questions submitted by Hon. Alan Cranston, ranking minority member of the Senate Committee on Veterans' Affairs, follows:]

RESPONSE OF THE VETERANS' ADMINISTRATION TO WRITTEN QUESTIONS SUBMITTED BY
HON. ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON
VETERANS' AFFAIRS

1. QUESTION: In your discussion of the registry, you mentioned the on-going physical exam process. With reference to the exams --

A.(i): What guidance is provided to the examining physicians on how to provide a veteran after the exam with information as to the results of that examination in cases in which the physician discovers that an individual veteran has a serious health problem?

RESPONSE: As outlined in DM&S Circular 10-81-12 and Chief Medical Director Letter IL 10-81-5, the environmental physician must advise the veteran of positive and negative findings from the Agent Orange examination both personally and in writing. In his absence, another physician must transmit the information to the veteran.

1. QUESTION:

A.(ii): What about cases in which the follow-up letter to a veteran would provide potentially upsetting information that may be inappropriate to send by mail -- for example, that the physician has diagnosed a psychiatric disability -- or information of a private nature -- such as that the physician has diagnosed a venereal disease?

RESPONSE: The environmental physician advises the veteran personally as well as in writing regarding any positive or negative findings. If a condition of a sensitive nature is diagnosed, the environmental physician is given the liberty to schedule a return appointment or telephone the veteran to discuss the medical condition.

Continued

1. QUESTION:

B: Would you please provide for the record how many Agent Orange exams had been scheduled and were pending as of November 1?

RESPONSE: As of October 31, 1981, there was a total of 2,777 Agent Orange examinations pending.

1. QUESTION:

C: You mentioned that, when you find that a medical facility has a significant backlog of examinations pending, program officials contact the station and direct the station to "take immediate action" to reduce the backlog. What type of action is anticipated and what is the impact of such action on other efforts at the medical facility?

RESPONSE: When a medical facility is contacted regarding a backlog of examinations, the facility initiates its own plan of action. This may include increasing the number of clinic appointments scheduled for Agent Orange examinations, assigning additional physicians to perform Agent Orange examinations or establishing clinics for examinations on Saturdays. Each plan of action will differ from facility to facility depending on geographic location and facility resources. The impact varies depending upon the precise local situation.

2. QUESTION: In your statement, you addressed the Agency's attempts to increase research efforts relating to Agent Orange. How much money will be available for these proposals, and how will the level of the Research Appropriation for FY 82 affect this effort?

RESPONSE: The Agent Orange research proposals must be funded from the monies available for support of the VA's general research & development programs. No money has been identified specifically for this purpose to date since it is unlikely that any projects can begin during the current fiscal year. The peer review process of proposals submitted in April, 1982, will not be completed until the end of FY 1982. Many potential VA investigators have expressed interest in working in the area but all proposals will have to be reviewed to insure their scientific excellence.

The VA is currently funding three investigator initiated projects relating to Agent Orange (see attachment). These research projects are being funded in addition to the special solicitation for Agent Orange related proposals.

AGENT ORANGE WORKING GROUP

VETERANS ADMINISTRATION

SCIENTIFIC ACTIVITY REPORT

(The following investigator-initiated projects are being conducted at VA field facilities)

<u>Title of Activity</u>	<u>Funding</u>		
	<u>FY 80</u>	<u>FY 81</u>	<u>FY 82</u>
1. Urinary 6-Hydroxy Cortisol; Physiologic and Pharmacologic Studies (including Agent Orange)	\$34,750	\$37,800	\$41,580
2. Effect of TCDD on Lipid Metabolism Dioxins	26,611	20,513	22,564
3. Mechanisms of Dioxin Induced Toxicity Using the Chloracne Model	-0-	15,000	5,500

3. QUESTION: With reference to your efforts to implement Section 102 of Public Law 97-72 which, as you know, establishes new eligibility for VA health care for Vietnam veterans who may have been exposed to Agent Orange--

A.(i): What Guidance are you providing VA Facility Directors as to reallocating resources to meet the potential new demand for services that may be created by this new eligibility?

RESPONSE: As a result of providing examinations to Vietnam veterans with Agent Orange related complaints, those veterans found to be in need of care are accorded an eligibility priority for treatment, with a ranking above the non-service-connected category. Thus, the need to reallocate resources due to increased demand created by implementation of the pertinent provisions of P.L. 97-72 will be accommodated automatically because the above noted eligibility priority ranking is already in place. The eligibility category that may be affected by P.L. 97-72 is the non-service-connected veterans.

Continued

3. QUESTION:

A. (ii): How will you monitor this impact?

RESPONSE: The key monitoring mechanism for tracking Agent Orange statistics is the Agent Orange Registry. To address the monitoring need specifically created by P.L. 97-72, however, we will ask the Facility Directors to add an additional element to an existing reporting system.

3. QUESTION:

B: Are you taking steps to ensure that any new information on the pattern of Vietnam veterans' health problems, that may become available as the result of this new eligibility, are collected and analyzed?

RESPONSE: Consideration is currently being given by the VA to the development of a system to retrieve statistical information derived from the examination of veterans under the new eligibility criteria provided for by Public Law 97-72. The medical information obtained from each veteran will be permanently recorded and maintained within a Consolidated Health Record (CHR) for future review of possible health patterns which may be reflected through the retrieval of this additional information base.

Continued

3. QUESTION:

C: In response to a question at the hearing on the costs associated with this new eligibility, you noted your personal view that there will be some costs associated with it.

(i): What is the magnitude of these costs over the next five fiscal years?

RESPONSE:

<u>Fiscal Year</u>	<u>Five-Year Cost Projection</u>			
	<u>Number of Hospitalizations</u>	<u>Number of Outpatient Visits (millions)</u>	<u>Total Cost (\$millions)</u>	<u>FTEE</u>
1 Full Year	17,352	.612	88.7	2,751
2	17,352	.612	88.7	2,751
3	17,352	.612	88.7	2,751
4	17,352	.612	88.7	2,751
5	17,352	.612	88.7	2,751
Total	86,760	3.060	443.5	

It should be noted that these costs are, at best, tentative and uncertain because we do not know the nature of the illnesses for which veterans will be seeking treatment nor the number of veterans who will actually seek such care under this authority.

4. QUESTION: In your summary, you state that the questions of whether a veteran was exposed to Agent Orange was resolved "by presuming that a veteran who served in Vietnam was exposed". I note that, although this is generally true, the D.V.B. Circular that is attached to your testimony provides for this presumption not to apply in cases in which "there is a positive evidence that a veteran could not have been exposed" and cites as examples of such cases veterans who served in Da Nang or Saigon. Bob, the Veterans' Affairs Committees in the explanatory statement describing the compromise agreement on H.R. 3499 indicated their intent that a standard along the lines of the one set forth in your testimony is the appropriate one -- that is, if the veteran served in Vietnam, then exposure is presumed.

- A. Do you agree?
(If yes) Will you take steps to see that the D.V.B. Circular is revised to reflect that approach?

ANSWER: Because the presumption of exposure to herbicides is rebuttable, Saigon and Da Nang were used in DVB Circular 21-80-1 as examples of the type of service to be considered during an evaluation of exposure in each veteran's claim. Such rebuttals are rare, however. Service in Saigon or Da Nang does not bar a finding of exposure. We are amending DVB Circular 21-80-1 to remove the reference to Saigon and Da Nang to ensure that there will be no misunderstanding by our claims examiners about a presumption of exposure.

5. QUESTION: With reference to the Agent Orange Working Group discussed on pages 2 and 3 of your statement:

Who is the VA's lead representative on that body?

RESPONSE: Mr. Charles Hagel, the Deputy Administrator.

6. QUESTION: You indicated your intention that the Policy Coordinating Committee "play a more active role in the development of policy initiatives" relating to Agent Orange. How do you see this taking place.

RESPONSE: In the past, the Policy Coordinating Committee served primarily as a vehicle for ensuring that the various departments and offices of the VA having program responsibility for some aspect of the Agent Orange controversy were kept informed of the activities of the Veterans Administration and the Federal government. To a limited degree, it played a role in making policy recommendations to the Administrator. The information function of the Committee will be performed through wider distribution of the weekly status report prepared by the Office of the Special Assistant to the Chief Medical Director for Environmental Medicine. This will permit a greater portion of the time available for Committee meetings to be devoted to a discussion of policy options and recommendations. Also, greater use will be made of task forces composed of individuals having particular expertise to address specific problems as they may arise.

7. QUESTION: Has the literature review been provided to individuals within the Department of Veterans' Benefits or on the Board of Veterans' Appeals?

(If yes) Specifically to which officials?

(If no) Will you see that it is so distributed. I believe that those responsible for adjudicating Agent Orange-related claims have as great a need for a document of this sort as anyone.

RESPONSE: The literature analysis consists of reviews of significant scientific papers on Agent Orange and other phenoxy herbicides and it is an invaluable resource document for research. Copies have been provided for information purposes to the following:

Department of Veterans Benefits -

Dorothy L. Starbuck, Chief Benefits Director, DVB

Board of Veterans Appeals -

Sydney J. Shuman, Chairman, BVA

James J. Butler, Chief Member, BVA

Edward R. Stanford, Chief Member, BVA

8. QUESTION:

A: With reference to your discussion of cooperation with the efforts of various states regarding the Agent Orange issue, has the VA made any attempt to avoid unnecessary duplication of effort, either as between Federal efforts and State efforts or as between various states?

(If no) Do you plan any such efforts?

(If yes) Have you been successful in this regard?

RESPONSE: Wherever the VA is aware of states' activities, we maintain contact with state governments in order to monitor their Agent Orange related activities and to share information with them. A number of state representatives have visited and consulted with the staff of the VA's Office of Environmental Medicine. In addition, VA staff personnel have on several occasions testified at various state legislative hearings related to Agent Orange issues. In this series of efforts on the part of the VA, attempts have been made to provide recommendations and guidance to state governments in order to avoid unnecessary or potentially counterproductive research efforts.

Continued

8.A. RESPONSE: At the same time we have made suggestions where research initiatives could be of mutual benefit. In New York, for example, the VA has worked very closely with that State's Dioxin Commission and Department of Health to develop a meaningful mortality study as well as other epidemiological research efforts which might best be conducted at the state level because of ready access to state record systems such as birth certificates, death certificates, and tumor registries. The VA views these contacts with state governments as mutually beneficial and very productive. Other states with which the VA has been in close contact include Texas, New Jersey, Wisconsin, Minnesota, Pennsylvania, and California. We look forward to working with other states as we become aware of their interest or activities in this area.

8. QUESTION:

B: Do you see any way in which the efforts of the various states can be of assistance to the Federal government in its efforts to find

RESPONSE: Question incomplete.

9. QUESTION: A key element in any study of the health effects of exposure to Agent Orange in Vietnam or, more generally, of the health effects generally of service in Vietnam, appears to be reliable information on the mortality of veterans. In this connection, it would seem to be desirable to be able to rely on the VA's beneficiary identification and records location subsystem -- BIRLS. However, the GAO in its statement today notes that a study completed earlier this year relating to the costs of providing VA health care to persons not eligible to receive such care raised "questions about the reliability of" data in BIRLS.

A. Do you share the GAO's concerns?

ANSWER: Yes.

B. What action do you plan to enhance the completeness and reliability of BIRLS data?

ANSWER: We are continually increasing the number of BIRLS records which contain verified or complete military service information. The vast majority of veterans discharged since 1973 have verified BIRLS records. Additionally, a reconciliation of data between the Compensation, Pension and Education systems of records should be completed by 1985; the information in all responses to regional office requests to the service departments is input into BIRLS; and we are studying a proposal to update the BIRLS record of any claims folder which is retrieved by Record Processing Center for an inquiry.

Continued

9.C. QUESTION: In the floor statement that I made at the time of final Senate passage of the Omnibus Reconciliation Act of 1981, which withdrew general eligibility of war veterans for the burial benefit, I urged that the VA take all steps necessary to maintain the cooperation it now receives from the private sector, specifically funeral directors, who I am sure will respond appropriately if made aware of the great importance of the data involved. I also noted my view of the importance of the VA making "administrative mechanisms . . . operational by October 1, 1981, for reporting to BIRLS information on the deaths of veterans who are buried in national cemeteries". Senator Simpson expressed similar concerns. What steps has the VA taken on these two fronts?

ANSWER: Effective October 1, 1981, the Department of Veterans Benefits began entering data into BIRLS for all veterans who are buried in national cemeteries. With respect to maintaining the cooperation from the private sector, representatives of DVB worked with the National Funeral Directors' Association (NFDA) during legislative consideration of the Omnibus Reconciliation Act of 1981. Also, a DVB representative addressed National Funeral Directors' Association national convention in October to explain the law and to stress the importance of their continued cooperation in providing us with the necessary mortality data.

Continued

9. QUESTION:

D.(1) What other steps has the VA taken to minimize the effects of that legislation on the completeness of BIRLS data on Veterans' mortality?

ANSWER: I believe that the steps that have already been taken will be sufficient to ensure the completeness of BIRLS data on Veterans' mortality.

D.(ii) Please provide, for the record, detailed information on this matter, including copies of all pertinent directives and guidance issued in this regard.

ANSWER: Attached is DVB Circular 23-81-13 which sets forth administrative procedures to be followed to ensure completeness of the mortality data in BIRLS.

Department of Veterans Benefits
Veterans Administration
Washington, D.C. 20420

DVB Circular 23-81-13

September 18, 1981

**PROCESSING NOD'S (NOTICES OF DEATH) FOR
VETERANS INTERRED IN NATIONAL CEMETERIES**

1. **BACKGROUND** - Public Law 97-35 changed the criteria for entitlement to certain veterans burial benefits. Consequently, deaths of veterans interred in national cemeteries may go unreported to BIRLS unless a subsequent application for benefits is filed. To provide for the proper recording of these NOD's, DMA (Department of Memorial Affairs) Cemetery Service (41) will route a copy of VA Form 40-4956, Record of Interment, for all veterans buried in national cemeteries to the WRO (Washington regional office) Administrative Division (23) for processing against BIRLS. These procedures are effective October 1, 1981.

2. **PURPOSE** - This circular provides instructions for FNOD (First Notice of Death) processing of VA Form 40-4956 by the WRO and subsequent processing of these cases by other field stations, including the RPC (Records Processing Center).

3. **PROCEDURES**

a. DMA Cemetery Service will forward a copy of all VA Forms 40-4956 pertaining to veterans to the WRO Data Terminal Unit. All processing of VA Forms 40-4956 will be accomplished in the Data Terminal Unit, regardless of whether a file number is present, and must be performed via the Target System. Upon completion of processing by the WRO, all VA Forms 40-4956 will be returned to the DMA Cemetery Service (41A).

b. A BIRLS inquiry (BINQ) will be made on each VA Form 40-4956 received from the Cemetery Service.

(1) If BIRLS locates a record and it contains a date of death, no further processing is required.

(2) If BIRLS locates a record with a file number but it does not contain a date of death, an FNOD will be entered based on information on the VA Form 40-4956.

(a) The office of jurisdiction will remain the same as shown in BIRLS. For cases located at the RPC, station number "376" must be entered as office of jurisdiction on line 18 of the NOD screen. This will prevent a request for transfer being sent to the RPC.

(b) A photocopy of the VA Form 40-4956 will be made and forwarded to the office of jurisdiction for association with the

September 18, 1981

veteran's claims folder. It will be annotated with the date of FNOD processing and the initials of the individual who entered the transaction.

(c) Upon receipt of VA Forms 40-4956 in regional offices, the claims folder will be XC'd and a VA Form Letter 21-15 dispatched, as appropriate.

(d) For folders located in the RPC, RPC personnel should XC the folder and file the VA Form 40-4956. The data terminal clerk at WRO will forward a VA Form Letter 21-15 to the next of kin if he/she is listed as spouse. The following sentence in the second paragraph of VA Form Letter 21-15 "Mail all documents and your application to the VA office shown above." will be blacked out. A note will be added at the bottom right side of VA Form Letter 21-15 to read: "Mail all documents and your application to (enter name and address of regional office of jurisdiction over spouse's address)." VA Form Letter 21-15 may be signed by the Chief, Administrative Division.

(3) If BIRLS shows "no record" or locates a record which does not contain a file number (e.g., VADS or insurance record), an FNOD will be entered.

(a) The Ready screen will be completed as follows:

COMMAND: Enter FNOD and operator's password.
 SCREEN NUMBER: Enter "DMA".
 FULL NAME: Enter veteran's full name.
 SOCIAL SECURITY NUMBER: Enter, if available.
 SERVICE NUMBER: Enter, if available.
 DATE OF BIRTH: Enter, if available.

(At least one identifying number must be entered.)

(b) When the NOD screen is returned, the date of death will be entered. Lines 17 and 18 (cause of death, death in service and jurisdiction) will not be displayed for data entry. "DMA" will be displayed in the folder location field and "NO FOLDER ESTABLISHED FOR DMA CASE" will be shown in the text portion of the screen.

(c) If the person shown as next of kin on VA Form 40-4956 is the spouse, the data terminal clerk will prepare VA Form Letter 21-15 for dispatch as outlined in subparagraph (2)(d) above.

4. RECEIPT OF SUBSEQUENT APPLICATIONS BY FIELD STATIONS - As indicated above, no claims folder will be established for those veterans who are assigned a file number based on receipt of a VA Form 40-4956. When a subsequent CEST or FNOD is entered by a regional office, the BIRLS record will be displayed showing "DMA"

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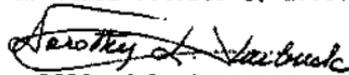
as folder location and in the text portion "NO FOLDER ESTABLISHED FOR DMA CASE." The clerk should enter his/her station number in folder location field and establish a lightweight XC-folder and continue processing as directed by governing procedures. Under duplicate records consolidation (DUFC) the retained record must be a claims record unless both records are DMA cases.

5. ADDITIONAL INFORMATION

a. Any questions concerning these procedures should be brought to the attention of Daphne M. Walker, DVB Administrative Service (231A), on FTS 389-3184.

b. The Chief Memorial Affairs Director concurs with these procedures.

6. RESCISSION: This circular is rescinded October 1, 1982.


DOROTHY L. STARBUCK
Chief Benefits Director

Distribution: CO: RPC 2902
FD: FLD: DVBFS, 15 each, plus 10 additional copies each
to Adjudication and Administrative activities
in ROA
EX: ASO & AR, 1 each

Continued

9. QUESTION:

E.(i) Have you consulted with the GAO on these issues in order to ensure that BIRLS data on mortality are as accurate and reliable as possible?

ANSWER: No.

E.(ii) (If not) Will you do so?

The completeness of the mortality data in BIRLS will be assessed to determine whether the changes necessitated by the Omnibus Reconciliation Act of 1981 have affected the level of reporting of veterans' deaths. We will consult with a variety of experts to assist us in the assessment, including the GAO.

10. QUESTION:

A. What steps has the VA taken to utilize the findings from the European studies that seem to suggest that a higher incidence of soft tissue sarcoma might be related to exposure to dioxin?

RESPONSE: The European studies have been called to the attention of the contractor designing the epidemiological study. He and others considering the possible health effects of the phenoxy herbicides are aware of the possible relationship to soft tissue sarcoma and pays special attention to this as a suggested consequence of exposure to Agent Orange.

Continued

10. QUESTION:

- B. What actions has the VA taken to develop more information to test the findings of these studies?

RESPONSE: As a result of this awareness, attention is being given to the detection of such pathology in the design of the epidemiology study, in reviews of the Agent Orange Registry, in the AFIP study of pathological specimens, and in a special AFIP protocol being developed to review soft tissue sarcomas.

11. QUESTION: What information is provided to Vet Center staff on Agent Orange so that they can most effectively advise their Vietnam veteran clients as to pertinent VA policies in connection with examinations and treatment for conditions that the veterans believe may have resulted from exposure to Agent Orange and also so that Vet Center staff can refer such veterans to appropriate individuals at nearby VA medical centers?

RESPONSE: Each Vet Center staff has a full complement of the literature produced by the VA Central Office on Agent Orange. Each Vet Center also has the videotape film on Agent Orange. The staff have all been made aware of the contents. Veterans who complain of Agent Orange are given the literature and are then referred to the nearest VA medical center, specifically to the Environmental Physician. The psychiatric and allied staff in the hospital or Ambulatory Service of the Medical Center are educated through general staff training, hospital seminars, rounds, etc., that consider Agent Orange problems.

12. QUESTION: A recent Office of Environmental Medicine's Weekly Status Report of Herbicide Orange, dated November 13, 1981, noted that a consultant has been selected to review claims of questionable skin conditions of Vietnam veterans to determine whether they might be chloracne?

- A. Who is this consultant and what are his or her qualifications?

RESPONSE: Dr. A. Betty Fischmann, Chief of Dermatology, VA Medical Center, Washington, D.C., is currently in the process of reviewing compensation claims related to skin conditions claimed by Vietnam veterans. Dr. Fischmann, who is a member of the VA's Chloracne Task Force, is being assisted by Dr. Leon E. Brown, a senior dermatology resident at the Washington D.C., VA Medical Center.

12. QUESTION:

- B. What is the timetable for this review?

RESPONSE: The review should be completed by June 30, 1982.

Continued

12. QUESTION:

- C. Will the veterans involved be contacted after their claims have been reviewed, to inform them of the findings.

RESPONSE: A veteran will be notified of the review only if some change is made in the diagnosis, further procedures are necessary to make a diagnosis, or there is a change in the determination that the condition is not service-connected.

12. QUESTION:

- D. Will this consultant also be participating in the revision of the educational materials being prepared for the field?

RESPONSE: It is likely that Dr. Fischmann, as a member of the Chloracne Task Force will be involved in the preparation and/or review of any future educational materials on chloracne.

Continued

12. QUESTION:

- E. What is the timetable for completion of these educational materials?

RESPONSE: The present review of cases where chloracne is claimed will contribute information on the current appearance and state of the condition if it can be diagnosed so long after exposure. Previous descriptions in the medical literature deal with the condition of chloracne within a year or so of its appearance. We will seek as much information as possible about its state some ten years after exposure to the causative agent, using the record review as a basis. For that reason, the educational materials will be prepared after the review is completed.

13. QUESTION: You mentioned that you are interested in developing "an action plan specifically designed to enhance the ability of the Veterans Administration to effectively maintain full communication with Vietnam veterans" and others on Agent Orange issues. In this regard, I want to note that members of the minority staff, together with majority staff members and others, saw the VA film on Agent Orange earlier this month. They have reported to me that the movie was quite good and, with some minor updating, would be an effective way to communicate the VA's efforts to Vietnam veterans and others concerned about this issue. Please provide, for the record, information on the number of showings this film has received to date and the estimated audience and any plans the agency has for updating it and for increasing the availability of the film so as to reach the widest possible audience.

RESPONSE: The Veterans Administration has not maintained statistics on the specific number of showings of the film "Agent Orange: A Search for Answers." This film was previewed by representatives of major service organizations prior to distribution to each of the 180 major VA health care facilities. Following this, special guidelines were forwarded with each film which provided instructions for ensuring that it would receive widespread viewing by

Continued

13. RESPONSE: VA health care staff, VA Regional Office staff, and Vet Outreach personnel and by veterans and the general public. An information letter from the Chief Medical Director further outlining the significance and utilization of this film was sent to the field on February 5, 1981.

The updating of this film will be contingent upon the development of significant new scientific or medical information which would justify a revision. Such new information will undoubtedly develop as a consequence of scientific research being undertaken by the VA, as well as other Federal and State agencies, other public institutions, and research efforts outside of the United States.

Through widespread distribution of this audiovisual film to 180 VA medical facilities, 58 regional offices, all Vet Outreach Centers, VA regional libraries, VA Central Office Library and Film Library, every effort has been made to ensure that the film is readily available for showing to concerned individuals or groups of Vietnam veterans.

14. QUESTION: In your statement you mentioned that the Australian Minister of Veterans Affairs met with various VA officials during a visit this year. To your knowledge, has the Australian Government been able to develop information as to which of its troops were exposed to Agent Orange or other toxic substances in Vietnam?

RESPONSE: It is my understanding that the Australian government is conducting an epidemiological study of Australian troops who served in Vietnam. That study will include a questionnaire to determine the nature of exposure to herbicides. The VA is not aware of any Australian military records per se that document exposure of troops to herbicides or other toxic substances.

15. QUESTION: Is there any summary of the findings of the symposium on dioxin discussed on page 8 of your statement?

(If yes) Would you please submit that summary for the record of this hearing?

RESPONSE: The International Symposium on Dioxin, held in Arlington, Virginia, from October 25-29, 1981, was essentially a meeting for the purpose of exchanging scientific information between researchers. Proceedings of this important scientific meeting are being compiled by non-government sponsors but are not yet available. The Veterans Administration was an active participant at this meeting with attendance by key VA Central Office staff and a sizeable representation of 50 environmental physicians from selected VA health care facilities.

16. QUESTION: With reference to the Vietnam veteran mortality study discussed on page 12 of your statement--

A. What will be the sources for the data that will be used in this study?

RESPONSE: The Vietnam veteran mortality study will use existing computer files from the Department of Defense and the Veterans Administration.

Continued

16. QUESTION:

B. What is the timetable for this study?

RESPONSE: The study protocol is currently under review by the Science Panel of the interagency Agent Orange Working Group and no timetable has been developed as yet.

16. QUESTION:

C. Will there be attempts to match the Vietnam-service and Vietnam-era deaths by age, race, geographic location of home, pre- and post-service, as well as service experience and other variables that might play a role in any difference in the rates of death?

RESPONSE: Analyses of mortality rates will initially be satisfied by age, race, education and Vietnam service. Subsequent analyses may make use of other variables.

16. QUESTION:

D.(1): What is the relationship between this study and the mortality study proposed by the contractor as part of the overall Public Law 96-151 study?

RESPONSE: We will not know the precise relationship between the two studies until we receive a protocol for the PL 96-151 study being prepared by UCLA.

Continued

16. QUESTION:

- D.(ii): Was the contractor advised of the VA study and, if so, when, by whom, and in what detail? (Please provide copies of all documents relating to the Agency's efforts to inform the contractor about this study.)

RESPONSE: Drs. Spivey and Krause were contacted by Dr. William Page in May 1981 by telephone and told of the VA's mortality study--no records were made of these telephone calls. An abstract of the American Public Health Association presentation on the study was sent to Dr. Krause on June 8, 1981 and Dr. Spivey was briefed by Dr. Page in detail on the study on November 3, 1981. A copy of the abstract is attached.

Standard Abstract Form for the 109th Annual Meeting

American Public Health Association
Los Angeles, CA Nov. 1-5, 1981

For directions on how to fill out abstract, see below

Epidemiology

June 8, 1981

*Submitted to (name of Section, etc.)

Date

Vietnam Veteran Mortality Study

**Title of Paper

Amy J. Kuntz, Ph.D., William F. Page, Ph.D., and Barclay M. Shepard, MD

***Authors, Affiliations, City, State (two letter abbrev.)

Veterans Administration Central Office, Washington, DC

***Which author will present the paper? William F. Page, Ph.D.

The Vietnam Veterans Mortality Study is a study of the mortality experience of veterans of the Vietnam era, those who served in Vietnam as well as those who didn't serve in Vietnam. The study involves matching selected personnel records from the Department of Defense with records of death from the Veterans Administration. The resulting file provides information to compute mortality rates adjusted for age, race, and educational attainment for men who served in Vietnam and men who did not serve in Vietnam. The presentation will include discussion on the definition of study cohorts, problems in file - matching and analysis, presentation of results, and future plans.

Type abstract within box.

Type abstract within box.

Rules applying to Abstracts

- Type title and authors affiliation(s) on lines provided above.
- Type abstract within space allotted
- Body of Abstract should follow these guidelines:
 - statement of purpose
 - statement of methods and data
 - statement of findings and conclusion reached
 - single space with 3 letter indentations
 - use upper and lower case

Sample

- Medical Care Section
- ** Medical Students and Group Practice
- *** Nathan Kays, MD, and Aeneas Fuller, DPH
- Dept. of Community Med., Lancaster Univ., Lancaster, PA
- *** Nathan Kays, MD

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Author/Coauthor Identification Form

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WILLIAM FRANK PH.D.

First Name

Middle

Degree (one only)

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Continued

16. QUESTION:

E: In light of the discussion at the November 19 VA Advisory Committee Meeting on this mortality study and the mortality study proposed by the contractors, will there be attempts to consolidate the two efforts?

RESPONSE: Until we see the revised protocol from UCLA we will not be able to decide whether an attempt to consolidate the studies should be made.

16. QUESTION:

F: You note that this study will focus on overall Vietnam service experience as opposed to focusing only on Agent Orange. Would it be possible, however, to further refine the study so that, in addition to the overall information, it could yield some data specifically on veterans who were assigned to units in Vietnam which had a significant chance of exposure to Agent Orange?

RESPONSE: The overall study cannot be readily modified to include data on unit assignments in Vietnam without causing undue delay. Identification of the units with significant exposure to Agent Orange is too incomplete at present to allow meaningful analysis of mortality in relation to exposure.

17. QUESTION: In response to a question from Senator Specter at the hearing, you indicated that, in your view, the government "would be looking at hundreds of millions of dollars going into probably the middle of the next century" if, for purposes of disability compensation, Congress established a presumptive causal relationship between, in Senator Specter's words, exposure to "Agent Orange and birth defects, cancer (and) tumors". What was the basis for this cost estimate?

ANSWER: The "estimate" of hundreds of millions of dollars was based on Senator Specter's scenario, which assumed that anyone exposed to Agent Orange would be compensated for birth defects, cancer, tumors or any other associated disability. Based on the anticipated incidence of serious disease and mortality in the general population without regard to the cause, the cost associated with such a scenario conceivably could be hundreds of millions of dollars. However, the cost of providing benefits for exposure to Agent Orange to individuals who were possibly exposed and for incidences of disease or birth defects in their children has not been determined. The cost cannot be estimated with any degree of accuracy until more data are available.

17. continued

At this point, I want to make it clear that the cost of compensation is not a factor in the endeavor to learn what, if any, deleterious effects result from exposure. We are committed, to the extent that science permits, to resolve this question and are prepared to compensate all veterans, no matter the cost, who are found to have become disabled by virtue of their exposure.

18. QUESTION: In response to a question from Chairman Simpson at the hearing, you indicated that "in the final analysis" the decision to approve a protocol for the epidemiological study would be yours. You noted that, in making that decision, you would be guided by the Policy Coordinating Committee but you made no mention of the statutory role of the Office of Technology Assessment?

A: Under Section 307(a) of Public Law 96-151, what role do you consider is required to be given to OTA with reference to the approval of a protocol?

RESPONSE: The Veterans Administration has had the cooperation of the Office of Technology Assessment at every stage in the development of the protocol for an epidemiological study. We very much appreciate their assistance and hope that we continue to work together. I have every intention of seeking the advice and guidance of the OTA before deciding whether to approve the protocol.

Continued

18. QUESTION:

- B. In the event that OTA did not approve a particular protocol, would you be prepared to approve such a protocol and proceed to use it for the conduct of the study?

RESPONSE: It seems unlikely that the VA would use any protocol found to be seriously flawed by peer review as it is conducted by OTA. If some minor disagreement arose, I can see that I might approve the protocol in the interest of expediting the study.

19. QUESTION: In light of the continuing controversy over the VA's action in not going forward with the mandated study during the pendency of the legal challenge to the initial attempts in 1980 to contract for the design of a protocol, please submit a detailed chronology relating to the legal challenge and the Agency's actions in response thereto. Also, please submit for the record any letters, memoranda, or notes of conversations relating to advice that the VA received from other agencies, such as the Department of Justice and the General Accounting Office, and any opinions of the VA's General Counsel on whether the VA should proceed.

ANSWER: On May 7, 1980, the National Veterans Law Center (NVLC) filed a bid protest with the General Accounting Office (GAO) and simultaneously sought a Temporary Restraining Order and Preliminary Injunction in U.S. District Court. Both actions were sought to prevent any award of the contract while the actions were pending. On May 8, 1980, after oral arguments, Judge Greene denied the motion for a Temporary Restraining Order but retained jurisdiction of the motion for a preliminary injunction. On June 13, 1980, as a result of a May 19, 1980, joint letter submitted by the Justice Department, acting on behalf of the VA, and the NVLC, Judge Greene requested the GAO to consider the bid protest.

19. continued.

As a result of these legal challenges, the VA had to determine whether it should proceed with negotiation and award of the contract.

Discussions were held between members of the General Counsel's Office, Supply Service, DM&S and the U.S. Attorney's office. No notes of conversations, letters, memoranda, or VA General Counsel opinions were written during the time frame that the decision making process was occurring on the determination as to whether to make an award.

Judge Greene refused the TRO motion which would have maintained the status quo pending the GAO determination. In addition, while generally an Agency is precluded from making an award pending a determination by GAO on a bid protest, the Federal Procurement Regulations at section 1-2.407-8(b)(4) allow an award if the Agency determines that (a) the procurement is urgently required, (b) delivery or performance will be unduly delayed by failure to make the award promptly, or (c) a prompt award will otherwise be advantageous to the Government.

19. continued.

Thus, while an immediate award would have been legally possible, the VA and its contracting officer were faced with certain countervailing considerations which ultimately led them to delay award of the contract until after the controversies were resolved. Primarily the contracting officer had to determine whether an immediate award or a delayed award would ultimately lead to a quicker completion of the contract. At the time he was making this determination he anticipated a ruling by the Comptroller General in November whereas the decision was not made until February 2, 1981, 7 months after the request by Judge Greene. Had he made an award and GAO ruled against the VA, there was an excellent chance, given the sensitive nature of this contract, that GAO would have ordered a cancellation of the awarded contract and resolicitation by the VA, thereby causing substantial delays. In addition, the officials at the VA were of the belief that, given the attitude of the NVLC, any action by the VA in awarding the contract

19. continued.

prior to resolution of the protest would have resulted in additional actions by the NVLC in U.S. District Court. The VA thus determined that the contract would be completed more quickly if award was delayed until the controversies were resolved.

On February 2, 1981, GAO ruled in favor of the VA. The VA then proceeded to contact the bidders to seek updated information about their continued interest in the protocol design contract. By letter dated April 8, 1981, copy attached, the U.S. Attorney's office advised the VA that they were unaware of any legal or administrative matter which would bar the awarding of the contract. On May 1, 1981, U.C.L.A. was awarded the contract. On June 25, 1981, the action in U.S. Court was voluntarily dismissed by the NVLC.

20. QUESTION:

A: On what day does the 35-day extension given to UCLA, the contractor, to refine its submission expire?

RESPONSE: The 35-day extension initially given the contractor was to have expired on December 30, 1981. A second extension to January 25, 1982, has been granted because of the illness of the principal investigator.

20. QUESTION:

B: What do you realistically expect to receive at that time?

RESPONSE: At that time the Veterans Administration expects to receive a draft protocol which will satisfy the terms of the contract with the University of California at Los Angeles, i.e., a draft study design suitable for peer review.

Continued

20. QUESTION:

C: What, if any, additional costs to the VA are associated with this extension?

RESPONSE: At the present time, the VA does not expect any additional costs.

20. QUESTION:

D: Please submit for the record a copy of the VA's letter or letters to the contractor regarding this extension and the comments of the reviewers on their review of the initial submission.

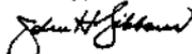
RESPONSE: The VA's letters to UCLA regarding the first submission are attached. Included also are letters from the Chairman of the review groups.

should provide justification for any decisions made about concealing exposure information and for how long. A clear presentation of the designers' plans to disclose health outcome measures and to disclose or to withhold exposure information will greatly reduce or eliminate concern that the alleged bias will compromise the study.

During the period of the OTA review, Secretary Richard Schweiker of the Department of Health and Human Services announced the existence of newly-found information about exposure to Agent Orange. That information would seem to be of great value to Dr. Spivey in designing an exposure index, and methods to share it with him are worthy of consideration.

Included in the attached OTA review packet is a list of the OTA Review Panel Members, a chronology of the epidemiologic study, a list of OTA staff who participated in the review, and written comments received from each OTA Review Panel Member. Should you or your staff have any questions, please call Mr. Michael Gough at 226-2070.

Sincerely,



John H. Gibbons

Enclosure

REVIEW OF THE VETERANS ADMINISTRATION
DRAFT PROTOCOL FOR
EPIDEMIOLOGIC STUDIES OF AGENT ORANGE

Office of Technology Assessment

U.S. Congress

September 1981

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INTRODUCTION

An OTA Advisory Panel met and considered the Draft Protocol for Epidemiologic Studies of Agent Orange. The protocol was prepared by the School of Public Health, University of California at Los Angeles, Gary Spivey, MD, MPH, principal investigator, and Roger Detels, MD, MS, and Dean of the School of Public Health, co-principal investigator.

The paucity and in some cases absence of details from the protocol prevented the Advisory Panel from reaching a decision about whether or not a study to answer questions about associations between Agent Orange and health effects can be successfully designed. To some extent the lack of detail is understandable because of the press of time to prepare the draft protocol, and the Panel is sympathetic on that count. The Panel is more concerned about the expressed intention of the study designers to withhold details from reviewers to protect the study's integrity. The Advisory Panel will consider swearing all or a subgroup of its members to secrecy in reviewing a detailed protocol, but it cannot discharge its duty unless those details are provided. Possible methods to deal with privacy and secrecy during conduct of the study are discussed in the body of this review.

The protocol describes:

1. A historical cohort study to assess possible associations between Agent Orange exposure and health effects.
2. A method to estimate Agent Orange exposure and the feasibility of assembling exposed and unexposed groups for the historical cohort study.
3. Three preliminary studies of mortality among Vietnam veterans that make use of existing records.

4. Two preliminary studies of morbidity among Vietnam veterans that make use of existing records.

The historical cohort study is slated to begin in 1983. The designers propose that the preliminary studies be carried out in the intervening period.

HISTORICAL COHORT STUDY REVIEW

Description of the Study

The contractors propose an historical cohort study to investigate: Is exposure to Agent Orange in Vietnam related to subsequent morbidity and mortality among veterans?

The appropriateness of the historical cohort approach is unchallenged, but the ability to carry out such a study rests on one large unknown and a number of other serious hurdles. The central question is whether or not an acceptable assessment of exposure to Agent Orange can be developed. Without such an assessment, the study is not possible. The other major concerns, discussed in this review, include: determination and specification of health outcomes, participation rates to be expected from veterans, sample sizes necessary for the study, organization and conduct of the study, and maintenance of privacy.

The study design is traditional, and proposes a comparison between the long-term health experience of a group of veterans exposed to Agent Orange and the experience of a similar but unexposed group. The cohorts will include Army and perhaps Marine Corps ground troops, selected to represent various levels of exposure. Active duty and veteran records of each member of the cohorts will be examined for pertinent information. All members of both the exposed and unexposed cohorts will be sent a questionnaire and asked to participate in a physical examination. The cohorts will be followed into the future to detect possible longer-term health effects. Data from all sources will be analyzed to

determine whether certain health outcomes are statistically more common in the exposed group.

General Comments

As the authors have noted, the historical cohort study is described very broadly, with few details. It is not possible, therefore, to either approve or disapprove the plan. Grave doubts were expressed by some panel members that any possible study would produce scientifically credible results. Until more preliminary work is completed, a definitive judgment cannot be made.

The panel favors proceeding with the proposed "Feasibility Test of Exposure Estimation," specification of health outcomes, and determining appropriate methods to measure outcomes (discussed in detail below). Development of the exposure index is seen as the most critical task at this time. If such an index can be developed, a decision can be made about the feasibility of an Agent Orange Study; if it cannot be developed, the study is impossible.

Assuming successful development of the exposure index and identification of outcomes, a pilot testing phase, which would be a scaled-down version of the large study, is recommended. The pilot study will define and standardize procedures and provide an estimate of the rate of veteran participation, another touchstone of the study.

Before any testing of the design is begun, however, decision criteria must be developed for application during and after the feasibility and pilot phases. Failure to meet threshold criteria in critical areas -- in development of an exposure index or in achieving an adequate response rate -- must lead to either abandoning the study or making specific alterations in design.

Exposure

The contractors' proposal to determine the feasibility of constructing an

exposure index allows for the possibility that a satisfactory index cannot be developed. Criteria to evaluate the feasibility study, and the basis for making a decision between success and failure, must be made explicit before the feasibility study is begun. Although a general outline for making an index was provided in the protocol, details which permit making a critical review are lacking.

The panel agrees about the desirability of constructing categories of probable exposures, but does not expect great precision in defining the categories. For instance, the number of times (0, 1, 2, 3, or more) that a soldier may have been exposed as probably sufficient to assign him to an exposure category. It may be that such an exposure index would obviate the need for a control group of veterans who did not serve in Vietnam. Elimination of that control group has advantages:

1. Differences between Vietnam veterans and other Vietnam-era veterans, which could act as confounding variables, and falsely obscure or enhance true associations between exposure and outcome are avoided.
2. The problem of differential response rates between Vietnam veterans and other Vietnam-era veterans is avoided. It is likely that Vietnam-era veterans who did not serve in Vietnam will be less motivated to participate than Vietnam veterans, to whom eventual benefits from the study might accrue.
3. Those who did not serve in Vietnam will be aware of their exposure status (not exposed), while others in the study might not be. This difference could produce biased responses. (The issue of disclosing exposure status to participants is discussed below.)

HERBS Data and Tape

Development of an accurate exposure grid depends heavily on the accuracy of

the HERBS data.¹ Validation of these data will improve the credibility of the exposure index. At the panel meeting, a staff member of the House of Representatives Committee on Veterans' Affairs stated that high altitude photographs showing areas of defoliation exist. The time-place coordinates of HERBS records could be matched against the information in the photographs as a measure of HERBS accuracy and possibly to fill in known gaps. Until more is known about these photographs, it is impossible to predict their usefulness. They are highly classified. It is our understanding that a mechanism can be established to allow the defoliation patterns to be interpreted and the information turned over to the study designers. If our information is accurate, this could prove a valuable source of data.

Health Outcomes Measurements

The Panel strongly recommends that health outcomes be specified by the end of the feasibility phase. Sources of information already available or available by the end of 1982 may be sufficient to specify outcomes. These include:

1. Scientific literature already published.
2. Review of the herbicide literature (mandated by the same law PL 96-151 that mandates this epidemiologic study) expected by October 1981.
3. Results from the questionnaires and physical examinations of the Air Force Ranch Hand Study, available toward the end of 1982.

As evidenced by their review of the popular literature, the authors appreciate that veterans have a wide range of complaints that have not been verified by medical science. It is important, in deciding upon which outcomes to measure, that the study look at health effects that veterans believe result from Agent Orange, even if scientific support is weak. The VA's Agent Orange registry provides relevant information.

Participation and Sample Size

The rate of response to invitations to participate in the study is one of the pivot points for deciding whether or not a study should be conducted. The anticipated response rate in the study is not discussed in the draft protocol, but it must be addressed promptly, either in the "feasibility phase," or as part of an initial pilot study. A breakpoint response, leading to alteration or abandonment of the study, should be specified in advance.

The designers should control for bias introduced by proportionately greater participation by veterans who both believe they were exposed to Agent Orange and have health complaints. Some check on this possible bias should be built into the protocol. A suggestion from the Panel is to ask participants what they believe their exposure status to be and then to look for associations between perceived exposures and the results of physical and laboratory testing. A comparison of the associations between health outcomes and perceived exposure and between outcomes and exposure as defined by the study, assuming that there are some differences in the two measures, can be used as an indicator of possible self-selection bias.

The manner of contacting cohort members is critical to the potential success of the study and details of the proposed procedure should be specified. Issues that will bear on the resulting response rate include:

1. Method of contact (personal interview, telephone interview, letter)
2. Contacting body or individual(s) (VA, DOD, contractor, other government officials). The Air Force has carefully considered this issue, and their deliberations are worthy of review by the study planners.
3. The availability and use of supporting statements from veterans' organizations to accompany invitations to participate.

4. Use of a publicity campaign to precede and coincide with the invitations.
5. The possibility of guaranteeing medical care for conditions detected in study participants.

By the end of the feasibility phase, the study designers must estimate the sample size that will be required. An important consideration in this estimation will be what health outcomes are to be measured. Estimates of the time and resources required for the cohort study will depend on sample size. The organizational structure for the eventual study will also be partially determined by the size of the study.

Physical Examination

The Panel is highly critical of the discussion of physical examinations in the protocol. The use of a general screening examination to detect potential specific, and often subtle, effects of toxic chemicals, is inappropriate. In addition, important areas of concern are not addressed by the physical examination. Neurological, reproductive, and psychological effects, for example, cannot be detected with the proposed exam. Although the examination and laboratory procedures cannot be fully determined until decisions concerning health outcomes are made, there can be no doubt that certain effects, including those mentioned above, must be included.

The lack of discussion of examination procedures disturbed Panel members. Data collection for this study must be carried out systematically and in a highly standardized fashion. To the extent possible, outcome measures should depend on objective measurement.

The proposed physical examination procedure, which apparently allows for ad hoc decisions by physicians to perform additional examinations and to require

additional laboratory tests, is unacceptable. Some mechanism should certainly be devised for study physicians to refer participants to VA physicians or to their own private physicians for additional tests or care, but all participants should receive the same study examination.

The following items might be considered in efforts to standardize both the physical examination and laboratory tests:

1. Physicians administering examinations should undergo training by the organization responsible for the study.
2. The number of physicians administering examinations should be as small as practicable.
3. Criteria should be specified for making decisions to carry out more detailed examinations and tests for particular conditions.
4. The number of centers at which examinations take place should be as small as possible, without reducing the participation rate because of time and travel inconvenience.
5. It is preferable that all laboratory procedures be conducted in a single place, or at least that all of one particular test be analyzed at one place. This is most important for tests known to be difficult to standardize.

Who will conduct the study?

The organizational structure for conducting the study is important but not discussed in the protocol. The structure can seriously influence participation rates. It appears that veterans will be most receptive to a design with minimal involvement of the VA. Veterans' groups believe that the credibility of the VA, with respect to Agent Orange, has been seriously compromised and that an outside

group should run the study.

Some roles for the VA may be possible in a study conducted by an outside group. For example, participants might accept examinations by adequately trained VA doctors in VA-affiliated hospitals if the data are given to a private contractor for analysis. There is universal pessimism that sufficient participation can be achieved if the study is conducted exclusively by the VA.

Some type of monitoring body, either with or without decisionmaking authority, should be considered as part of the study's administrative structure. Such a group might be useful not only for scientific purposes but as an impartial group that would enhance the credibility of the study in the eyes of the public.

Privacy

The issue of privacy has two facets which concern the Panel: withholding of information from review groups, and withholding of information from study participants and the public. The Panel feels strongly that all details of the study protocol must be made available to review groups if these groups are to comment usefully and, in OTA's case, to fulfill the Congressional mandate to approve or not to approve the study design.

The study designers identify some risks involved in making the study plan public, and the Panel recognizes the same risks. However, the Panel believes that these risks must be accepted. Objective measures and standardized examinations can, in part, offset the risks. The following reasons argue for making the health outcomes of the study public.

1. Because of the political and social tension associated with Agent Orange, studies bearing on the question of health effects must, to be credible, be carried out in an open manner.
2. If outcomes are not initially public, but become so only after the

study is completed, the study can be faulted for failing to look for certain health effects. Rationales for including or excluding particular outcomes should be stated initially, and arguments pro and con entertained before the study is begun.

3. Based on information already public, interested parties will know most of the outcomes being considered. As soon as the questionnaire and examination are administered to the first participants, interested parties will be able to determine, at least generally, what outcomes are being assessed. The conspiratorial atmosphere generated by withholding information could have a deleterious effect on the results of the study.

The protocols should discuss the issue of revealing exposure information to participants. To compound the problem of concealment of exposure status, there exist a number of mechanisms whereby veterans can get partial information about potential exposure status:

1. Copies of the HERBS data tape are available for a fee from Department of Defense (DoD). A veteran can place himself in the time-place grid contained in HERBS.
2. The DoD will, upon request, provide veterans with information bearing on the exposure status of their battalion.
3. A private group in Berkeley is selling veterans what they claim to be information about potential exposure to Agent Orange.

Veterans using information from one of these three sources to guess at their exposure status might compromise the study more seriously than if they are told their status by the investigators.

It was suggested by representatives of veterans' groups that as long as

veterans were assured they would be informed of any health problems found and provided necessary medical treatment that revealing exposure status might not be necessary. This contention is supported by a policy of the VA that assumes a veteran claiming exposure to Agent Orange was, in fact, exposed in the absence of positive evidence to the contrary. Thus, exposure status, as determined by the study, will not necessarily bear on any eventual claims made by study participants.

Treatment of the issue of making information available to participants is inadequate in the present protocol. Protection of participants' reasonable rights is as important as protection of study integrity, but it is not discussed. The study designers should discuss an informed consent procedure and should specify the ethical problems they anticipate and how they will deal with them.

REVIEW OF PRELIMINARY STUDIES

General

The proposal outlines three studies of mortality and two of morbidity "to provide a relatively quick look at several questions ... in a reasonable period of time."

Description of Three Preliminary Mortality Studies

1. A proportionate mortality analysis to "determine if there is unusual cause of death or pattern of causes of death among Vietnam veterans or a specific subgroup of Vietnam veterans."
2. A determination and comparison of death rates for Vietnam veterans and Vietnam-era veterans who did not serve in Vietnam.
3. The "frequency of experience in types of military units and of service in geographic regions of heavy defoliant use" will be compared between

each of 2,000 deceased Vietnam veterans (cases) and 2,000 living Vietnam veterans (controls). The cases and controls will be matched for age, race, and educational level at the time of induction into the armed forces.

All of the studies depend on existing records and are to be completed within 14 months. Of the proposed mortality studies, the Advisory Panel supports the proportionate mortality analysis, but doubts that it can be completed in the time allowed in the protocol. The other preliminary mortality studies, as proposed, are unlikely to yield information commensurate with the efforts required to complete them.

A general criticism of the proposed mortality studies is that they do not directly address the possible connection between exposure to Agent Orange and mortality. Because the thrust of the current contract with UCLA is to investigate that connection, the Panel questions undertaking studies that do not bear on that question. While such studies would reveal nothing about Agent Orange, results from them could be interpreted as having something to do with the study of the herbicide, and might be misused in arguments about Agent Orange and health. A related concern deals with the proposal's suggestion that results from the preliminary studies might be used with the exposure index, which will still be under construction at the time the preliminary studies are being conducted. Until the exposure index is firmly established and validated, it should not be used.

Critique of the Proportionate Mortality Analysis

The Advisory Panel generally favors undertaking the proportionate mortality analysis. Such an analysis may reveal unusual causes of death or unusual patterns of causes in Vietnam veterans if they have occurred. However, it appears impossible to complete the study in the 14 months as planned.

The crux of the proposal is that the VA's BIRLS (Beneficiaries Identification and Records Location System) can be used to identify Vietnam veterans and other Vietnam-era veterans, discharged 1965 through 1972, who died during the years 1966 through 1981. BIRLS is a relatively new system, and the completeness of its records has not been evaluated, but the system preceding it included the fact of death for more than 95 percent of all deceased veterans. It is expected that the percentage of deceased veterans identified in BIRLS is nearly as high.

On the negative side, there is no way for the BIRLS system to discriminate between a veteran who served in Vietnam and another Vietnam-era veteran who served somewhere else. (Personal communications, J.F. Bub, VA; S. Jablon, National Academy of Sciences; G. Peterson, VA.) Furthermore, since the emphasis of the proposed study is on ground troops, it is important to note that BIRLS has information about branch of service for only about 75 percent of veterans. Therefore, BIRLS cannot identify those veterans who served in Vietnam, and it cannot provide information about the branch of service on a significant percentage of veterans.

The timetable for the mortality studies allows two months to obtain death certificates for identified deceased veterans. According to the National Academy of Sciences Follow-up Agency, which has had extensive experience with such efforts, about 6 months is usually required to accumulate 2,000 death certificates. The two-month period seems impossibly optimistic, especially if 130,000 death certificates are to be studied.

It is beyond the scope of this review to estimate how long a time will be required to complete the proportionate mortality analysis. Nevertheless, it seems evident that it cannot be completed within 14 months. Whether or not it should be undertaken can be decided only when additional information is presented. A sampling plan which would not require collection and examination of

130,000 death certificates might offer the possibility of a manageable study.

A specific criticism is directed at the protocol's plan to divide the Vietnam veteran population into "subgroups" for the proportionate mortality analysis. No justification is presented for making such divisions, the subgroups are poorly specified, and no criteria for inclusion or exclusion are detailed. Some concern was expressed that certain "subgroups," say "combat units," might be equated with "more likely exposed" while "logistic units" might be grouped into "not likely exposed." Such parallels, even if not drawn by the investigators, might be made by others and be very misleading.

Critique of the Comparison of Death Rates

If, as suggested in the protocol, the Armed Forces Separation One-Percent Sample can be used to provide denominator (population at risk) information, and if the proportionate mortality analysis is completed, calculation of death rates will be an easy exercise. If the One-Percent Sample is not adequate, the calculation becomes more difficult and time-consuming.

Although the Advisory Panel expresses little enthusiasm about this study, arguments have been made in Congress that the Vietnam veteran population is experiencing higher-than-expected death rates. Reliably-calculated death rates would be useful in that discussion. However, a decision to proceed requires better estimates of the time and effort necessary to complete the study.

Critique of the Case-Control Study

The proposed case-control study is not strongly supported by the Panel. A study with 2,000 cases is much too small for a "fishing expedition" to associate particular causes of death with either a geographic location in Vietnam or service in a certain type of military unit. Case-control studies of selected causes of death are viewed more favorably.

Some Advisory Panel members expect that the proposed case-control study would provide very little or no information beyond that to be expected from the proportionate mortality analysis. The case-control study shares a problem with the proportionate mortality analysis. There is concern that information about geographical location and service unit will be transposed into surrogates for Agent Orange exposure and lead to erroneous conclusions by the public.

Morbidity Studies

The protocol describes two preliminary morbidity studies:

1. VA files will be examined to compare claims made before and after widespread publicity about Agent Orange. A proportionate morbidity analysis and a comparison between medical claims filed by Vietnam veterans and Korean War veterans at comparable time periods after the two conflicts is also proposed.
2. The VA's Agent Orange Registry will be used to determine the frequency of different types of complaints associated with Agent Orange by veterans.

Morbidity studies are necessary, as the protocol states, to detect adverse health effects which do not result in death. Furthermore, results from preliminary morbidity studies may be especially useful in developing outcome measures for the planned cohort study. The Advisory Panel supports only the second of the proposed studies.

Results from the Ranch Hand Study physical examinations are expected late in 1982 at about the time that results can be expected from the first proposed morbidity study. The Ranch Hand results in combination with the results of the VA-funded literature review may provide the necessary information to design the questionnaire and physical for the cohort study. If those two studies do not

provide sufficient information, more extensive morbidity studies might be desirable.

Critique of the Morbidity Study Using Claims Files

The investigators intend to sample claims made by veterans during the period 1965 through 1975 and compare those to a sample of claims made during the period 1976 through 1980. The purpose of sampling two periods is to examine claims made before much of the publicity about Agent Orange, and compare those to claims made subsequently. Examination of the two time periods may well reveal a difference in complaint patterns, but interpretation of such a difference will be difficult. As one possible explanation for changing patterns, consider a veteran who had been suffering from a minor complaint. He might not report the complaint to VA until he learned that it had been associated with Agent Orange. Alternatively, another veteran, hearing of a subjective complaint being associated with Agent Orange might report a similar subjective complaint that was either nonexistent or generated by hearsay. In the first example, case finding is improved; in the second, a complaint is generated.

Only about 25 percent of Vietnam-era veterans depend on VA for medical care. A study based on VA records will necessarily be incomplete and the potential bias introduced by such a sample is not discussed in the protocol. The incomplete coverage of veterans in the VA files would decrease the reliability of any results from a proportionate morbidity analysis that depends on those files.

The Panel members find no value in the proposed comparison of claims made by Vietnam veterans against claims made by Korean War veterans. Times, conditions, standards, and practices changed so much during the period between the wars that no useful information is expected from the comparison.

The VA file called "Veterans, Dependents, and Beneficiaries Compensation and Pension Records" has many advantages for a morbidity study as is pointed out in

the protocol. However, it does not differentiate between Vietnam veterans and other Vietnam-era veterans, (T. Preston, National Academy of Sciences), and it includes information only about veterans who have filed claims with VA.

Critique of the Agent Orange Registry Analysis

The investigators propose to determine the frequency distribution of complaints filed by veterans in relation to Agent Orange from the VA's Agent Orange Registry computer file. With some reservations, the Advisory Panel favored going ahead with this analysis, in large part because it appears to be a relatively easy, straightforward task. Should major obstacles present themselves in the undertaking, which would require more time and resources, the question of whether or not it should be completed should be reopened.

Reservations about the study were raised because the registry suffers from a number of shortcomings that reduce its usefulness for a morbidity study. For example the complaints are from a self-selected sample, and the registry was not designed as a research tool.

The VA is currently comparing Agent Orange Registry complaints against VA hospital treatment records, and VA is able to provide the contractors with some information.

RECOMMENDATIONS FOR PROTOCOL REVISION

The OTA Advisory Panel makes the following suggestions for preparing a revised protocol:

1. Highest priority should be placed on:
 - a. construction and validation of an exposure index, and determining the feasibility of associating units or individuals with levels of exposure,
 - b. detailing and justifying the health outcome to be evaluated in the cohort study and developing methods to measure them,
 - c. preparing estimates of the size of study population necessary to study health outcomes.
2. Planning of the proportionate mortality analysis should continue, but neither its planning nor execution should delay beginning the cohort study.
3. Information from inspection of the Agent Orange Registry to learn about veterans' complaints should be considered and evaluated in detailing health outcomes for the cohort study.
4. Decision criteria should be built into the cohort study plan to guide decisions to continue, alter, or discontinue the study. In particular, such criteria should be specified for the following activities:
 - a. the construction of an exposure index and its application to associating units or individuals with exposure levels,
 - b. methods to measure specific health outcomes in such a way as to provide meaningful results,

- c. estimating the size of the study necessary to provide meaningful results,
 - d. insuring an adequate participation rate among all the study cohorts.
5. The study of death rates, the case-control study, and the morbidity study using veterans' claims should either be dropped or more strongly justified.
 6. The Review Panel must be allowed to see details of the exposure index and health outcome measures. Protection of privileged information can be provided as necessary.
 7. Plans for making public or withholding information about exposures and health outcomes should be discussed in the revised protocol.

In whatever manner the VA and the contractor proceed in revising the protocol after receiving comments, the Advisory Panel agrees that it is imperative that each proposed preliminary study and feasibility test be thoroughly justified. Certain minimal criteria must be met, including a clear statement of the hypotheses being tested, a detailed timetable for each aspect of the study, explanations for inclusions and exclusions of groups of veterans and particular outcomes, and the information expected to be gained toward answering the larger question about the health effects of Agent Orange on Vietnam veterans.

If the contractors are severely constrained by time, the VA might consider asking that the contractors concentrate on determining the feasibility of constructing exposed and unexposed cohorts and on specifying health outcomes to be measured. Alternatively, consideration might be given to extending the revision period.

A Chronology of Events in the Congressionally Mandated Epidemiologic Study of Viet Nam Veterans and Projected Dates for the Completion of Various Tasks in the Design of the Study.

- December 1979 Congress passes Veterans Health Programs Extension and Improvement Act of 1979 (PL 96-151). The Act directs (1) the Administrator of the VA to prepare a protocol (plan) for the study of Viet Nam veterans who may be experiencing health effects resulting from exposure to dioxins contained in Agent Orange; (2) the Director of the Office of Technology Assessment to review and approve the study protocol within 180 days after passage of Act (that time period ended about June 20, 1980). If the OTA Director did not approve the plan by then, he was periodically to report to Congress reasons for the lack of approval.
- Dec. 20, 1979 President signs Act into Law.
- December 1979 VA decides to use competitive bid procedure to select an epidemiologist to design the study protocol.
- Feb. 4, 1980 VA publishes its intention to let contract for design of the protocol in the Commerce Business Daily.
- Mar. 19, 1980 VA issues Request for Proposals (RFP).
- Apr. 11, 1980 Conference of potential bidders hosted by VA.
- May 6, 1980 National Veterans Law Center initiates legal action and bid protest about procedures used by VA in soliciting bids.
- May 8, 1980 Last day for receipt of bids.
- May 1980 A selection board of government experts reviews the bids and makes tentative ranking. No further action is taken because of legal suit and bid protest pending against VA.
- Jun. 13, 1980 Judge Harold H. Green of the DC District Federal Court asked that GAO make a ruling about the issues raised in the bid protest.
- August 1980 OTA begins making periodic reports to the Committees of Congress about reasons it has not approved the study protocol. At that time, VA expected to issue contract in September. Subsequent reports kept Congressional Committees informed of continuing legal delays.
- Feb. 2, 1981 GAO finds in favor of VA, and VA can proceed with letting contract.

- Feb/Mar 1981 VA contacts bidders and seeks updated information about their interest in and capability to design the study protocol.
- April 1981 VA reconstitutes selection board of government experts to examine revised bids.
- May 1, 1981 VA selects the School of Public Health, University of California at Los Angeles (UCLA) to design the study protocol.
- May 1981 OTA begins to assemble panel to review the study protocol.
- May 26, 1981 UCLA requests and is subsequently granted a 30-day extension of the contract.
- Aug 18, 1981 OTA receives draft protocol from VA.
- Aug 19, 1981 OTA sends copies of draft protocol to Advisory Panel members.
- Sept 2, 1981 Interagency Work Group on Agent Orange Science Panel receives draft protocol for review.
- Sept 8, 1981 OTA Advisory Panel meeting.
- Sept 23, 1981 Department of Health and Human Services announces newly-discovered military records of aborted Agent Orange defoliation missions, which may provide the basis for identifying heavily exposed veterans.
- Sept , 1981 OTA Director sends review of draft protocol to VA and Congress.

THIS BRINGS US TO THE PRESENT

Following receipt of all official reviews, the VA will forward comments to UCLA for revision of the protocol. The official timetable allows 30 days for UCLA to respond. The revised protocol may require additional review by OTA and others. Events after that step are uncertain.

Revised September 1981 OTA

AGENT ORANGE STUDY PROTOCOL REVIEW

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AGENT ORANGE STUDY PROTOCOL REVIEW

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PREVENTIVE MEDICINE
AND BIOMETRICS

UNIFORMED SERVICES UNIVERSITY
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November 6, 1981



TEACHING HOSPITALS
WALTER REED ARMY MEDICAL CENTER
NATIONAL NAVAL MEDICAL CENTER
MALCOLM GROW AIR FORCE MEDICAL CENTER
WILFORD HALL AIR FORCE MEDICAL CENTER

Barclay M. Shepard, M.D.
Special Assistant to the Chief Medical Director
for Environmental Medicine
Department of Medicine and Surgery
Veterans Administration
Washington, D.C. 20420

Dear Barclay:

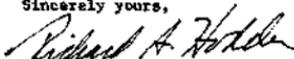
Attached are the collated comments on the draft protocol. I have left out identifying information and edited section comments that were clearly not relevant to protocol review. I think it is crucial to view this as a "draft" to which we are providing input and not a final protocol to be judged "yea or nay". I think the key question for the scientists here is "Was exposure to Agent Orange during RVN Service harmful to our soldiers?" The issue of whether we should look into other agents or whether RVN service itself was harmful are important questions but are not relevant to review of this protocol for merit. The RFP is the benchmark against which the protocol should be measured.

The question of whether the VA should conduct the study however, must be raised in the protocol when the question of bias in study design is broached. I have confidence that, if scientific method is adhered to in the investigation and the process is monitored by an objective steering group, there is no problem. I do have reservations about the idea that Science will give us the answer. We are unlikely to provide results as strong and convincing as the case against tobacco. Yet, as you know, when there are strong interests to the converse, interpretation of scientific evidence (" $p < .05$ ") is very vulnerable to its self-imposed "confidence" limits and ultimate lack of "complete certainty."

In short, the protocol should be critiqued as a scientific writing. However, Dr. Spavey can best assure this by minimizing comments on veteran bias, the VA's ability to run the study, the whole RVN exposure, likely results of the

investigation, etc. Careful attention to materials and methods, a meticulous exposition of his assumptions and ultimate analysis of the basic question posed by the RFP should be his guide. Although I might agree that the study should cover more than Agent Orange, that only clouds the current issue.

Sincerely yours,



Richard A. Hodder, M.D., M.P.H.
COL, MC, USA
Director, Division of Epidemiology
Department of Preventive Medicine
and Biometrics

Enclosure



PREVENTIVE MEDICINE
AND EPIDEMIOLOGY

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November 6, 1981



TEACHING HOSPITALS
WALTER REED ARMY MEDICAL CENTER
NATIONAL NAVAL MEDICAL CENTER
MALCOLM GROW AIR FORCE MEDICAL CENTER
WILFORD HALL AIR FORCE MEDICAL CENTER

MEMORANDUM FOR SPECIAL ASSISTANT TO THE CHIEF MEDICAL DIRECTOR
FOR ENVIRONMENTAL MEDICINE

SUBJECT: Review of UCLA draft protocol for Epidemiologic Studies of Agent Orange for the Veterans Administration Advisory Committee on the Health-Related Effects of Herbicides.

Members of the VA Advisory Committee on the Health-Related Effects of Herbicides were provided copies of "The Draft Protocol for Epidemiology Studies of Agent Orange" submitted by Drs. Spivey and Detels of the School of Public Health, UCLA. This protocol is submitted as a working draft of the approach to be taken. The authors state the final protocol could not be completed due to inability to access data crucial to the design. The protocol is thus submitted for interim review. Individual comments were submitted by members and are attached. The remainder of this memo will summarize some of the specific needs for improvement in protocol design as suggested in these comments. It is assumed that the fundamental question the protocol should ask is "Was exposure of our troops to Agent Orange in RVN associated with long term health effects?"

The protocol takes a fairly standard epidemiologic approach. The authors propose a historical cohort study as the best study design to answer the question in a definitive way. Typically, preparation for such a study includes simpler preliminary studies (the morbidity and mortality studies) to look for supporting evidence, confounding variables, outcomes and data to estimate sample size and determine statistical methods. In addition, a feasibility study of the record system and of the ability to define exposure cohorts is essential before committing large resources to the cohort study. With the information gained from these studies and initial planning, it should be possible to say if the main study is possible and likely to provide useful information. If so, the preliminary studies could provide initial guidelines while the cohort study is progressing. If not, the preliminary studies combined with ranch hand and industrial experience will be almost all the scientific input the policy makers will have on human disease from this agent.

While this approach is reasonably developed, there is considerable room for improvement in the protocol. This is noted in the comments of members of The VA Advisory Committee on the Health-Related Effects of Herbicides. A frequent observation by the members was that criticism of the design was precluded by the inadequate detail in the protocol. Despite the authors' concerns for bias, the variables and outcomes of the studies must be stated, if only to a select steering committee. This is specifically required by the RFP and was known to the designers when they applied for the project. Concern with potential bias is not unique to Agent Orange studies and has been overcome by others. Nor does inadequate access to records excuse the lack of details on analysis. As a minimum the specific data expected to be collected could be listed and discussed. In addition, information on the collection, verification and storage of laboratory and examination data should be provided in greater detail. Finally, the procedures for data coding and analysis should be presented based on current assumptions, recognizing that some modifications may have to be made.

Additionally, several members questioned why certain groups (officers, career soldiers, those with more than one RVN tour and those who died within a year of service in RVN) were excluded. The assumptions that justify these exclusions were not clearly stated although it apparently was related to concern for homogeneous exposure. Since this has implications for the final analysis it should be carefully discussed and not merely dismissed. An alternative approach might be to weight the cases for intensity of exposure rather than exclude heavy exposure. Discussion of this and other alternatives and the rationale for their rejection or inclusion should be presented. This is particularly important since the ability to realistically measure exposure or even outcome for a veteran cohort was raised and is a source of controversy. (Some members felt exposure could not be meaningfully estimated while another member feels excellent data exists.)

Both the protocol and several members questioned whether the VA should run the study or whether an objective study could be guaranteed under those circumstances. Therefore a study design that blind the data collectors and allows monitoring of the analysis by an independent panel should have commanded as much attention (in the protocol) as subject bias.

Many other specific points were raised and can be found in the individual comments. Some are specific suggestions to solve minor problems in the design. The ability of the study to be done due to the military record system or exposure indices was questioned. Other concerns about the scope of the study, who should monitor it, etc. were also expressed and are included in the comments. However, only those directly relevant to design of the protocol are highlighted above.

Conclusion

The present "draft protocol" should be considered as an interim document which describes work in progress. It is actually the skeleton of a reasonable approach. The investigators state that the lack of detail is due to

actual inability to gain access to needed information as well as their concern with introducing bias. There was a consensus that both of these problems could be overcome. This "draft" will need considerable expansion and detailing of the assumptions, methods and proposed analysis to meet the benchmarks provide in the RFP.

In particular, the variables and outcomes to be measured should be stated. Criteria for inclusion or exclusion should be openly presented and justified. The materials and methods section should be expanded with full discussion of data collection, coding, validation and statistical analysis. Steps to estimate sample size and power should be outlined. Subsequent steps in deciding whether exposure data and personnel records allow cohort definition should be described. A final statement of the hypotheses and the statistical methods which will test them should follow. Hopefully, access to the records will enable the investigators to present the details of their study design.



Richard A. Hodder, M.D., M.P.H.
COL, MC, USA
Director, Division of Epidemiology
Department of Preventive Medicine
and Biometrics



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
Atlanta, Georgia 30333
FTS 236-4111

October 21, 1981

Dr. Barclay Shepard
Special Assistant to the Chief
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Veterans Administration
810 Vermont Avenue, N.W.
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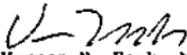
Dear Dr Shepard:

The Science Panel has reviewed the Draft Protocol for Epidemiological Studies of Agent Orange submitted by Gary H. Spivey, M.D., MPH, and Roger Detels, M.D., MS.

A copy of the review and individual comments are enclosed. Basically, the Science Panel had difficulty in providing a meaningful review because the document was not a protocol. Instead it appeared to consist of three parts. The first 19 pages were primarily an introduction. The second 65 pages represented a discussion of the difficulties normally faced in epidemiological studies, and the rest of the document was a literature review covering 141 pages. Every member expressed concern about the lack of details to the point that it was not possible to constructively review the proposal.

The final conclusion was that the present proposal is inadequate and the Science Panel recommends to the VA that a course of action be developed that will not cause any further unnecessary delays in attempting to answer questions about health issues in Vietnam veterans. A specific protocol should be developed. There was substantial discussion at yesterday's meeting of the Science Panel, which you attended, that should help resolve some of these issues.

Sincerely yours,


Vernon N. Houk, M.D.
Chairman, Science Panel
Agent Orange Working Group

Enclosure

SUBJECT: Review of the Draft Protocol for Epidemiological Studies of Agent Orange

Submitted by Gary H. Spivey, M.D., MPH, Principal Investigator
 Rogert Detels, M.D., MS, Co-Principal Investigator
 Division of Epidemiology
 School of Public Health
 University of California
 Los Angeles, California

Attached please find the individual comments of members of the Science Panel of the Agent Orange Working Group. Basically, every member expressed concern about the lack of details in the protocol to the point that it is not possible to constructively review the proposal.

The following paragraphs taken from comments submitted by individual members highlight these concerns:

General Comments

1. "While we certainly appreciate Dr. Spivey's concern that release of certain specifics of his anticipated protocol might induce bias in the eventual study, we cannot provide an effective analysis of a protocol without such information. We suggest that at least a small subcommittee of the Science Panel be supplied with all of the details of the protocol and that the report of this subcommittee be held in confidence and not be released to the general public. We believe that an informed evaluation is absolutely essential before any further action is undertaken to initiate any subsequent studies."
2. "The section on proposed outcome measures is particularly weak. The statement that an examination will be done because '...the veterans will expect a physical exam' is inappropriate. The inclusion of special examinations for individuals with recognized disease unrelated to Agent Orange, for example, an examination of the eye backgrounds and peripheral pulses in subjects with a history of diabetes mellitus is of questionable value in such a protocol. At the same time the protocol ignores entirely the neurological examination, which both animal and human data suggest may be of importance.

 "Statements such as the one included on page 9 which opines that chloracne is a 'self-limiting skin condition' raise further questions about the authors' full understanding of the potential health effects of dioxins. Chloracne can be a severe skin condition that in some individuals is persistent for years even following discontinuation of exposure. The statement on page 18 that 'Chloracne is the only established health outcome associated with dioxin exposure' is not justified."
3. "It is clear that the current UCLA protocol is inadequate. Therefore, a study is yet to be designed and conducted. Overall, it is our opinion that two important factors must be present for the design and conduct of

a study. First, it is critical that adequate epidemiologic expertise be available within the Group or Agency which assumes responsibility, and second, there must be continuous interface with and cooperation from the DOD and VA so that details of records and activities during the Vietnam War are accessible to the researchers.

"Finally, any delay dependent upon further review of this UCLA protocol should be avoided due to its incomplete nature. Any further review should be postponed until an appropriate scientific protocol based upon a complete iteration of exposure data and veterans' data is available."

4. "In summary, prior to any further attempts to design a study on Vietnam veterans, it is recommended that the Veterans Administration review the morbidity data they have collected thus far, that the Department of Defense establish information on exposure data and determine what the sizes of prospective cohorts might be, and that the Veterans Administration embark on a mortality study. Since any outside group is unfamiliar with the record keeping system of the military, it would be redundant, wasteful, and time-consuming to have outside groups do this preliminary work for the military."

Specific Comments

Exposure

1. "I am deeply troubled by this aspect of the report. On page 43, the authors correctly surmise, 'We have not identified a mechanism which would document actual exposure.' Over the past year in our Committee, as well as the Agent Orange Working Group in the White House, we have wrestled, frankly unsuccessfully, with trying to establish some mechanism for documenting exposure. I recall clearly our meeting with the members of the National Academy of Sciences and their comments regarding any proposed epidemiological study on Agent Orange exposure in Vietnam. The take-home message was, 'If we cannot scientifically validate and document exposure, we cannot do a scientific epidemiological study.' Although Spivey's approach suggests a mechanism by which we might overcome this problem, I suspect we are justifiably due some criticism for the grouping approach. I am now persuaded that we will never be able to do an epidemiology study on individual veterans per se, but must examine military units serving in specific spray areas. There is now some hope from recent DOD activities that we might be able to document some segments of the military population in Vietnam exposed to Agent Orange. Every effort then must be made to work closely with Mr. Christian and his associates in DOD in meticulously reviewing records and films to establish some case for exposure. I recommend we do not fund any additional feasibility studies until a thorough and comprehensive search and cataloging of available DOD records, films, and reports are completed."
2. "In conclusion, I am not convinced that significant ground troop exposure to 2,4,5-T containing herbicide occurred as a result of aerial application. Other uses of the herbicide most likely represented a greater exposure. Additionally, the study must address the question of did the Vietnam

conflict participant incur a health decrement risk over and beyond that which was expected and secondly, if a risk was incurred, is it service connected? This protocol requires greater examination of the exposure criteria and further discussion and refinement."

Use of Terminology

"Definition of Antipersonnel gas: Riot agents such as CS and CN used in Vietnam were not antipersonnel gases since they do not kill or incapacitate for an extended period of time. Both CS and CN have been used throughout the world by civilian police to control riots of civilians and in prisons without causing fatalities. This improper definition should be corrected.

"The substitution of 'riot control agents' in place of 'antipersonnel gases' is suggested."

Conclusion

The members of the Panel had many other specific comments and only some of their major concerns were quoted here. The present proposal is inadequate and it is recommended that a course of action be developed that will not cause any further unnecessary delays in attempting to answer questions about health issues of Vietnam veterans. A specific protocol should be developed in which the size of the cohorts and their perceived exposures are characterized and which will serve as the basis for the studies.

Office of Procurement
and Supply

Washington DC 20420

**Veterans
Administration**CERTIFIED MAIL RETURN - RECEIPT

NOV 25 1981

In Reply Refer To: 93B

Mr. Phillip Costic
Contracts & Grants Officer
University of California, Los Angeles
Murphy Hall
Los Angeles, CA 90024

Dear Mr. Costic:

Pursuant to the conference call conducted on Tuesday, November 17, 1981, I am taking this opportunity to convey to you the comments of the Veterans Administration on the submittal sent to us in response to Contract V101(93)P-842, Development of an Epidemiological Protocol for a Study of Phenoxy Herbicides, including "Agent Orange."

The views set forth in this letter represent the official position of the Veterans Administration as to the product that was delivered to the agency on August 6, 1981. After a careful review, it is our considered opinion that the initial submittal did not meet the requirements set forth in the contract. Specifically, the draft study design did not contain plans to identify and evaluate possible significant dependent variables and relate the dependent and independent variables. This approach was to be justified by reference to world literature and other relevant information.

You failed to provide for an organ system identification most likely affected by exposure to the chemicals in Agent Orange. The protocol was to specify data to be obtained from medical history, physical examinations and laboratory studies. It did not. Furthermore, testing in order to identify and evaluate the dependent variables was to be stipulated as were the reasons for specifying each procedure. This also was omitted.

The numbers of study subjects and control populations required for successful study completion were not estimated. The mechanism by which individual subjects and controls were chosen was not specified.

Additionally, you failed to recommend the level of certainty that the study should reach in concluding that specific effects are or are not due to phenoxy herbicides.

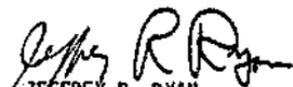
In addition to the preceding, the following deficiencies are also noted:

- a. A method of evaluating data collected was not provided.
- b. Training materials for instructing VA health care professionals were omitted.
- c. A detailed description of statistical methods used to analyze the study data was also omitted as was the rationale for the choice of method.
- d. There were no data collection forms on which health care professionals will report the required data nor were there any directions regarding coding of data for computer analysis.
- e. We were not advised as to how long the study might take nor were we informed as to the timetable for the study and significant milestones.

In view of the inadequacy of your August 6, 1981, submission, you are hereby granted a time extension of 35 calendar days from the date of this letter to submit a design which is adequate for critical review by experts. The submission will be submitted for such review and you will be required to incorporate any appropriate comments within 30 days as required by paragraph 6 of the instructions for the preparation of the proposal.

If the Veterans Administration may be of any assistance or if you have any questions, please contact me at once.

Sincerely,


JEFFREY R. RYAN
Contracting Officer

Office of Procurement
and Supply

Washington DC 20420

**Veterans
Administration**CERTIFIED MAIL RETURN RECEIPT REQUESTED

DEC 23 1981

In Reply Refer To: 93B

Mr. Phillip Costic
Contracts & Grants Officer
University of California, Los Angeles
Murphy Hall
Los Angeles, CA 90024

This is in response to your letters of December 14, December 17, and our conference call of December 16, 1981. We have conducted an exhaustive review of the information presented to us and are prepared to offer the following comments.

Based on our telephone conference call, UCLA will provide the questionnaire referred to in paragraph 3 of your December 14, 1981, letter. As previously indicated, the matter of public access will be handled by the Veterans Administration. Accordingly, we will assume responsibility for the confidentiality of all data physically forwarded to us.

We agree with your interpretation of paragraph 6 in the Design of the Protocol for the Agent Orange Epidemiological study. Our November 25, 1981, letter is so modified.

UCLA will provide the questionnaire for medical history referred to on page 2, paragraph 2 of your December 14, 1981, letter as discussed on December 16, 1981. The matter of public disclosure is addressed above. While we agree that pilot testing is not called for in the contract, we expect the questionnaire to be tested to the extent necessary to make it an acceptable instrument in accordance with generally accepted scientific validation techniques. Therefore, the contract will not be modified on this point as you requested.

With respect to paragraph 4 of your December 14, 1981, letter, we do not concur with your opinion of ambiguity on paragraph 4 of the statement of work. Furthermore, it is my understanding that UCLA has never requested any information as to the "realistic constraints" noted in the contract. We have no objection, however, to the language proposed in paragraph 4 of your December 17, 1981. You may consider the contract modified accordingly. I believe that this will resolve this issue.

We agree that the contract does not require you to develop an "exposure likelihood index." However, the contract does require a mechanism for determining exposure. We consider the mechanism a step-by-step procedure which if implemented by a third party, would result in the identification of exposed/unexposed cohorts to be studied.

With respect to paragraph 3 of your December 17, 1981, letter, we do not believe that the VA is contractually obligated to provide the information you have requested in the format you have stipulated. We have learned that Dr. Spivey has talked to Mr. Christian about what is available and in what form the data requested must be in. Despite the lateness of the request for this data, we are ready to assist you in securing the material you deem necessary to complete the development of the draft protocol by January 25, 1982.

Based on our common understandings and as noted above, your request for a time extension at no additional cost to the VA through January 25, 1982, is granted, due to Dr. Spivey's illness. You will be expected to provide verbal weekly updates to Dr. Hobson, the contracting officer's technical representative during the period of this extension on your continuing progress in the development of the draft protocol.

If we may be of any assistance in this endeavor, please contact us at once.

Sincerely,


JEFFREY R. RYAN
Contracting Officer

Continued

20. QUESTION:

E.(i): Once the revised protocol is received, what entities will review it?

RESPONSE: The amended draft protocol will be submitted for review by the following groups: the Science Panel of the Agent Orange Working Group, the Congressional Office of Technology Assessment, the VA's Advisory Committee on Health-related Effects of Herbicides, and the National Academy of Sciences - National Research Council.

20. QUESTION:

E.(ii): What is the timetable for those reviews?

RESPONSE: We have not developed a timetable for the reviews, but they will be completed as expeditiously as possible.

Continued

20. QUESTION:

F: Once the review process is completed, how much time will the contractor have to submit a final proposed protocol to the Agency?

RESPONSE: The contract calls for the contractor to submit a final protocol within 30 days.

20. QUESTION:

G: Will you arrange for copies of the revised submission to be provided to both the majority and minority staff of the committee as soon as possible after the document is received by the Agency?

RESPONSE: Copies of the revised submission will be provided in a manner that does not compromise the scientific usefulness of the protocol.

21. QUESTION: In response to a question I asked about the implementation of Section 102 of Public Law 97-72, you noted your personal disagreement with the opinion of OMB that the Agency could implement this new authority within existing resources. In this regard, you stated that "there will be some costs in connection with (this new eligibility)."

A: What is your estimate of these costs for FY 1982 and each of four fiscal years?

RESPONSE: An estimate of the cost under the Agent Orange-related provisions of Public Law 97-72 for the treatment of veterans requesting care is as follows:

	<u>FTEE</u>	<u>(\$'s 000)</u>
FY 1982	1,719	\$55,000 *
FY 1983	2,751	88,700
FY 1984	2,751	88,700
FY 1985	2,751	88,700
FY 1986	2,751	88,700

*Assumes implementation by mid-February 1982.

It should be noted that these costs are, at best, tentative and uncertain because we do not know the nature of the illnesses for which veterans will be seeking treatment nor the number of veterans who will actually seek such care under this authority.

Continued

21. QUESTION:

B: Please provide a detailed explanation of that estimate.

RESPONSE: The following assumptions were made:

1. Estimated number of veterans serving in the Republic of Vietnam - 2.4 million.

2. Assume that 15% of this population, as a result of the increased level of eligibility and awareness of eligibility, will seek their inpatient and outpatient care from the VA and that this is in addition to the current services provided to Vietnam veterans.

3. For males ages 15-44, the non-federal short stay hospitalization rate is 98.5 discharges/1000 population.

Continued

21. RESPONSE:

B: If by regulation, we can exclude certain diseases the short term hospitalization rate becomes 48.2/1000.

4. Using this rate, we would expect 17,352 discharges per year or $2,400 \times 48.2 \times .15$.

For outpatient visits, the rate is 3.5 visits per year.

5. The average length of stay of these veterans would be the same as veterans currently using the system, 15.3 days.

6. The cost per day for inpatient care is \$192.17.

7. The cost per outpatient visit is \$61.60

8. The cost of this care would be \$51.0 million or $17,352 \times 15.3 \times \192.17 .

9. If the visit rate drops proportionately to the hospital rate, the visit rate would be 1.7 visits per person or $(48.2/98.5) \times 3.5$.

10. The number of outpatient visits would be 612,000 or $2,400,000 \times 1.7 \times .15$.

Continued

21. RESPONSE:

B: 11. The cost of these visits would be \$37.7 million or $612,000 \times \$61.60$.

12. The total five-year cost under these circumstances would be \$443.5 million or $.5 \times (51.0 + 37.7)$.

13. The FTEE would be 2751 or
for inpatients: $\frac{2.1 \times 17,352 \times 15.3}{365} = 1527$

for outpatients: $\frac{612,000}{500} = 1224$

Five-Year Cost Projection

<u>Fiscal Year</u>	<u>Number of Hospitalizations</u>	<u>Number of Outpatient Visits (millions)</u>	<u>Total Cost (\$millions)</u>	<u>FTEE</u>
1 Full Year	17,352	.612	88.7	2,751
2	17,352	.612	88.7	2,751
3	17,352	.612	88.7	2,751
4	17,352	.612	88.7	2,751
5	17,352	.612	88.7	2,751
Total	86,760	3.060	443.5	

Continued

21. QUESTION:

C.(i): Do you plan to seek an FY 82 supplemental to cover these costs?

RESPONSE:

No.

21. QUESTION:

C.(ii): If not, or in the interim, from what source will these additional costs be borne in FY 82; specifically, what activities will not be carried out in order that this new eligibility may be implemented?

RESPONSE:

Implementation of Section 102 of Public Law 97-72 without additional resources will not result in the termination of activities but may result in reducing care to the lowest priority non-service-connected veteran as they are provided care only as resources are available.

21. QUESTION:

D: Is the Agency seeking additional funding for the costs of implementing the new eligibility in the FY 83 budget process now underway?

RESPONSE: A response will be provided when the budget for FY 83 is submitted.

22. QUESTION: If a veteran comes to the VA today and expresses a concern about possible genetic harm resulting from exposure to Agent Orange, does the Agency provide genetic counseling services?

RESPONSE: It has not yet been determined that the exposure of veterans to Agent Orange or other herbicides results in birth defects in their offspring. The Veterans Administration does not have legislative authority to provide genetic services to family members of veterans, nor does it have either the expertise or resources to provide this service. Nevertheless, the Veterans Administration has taken action to provide an alternative for veterans and their families seeking such assistance. A listing of genetic counseling resources prepared by the March of Dimes Birth Defects Foundation was recently forwarded by VA Central Office to each environmental physician and to each VA medical center library. This publication, entitled Birth Defects: Genetic Services, will serve as a resource for environmental physicians in referring veterans to genetic counseling services within their geographic regions.

23. QUESTION: During her testimony, Ms. Joan Bernstein, representing Vietnam Veterans of America, recommended that two studies be done -- one that would examine the general health status Vietnam veterans without any findings of exposure to specific substances and one focusing on the health effects in Vietnam veterans of exposure to dioxin as found in Agent Orange. I realize that, at the hearing, you indicated that you wouldn't make a final decision on expanding the Agent Orange-only study until you receive an acceptable protocol. I would appreciate it, however, if you could provide your preliminary reaction to Ms. Bernstein's suggestion now and a more detailed response on this overall issue once you receive a revised proposal from the contractor.

RESPONSE: The Veterans Administration can envisage an investigation of the health effects of the Vietnam experience as a whole conducted in either of two ways: as the separate epidemiological study or as a part of the phenoxy herbicide study. The latter would involve including veterans who were never in Vietnam as one control group, as well as Vietnam veterans with little or no likelihood of exposure to the herbicides as the other control. It may even prove impossible to discriminate between Vietnam ground troops who were and those who were not exposed. In that event the study of the overall Vietnam experience would be the only reasonable one.

24. QUESTION: During his testimony, Dr. Houk discussed a possible role for the Science Panel of the Agent Orange Working Group to play in the development of an exposure index.

A: Is the VA considering such a role for the Science Panel?

RESPONSE: Yes, we are considering a role for the Science Panel as described in the answer to Part B of this question.

Continued

24. QUESTION:

B: What discussions are being held involving VA, the working group, or others, such as the contractor or the Department of Defense, on this proposal?

RESPONSE: The VA, as an active participant in the Agent Orange Working Group, as well as the Science Panel, has been involved in discussions of exposure of ground troops to herbicides. It has been suggested that the Science Panel should develop a set of criteria which would constitute a presumption of probable exposure. The Department of Defense records personnel would then be asked to identify military units which met these criteria and establish a procedure to determine the individuals assigned to these units. The UCLA contractor for the protocol development is aware of this proposal. The approach of the UCLA team differs from the above plan in that they have been attempting to develop an exposure index which would establish documented exposure of specific individuals.

RESPONSE OF THE VETERANS' ADMINISTRATION TO ADDITIONAL WRITTEN FOLLOW-UP
QUESTIONS SUBMITTED BY HON. ALAN CRANSTON, RANKING MINORITY MEMBER OF THE
SENATE COMMITTEE ON VETERANS' AFFAIRS

1. QUESTION: In your reply to question 1(A)(ii), you indicated that "the environmental physician is given the liberty" to communicate personally with a veteran -- presumably rather than in writing -- when the physician has diagnosed a problem that it might be inappropriate to disclose in a letter. I am concerned that, in light of the requirement described in reply to question 1(A)(i) that the environmental physician "must advise the veteran of positive and negative findings ... both personally and in writing" (emphasis added), some environmental physicians may be sending letters to veterans with information that should not be communicated in that form. Would you be willing to provide further guidance to the field so as to preclude such a result?

RESPONSE: The environmental physician has been directed to communicate verbally and in writing to the veteran the results of the physical examination. When appropriate, the personal communication may be more detailed than the written communication. The determination of when circumstances are present to warrant a general written communication devoid of specific details is shaped by the personal circumstances of the veteran. This type of situation is one which is faced by physicians generally and is not restricted to the specific situation of an Agent Orange examination. A VA physician is expected to be sensitive to the needs of the veteran patient, including knowing how best to communicate information of a confidential nature. We would be happy to remind our environmental physicians that their best professional judgement is needed when communicating sensitive information to the Agent Orange Registry veterans.

2. QUESTION: In reply to question 1(C), you noted different steps that a facility with a backlog of Agent Orange examinations could take to reduce such a backlog. In response to my question about "the impact of such action on other efforts at the medical facility" you noted that the impact "varies, depending upon the precise local situation". For the record, please describe the five most recent cases in which local facilities were directed to take action to reduce their backlogs of Agent Orange exams, including specific information on what impact that action had on other efforts at the facility concerned.

RESPONSE: The stations having a backlog of Agent Orange examinations were contacted. All stations were able to reduce their backlogs with a minimal impact on other facility functions. The most recent stations contacted were:

<u>Station</u>	<u>Number of Pending Exams as of Dec 31</u>	<u>Date of Contact and Number Pending</u>
Brockton	53	Feb 10 - 19 exams
Togus	149	Feb 10 - 40 exams
Columbus	99	Feb 10 - 22 exams
Dallas	53	Jan 31 - 31 exams
Philadelphia	73	Jan 31 - 21 exams

3. QUESTION: In reply to question 3(A)(ii), which asked how the agency will monitor the impact of Vietnam veterans who seek health care under section 102 of Public Law 97-72, you noted that the Agent Orange Registry is the "key monitoring mechanism for tracking Agent Orange statistics" and that facility directors will be asked to "add an additional element to an existing reporting system". How does this mechanism ensure that data will be kept on those veterans who present themselves for treatment for Agent Orange-related disabilities who are not included in the Registry and on those who seek care for disabilities related to radiation exposure? (If it does not, what steps are you taking to ensure that a more adequate mechanism is established?)

RESPONSE: The modification of the existing reporting system to track the impact of Public Law 97-72 will include the revision of inpatient and outpatient forms to provide for the identification of all Vietnam veterans applying under the provisions of this legislation for care of disabilities or illnesses related to their possible exposure to Agent Orange or ionizing radiation. Vietnam veterans who apply to VA health care facilities under this legislative authority but who have not received an initial Agent Orange related examination, are invited to participate in the Agent Orange Registry. The revised reporting system, together with the data obtained through the Agent Orange Registry, will ensure that essential data are obtained and maintained on all those veterans applying for such care or treatment.

4. QUESTION: In reply to question 7, you indicated that the Agent Orange literature review has been provided only to three members of the Board of Veterans' Appeals and to Ms. Starbuck as the Chief Benefits Director. As I indicated in one part of question 7, I believe that those responsible for adjudicating Agent Orange-related claims have a substantial need for a document such as the literature review, and I believe a wider distribution -- for example, one to each Regional Office for the use of rating board members -- may be appropriate. Is there a valid reason for not making such a distribution?

RESPONSE: The primary value of the Agent Orange literature review is as a resource tool for identifying areas appropriate for future scientific investigations. It is also important as a current statement of scientific knowledge about the effects of exposure to Agent Orange. In this regard, the review may serve to aid rating board members in the adjudication of claims for compensation. It is a technical document which we agree could serve as a useful reference. We will be happy to see that copies are available at all regional offices.

5. QUESTION: In reply to question 8(A), you described the VA's efforts on Agent Orange in relation to various States' activities. Your reply was restricted, however, to instances in which "the VA is aware of states' activities" and made no mention of any action on the agency's part to become aware of such efforts. I believe that it would be desirable to designate at least one VA environmental physician in each state to serve as liaison between appropriate state officials and the VA's Office of Environmental Medicine. Each such environmental physician could track state efforts on Agent Orange and serve as a source of information for state officials regarding federal efforts and as a communications link to the VA. What are your views on such an approach?

RESPONSE: The VA's environmental physicians have served an important role in developing contacts with state offices and veterans' organizations. They have provided state offices with medical and scientific information. They have spoken at local Agent Orange conferences and meetings, and have joined state Agent Orange committees. They have advised VA Central Office of activities of which they become aware. We believe that this type of involvement is the most appropriate use of these professionals. The VA has taken other steps to help ensure that we are aware of all official and legislative Agent Orange related activities conducted by the states, as well as the activities of the veterans service organizations. In June 1980 and August 1981, all VA District Counsels were asked to keep VA General Counsel staff

5. (cont'd)

RESPONSE: advised of state legislative activity involving Agent Orange. VA staff personnel addressed the National Association of State Veterans' Affairs Directors at their annual convention in September 1981, and asked for their assistance in keeping us advised of state programs related to Agent Orange. We recently completed a telephone survey of the states during which we reaffirmed our interest in and desire to cooperate with state activities. The Agent Orange Working Group monitors state activities and keeps us informed of programs or proposals that come to their attention. The Office of Public and Consumer Affairs reviews Agent Orange related news articles from across the country, including those discussing state activities. Within the newly created Agent Orange Research and Education Office information exchange function has been defined. We intend to establish regular correspondence with all state and service organization Agent Orange offices, and to facilitate the sharing of information among the state offices. I believe that these efforts demonstrate our commitment to keeping informed of Agent Orange related activities throughout the country.

6. QUESTION: The phrase that was inadvertently omitted from the end of question 8(B) was "answers on Agent Orange?". I would have appreciated your having asked your staff to contact us to ask for that omission to be supplied rather than your simply not answering. Please provide your response to this question.

[8(B) Question: Do you see any way in which the efforts of the various states can be of assistance to the Federal government in its efforts to find]

RESPONSE: The VA will continue to monitor the various state activities related to Agent Orange. We have been especially supportive of programs designed to educate and inform Vietnam veterans concerning what is known about the effects of Agent Orange. Wherever possible, we offer to assist the states in this effort. We are very interested in several research efforts which have been or will soon be undertaken by the states relating to Agent Orange. The results of those efforts will be considered by the VA in its own efforts to find answers on the possible adverse health effects of Agent Orange on Vietnam veterans.

7. QUESTION: In reply to question 9(C), you described the agency's efforts, through DVB, to work with funeral directors so as to solicit their support in continuing to provide data to the VA on veterans' deaths.
- A. Are there continuing efforts in this regard?
- B. Has the VA attempted to have information on the importance of continuing cooperation publicized to funeral directors around the country through articles and notices in trade publications?

7.A.

QUESTION: Are there continuing efforts in this regard?

RESPONSE: Close contact is continuing to be maintained between the VA and the National Funeral Directors Association for the purpose of obtaining data relating to veterans deaths. In this regard, Funeral Directors are continuing to apply directly to the VA for plot allowances. This arrangement enables the VA to receive essential statistical epidemiological data on deceased veterans as a result of the application process. The statistical data, together with a copy of the death certification of the veterans, remains an invaluable statistical resource for epidemiological research.

7.B.

QUESTION: Has the VA attempted to have information on the importance of continuing cooperation publicized to funeral directors around the country through articles and notices in trade publications?

RESPONSE: It has been emphasized to the association that although many veterans will no longer be entitled to the \$300 burial allowance, the eligibility criteria for the \$150 plot/interment allowance have not changed. The association has been asked to remind their members of the availability of the plot allowance and information to this effect has been published by the association.

8. QUESTION: In reply to question 9(E)(ii), you noted that the "completeness of the mortality data in BIRLS will be assessed to determine whether the changes necessitated by the Omnibus Reconciliation Act of 1981 have affected the level of reporting of veterans' deaths."

A. When will this assessment take place?

B. Who will conduct the assessment?

C. Will you please provide the results of this assessment as soon as it is completed?

8.A.QUESTION: When will this assessment take place?

RESPONSE: The Department of Veterans Benefits is reviewing the number of new death cases added to BIRLS each month. An analysis of the data available to the system has been in effect since enactment of the Omnibus Reconciliation Act of 1981.

8.B.QUESTION: Who will conduct the assessment?

RESPONSE: Consideration is being given to a contract with NAS-NRC for an evaluation of the impact of the Act. The timing of this evaluation is not yet determined.

B.C.QUESTION: Will you please provide the results of this assessment as soon as it is completed?

RESPONSE: A copy of the review will be made available to the Committee when it is completed.

9. QUESTION: In reply to question 10(A), you indicated that the only step that the VA has taken with regard to the European studies that seem to suggest that a higher incidence of soft tissue sarcoma might be related to exposure of dioxin is to call the studies to the attention of the contractor designing the protocol for the epidemiological study. In reply to question 10(B), you noted that "attention is being given to the detection of such pathology in the design of the epidemiological study, in reviews of the Agent Orange Registry, in the AFIP study of pathological specimens, and in a special AFIP protocol being developed to review soft tissue sarcomas."

- A. What specific action has been taken by other bodies such as the Interagency Working Group, AFIP, or others, to do follow-up studies to validate or refute the findings of the European studies?
- B. What, if any, information has been provided to VA field personnel, including both DM&S and DVB personnel, regarding these studies and their possible relationship to veterans' claims for treatment or compensation?

9.A.

QUESTION: What specific action has been taken by other bodies such as the Interagency Working Group, AFIP, or others, to do follow-up studies to validate or refute the findings of the European studies?

RESPONSE: The VA maintains close contact with other groups working on the problem of dioxin toxicity through personal contacts and the Agent Orange Working Group.

The AFIP is looking specifically for instances of soft-tissue sarcoma in its review of pathological specimens from Vietnam veterans and is mounting a special investigation of soft-tissue sarcoma cases made available from all sources. This investigation seeks to determine whether it is possible to relate the occurrence of such sarcomas to Vietnam service.

9.A. (cont'd)

RESPONSE: The National Institute of Occupational Safety and Health (NIOSH) is creating a registry of all American industrial workers likely to have been exposed to dioxin in the manufacture and use of chlorinated cyclic hydrocarbons. NIOSH is also actively assisting the World Health Organization in the establishment of a parallel registry of exposed workers in other countries. These efforts are in furtherance of the Institute's interest in the possible relation between soft-tissue sarcomas and industrial exposure.

The European studies have been discussed, by virtually every group concerned with dioxin. There is still no consensus as to the validity of a causal relation between dioxin exposure and the very heterogeneous malignancies grouped as "soft-tissue sarcomas." It is hoped that the Ranch Hand study and the VA's epidemiology study will substantially contribute to the resolution of this question.

9.B. QUESTION: What, if any, information has been provided to VA field personnel, including both DM&S and DVB personnel, regarding these studies and their possible relationship to veterans' claims for treatment or compensation?

RESPONSE: The European studies were reviewed and references were summarized in the literature survey prepared for the VA. Copies of this survey are readily available to both DM&S and will be provided to DVB field facilities.

The European studies were also discussed with DM&S field personnel during various telephone conferences including a March 16, 1981, Conference Call. There is no unanimity among experts as to the significance of the Scandinavian studies in establishing a cause and effect relationship between exposure to dioxin and the soft tissue sarcomas. Consequently, it is not considered advisable at this time for the VA to provide a conclusive interpretation which would bear on the adjudication of claims for compensation.

10. QUESTION: In reply to question 11, you noted that "[e]ach Vet Center staff has a full complement of the literature produced by VA Central Office on Agent Orange".

A. What exactly is included in this compilation?

B. Do Vet Center staff have copies of the literature review?

C. Do Vet Center staff receive periodic updates on the status of various governmental studies and other efforts on Agent Orange so that they can provide their clients with the most up-to-date information?

10.A.

QUESTION: What exactly is included in this compilation?

RESPONSE: Literature produced by VA Central Office on the subject of Agent Orange includes the pamphlet "Worried About Agent Orange?" and the film "Agent Orange: A Search for Answers". A supply of the pamphlets and a copy of the film were sent to all Vet Centers for distribution and showing to veterans. In addition, copies of the Agent Orange Bulletins are routinely sent to all Vet Centers for information of staff and veterans. Copies of VA testimony for Congressional hearings and all DM&S circulars on the subject of Agent Orange have been sent to the Vet Centers parent VAMC facility and are available upon request;

A new pamphlet is being prepared to replace the present one, and a newsletter is planned to help keep all interested offices and individuals advised of current Agent Orange events.

10.B.

QUESTION: Do Vet Center staff have copies of the literature review?

RESPONSE: Copies of the literature review have been sent to the libraries of all VAMCs as well as to each Environmental Physician. They are available for review by Vet Center team leaders and staff. Copies were not sent directly to the Vet Centers since the literature review consists of a scientific effort useful primarily to physicians and research scientists. As regards Agent Orange, Vet Center staff primarily attempt to allay the fears and concerns of veterans worried about herbicide exposure, they are instructed to refer the veterans to the parent VAMC environmental physician for answers to medical concerns and scientific (medical) opinion and other matters relating to health problems.

The VA is considering the development of a lay summary of the literature review in conjunction with other lay interpretations of scientific reports now being discussed by the AOWG. We feel that this type of material is better suited for distribution to Vet Centers than copies of the literature review in its current form.

10.C.

QUESTION: Do Vet Centers receive periodic updates on the status of various governmental studies and other efforts on Agent Orange so that they can provide their clients with the most up-to-date information?

RESPONSE: Vet Centers staff receive copies of the "Agent Orange Bulletin" - which contain articles on the status of key studies relating to Agent Orange. The other materials mentioned above are now being prepared and will also serve to keep Vet Center staff informed. For more detailed and personalized help, Vet Center clients are referred to the parent VAMC environmental physician for information on the status of various scientific studies.

11. QUESTION: With reference to the reply to question 13:

- A: Is it possible to develop some retrospective estimates of the number of showings that the film "Agent Orange: A Search for Answers" has had to date and of the sizes of the audiences at such showings?
- B. Will the VA keep statistics on future showings and audiences?
- C. Do all Vet Centers have the equipment needed to show this film?

11.A. QUESTION: Is it possible to develop some retrospective estimates of the number of showings that the film "Agent Orange: A Search for Answers" has had to date and of the sizes of the audiences at such showings?

RESPONSE: Field facilities were directed by a Chief Medical Director's Letter, IL 16-81-3, dated February 5, 1981, to maintain a log describing the dates and places of all showings and the type and size of audiences viewing the film. Although a retrospective study of the results has not yet been conducted, such a study is possible. Consideration is now being given to a review of the history of these showings at our facilities.

11.B. QUESTION: Will the VA keep statistics on future showings and audiences?

RESPONSE: Yes.

11.C. QUESTION: Do all Vet Centers have the equipment needed to show this film?

RESPONSE: Almost all of the Vet Centers currently have equipment for the showing of the film. Recently established Vet Centers that lack the equipment have been authorized to purchase essential video equipment. In the interim, these facilities have access to equipment loaned from their parent VA Medical Centers.

12. QUESTION: With reference to the reply to question 15:

- A: When will a report on the proceedings of the International Symposium on Dioxin be available?
- B. Will you provide me with a copy and submit a copy of this report for the record of the Committee's hearing once they become available?

12.A. QUESTION: When will a report on the proceedings of the International Symposium on Dioxin be available?

RESPONSE: We have been advised that the proceedings will be published by Plenum Publishing Corporation as part of their Environmental Science Series in the third quarter of this year. The Veterans Administration has reproduced copies of the "blue-ribbon" panel reports for distribution to our environmental physicians. Enclosed are two copies of the panel reports provided to us by ENVIRO CONTROL.

12.B. QUESTION: Will you provide me with a copy and submit a copy of this report for the record of the Committee's hearing once they become available?

RESPONSE: The Veterans Administration did not sponsor the symposium and therefore is not responsible for the publication of the proceedings. We understand that copies of the proceedings will be available from Plenum Publishing Corporation.

13. QUESTION: In reply to question 16(B), you noted that the "study protocol [of the VA's Vietnam veteran mortality study] is currently under review by the Science Panel of the interagency Agent Orange Working Group".

A: When will the Science Panel receive the study protocol?

B. Please provide a copy of the Science Panel's evaluation of the protocol as soon as it is submitted and advise us regarding any further actions by the VA or others relating to this study.

13.A.

QUESTION: When did the Science Panel receive the study protocol?

RESPONSE: We provided a copy of the mortality study protocol to the Science Panel in November 1981.

13.B. QUESTION: Please provide a copy of the Science Panel's evaluation of the protocol as soon as it is submitted and advise us regarding any further action by the VA or others relating to this study.

RESPONSE: The Science Panel has discussed the protocol in considerable detail and is in the final phase of the review process. We will be happy to provide the committee with a copy of the protocol when completed. In addition, we will provide you with an action plan for implementation of the study when this is ready. We are prepared to begin this project quickly, and are as anxious for the Science Panel to instruct us to get on with it as you are.

14. QUESTION: With reference to the reply to question 16(D)(1), now that a draft protocol has been received, please comment on the relationship between the VA mortality study and that proposed by the contractor and on whether consolidation is desirable.

RESPONSE: The mortality study proposed by UCLA in its original submission was not suggested in the second, current draft of the protocol. The study initially proposed was for the same purpose and generally used the same methods as those designed by the VA investigators. The VA proposal is being reviewed by the Science Panel of the Agent Orange Working Group and its suggestions are now being considered. It is unlikely that a second mortality study will be conducted as part of the epidemiological study being designed by UCLA.

15. QUESTION: With reference to the reply to question 20(B)(1):

- A: On what date was the amended draft protocol submitted to each of the four listed entities and what is the timetable for each entity to provide the VA with its comments on the draft protocol?
- B: Please provide copies of these reviews for the record of this hearing with any excising that is necessary and full copies for the Committee's background use.

15.A. QUESTION: On what date was the amended draft protocol submitted to each of the four entities and what is the timetable for each entity to provide the VA with its comments on the draft protocol?

RESPONSE: The UCLA draft protocol was submitted to the Office of Technology Assessment on February 2. The Science Panel of the Agent Orange Working Group received its copies on February 4, the VA's Advisory Committee on February 25. The VA is currently planning to contract with the Medical Follow-up Agency of the National Academy of Sciences - National Research Council to review the final protocol when completed.

The OTA and the Science Panel hope to submit their written comments by March 16 and the Advisory Committee's evaluations are expected by March 23. The comments will be submitted to UCLA to assist them in preparing the final protocol which is due 30 days following receipt of the peer review comments.

15.B. QUESTION: Please provide copies of these reviews for the record of this hearing with any excising that is necessary and full copies for the Committee's background use.

RESPONSE: The comments have not yet been received from the reviewing groups. We will be pleased to submit copies to the committee at the time that they are forwarded to UCLA.

16. QUESTION: With reference to the reply to question 21(B):

A. What percentage of the 2.4 million veterans who served in the Republic of Vietnam had previously sought, or were seeking at the time Public Law 97-72 was enacted, inpatient and outpatient care from the VA?

B. What is the basis for the assumption that an additional 15% of this population of veterans --

(i) has disabilities that would provide a basis for care under the new eligibility; and

(ii) would seek such care from the VA?

C. What assumptions were made regarding those veterans exposed to radiation?

16.A.

QUESTION: What percentage of the 2.4 million veterans who served in the Republic of Vietnam had previously sought, or were seeking at the time Public Law 97-72 was enacted, inpatient and outpatient care from the VA?

RESPONSE: We do not know the percentage prior to Public Law 97-72. Immediately following the passage of Public Law 97-72 on November 3, 1981, the VA established an Ad Hoc committee to design a "tracking system" to measure the impact of this legislation. The committee is in the final stage of developing a mechanism, utilizing an existing reporting system, to capture relevant statistical data which will include the identification of all veterans applying for inpatient or outpatient care under the provisions of Public Law 97-72. A tentative target date of October 1, 1982 has been identified to make this system operational with a report to Congress during the 2nd quarter Fiscal Year 1983.

16.B.

QUESTION: What is the basis for the assumption that an additional 15% of this population of veterans --

(i) has disabilities that would provide a basis for care under the new eligibility; and

(ii) would seek such care from the VA?

RESPONSE: (i) Public Law 97-72 established eligibility for care and treatment to a new population of veterans for exposure to Agent Orange. The assumption is based on the VA's experience to date that Vietnam veterans have disabilities requiring care or treatment in approximately the same ratio as veterans of other periods of active military service.

(ii) It is again assumed that a percentage of Vietnam veterans will seek such care in approximately the same ratio as their veteran counterparts from other periods of active military service.

16. C.

QUESTION: What assumptions were made regarding those veterans exposed to Radiation?

RESPONSE: The following assumptions were made regarding veterans exposed to radiation at Nagasaki or Hiroshima, or the detonation of other nuclear devices:

(See Attached)

RESPONSE: 16C

Medical Care for Veterans Exposed to Radiation

1. It has been estimated that there were 250,000 veterans exposed to radiation during atmospheric nuclear testing and 140,000 at Hiroshima and Nakasaki.
2. It is assumed that since time of exposure 20% of these veterans have died from all causes.
3. There now remain 200,000 veterans who were exposed to radiation during atmospheric nuclear testing and 112,000 at Hiroshima and Nakasaki.
4. The prevalence of cancer in veterans of this age group, 55 through 70, is 10%.
5. We would expect 31,200 cases of cancer through the remaining life time of these veterans which is assumed to be an average of 20 years. Thus, the average incidence of these cases would be 5% per year and therefore in any given year, we would expect $31,200 \times .05 = 1,560$ veterans to exhibit a malignant neoplasm.
6. We assume that 50% of these veterans ($.5 \times 1,560 = 780$) would use the VA and that they would generate an average of three discharges in their first year--also, that they would have an additional discharge in their third year. The length of stay is assumed to be 15.3 days. The number of outpatient visits per discharge is assumed to be an average of four.
7. First year experience:

$780 \text{ veterans} \times 3 = 2,340 \text{ discharges}$

$2,340 \times 4 = 9,360 \text{ outpatient visits}$

RESPONSE: 16C (Cont'd)

8. Summary workload experience:

<u>Year</u>	<u>Discharges</u>	<u>Visits</u>
1	2,340	9,360
2	2,340	9,360
3	3,120	12,480
4	3,120	12,480
5	3,120	12,480

9. The current used staffing ratios are: 2.1 FTEE per ADC and 1 FTEE per 500 outpatient visits. On this basis, we would require 225 FTEE in the first two years and 300 FTEE in the following three years.

$$\begin{array}{r}
 \underline{2.1 \times 2,340 \times 15.3} = 206 \\
 365 \\
 \underline{9,360} = 19 \\
 500 \quad \text{---} \\
 \text{Total} = 225
 \end{array}$$

$$\begin{array}{r}
 \underline{2.1 \times 3,120 \times 15.3} = 275 \\
 365 \\
 \underline{12,480} = 25 \\
 500 \quad \text{---} \\
 \text{Total} = 300
 \end{array}$$

RESPONSE: 16C (Cont'd)

Cost for this proposal was computed as follows:

- a. Inpatient Care -- Number of discharges x \$192.17
(cost per day) x 15.3 days (average length of stay).
- b. Outpatient Care -- Number of visits x \$61.60 (cost per
outpatient visit).
- c. Using the above, we would expect the cost of inpatient
care to be \$6.9 million or $2,340 \times \$192.17 \times 15.3$.
- d. We expect the cost of outpatient care to total \$.6 million
or $9,360 \times \$61.60$.

10. These are FY 1982 costs:

<u>Year</u>	<u>Discharges</u> <u>(\$000's)</u>	<u>Cost</u> <u>Visits</u> <u>(\$000's)</u>	<u>Totals</u> <u>(\$000's)</u>	<u>FTEE</u>
1	6,900	600	7,500	225
2	6,900	600	7,500	225
3	9,200	800	10,000	300
4	9,200	800	10,000	300
5	9,200	800	10,000	200
Totals	41,400	3,600	45,000	

11. The estimated five-year cost for both inpatient and outpatient care is \$45 million with a requirement of an additional 225-300 FTEE.

17. QUESTION:

In reply to question 22, you stated that the VA "does not have legislative authority to provide genetic services to family members of veterans". Without disputing that assertion, it clearly does not answer the question that I asked, which was, whether the agency provides genetic counseling to a veteran who comes to the VA and expresses concern about genetic harm to himself or herself. I believe that, as to such veterans, the agency has clear legislative authority to provide assistance, whether on an in-house or, under certain circumstances, a contract basis, and I would like to know how the agency responds to such veterans at present.

RESPONSE:

The VA may not provide genetic services which require the examination of both members of a married couple for purposes of family planning. However, the VA does provide a wide range of medical and diagnostic services to eligible veterans including genetic counseling and screening where the family history and/or medical problems of the particular veteran indicate the need for such services.

In the case of an individual veteran who expresses a concern about possible genetic harm resulting from exposure to Agent Orange, the VA provides counseling to reassure the veteran that at the present time there is no scientific evidence to suggest that a male exposed to Agent Orange in the past has a higher than normal risk of having a child with a birth defect.

18. QUESTION: In reply to question 24(B), you noted that the contractors on the epidemiological study "have been attempting to develop an exposure index which would establish documented exposure of specific individuals."

A. Is this approach reflected in the revised draft protocol submitted by the contractor?

B. Do you have any basis, other than the contractor's proposal, for believing that an individual-by-individual exposure index can be developed or is necessary for the conduct of the epidemiological study?

18.A. QUESTION: Is this approach reflected in the revised draft protocol submitted by the contractor?

RESPONSE: The current UCLA draft protocol recommends using a method developed by the Department of Defense which identifies cohorts of veterans most likely and least likely to have been exposed to Agent Orange.

18.B. QUESTION: Do you have any basis, other than the contractor's proposal, for believing that an individual-by-individual exposure index can be developed or is necessary for the conduct of the epidemiological study?

RESPONSE: We believe that in order to study the possible health effects of exposure to Agent Orange, some method is needed to determine whether individual veterans had a greater or lesser likelihood of exposure to Agent Orange. For the past several months the Department of Defense has been developing a method for establishing groups of veterans who had essentially the same relative risk of exposure.

Chairman SIMPSON. Senator Specter, I believe you have some questions.

Senator SPECTER. Yes, thank you very much, Mr. Chairman.

May I first ask that an opening statement be included in the record at the appropriate point. I could not be here at the outset of the hearing because of other commitments.

Chairman SIMPSON. Indeed it will be accepted and I appreciate your great interest in the Veterans' Affairs Committee and in this issue.

[The prepared statement of Hon. Arlen Specter, a U.S. Senator from the State of Pennsylvania, follows:]

PREPARED STATEMENT OF HON. ARLEN SPECTER, A U.S. SENATOR FROM THE STATE OF
PENNSYLVANIA

During the last several months, I have conducted a series of Senate Veterans' Affairs Committee field hearings throughout Pennsylvania to consider the readjustment problems of Vietnam veterans. The focus of these hearings has been on the physical suffering that has been allegedly afflicted due to the exposure to Agent Orange during the War.

Until some resolution of these complaints of injuries is reached, the human toll of the Vietnam War will continue.

From testimony given by both veterans and Veterans Administration officials, it is clear that frustration is mounting on both sides. Injuries alleged by veterans range from tumors to debilitating stomach ailments to genetic damage to children. For these veterans, already a decade after the War's end, there is little, if any, solace in the impressive array of interagency studies being conducted on the effects of exposure to dioxin and other toxic substances.

The Federal Government has imposed a impossible burden on these veterans to establish service-connection for their injuries and never receive compensation. It is a burden of proof which far exceeds any imposed on litigants in civil trials who must establish liability for their injuries. It is difficult to understand why these veterans are subjected to such a difficult legal barrier.

Clearly, progress has been made. Granting priority medical treatment for these veterans will alleviate some

suffering. However, until formal recognition is given to the cause of their injuries, and compensation offered, Vietnam veterans will understandably continue to feel that they have been ignored by the government they served. For this reason, I am seriously considering the introduction of legislation which will alter the burden of proof so that Vietnam veterans are required only to establish reasonable grounds for liability as is required civil litigants. A similar burden is applied for claims of compensation for Black Lung disease.

I trust that the numerous studies on the effects of Agent Orange will be concluded expeditiously. However, there is a serious question in my mind whether the human price imposed by waiting for the results of these investigations should be borne by Vietnam veterans.

I look forward to today's testimony.

Senator SPECTER. Yes, thank you, Mr. Chairman.

I am especially interested in this matter, arising out of a very heavy incidence of mail and contacts which I have received from veterans and veterans' organizations in the Commonwealth of Pennsylvania, which have prompted me to hold a series of hearings throughout the State; some four hearings, with the authorization of the committee.

And I have found of all the issues which confront us, and there are many, none is of greater importance in the minds of the very large group than is the problem of agent orange.

The central concern I have is how long will the studies take to determine whether there is a cause and effect relationship between exposure to dioxin, agent orange and the rashes and tumors and cancers and genetic defects which we have heard so much about.

Mr. NIMMO. Well, if I may, Senator, I would defer to Dr. Shepard. But I would just say before doing so that I think it is impossible to provide a definitive answer to that until we have an acceptable protocol and it will be some days before we know that.

Senator SPECTER. Dr. Shepard, perhaps you want to expand on that.

Dr. SHEPARD. I don't have very much more to add, Senator, other than it is difficult to predict how long it will take until we have a protocol that's agreed upon.

Senator SPECTER. Well, I will say it's difficult to predict. What is the outer stretch of a protocol?

Dr. SHEPARD. Well, as you know, the protocol has not been completed yet. I would suggest that, in keeping with other generally

similar types of studies, there will not be a single point in time at which we will have all the answers.

I think it's safe to assume that the study will be conducted in phases. For example, we will probably see something relating to the cause of death of Vietnam veterans who have died since serving in Vietnam. Then probably a phase which will address itself to the current state of health of these veterans to see if there are any patterns of illness emerging.

And third, probably a prospective, long range study to look at possible delayed subtle effects that may develop over a longer period of time.

Senator SPECTER. Well, you say there is not a single point in time when we will have all the answers. Is it 25 years?

Dr. SHEPARD. Hopefully by then we should, yes.

Senator SPECTER. Well, that's not acceptable, 10 to 15 years on the hearings in Philadelphia, a series of people came from Washington, and the studies were in segments and one of the studies was projected to be 10 to 15 years away.

Now, is that the reality, 10 to 15 years before we have some answers on genetic defects for example?

Dr. SHEPARD. No, sir. The question of birth defects, which I presume you are addressing, will be answered in a study that is being undertaken by the Center for Disease Control in Atlanta. I believe among the witnesses this morning you will be hearing from people who are involved in that study.

Senator SPECTER. Well, are you in a position to give me an estimate as to how long we will—it will be before we know the answer to causal connection between exposure to agent orange and birth defects?

Dr. SHEPARD. It's my understanding we should have some of those answers by the middle of 1983. That study is now just getting underway.

Senator SPECTER. And what studies, some of the answers, what do you mean by "some of the answers"?

Dr. SHEPARD. Senator, I would prefer to defer that question to Dr. David Erickson who is really more knowledgeable on the details of this study.

Senator SPECTER. Well, are some of the answers really going to be as late as 10 or 15 years away as was suggested in the testimony which was presented at the field hearing in Philadelphia?

Dr. SHEPARD. I think it's safe to assume, Senator, that we will not have all the answers to these questions until several years from now because part of that effort is to look at delayed subtle effects which may take several years to develop. Many illnesses have their precursors many years prior to their onset.

So, in order to detect whether a relationship exists between an illness and a prior exposure often takes many years to determine.

Senator SPECTER. Well, it troubles me to have a conclusion that it's going to take many years, like 10 to 15 years, as being a matter of basic and fairness to answering the question one way or another.

It may be that the Veterans' Administration is going to say that there is no compensation for exposure to agent orange. There is not a cause and effect relationship, or it may be that the Congress will ultimately say that.

But it's my sense that there ought to be an answer to the question which has been posed, and the U.S. Government has a preferred position in a litigation context because the sovereign cannot be sued. But if this were an ordinary civil litigation matter and a claimer was presenting a claim against a chemical manufacturer, it would be necessary only to provide some expert testimony, probably a physician who would testify about cause and effect and then the issue would be submitted to the jury and if the jury returned a very substantial verdict of hundreds of thousands of dollars or more, that would be sustainable. That is the way we answer questions in our society in the context of a dispute as to whether some item caused some defect.

It seems to me that it is just unacceptable with so many people suffering from ailments, and I saw a long string of people who came in with specific complaints about cancer and about genetic defects, birth defects, and in my own lay mind it seemed to me there was good reason to believe that the causal connection existed, but I am not about to draw such a conclusion with finality because it is too involved.

But on the issue as to when it is to be decided, it seems to me that you simply can't say it's going to be decided at a point in time where we can't determine, or when pushed to say that some of the tests may take 10 to 15 years.

Dr. SHEPARD. If I may comment, sir.

Senator SPECTER. Please.

Dr. SHEPARD. We will have some of the answers much sooner than that. I feel confident that we will have a good handle on the genetic defects, or birth defects problem much sooner than that.

Senator SPECTER. Well, when you say "much sooner" do you really mean 1983?

Dr. SHEPARD. Well, that was my understanding, sir. But I suggest that that question be directed to Dr. David Erickson who is here and will be testifying on that point.

The mortality study from the Ranch Hand experience and the details of that will be presented by General Myers, Surgeon General of the Air Force, this morning. But it's my understanding that that data will be available within the next year.

Senator SPECTER. But what is going to take the longest time as you understand it?

Dr. SHEPARD. It's my impression that the thing that will require the longest time will be to determine the subtle effects of exposure, which may take a long time to develop or effects which may occur rarely. For example, there may a very subtle effect which develops in only one-tenth of 1 percent population. In order to detect subtle effects we will have to examine a large number of individuals over a prolonged period of time.

Senator SPECTER. What is such a subtle effect, as you define it?

Dr. SHEPARD. Well, if we may take an example of a tumor which is known to be the result of asbestos for example. Mesothelioma is a tumor which is known as to result from exposure to asbestos.

Senator SPECTER. OK; 15 years. Are you suggesting that something like that is present as a delayed reaction from exposure to agent orange?

Dr. SHEPARD. We don't know, sir. We don't know. We are just beginning to scratch the surface on that issue.

Senator SPECTER. There is lurking in the background of all of these issues the question of cost, because the Government is always cost conscious but never as cost conscious as in the year 1981 and for good cause. We are dancing around the issue as to whether agent orange has caused this chamber of horrors because if it is decided that agent orange has caused it, there is going to be a very heavy impact on cost.

What is the estimate of cost if agent orange is found to be the cause of the factor of the chamber of horrors which we have heard about from so many people in this country?

Mr. NIMMO. I think it would be very difficult, if not impossible, to isolate that cost. What we are doing, Senator, as you know, as a consequence of recent legislation, is that we are treating all veterans on a priority basis who claim a condition related to agent orange.

So, we are and will continue to deliver whatever medical treatment is indicated for those conditions.

Senator SPECTER. Mr. Nimmo, when you comment on that let me digress for just a moment—

Chairman SIMPSON. Not too far.

Senator SPECTER [continuing]. Notwithstanding the red light. Well, I won't digress. I will just say that I have heard testimony that the treatment is not on a priority basis, but I will take that on the next round and press while there is still some patience in the Chair.

On this issue of cost, what are we thinking about that seems to be inhibiting us from coming to a conclusion? Maybe not a study conclusion in the protocol and tests, but I sense as a major inhibiting factor in the Congress in saying we want to change the burden of proof or change the presumption or make it easier to collect in these situations. Are we talking about hundreds of millions of dollars? Are we talking about billions of dollars?

If the Congress were to say that there is a presumption between anybody who is exposed to agent orange and birth defects, cancer, tumors for compensation, what kind of a price tag would we be looking at?

Mr. NIMMO. We would be looking at costs of hundreds of millions of dollars per year going probably into the middle of the next century.

Senator SPECTER. Thank you very much.

Chairman SIMPSON. Thank you, Senator Specter. I do know your deep interest in this issue. You have conducted those hearings in the field and knowing your skill as an attorney, and realizing that we both used to do that line of work, this is the tough part of it all: Cause and effect, and civil action in tort. If we were doing that litigation, we would have to prove the ancient things you have to prove in such action for damages, which are injury, approximate cause, negligence, responsibility, and due care. Those are the tough issues. Those are the real "gut" issues and I think they are the subject of another hearing in which we will direct ourselves only to those issues. I will look forward to your participation in that.

I apologize to my good colleague from Maine who has been sitting patiently there while I skipped him. And, George, I do apologize. I believe you had an opening statement and some questions. I am sorry, and please proceed.

Senator MITCHELL. Thank you, Mr. Chairman. I will not read my opening statement, but ask that it be inserted in the record at the appropriate point. At this time, I would like to ask a few questions of Mr. Nimmo and the other gentlemen.

[The prepared statement of Hon. George J. Mitchell, a U.S. Senator from the State of Maine, follows:]

PREPARED STATEMENT OF HON. GEORGE J. MITCHELL, A U.S. SENATOR FROM THE STATE OF
MAINE

MR. CHAIRMAN, THIS IS MY FIRST OPPORTUNITY TO PARTICIPATE AS A MEMBER OF THIS COMMITTEE IN AN OVERSIGHT HEARING ON THE AGENT ORANGE CONTROVERSY. I WANT TO COMMEND THE CHAIRMAN FOR SCHEDULING THIS HEARING AND FOR HIS RECOGNITION OF THIS COMMITTEE'S RESPONSIBILITY TO CONTINUE ITS EFFORTS TO ACHIEVE A RESOLUTION OF THIS MOST DIFFICULT ISSUE. I LOOK FORWARD TO THE TESTIMONY OF THE WITNESSES.

THE STEPS THAT HAVE BEEN TAKEN BY THE VA, AND BY THIS COMMITTEE, TO FIND ANSWERS TO THE COMPLEX MEDICAL QUESTIONS SURROUNDING THE ISSUE HAVE BEEN PERCEIVED BY MANY AS TOO SLOW AND DELIBERATE. IN SOME INSTANCES, THIS CRITICISM HAS BEEN JUSTIFIED; IN OTHER INSTANCES, IT HAS REFLECTED THE GROWING FRUSTRATION AND SENSE OF HOPELESSNESS OF MILLIONS OF VIETNAM-ERA VETERANS WHO HAVE EVERY RIGHT TO DEMAND A PROMPT RESOLUTION OF THE CONTROVERSY.

I SHARE THEIR FRUSTRATION. THERE IS A LARGE VOID OF KNOWLEDGE OUT THERE WHICH HAS BECOME THE STUMBLING BLOCK ON ALL ATTEMPTS TO MOVE FORWARD QUICKLY ON THIS ISSUE. THE AGENT ORANGE REGISTRY, THE LITERATURE ANALYSIS, THE EPIDEMIOLOGIC STUDY, THE MORTALITY STUDY - ALL OF THESE EFFORTS ARE STEPS IN THE RIGHT DIRECTION. I AM CONFIDENT THAT EVENTUALLY THEY WILL BRING LIGHT AND UNDERSTANDING INTO THE DARK AND SHADY AREAS OF SCIENTIFIC KNOWLEDGE ON THIS ISSUE. BUT LIKE THE WHEELS OF JUSTICE, THESE EFFORTS "GRIND EXCEEDINGLY SLOW." AS I STATED, I SHARE THE FRUSTRATION OF THE MEN AND WOMEN WHO MUST AWAIT THE RESULTS OF THIS TIME-CONSUMING SCIENTIFIC PROCESS.

IT IS SMALL SOLACE TO AN INDIVIDUAL WHO BELIEVES THAT HIS OR HER EXPOSURE TO AGENT ORANGE IS CAUSING OR MAY CAUSE SERIOUS HEALTH PROBLEMS TO BE INFORMED THAT A STUDY IS BEING DESIGNED. WE MUST DO ALL THAT WE CAN TO SEE THAT PROGRESS OCCURS AS RAPIDLY AS POSSIBLE AND, EQUALLY IMPORTANT, TO SEE THAT WHATEVER PROGRESS IS MADE BE ACCURATELY AND PROMPTLY REPORTED TO THE INDIVIDUALS DIRECTLY AFFECTED BY AGENT ORANGE EXPOSURE.

MR. CHAIRMAN, I AM PLEASED TO BRING TO THIS COMMITTEE'S ATTENTION THE SUCCESSFUL EFFORTS OF SEVERAL CONCERNED VETERANS AND VETERANS' GROUPS IN MAINE TO MOVE FORWARD WITH THIS ISSUE. THIS YEAR, MAINE BECAME THE FOURTH STATE IN THE NATION TO FORMALLY RECOGNIZE THE CONCERNS OF ITS VIETNAM VETERAN POPULATION IN THIS AREA BY FORMING AN AGENT ORANGE INFORMATION COMMITTEE.

THIS COMMITTEE HAS HAD DRAMATIC SUCCESS IN RESOLVING AN IMPORTANT ASPECT OF THE AGENT ORANGE PROBLEM; THAT IS, THE LACK OF STATISTICALLY VALID HUMAN DATA. THE MAINE COMMITTEE HAS PREPARED AND CIRCULATED A SELF-HELP GUIDE ON AGENT ORANGE WHICH PROVIDES RESPONSIBLE, FACTUAL INFORMATION TO THE CONCERNED VETERAN. I WOULD ASK THAT A COPY OF THIS GUIDE BE INSERTED IN THE HEARING RECORD.

MAINE'S VIETNAM COMBAT VETERAN POPULATION IS AROUND 16,000. IN JULY, WHEN THE MAINE AGENT ORANGE INFORMATION COMMITTEE WAS FORMED, THE TOTAL NUMBER OF VETERANS WHO HAD RECEIVED A FREE SCREENING EXAMINATION AT THE TOGUS VA FACILITY WAS 375. THROUGH THE EFFORTS OF THE COMMITTEE, THIS NUMBER HAS ALMOST DOUBLED. THE SELF-HELP GUIDE AND OTHER CONTINUED EFFORTS OF THE MAINE COMMITTEE WILL UNDOUBTEDLY SUCCEED IN FURTHER DRAMATIC INCREASES IN THE NUMBER OF EXAMINATIONS ENTERED INTO THE AGENT ORANGE REGISTRY.

I BELIEVE THAT THEIR SUCCESS CAN BE DIRECTLY ATTRIBUTED TO THEIR EMPHASIS ON PROVIDING FACTUAL, RESPONSIBLE INFORMATION TO VETERANS. I WHOLEHEATEDLY ENDORSE THEIR APPROACH AND HOPE THAT THEIR EFFORTS WILL BE EMULATED BY OTHERS ACROSS THE COUNTRY. I MIGHT POINT OUT THAT ALTHOUGH THE PERCENTAGE OF MAINE VETERANS WHO HAVE PARTICIPATED IN THE FREE SCREENING PROCESS IS EXTREMELY SMALL, IT IS ALMOST DOUBLE THE NATIONAL AVERAGE.

I WOULD ALSO NOTE, MR. CHAIRMAN, THAT THE PRIMARY ARCHITECT AND FIRST CHAIRMAN OF THE MAINE AGENT ORANGE INFORMATION COMMITTEE IS THE NEW DEPUTY NATIONAL DIRECTOR FOR SERVICE AND LEGISLATION OF THE AMVETS, PETER CURRIER. PETER HAS RECENTLY SERVED MAINE'S VETERANS AS AN AMVETS NATIONAL SERVICE OFFICER. I CONGRATULATE PETER ON HIS APPOINTMENT BUT I KNOW THAT HIS ABSENCE WILL BE SORELY FELT BY MAINE'S VETERANS.

I LOOK FORWARD TO THE TESTIMONY OF THE WITNESSES. I HOPE THAT WE CAN MAKE SIGNIFICANT PROGRESS TOWARD RESOLVING THIS COMPLEX AND EMOTIONAL ISSUE IN THE MONTHS AHEAD.

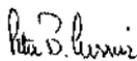
The Vietnam Veterans'



Self-Help Guide On Agent Orange

Prepared by:
MAINE AGENT ORANGE INFORMATION COMMITTEE

The State of Maine Agent Orange Information Committee thanks the New Jersey Agent Orange Commission for inspiration which has enhanced our efforts to assist the Viet Nam combat veteran of Maine.



Chairman



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Dear Viet Nam Veteran:

The Maine Agent Orange Information Committee is committed to bring to you the best and most usable information about Agent Orange available. Our hope is that you will request a scheduled examination at the VA Center at Togus and "help us help answer the questions" about the issue.

The following page of this self-help guide is designed so as to answer the first question you may have, "Was I exposed to defoliant spray in Viet Nam?" The map is not exact, as some information about the war still remains classified by the Defense Department. It does, however, indicate known areas of heaviest spray operations, and since the best information available indicates that 66% of Viet Nam was sprayed at least once, we must conclude that due to the transient nature of the war anyone who served in Southeast Asia could have been exposed.

With the above in mind, the members of the Maine Agent Orange Information Committee encourage you, the veteran of Viet Nam (male or female), to become more aware of the Agent Orange issue. We urge you to request your free screening examination at the VA Center at Togus.

Sincerely yours,

Peter B. Currier
Chairman

PBC:b1b

Help Us Help Answer The Questions



THE MAP ABOVE SHOWS THE LOCATION OF U.S. ARMY UNITS THAT WERE STATIONED IN VIETNAM.

THE DARK AREAS INDICATE HEAVIEST AREAS OF SPRAYING.

THE LIGHTER AREAS INDICATE AREAS OF LESS INTENSE SPRAY OPERATIONS.

A BRIEF BACKGROUND

Historical

During the period 1962-71, a number of chemical herbicides were used extensively in South Viet Nam. These herbicides or defoliants, were designed primarily to deprive enemy forces of ground cover and to restrict food supplies. The most common of these defoliants was "Agent Orange", so named because of the orange stripes on the 55-gallon drums shipped to Southeast Asia. An estimated 18.85 million gallons of herbicide sprays were used with two-thirds of that total being Agent Orange.

Briefly stated, Agent Orange is a 50/50 mixture of 2,4,5-trichlorophenoxyacetic acid (2,4,5-T which contains TCDD or dioxin in trace amounts) and 2,4-dichlorophenoxy-acetic acid (2,4-D). In terms of toxicity, dioxin is one of the most toxic substances known to man. Dioxin or TCDD, is of special concern because it has caused cancer in laboratory animals exposed to it. In addition, birth defects have also been reported when the female laboratory animal was exposed to TCDD during pregnancy. Experiments using small numbers of laboratory animals (too limited to be statistically valid) exposed to low levels of TCDD in their diets have shown reproductive problems including menstrual irregularities, poor conception, and miscarriage. The exact effects of Dioxin on humans is scientifically inconclusive at this time, except for a specific skin condition known as chloracne.

Research

A number of scientific studies on dioxin related-groups have been completed and others are underway. Some of the studies are aimed specifically at trying to find answers to questions about Agent Orange as used in Viet Nam. Scientific studies take time and there can not be any shortcuts on so important an issue.

In addition, several other important efforts have been undertaken at the federal level. In mid-1979, a Veteran's Administration Advisory Committee on the Health-Related Effects of Herbicides was formed. An Interagency Work Group to Study the Possible Long-Term Effects of Phenoxy Herbicides and Contaminants (IAG), was established by the White House to oversee federal research it is conducting. The U.S. Air Force will be doing a study on some 1160 airmen involved directly in the spraying activity in Viet Nam. These airmen were part of a special air unit known in Viet Nam as the "Ranch Hands".

State of Maine

At the state level, Maine was the fourth state in the nation to organize an effort aimed at a resolution to the issues surrounding Agent Orange.

In July of 1981, the Agent Orange Information Committee met for the first time, comprised of ten distinguished citizens appointed to serve on the panel. Five members saw combat in Viet Nam, and all members are sincerely concerned with the issue.

The primary objectives of the committee are to increase public awareness of the Agent Orange issue through an extensive media effort, provide factual data, alert the medical community, and most importantly encourage the Viet Nam veteran to seek a free Agent Orange Screening Examination at the Veterans Administration.

Although laboratory research into the long-term health effects of dioxin exposure is underway in both the Veterans Administration and private sector, a key ingredient to the puzzle is sorely missing. Due to the small number of Agent Orange examinations performed to date, insufficient human data exists to prove a relationship between exposure to herbicides and specific chronic health effects. The Maine Agent Orange Information Committee will endeavor to see to it that all Maine's 16,000 combat veterans participate in supplying this needed data by encouraging them to seek an examination at the Veterans Administration.

Committee Members

Peter Currier, Chairman
 Michael Carpenter, State Senator
 Robert E. Comeau, Veterans Center
 Sterling Doughty, Viet Nam Era Veterans of Maine
 Frank Lawrence, M.D., Maine Poison Control Center
 William Nersesian, M.D., Maine Department of Human Services
 Gerald M. Roy, Maine Veterans Coordinating Committee
 James H. Tukey, Veterans Center
 John G. Weaver, Maine Bureau of Veterans Services
 Robert I. Wise, M.D., Veterans Administration Medical Center, Togus

STEP 1: Medical Records

The committee wants you to be officially on record with the Veterans Administration. The only way to do that, is to obtain an Agent Orange Screening Examination. The exams are free and normally take two hours including the various tests that are performed. Being on record, (whether you are experiencing any health problems or not), protects you and your family in the future; the data you provide on the VA Agent Orange questionnaire, plus your exam results play an important part in determining health patterns resulting from our service in RVN; and finally, your name will be added to the VA Agent Orange Registry for possible follow-up. As always, your records with the Veterans Administration are confidential, and cannot be used without your permission.

Your medical records, whether they are from the military, a personal physician, or the Veterans Administration could be an important part of your Screening Examination. You can obtain your military medical records by completing Standard Form 180 (Attachment C). The SF 180 will provide an address for mailing. You can request your personal physician to provide copies of any illnesses related to the Screening Examination. If you have used the Veterans Administration Medical care, ask for and complete VA Form 07-3288.

In any case, ensure that the examining physician is aware of any medical records that may be part of your claim. Please remember that the medical history of you and your family is an important part of the Screening Examination.

You may even want to write down some brief notes before going in for the examination.

STEP 2: Get Your Facts Together

Before you actually file for an examination, gather up any personal notes, records, or any other materials that will be important to your case. Fill out Attachment "B" and ask that it be made a part of your records. Many veterans will not remember exact dates, units, or locations. If you just can't remember, write that. The Veterans Administration may have access to some of those records. Once again, by making some brief notes, you may be able to recall some important information. An important rule of thumb when dealing with the Veterans Administration is: **MAKE A COPY FOR YOUR OWN RECORDS!**

STEP 3: Scheduling an Examination

It is not necessary for you to travel to the Togus Veterans Administration to schedule an examination. However, you must schedule an Agent Orange examination. To schedule an examination, you need only provide your name, address, and Social Security number. Bring proof of Veterans Status to the exam, if possible.

Attachment "A" will give the telephone numbers of various Veterans Offices that can assist you. Some colleges will have a Veterans Affairs Office that can also assist you. Another source of assistance is the Service Office of your local American Legion, AMVETS, DAV, or VFW organizations. They want to help and will help. If you wish, you may call the Maine Agent Orange Information Committee direct at 623-8411 Ext. 562, and we will be glad to help in scheduling a Screening Exam date.

There are many places where you can get assistance - USE THEM!

COMMITTEE PHONE NUMBER

623-8411 ext. 562

STEP 4: Filing Your Claim

We all appreciate a minimum amount of hassle and paperwork. Filing for a claim for Agent Orange need not be difficult. Included as part of this Guide is a VA Form 4138 "Statement in Support of Claim" (Attachment B), which can be used. Complete all the necessary information. Specifically request an Agent Orange Screening Examination, listing all medical problems you feel are related and service-connected.

Special Note: Always include your VA File number and Social Security number, (they may be the same).

After you complete Attachment "B" mail to:

Veterans Administration
Togus, Maine 04330

STEP 5: The Examination

While you have not been overwhelmed with forms to fill out, there are some forms that will be required at the Examining Station. One form to be completed will be the "Agent Orange Questionnaire". This form should be completed only with the assistance of qualified medical personnel. In all cases, if you need help in filling out any of the VA forms, ask for assistance. In all cases, you should find Veterans Administration personnel to be courteous and professional.

Try to keep your scheduled appointment. (If you can't make it, call the Veterans Administration). The examination is FREE and every Veterans Administration Medical Facility has at least one physician designated to give examinations. Tell your physician everything. Do not minimize any illness or medical problem you have experienced since returning from Southeast Asia. The more information you can provide, the more detailed the examination will be.

SPECIAL NOTES: When you report to the examining site, ask to see a Veterans Benefit Counselor.

IT MAY BE HELPFUL FOR YOU TO RECEIVE PRE-EXAMINATION COUNSELLING. IF YOU REQUEST IT, THE VETERANS ADMINISTRATION WILL REFER YOU TO THE SERVICE ORGANIZATION OF YOUR CHOICE (SEE ATTACHMENT A). THE MAINE AGENT ORANGE INFORMATION COMMITTEE RECOMMENDS THAT YOU RECEIVE PRE-EXAM COUNSELLING TO ANSWER ANY QUESTIONS YOU MAY HAVE.

One final note: Upon receiving a scheduled exam, you may be eligible for travel reimbursement. See the travel clerk in building 209, Togus Veterans Administration. It should be emphasized that travel pay is provided for those most in need, to ensure that all veterans will be able to get to the Togus Veterans Administration for an examination.

Personal Notes

ATTACHMENT A

Where To Get Help

AMVETS

Peter Currier - National Service Officer
VAM & ROC
Building 205, Room 121
Togus, Maine 04330
Telephone: 623-8411 Extension 562/563

AMERICAN LEGION

Mark Andrews - Department Service Officer
P.O. Box 411
Togus, Maine 04330
Telephone: 623-8411 Extension 234/575

AMERICAN RED CROSS

Rita Tardiff - Field Director
P.O. Box 3364
Togus, Maine 04330
Telephone: 623-8411 Extension 334

DISABLED AMERICAN VETERANS

Gary Burns - National Service Officer
James Wyatt - National Service Officer
P.O. Box 3151
Togus, Maine 04330
Telephone: 623-8411 Extension 556/367

VETERANS OF FOREIGN WARS

Gerald Roy - Department Service Officer
P.O. Box 3311
Togus, Maine 04330
Telephone: 623-8411 Extension 219/263

VIET NAM ERA VETERANS OF MAINE

Sterling Doughty - State President
P.O. Box 3674
Portland, Maine 04104
Telephone: 780-3219

VET CENTER

James Tukey - Team Leader
Robert Comeau - Counselor
175 Lancaster Street
Portland, Maine 04101
Telephone: 780-3584

BUREAU OF VETERANS SERVICES
STATE OF MAINE
LOCAL OFFICES

AUGUSTA

Leo J. Trahan - Veterans Counselor
Camp Keyes
Augusta, Maine 04333
Telephone: 289-3441

BANGOR

John Weaver - Veterans Counselor
Phillip McTigue - Veterans Counselor
Bangor, Maine 04401
Telephone: 947-0548

CARIBOU

Clement E. Lynch - Veterans Counselor
National Guard Armory
55 Riverview Avenue
Caribou, Maine 04736
Telephone: 496-2391

LEWISTON

Marc A. Nadeau - Veterans Counselor
460 Main Street
Lewiston, Maine 04240
Telephone: 782-9692

MACHIAS

Jere Moynihan - Veterans Counselor
Sullivan Block, Box 114
Machias, Maine 04654
Telephone: 255-3136

PORTLAND

Harold M. Sanborn - Veterans Counselor
987 Forest Avenue
Portland, Maine 04103
Telephone: 797-4697

ROCKLAND

Forrest Austin - Veterans Counselor
356 Main Street
Rockland, Maine 04841
Telephone: 594-5705

or

Call Veterans Administration
TOLL FREE 1-800-452-1935

ATTACHMENT C

REQUEST PERTAINING TO MILITARY RECORDS		Please read instructions on the reverse if more space is needed, use plain paper		DATE OF REQUEST
<p>PRIVACY ACT OF 1974 COMPLIANCE INFORMATION. The following information is provided in accordance with 5 U.S.C. 552(a)(3) and applies to this form. Authority for collection of the information is 44 U.S.C. 2907, 3101, and 3102, and E.O. 9397 of November 22, 1943. Disclosure of the information is voluntary. The principal purpose of the information is to assist the facility retaining the records in locating and verifying the correctness of the requested records or information to answer your inquiry. Routine uses of the information as established and published in accordance with 5 U.S.C. 552(a)(4)(D) include the transfer of relevant information to appropriate Federal, State, local, or foreign agencies for use in civil, criminal, or regulatory investigations or prosecution. In addition, this form will be filed with the appropriate military records and may be transferred along with the record to another agency in accordance with the routine uses established by the agency which maintains the record. If the requested information is not provided, it may not be possible to service your inquiry.</p>				
SECTION I—INFORMATION NEEDED TO LOCATE RECORDS (furnish as much as possible)				
1. NAME USED DURING SERVICE (Last, first, and middle)		2. SOCIAL SECURITY NO	3. DATE OF BIRTH	4. PLACE OF BIRTH
5. ACTIVE SERVICE, PAST AND PRESENT (For an effective records search, it is important that ALL service be shown below)				
BRANCH OF SERVICE (Also, show last organization, if known)		DATES OF ACTIVE SERVICE		Check one
		DATE ENTERED	DATE RELEASED	ON SER
				OR LISTED
				SERVICE NUMBER DURING THIS PERIOD
6. RESERVE SERVICE, PAST OR PRESENT (If "none," check here <input type="checkbox"/>)				
a. BRANCH OF SERVICE		b. DATES OF MEMBERSHIP		c. Check one
		FROM	TO	ON SER
				OR LISTED
				SERVICE NUMBER DURING THIS PERIOD
7. NATIONAL GUARD MEMBERSHIP (Check one) <input type="checkbox"/> a. ARMY <input type="checkbox"/> b. AIR FORCE <input type="checkbox"/> c. NAVY				
d. STATE	e. ORGANIZATION	f. DATES OF MEMBERSHIP		g. Check one
		FROM	TO	ON SER
				OR LISTED
				SERVICE NUMBER DURING THIS PERIOD
8. IS SERVICE PERSON DECEASED <input type="checkbox"/> YES <input type="checkbox"/> NO (If "yes," enter date of death: _____)				
9. IS (WAS) INDIVIDUAL A MILITARY RETIREE OR FIRST RESERVIST <input type="checkbox"/> YES <input type="checkbox"/> NO				
SECTION II—REQUEST				
1. EXPLAIN WHAT INFORMATION OR DOCUMENTS YOU NEED, OR CHECK ITEM 2, OR, COMPLETE ITEM 3				2. IF YOU ONLY NEED A STATEMENT OF SERVICE (check here <input type="checkbox"/>)
3. LOST SEPARATION DOCUMENT REQUEST (Complete a or b, * and c)				
a. REPORT OF SEPARATION (DD Form 214 or equivalent)		YEAR ISSUED		
b. DISCHARGE CERTIFICATE		YEAR ISSUED		
1. EXPLAIN HOW SEPARATION DOCUMENT WAS LOST				
4. EXPLAIN PURPOSE FOR WHICH INFORMATION OR DOCUMENTS ARE NEEDED				
a. REQUESTER (check appropriate box)				
<input type="checkbox"/> Same person identified in Section 1 <input type="checkbox"/> Existing spouse				
<input type="checkbox"/> Next of kin (relationship) _____				
<input type="checkbox"/> Other (specify) _____				
b. SIGNATURE (see instructions 3 and 4 on reverse side)				
5. RELEASE AUTHORIZATION, IF REQUIRED (Read instruction 3 on reverse side)				
I hereby authorize release of the requested information/documents to the person indicated at right (Item 7).				
7. Please type or print clearly — COMPLETE RETURN ADDRESS				
Name, number and street, city, State and ZIP code				
TELEPHONE NO. (include area code) _____				
VETERAN SIGN HERE: _____				
(If signed by other than veteran, show relationship to veteran)				

INSTRUCTIONS

1. **Information needed to locate records.** Certain identifying information is necessary to determine the location of an individual's record of military service. Please give careful consideration to and answer each item on this form if you do not have and cannot obtain the information for an item, show "NA," meaning the information is "not available." Include as much of the requested information as you can. This will help us to give you the best possible service.
2. **Charges for service.** A nominal fee is charged for certain types of service in most instances service fees cannot be determined in advance. If your request involves a service fee you will be notified as soon as that determination is made.
3. **Restrictions on release of information.** Information from records of military personnel is released subject to restrictions imposed by the military departments consistent with the provisions of the Freedom of Information Act of 1957 (as amended 1974) and the Privacy Act of 1974. A service person has access to almost any information contained in his own record. The next of kin (see item 4 of instructions) if the veteran is deceased and Federal officers for official purposes are authorized to receive information from a military service or medical record only or specified in the above cited Acts. Other requesters must have the release authorization, in item 5 of the form, signed by the

veteran or, if deceased, by the next of kin. Employers and others needing proof of military service are expected to accept the information shown on documents issued by the Armed Forces at the time a service person is separated.

4. **Precedence of next of kin.** The order of precedence of the next of kin is: unmarried widow or widower, eldest son or daughter, father or mother, eldest brother or sister.

5. **Location of military personnel records.** The various categories of military personnel records are described in the chart below. For each category there is a code number which indicates the address at the bottom of the page to which this request should be sent. For each military service there is a note explaining approximately how long the records are held by the military service before they are transferred to the National Personnel Records Center, St. Louis. Please read these notes carefully and make sure you send your inquiry to the right address. (If the person has two or more periods of service within the same branch, send your request to the office having the record for the last period of service.)

6. **Definitions for abbreviations used below:**

NPRC—National Personnel Records Center PERS—Personal Records
TDRI—Temporary Disability Retirement List MED—Medical Records

SERVICE	NOTE	CATEGORY OF RECORDS	WHERE TO WRITE ADDRESS CODE	
AIR FORCE (USAF)	Air Force records are transferred to NPRC from Code 1, 90 days after separation and from Code 2, 30 days after separation.	Active members (includes National Guard on active duty in the Air Force), TDRI, and general officers retired with pay.	1	2
		Reserve, retired reservist in nonpay status, current National Guard officers not on active duty in Air Force, and National Guard released from active duty in Air Force	2	1
		Current National Guard enlisted not on active duty in Air Force	3	13
		Discharged, deceased, and retired with pay (except general officers retired with pay)	4	14
COAST GUARD (USCG)	Coast Guard officer and enlisted records are transferred to NPRC 3-6 months after separation	Active, reserve, and TDRI members	3	3
		Discharged, deceased, and retired members (see next item)	4	14
		Officers separated before 1/1/29 and enlisted personnel separated before 1/1/15.	6	6
MARINE CORPS (USMC)	Marine Corps records are transferred to NPRC 4 months after separation	Active and TDRI members, reserve officers, and Class II enlisted reserve	4	4
		Class III reservists and Fleet Marine Corps Reserve members.	5	5
		Discharged, deceased, and retired members (see next item)	6	14
ARMY (USA)	Army records are transferred to NPRC as soon as processed (about 30 days after separation)	Officers and enlisted personnel separated before 1/1/1896	6	7
		Reserve, living retired members, retired general officers, and active duty records of current National Guard members who performed service in the U.S. Army before 7/1/72.*	7	6
		Active officers (including National Guard on active duty in the U.S. Army)	8	8
		Active enlisted (including National Guard on active duty in the U.S. Army) and enlisted TDRI.	9	9
		Current National Guard officers not on active duty in the U.S. Army.	12	12
		Current National Guard enlisted not on active duty in the U.S. Army.	13	13
		Discharged and deceased members (see next item)	4	14
		Officers separated before 7/1/17 and enlisted separated before 11/1/12.	6	6
NAVY (USN)	Navy records are transferred to NPRC 6 months after retirement or complete separation	Officers and warrant officers (DBI)	8	8
		Active members (including reservists on active duty)—PERS and MED	10	10
		Discharged, deceased, retired (with and without pay) less than six months, TDRI, drilling and non-drilling reservists	11	11
		Discharged, deceased, retired (with and without pay) more than six months (see next item)—PERS & MED	14	14
		Officers separated before 1/1/03 and enlisted separated before 1/1/1886—PERS and MED	6	6

* Code 12 applies to active duty records of current National Guard officers who performed service in the U.S. Army after 6/30/72

Code 13 applies to active duty records of current National Guard enlisted members who performed service in the U.S. Army after 6/30/72.

ADDRESS LIST OF CUSTODIANS (BY CODE NUMBERS SHOWN ABOVE)—Where to write / send this form for each category of records

1	USAF Military Personnel Center Military Personnel Records Division Randolph AFB, TX 78148	5	Marine Corps Reserve Forces Administration Center 1500 E. Bonham Road Knoxville, MO 64131	8	USA MILPERCEN Attn: DAPC-PSR-R 200 Shoval Street Alexandria, VA 22332	12	Army National Guard Personnel Center Columbia Pike Office Building 5000 Columbia Pike Boulevard Falls Church, VA 22041
2	Air Reserve Personnel Center 7300 East 1st Avenue Denver, CO 80280	6	Military Archives Division National Archives & Records Service General Services Administration Washington, DC 20408	9	Commander U.S. Army Enlisted Records and Evaluation Center Ft. Benjamin Harrison, IN 46249	13	The Adjutant General (of the appropriate State, DC, or Puerto Rico)
3	Commandant U.S. Coast Guard Washington, DC 20390	7	Commander U.S. Army Reserve Components Personnel & Administration Center 9700 Page Boulevard St. Louis, MO 63132	10	Chief of Naval Personnel Department of the Navy Washington, DC 20370	14	National Personnel Records Center (Military Personnel Records) 9700 Page Boulevard St. Louis, MO 63132
4	Commandant of the Marine Corps Headquarters, U.S. Marine Corps Washington, DC 20380			11	Naval Reserve Personnel Center New Orleans, LA 70146		

Senator MITCHELL. Bob, in your statement you indicated regarding the agent orange registry that since 1978 over 67,000 veterans have participated in the program. What percentage of the total eligible persons, or total possible number who could participate, does that represent?

Mr. NIMMO. If I may, I would defer to Dr. Shepard.

Dr. SHEPARD. We impose no restriction on Vietnam veterans' participation in the agent orange registry. Any Vietnam veteran who is worried about the possible health effects of exposure to agent orange, or who is just curious about the problem, may come to a VA medical facility for physical examination, laboratory studies and be entered into the registry.

Senator MITCHELL. Well, do you know what number of persons could be defined as any Vietnam veteran?

Dr. SHEPARD. Well, the Department of Defense has given us a figure of 2.4 million who served in Vietnam during the period of time when agent orange was used.

Senator MITCHELL. 2.4 million. So, 67,000 represents a rather small percentage of that total; would you agree?

Dr. SHEPARD. Yes, sir. On the other hand, I would like to point out that I don't think anybody has claimed that 2.4 million were potentially exposed.

Senator MITCHELL. Right.

Dr. SHEPARD. That's the total universe of individuals who served in that period.

Senator MITCHELL. Right. So, it's somewhere between 67,000 and 2.4 million and no one knows for sure.

Are you engaging in any outreach efforts, any informational efforts to inform Vietnam veterans of this opportunity?

Dr. SHEPARD. Yes, sir. We have produced a pamphlet which outlines the VA's activities in this regard and we will soon hopefully be updating that pamphlet. We have prepared a 30 minute audio-visual film which goes into the whole issue of agent orange in some detail. This was designed for the veteran in order to provide him with such information as what he should do and where he should go for the VA to assist him.

Senator MITCHELL. I would like to call your attention to what has occurred in four States, including my own State of Maine, where a Maine Agent Orange Information Committee has been established. I'll tell you what they have done and indicate what the results have been.

In July of this year they began their program of information, trying to reach as many Vietnam veterans as possible and the number who have now registered has doubled just in the few months over the previous couple of years.

Among the efforts, and this is the fourth State as I indicate, Maine was not the first State. Among the efforts they did was to produce this pamphlet, which is really very, very useful. They also have produced this poster which is being placed in public facilities throughout the State. They have engaged in a media campaign, which has produced positive results.

And I want to ask if you would not, Bob, have someone take a look at those State efforts and perhaps develop a method by which you can, either directly or in coordination with state organizations,

because I tend to think that they probably could do it better in individual cases, try to develop some mechanism. Because there was a lot of discussion about the importance and value of the registry, and certainly at the point at which the studies are completed and conclusions are drawn, the registry will take on an increased significance because it will then indicate, at least as to those persons, the numbers, the numbers of persons and the individuals who are potentially eligible for whatever assistance or compensation may be determined.

Do you agree with that.

Mr. NIMMO. I do and I would be pleased to follow your suggestion.

Senator MITCHELL. I wish you would do that because I think it is significant. This is an uncharted area, and it is an area in which science doesn't have an answer and it might well be that a screening now prior to a final decision on the study would indicate something that might not be indicated 2, 3, 4, 5, 10 years down the road when the study is completed. And I think, therefore, we have an obligation, the U.S. Government has an obligation to all of those who are potentially exposed to make them aware of this, to make them aware of the significance of the registry, and to encourage them to participate in the sense that it is very much in their self-interest to do so and it is very much in the interest of our Nation to do so as a means of honoring whatever commitment we have, or the studies that have been discussed here find that we have.

Mr. NIMMO. I agree with you, Senator, and we will follow your suggestions and see what we can do in that regard.

Senator MITCHELL. Did you want to say something more about this?

Dr. SHEPARD. I just wanted to add that we have cooperated extensively with other State initiatives. I am delighted to learn that Maine is also involved. I am a native of Maine. I am pleased to hear that.

Senator MITCHELL. Are you? Where are you from?

Dr. SHEPARD. Boothbay Harbor.

Senator MITCHELL. Are you still a registered voter up there? [Laughter.]

Dr. SHEPARD. I was until I retired from the Navy in 1978.

Chairman SIMPSON. His permanent address is still there though. [Laughter.]

Senator MITCHELL. If you are from Boothbay Harbor, the odds aren't very good on my side anyway. [Laughter.]

That's alright.

I would also like to ask that in addition to looking at this that you provide myself and the chairman and the other members of the committee with a report at some appropriate point, perhaps 60 or 90 days from now, on what your analysis is of it and what you feel you can do to encourage this kind of activity that I believe to be vitally important in terms of meeting our obligation to our Vietnam veterans.

Thank you very much. Thank you, Mr. Chairman.

Chairman SIMPSON. Thank you, Senator Mitchell.

[Subsequently, the Veterans' Administration submitted the following information:]

In response to your request for a report on our monitoring of agent orange-related activities by various States, the following is provided:

During the past 2 years, the Veterans' Administration has maintained a continuing exchange of information and assistance with various States involved in agent orange-related activities. We have particularly been involved with the States of Texas, California, Wisconsin, Minnesota, New Jersey, Ohio, and Pennsylvania where legislation related to agent orange has been introduced or enacted. Representatives of several of these States have been visited by VA Central Office program staff to discuss issues of mutual interest on agent orange. In turn, these representatives have visited VA Central Office for special meetings on this subject, particularly, the quarterly meeting of the VA Advisory Committee on Health-Related Effects of Herbicides, where they provided an update on progress in their respective States and addressed comments of concern to members of that committee.

We are currently kept advised of general agent orange activities by our field staff. In this regard, we are frequently informed by VA Medical Center Station Directors, environmental physicians and other VA staff of developments in these States. Our District Counsel offices also provide reports to our General Counsel of pending or enacted legislation on agent orange. Every effort is made by the VA to advise or assist these States whenever possible.

Many States have produced excellent informational programs to inform their veterans of assistance which can be provided by their State governments or by the Veterans' Administration. We applaud their efforts, in particular their role in making known the examination provided through the auspice of the VA's Agent Orange Registry. The VA's Office of Consumer and Public Affairs is currently reviewing the development of a more aggressive information outreach program which will make not only the significance of the registry known, but other sources of VA assistance as well.

Chairman SIMPSON. We are running significantly behind schedule with a very heavy agenda. I am going to submit the balance of my questions in writing. Senator Cranston has some further questions that he will also submit in writing. I regret having to close off the questioning now, but we must move on with the next witness, which is Dr. Detels.

Thank you so much, Bob, and your staff. We appreciate your being here and we look forward to a very cooperative union between Congress and the VA to resolve this vexing issue. Thank you so much.

Mr. NIMMO. Thank you, Mr. Chairman.

[The Veterans' Administration's response to written questions submitted by Hon. Alan K. Simpson, chairman of the Senate Committee on Veterans' Affairs, follows:]

RESPONSE OF THE VETERANS' ADMINISTRATION TO WRITTEN QUESTIONS SUBMITTED BY
HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS'
AFFAIRS

Question No. 1: I would like to understand fully the timetable that will be involved in reacting to the peer groups' comments on Dr. Spivey's and Dr. Detels' protocol.

Answer: On November 25, 1981, UCLA was granted a time extension of 35 calendar days to submit a study design to the VA. A determination will be made by the VA as to whether the design conforms to the requirements outlined in the contract. Following this submission, the design will again be submitted to the peer groups for critical review to determine whether or not it can serve as an effective and reliable mechanism for the conduct of an epidemiology study. The review will indicate whether the study can be initiated and completed with a reasonable expectation that it will meet the scientific and medical goals originally envisioned to resolve the health care issues surrounding Agent Orange.

Question No. 2: Are there guidelines that the VA has adopted by which to determine whether the protocol is acceptable?

Answer: Yes. The terms of the contract with UCLA outlined specific requirements for the design of a protocol. A review of the protocol submitted by UCLA to the VA on August 6, 1981, indicated that certain vital research elements were not built into the design. These deficiencies were outlined in a November 25, 1981, letter which granted UCLA a 35-calendar-day extension to submit a design which would be adequate for a critical review by the peer groups.

Question No. 3: Would you please give us a detailed definition of a protocol and a request for proposal (RFP)?

Answer: "Protocol" as used by scientists designates a preliminary plan or design for a scientific study. It differs as to the detail specified depending upon the nature, complexity, and magnitude of the undertaking.

An RFP is used in procurement when it is determined that it is impractical to secure bids by formal advertisement. An RFP provides leeway in drafting specifications and permitting offerors to propose methods of approach in accomplishing the tasks outlined in the statement of work.

Question No. 4: At what point did VA realize submission would not be full protocol?

Answer: The UCLA contract provides for the development of a protocol by a two-step process. The first step requires submission of an initial draft study design adequate for critical review by experts. The August 6 submission was to be an initial draft study design. Following a detailed review by peer groups, the VA formally notified the UCLA Contracts and Grants Office on November 25 that the August submission did not meet the terms of the contract and outlined the reasons for this decision. UCLA was given a 35-day period in which to complete and submit such a design. This submission is due by December 31, 1981.

Question No. 5: Will UCLA have to do more than revise the draft protocol in 35 days to receive full payment? If so, what?

Answer: UCLA will not receive full payment until they have submitted a product which complies with the requirements of the contract, that is, a final protocol.

Question No. 6: What weight will be given to recommendations by OTA, the Working Group and others for changes in the protocol or VA's contract with UCLA?

Answer: It is the goal of the VA that the final design of the protocol for the epidemiology study be one which will ensure some reasonable expectation of success. Every consideration will be given to substantive comments or recommendations by the peer groups and others which will assist us in meeting the objectives originally identified for the conduct of this study.

Question No. 7: The document submitted by UCLA does not explain how an exposure index will be established. The Law Center has stated that this effort is not a protocol because the cohort study, a major focus of the design is based on an exposure index and exposure is hard to estimate. This fact has been known since 1979 and discussed repeatedly by the Agent Orange Working Group.

A. Did VA anticipate that UCLA's submission would run into these difficulties because of the exposure problems? If so, why? If not, why not?

B. What did the VA do in the period between 1979-1981 to get its data and DoD data in the form that would enable UCLA to proceed with the protocol in as efficient manner as possible? What role does Col. Young have in these efforts?

C. What are the relevant qualifications of the VA staff members who are involved in these efforts?

Answer:

A. The Veterans Administration anticipated that selection of the epidemiological groups of veterans would be difficult because of the nature of records on the use of Agent Orange and on the location in space and time of American servicemen. During the entire period from early 1979 to the present, Department of Defense records personnel have been expanding our knowledge of the use of the agent and the location of personnel.

Answer to No. 7: Development of an exposure index would be the best outcome of information search but not necessarily the only workable one. An exposure index requires the identification and characterization of groups with three or more levels of exposure, e.g., those with a high likelihood, those with a good likelihood, those with a slight likelihood, and those with no opportunity of exposure. A simple, two-part division of exposed and unexposed individuals could also be used but less satisfactorily. It would divide the Vietnam veteran population into two groups, those with a good likelihood of exposure and those with little or no likelihood. The VA continues to expect that the two-part division will be possible while encouraging the hunt for data allowing establishment of an index of exposure.

B. The VA has had an on-going effort to arrange and examine the data from the Agent Orange Register and the claims files in order to extract such helpful information as they contain. DoD has also arranged the information they have obtained from the files

Answer to No. 7:

(Continued)

as judged by their several presentations of it. Details of their procedures should be obtained from the DoD personnel conducting the records review. Major Alvin L. Young has played no direct role in the extraction and arrangement of the data from the records of the VA or the DoD although he has frequently consulted with both groups.

C. The VA records review is under the direction of a Registered Medical Records Administrator with six years experience in the field. In addition two physicians, each with at least two years experience in Agent Orange matters, have supervisory and consulting responsibilities. Two Ph.D. statisticians have more recently been participating in data interpretation. The entire effort is monitored by a Data Analysis Task Force whose members include data processing expertise as well as the skills mentioned above.

Question No. 8: What level of cooperation and coordination is there between VA and DoD in establishing data for the study? Please be specific.

Answer: There is a high level of cooperation and coordination. The VA and DoD are members of and active participants in the Agent Orange Working Group (AOWG) as well as the Science Panel of the AOWG. The agenda of these meetings have in almost every instance included presentations and discussions relating to military records and data concerning herbicide use and possible exposure of ground troops and others to the herbicides. In addition VA staff personnel have held several meetings with the Army records staff to share information on various aspects of the records relating to the content quality, level of detail and usefulness to the VA's epidemiological study.

Question No. 9: What could be done differently by VA and DoD to improve these efforts?

Answer: I believe that it would be helpful to augment the Army records staff so as to permit the establishment of an adequate full-time Agent Orange records research team. In addition it might be helpful to form a subcommittee of the AOWG Science Panel with particular expertise in epidemiology and data collection and analysis to work closely with the Army records personnel.

Question No. 10: Is there an established communication channel between VA scientists and scientists who do research on a contract basis for the VA?

Answer: As a general rule, the VA does not conduct research by way of contract. The VA, however, has engaged the services of the UCLA School of Public Health to develop a protocol to conduct an epidemiology study relevant to Agent Orange. In this connection the contractor has access to any VA scientists who can assist in fulfilling the contract.

Question No. 11: Do both parties generally share findings? For example, Dr. Spivey's proposed mortality study demonstrates no knowledge of the VA mortality study that was presented recently to the Agent Orange Working Group, originally prepared for the American Public Health Association meeting.

A. Would these two studies overlap?

B. Why wasn't the Working Group made aware of this study at an earlier date?

Answer:

A. It is not necessarily the case that the two mortality studies will overlap. A definite answer to that question will have to wait until VA can review Dr. Spivey's mortality study plan.

B. The original members of the Agent Orange Working Group were aware of the VA's mortality study at the time VA first started planning it. The VA mortality study was mentioned to Dr. Spivey in a telephone conversation prior to August.

Question No. 12: Did the VA inform Dr. Spivey of the problems it had experienced earlier with interpreting the Agent Orange Registry?

Answer: The Veterans Administration discussed with Dr. Spivey the limitations of the data in the Agent Orange Registry and their use for formal epidemiological studies, namely the self-selected population and the limited information included in the coding sheets.

Question No. 13: What steps did the VA take to ensure that UCLA and Dr. Spivey were not biased and did not have opinions on Agent Orange before entering the contract?

Answer: The Request for Proposal stipulated that the investigator should not have a publicized position on the health effects of the dioxin-containing herbicides. The VA was aware of the public reports of statements made by various epidemiologists and know of none by the individuals listed as investigators in the UCLA proposal. The epidemiologists on the selection panel specifically considered the investigators and consultants in each proposal, including that of UCLA, as to any publicized position they may have taken.

Question No. 14: Was Dr. Spivey informed of all available VA Agent Orange information before he started the protocol?

Answer: All information and all sources of information on Agent Orange known to the VA were made known to Dr. Spivey.

Question No. 15: What efforts were made by the VA to assist Dr. Spivey once the contract was awarded?

Answer: Dr. Spivey's requests for assistance were responded to insofar as the VA was able to do so. Care was taken that the VA did not direct, instruct or attempt to influence Dr. Spivey in the development of an epidemiological design.

Question No. 16: Time is a major consideration in making decisions which effect the study process. Do you agree that if the VA and DoD cooperated with an outside entity appointed to direct the study that no time at all would be lost?

Answer: Appointment of an outside entity to direct the VA's epidemiology study would predictably lengthen the time required to complete the study. In all likelihood the examination of veterans will be performed in VA hospitals or with closely associated units. Any outside supervisory body would need time to familiarize itself with the relevant VA facilities, procedures, etc. It is likely that portions of the study should and will be accomplished by contract to an outside group. However, if past experience is any indicator, this often prolongs the process. Oversight of the study by an outside advisory body, on the other hand, would not delay and should benefit the study.

Question No. 17: It has been said by the Veterans' Law Center that the VA's Request for Proposal (RFP) was lacking in specifics which in turn made it harder for Dr. Spivey to structure his protocol in a way which would have been more detailed and more specific. Will you comment on that?

Answer: The UCLA response to the Request for Proposal reflected an understanding of the requirements for a protocol. UCLA and any other potential bidders were afforded an opportunity to request explanation and expansion of the RFP requirements at a bidder's conference prior to preparing their proposals. So far as the VA knows, all requests for such additional information were answered at that conference.

Question No. 18: If Dr. Spivey and Dr. Detels insist on retaining the aspect of secrecy as a major part of their study design, what are the views of the VA with respect to the impact of this decision? I ask this in light of the strong recommendations from the peer review groups, that secrecy is impossible if the protocol is to be adequately reviewed and that a scientific community is used to dealing with issues like this and there are established methods to compensate for any problems which might come up as a result of possible bias of the group being studied.

Answer: The veterans' groups, as well as the scientists, have expressed concern that any epidemiology study be free of bias. We are assured that most epidemiologists believe that advance publication of questions and certain aspects of the protocol prejudices the responses of subjects. This is especially likely when subjects are emotionally involved with the matter under investigation, as veterans are with Agent Orange.

On the other hand, veterans and scientists alike desire a well constructed and reviewed protocol including all its aspects. Peer review groups commonly have access to an entire protocol which is considered a confidential document until it is put to use. The fact that the UCLA submission

Answer to No. 18: has been exposed to public scrutiny, does pose
(Continued) some problems.

The VA agrees with recommendations that there be a peer review of all questions and procedures in the protocol, but we also agree with UCLA and those epidemiologists who want to avoid premature public disclosure of the details. We intend, therefore, to make the entire protocol available to a qualified group of scientists for a thorough review and comment. It is our desire that the peer review be performed on a confidential basis. Once each component of the protocol has served its purpose, it will be made public.

Question No. 19: Please comment on the view, which is expressed by many veterans as well as some others, that the study would be better off in the hands of a government agency other than the VA, such as NIH or CDC, so that there would not be any possibility of an accusation of bias. Can you weigh this fear with the need for the VA to have some control of the study process, especially in light of the fact that the VA would be responsible for providing compensation should any health effects be service-connected to Agent Orange and is currently responsible for providing interim health care to veterans who may have been exposed to Agent Orange?

Answer: The critical review of the protocol by the peer groups is to ensure not only that the design is a reliable structure for the conduct of such a study, but also that any inherent bias which might be present will be recognized and, if possible, eliminated as a result of this review process. The introduction of a third party to direct such a study might, in fact, complicate the research process. The VA, as the largest health care system in the United States, is the logical and perhaps, only system capable of providing adequate facilities and other resources for the conduct of the study if it involved the examination of a large number of veterans.

Answer to No. 19: The issue of possible compensation for effects of exposure to Agent Orange is not a critical factor in this regard. The need to provide resources which assist in achieving research objectives is a critical factor. Such resources should not only be accessible on a nationwide basis to the Vietnam veteran population, but should be research resources which are uniformly administered and monitored by the agency best able to direct, monitor and coordinate both resources and research objectives.

Question No. 20: Can you tell us the qualifications of VA epidemiologists who might be involved in the study if the contract be awarded to the VA versus epidemiologists in other government agencies?

A. In other words, are VA scientists qualified to do the actual study?

B. If there are no in-house scientists who could do the study, how would the VA go about recruiting such persons and would other agencies' resources be tapped?

Answer: That portion of the study which involves the collection of such data as medical and occupational history, physical examination results, and laboratory and other diagnostic studies would not require the skills of epidemiologists. This type of data can be gathered by medical personnel with general and specific expertise. Epidemiologic expertise is needed for the design of the study for analysis of the data, and in part, for drawing conclusions.

A. Design of the epidemiology study is being done under contract with the VA; execution of the study does not require active participation of epidemiologists. A questionnaire to elicit reports of exposure and medical histories generally is administered by clerical personnel and clinicians. Physical examinations are also

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Answer to No. 20: performed by clinical personnel. The VA
(Continued) medical staff is capable of performing these
functions.

B. The VA would look to other Federal agencies through the Agent Orange Working Group should it be necessary to augment the VA's own expertise in conducting, supervising and interpreting the epidemiological study. Should it not prove feasible to obtain adequate assistance in this fashion, it would be necessary to contract for outside augmentation of the VA's facilities.

Question No. 21: Please comment on the proposal recently submitted by the State of Wisconsin, which would develop a series of detailed maps of Vietnam based on HERBS tape and questionnaire data. I would like to know if you have been advised of this effort and if there are other such efforts being made of which you are aware, and if so, if there has been any attempt at coordination.

Answers: The VA is aware of the proposal by the State of Wisconsin to develop a series of detailed maps of Vietnam based on the HERBS tape and questionnaire data. A copy of this proposal has been submitted by the VA to the Science Panel of the Agent Orange Working Group for review and comment. We are also aware that a somewhat related project is underway in California by a local veterans' group, but we do not have the full details of their efforts in this regard. Every attempt is being made to monitor such state activities as they develop. Visits by VA officials with representatives of several states involved in Agent Orange activities, including Wisconsin and California, have occurred on numerous occasions. State representatives, in turn, have visited VA Central Office to meet with program officials on Agent Orange-related matters and have

Answer to No. 21: presented an update on their own Agent Orange
(Continued) activities during quarterly meetings of the
VA's Advisory Committee on Health-Related
Effects of Herbicides.

Question No. 22: What has the VA done regarding locating Vietnam
veterans?

A. Will it be possible to find these
veterans--cohorts--so that a study can take
place?

B. What has been the success of the VA in
locating such veterans--for its other studies?

Answer: The VA has a registry at each VA medical center
which contains the names and addresses of all
those Vietnam veterans who have had a VA "Agent
Orange" examination. We are in the process of
centrally computerizing these names and
addresses.

A. Whether veterans in a given study can be
located depends, in part, on how the study
cohort is defined. It will probably be
possible to use the IRS system to find
addresses for the veterans.

B. We are not aware of any other studies
currently in progress and so have not needed to
locate Vietnam veterans for such.

Question No. 23: Spivey cites using:

- Social Security Records
- The IRS
- State Property Tax and Motor Vehicle Records
- Use of Vets Groups and Vets Associations
Related to Military Units
- VA Veterans Beneficiary Identification and
Records Locator System (BIRLS) Files, for
the Morbidity Studies

Are these systems feasible? Are there any Privacy Act problems?

Answer:

These administrative record systems contain information which may be of use to the epidemiology study. However, we cannot determine the feasibility of using these systems until we see a detailed description of the plans for their use. There could be Privacy Act problems with their use.

Question No. 24: Do you believe that Dr. Spivey has retained total credibility as an unbiased investigator? After all, UCLA's product will reflect on the VA as the contractor. I assume that you are very concerned that Dr. Spivey not be accused of bias--especially if his protocol is ultimately accepted as the basis for the Agent Orange study.

Answer:

The peer review of the protocol is, in part, directed towards insuring that the protocol and the study are as free from bias as possible. Further, the VA believes that Dr. Spivey's statement before the California committee did not reflect bias that would impair his ability to design an impartial epidemiological study.

Question No. 25: Do you agree with Ms. Bernstein that the issue of bias can and should be resolved by oversight of the protocol and study by an independent peer review committee such as was done for the Ranch Hand study?

Answer: It has always been the intention of the Veterans Administration to have a peer review of the protocol and monitoring of the study's progress by qualified scientists.

Question No. 26: Once the protocol is completed, is it generally assumed that the UCLA School of Public Health will also get the contract to complete the study?

Answer: It cannot be assumed that UCLA will get the contract to complete the epidemiological study.

Question No. 27: If the protocol is not broadened to include study of adverse health effects resulting from other herbicides and chemicals in Vietnam, are there plans to contract for another epidemiological protocol to study them?

Answer: To compare the health status of veterans who served in Vietnam with that of veterans who served at the same time, but in other locations seems feasible. It would not determine the role of specific experiences, however. To determine the precise role of individual factors such as Agent Orange, drug abuse, certain combat experiences, or dapsone is considerably more difficult. In each instance we must somehow identify groups of individuals with a high probability of exposure to whatever it is we are studying, as well as those with a low probability of exposure. We are finding in the case of Agent Orange, that exposure is very hard to document. This is an area that both the VA and the Interagency Science Panel needs to look at more carefully. It is unlikely that a successful study of each factor could be conducted under present circumstances.

It has not been decided precisely how the Veterans Administration would incorporate a study of the Vietnam experience as contrasted

Answer to No. 27: to Agent Orange exposure only. It could be
(Continued) done either by expanding the epidemiological
study of dioxin or under a separate protocol.
If the latter course is taken, the VA would not
design the second study intramurally.

- Question No. 28: Is it possible for a study that examines
adverse health effects resulting from general
service in Vietnam to be initiated by the VA?
- A. Could this study be implemented while the
UCLA protocol is being revised?
- B. What are your thoughts on this idea?

Answer: The Veterans Administration could initiate a
study of the health effects of service in
Vietnam by one of several methods. Any study
to be undertaken would require a protocol,
carefully designed and thoroughly reviewed. If
the VA were to solicit a contract with another
group for this design, it would take several
months to award such a contract. Should we
modify the present UCLA contract to include the
expanded protocol, somewhat less time would be
needed, but it would delay the delivery of the
protocol now being prepared. Another option
might be to request the Science Panel of the
Agent Orange Working Group to design a protocol
for a study to examine the health effects of
Vietnam service.

Question No. 29: Will you outline the problems the VA has encountered in retrieving information from the Agent Orange Registry and explain what the VA is doing to solve these problems so that the information can be utilized for the protocol or any other study?

Answer: The Agent Orange Registry was designed primarily to identify and gather certain specific information on any Vietnam veteran concerned about the possible adverse health effects from exposure to Agent Orange. The registry will also be used as a mechanism for contacting these veterans for further follow-up medical care if evidence is established that exposure causes health problems. Several problems have occurred in gathering and retrieving information. Encoding errors and the inability to retrieve specific medical diagnoses on a veteran are among the problems. We are currently working on a registry revision which it is hoped will reduce the encoding errors and will enable us to retrieve a veteran's specific medical diagnosis. The new information gathered from this revision will be entered into the existing Agent Orange Registry.

Question No. 30: Is there a limit on the number of revisions UCLA may do?

Answer: The intent of the VA is to obtain a satisfactory protocol for a meaningful epidemiology study of the health effects of phenoxy herbicides. It is hoped that the next submission will meet most, if not all, of the reviewers' objections and incorporate their suggestions. If necessary, another revision will be made to satisfy the results of the next review.

- Question No. 31: What actions will the VA take if a satisfactory protocol is not produced within the next five months?
- A. Will payment be withheld?
 - B. Will another investigator be found?
 - C. What is the bottom line that would result in an unacceptable protocol?

Answer:

The determination as to whether to withhold payment will be made by our legal and contractual experts within the VA by judging the protocol against the contract terms.

It is impossible to say at this time if another investigator will be found. We would probably only pursue that route if, after reviewing UCLA's submission, we are convinced that the problems encountered by UCLA could be overcome, that the protocol is indeed capable of development by another contractor, and that other capable contractors are willing to perform the contract.

It is possible that a protocol which meets the terms of the contract might be developed which our scientific experts determine to be

Answer to No. 31: technically unacceptable. A protocol which does not meet the contract terms would be clearly unacceptable. A protocol which is contractually acceptable might, nevertheless, be judged to be scientifically unacceptable. This determination can only be made after all the peer reviews are completed.

Question No. 32: Will the cost of the protocol change because of the extensions?

Answer: No. The only increase in costs that would be allowed would be due to the issuance of a change order by the VA requiring additional work not contracted for on the basis of the original RFP and proposal submitted by UCLA.

Question No. 33: Has the VA set a maximum cost figure for the protocol and the study?

Answer: The VA has not set any limitations on the resources which will be required for the design of a protocol, or for the actual conduct of the epidemiology study. Until a final protocol has been submitted to the VA by UCLA, outlining the requirements for the conduct of the study, it is not possible to ascertain the total resources which will be required.

Question No. 34: Several witnesses, including GAO, National Veterans Law Center and the Vietnam Veterans of America suggested expanding the present epidemiological protocol to include the study of adverse health effects, resulting from exposure to other herbicides and environmental agents, of those veterans who served in Vietnam.

Response: To compare the health status of veterans who served in Vietnam with that of veterans who served at the same time, but in other locations seems feasible. It would not determine the role of specific experiences, however. To determine the precise role of individual factors such as Agent Orange, drug abuse, certain combat experiences, or dapsone is considerably more difficult. In each instance we must somehow identify groups of individuals with a high probability of exposure to whatever it is we are studying, as well as those with a low probability of exposure. We are finding in the case of Agent Orange, that exposure is very hard to document. This is an area that both the VA and the Interagency Science Panel needs to look at more carefully. It is unlikely that a successful study of each factor could be conducted under present circumstances.

It has not been decided precisely how the Veterans Administration would incorporate a study of the Vietnam experience as contrasted

Response to
No. 34
(Continued)

to Agent Orange exposure only. It could be done either by expanding the epidemiological study of dioxin or under a separate protocol.

Question No. 35:

Ron Simon, of the Law Center has promoted the idea of undertaking another more general study, while the protocol is being revised, of possible adverse health effects resulting from general service in Vietnam.

Response:

The Veterans Administration could initiate a study of the health effects of service in Vietnam by one of several methods. Any study to be undertaken would require a protocol, carefully designed and thoroughly reviewed. If the VA were to solicit a contract with another group for this design, it would take several months to award such a contract. Should we modify the present UCLA contract to include the expanded protocol, somewhat less time would be needed, but it would delay the delivery of the protocol now being prepared. Another option might be to request the Science Panel of the Agent Orange Working Group to design a protocol for a study to examine the health effects of Vietnam service.

Question No. 36: This process could be made more efficient by improving the general communication between UCLA, the VA, and the Agent Orange Working Group by holding open general meetings periodically.

Response: It is not clear exactly what is meant by "open general meetings." The VA meets with the Agent Orange Working Group and its Science Panel regularly participating as members in both. The Working Group is not primarily involved in research matters, the Science Panel is. To have the UCLA as a member meet regularly with the latter would require reconstituting it as an advisory committee bringing it under the legal requirements for such a committee. The UCLA investigators might meet with the Science Panel as an observer or information source without changing its character and could improve the efficiency of the process at an appropriate time.

Question No. 37: The fear of bias would be removed by establishing an advisory committee to oversee the proceedings of the protocol and the study.

Response: The establishment of an advisory committee to monitor, rather than direct, the conduct of an epidemiology study based upon the protocol being developed by UCLA has some merit. Although we believe that any inherent bias in the protocol would be recognized and, if possible, minimized or eliminated by the peer review process, the creation of such a committee to oversee the VA epidemiology process would provide some additional measure of research objectivity. It should be emphasized however, that the committee would function primarily as an "advisory body" without administrative control over the actual conduct of the epidemiology study.

Question No. 38: It would save time and improve results by revising the contract with Dr. Spivey to direct a UCLA staff epidemiologist to work with DOD as it retrieves necessary documents for the protocol.

Response: We believe it would be unwise to interfere with UCLA's performance of the contract. Directing any specific manner of performance, including the requirement of a UCLA staff epidemiologist to work with DOD, would not necessarily save time or improve results and may be counterproductive.

Question No. 39: Dr. Vernon Houk suggested that the process of finishing the protocol would be greatly helped by another group, such as the Science Panel, defining "exposure". This would save time and money for DOD as it retrieves the records for the various studies and for UCLA as it develops an exposure index.

Response: The VA is aware of Dr. Houk's suggestion that the Science Panel itself establish an exposure index and then provide this to the Army records office for the purpose of identifying military units with high and low probabilities of exposure. It should be examined in greater detail for feasibility. But, as we have indicated, this approach would require whoever conducts the study to examine many more individuals than would be required in a study in which individual exposure levels were known. It may be that we will want to pursue both answers.

Chairman SIMPSON. Dr. Roger Detels, dean of the School of Public Health of the University of California at Los Angeles, is our next witness. We appreciate hearing your remarks, sir. It is nice to see you this morning.

Dr. DETELS. Thank you.

TESTIMONY OF DR. ROGER DETELS, DEAN, SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF CALIFORNIA, LOS ANGELES, CALIF.

Dr. DETELS. Senator Simpson, Senator Specter, Senator Mitchell, thank you for the opportunity to appear before you to discuss the development of the protocol for the study of the possible adverse health effects of exposure to agent orange.

My coinvestigator, Gary Spivey, regrets that he was unable to join you today, but he and I have worked together to develop this testimony for your committee.

The question of possible health effects of exposure to agent orange is an important issue of major concern, not only to the veterans of the Vietnam war, but to all Americans.

We, at UCLA, recognize the responsibility of the public health professionals to assist the Veterans' Administration in attempting to resolve the question of the health effects of exposure to agent orange.

I would like to review with you the history of the protocol, which we have developed, and are continuing to refine. On May 8, 1980, we submitted a proposal in response to a request for proposal from the Veterans' Administration.

In March 1981 we revised that statement at the request of the Veterans' Administration.

On May 1, 1981, we were awarded the contract. Between May 1, 1981, and August 6, 1981, when we submitted the draft protocol, we hired staff, reviewed the previous studies and literature, and developed the protocol.

I would like to emphasize that what was called for was a draft protocol and that is indeed what we have submitted and we expect to refine that draft protocol per the contract with the Veterans' Administration.

I would also like to point out that although we have handed in the protocol on the date of August 6, as required by the contract, we did not receive security clearance for viewing documents crucial to developing an exposure index until October 30; some 3 months after submission of the proposal.

We are proposing in the protocol to study two cohorts. One cohort would have a high probability of having had a high exposure to agent orange. The comparison cohort would have a high probability of having had a low exposure to agent orange.

We would complete a history and physical on members of the two cohorts which was designed to uncover anything suspected from previous work on humans and from animal studies.

We would then compare the health status of the two cohorts; the cohort with the probability of high exposure and the cohort with the probability of low exposure.

There are three major problems facing the development and execution of a protocol for the study of health effects of agent orange.

We have noted these in our draft protocol and they have been noted, rightly, by the three review committees. These are: First, the difficulty of developing an index of exposure; second, the problem of developing a screening technique which will be of sufficient sensitivity to identify unexpected outcomes of exposure to agent orange. The third problem is the problem of bias if respondents know their exposure status and know the expected outcomes of that exposure.

There have been numerous studies which have suggested problems of bias when the respondents both know what is expected of them and what their exposure category is.

So, the question is can we distinguish a true outcome from a false outcome.

Let me discuss the problems of the exposure index. First, we have discovered and, in fact, anticipated that in order to develop an exposure index we would have to review documents about spraying missions, both fixed wing and nonfixed wing, and we would have to review records of troop movements concurrent with the spraying operation.

The records which are kept were handwritten records which were not intended for the type of scrutiny which is necessary for the development of an exposure index. There were thousands of missions, in addition to the fixed wing missions, and there were 2.5 million troops in Vietnam during this period. Neither we, nor for that matter the Veterans' Administration, anticipated the magnitude of the problem of trying to review these records for the development of an exposure index when the RFP was developed and the timetable established.

Even if we had had access to the records, which we did not, 3 months is simply not enough time to do an adequate job of reviewing the exposure records.

The second problem, as I noted, was the development of the screening technique and we are in the process of reviewing the previous scientific reports and the reports to the agent orange registry. We have been pleased for the most part with the cooperation of the Veterans' Administration and the Department of Defense. It takes time to develop a mutual language between the epidemiologists and the administrators.

I know that you would like to have a timetable as we see it. We have estimated that the development of an exposure index, which we think is a crucial question for the implementation of a protocol may take up to 14 months to develop.

Once that exposure index has been developed, we anticipate that it might, unfortunately, take as long as 3 years before that protocol can be implemented and the results analyzed thoroughly.

Finally, I would like to restate that we at UCLA are committed to develop as good a protocol as possible and we will look forward to submitting that protocol within the 35 days from submission of the comments from the Veterans' Administration.

Thank you.

Chairman SIMPSON. Thank you, Doctor. I do regret that Dr. Spivey is not here to join with you in presenting this testimony and responding to questions about the protocol that you have both sub-

mitted to the peer review process. But I appreciate your willingness to be here and field the questions that we do have for UCLA.

[The prepared statement of Dr. Roger Detels, dean, School of Public Health, University of California, follows:]

PREPARED STATEMENT OF DR. ROGER DETELS, DEAN, SCHOOL OF PUBLIC HEALTH, UNIVERSITY
OF CALIFORNIA, LOS ANGELES, CALIF.

Senator Simpson, members of the Committee. Thank you for this opportunity to appear before you to discuss the development of a protocol for a study of the possible adverse health effects of exposure to Agent Orange. My co-investigator, Professor Gary Spivey, regrets that he was unable to join you today. He and I have worked together to develop this testimony for your Committee.

The question of the possible health effects of exposure to Agent Orange is an important issue of major concern not only to the veterans of the Vietnam War but to all Americans. We at UCLA recognize the responsibility of public health professionals to assist the Veterans Administration in attempting to resolve the question of the health effects of exposure to Agent Orange.

I would like to review with you the history of the protocol which we are in the process of developing. On May 8, 1980, we submitted a proposal to design a study on Agent Orange to the Veterans Administration. Ten months later we submitted a revised statement of our resources for such a study at the request of the Veterans Administration. Two months later on May 1, 1981, we were informed that we had been selected to develop the protocol for an Agent Orange study. Between May 1, 1981 and August 6, 1981, we had to hire staff, review the previous studies and experiments in this area, and develop a working protocol. We were not able to examine the documents on spraying missions, troop movements, or much of the Department of Defense literature prior to submission of the protocol because security clearance for any of the investigators was not obtained until three months after the protocol was submitted.

The protocol proposes that two cohorts of Vietnam veterans be identified: one cohort which would have a high probability of having received heavy exposure to Agent Orange, and a second cohort which would have a high probability of having received minimal exposure to Agent Orange. The cohorts would be given a complete health examination. The health of these two groups in the interval between the time of departure from Vietnam and now would then be compared.

In the protocol which we submitted we underscored the three major questions that must be answered before a completed protocol could be implemented. These three questions are:

- (1) Is it possible to develop a reasonable index of exposure to Agent Orange using the data available on spraying missions, troop movements, etc.?
- (2) Can we select appropriate techniques which will identify possible adverse health outcomes due to exposure to Agent Orange?

- (3) Will it be possible to ascertain a true difference in the frequency of adverse health outcomes between the cohort with suspected high exposure and the cohort with suspected low exposure if members of the two cohorts know if they were or were not exposed and if they know, what outcomes are expected in them because of their exposure status. There are numerous studies which demonstrate the biases which affect the findings when the subjects know the purpose of the study and of the study and their classification.

We agree with the findings of the three review groups that these three factors which we also pointed out in the preliminary protocol must be resolved before a final protocol can be completed and evaluated.

Let me review with you briefly the problems in developing an exposure index which may in part explain why we have not yet completed that index. First, we received clearance to review many of the documents regarding troop movements and spraying missions three months after the deadline for submission of the protocol. Second, the records of troop movements and of non-ranchhand spraying are not on computer records but are on handwritten sheets of paper which must be hand-searched and entered into computer language. These reports were never intended for this type of scrutiny and were often prepared by clerks who were not aware of the importance of record-keeping of this type and of the potential demand for these records several decades later. Third, not only are these records difficult to review and interpret, the sheer volume of them will require considerable work. There were probably thousands of smaller spraying operations in addition to the known fixed wing spraying missions, and, approximately two and one-half million soldiers who could have been exposed to Agent Orange. This sheer volume makes the matching of spraying records to records of troop movements a monumental task. This does not mean that this task cannot be performed but that a major effort must be made.

Problems also exist over the development of screening techniques which are adequate to identify possible adverse health effects due to exposure to Agent Orange. We can and have reviewed the animal experiments and what is known from past human exposures. The current scientific knowledge provide little direction. The Veterans Administration is currently reviewing 30,000 of the claims made through the Agent Orange Registry. We need to consider these claims and the current scientific knowledge carefully in developing a broad series of screening procedures and tests which can identify outcomes.

Finally, I would like to review with you the cooperation which we have received from the various federal agencies. We have found the Veterans Administration to be supportive of this study and the Department of Defense to be very responsive to our requests. In the future we will need to count on the cooperation of the General Services Administration as well. We have found that it takes time to develop a mutual language between the various federal agencies and ourselves which conveys to them the special needs of the epidemiologist and for us, in turn, to know what to ask for and how to ask for information which will be of

service to us. The Veterans Administration and the Department of Defense have made an earnest effort to communicate with us, and we anticipate that this communication will improve as we become more familiar with each other.

I know that you would like to receive a timetable for the development and implementation of a protocol and for completion of the study. I regret that we cannot at this point give you a firm timetable for completion of this study because the development of the protocol is dependent upon the quality and completeness of records on spraying operations and troop movements. It is clear that the development of an exposure index is going to be more complicated than either we or the Veterans Administration had originally anticipated. We have estimated fourteen months to develop an exposure index. Of equal importance, the resources originally allocated for the development of a final protocol which includes development of the exposure index are clearly insufficient, given the current condition of the records.

Professor Spivey and I would estimate that it would be possible to deliver a final report on this study within three years after development of an exposure index. However, we would like it to be well understood that it is possible we will be unable to develop an exposure index because the records are simply inadequate in scope and detail.

Finally, I would like to reaffirm the commitment of UCLA to this study. We recognize that Agent Orange is an important public health problem, and that we as a school of public health have an obligation to contribute our expertise to the resolution of this significant health problem.

Chairman SIMPSON. There seems to be an incompleteness and vagueness throughout the protocol that does not appear to allow for adequate peer review by the OTA and by the agent orange working group.

How long do you think it will take to prepare the more detailed protocol again for the record?

Dr. DETELS. Let me take that question, if I may, in parts. I am afraid that we were concerned about the problem of programing responses from potential participants and I think we were overly conservative in the development of the draft protocol.

I think that we will be able to expand the sections on the development of the screening technique looking for possible health outcomes of exposure to agent orange. We will be able to address further the problems of administering a history and physical and more about the nature of the laboratory tests and the examinations which we think should be administered as part of a good protocol.

I think the major area which will be a problem is the development of an exposure index. We can go into further discussion about what we feel must be present in those records and the completeness of the records that will be necessary in order to develop that exposure index.

But I don't think, given the amount of time we have left and the resources left under that contract, that we will be able to develop a final resolution of the question of an exposure index.

If I may just add one thing however? I do feel that it is important that the development of a final exposure index be done collaboratively between epidemiologists and people with expertise in the record. It is the epidemiologists, whether it be people at UCLA

or some other institution, that will need to know the quality of the records in order to be able to judge whether the resultant exposure index is sound.

Chairman SIMPSON. Yes. I am concerned that the issue of secrecy seems to present itself throughout the protocol. Is the protocol written so that no one else will be able to perform the study? Is there any reason for the references to secrecy? I would like your response to that.

Dr. DETELS. I would say that we erred on the side of conservativeness in developing the protocol. I think that we can and should provide more information. I think our major concern, if I may just give you an example, is that we will program the results.

When I first began as an epidemiologist, I did a study of a neurologic disease that unfortunately killed children within 1 year. I asked the parents about a history of neurologic disease in their families. If I asked the mother the neurologic disease was inevitably in the husband's family. If I asked the husband the neurologic disease was inevitably in the wife's family.

This experience has made us somewhat wary of viewing results when we know that the respondents both know their exposure category and the type of response that is expected. Therefore, we are concerned that this not occur.

On the other hand, we are very concerned, too, that this protocol be carried out as publicly and with as much review as possible.

Chairman SIMPSON. You mention in your testimony that current scientific knowledge provides little direction for determining possible adverse health effects due to exposure to agent orange. You then state in the protocol that chloracne is the only established health outcome associated with dioxin exposure.

Is it not true that some special concerns can already be identified? We have the animal studies indicating some dioxin carcinogenic potential. We have several studies that link the development of soft tissue sarcomas to exposure to herbicides. After the industrial incident in Italy there were reports of liver effects and delays in nerve impulses, and there have been numerous concerns expressed by Vietnam veterans that exposure to agent orange, will result in birth defects in their offspring.

It would seem that some of these significant effects would be targeted for special attention in the section of the protocol which provides for a physical examination. Why does the protocol fail to address or mention these issues? Do you feel that they are not relevant? What was the reasoning that went into that decision, please?

Dr. DETELS. I think the statement originally was made on the basis of the information which we really have that is extremely firm. We are aware of the studies that have been done on animal experimentation. There are problems with extrapolation of results in animals to humans.

Nonetheless, we feel strongly that the effects that have been reported in animals should also be looked for in this protocol, and we will include in the effects to be looked at all those that have been noted from animal experiments and from the previous literature.

We are aware of them and I am sorry that that statement was misleading.

Chairman SIMPSON. I noticed that special examinations for individuals with recognized diseases unrelated to agent orange are included in the protocol, while a neurological examination, which both the animal and the human data suggest to be of some importance, is not.

What physical outcomes do you expect to find with the use of the general examination that you describe in the protocol? It would seem to me that the protocol for the veterans' physical exam is one of the most important aspects of the study. And yet it is stated in the protocol that the physical examination is included only because the veteran expects it.

Could you share your comments on that, please?

Dr. DETELS. OK. I think that it's important that the examination which we propose in this protocol cover two points. One is that we have some suspicion of what might possibly be outcomes based on previous work and on animal experiments.

Therefore, things such as the neurologic examination, which we certainly feel should be included as part of this protocol, and tests for, among other things, liver function, the status of the kidneys, the status of the cardiovascular system, should all be included.

The other aspect of this is that there may be things that occur as a result of exposure to agent orange which we do not know about from the previous studies and previous experimentation in animals. We must, as well, look for those. And I believe that is our objective of doing as thorough as possible a standardized physical examination and history to find possibly unexpected outcomes.

Chairman SIMPSON. You heard the question earlier this morning about the expansion of the study. That interests me as a possibility. Do you recommend any type of expansion of the development of the exposure index to include all those veterans who served in Vietnam, rather than just those exposed to agent orange? If it is expanded, perhaps we then can deal with those who have been exposed to agent blue or agent white, if down the road there is no satisfaction with the findings of this study. If the study is expanded, would the protocol be completed more quickly and at less cost?

Dr. DETELS. Let me answer the last question first if I may. If the study is expanded to include other defoliants, then I think that the complexity of the study is considerably increased. It may be possible to do it, but I think it will be a more difficult study since one will also have to develop exposure indexes for the other defoliants as well. And that will increase the magnitude of the problem and make it a more difficult study to do.

So, it will not, as I see it, make the outcome of the study any quicker.

Chairman SIMPSON. Well, I have more questions, but my time has expired.

Senator Specter.

Senator SPECTER. Thank you very much, Mr. Chairman.

You have estimated that it will take 14 months to develop an exposure index. When does that time period begin to run?

Dr. DETELS. That time period would begin at the time that a group was selected to develop a specific exposure index and was guaranteed access to all the records that it needed in order to develop that exposure index.

Senator SPECTER. Well, you talk about 14 months for an exposure index and then 3 years beyond that. That's a total of 4 years and 2 months, and when do we get to the beginning of the exposure index? What is the time parameter to accomplish whatever prerequisites are necessary for the first 14 months to begin to toll?

Dr. DETELS. I think the question of when that would begin is one that would be better directed to the Veterans' Administration. I think our—

Senator SPECTER. Well, have you directed that question to them?

Dr. DETELS. We have suggested to them that we think it would take approximately 14 months from the time of the initiation of a contract to that effect and clearance for review of documents.

Senator SPECTER. Well, you are saying that all you need is a contract and clearance in order for that 14 months to for completion of the exposure index?

Dr. DETELS. That was our estimate. I would like to stress, however—

Senator SPECTER. There's nothing that they have to do in advance, because I notice a comment that you make in your prepared text that you received clearance to review many of the documents regarding troop movements and spraying missions 3 months after the deadline for submission of the protocol.

Dr. DETELS. That's correct.

Senator SPECTER. What import does that have on the issue of potential delay?

Dr. DETELS. It has, in terms of developing a final protocol that will be immediately implementable. It is very crucial. We can't judge the quality of the records about troop movements, about the spraying activities, unless we have access to those records and can see the form in which they are, the completeness in which they are done and things of that nature.

Senator SPECTER. And you say in the next to the final paragraph in your prepared text that you would like it well understood that if it's possible that we would be unable to develop an exposure index because the records are simply inadequate in scope and detail. So, that in beginning this 4-year, 2-month process, you have substantial reservations that you can even accomplish it unless there are adequate records that you don't really know about.

Dr. DETELS. I feel strongly, as do Dr. Spivey and our coinvestigators, that we must be up front with the possibility that these records, which were never intended for this kind of scrutiny, simply may not be adequate to develop an exposure index so that we can establish cohorts with a high probability of high exposure and cohorts with a high probability of low exposure.

Senator SPECTER. Well, then the concern that I had while listening to your testimony and reading your text is that we may well find—you are giving us good warning we may well find a dead end a couple of years down the road.

Dr. DETELS. That is possible.

Senator SPECTER. How likely?

Dr. DETELS. I would prefer to reserve judgment on that. I think more and more information is coming to light. Information came to light within a week after we had submitted the protocol which suggested that there were accidents which occurred, which exposed

considerable numbers of people to agent orange. We didn't know that at the time.

Senator SPECTER. Well, you want to reserve judgment. When will you be in a position to give us a judgment on that?

Dr. DETELS. I would hope, certainly I would hope by the end of that 14 months if, in fact, we were the ones that were selected to develop that exposure index. I would hope—

Senator SPECTER. Well, now, wait a minute. I would expect you to know if you can have an exposure index by the time that the exposure index is supposed to be prepared, which is what you are saying. But that's hardly adequate. If we are going to make an investment of 14 months and a substantial amount of money, I, for one, would like to know what the chances are that it's going to be successful, because you have got a lot of red flags in the middle of our—in the middle of your approach here. And I appreciate that, but I think we ought to know what the chances are you are going to get somewhere.

Dr. DETELS. I would like to be able to give you an answer to that. If I gave you a probability statement, it would not be a well-founded probability statement. I would hope that several months after we had access to these records that we would begin to get a distinct feeling as to whether it's going to be possible to develop this kind of an index. But I regret that I can't give you a more firm statement since I haven't reviewed the records.

Senator SPECTER. Well, can you—what you are saying is it's impossible for you to review the records in any short order, but it's necessary to have a very extensive review of the records which in itself may take 14 months before you know whether the index will be valid at all.

Dr. DETELS. I regret that that is what we are saying. I would much prefer to be able to do it much quicker, but I have to be honest with you.

Senator SPECTER. And how much is it going to cost to develop this exposure index?

Dr. DETELS. I'm sorry, I don't have the figures at hand. I am sure that the Veterans' Administration can give you that.

Senator SPECTER. You don't have the figures at hand?

Dr. DETELS. I don't have them at hand; I'm sorry.

Senator SPECTER. Can you give me an estimate?

Dr. DETELS. I'm sorry, I just don't have those.

Senator SPECTER. Why is it, Dean Detels, that you don't know the cost?

Dr. DETELS. I'm sorry, I didn't review the cost for that.

Senator SPECTER. Do you know—

Dr. DETELS. I'll be glad to get it for you.

Senator SPECTER. Fine. Do you know what the final 3-year study is going to cost?

Dr. DETELS. I'm sorry, I don't have those figures at my fingertip. I will get it to you.

[At the time of printing, the requested information had not yet been submitted.]

Senator SPECTER. After you complete the study, what will we then know as you now project the study?

Dr. DETELS. I would hope that if we are able to develop the exposure index and an acceptable protocol that we would be able to tell you with some degree of probability what the likelihood is that there were adverse health outcomes as a result of exposure to agent orange.

Senator SPECTER. Adverse health outcomes?

Dr. DETELS. Yes, adverse health outcomes.

Senator SPECTER. What do you include within a health outcome category?

Dr. DETELS. I would include things like neurologic disease, cancers, some diseases—disorders of some of the systems which may have been incriminated from experimental studies, including liver, perhaps heart disease.

Senator SPECTER. Would that include all the ranges of cancer? Would there be some facets of cancer not included within your protocol?

Dr. DETELS. This is a question of sample size. It depends on the incidence of the cancer that you are talking about. If you are taking a very rare cancer and seeing a two- or three-fold increase, we may not have large enough numbers to be able to detect that specific cancer.

Senator SPECTER. Well, what larger number of numbers would you need to answer that question?

Dr. DETELS. It depends on the specific outcome that you are looking for.

Senator SPECTER. And how about the issue of birth defects? Would your study comprehend that answer?

Dr. DETELS. Well, as you know, the CDC is doing a study of birth defects. We would, of course, include this as part of our study, looking at individuals in the low exposure and high exposure cohorts. We would look at the outcomes of their children.

Senator SPECTER. So, birth defects would then be included in your study?

Dr. DETELS. Yes, it would, yes.

Senator SPECTER. Is there any range of health hazards which would be excluded from your study?

Dr. DETELS. I think that it is possible that there may be some health outcomes with a long latent period, on a slow development, which we would not see within the period covered since the time that the exposure incidence occurred.

In other words, we are talking about a period of 1965 to say 1985; that would be 20 years. There are some diseases that may have a latency of greater than 20 years. We would not, in all likelihood, be able to provide the information about those.

Senator SPECTER. Is it necessary to have the CDC study on birth defects if your study is going to encompass that?

Dr. DETELS. I would think that indeed it was.

Senator SPECTER. Why?

Dr. DETELS. They are taking a somewhat different approach than we are. We are using different methodologies. If they find a relationship and we find a relationship, then that would be very strong, consistent evidence that there is a relationship.

If they find a relationship and we don't, or vice versa, then the question arises of methodology, a chance finding, and other prob-

lems. So, I think it is very important that we both look for it. It is not a significant increased cost in our study.

Senator SPECTER. When you conclude your study, what kinds of statistics will you have available to basic conclusion on cause and effect?

Dr. DETELS. Because of the nature of the study, it is a historical cohort study, we should be able to tell you what the incidence of specific diseases or adverse health outcomes are in the group with the high probability of high exposure and the group with the high probability of low exposure and to provide you with an estimate of what we call relative risk. That is to say, how many more times disease occurred in the high exposure cohort than in the low exposure cohort.

Senator SPECTER. Can you give me a specific example as to how that would play out statistically say on birth defects? The question that would be posed to you is does exposure to agent orange cause birth defects. How would you respond to that hypothetically at the conclusion of your study?

Dr. DETELS. We would expect to be able to say that the risk of birth defects in offspring of veterans in a high exposure category would be three or four or five or whatever times as frequent as the risk in the low exposure cohort.

We may, of course, find the reverse. That it is half as frequent. But that would be the kind of statement we would be able to tell you.

We will tell you the ratio in the high exposure category to the frequency in the lower exposure category.

Senator SPECTER. If I may ask just one more question, Mr. Chairman. Would you have then any guidance for the Veterans' Administration or the Congress as to what should be the conclusion as to cause and effect for compensation?

Dr. DETELS. We can tell you the statistical probability that the higher frequency, if that is found, in the high exposure group occurred, is due to exposure to agent orange.

Senator SPECTER. Thank you very much, Mr. Chairman.

Chairman SIMPSON. Let me ask for the record if you would please define the term "historical cohort study"?

Dr. DETELS. Yes. A cohort study is when you take two cohorts of people which you define on the basis of their exposure, and then you follow them for the occurrence of disease or adverse health outcomes. That's a straight cohort study.

The historical cohort study is when you have the opportunity to be able to establish a cohort which actually occurred some years prior to the time that you are doing the study. And example of this would be the studies of leukemia in the survivors of Hiroshima and Nagasaki. Those studies were not initiated until 10 or 20 years after the time of the atomic bomb explosions in those two cities. But those cohorts are reconstituted by identifying survivors and the incidence of leukemia determined in those groups. That is an historical cohort.

Chairman SIMPSON. Thank you. That will be all, unless there are further questions by any members of the panel.

[The responses of the University of California to written questions submitted by Hon. Alan K. Simpson, chairman of the Senate

Committee on Veterans' Affairs and Hon. Alan Cranston, ranking minority member of the Senate Committee on Veterans' Affairs, follow:]

RESPONSE OF THE UNIVERSITY OF CALIFORNIA TO WRITTEN QUESTIONS SUBMITTED BY HON.

ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1. Isn't it true that you were already given a one month extension to complete this version of the protocol. How long do you estimate it will take to prepare a revised and completed protocol?

Response: It is correct that we received a one-month extension to complete this initial draft of the protocol. The original RFP had an expected start-up date which was almost one year prior to the time when the contract was actually awarded. This sudden contract award after one year delay meant that we had to hire staff and reorder our concurrent commitments in order to meet this demand. Two major issues were not clarified prior to initiation of the contract--access to records requiring security clearance and whether the detailed protocol would be subject to the Freedom of Information Act. Three months is a very brief time to develop a complex protocol which will be reviewed by scientific experts and the Senate Committee on Veterans' Affairs. Very few, if any scientifically sound protocols for studies as complex as this are completed within this short a time. We agree with the statement of Dr. Vernon Houk, the Chairman of the Agent Orange Working Group that it would have been impossible for any group to have come up with a detailed protocol given the time constraints of the original RFP.

Because of the thoughtful input of the review committees and our opportunity to discuss the protocol amongst ourselves we believe that it will be possible to prepare a more detailed protocol which incorporates the appropriate suggestions of the review committees by early 1982. As I indicated in my testimony, this will include a list of the minimum information on the use of Agent Orange and of troop movements which we feel will be necessary in order to develop an exposure likelihood index. It will not, however, identify cohorts of soldiers with a maximum or a minimum likelihood of exposure to Agent Orange. We will be able to provide a suggested screening procedure to identify those health outcomes which are predicted from animal experiments, accidents involving dioxin and occupational studies. It will not include a detailed questionnaire for several reasons: selection of a final questionnaire will be dependent upon a pilot testing (which is not called for in the contract); inclusion of a questionnaire in a public document would decrease the probability of getting unbiased answers to specific questions (the Ranch-hand questionnaire is still strictly confidential); and the characteristics of the cohorts to which the questionnaire will be administered are not known. This will have some bearing on the details of the questionnaire to be developed.

We are optimistic that a protocol of sufficient detail to permit scientific review can be completed by early 1982. Details of the final questionnaire, and a manual of procedures, however, are most properly developed during pilot testing which would be the appropriate next step.

Question 2. Unless some people are supplied with all the details of the protocol, how can an effective analysis of it be made? Wouldn't it be possible for a small number of people on the OTA and Agent Orange Working Group science panels to be supplied with the details? Don't you agree that 'an informed' evaluation is necessary at this time?

Response: We agree that a more specific protocol should be provided. I think that it will be possible for us to provide that protocol, given the constraints outlined in the response to Question #1, which can be reviewed by all members of the several science panels. We do agree that an informed evaluation is appropriate and necessary before a protocol is accepted for implementation. The question of public access to the questionnaire and the membership in the two exposure groups, however, does need to be resolved. We would be agreeable to permitting access to additional details by small numbers of people on the review panels.

Question 3. Are you aware that peer reviews go on all the time and that there are scientific methods which are used by researchers to compensate for any potential bias? Why are you and Dr. Spivey reluctant to go along with such established procedures?

Response: First, let me state strongly that Dr. Spivey and I are well acquainted with peer review, having served on numerous peer review panels and having ourselves submitted a considerable number of grants which have gone through the peer review procedures. We are strong proponents of the need for peer review. I am concerned about the way in which this question is asked since it implies that Dr. Spivey and I do not believe in peer review. That is absolutely incorrect. However, research proposals submitted for peer review rarely include detailed questionnaires and manuals of procedures, nor are they as subjected to public scrutiny including scrutiny by potential respondents.

We are aware that there are techniques for trying to evaluate the presence of bias in questionnaire responses. Unfortunately, these procedures seldom provide any formula for estimating the percentage of responses to an individual question which are the result of bias. To our knowledge there is no universally accepted scientific procedure for "compensating" for bias. The standard epidemiologic approach is to minimize bias by designing "double blind" procedures for data collection. It is far preferable to take all possible steps to reduce the potential for bias rather than be confronted with a result you suspect is a result of bias, but for which you cannot measure the degree of bias present.

Question 4. On page 2 of your testimony, you mention that you agree with the findings of the three review groups in their assessment of the protocol. Which three groups are you referring to? The National Academy of Sciences has not yet submitted its review of the protocol.'

Response: We have reviewed the comments of 1) the Expert Committee of the Office of Technology Assessment, 2) the Veterans Administration Advisory Committee on the Health-Related Effects of Herbicides and 3) the Science Panel of the Agent Orange Working Group. It is my understanding that the National Academy of Sciences will not review the draft protocol submitted in August.

Question 5a. It is important that the protocol receives adequate peer review and be approved by this process; therefore, it is necessary that a complete protocol be presented. The publicity which already surrounds the study has already influenced those individuals who will eventually be included. Won't withholding pertinent details cause more harm, by damaging public confidence in the credibility and independence of the study, and thus introducing a negative bias? Is it possible to design a protocol in which bias, due to a lack of secrecy about the expected outcome, is taken into account? Other studies of environmental agent effect that have been completed have potential bias factors as well, that were taken into account. Can you comment on this?

Response: Please see our response to question #2 in reference to the issue of managing bias in epidemiologic studies.

I do not understand the term "negative bias". I agree that a very real problem with the implementation of a scientifically sound protocol will be the risk of alienating veterans so that they will not participate in a proposed study. I would not call this "negative bias". But I would recognize it as a major source of concern about the implementation of a final protocol.

Question 5b. You state that resources originally allocated for the development of a final protocol are clearly insufficient. For the record, would you please estimate how much more money is necessary? Have you received all of the original grant money? If UCLA protocol is not accepted, would the Veterans Administration expect a refund of the money?

Response: We estimate that we will be able to provide a more detailed protocol for submission to the Veterans Administration and the review panels by early January 1982 without requesting additional money. We have, in fact, not received all of the original contract money under a fixed price agreement. I cannot comment at this time what the expectation of the Veterans Administration will be concerning the outcome if they do not accept the protocol submitted by UCLA. I do not anticipate that this will be a problem given good will between the Veterans Administration and UCLA and our common commitment to the development of the best possible protocol. Neither the Veterans Administration nor we at UCLA anticipated all the problems which would need to be overcome in the development of a protocol. Thus, the Veterans Administration has itself not met all the conditions of the contract as signed by both parties. For example there have been unexpected problems in providing us with all the data requested. I sincerely hope that the contract terms will not become an issue. I am concerned that these detailed hearings and the manner in which some questions are addressed to the Veterans Administration as well as to us seem to be designed to place us in an adversary position rather than in a partnership role. This is not the case. We have worked closely with members of the scientific staff of the Veterans Administration in all phases of the development of the protocol and have benefited from their advice on a number of aspects of the development of the protocol.

We have estimated that it would take an additional fourteen months and \$774,434 dollars to develop an exposure likelihood index and to thoroughly evaluate the quality of the records on veterans in sufficient detail to be able to predict the likely success of an historical cohort study. From our discussions with Mr. Christian and others it is clear that the records of spraying operations and troop movements are not so well organized as we and the VA had assumed. I would hope that we would be able to provide the committee with a negative answer (if that is the result of further investigation) on the likelihood of being able to develop an exposure likelihood index earlier than fourteen months. Nonetheless, given the seriousness of the question regarding health effects of exposure to Agent Orange, we feel it important to make the most careful analysis of the quality of the exposure data and of troop movement records possible before concluding that a study is or is not feasible.

Question 6. You state first in your testimony that current scientific knowledge provides little direction with regard to proposed health outcomes. Then you state one sentence later that you will take current scientific knowledge as well as information from the Agent Orange Registry into account in developing health outcomes. Could you comment on this contradiction?

Response: I regret that we were not more explicit in the statement regarding the relationship of current scientific knowledge to health outcomes. The scientific community has not yet pinpointed with certainty any health outcome to humans other than chloracne. This is what we meant to imply by that statement. On the other hand, the animal experiments, occupational studies and accidents involving dioxin have suggested a number of possible health outcomes. It is important that we seek information on these suspected health outcomes in our protocol and will do so in considerably more detail in the draft protocol to be submitted in January 1982.

Question 7. Are you familiar with the problems that the Veterans Administration has had in the past interpreting the information from the Agent Orange Registry?

Response: We are familiar with a number of the problems that the Veterans Administration has had in the past interpreting information from the Agent Orange Registry. Our objective is to obtain a list of possible outcomes which may have resulted from exposure to Agent Orange. This is different from trying to establish a relationship between Agent Orange and specific outcomes from the Agent Orange Registry alone. Therefore, we feel that some guidance can be given to us in developing the protocol from the information derived from the Agent Orange Registry.

Question 8. Why was the "historical cohort study" limited to draftees and one-time enlisted men? Wouldn't excluding individuals with longer service exclude some individuals with great potential exposures?

Response: Yes, we undoubtedly will exclude some individuals with the highest exposure. The concern is to develop a scientifically valid study. To do this requires the definition of two cohorts which ideally are identical in every respect except for their exposure to Agent Orange. To the degree these groups differ in other ways, the results of the study will reflect those differences rather than Agent Orange. Career military personnel and those who volunteered for multiple tours of duty differ in many ways from the draftees and one-term enlisted men. A second problem is the need to establish an exposure likelihood index which will allow us to place individuals into either a high exposure or low exposure group. While we propose to use company movements to estimate exposures to Agent Orange, it will be necessary to assign that company's exposure to individuals within the company for the time that they were with the company. We cannot use companies per se since the individual soldiers in the company changes constantly. This need to assign exposure probabilities to individual men is a complicated procedure and will become much more difficult if individuals who have repeated enlistments are

included. It would, perhaps, be possible to attempt to identify re-enlistees and career personnel as separate cohorts. The problem of developing an exposure likelihood index on these individuals would be much greater than for the one-term enlisted men and draftees and, thus, it would increase considerably the cost of carrying out the study. In addition, the chances of finding a comparable unexposed group are remote, thus, making the usefulness of such a cohort for a valid study very low. Limiting the study to draftees and one-term enlisted men, therefore, provides the best opportunity, at the lowest cost, of determining the health effects from Agent Orange.

Question 9. What are the symptoms of chloracne? What is the difference between chloracne and common acne? Is chloracne a good indicator of exposure to Agent Orange? It is my understanding that chloracne can be a severe skin condition that persists for many years, even after exposure is discontinued.

Response: Chloracne presents as a severe acne which sometimes has a characteristic distribution in humans and which may persist. Properly biopsied active lesions can be distinguished from other acne by an experienced dermatologist. Milder cases may go undetected and the majority of cases last less than one year. However, in severe cases chloracne has been reported for as long as 29 years. The majority of the literature suggests that the risk of other adverse outcomes of exposure to dioxin is much greater in individuals who have chloracne than among exposed individuals who do not develop chloracne. Nonetheless, there has been at least one report of complaints in the absence of chloracne. This point was the subject of considerable debate at the recent International Symposium on Chlorinated Dioxins and Related Compounds and is not firmly established in the scientific community. This observation is further complicated by the fact that there may be a latency period between exposure and the development of symptoms ascribed to dioxin exposure. Dr. Spivey has discussed the use of chloracne as an indicator in Vietnam veterans with Dr. Kenneth D. Crow (the leading world authority on this condition). Dr. Crow feels that chloracne is not likely to be of use in any proposed study of Vietnam veterans because it will have disappeared by now in most veterans and cannot be accurately diagnosed in retrospect even if severe scarring resulted. This point will need to be explored further.

Question 10. All reviewers continue to state that this document is only a preliminary outline for an epidemiology protocol, mainly because Dr. Spivey was unable to assess the data resources on which such a study depends. Yet you state that the Department of Defense has been responsive to your request. How is that possible?

Response: The major problem was the need to obtain security clearance. As part of the contract it was agreed that the Veterans Administration would provide all necessary documents for the development of a protocol. It became apparent very shortly after the contract was initiated that the Veterans Administration could not provide all the information which would be necessary in part because of the bulk of 40,000 linear feet of paper records which

are in the possession of GSA and we did not have clearance to review the records directly. The mechanics of reviewing these records involves a tedious search of approximately 15-20 file cabinets of indexes to the records (in the Army Records Center), searching for evidence of records which might be of use to the study. These records found to be of interest must be requested from the GSA warehouse--a procedure which takes a minimum of two weeks. The records must then be gone through by hand. Obviously such a procedure takes a great deal of time and many people to accomplish. This problem was not anticipated by the VA or by us. From a review of a few unclassified documents it appears that the records are quite difficult and tedious to read.

Since we did not have security clearance, it has not been possible to fully evaluate the extent of further difficulties we might encounter. As soon as the need for security clearances became apparent, we initiated procedures to obtain security clearance. Dr. Spivey and I do not feel that there was any unnecessary delay in processing our request for security clearance. It simply takes time to complete all the security checks necessary before clearance can be given. Because the period for the development of the protocol was only three months, it was impossible to complete processing of those security clearance applications early enough to permit access to any of the sensitive records before the protocol needed to be completed. In retrospect, the Veterans Administration probably should have anticipated the need for us to obtain security clearance and we should have demanded that the contract not be initiated until security clearance had been obtained for the investigators and their key staff. Within the constraints of providing us with non-sensitive materials, the Department of Defense has been responsive to our requests. Dr. Spivey has met on several occasions with Mr. Christian and other individuals from the Department of Defense, and has been provided a great deal of information from their prior and ongoing record reviews. Nonetheless, we have not yet had full access to the records necessary to develop an adequate exposure likelihood index, and cannot do so under the current contract.

Question 11. Richard Christian of the Army describes numerous ongoing projects of the AD Task Force, and the fact that there are only three full-time staff people, and that there are 40,000 linear feet of records still waiting to be indexed. Can you comment on this please?

Response: Professor Spivey and I have been impressed with the dedication of Mr. Christian and his staff to this monumental problem of processing 40,000 linear feet of records (see response to question #10). Obviously, this is an insufficient staff to complete the assignment made to Mr. Christian. We agree with Mr. Christian and with the Committee that more resources should be assigned to Mr. Christian for this task. We also believe that it is important that an epidemiologist be included among those individuals working with Mr. Christian. The most appropriate individual to work with Mr. Christian would, of course, be someone who is intimately involved in the development of the protocol or someone who will be assigned to the task of implementing a protocol. The investigative staff of a study is the most qualified group to

assess the appropriateness of records to implement that protocol and would be the most likely to recognize the opportunities for modification of the protocol based on unexpected information which might be contained in those records.

Question 12. You also state that the Veterans Administration has been very supportive of your efforts with the protocol, yet you did not have security clearance to examine any records until this month, and you were not briefed on all the scientific information already available about Agent Orange. For example, were you aware of the Veterans Administration mortality study that was prepared for the American Public Health Association before you designed your own version? Is that a supportive role, and/or an honest effort to communicate on the part of the Veterans Administration?

Response: As I indicated above in the response to Question #10, we feel that the Veterans Administration has, for the most part, been supportive of our efforts. The problem of security clearance had to do with the amount of time allotted for the development of a protocol and the amount of time required for all the checks necessary to confer security clearance for the investigative staff.

We were indeed aware of the proposed Veterans Administration mortality study. As was indicated by Dr. Houk in his testimony, the study design for our proposed mortality study and that of the Veterans Administration are different and were proposed to meet different objectives.

I am disturbed by the last sentence of the question. I would like to see all parties in this endeavor attempt to promote good communication amongst the various groups addressing this very important problem. To date, it is our feeling that the Veterans Administration has attempted to work with us. We are aware that the Veterans Administration is under considerable pressure. We are concerned that our communications with the Veterans Administration must be made with both the legal staff and the scientific staff. Our communications should be made primarily with the scientific staff, in my opinion.

Question 13. Have you ever seen any classified photographs of defoliated areas in Vietnam that the OTA refers to in its review of the protocol? Would this type of record be helpful to you? Are there any plans to improve your access to DOD records?

Response: Dr. Spivey and members of the investigative staff have not yet seen the classified photographs of defoliated areas in Vietnam although we have requested such photographs. Dr. Spivey has had an ongoing negotiation with the DOD to review the extent of the photographic record and its potential usefulness. This procedure has also been seriously delayed by the lack of security clearance. These photographs might be extremely useful in validating the information obtained from the records of spraying maintained by both the Army and the Air Force. Unfortunately, current information suggests that the

most useful photos were destroyed in routine file maintenance programs. Since we have only 35 days in which to develop a more detailed protocol, we will be unable to review in any more depth the photographic files or other Department of Defense records. However, we feel strongly that in the development of an exposure likelihood index it will be essential to have complete access to the Department of Defense records. We would anticipate that whoever is assigned the task of developing this exposure likelihood index will have to work closely with all DOD individuals who are most familiar with the records.

Question 14. Would such records be more helpful in evaluating where and how much Agent Orange was sprayed, rather than only the HERBS tapes?

Response: It is difficult to answer this question without further information. It certainly might be possible to distinguish other areas of defoliation such as along roadsides and base camp perimeters. Unfortunately, it is difficult by photograph to distinguish between the effects of different herbicides so that photographic evidence of defoliation alone does not tell us whether it was the result of Agent Orange or another herbicide. This question must be pursued, however, as part of exposure likelihood index development.

Question 15. Will you respond to the Veterans Law Center's concern that the lack of specifics in the Veterans Administration's RFP made your job more difficult?

Response: We agree with the comments of Dr. Vernon Houk, the Chairman of the Agent Orange Working Committee review panel and of others that the major problem with the RFP was the unrealistic time frame for the development of a detailed protocol. I do not know to what extent this can be blamed on the Veterans Administration. It is clearly easier to criticize the game on Monday than to predict it on Friday.

Question 16. As you revised the protocol, do you have suggestions and ways that the Veterans Administration and the DOD could be more helpful?

Response: I do not have suggestions at this time beyond those which I have made above. We have talked with Mr. Christian of the Department of Defense and Dr. Houk about the importance of including an epidemiologist on the team reviewing the records of spraying operations and troop movements. We will incorporate additional suggestions as we proceed with the further development of the protocol in the next month. This will include a listing of the essential ingredients for the development of an exposure likelihood index.

Question 17. Do you think it would be helpful if the Veterans Administration rewrote the RFP and/or the contract?

Response: From a legal point of view I understand that it is not possible to rewrite the RFP but that the contract "Statement of Work" could be amended so that it would be more commensurate with the information we now have about the difficulties which are inherent in developing a detailed protocol for the

study of the health effects of Agent Orange as used in Vietnam. It would probably, however, delay the process of obtaining the protocol and of ultimately implementing the study if approved. I believe that if the Veterans Administration, the Senate Committee of Veterans Affairs and the review committees continue to operate in a spirit of cooperation, this should not be necessary.

Question 18. If UCLA's protocol is not changed to meet the concerns expressed by the peer review groups, do you believe that the Veterans Administration would consider the protocol contract to be broken and give the task of developing a protocol to another group?

Response: Since we intend to submit a revised protocol which meets the major concerns expressed by the peer review groups, we do not anticipate that this problem will occur. Again, I would not presume to predict what actions the Veterans Administration will take, nor do I feel it appropriate to speculate on this issue.

Question 19. Do you agree with Ms. Bernstein who states on page 4 of VVA's testimony that there should be a decision criteria built into the study design so that at each step a decision could be made whether to continue, alter or abort the study?

Response: As the OTA review committee noted the major problem with implementing a study of the health effects resulting from the use of Agent Orange in Vietnam is the quality of the records established some fifteen years ago and on the willingness of veterans to participate in the study. For these reasons we agree that it is important to establish decision criteria for continuation, alteration or abortion of the study.

Question 20. Do you believe after discussions with Army records experts and others that there is adequate information available to develop individual exposure estimates?

Response: I am reluctant to answer this question until we have had more opportunity to review the records on spraying operations and troop movements. The presentations by Mr. Christian and others at the hearings and the conversations which we have had with individuals from the Department of Defense suggest that it will be possible to develop an exposure likelihood index but that it will be an extremely complicated and time consuming task.

Question 21. Can an adequate exposure index be developed based on comparisons of company, rather than individual, locations and the HERBS tapes?

Response: I have addressed this question above under Question #8. As I indicated, we feel it will be necessary to develop exposure likelihood indices by assigning an individual an exposure which reflects the company with which he was attached at a specific time. However, it will be necessary to derive

the exposure index for the individual from a composite of the companies in which he served and the times that he was with those companies. Because there is considerable turnover in company personnel, we do not think that it is possible to merely identify all members of a specific company for 1966, for example, and then treat them as if they were a cohort who had a uniform exposure. Thus, we feel that it will be necessary to use the company exposure as the source of a composite individual exposure, but that treating a company as a cohort will lead such considerable misclassification as to make the study scientifically unsound.

Question 22. Why do you believe the feasibility study is necessary when the Agent Orange work groups, the Army and the GAO have identified the difficulties in developing exposure estimates at levels more specific than the company level?

Response: There is an important difference between identifying difficulties and finding solutions. We feel that it will be necessary to use the company daily exposure likelihood as the basis of the index for the individual (see responses to questions #8 and #21). However, we feel that a company, because it is not a uniform entity over time, cannot be substituted for attempting to develop a composite exposure likelihood index. Treating a company as a cohort will result in significant misclassification.

Question 23. Why doesn't your draft protocol discuss how already completed records searches can be used to identify exposed populations?

Response: Because we have not had the opportunity to fully evaluate the existing records (see responses to questions #5, #10 and #11) we cannot at this time be certain how or whether the already completed record searches may be utilized. This question cannot be fully answered until the exposure likelihood index procedure has been developed.

Question 24. Your draft protocol proposes to estimate exposure to other chemicals, drugs, etc. used in Vietnam, are you aware that GAO found that no records were maintained on the use of pesticides (other than herbicides)?

Response: We can, of course, only estimate exposure to other factors which are, in fact, documented. Having observed the progress in knowledge of the Army records which Mr. Christian's group has achieved, we are optimistic that more relevant information may be found. The GAO may have been correct in terms of records of the quality of the HERBS records. There may, however, be other records which could be used by an epidemiologist to provide an assessment of the likelihood of comparability of two cohorts on, e.g. their potential for exposure to pesticides.

RESPONSE OF THE UNIVERSITY OF CALIFORNIA TO WRITTEN QUESTIONS SUBMITTED BY HON.
ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON VETERANS'
AFFAIRS

QUESTION 1. In the course of designing the so-called draft protocol, did you receive regular updates on the status of ongoing VA efforts on the Agent Orange issue as well as on any new initiatives?

QUESTION 1-A.(i) Did you receive a briefing on the VA's own Agent Orange research efforts when you undertook the design of the protocol?

RESPONSE: Yes, we were briefed on the VA's research efforts on Agent Orange.

QUESTION 1-A.(ii). Did you receive any written descriptions of these activities from the VA?

RESPONSE: We did not receive written descriptions prior to the initiation of the contract for the development of a protocol. During the development of the initial draft protocol we did receive verbal descriptions of these activities. We did not receive written descriptions until October, 1981.

QUESTION 1-B. In the draft protocol you recommend that an analysis for frequency distribution of complaints be made of the Agent Orange Registry and that a mortality study of Vietnam veterans be conducted. When making those recommendations, were you aware of the VA's then-current efforts in these two areas?

RESPONSE: We were aware of the VA's efforts in these two areas. The frequency distribution of complaints made to the Agent Orange Registry was requested to provide clues to the types of health outcomes which might be a result of exposure to Agent Orange in Vietnam.

QUESTION 1-B.(i) [if yes] Did you include similar studies in the draft protocol because you were dissatisfied with the VA's efforts?

RESPONSE: Our objective in including the proportionate mortality study of Vietnam veterans was different than the objectives of the proposed mortality study of the VA. Our primary objective was to provide information about possible health outcomes due to exposure to Agent Orange in Vietnam which could be included in the questionnaire and to evaluate the quality of the mortality statistics for use in the final protocol.

QUESTION 1-B.(ii) [if no] If you had known of the VA's efforts, would you have modified the draft protocol and, if so, are you now doing so in these respects?

RESPONSE: Please see response to question 1-B.(i).

QUESTION 1-C. On page 3 of your statement, you note that the VA has made an earnest effort to communicate with us, and we anticipate that this communication will improve as we become more familiar with each other." What measures would you recommend be taken to improve the lines of communication between you and the VA?

RESPONSE: We believe that the VA sincerely wants to know if there are health hazards which result from Agent Orange exposure in Vietnam and recognizes the need for a scientifically sound study to provide that information. Moreover, it is our impression that the VA is under tremendous pressure from veterans groups and from the various oversight agencies. Some of this pressure has been transmitted to us in terms of inflexibility on the part of the VA. For example, it is clear from our experience with the development of this protocol and as reflected in the statements of several of the witnesses at the hearings that the VA was not realistic in the development of the guidelines for the RFP given the state of the records on spraying missions and troop movements. Our initial contacts with the VA were not with individuals who were in a position to make decisions. This has been rectified. Both UCLA and the VA are working towards a further coming together in our understanding of the reasonable expectations from the contract.

QUESTION 2-A. Please describe the briefing you received from the Department of Defense on the status and content of Army records that relate to the development of an Agent Orange exposure index.

RESPONSE: We received detailed briefings from the Army on the types of records available, the locations of the records, their general quality and the mechanics of searching them. These briefings also included a detailed description of the record reviews undertaken by Mr. Christian's staff. We were able to view a few selected records which had been declassified. We received a similar, although briefer, discussion from the Marine Corps.

These briefings were sufficient to gain an understanding of the complexity of the task of developing a detailed exposure likelihood index but were not sufficient to develop the index itself.

QUESTION 2-B. To what extent did you have use of and access to DOD personnel in your work with the records?

RESPONSE: The DOD personnel have been willing to give us access to the necessary records. However, we did not receive security clearance which would give us access to these records prior to November 1981.

QUESTION 2-C. Did DOD personnel physically locate records for you?

RESPONSE: Yes, they have helped locate history books and some declassified records.

QUESTION 2-D.(f) Do you believe that DOD personnel were as cooperative and helpful to you as they should have been?

RESPONSE: Yes, we do believe that they have been as cooperative and as helpful as they should have been.

QUESTION 2-E. Did you consider hiring a military records expert or requesting that one from DOD be assigned to work with you?

RESPONSE: We worked closely with Mr. Christian who is probably the most experienced and knowledgeable expert on the records.

QUESTION 2-F. I understand that in late September or early October Secretary Schweiker offered to provide personnel to assist you with military records searches. Is that correct?

RESPONSE: No, we were not aware that Secretary Schweiker offered to provide personnel to assist us with military records searches.

QUESTION 3-A. With respect to security clearances for you and your investigators, when and how did it become evident that you would need security clearances?

RESPONSE: By early June after we had spent time with the DOD personnel it became clear that it would be necessary for us to have security clearance in order to evaluate the necessary records.

QUESTION 3-B. How long did it take from the time it became evident that you needed such clearances until the clearances were granted?

RESPONSE: Clearances were obtained approximately five months after we initially requested them from the VA.

QUESTION 3-C. Who was responsible for arranging for you to receive clearances?

RESPONSE: The VA. The request was submitted to the Contract Technical Monitor, Dr. Larry Hobson.

QUESTION 4. I understand that, in your efforts to develop an exposure index, you learned that there was Defense Intelligence Agency satellite photographs from which specific gradations of defoliation in Vietnam might be ascertained.

QUESTION 4-A. Is that correct?

RESPONSE: Dr. Spivey and members of the investigative staff have not yet seen the classified photographs of defoliated areas in Vietnam although we have requested such photographs. Dr. Spivey has had an ongoing negotiation with the DoD to review the extent of the photographic record and its potential usefulness.

QUESTION 4-B.(i) Do you believe that these photos can be a useful supplement for the data provided in the HERBS tapes?

RESPONSE: These photographs might be useful in validating the information obtained from the records of spraying maintained by both the Army and the Air Force. Unfortunately, current information suggests that the most useful photos were destroyed in routine file maintenance programs.

QUESTION 4-B (ii) [if yes] Have you requested access to these photos and what disposition has been made of that request?

RESPONSE: On Friday, October 30, Dr. Spivey met with members of the Defense Intelligence Agency. The DIA suggested that an experienced photointerpreter with a secret security clearance be obtained from the US Geological Survey to read the film. Dr. Spivey transmitted that request to Dr. Lawrence Hobson of the VA on the same day.

QUESTION 4-C. Is the information from these photographs available to supplement the tapes on a daily, weekly, or other basis?

RESPONSE: We do not know yet whether the photographs are available on a daily, weekly, or other basis. Our current impression is that the photographs are not so systematically organized and labeled.

QUESTION 5. With regard to your concerns about bias in the study that led to your emphasizing the need for secrecy with respect to both the exposure index and the specific health outcomes to be studied, numerous reviewers expressed concern that such secrecy is neither appropriate nor effective as a means of dealing with the problem of bias.

QUESTION 5-A. Do you agree with many of the reviewers that your withholding certain information in these areas effectively precluded the reviewers from passing a competent scientific judgment on the protocol?

RESPONSE: Yes, we agree that it would be difficult to review the protocol without additional information. We have now been informed by the VA that we should not concern ourselves about public access to the protocol. This does not reduce our concern about the problems in carrying out a scientifically sound study of the possible health effects of Agent Orange exposure in Vietnam given public access to both exposure criteria and expected outcomes. We believe, as have the Ranch Hand investigators and the Australian group, that it is important that the respondents not know either their presumed exposure category or the anticipated health outcomes. The questionnaire content in the Ranch-Hand study has remained confidential.

QUESTION 5-A (i) Isn't it possible to verify at least some reports of medical complaints during physical examinations, thereby reducing the risk of inaccurate self-reporting?

RESPONSE: It will be possible to verify the presence of a number of reported diseases through the physical examination as well as through several of the laboratory tests which we will be recommending in the revised protocol. It is also possible to request verification of reported diseases from the diagnosing physician or treating hospital. It is more difficult to uncover the existence of diseases which were not reported. Our previous experience suggests that we can uncover some of these by sending a general questionnaire to the current physician. However, it is probable that there will still be some conditions which were not reported by the respondents.

QUESTION 5-A (f) Shouldn't a requirement of such verification be part of the design for the cohort study?

RESPONSE: Yes, and we have incorporated such into the revised protocol to be submitted to the VA.

QUESTION 5-B. Although you made no mention in the draft protocol of specific health outcomes that you believe should be addressed in the study, have you in fact compiled such a list?

RESPONSE: Yes, we have a list of suspected health outcomes based on the reports in the literature and the preliminary results of other studies.

QUESTION 6-A. Do you believe that an exposure index can be developed that will take into account not only aerial spraying of Agent Orange, but also perimeter and ground spraying?

RESPONSE: It is not clear to us at this point whether it will in fact be possible to develop an exposure likelihood index which can take into account not only aerial spraying of Agent Orange but also perimeter and ground spraying. It is for this reason that we have recommended that a specific contract be let for the development of that exposure likelihood index.

QUESTION 6-B. How long do you estimate it will take to develop a satisfactory exposure index?

RESPONSE: We have estimated a maximum of fourteen months given the information we currently have at hand and assuming that security clearance for all personnel has been obtained.

QUESTION 6-C. What additional resources--in terms of funding, records personnel, and other items you believe essential--do you estimate will be needed to complete an exposure index?

RESPONSE: We have estimated that it would take an additional 14 months and \$774,434 to develop an exposure likelihood index and to thoroughly evaluate the quality of the records on veterans in sufficient detail to be able to predict the likely success of an historical cohort study. From our discussions with Mr. Christian and others it is clear that the records of the spraying distributions and troop movements are not so well organized as we and the VA had assumed. It might be possible to provide the committee with a negative answer (if that is the result of further investigation) on the likelihood of being able to develop an exposure likelihood index earlier than 14 months. Nonetheless, given the seriousness of the question regarding health effects of exposure to Agent Orange we feel it important to make the most careful analysis of the quality of exposure data and of troop movement records possible before concluding that a study is or is not feasible.

QUESTION 6-D. Do you continue to believe that you will be able to develop an exposure index at the company level, as the draft protocol suggests, or, as the Working Group suggested in its review, will such an index have to be developed at the battalion level?

RESPONSE: We believe that the exposure likelihood index will have to be applied at the individual level. However, we feel that the exposure likelihood will have to be assigned to the individual on the basis of his cumulative company assignments. The exposure to the companies will be developed by looking at grids which correlate troop movements and spraying operations. The individual will then be assigned the exposure of the company in which he was at the time. This makes several assumptions but would provide a more precise estimate of exposure than trying to estimate exposure from the battalion level. The battalions are too large to provide a precise enough grid development. We also believe that it is not possible to treat a company as a cohort per se because of the considerable movement of individual soldiers in and out of the company due to overlap of service in Vietnam, temporary leaves due to wounds or other reasons and transfers between companies.

QUESTION 6-E. At the hearing, Dr. Houk discussed a possible role for the Science Panel of the Working Group to play in the development of the exposure data. What are your views on this suggestion?

RESPONSE: We feel that the Science Panel of the Working Group could be of assistance in the development of the exposure likelihood index and would recommend that the group assigned the task of developing the exposure likelihood index work closely with the Science Panel.

QUESTION 6-F. If an adequate exposure index cannot be developed, will it still be possible to conduct a study of the health effects in Vietnam veterans of exposure to Agent Orange or will the study have to be limited to a study of the overall health status of Vietnam veterans?

RESPONSE: Our current thinking is that it will be necessary to develop some measure of the likelihood of exposure in order to ascribe health effects to the use of Agent Orange. There were, of course, other herbicides which were used in Vietnam and in many ways Vietnam service differed from service in Korea, or Europe. We feel that a study limited to the overall health status of Vietnam veterans will not address the question of Agent Orange. Although we are aware of the fact that it has been suggested that the health outcomes of Vietnam veterans be compared to other groups we have considerable reservations about the ability to carry out a scientifically sound study to meet that objective. We suspect that there were considerable differences in the characteristics of individuals assigned to service in Vietnam and elsewhere. It would seem very difficult to separate out whether differences in the current health status of Vietnam veterans were due to service in Vietnam or to factors which were operative in determining that certain soldiers went to Vietnam whereas others did not.

Chairman SIMPSON. I would like to recognize Senator DeConcini, who has been a very helpful member of this panel on the Veterans' Affairs Committee. Unless there are more questions, we will proceed on to the next witnesses, which are Peter Flynn, captain of the Medical Corps, U.S. Navy, Office of the Assistant Secretary of Defense for Health Affairs, the Pentagon, Washington, D.C., and Richard Christian, Chief of the agent orange task force, Department of the Army, Washington, D.C.

Good morning to you. If you will please proceed, Dr. Flynn, Captain Flynn.

TESTIMONY OF A PANEL OF REPRESENTATIVES FROM THE DEPARTMENT OF DEFENSE CONSISTING OF CAPT. PETER A. FLYNN, U.S. NAVY, SPECIAL ASSISTANT FOR PROFESSIONAL ACTIVITIES, OFFICE OF THE ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, ACCOMPANIED BY DR. JEROME BRICKER, AND RICHARD S. CHRISTIAN, CHIEF, AGENT ORANGE TASK FORCE, DEPARTMENT OF THE ARMY

Captain FLYNN. Mr. Chairman, I serve, as you said, in the Office of the Assistant Secretary of Defense and serve as the principal point of contact within Department of Defense for matters relating to herbicide orange and also serve as our delegate to the agent orange working group and its scientific panel.

I have with me also Dr. Jerome Bricker, to my right, who has worked closely with me on this subject.

My remarks will be brief and general, mainly devoted to the context of herbicide usage and study, with the purpose of providing a broad perspective on the subject. DOD's involvement in herbicide orange now centers about the Ranch Hand study and military records research to delineate specific herbicide usage and exposure in Vietnam. These are relatively independent topics and you will be learning about both in more detail in this morning's hearings.

I will devote my comments to the records research which, while not glamorous, is absolutely pivotal to all of the rest of our ground

troops study efforts and any documentation of personal exposure. It is a difficult and prodigious effort and the Army has done a splendid job in supporting us.

The military use of herbicides was tested beginning in 1961, was put into limited operational use in the following years, and then in the time period 1965 to 1971 was widely used in Vietnam in prosecuting our war effort by denying the enemy cover, concealment, and crops.

The methods of delivery varied from massive multiplane, fixed-wing aircraft spraying missions through helicopter, vehicle and small boat application—

Chairman SIMPSON. Captain, could you bring that microphone a bit closer to you, please? I think that would be helpful.

Captain FLYNN. Yes, sir.

Chairman SIMPSON. Thank you.

Captain FLYNN. To highly personal spraying by individual soldiers with versions of the familiar garden sprayer. The sites of application varied from enemy territory to lines of communication to our own base perimeters. Approximately 10 percent of the South Vietnamese mass was sprayed with herbicides.

Herbicides were so widely used in Vietnam that it is difficult to find individuals whom we can say with certainty were not exposed. Lack of Vietnam service is no guarantee either, since the components of herbicide orange were widely used in the United States, in excess of 100 million pounds of phenoxy herbicides were applied there between 1961 and 1970. For example, at that time GSA catalogues listed 36 phenoxy herbicide stock numbers available in various packaged quantities for Government use.

The use of herbicide orange was suspended in 1971 when concerns were raised about its human and ecological effects. Beginning with the National Academy of Sciences study in 1972, extensive scientific research has failed to either conclusively prove or disprove that low levels of exposure to orange or its contaminant, dioxin, will cause ill health in men. Today we are still trying to answer that same question.

As the conditions of combat controlled and influenced herbicide orange's use, so combat still influences our efforts to study its use. We are using combat records generated under trying and uncertain circumstances for entirely different purposes than those to which we now put them.

There are errors, there are gaps, and while the records were adequate for combat purposes, they may be entirely inadequate for epidemiological study. When the records were retired, they were hastily and often inaccurately boxed and we are now confronted by 40,000 shelf-feet of typed records which are understandable only to knowledgeable and experienced historians. It is a formidable undertaking.

Because of widespread concern about ground troop exposure to fixed-wing spraying and using approaches and techniques initially developed by the General Accounting Office, our initial efforts focused on various military units in the field. We had hopes that this would be fruitful but, as you will learn in more detail, these efforts have met with frustration and disappointment at virtually every turn.

Looking for alternative groups of potentially exposed individuals, we have recently begun to examine the records for evidence of exposure which may have arisen from perimeter and lines of communication spraying, and from herbicides rapidly dumped from aircraft under various emergency situations.

The knowledge of these "abort" missions is not new, they having been mentioned on page III-34 of the 1974 NAS report, but detailed examination and verification of them is. You will learn of our progress in this investigation; it is still evolving and the numbers must be considered preliminary.

The records examination is an ongoing process, the more we look, the more we will find. We are concealing nothing, but much remains to be found as the vast majority of records remain unexamined. We are working from multiple sources which permits confirmation of data but also presents the risk of duplicate counts as well. Undoubtedly there are a finite number of events relating to herbicides; we do not know how close we are to them but there will come a time of diminishing returns for the effort invested.

We will continue to work actively to find the answers. We are as anxious as anyone to have the matter settled. We must bring all the modern expertise to this task that we can but, at the same time, we must be careful not to impose today's knowledge, standards and beliefs in judging events that occurred over a decade ago.

Chairman SIMPSON. Thank you very much, Captain. And now Mr. Christian, please.

Mr. CHRISTIAN. Mr. Chairman, members of the committee. I am the Chief of the Army's agent orange task force, Office of the Adjutant General, Department of Army. It is a pleasure to appear before the committee to discuss the Department of the Army's role in agent orange, the records of our involvement in Vietnam, ground troop studies, and aborted missions.

Our role is a key one because we have custody of the records.

In early 1980, the Department of Defense held the first full-scale meeting on agent orange. The Veterans' Administration had asked for the names and addresses of all Vietnam veterans who may have been exposed to agent orange—a major undertaking since 2.4 million members served in Vietnam. An assessment of what it would require in terms of resources indicated that it would cost between \$27 and \$41 million and take 3 to 4 years to obtain the information desired.

There were no documents created to record exposure to agent orange. We are faced with manually searching some 40,000 linear feet of combat records to provide information on ground troop locations. The locator data is often generalized. We have to examine several types of documents, combat operations reports, situation reports, and other categories of records.

We began a series of studies to determine the feasibility of reconstructing the movements of combat battalions. Three battalions were selected. In two battalions we were able to place a small number of troops within 1 kilometer of a target area within 7 days after a Ranch Hand spray mission. From our analysis, we were able to retrace by grid coordinates the movement of each battalion for over a year.

Following the ground troop studies, we retrieved the records of all chemical units that served in Vietnam. We have located records on defoliation missions which were conducted by tank truck, riverboat, and helicopter perimeter spraying. In addition, we uncovered records on a ground leak of herbicides from one of our storage facilities.

We have provided Dr. Spivey of the University of California, Los Angeles, with detailed briefings on the records collection from Vietnam, and furnished him with the battalion studies and several other documents. We are continuing to support the Veterans' Administration in this important effort. I hasten to point out that locating records and documents on agent orange and identifying troop movements has proven to be a difficult task and only the start of an extensive records retrieval effort. There are no locator or automated systems we can use to locate the data we need.

After the ground troop studies, we were asked to find the names of the individuals in these units. In one battalion, there were 2,400 troops who served during the 1-year period selected which was July 1967 to June 1968. We were also asked to identify troops that were not exposed to any sprayed areas. For purposes of a control population, we selected a battalion at Cam Ranh Bay. The helicopters repaired by this battalion were later found to have been used for herbicide spray operations. Therefore, the battalion did not qualify as a nonexposed control population.

We were assigned a task by the White House Agent Orange Working Group to locate troop populations with possible exposure to intense concentrations of herbicides. We chose units that might have been operating where herbicides were jettisoned. During this phase of our research we located a listing of general information on aborted missions and additional incident reports. I have provided detailed information concerning this in my written testimony.

We were able to say that we had records on approximately 90 aborted Ranch Hand missions. However, only 28 of these 90 could be fully documented in the paper records retired from Vietnam. By matching the aborted mission locations and troop concentrations, we were able to suggest further study of a group of service personnel who may have been in the aborted mission areas.

Much progress has been made in our research. We have now located about 174 incidents of possible exposure. We learned that there were situations of jettisoning the herbicides on and off targets, spraying off target, plane crashes, a runway spill, and leaks.

In a further effort to find a non-agent orange exposed population, we are currently examining the spray missions and troop locations prior to 1965.

In conclusion, in addition to the already described searches, we have answered hundreds of requests from concerned veterans and provided them with whatever pertinent documentation that could be found. During the past year, we have worked very closely with a number of veterans' organizations and provided them with briefings on the ground troop studies.

This concludes my presentation. I would be most pleased to answer any questions.

Chairman SIMPSON. Thank you very much.

[The prepared statement of Richard S. Christian, Chief, agent orange task force, Department of the Army, follows:]

PREPARED STATEMENT OF RICHARD S. CHRISTIAN, CHIEF, AGENT ORANGE TASK FORCE,
DEPARTMENT OF THE ARMY

Mr. Chairman and Members of the Committee:

I am Richard S. Christian, Chief of the Agent Orange Task Force, Office of The Adjutant General, Headquarters, Department of the Army. It is a pleasure to appear before the Committee to discuss the Department of the Army's current role in the Agent Orange issue and its concern about the possible health effects in Vietnam service personnel. I should like to review for you our activities to date and provide you with information about the records of our involvement in Vietnam, U.S. ground troop studies, and research on aborted herbicide spraying missions.

Since 1978, my office has participated in many of the events leading to the national attention now focused on Agent Orange. Our role is a key one because we have custody of the records created by the Army and joint activities that were in Vietnam.

There were two early major actions that brought us into direct involvement in Agent Orange. The first action was the DOW Chemical Company litigation. Although we are not a party to the litigation, we have a responsibility to provide documents in response to discovery notices. The other action was the General Accounting Office review dealing with records of the units near herbicide spraying.

Military Departments and the Veterans Administration, in early 1980, held the first full scale meeting on Agent Orange. The previous Administrator of the Veterans Administration had asked for the names and addresses of all the Vietnam veterans who may have been exposed to Agent Orange. This would have certainly required a major undertaking since

some 2.4 million members of the Armed Forces served in Vietnam. Following the meeting, the Defense Department ordered an assessment of what it would take in terms of resources to respond to the Veterans Administration request. We were asked to provide cost estimates and a time frame for completion. We estimated at that time that it would cost between 27 and 41 million dollars and take from three to four years to obtain the information requested. This was the beginning of a long series of tasks that have increased our workload tenfold.

We now have a full time staff of 3 and make use of significant amounts of time of 2 other employees.

On 14 August 1980, we took action to prevent destruction of all Agent Orange related records for any reason and required that they be held in place until further notice. In addition, we required each custodian to furnish us with an inventory showing the type of records and their locations and volume. We notified the General Services Administration to "freeze" destruction of the records in its centers pertaining to herbicides.

I should point out that there were no documents created to record exposure to Agent Orange. There was no requirement to do so since the herbicides were not considered toxic. As a result, we are faced with manually searching some 40,000 linear feet of combat records to provide information on ground troop locations. The locator data prepared by soldiers or Vietnamese employees is often generalized in nature and does not identify individual documents containing Agent Orange information. Because of these two conditions, we have to examine several types of documents. For example, to determine where a particular unit was at

a given period of time, combat operations reports, unit daily journals, situation reports, unit histories, and several other categories of documents must be examined.

In May 1980, we began a series of studies to determine the feasibility of reconstructing the movements of combat battalions in Vietnam. Three battalions were randomly selected and their records were thoroughly scrutinized. These efforts were to pinpoint company size units by Universal Transverse Mercator coordinates on a day-to-day basis and not to establish the whereabouts of individual service members. We matched the daily unit grid coordinates against the HERBS tapes to obtain company proximity to spraying missions. Normal battalion records holdings are approximately 20 linear feet per unit for Vietnam. In 2 battalions, we were able to place a small number of ground troops within 1 kilometer of a target area within seven days after an Operation Ranch Hand herbicide spray mission. From our analysis, we were able to retrace by grid coordinate the movement of each battalion over a full year. The cost was \$3,500.00 per battalion; each battalion study required 265 manhours.

Following the ground troop studies, we retrieved the records of all the U. S. Army chemical units stationed in Vietnam. These units included about 800 people. We have located records on defoliation missions which were conducted by tank truck, river boat, and helicopter perimeter spraying. In addition, we uncovered records on a ground leak of herbicides from one storage facility. The chemical unit project is continuing as fast as we can review the records.

There are several other specialized search efforts planned or underway at the present time, such as examination of the total Military

Assistance Command, Vietnam (MACV) staff collection and the Historical Information Management System developed by the MACV Historian. In these, we have a great deal more work to accomplish. We anticipate that many more categories of records will have to be located and researched for morbidity and mortality studies.

When the Veterans Administration contract for the protocol development of the epidemiological study was awarded to the University of California, Los Angeles, we provided Dr. Spivey and his investigators with information on the records collections from Vietnam. Further, we provided them with maps, the HERBS tapes, and several other documents for their study. We are continuing to support the Veterans Administration in this important effort.

During the time the University of California, Los Angeles submitted its proposal for a protocol, we provided the Office of Technology Assessment information on the Vietnam records collections and our ground troop studies.

I hasten to add that locating documents on Agent Orange and identifying troop movements has proven to be only the start of an extensive records retrieval effort. Once the records are located, it is necessary to compare one category of records (e.g., spray records) with other categories of records (e.g., troop location reports). In addition, a time-consuming, cross-checking of records to detect, correct, and explain inconsistencies is also often necessary. And further, we have consistently found time and location gaps in the records. In short, there are no automated systems we can access to locate the data we need. There were simply no data bases established to provide this type of information.

After the ground troop studies, we were asked to find the names of the individuals in the units. In one battalion there were 2,400 troops who served during the one year period selected: July 1967 to June 1968. In addition, we were asked to identify troop units that were not exposed to any sprayed areas. We selected a battalion stationed at Cam Ranh Bay for this purpose. This battalion was a helicopter maintenance organization operating on a converted aircraft carrier, the Corpus Christi Bay, anchored at Cam Ranh Bay. Identification of this unit as a candidate for non-exposure to herbicides was unsuccessful. The battalion had to be excluded from the study because it was learned that the helicopters being repaired had been used for herbicide spray operations and were likely to be contaminated.

Most recently, we were assigned the task by the Agent Orange Working Group to conduct additional research projects regarding troop exposure to herbicides. It was thought that possibly more intense concentration of herbicides could have resulted from emergency jettisons from the aircraft.

We began developing information on those units that might have been in close proximity to the areas where herbicides were jettisoned. First, we located a listing of aborted missions which was developed in 1972. The listing provided general information about each mission and its location. We then searched the Vietnam locator data for records retirements and found what were called "incident reports". These reports were brought in from the General Services Administration Records Center and matched up with the printout. This data provided us with precise information on geographical locations of herbicide jettisons. We then plotted

the aborted missions on a 1:250,000 map of Vietnam. From the statistical reports created by the Military Assistance Command, Vietnam, we were able to obtain the locations and quarterly end strength of U. S. troops.

At the time of the Health and Human Services press conference, we were able to say that we had records on approximately 90 aborted missions. However, only 28 of these 90 could be fully documented in the paper records retired from Vietnam. Obviously, more searching was required. Thirty-nine of these missions resulted in jettisoning Agent Orange. By matching the aborted mission locations and troop concentrations, we were able to suggest further study of a group of service personnel who may have received a higher exposure to herbicides having been in the aborted mission areas, as opposed to troops who may have been exposed to a moderate or lower exposure in the jungle, under canopy cover. This was the primary reason why we embarked on the search for records of aborted missions. Since the end of September 1981, much progress has been made in our research and we have now located data about 174 incidents of possible exposure. We felt the need to expand the understanding of data on aborted missions. The following information on incidents is therefore provided:

We have evidence of 37 jettisons that were clearly not within the target area. Of these, 16 have been estimated as jettisoned Agent Orange.

There are 13 jettisons for which we lack information about the type of herbicide involved.

There were 27 instances of jettison on target which presented higher chemical concentrations due to dumping through a 10 inch valve.

Records of spraying wrong targets were noted in 23 situations.

We can document 1 plane crash with Agent Orange on board.

There may be 7 other crashes with herbicide payloads. There was one spill on a runway when the plane was taking off.

In 1972, a listing of aborted missions was prepared for use by the National Academy of Sciences (NAS). This abort list contained 62 entries which we later found to cover 73 aborted missions. In reviewing and substantiating the list with other documents, we have determined that 58 other aborted missions did not involve herbicide dumping. Rather, we believe each aircraft returned to base with the herbicide on board or it never got off the ground.

Indications are there were 162 aborted missions. Of those, we have been able to document 150 incidents. Thus, 12 remain unverified. We have not plotted 41 incident locations because we do not have precise grid coordinates. The records are sketchy in terms of exact location information. As an example of the problem we are encountering:

Of 73 listed aborts, only 3 were verified jettisons.

58 were due to maintenance or weather problems and not to battle damage.

And 12 are still unverified. We have found records indicating an additional 12 aborted missions which occurred in 1965 that we cannot document.

In summary, we have records on 89 aborted missions documented in the Vietnam files and 73 aborted missions on the 1972 listing.

Research continues on the herbicide incidents. We can place troops in several situations of possible exposure such as Ranch Hand spraying, aborted missions, perimeter spraying, and leaks.

Concurrently with the aborted mission study we were asked by the Agent Orange Working Group Science Panel to examine the spray missions and troop locations prior to 1965. The objective was to identify personnel during the early part of our involvement in Vietnam when spraying activity was low. Prior to 1965 we have no HERBS tape documentation. What we are attempting to do, therefore, is to locate all the records available between 1961 and 1964. We have already begun examination of the records involved. The search involves 125 linear feet of files which will require extensive research.

In conclusion, the Army has responded to requests for records and information from all the agencies involved. We have answered more than 400 requests from concerned veterans and provided them with whatever pertinent documentation that could be found. We will continue to do so. During the past year we have worked with all the major veterans organizations. We have provided many organizations with detailed briefings on the ground troop studies and records situations.

I shall be most pleased to answer any questions.

Chairman SIMPSON. It is certainly apparent that we face tremendous difficulties trying to sort through the vast number of records that need to be manually searched.

I would wonder if the Department of Defense has any plans to direct any more resources to that effort. If so, could you provide us details as to what you would intend to do with such resources? That would be helpful.

The records apparently must be searched by hand, and the troop locations apparently are not coordinated with the spraying locations in any form. Would it be helpful to have a professional person, an epidemiologist, assigned to work with you and your group? Would that be of assistance in trying to make some sense of the records or would that be an feckless effort? Would you comment on that, Mr. Christian?

Mr. CHRISTIAN. We recognize that it takes records management specialists to retrieve and organize the records that UCLA would need. We also recognize that the make up of the records is certainly not such that an epidemiologist can examine them. However, it certainly would be helpful to have an epidemiologist working with us on a day-to-day basis as we begin to search for the records.

One of the problems we have is that we don't know what precise records UCLA is looking for. We would work much better if someone would place a definite requirement on a specific collection of records.

Chairman SIMPSON. Extraordinary request.

Captain, if you could, explain to the committee the ways in which the Department of Defense could be of greater assistance to the VA and to the parties doing the protocol and the study on agent orange. Are there some avenues which have not been explored, with respect to declassifying records or providing security clearances for persons involved in the study effort? I would like your thoughts on that please.

Captain FLYNN. Well, the matter of the security clearance for Dr. Spivey and his researchers I believe has now—has been settled and that he has clearance which gives him access, full access to the records.

Chairman SIMPSON. What was the reason for the delay in obtaining that clearance?

Captain FLYNN. I think basically I would say that it was a breakdown in communications. It was sort of realized too late by everybody involved that he needed this clearance for access to the records.

Chairman SIMPSON. Now, go ahead, I interrupted your response to the question.

Captain FLYNN. In terms of what DOD might do, basically I think at this point it would be the judicious additional application of the people to work with the records and where, as a matter of fact, are in the process of doing this now, of seeking another four individuals to work in the Army task force to provide records.

Also at this point we have requested the Air Force and the Navy who—the Air Force with the exception of Ranch Hand have really only been peripherally involved in the ground troop locations to also form within each of the services a task force to be prepared to respond to requests for information about things that they hold

within their records as now we begin to look at camp and base perimeter sprayings, spraying from riverine operations and things of this nature.

Chairman SIMPSON. With regard to the recent examination and verification of the aborted missions mentioned in your testimony, the numbers apparently represent preliminary information. Can you speculate on how many more of those types of missions might be uncovered as you continue your records search? I would be interested to hear a general figure.

Mr. CHRISTIAN. Mr. Chairman, first of all, we learned early in our search that we were uncovering not only precise records on jet-tisoning of herbicides but we were also identifying records that indicated spraying on the wrong target and dumps on target. Of course, when you have a dump on the target right after the regular spraying, there is a higher concentration of the herbicide.

We are continuing with this investigation. It is by no means complete. Every day we are uncovering new records from both the Army and the other services. At this time I cannot give you an estimate as to when this phase of the research will be completed.

Chairman SIMPSON. I understand that there is some highly classified photographs which rather clearly depict the areas that were sprayed in Vietnam. They are apparently clear enough to show varying degrees or levels of defoliation.

What can you tell us about those photographs and their availability? If those photographs are too highly classified for those participating in the study to interpret, is there any reason why some other persons have not been given the task of interpreting the data that those photographs might produce? Are there any links between the Department of Defense and the Veterans' Administration in that effort?

Captain FLYNN. It was hoped that perhaps intelligence photographs taken during the course of the war might provide confirmatory evidence about the location of spray sites. Indeed, we have been in touch with the Defense Intelligence Agency. We have provided them, at Dr. Spivey's selection, dates, and grid coordinate locations to try to see what their photographic collection might afford us.

We had a meeting with them perhaps 2 to 3 weeks ago now and at least after the initial pass through the records, first of all, it was found that very little of the ground area under question was actually included in the photographs, or say was covered with cloud cover.

Additionally, the problem appears to be that the resolution of the photographs, which are in black and white, are insufficient to provide information about spray tracks. An additional increment of places and locations has been provided and are being looked into to see if this can be of any help to their efforts.

Chairman SIMPSON. I think, Captain, that it is essential that we establish the fact that the Department of Defense is actively participating in this effort. We have clearly established that the Department of Defense is attempting to help us determine an exposure index as closely as possible. It is obviously a very difficult task to define the levels of exposure for these veterans who served in Vietnam during the time that agent orange was used.

But even as I review the reports of Mr. Christian's efforts and his excellent background, I must say I have difficulty seeing why, with all the resources available to the Department of Defense, that the agent orange task force actually consists of Mr. Christian and two other employees, plus some staff time from two other workers. I must ask you to comment on the DOD effort in general, with respect to agent orange and the serious lack of manpower being utilized. And specifically, please comment on your plans to expand this effort of the agent orange task force at DOD.

Captain FLYNN. Yes, sir. First, and perhaps most specifically, we are in the process, as I mentioned earlier, of securing four additional people to work with the task force full-time to supplement the efforts that have gone on already. By and large, our approach up until now has been a rather selective one. We have gone into the records to basically see whether a given approach would prove fruitful or not, rather than an effort to go into the records in a wholesale fashion.

As we mentioned, we tried the ground troops records and have found difficulties with them. We have then, in turn, turned to other areas. So, this has been generally the approach we have followed. There is a sort of very delicate interplay between what the records will allow the epidemiological study to accomplish and, in turn, the burden that the eventual study will impose on the records management. And we have tried, by working closely with the Army and working through the science panel, particularly of the Agent Orange Working Group, to key our efforts to their requirements and needs.

Chairman SIMPSON. It seems there is much to be done with those types of problems, especially the manual search methods. We will be working closely with you on that.

Unless other members of the panel have questions, we will now move on to the next witness. I thank you very much, Captain Flynn and Mr. Christian.

Captain FLYNN. Yes, sir.

Chairman SIMPSON. We appreciate that very much.

[The response of the Department of Defense to written questions submitted by Hon. Alan K. Simpson, chairman of the Senate Committee on Veterans' Affairs, Hon. Alan Cranston, ranking minority member of the Senate Committee on Veterans' Affairs, and letters dated December 28, 1981, and February 5, 1982, from the Department of the Air Force to Hon. Alan Cranston, follow:]

RESPONSE OF THE DEPARTMENT OF DEFENSE TO WRITTEN QUESTIONS SUBMITTED BY
HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS'
AFFAIRS

Question 1. Mr. Christian's testimony mentions the difficulties he and his staff face trying to sort through the vast number of records that need to be manually searched. I would like to know if DoD has any plans to focus more resources in this effort and if so, if you could provide some details it would be very helpful.

Answer 1. Up to the present time, the Army and Marine records personnel have conducted a series of test studies with regard to the records retrieval and analysis process. These studies were undertaken at the request of our office for the purpose of providing the Interagency Working Group and now the Agent Orange Working Group with information about our capability to retrieve records, their relative accuracy (e.g., morning report entries), and our ability to predict and establish troop unit operating locations near fixed wing aircraft spraying tracks as presented in the HERBS tape. We also conducted studies to try and locate units which we could state with confidence had had no exposure to herbicides. All of this information was immediately reported to the Science Panel of the Interagency Working Group. The objective was to provide the Science Panel with sufficient information so that the epidemiologists and other scientific members could determine if the development of an acceptable protocol was feasible. We have deliberately gone into the records in a very selective fashion. There is a delicate interplay between the records and the study. On one hand the records will limit the kind of study that can be done and, on the other hand, the study will determine the kinds of record research that will be needed. This is a back and forth process and will not necessarily be significantly accelerated by a massive assault on the records.

Our office continues to work with the Army Agent Orange Task Force on a daily basis. In October we began to gear up for new information request from the Science Panel and discussed their needs with Mr. Christian. The Department of the Army has provided four new manpower spaces together with the necessary FY 1982 funding. Position descriptions are in development and hiring will take place in the near future. We believe this 100% augmentation of their manpower will cover their needs for the near future. On 10 November 1981, our office also requested the Departments of the Navy and Air Force to establish their initial cadres of personnel for similar Agent Orange Task Forces to further assist us in persuing records searches and records retrieval in the Navy and Air Force records systems. We requested a minimum of two to three persons be made available as necessary to meet Science Panel requirements and as a standby group to support the Veterans Administration in records searches as needed. We will monitor future records personnel requirements and seek additional personnel as needed. The Agent Orange Working Group is aware of the additional resource requirements posed by the various study efforts.

Question 2A. Have you previously requested funds through the Army's budget to obtain additional staff for work on records?

Answer 2A. No we have not, although it may be necessary in the future.

Question 2B. If these requests were denied by the Army, what was the reason for denial?

Answer 2B. The recent Army request for authorization of four additional spaces for the Army Agent Orange Task Force was very expeditiously handled by the Department of the Army manpower and comptroller staffs giving Mr. Christian the authority to hire the necessary additional staff members.

Question 3. Please explain to the Committee the ways in which DoD can be of greater assistance to the VA and to the parties doing the protocol and the study of Agent Orange than they have been to date. I mean by that are there some avenues which have not been explored with respect to declassifying records or providing security clearances for people involved in the study effort?

Answer 3. We believe that the Department of Defense has provided full assistance to the Veterans' Administration beginning in the Spring of 1980 when initial meetings were held with VA representatives. Full briefings were given on the 40,000 shelf feet of records now in storage pertaining to the Vietnam war. A series of battalion studies designed to locate troop units operating in close proximity to the Ranch Hand herbicide spray tracks were done by the Army and Marine records personnel at the direction of the DoD. Subsequent location and listing of the names of about 2,400 members in the 1st of the 1st Air Cavalry Division was also done at our request. All study reports were immediately provided to the Interagency Working Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants. The VA was a full member of this Working Group and was thus kept constantly informed of the status of the DoD sponsored records searches.

Dr. Spivey of the UCLA team was provided extensive briefings by the Department of the Army and Marine Corps records personnel concerning the battalion studies, including both successes and problems. In addition, Dr. Spivey's group was provided with a complete HERBS tape, bibliographies from Defense Technical Information Center (DTIC) on special topics, a geographic gazetteer of Vietnam, maps of Vietnam, and other records including the battalion studies. Declassification is not considered to be a valid problem with respect to the development of a protocol. Initiation and follow through of the necessary security clearances for contractor personnel is the responsibility of the sponsoring contracting agency. In our opinion no significant documents were ever denied Dr. Spivey on the grounds of being classified. Whenever documents were found that might prove of value, immediate declassification reviews were carried out.

Question 4A. In your opinion, are the HERBS tapes accurate?

Answer 4A. They are reasonably accurate, considering the conditions under which the basic data were generated. Much obviously erroneous data was never entered in the first place. There are problems with the remaining data, but it is difficult to say at present how severe they are.

Question 4B. How have they been verified since the end of the war, as accurate measures of where and how much Agent Orange was actually sprayed?

Answer 4B. No, the HERBS tape have not been verified since the end of the war. The National Academy of Science report also noted data problems. The National Academy of Science report (pg. III-39) stated that it was necessary to correct for 575 missions with faulty location records and to eliminate 305 missions having erroneous location records which could not be corrected. It was further stated that information and estimates for herbicide operations not covered by the HERBS tape may account for an additional 2,400,000 gallons (all agents) and 540,000 acres, so that the HERBS tape data account for about 86% of all herbicide operations. We are now seeking the basic data sources to see if it is possible to confirm the information in the tapes.

Question 5. It seems to me that we need to do a thorough and comprehensive search and cataloging of available DoD records, films, and reports before a feasibility study for the epidemiology study is undertaken. How long would such a record indexing take, and how much do you estimate it would cost?

Answer 5. The Army very recently has begun a computer indexing process which will contain the document location, author, date, and summary (if available) of all known records pertinent to the subject of Agent Orange under the control of the Department of the Army. Since 20 November 1981 the Army records staff have entered over 200 records. They estimate that they will be able to enter 1100 records per month. The cost is being borne by the Army at a rate of 88 manhours per month for a monthly cost of \$345.00. It should take about four months to enter the documents which the records staff are now aware of. It seems that more documents pertinent to Agent Orange are consistently being found. The Army index, however, is presently limited to documents which contain known Agent Orange information and other data. The index will not include listings of all battalions and their locations, or their relationships to herbicide spraying as this is presently beyond the capability of the staff.

A reasonable time estimate and costing projection is not available without more definitive information as to the depth of search of the records and the cataloging requirements and such other factors as "key word" search capability. A great deal depends on the requirements to be levied by the VA in the actual accomplishment of the epidemiological study of veterans exposed to Agent Orange. The forty thousand linear feet of records do have various record retirement indexes with a degree of specificity, and these are the indexes that have been used to produce the battalion studies and the aborted mission research. We believe that an unfocused major indexing project started at this time without guidance as to specific information needs could be very expensive and use resources that might be better applied elsewhere.

Question 6. Can individual estimates of exposure to Agent Orange be developed from available records?

Answer 6. Only with the greatest difficulty and then only, if the epidemiologists are willing to accept a series of graded exposure indexes ranging from probably high to extremely low. The Problem really centers on the definition of an "exposure index" and the degree of precision required. In discussing an exposure index it is important to define precisely what is meant by the term. When I use the term I mean the following: It is a measure or estimation of the amount of a given substance present at a specific time and place. In the case of Herbicide Orange it takes the following kinds of factors into consideration: The composition and concentration of the herbicide, its rate of application, its rate of evaporation, absorption into leaves, its dispersion subject to meteorological conditions and finally its rate of decay and detoxification in air, foliage and soil. These factors then allow potential chemical exposure to be calculated with ranges from none to maximal and may well be able to be characterized by numerical values for the various constituents of Orange. In general this may be constructed quite independent of troop movement and location investigation based on available test data or on studies that would provide the data. On the other hand the troop record studies allow us to place or estimate the location of an individual person or unit so that an estimation of exposure may be generated. Substantial difficulty in fixing either the amount of herbicide present in the environment or peoples exposure to it may seriously impair the ability to carry out a satisfactory epidemiological study.

The best we may be able to do is to estimate the average exposure of an operational unit and then postulate that same exposure for all members of the unit.

Question 7. Do you believe available records can be used to estimate the probability that companies operated in or near sprayed areas?

Answer 7. Yes, we think it is possible. There will, however, always be some uncertainty.

Question 8A. Based on already completed records searches, do you believe you can identify units (companies) with different probabilities of exposure?

Answer 8A. Yes, it seems probable that we can, but more work on this aspect of the records will be necessary to make this assertion with certainty.

Question 8B. Do you believe this is the best estimate of exposure which can be developed from available records?

Answer 8B. Other than Ranch Hand personnel, yes it is.

Question 9. Have you located any unit records where the unit describes being sprayed by Ranch Hand missions?

Answer 9. We have located records from the II Corps Advisory Group, U.S. Military Assistance Command, Vietnam which describe defoliation missions being flown by aircraft over static positions of the 101st Airborne Division and the 1st Cavalry Division (Air Mobile) located in the An Khe Pass and Mang Yang Valley during combat operations in December 1965.

Question 10. Would you explain the process by which an individual's record is researched to establish data which could be used to establish an Agent Orange Exposure Index?

Answer 10. Actually, it is necessary to search several different types of organizational and personnel records. For instance, brigade situation reports, and battalion daily journals provide information on the day to day locations of the unit. Unit morning reports record present for duty information on individuals. In addition, there were herbicide reports which contain spray data. By matching the unit locations with the herbicide reports, it is possible to determine whether an element has been in a base camp, fire base, or "Ranch Hand" target area. A review of the appropriate morning report of the unit under investigation will verify whether the individual was present for duty at the time. The remaining portion of the research is then in the individual's personnel and medical file for verification, such as duty assignments, arrival and departure, and treatment for illnesses while in Vietnam. The entire question as to whether sufficient data for an index has been established depends on the findings of an epidemiologist.

Question 11. How much time would you estimate that it takes to accomplish this task for each record?

Answer 11. The time it takes to search an individual's personnel file is relatively short. All that is necessary is to verify Vietnam service, his or her unit assignment, duties, and medical records. Although the records of a single soldier can be reviewed in two hours or less, it may require several weeks to obtain all the records from the records centers. The length of time to research unit morning reports takes longer. It took 30 man days to examine and record one year's morning report entries for one battalion of 2400 names to validate present for duty status. The next step is to retrieve and research organizational records to account for unit locations during operations. Locating the records and detailed research took two months for one combat battalion. In some cases we have found voids in locations of a given unit for varying lengths of time, up to six months in one instance. There were 333 combat battalions, as well as many other support units, on duty in Vietnam from 1965 through 1971.

Question 12. It seems to me that we need to do a thorough and comprehensive search and cataloging of available DOD records, films, and reports before a feasibility study for the Epidemiology Study is undertaken. How long would such a record indexing take, and how much do you estimate it would cost?

Answer 12. There is a wide range of uncertainty in estimating the cost and length of time it will take to index records, such as those an epidemiologist desires for this kind of study using the 40,000 linear feet of Vietnam records. Any estimates would not be completely accurate because we are continuing to locate new records. There is a risk of entering more records than necessary. We know from our past experience that a highly trained researcher can probably examine one linear foot in an hour. If we were to examine the entire 40,000 linear feet collection it would take three to four man years of effort at a cost of approximately 5 to 20 million dollars for organizing the records, extracting the data, data entry and computer time. On the other hand, the cost of manually searching the records of one battalion was \$3500.00 for twenty linear feet of files. This figure was just personnel costs and did not cover locating individual names within the battalion, withdrawal of records from WNRC, xeroxing or computer time. In March 1980, the Army surveyed the cost of searching records and determining possible exposure of the total Vietnam veteran population of 2.4 million service-members. Our estimates ranged from 27 to 41 million dollars at the time. The variance was in the computer costs. The Defense Communication Agency personnel who did the estimates figured that it would take about 20 million dollars considering the worst case situation. The estimates today would be higher due to inflation.

Question 13. Can individual estimates of exposure to Agent Orange be developed from available records?

Answer 13. We believe it may be possible. We can place a unit in Ranch Hand spray areas, locate units at base camps, and fire bases which were subjected to perimeter spraying approximately every five weeks and find the same unit operating or stationed in an area where herbicides were aborted and involved with other incidents. Epidemiologists may wish to consider this element as a highly likely exposure group. We can also identify units who operated in areas of South Vietnam that were not near Ranch Hand spray missions but were exposed to perimeter spraying. These units might be categorized by epidemiologists as a moderate or low exposed group, such as troops stationed at Cam Rahn Bay who were at the most subjected to perimeter spraying.

Question 14. Do you believe available records can be used to estimate the probability that companies operated in or near sprayed areas?

Answer 14. Yes. The research involving the two combat units and the support organization demonstrated that it can be done with fair precision. Company positions were radiocoded back to battalion command posts and recorded in daily journals and situation reports. The possibility existed for errors in transmission or inaccurate recording of grid coordinates. We found gaps in the records of one battalion. By piecing together several other categories of records, we obtained troop locations for the unit over a one year period. The possibility of gaps in the records of any particular unit must be recognized, however.

Question 15A. Based on already completed records searches, do you believe you can identify units (Companies) with different probabilities of exposure?

Answer 15A. (Yes. In the case of combat battalions, letter companies operating as maneuver elements will have a greater exposure over a longer period of time than the Headquarters Company which was generally stationary. This is applicable to exposure from Ranch Hand spray missions. We know from the morning reports who was present for duty in the company unit. What we cannot determine with precision, is who was left back at the base camp during a particular operation.

Question 15B. Do you believe this is the best estimate of exposure which can be developed from available records?

Answer 15B. Yes. The battalion studies represent the best estimates of exposure.

Question 16. Have you located any unit records where the unit describes being sprayed by Ranch Hand missions?

Answer 16. Yes. We have records of the Deputy Advisor, II Corps Advisory Group, U. S. Military Assistance Command, Vietnam, which shows the 101st Airborne Division and the 1st Cavalry Division (Air Mobile) in static positions where Ranch Hand spray missions occurred. The areas involved were in the An Khe Pass and Mang Yang Valley, during combat operations in December 1965.

Question 17. In your opinion, are the HERBS tapes accurate? How have they been verified since the end of the war, as accurate measures of where and how much Agent Orange was actually sprayed?

Answer 17. Not in their entirety. We know from the National Academy of Science Study, "The Effects of Herbicides on South Vietnam," that the HERBS tape contains a 14% error rate. This may be the low boundary of error. The earliest Ranch Hand mission recorded on the HERBS tape is 4 August 1965. We have other records which indicate Ranch Hand missions between January 1962 and 1 October 1965 in the U.S. Military Assistance Command, Vietnam 202 Committee records. The earliest helicopter spray mission was recorded in June 1968 according to the HERBS tape. Our records show there were helicopter spray missions flown as early as 1961. The HERBS tapes also do not include ground spraying or other uses of Agent Orange.

Question 18. Concerning the 91 aborted missions reported in September by HHS, how many of these were on the National Academy of Science's list of 72 aborted missions already known about in 1972?

Answer 18. Of the 90 aborted missions reported by HHS, 62 were on the NAS list of aborts prepared in April 1972.

Question 19. Will these new records eventually provide transferable documented information to help develop an exposure index?

Answer 19. Yes. Identification of areas of herbicide incidents, perimeter spraying, Ranch Hand spray missions, leaks, and troop units that were in the areas will enable us to develop information about the likelihood of individual and unit exposure.

Question 20. If you could give us some information specifically on the aborted missions in the context of what would be helpful to Dr. Detels' effort to establish an exposure index it would be a step in the right direction. Are there known aborts, spills, crashes, etc., that could be documented or that are documented with a specific number of veterans who were involved in the clean-up or other aspects of direct contact that could be documented?

Answer 20. We can document 62 aborts, one major leak of 7,500 gallons and several 500 gallon leaks of Agent Orange, nine plane crashes, and a runway spill. We have not completed plotting all the abort incidents and conditions because there are gaps in the records. We are continuing to search for them. We have identified all the units at the abort sites. The statistical records indicate a troop strength at Bien Hoa, the site of several aborts, the runway spill, and several leaks at 12,000 troops. The areas where abort missions occurred with troop strengths are as follows:

Locations in <u>South Vietnam</u>	End Strength Years	
	1966	1969
Bien Hoa	12,488	12,337
Di An	16,876	9,545
Phuoc Vinh	576	9,108
Xuan Loc	116	1,721

We have not yet found the records on clean-up operations.

Question 24A. Have you previously requested funds through the Army's budget to obtain additional staff for work on the records?

Answer 24A. The reason for not requesting funds previously is because the Veterans Administration had not defined the demands which may be placed upon us. We were without any guidance as to the methodology to be employed by the VA to conduct the epidemiological study. The White House Interagency Work Group (WHIAWG) was unable to establish an exposure criteria by which selection of exposed troop populations could be made. The VA was unable to provide even a broad estimate of exposed and unexposed troop units to be located so names could be retrieved from the morning reports. In an effort to provide both the VA and the WHIAWG with as much factual information as possible, the DOD, under its own auspices, directed the Army and Marine Corps to embark on the battalion studies. In May 1980, the Army established a special Agent Orange Task Force to cope with this research effort. Three civilian spaces were allocated for the Task Force. Our task was to at least estimate for the benefit of the WHIAWG and the VA reasonable forecasts of manpower and funding resources necessary to conduct specific locational studies in relation to Ranch Hand spray missions. These studies proved the complexity of the problem. When the WHIAWG meetings indicated future epidemiological studies would indeed require full information on individual soldiers, a second phase of the study was undertaken to find the names of the soldiers in the battalions. The range of possible requirements such as the VA Epidemiological Study, the Centers for Disease Control Birth Defects Study, mortality studies, and Armed Forces Institute of Pathology Agent Orange Register and Soft Tissues Studies have not been clearly defined. Worst case estimates could lead to hiring too many people and might lead to non-productivity of employees.

Question 24B. If these requests were denied by the Army, what was the reason for denial?

Answer 24B. On 23 October 1981 the DOD requested information on the availability of resources within the Army. On 20 November 1981 the Army allocated four civilian spaces and funding for the remainder of FY82 to augment up the Agent Orange Task Force. Further, manpower officials directed that a request be submitted for approval of funds for FY83 out to cover the four spaces and that a formal request should be made to them as an out of cycle resource request for the remaining eleven civilian spaces which we estimate to be sufficient to carry out what we believe is the mission in front of us at this time.

Question 21. Is there enough evidence that can be gathered from these missions which could provide a large enough population upon which we could base the study?

Answer 21. Yes, we think so. We view the aborted mission/incidents as only one part of the overall herbicide exposure environment. The same troops exposed to the jettison may also have been exposed to Ranch Hand missions and lived in camps undergoing perimeter spraying. As pointed out in our response to the previous question, there were large complements of troops stationed at several of these jettison locations.

Question 22. What would be the time frame for adequately searching through these records to document troop locations, and do you have any suggestions as to how that can be speeded up?

Answer 22. An experienced researcher who is familiar with both the records and military organizations can examine one linear foot in about one hour. The normal records holding of a battalion in Vietnam is approximately twenty feet. There are 333 combat battalions involved plus the support elements' records or 6660 manhours. An additional 50% of these manhours might be required to record, index, and correlate troop locations with other data. By developing an exposure index model from the previous battalion studies already conducted along with the known information on the incidents/aborts, leaks, etc., we might be able to reduce the records searches to a limited number of battalions. The more researchers we are able to assign to the various collections the quicker we can locate and present the data to the epidemiologists.

Question 23A. In light of your incredibly increased workload and numerous on-going projects, do you have any reason for the lack of staff in your Agent Orange Task Force?

Answer 23A. Over the past 18 months we have received many individual requests for information and records. Although the requests were beyond the normal research workload for the regularly assigned staff, we were nonetheless able to shift personnel on a temporary basis to meet the deadlines. We were never able to document a request for more personnel over the long haul because of the uncertainty over the total numbers of personnel and troop units to be designated as a valid historical cohort group for epidemiologic study. Epidemiologists and scientists were unsure about their record needs. No one yet has come up with an acceptable epidemiological protocol with which we can work so that we will know which types of records to retrieve and research for the necessary facts concerning troop exposures.

Question 23B. Does it appear to be a "Back Burner" item for DOD? Do you have the sense of being way down the ladder when it comes to priority items in the Department of Defense?

Answer 23B. No to both questions. The direction and leadership at the DOD level exercising operational control over my activity by the medical and scientific staff has been outstanding. They have supported us fully. We are working with the principal action officer on a daily basis. Since the VA has been mandated by law to conduct the Epidemiological Study, our role is supportive and is driven to a certain degree by selective requirements placed upon us for records and information. We know generally what our record holdings are in this vast collection and have constantly made this fact known to the DOD, VA, the Agent Orange Working Group, the GAO, and many veterans groups.

Question 27A. Please explain to the committee the ways in which DOD can be of greater assistance to the VA and to the parties doing the protocol and study on Agent Orange.

Answer 27A I believe that DOD has already taken the lead role. It is my personal opinion that the progress in researching the records provided by DOD is proceeding at a faster rate than the epidemiological aspects of the issues.

Question 27B. Are there some avenues which have not been explored with respect to declassifying records or providing security clearances for people involved in the study effort?

Answer 27B. It is necessary that the investigators and consultants working under the Veterans Administration contract for epidemiologic studies of Agent Orange be cleared to handle classified documents. The agency letting the contract, in this case the VA, is responsible for obtaining a contractor's security clearance in advance. Dr. Spivey did not possess a valid clearance. On 14 May 1981, during Dr. Spivey's first visit we notified VA that he would need one. On 28 October 1981 we received his clearance. The actual clearance, of course, is done by the Office of Personnel Management through the FBI. The incidental problems to troop locations and classification and security problems, therefore can be found in any combat situation. We have had an on-going process of systematically declassifying Vietnam records as we have recalled them from the centers, where we have the authority to do so. To the extent that the various collections contain third party information such as the State Department, we had them come in to look at their records. As an example of our progress in declassifying records, over 30 linear feet of U.S. Military Assistance Command, Vietnam staff documents were declassified between the first and second visits of Dr. Spivey and his assistants. However, many documents must properly remain classified even after review. Therefore, it is essential that the agency sponsoring any contract for research take prompt action to request clearance for researchers. The matter of classified documents is a problem, but it can be dealt with.

Question 25A. What is the process by which you would request more staff, greater resources in general, more access to whatever it is you would need?

Answer 25A. I would apply to my director, and he would forward my request to the manpower officials which control the allocation of spaces and funds for the Office of The Adjutant General. That office would then request spaces and funds from Department of the Army headquarters. The final decision rests with the Office of the Deputy Chief of Staff, Personnel, and the Comptroller of the Army.

Question 25B. Is it up to DOD to provide more resources, or is there another channel by which you would request further assistance?

Answer 25B. First we must ask for spaces and funding within Army channels. If both were not available we would then go to DOD, who we believe would do their best to meet our needs.

Question 25C. It appears from my reading of Dr. Detels' protocol that it would have been helpful if there had been a basic briefing by DOD, as well as a VA briefing. Do you have any idea if such a briefing was ever contemplated and since it didn't occur this time, what plans are in the works to do such a thing in the next stage?

Answer 25C. There were many briefings given to the VA and Dr. Spivey on the volume and condition of the records as early as March 1980, culminating in three visits by the UCLA investigators on 14 May 1981, 3 June 1981, and 29-30 June 1981 to personally inspect both the locator data and Military Assistance Command, Vietnam and U.S. Army Vietnam records. Extensive documentation was provided Dr. Spivey for his personal use. We have made every effort to be cooperative and will continue to do so.

Question 26. Do you believe that there should be a formal relationship between the VA, DOD, and the person or group who has the contract for the protocol and the study?

Answer 26. Yes. A formal relationship between the VA, DOD, and other involved groups would surely expedite matters. Precise roles of each entity involved, including administration and logistical managements is needed. One possible method would be for the VA and DOD to draft a Memorandum of Understanding outlining their specific roles.

Question 7. What backgrounds should those personnel have?

Answer 7. Military background, and especially the Vietnam experience along with the basic records management skills.

Question 8. To what extent will DOD make these personnel available if requested?

Answer 8. It is our expectation that the request for the additional 11 spaces will be favorably considered. Recruiting announcements will contain the special qualifications needed so that qualified personnel can work with the combat records.

Question 9. Do the records under your control include information with respect to only Army personnel, or do they also include information with respect to personnel in the other Services?

Answer 9. We have records which include information about the Air Force, Navy, and Marine Corps. These records are found in the Joint Military Command, the U.S. Military Assistance Command, Vietnam collection. The Department of the Army is the Executive Agent for this category of records.

Question 10. On page 2 of your statement, you referred to "Agent Orange related records". Do these records include all records relating to ground troop movements and location, as well as records of chemical units and aerial spraying information?

Answer 10. Yes sir. By Agent Orange related records I meant all types of herbicide spraying operations, storage, dispensing, Combat Operation Reports, research and development, evaluation reports, and incident reports as well as troop movements, and any records leading to possible exposure. We have records on 23 Army Chemical Units that operated in South Vietnam.

Question 11. What additional records are you aware of that could contain information on other possibly hazardous agents or substances that troops in Vietnam would have been likely to have been exposed to, such as other herbicides and defoliants, malaria-preventive medication, and insecticides?

Answer 11. During our search for Agent Orange records we uncovered records on all the other types of herbicides used in aerial spraying, ground spraying, riverine force spraying and truck and hand spraying. This information is contained in unit daily journals and operational reports, and must be extracted from all of the other information which they contain. There are records of troop use of Chloroquine-Primaquine, Dapsone; insect repellants such as Deet, insecticides Malathion and Diazinon, and the riot control chemicals (CS and CS Persistent) in this vast collection. However, we do not have any information on computer tapes as we do in the HERBS tape. To date, we have not yet embarked on a special research effort to gather the data on the other chemicals, insecticides, and medications. We can begin such a project if this is desired once staffing is complete. Other herbicides such as Dinoxol, Trioxol, Purple, Pink, Green, and Pink and Green mixtures were used in defoliation operations from 1961 to 1965. After 1965, Orange replaced Purple as the Purple stocks were depleted. White and Blue were used extensively after 1965, and are reported on the HERBS tapes.

RESPONSE OF THE DEPARTMENT OF DEFENSE TO WRITTEN QUESTIONS SUBMITTED
BY HON. ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE
COMMITTEE ON VETERANS' AFFAIRS

Question 1. You stated in your testimony that you have a full time staff of three. Is this the staff of the Agent Orange Task Force in the Office of The Adjutant General, Department of the Army?

Answer 1. Yes. The full time staff is an integral part of a branch of the Records Management Division, Directorate of Administrative Management, Office of the Adjutant General.

Question 2. When was this task force first established?

Answer 2. The Army Agent Orange Task Force was formed on 21 May 1980. We were informed that the Defense Department would issue instructions to conduct detailed research into combat battalions records at that time. Further, it was expected that more extensive research efforts would most likely evolve, which later proved to be the case.

Question 3. Did you receive any additional staff when the VA's contractor began an examination of the military records for use in designing the protocol?

Answer 3. No sir. We learned on 6 May 1981, that the VA contract for the protocol for the Epidemiologic Studies of Agent Orange was awarded to UCLA. Further, that UCLA investigators would be visiting us shortly. We then began preparing to receive the investigators by gathering all available records for their use.

Question 4. Will you receive any additional staff in the future?

Answer 4. Yes. Four civilian spaces and funding were provided by the Army on 20 November 1981. We are now drafting a request for an additional 11 civilian spaces for researchers to support the Epidemiologic Studies.

Question 5. To what extent did your staff assist the contractor?

Answer 5. Three meetings were held on 14 May 1981, 3 June 1981, and 29-30 June 1981. We provided the UCLA investigators with detailed briefings on our ground troop studies and a thorough explanation of the Army's Vietnam records collection. We also provided copies of our combat battalion studies, NIS Gazetteer of South Vietnam, Defense Information Center Bibliographies (Herbicides, Drug Use In Vietnam, and Antipersonnel Agents In Vietnam), and large maps of Vietnam. We gave the investigators detailed military organizational background information including the staffing, missions, and functions of battalions, brigades, and divisions.

Question 6. What is the maximum number of personnel that could be used in an effective manner to expedite the records search process?

Answer 6. We believe that the total of eighteen civilian records experts and researchers can accomplish the job of retrieving, evaluating, organizing, and researching the data in support of the Epidemiological Studies.

ARMY AGENT ORANGE TASK FORCE
Proposed Personnel Requirements

TEAM A:

25 Bn studies at 500 manhours each	12,500	manhours
RCPAC 201 file search (four per hour, pull, review, refile)	3,000	" "
Data entry, 1 man-year	2,080	" "
Perimeter spray data	4,160	" "

TEAM B:

10 Bn studies at 500 manhours each	5,000	manhours
RCPAC 201 file search (four per hour, pull, review, refile)	3,000	" "
Data entry, 1 man-year	2,080	" "

TEAM C:

Research	1,040	manhours
RCPAC 201 file search (four per hour, pull, review, refile)	3,000	" "
Data entry, 1/2 man-year	1,040	" "

TEAM D:

CDC Birth Defects Study (2-3,000 names, multi-Bn studies)	5,000	manhours
VA Agent Orange Registry (12,000 names)	3,000	" "
Chemical unit personnel	1,080	" "
Women in Vietnam	240	" "
Various other diseases	2,080	" "
Admin Support	6,240	" "
FOIA/PA requests		
Correspondence review		
Briefing preparation		
Testimony preparation		
Coordination of Teams A, B, and C		
VA Mortality Study "Pilot"		

TOTAL	54,540	Manhours
	26.14	Man-years

RESPONSE OF THE DEPARTMENT OF THE ARMY TO ADDITIONAL WRITTEN FOLLOW-UP QUESTIONS
 SUBMITTED BY HON. ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE
 ON VETERANS' AFFAIRS

Question 1. On the first page of your responses, in answer to my question regarding "the maximum number of personnel that could be used in an effective manner to expedite the records search process", you stated your belief "that the total of eighteen civilian experts and researchers can accomplish the job" in support of the epidemiological studies. Although I appreciate that information, I continue to be concerned that the government should not be sparing in its efforts to resolve the Agent Orange issue. Thus, I would like to know if eighteen is the maximum number of personnel that could be used in an effective manner to expedite the records search process or whether, without reference to current funding, staffing, or space restrictions, more personnel could be used and, if so, what is that number?

Answer 1. My estimate of the eighteen researchers was based on a timeframe proposed by Dr. Spivey of UCLA in his initial protocol. Dr. Spivey envisioned that the contractor would accomplish the abstracting of the information from the military records. Since that time, Dr. Spivey has revised his protocol to suggest that the Army accomplish the retrieval, screening, and abstracting of the combat troop locations and personnel information. I believe that the maximum number of researchers and records experts that can effectively accomplish this task to be 27. We have developed extensive milestones for the records search, culminating in computerization of the final product. In addition to the civilian spaces already provided to me by the Army, two part time employees working with us have now been assigned to the Agent Orange Task Force. They will be utilized to cope with the mounting workload, and have become part of the planned study groups. The additional personnel requested will speed up the research and includes an epidemiologist and computer experts in support of the mission. The nucleus of the Army Agent Orange Task Force for the cohort group studies is already in place and we are prepared to begin work on the research when the protocol is finalized. The Army has taken action to fund the personnel resources and DOD has responded to past office space requests. I have every reason to believe that future space requests will be honored as we move to add more personnel and call in the vast quantities of records involved.

Question 2. On the final page of your responses, in answer to my question about the existence of additional records "that could contain information on other possibly hazardous agents or substances", you mentioned a number of other substances as to which you "do not have any information on computer tapes". You then mentioned other herbicides that were used in Vietnam including "Dinoxol, Trioxol, Purple, Pink, Green, and Pink and Green mixtures". Are data regarding the use of these defoliants on the HERBS tapes?

Answer 2. No sir. We are not aware of any other computerization as to the use and dissemination of these agents.

-2-

- Any suggestions the Working Group might have for other governmental action, including Congressional action, to help resolve the many difficult issues entailed in its mission.

At present, we anticipate at least one day of oversight hearings on the Agent Orange issue -- scheduled for November 18 -- and would appreciate having a representative from the Working Group appear at that hearing. We will be in touch with you with specific details regarding this hearing in the near future.

With warm regards,

Sincerely,

Alan K. Simpson
Chairman

Alan Cranston
Ranking Minority Member

ALAN E. SIMPSON, WYO., CHAIRMAN
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THOMAS E. HARVEY
 CHIEF CLERK AND STAFF DIRECTOR

United States Senate

COMMITTEE ON VETERANS' AFFAIRS
 WASHINGTON, D.C. 20510

November 2, 1981

Honorable Richard S. Schweiker
 Secretary of Health and Human
 Services
 Washington, D.C. 20201

Dear Dick,

We are writing to express our great satisfaction with the Administration's actions to reconstitute the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (IAG) as the Agent Orange Working Group, to raise the group's status to Cabinet Council level, and to expand its membership.

Through its efforts during the 96th Congress, the IAG, and particularly its Science Panel, developed a reputation, both inside and outside of government, as an objective, highly qualified body. We view such a group as the IAG and now the Agent Orange Working Group as absolutely critical to the Federal Government's efforts to resolve the many complex issues surrounding the controversy over the health effects of the use of Agent Orange and other herbicides in Vietnam. Thus, we are pleased that the Administration has recognized the importance of the group and look forward to maintaining and strengthening the relationship between our Committee and the Working Group during this Congress.

In this regard, we would like to recommend that the Working Group give priority consideration to the following matters:

- A comprehensive update of the IAG's cataloguing of government-wide efforts relating to dioxin, including those of the Agriculture Department, the National Institute of Occupational Safety and Health, and the Environmental Protection Agency.
- An evaluation of ongoing and planned efforts by the Department of Defense and the Veterans' Administration to determine where and how Agent Orange was used in Vietnam and which U.S. service personnel might have been exposed to it while serving there, together with any suggestions on how to speed up or otherwise improve these efforts.
- An evaluation of DoD and VA's ongoing and planned efforts to determine the health effects on U.S. service personnel of exposure to Agent Orange, again with any suggestions for speeding up or otherwise improving these efforts.

Chairman SIMPSON. Robert Peterson, the Senior Associate Director of the General Accounting Office, accompanied by James Linz, Senior Evaluator, and John Hansen, Senior Evaluator.

I would indicate again to the previous witnesses, we will have further questions of various members of the Senate panel. We will get those to you as soon as possible.

TESTIMONY OF ROBERT A. PETERSON, SENIOR ASSOCIATE DIRECTOR, HUMAN RESOURCES DIVISION, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY JAMES LINZ AND JOHN HANSEN, SENIOR EVALUATORS

Mr. PETERSON. Thank you, Mr. Chairman.

Mr. Chairman and members of the committee, we are pleased to be here today to discuss our concerns about the draft protocol for epidemiological studies of veterans exposed to agent orange and the need to expand the study to determine whether service in Vietnam, rather than solely exposure to agent orange, may have adversely affected the health of Vietnam veterans.

We believe expansion of the epidemiological study would eliminate the need for the costly and time consuming feasibility study and at the same time eliminate the need for future studies on the health effects of other chemicals used in Vietnam.

The draft protocol lacks adequate details on the feasibility study to determine whether exposure indexes, sufficiently accurate for the proposed historical cohort study, can be developed. However, previous record searches similar to the one proposed for the feasibility study have proven to be costly and time consuming with only limited results.

While it is possible to determine that personnel were in or near sprayed areas by comparing ground troop locations with herbicides spraying missions, it is difficult to make estimates on the nature and extent of the exposure.

The problems encountered by the Army and Marine Corps in gathering this information raises serious questions about the reliability of military records and the potential of the proposed feasibility study to establish individual exposure indexes.

Not only may the feasibility study have difficulty in measuring troop exposure to agent orange, but the records search and analysis necessary to complete the study would be costly and time consuming. The difficulty in documenting agent orange exposure was a major reason the agent orange work group recommended that large-scale epidemiological studies should focus on determining if service in Vietnam rather than solely exposure to agent orange may have placed Vietnam veterans at a higher risk of suffering certain health problems.

The National Academy of Sciences has stated that it would be impossible to execute any scientifically valid study of the health of Vietnam veterans exposed to agent orange in the absence of information about the mortality of veterans. The UCLA researchers proposed using VA's beneficiary identification and records locator subsystem [BIRLS] to identify deceased Vietnam veterans to determine if there is an unusual cause of death or pattern of causes of death.



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Honorable Alan Cranston
United States Senate
Washington, D.C. 20510

Dear Senator Cranston: *Alan:*

Thank you for your warm letter on behalf of the Senate Veterans' Affairs Committee. I appreciate your support of the Administration's actions in reconstituting the Interagency Work Group to study the Possible Long Term Health Effects of Phenoxy Herbicides and Contaminants as the Agent Orange Working Group and in raising the Group's status to Cabinet Council level.

I am honored that President Reagan has entrusted me with the lead in this combined Federal effort. Moreover, I am heartened at the level of support from the increased membership which includes the Congress' Office of Technology Assessment as an observer.

I note your recommendations for the Working Group's priority consideration. The Working Group discussed these important recommendations during the November 12 meeting and has begun appropriate action.

As you know, James S. Stockdale, whom I have appointed Chair of the Agent Orange Working Group, and Dr. Vernon Houk, Chair of the Working Group Science Panel, also addressed these issues during their November 18 testimony before your Committee.

Again, thank you for your kind words. You have my assurance that the President and I are committed to working with you in the search for answers to the critical questions that have arisen as a result of the use of Agent Orange in Vietnam.

Sincerely,

Richard S. Schweiker
Secretary

PREPARED STATEMENT OF ROBERT A. PETERSON, SENIOR ASSOCIATE DIRECTOR,
HUMAN RESOURCES DIVISION, GENERAL ACCOUNTING OFFICE

Mr. Chairman and Members of the Committee, we are pleased to be here today to discuss

--the draft protocol for epidemiological studies of veterans exposed to Agent Orange, and

--the need to expand the study to determine whether service in Vietnam, rather than solely exposure to Agent Orange, may have adversely affected the health of Vietnam veterans.

Based on our prior work with military unit records to determine the proximity of ground troops to areas sprayed with Agent Orange, other VA data bases proposed for use in the study, and our work on the potential adverse affects of Agent Blue and other pesticides used in Vietnam, we believe

--the proposed feasibility study to determine troop exposures would be costly with no guarantee that it would identify a population of ground troops with measurable exposure and would delay the start of the epidemiology study,

Although we have not evaluated the completeness of BIRLS for death certificates, a previous audit has shown that BIRLS may not be updated regularly. The reliability of BIRLS must be considered in determining the usefulness of this data base for the proposed mortality studies.

The draft protocol proposed using VA's agent orange registry as a basis for morbidity studies, comparing the health problems claimed by veterans with their recollection of exposure to agent orange. However, the registry was not intended to be used for epidemiological purposes. Rather, it was established to provide general information about the health status of veterans concerned about agent orange who presented themselves at VA medical facilities.

Also, VA has identified problems with the registry's accuracy and reliability. First, the veterans included in the registry are a self-selected sample and may not be representative of Vietnam veterans exposed to agent orange. Second, many veterans could not specify the number of times they were exposed to agent orange, making it difficult to correlate exposure with health problems. Third, VA's Inspector General concluded that the integrity of the data in the registry was questionable.

Veterans who served in Vietnam may have been exposed not only to agent orange but to agent blue and other toxic chemicals. Agent blue, or cacodylic acid, was used in Vietnam primarily for crop destruction, defoliation, and control of grasses around the perimeters of base camps. Agent blue's use on grasses surrounding base camp perimeters increases the probability that troops were exposed.

Although cacodylic acid is an organic arsenic compound, some studies have indicated that it may be transformed into cancer-causing inorganic arsenic compounds in the environment. Other pesticides which may have been used in Vietnam around base camps have caused cancer in laboratory animals.

Public Law 97-72 authorizes, but does not require, VA to expand the epidemiological study to determine whether service in Vietnam, rather than solely exposure to agent orange, may have adversely affected the health of Vietnam veterans. A study focusing on agent orange will only answer veterans' questions about one possible cause of their health problems.

If such a study finds no adverse effects from exposure to agent orange, additional studies may be needed to determine whether other factors related to Vietnam service may have caused health problems.

In the past we have supported an expanded study. Such a study could provide information on the general health of those most likely to have been affected by pesticides, which would be valuable to VA and others concerned with determining if there is a basic health problem among personnel who served in Vietnam. We continue to hold this view.

Mr. Chairman, this concludes my summary. We will be happy to respond to any questions you may have.

Chairman SIMPSON. Thank you very much.

[The prepared statement of Robert A. Peterson, Senior Associate Director, Human Resources Division, General Accounting Office, follows:]

The draft protocol includes four proposed studies. First, a feasibility study to determine whether exposure can be accurately estimated from military records. Next, the results of this study will be used to select populations for a historical cohort study. In this type of study, the exposed and nonexposed populations are followed to observe disease outcome.

Third, mortality studies to determine whether there is an unusual cause or causes of death among Vietnam veterans.

Finally, morbidity studies to determine whether Vietnam veterans are experiencing an unusual pattern of diseases or health problems.

FEASIBILITY STUDY TO ESTIMATE EXPOSURE

The draft protocol lacks adequate details on the feasibility study to determine whether exposure indexes, sufficiently accurate for the proposed historical cohort study, can be developed. Without additional details on the criteria to be used in developing these indexes, it is difficult to judge the likelihood that the study will succeed. However, previous records searches, similar to the one proposed for the feasibility study, have proven to be costly and time consuming with only limited results.

While it is possible to determine that personnel were in or near sprayed areas by comparing ground troop locations with herbicide spraying missions, it is difficult to develop estimates on the nature and extent of the exposure. For example, the Army and the Marine Corps have been able to determine the proximity of companies to sprayed areas, however, the exact location

--the data bases the UCLA researchers propose using for the mortality and morbidity studies may contain inadequate or inaccurate information which could limit the usefulness of these studies, and

--there are serious questions about the possible adverse affects of exposure to Agent Blue and other chemicals used in Vietnam.

Expansion of the epidemiological study to determine whether service in Vietnam, rather than solely exposure to Agent Orange, may have adversely affected the health of Vietnam veterans would eliminate the need for the costly and time-consuming feasibility study and, at the same time eliminate the need for future studies on the health effects of Agent Blue and other chemicals used in Vietnam.

ORIGIN OF STUDY

Public Law 96-151 directed the Veterans Administration (VA) to design and conduct an epidemiological study of the long-term health effects of exposure to Agent Orange on Vietnam veterans. On May 1, 1981, VA awarded a contract to researchers from UCLA to design the study protocol. The researchers submitted a draft protocol to VA on August 6, 1981, which was sent for peer review to the Office of Technology Assessment (OTA), the Agent Orange Work Group, and others. Comments submitted to VA will be forwarded to the UCLA researchers who have 30 days in which to revise the protocol. The revised protocol may undergo additional peer reviews once completed.

While our evaluation of BIRLS focused only on eligibility determinations and not on death certificates, we believe it raises questions about the reliability of BIRLS which must be considered in determining the usefulness of this data base for the proposed mortality studies.

Recent congressional actions limiting eligibility for VA's burial allowance may also affect the usefulness of BIRLS in assessing the health status of veterans. The National Academy of Sciences informed both the House and Senate Veterans Affairs Committees that restrictions on eligibility for burial allowances may reduce the reporting of veteran deaths which will seriously impair the value of BIRLS as a source of information about veterans' health.

MORBIDITY STUDIES

The draft protocol proposed using VA's Agent Orange registry as a basis for morbidity studies comparing the health problems claimed by veterans with their recollection of exposure to Agent Orange. However, the registry was not intended to be used for epidemiological purposes. Rather, it was established to provide general information about the health status of veterans concerned about Agent Orange who presented themselves at VA medical facilities. Also, VA has identified problems with the registry's accuracy and reliability.

VA has identified several problems with the Agent Orange registry which would seriously affect its usefulness for research purposes. First, the veterans included in the registry are a self-selected sample and may not be representative of Vietnam

be impossible to execute any scientifically valid study of the health of Vietnam veterans exposed to Agent Orange in the absence of information about the mortality of veterans. The UCLA researchers proposed using VA's Beneficiary Identification and Records Locator Subsystem (BIRLS) to identify deceased Vietnam veterans for mortality studies to determine if there is an unusual cause of death or a pattern of causes of death among Vietnam veterans. The draft protocol notes that VA and the National Academy of Sciences have estimated the completeness of the BIRLS file for death certificates at better than 95 percent. However, this estimate is based on a 1973 survey of VA's Master Index, the predecessor of BIRLS, and no study has since been made of BIRLS completeness for death certificates. The National Academy of Sciences is currently planning a new study.

Although we have not evaluated the completeness of BIRLS for death certificates, BIRLS may not be updated regularly. In our report "Cost of VA Medical Care to Ineligible Persons is High and Difficult to Recover" (HRD-81-77, July 2, 1981), we noted that BIRLS records

- were not always created when veterans are discharged from the service,
- could indicate that a veteran has no record when actually VA has full information on the veteran, and
- could have been updated incorrectly or mistakes could have been made in creating the record.

Not only may the feasibility study have difficulty in measuring troop exposure to Agent Orange, but the records search and analysis necessary to complete the study would be costly and time consuming. In our November 16, 1979, report entitled "U.S. Ground Troops In South Vietnam Were In Areas Sprayed With Herbicide Orange" (FPCD-80-23), we noted that Army records from the Vietnam conflict are neither complete nor well organized because of the rapid pullout from Vietnam. Recent work performed by the Army for the Work Group demonstrated this problem. The Army's records search for the location of companies in one combat battalion during a 1 year period took 2 months, 265 staff hours, and cost about \$3,500 not including computer time or the cost of locating the approximately 2,400 personnel who were assigned to the unit during the 12-month period. Performing the same analysis for the approximately 330 Army combat battalions in Vietnam could cost over \$1.1 million. Also, it took almost 2 months to identify Army chemical units who operated in Vietnam and locate the records for these units.

Because of the difficulties in conducting the type of records search proposed for the feasibility study, we believe the epidemiology study should make maximum use of the information the Army has already compiled for the Work Group. The draft protocol does not mention whether previous Army records searches will be used in an epidemiological study.

MORTALITY STUDIES

The National Academy of Sciences has stated that it will

of individuals assigned to these companies cannot be determined from military records. Also, companies may have reported numerous locations, only a general location, or no location on a given day. The problems encountered by the Army and the Marine Corps in gathering this information raise serious questions about the reliability of military records and the potential of the proposed feasibility study to establish individual exposure indexes.

In their August 1, 1980, progress report, the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (now the Agent Orange Work Group) noted the difficulties in developing a population with definable Agent Orange exposure which could be used for epidemiological study. Again, in their April 24, 1981, progress report, the Work Group noted that while Department of Defense (DOD) records searches were able to determine that certain units operated in proximity to areas sprayed with Agent Orange, they were not able to identify individuals or units whose exposure could be reliably documented. The Work Group concluded that ". . . a study based on no more than presumed exposure could represent such a serious flaw in scientific design as to be of questionable validity." The difficulty in documenting Agent Orange exposure was a major reason the Work Group recommended that large scale epidemiology studies should focus on determining if service in Vietnam, rather than solely exposure to Agent Orange, may have placed Vietnam veterans at a higher risk of suffering certain health problems.

Other pesticides which may have been used in Vietnam for insect or rodent control around base camps have now been banned from some or all uses in the United States because of adverse health effects reported in animal testing. These pesticides include DDT, chlordane, dieldrin, lindane, and mirex, all of which have been found to cause cancer in laboratory animals.

While the draft protocol mentions the possibility that exposure to other chemicals may confound the results of the proposed study, it assumes that these exposures are equally distributed among similar military units. The researchers will attempt to measure these exposures during the feasibility study. However, records do not adequately document uses of non-tactical pesticides and base camp perimeter spraying of herbicides. As a result, it is unlikely that the proposed study can determine the nature and extent of exposure to other chemicals used in Vietnam.

VA'S STUDY SHOULD
BE EXPANDED

Public Law 97-72 authorizes, but does not require VA to expand the epidemiology study to determine whether service in Vietnam, rather than solely Agent Orange, may have adversely affected the health of Vietnam veterans. This law was enacted because of concerns that other factors related to service in Vietnam may be responsible for health problems being experienced by Vietnam veterans. An epidemiology study focusing on Agent Orange will only answer veterans' questions about one possible cause of their health problems. If such a study finds no adverse affects from exposure to Agent Orange, additional studies may be needed to determine whether other factors related to

veterans exposed to Agent Orange. Second, many veterans included in the registry could not specify the number of times they were exposed to Agent Orange making it difficult to correlate exposure with health problems. Third, VA's Inspector General concluded that the value and integrity of the data in the registry was questionable because poorly designed data collection sheets caused keypunching errors, and there are no controls to prevent duplicate records from entering the registry. As a result, the registry contains inaccurate and unreliable data.

OTHER CHEMICALS
USED IN VIETNAM

Veterans who served in Vietnam may have been exposed not only to Agent Orange, but to Agent Blue and other toxic chemicals.

Agent Blue or cacodylic acid was an organic arsenic-based herbicide used in Vietnam primarily for crop destruction, defoliation, and control of grasses around the perimeters of base camps. Estimates of the amount of Agent Blue used in Vietnam range from 1.1 million to 2.2 million gallons. While it is difficult to determine the number of personnel possibly exposed to Agent Blue, this herbicide's use on grasses surrounding base camp perimeters increases the possibility that troops were exposed.

According to the International Agency for Research on Cancer of the World Health Organization inorganic arsenic compounds cause skin and lung cancer in humans. Although cacodylic acid is an organic arsenic compound, some studies have indicated that it may be transformed into inorganic arsenic compounds in the environment.

Serious questions about the reliability of military records for developing individual estimates of exposure to Agent Orange and determining exposure to other chemicals used in Vietnam will make it difficult to determine whether exposure solely to Agent Orange can cause health problems. By expanding the epidemiology study to evaluate the effects of service in Vietnam on veterans health, VA could eliminate the need for costly and time-consuming additional studies of the effects of other factors present in Vietnam. This approach would also alleviate the two most serious problems the UCLA researchers have identified in their proposed study, those of developing individual exposure estimates and assessing the impact of confounding factors, such as exposure to other chemicals.

We continue to believe that scientific study of personnel who served in Vietnam would be most valuable to VA and others in determining if veterans who served in Vietnam are experiencing health problems resulting from their service.

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Mr. Chairman, this concludes our statement. We will be happy to respond to any questions you or other Members of the Committee may have.

Vietnam service may have caused health problems. As a result, a series of studies taking many years to complete may be necessary to determine whether service in Vietnam caused health problems. In a May 27, 1981, letter to the Chairman, Subcommittee on Hospitals and Health Care, House Committee on Veterans' Affairs, we supported expansion of the epidemiology study because it is consistent with the recommendation in our April 6, 1979, report entitled "Health Effects of Exposure to Herbicide Orange in South Vietnam Should Be Resolved" (CED-79-22) that the long-term health effects on military personnel of exposure to herbicides, including Agent Orange, in Vietnam be studied. Such a study could provide information on the general health of those most likely to have been affected by herbicides which would be valuable to VA and others concerned with determining if there is a basic health problem among personnel who served in Vietnam.

The UCLA researchers believe that an expanded study to determine the effect of service in Vietnam on veterans health, while possible, would not be useful because it would not identify the factors associated with diseases nor would it determine which of those serving in Vietnam were most likely to have been effected. However, VA has stated that it is not necessary to show the cause of a disability to award compensation, but only to show that the disability occurred or was aggravated during a veteran's military service. Also, since VA concedes that a veteran who served in Vietnam was exposed to herbicides it is not necessary to determine which veterans were effected.

We really haven't analyzed the cause of this, but it is certainly going to be a factor in trying to determine whether or not the health complaints that veterans are lodging with the VA correlate in any way with their recollection of their exposure.

Chairman SIMPSON. There is the problem. The Agent Orange Working Group, as well as other parties, have not yet been able to establish a mechanism for documenting exposure of individual veterans, even self-selected. How is it ever going to be possible to distinguish companies or divisions and their locations, eventually developing some more general type of exposure index?

Mr. PETERSON. We have, in the past, done similar studies as UCLA proposed in tracking over time troop locations as compared to spraying missions. And you can to some degree assess the probability that units were in areas where they were likely to have been exposed.

The individual soldier, or marine, when he presented himself to VA as part of the agent orange registry was unable in something like 54 percent of the cases to specify whether he had been exposed more than once, more than twice, more than three times. And I am not sure that problem is ever going to be satisfactorily resolved.

Chairman SIMPSON. I have used all of my time. We have a roll-call vote at the present time, in which one vote counts for nine. I am not going to miss that one.

Senator Murkowski will be back here at noon. We will recess for 10 minutes. Have you voted, Senator SPECTER?

Senator SPECTER. No.

Chairman SIMPSON. No, and if you think I am going to miss that one, too, I'll join you.

We will take up again at noon. Senator Murkowski will handle the hearing. We will have to leave this room at 1 o'clock. I don't know how much longer we will require, but we will continue after 1 o'clock, giving us about 20 or 30 minutes to reset for the remaining part of the agenda. We will be back in the Veterans' Affairs Committee room, in room 412. That will take place at about 1:30 and I will be back at that time to conclude the hearing. I have a classified briefing at 2 o'clock that I must attend, but we will have gone significantly into the agenda by that time.

I thank you so much. There will be further questions submitted by various members of the panel. Thank you for your very effective testimony.

Mr. PETERSON. Thank you, sir.

[Whereupon, a recess was taken.]

[Hearing resumed.]

Senator SPECTER [presiding]. Senator Murkowski, who is scheduled to preside, will be along momentarily. We regret the interruption occasioned by the vote that Senator Simpson and I left on and a succeeding vote. And until Senator Murkowski returns, there are a few questions which I would like to ask of Mr. Peterson.

Mr. Peterson still with us?

Well, Senator Simpson may have been through. [Laughter.]

Well, would you mind returning and I have a couple of questions? The other panel should keep their seats. There is no reason to go back.

Chairman SIMPSON. How much would a feasibility study, such as you describe in your testimony, cost if it were be expanded to general service in Vietnam, as compared to one based solely on exposure to agent orange? Would a broader feasibility study encounter the same problems that Dr. Spivey and other groups have had concerning proposing a feasibility study for exposure to agent orange? Could you give me your thoughts on that?

Mr. PETERSON. Yes, sir. I think what we are proposing is that the feasibility study as proposed by UCLA not be performed and that we go into an expanded study right away. We have very serious reservations about the ability, given the condition of the military records, to establish individual exposures indexes. We have had firsthand working knowledge of those records and have found it very, very difficult to establish locations of units, no less individuals in those units.

A feasibility study, if I heard the testimony correctly this morning, will take about 14 months to complete the exposure indexes. There may be some argument as to whether or not an expanded study would take more time, but I think the kind of study we are talking about would not require that exposure indexes be developed for each chemical, but rather service in Vietnam be considered the triggering mechanism that we would test against.

Chairman SIMPSON. But as you see, it is an extraordinary task to deal with the available records in their present form. Is that correct?

Mr. PETERSON. That's exactly correct; yes, sir.

Chairman SIMPSON. How would you best describe the present situation without using the word "mess"?

Mr. PETERSON. Well, in earlier studies that we did, we tried to work with company level records and found that extremely difficult. The Army records were, indeed, in a poor state. We were able to work with Marine battalion records more effectively in the previous reports that we have issued.

When you get down below the company level as to where individual soldiers or marines may have been located, we have very serious doubts as to whether or not that can ever be done.

Chairman SIMPSON. Having been a battalion leader at one time, I can assure you that you will never find that out. [Laughter.]

Can you suggest any methods by which the agent orange registry can be effectively utilized for compiling examples of the health effects of agent orange?

Mr. PETERSON. Well, I am not convinced that it can't be of some use. I think that the fact that it is a self-selected sample has to be taken into account by anybody who is going to design a study. And in our view, the UCLA protocol did not adequately address those concerns about self-selection.

John, would you like to?

Mr. HANSEN. I think I might also add, Mr. Chairman, that there is somewhat of a problem in the data the agent orange registry has gathered about each individual's recollection of their exposure to agent orange. In fact, better than half of the individuals that have been examined as of the end of August of this year were not able to specify their exposure.

Senator SPECTER. And are the records available from those units to provide the basis for coming to the conclusion on the cause and effect issue?

Mr. HANSEN. Well, you are getting into an epidemiological area there, Senator, that I am not sure I am qualified to speak to.

Senator SPECTER. Well, what does it boil down to? You talk about an epidemiological area, you are—

Mr. HANSEN. I think those units can be studied.

Senator SPECTER. Excuse me, I haven't finished the question.

Mr. HANSEN. I'm sorry.

Senator SPECTER. When you are talking about an epidemiological area, you are qualified to say that their base is inadequate, but you don't have qualifications to say what is adequate as a study base?

Mr. HANSEN. Well, we are talking about adequate from an epidemiological standpoint and what—

Senator SPECTER. What's your basis for saying it's inadequate?

Mr. HANSEN. The basis for saying it is inadequate is that based on our review we do not feel that military troop records can be used to establish individual exposure estimates.

Senator SPECTER. What can be used to establish individual—

Mr. HANSEN. Estimates can—

Senator SPECTER. Wait, wait a minute, you have to let me finish the question. What can be used to establish the individual troop unit basis?

Mr. HANSEN. You can look at units as opposed to individuals and determine the units' proximity to sprayed areas. You would have to assume that all individuals who are assigned to that unit were, in fact, together at one particular location.

Senator SPECTER. Mr. Hansen, what I am trying to get to is can we have a study? Do we know how to make a study to come to these conclusions?

Mr. HANSEN. I am not sure I understand your question, Senator. We can study—

Senator SPECTER. Well, let me begin at the beginning. We would like to know whether agent orange causes cancer, rashes and birth defects. Now, a suggested study has been proposed and GAO has come in and told us a lot of reasons why the proposal is inadequate. And I want to know how do we move toward a study which will answer the question I just posed.

Mr. HANSEN. Senator, I am going to have to supply that for the record for you because I have tried to explain what our concerns were with regards to the military records and what uses could be made of those records.

We think that some uses can be made of those records for epidemiological study. We are not epidemiologists and I can't tell you specifically how you would proceed with an epidemiological study of those units. However, we think that they present some real possibility for study.

Senator SPECTER. You don't have to be an epidemiologist in order to criticize the UCLA study?

Mr. HANSEN. We criticized the data bases that UCLA proposed using. We pointed out some problems inherent in those data bases which needed to be considered in determining whether or not the

As I said a moment ago, Senator Murkowski will carry on the hearing.

Frank, I have a couple of outstanding questions on the GAO panel which I would like to ask at this time.

Senator MURKOWSKI [presiding]. Please proceed. We will call the hearing back to order and I apologize for the time that it took to get back. Please go ahead.

Senator SPECTER. Let's see. Who is here now from GAO? Will you please step forward? What is your name, sir?

Mr. HANSEN. My name is John Hansen.

Senator SPECTER. Mr. Hansen, on the basis of the testimony which Mr. Peterson had given, I have just a few questions and perhaps you are in a position to answer them.

In concluding that the UCLA study was not adequate, what recommendation does the GAO have for a study which would be adequate to establish whether agent orange has caused the series of problems, birth defects, cancers, rashes, tumors, et cetera?

Mr. HANSEN. We looked at sections of the protocol which discussed the use of certain data bases and records with which we were familiar. We are not epidemiologists. We did not review the protocol from an epidemiological standpoint, only as it pertained to the troop location records and to some of the VA data bases they proposed using. We pointed out some of the shortcomings in using those data bases and factors which need to be considered in deciding whether or not they are adequate for use in trying to determine the nature of the veterans health problems.

Senator SPECTER. Well, you concluded that the protocol and projected study was inadequate, correct?

Mr. HANSEN. We concluded that there were problems in using the three data bases that we talked about. We did not present any overall conclusion on the draft protocol. We did note that the protocol lacked adequate details, as have other reviewers.

Senator SPECTER. What is the answer to the problems that you have raised?

Mr. HANSEN. Well, as applying to the feasibility study, for example?

Senator SPECTER. Yes.

Mr. HANSEN. We have spent a good deal of time looking at the military unit records. We have worked closely with Mr. Christian, with members of the Agent Orange Work Group, and with the Department of Defense. There are indices which can be developed to look at exposure questions. They can put units in proximity to sprayed areas.

Senator SPECTER. Well, the concern I have is I understand the criticism which you have stated. But do you have a suggestion as to how the data base can be expanded or corrective action can be taken on the items which you have raised which would then enable us to go forward with an appropriate study?

Mr. HANSEN. I think that there are a number of units which have been identified as being in close proximity to sprayed areas which could be used as populations for epidemiological study. These are not units which you could provide an individual exposure estimate on each person who served in those units, but we certainly know that they were in or near sprayed areas.

Senator SPECTER. Thank you very much, Mr. Hansen. Thank you very much, Mr. Chairman.

[Subsequently, the General Accounting Office submitted the following information:]

The lack of information available on the disabilities that may be caused by exposure to phenoxy herbicides contaminated by dioxins makes it difficult to develop realistic estimates of the cost of paying disability benefits to exposed Vietnam veterans.

VA has developed a cost estimate for H.R. 6377, a bill to amend section 312 of title 38, United States Code, to provide a presumption of service connection for compensation and dependency and indemnity compensation benefits for Vietnam veterans, or their survivors, presumed to have disabilities relating to agent orange exposure. The bill also provided compensation for children suffering birth defects resulting from one of the child's parents being exposed to agent orange.

VA estimated the cost of paying benefits under this bill for fiscal years 1981 through 1985 at more than \$7 billion. The administrative cost to VA of handling these benefits was estimated at over \$13 million.

Although we have not evaluated the methodology VA used in developing these estimates, they are the only available estimates of which we are aware.

[The responses of the General Accounting Office to written questions submitted by Hon. Alan K. Simpson, chairman of the Senate Committee on Veterans' Affairs and Hon. Alan Cranston, ranking minority member of the Senate Committee on Veterans' Affairs, follow:]

studies they wanted to use those data bases for were going to be fruitful or not. We didn't say don't do the studies.

Senator SPECTER. I will accept your invitation to provide it for the record because I am interested to know how to go with the study.

Mr. HANSEN. Yes, sir.

Senator SPECTER. We place a great deal of value on a GAO conclusion, but I think it is important to do something more than say where the areas of deficiency, if you can, to tell us what the corrective measures to be taken so that we can move ahead to get the answers.

[Subsequently, the General Accounting Office submitted the following information:]

We believe the proposed epidemiological study should be expanded to determine whether service in Vietnam, rather than solely exposure to agent orange, may have adversely affected the health of Vietnam veterans. Both the Agent Orange Working Group and the Office of Technology Assessment agree that such a study is necessary and feasible.

An expanded study could use already developed general exposure indexes to identify populations with high and low potentials for exposure based on their proximity to sprayed areas. A third population consisting of military personnel who did not serve in Vietnam should also be included in the study.

We believe a study comparing the health status of these three groups could determine whether exposure to agent orange and/or service in Vietnam has adversely affected the health of Vietnam veterans.

Senator SPECTER. I will have just one more question for you and that is a repeat of a question which I asked earlier of Mr. Nimmo. I have a sense that we are, we may be, the Government, the VA, the Congress, even the GAO, may be avoiding the problem of causal connection between exposure to agent orange and the many problems, cancer, birth defects, et cetera, because of the tremendous cost involved. And my question is does GAO have any idea as to what the range of cost might be if the Vietnam veterans exposed to agent orange were concluded to be entitled to compensation for the so-called chamber of horrors?

Mr. HANSEN. Senator, we have not developed such an estimate.

Senator SPECTER. Would it be possible for you to do so?

Mr. HANSEN. We could certainly try and work with the VA and see. We would have to certainly talk to them with regards to estimates of the number of people involved.

Senator SPECTER. I would appreciate it if you would, because a question which came up on the change of medical policy, for example, where there was an issue as to whether the change could be made involved the cost factor and concerns from the Office of Management and Budget as to whether it could be afforded and whether the legislation were to be vetoed and there is always the lurking problem about whether we are willing to face up to the responsibility if we owe it, let's pay it. If it is causally connected, let's recognize it and let's compensate. And there is always lurking in the background whether we can afford to do that or what the cost is going to be, especially now with the very emphasis on economy.

So that I think it would be very important if you could give us an idea of what the cost could amount to.

Mr. HANSEN. We would be happy to do that for the record, Senator.

Question:

Can any other type of exposure index be developed, utilizing information now available from the records, or utilizing information that will soon be available from your work with the DOD records?

Answer:

Yes. General exposure indexes have been developed from available records to determine the time and geographic proximity of military units to areas sprayed with Agent Orange. These indexes have been used by GAO, the Army, and Marine Corps to determine the likelihood that units were exposed to Agent Orange.

Question:

Dr. Detels stated that expanding the study to general service in Vietnam would greatly increase the complexity of the epidemiological study. Do you agree with his opinion?

Answer:

The UCLA researchers' approach is to develop individual exposure indexes that can be used to establish a cause and effect relationship between a veteran's exposure to Agent Orange and adverse health outcomes. As we understand Dr. Detel's position, the expanded epidemiological study he envisions requires the development of individual exposure indexes for Agent Blue and the other chemicals used in Vietnam, as well as the Agent Orange exposure index.

From an epidemiologist's view, the ability to establish a cause and effect relationship between exposure to a specific herbicide and a specific adverse health outcome may be extremely important. However, the Veterans Administration only needs to satisfy itself that the health problems a veteran is experiencing were service connected to determine eligibility for compensation.

In a very real sense, the expanded study, using service in Vietnam as the causal factor, would be a simplified study by using the general exposure indexes already developed and eliminating the need to develop exposure indexes for each individual. Indeed, our experience with the military records causes us to have serious reservations that individual Agent Orange exposure indexes can be developed.

Both the Agent Orange Working Group and the Office of Technology Assessment believe an expanded study to evaluate the effects of Vietnam service, rather than solely exposure to Agent Orange, is necessary and feasible. In large part, they reached this conclusion because of the extreme difficulty in documenting Agent Orange exposure from the military records and viewed the expanded study as a more feasible alternative.

RESPONSE OF THE GENERAL ACCOUNTING OFFICE TO WRITTEN QUESTIONS SUBMITTED BY

HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS'

AFFAIRS

Question:

In your opinion, are the HERBS tapes accurate? How have they been verified since the end of the war, as accurate measures of where and how much Agent Orange was actually sprayed?

Answer:

GAO has not evaluated the HERBS tapes to verify their accuracy. However, the National Academy of Sciences (NAS) conducted an investigation which was reported in its 1974 study entitled "The Effects of Herbicides in South Vietnam." NAS found that 13.6 percent of the missions on the HERBS tapes contained inaccurate information on where the mission was conducted. NAS also noted that the source of information for compiling the HERBS tapes was not intended for use in determining the locations of herbicide missions conducted in Vietnam. Despite these shortcomings, NAS concluded that the HERBS tapes were the best and only available compilation of herbicide operations conducted in Vietnam.

More recently, Army records management officials have identified records of herbicide missions that were not available to NAS when it evaluated the HERBS tapes. Although the analysis of these newly found records is not complete, it may provide information on the accuracy of the HERBS tape.

Question:

The Agent Orange Working Group, as well as other parties, have not as yet been able to establish a mechanism for documenting exposure. If we cannot document exposure of individual veterans, is it possible to distinguish companies and/or divisions and their locations, eventually developing some more general type of exposure index?

Answer:

Yes. GAO, the Army, and the Marine Corps have been able to determine the proximity of military units, down to the company level, to areas sprayed with Agent Orange. While these indexes do not document exposure, they provide a general index of exposure probability.

The organization of Army records need not be a prerequisite to developing populations for epidemiological studies. Army officials agree that the two tasks could be performed simultaneously. Nonetheless, we have serious reservations that it will facilitate development of the individual exposure indexes suggested by the UCLA researchers.

Question:

On page 7 of your statement, you note that "[R]ecent Congressional action limiting eligibility for VA's burial allowance may also affect the usefulness of BIRLS."

A. Do you have any data that suggests that such a result is occurring or likely to occur?

B. Will you please work with the VA to help ensure that your concerns regarding the continuing reliability of BIRLS data on mortality are addressed effectively?

C. Can you get back to the Committee in about 60 days with a report on efforts being made in this regard?

D. Can you recommend any alternative means that would be superior to BIRLS for obtaining mortality data on veterans?

Answer:

Our comments on the draft protocol's proposal to use the death certificate information in BIRLS for mortality studies were intended to alert the UCLA researchers to questions which have been raised about the reliability of the information in BIRLS. While we believe BIRLS can be used to conduct mortality studies, the limitations of the system should be considered in developing the study protocol.

In June 1981, the National Academy of Sciences expressed its concern that Congressional action limiting eligibility for VA burial benefits would reduce the reporting of veteran deaths to VA for inclusion in BIRLS. Although the Congress did not enact all proposed restrictions to burial benefits, veterans buried in national cemeteries will no longer qualify

RESPONSE OF THE GENERAL ACCOUNTING OFFICE TO WRITTEN QUESTIONS SUBMITTED BY
HON. ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON
VETERANS' AFFAIRS

Question:

What is the status of your review of the VA's efforts to provide information and services to Vietnam veterans concerned about Agent Orange?

Answer:

We have completed our work at 14 VA medical facilities, and most of the analysis of this information, as well as the responses to the 1200 questionnaires we sent to a random sample of veterans who had Agent Orange examinations. Our report should be issued in the Spring of 1982.

Question:

In your statement you noted that "the records search and analysis necessary" to complete a feasibility study of determining troop exposure to dioxin "would be costly and time consuming" because "Army records from the Vietnam conflict are neither complete nor well organized." Although I understand and appreciate this point, wouldn't it be highly desirable for a variety of reasons, including for purposes of evaluating the effects of possible exposure to Agent Orange, to organize and catalog records relating to troop activity in Vietnam?

Answer:

Organizing and cataloging the Army's Vietnam records collection would enhance the ability of records management officials to access unit records and determine troop locations. This would be helpful in identifying units who served in sprayed areas.

Question:

The GAO clearly advocates an expansion of the scope of the Public Law 96-151 epidemiological study. I found your analysis on this point to be very helpful.

A. However, given the study's focus to date on Agent Orange, is there a possibility that a decision to expand the scope of the study might lead to more delay in getting answers about Vietnam veterans health?

B. If a more generalized study is done -- that is, without any effort to control for exposure to different elements in Vietnam -- would there be a risk of masking the adverse health effects of exposure to a particular hazard or hazards?

Answer:

Rather than delay the study, we believe an expanded study could begin sooner because it would eliminate the proposed feasibility study and the need to develop individual exposure indexes.

To determine a veteran's eligibility for benefits, VA needs to know only that the veteran's health problem was service connected, and not the specific cause of that condition. If a more generalized study is done the ability to link health outcomes with exposure to a specific chemical could be lessened. A study focusing only on the health effects of exposure to Agent Orange, however, may not identify health problems caused by other factors related to Vietnam service which could be detected in an expanded study.

for burial allowances, and their deaths may not be reported to VA. VA is planning administrative changes to insure that death certificates are obtained for those veterans no longer eligible for burial allowances. However, a thorough evaluation of BIRLS completeness for death certificates is necessary to determine the affect of the new eligibility rules.

The National Academy of Sciences (NAS) is currently planning a study to evaluate the completeness and reliability of BIRLS for death certificates. Also, NAS in cooperation with VA intends to organize a program monitoring the completeness of BIRLS to insure that recent changes in eligibility requirements for VA burial allowances do not adversely affect the death certificate information in BIRLS.

In a September 1, 1981, letter the President of NAS offered to inform the Chairman, Senate Committee on Veterans' Affairs of any problems arising from these changes. NAS officials have agreed to keep us informed of the progress of their monitoring program, and we will provide this information to your staff.

We have not evaluated any alternatives to BIRLS for obtaining mortality data on veterans. However, we understand that several state Agent Orange commissions are planning mortality studies using State death records to identify deceased Vietnam veterans.

We continue to believe that BIRLS can be used to conduct mortality studies provided that its limitations are recognized and addressed in the study protocol.

Question:

On pages 7 and 8, you describe a number of problems with VA's Agent Orange registry.

A. In light of these problems, what, if any, use do you believe can be made of the data in the registry?

B. What steps can be taken to make the data presently available as useful as possible and to ensure that information placed in the registry in the future is useful?

Answer:

We are currently evaluating the registry's reliability and usefulness as part of our review of VA's efforts to assist veterans concerned about Agent Orange. We intend to work with VA to ensure the future usefulness of the registry data.

I am accompanied, as you mentioned, today by Dr. Vernon Houk, to my right, and Mr. Leslie Platt. Dr. Houk is the Acting Director of the Center for Environmental Health of the Center for Disease Control and is Chair of the working group science panel.

Mr. Platt is legal counsel to the Department of Health and Human Services and serves as the working group's legal counsel and staff director.

As members of the committee will recall, the Agent Orange Working Group had its genesis in the interagency work group to study the possible long-term health effects of phenoxy herbicides and contaminants. As originally structured, the working group was comprised of three agencies: The Department of Health and Human Services, Defense, and the Veterans' Administration as full members with several other agencies as observers.

When this administration assumed office, the excellent work of the interagency work group was reviewed and a decision was made by the President to update its visibility, to encourage accelerated development of research and to broaden the availability of resources and personnel.

At a White House meeting in July, President Reagan announced that he had reestablished and expanded the working group, renamed it the Agent Orange Working Group and raised its status to Cabinet counsel working group level.

Under its new charter, the Department of Health and Human Services continues as a lead agency, with full participation by the Veterans' Administration and the Department of Defense. Additionally, a number of other agencies have been designated as full participants.

The Congressional Office of Technology Assessment continues as an observer.

I would like to briefly review some of the research being conducted. The working group is currently in the process of preparing a comprehensive updated catalog of all relevant Federal research, a registry of workers in the United States who have been involved in the manufacture of 2,4,5-T is being compiled. The Air Force Ranch Hand study has begun. The Air Force has begun now contacting the approximately 1,200 Air Force pilots and maintenance crews who were engaged in the spraying of herbicides in Vietnam.

A comprehensive review of the world's technical publications of herbicides has now been completed. A preliminary protocol for the congressionally directed Veterans' Administration epidemiological study of Vietnam veterans has been received and reviewed.

These and other research activities planned and underway have been and will be discussed before this committee in more detail by the individuals closely associated with them.

On a related matter, we were recently advised by the science panel of a potential new avenue of research. Working with the Department of Defense records personnel, information was developed dealing with the possible high dose exposures from incidents such as emergency herbicide jettisoning. The incidents resulted from spray aircraft malfunctions or battle damage. In some cases these incidents appeared to have occurred directly over or near American military installations.

Senator MURKOWSKI. We will proceed with the new panel and I might recognize those members of the panel: Mr. Bart Kull, is that the correct pronunciation?

Mr. KULL. Correct, yes, sir.

Senator MURKOWSKI. Special Assistant to the Deputy Undersecretary for Intergovernmental Affairs, HHS, and the alternative Chairman of the Agent Orange Working Group and he will testify in place of Mr. Stockdale who I regret to announce has been taken ill.

Before Mr. Kull presents his working group testimony, I want to recognize Leslie Platt, legal counsel for the Agent Orange Working Group. Leslie is leaving on Friday. He's going into private practice and we commend your assistance. You have been a valuable asset to the working group and you will be missed. Mr. Michael Gough, Office of Technology Assessment. Mr. Gough, welcome to the committee. And let's see, have we got anybody else here? I am looking here, Mr. Houk, for your pedigree on the—here we go. Dr. Houk, Chairman of the Agent Orange Working Group Science Panel, Director of Center for Environmental Health, Center for Disease Control, Atlanta, Ga. We welcome you to the committee.

I'm sorry, it's Mr. Gough, is that correct?

Mr. GOUGH. Yes, sir.

Senator MURKOWSKI. With that I would request that Mr. Kull proceed as a first witness.

TESTIMONY OF A PANEL CONSISTING OF BART KULL, SPECIAL ASSISTANT TO THE DEPUTY UNDERSECRETARY FOR INTERGOVERNMENTAL AFFAIRS, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY DR. VERNON N. HOUK, CHAIRMAN, AGENT ORANGE WORKING GROUP SCIENCE PANEL AND DIRECTOR, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR DISEASE CONTROL, ATLANTA, GA.; LESLIE PLATT, LEGAL COUNSEL, AGENT ORANGE WORKING GROUP, WASHINGTON, D.C.; AND DR. MICHAEL GOUGH, PROJECT DIRECTOR, OFFICE OF TECHNOLOGY ASSESSMENT

Mr. KULL. Thank you, Senator Murkowski.

Mr. Chairman, members of the committee. I am Bart Kull, the Special Assistant to James Stockdale, the Deputy Undersecretary for Intergovernmental Affairs, Department of Health and Human Services and who is also Chair of the Agent Orange Working Group of the Cabinet Counsel, the working group of the Cabinet Counsel on Human Resources. I am the alternate Chair, substitute Chair.

Mr. Stockdale, as you mentioned, is ill and he asked me to come here today and extend his apologies for not being present and to present testimony on his behalf.

I am pleased to have this opportunity to appear before the committee to report on the Federal Government's ongoing efforts to study and hopefully reach scientifically valid conclusions about the possible long-term human health effects of exposure to phenoxy herbicides and contaminants with a particular focus on the results of the exposure of American service personnel to the herbicide known as agent orange in Vietnam.

PREPARED STATEMENT OF BART KULL, SPECIAL ASSISTANT TO THE UNDERSECRETARY FOR
INTERGOVERNMENTAL AFFAIRS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

I am James Stockdale, Deputy Under Secretary for Intergovernmental Affairs, Department of Health and Human Services, and Chair of the Agent Orange Working Group of the Cabinet Council on Human Resources. I am pleased to have this opportunity to appear before the Committee to report on the Federal government's ongoing efforts to study and hopefully to reach scientifically valid conclusions about the possible long-term human health effects of exposure to phenoxy herbicides and contaminants, with a particular focus on the results of exposure of American service personnel to the herbicide known as Agent Orange in Vietnam.

I am accompanied today by Dr. Vernon Houk and by Mr. Leslie Platt. Dr. Houk is the Acting Director of the Center for Environmental Health of the Centers for Disease Control and is the Chair of the Working Group's Science Panel. Mr. Platt is Legal Counsel to the Department of Health and Human Services and serves as the Working Group's legal counsel and staff director.

As members of the Committee will recall, the Agent Orange Working Group had its genesis in the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (IWG). The IWG was chartered by the White House in late 1979 and held its first meeting in February, 1980. Meetings of the IWG and its successor, the Agent Orange Working

This may well result in a broader spectrum of identifiable exposures that could significantly aid research efforts.

I would emphasize, regarding the avenues of research that are currently underway and those that are to come, that no one in this administration, on the Agent Orange Working Group, or elsewhere, is prejudging the outcome of this massive inquiry. It should also be borne in mind that absolutes in terms of answers may be beyond the reach of science.

It is hoped, at the very least, that interim and final research results will provide enlightened guidance for the development of basic social and legislative policy in this area.

Earlier in my testimony I briefly discussed the preliminary protocol for the Veterans' Administration epidemiological study. I offer for the record a copy of Dr. Houk's letter to Dr. Shepard at the VA regarding the proposed protocol. As is obvious from the letter, the science panel believes we still have a long way to go before we are ready to begin the VA study.

I would emphasize that the Agent Orange Working Group shares the committee's concern that all Federal research activities be as scientifically competent and free from bias as humanly possible.

I would offer for the record my full written statement and supporting documents and we do look forward to a continuing and strengthening the close cooperative working relationship that we have enjoyed with the committee as we move forward.

Thank you very much. My colleagues and I would be happy to answer any questions the committee may have.

Senator MURKOWSKI. Thank you very much, Mr. Kull. I appreciate you staying within the timeframe which has been allowed and I have no specific questions. Does the staff have questions?

[The prepared statement of Bart Kull, Special Assistant to the Deputy Under Secretary for Intergovernmental Affairs, Department of Health and Human Services, follows:]

When this Administration assumed office, the excellent work of the Interagency Work Group was reviewed and a decision was made by the President to upgrade its visibility, to encourage accelerated development of research, and to broaden the availability of resources and personnel. At a White House meeting in July, President Reagan announced that he had re-established and expanded the Working Group, renamed it the Agent Orange Working Group, and raised its status to Cabinet Council working group level.

As such, the Working Group reports directly to the White House Cabinet Council on Human Resources which is chaired by Secretary of Health of Human Services Richard Schweiker. This action clearly reflects the President's commitment to the goals of the Working Group and accords the highest priority to its mission. I would like to offer for the record a copy of Secretary Schweiker's August 21, 1981, memorandum which formally re-established the Working Group (Attachment A).

Under its new charter, the Department of Health and Human Services continues as the lead agency with full participation by the Veterans Administration and the Department of Defense. Raised to the status of full participants have been the Departments of Agriculture and Labor and the Environmental Protection Agency. Also designated as full members are the ACTION Agency, the Office of Management and Budget, the Council of Economic Advisors, and the White House Offices of Science and Technology

Group, have been held almost every month since that time. The mission of the Working Group, then as now, is to monitor, coordinate and set priorities among Federal Government research activities, to design a research agenda, and to organize the means to assure that the research agenda is carried out. Thus, the Working Group does not itself conduct any research but is charged instead with being the overall coordinator, clearing-house and evaluator of the Federal research effort.

Since its inception, the Working Group has been advised by a scientific panel of knowledgeable scientists from the various government agencies concerned with the broad issues of public health under the jurisdiction of the Working Group.

As originally structured, the Working Group was comprised of three agencies -- the Departments of Health and Human Services and Defense and the Veterans Administration -- as full members. The Department of Health and Human Services was designated the lead agency, and the Departments of Agriculture and Labor, the Environmental Protection Agency and the Congressional Office of Technology Assessment fully participated as observers. The General Accounting Office was very early brought into the effort and has been kept abreast of developments. Additionally, the White House Office of Science and Technology Policy participated as an ex-officio member.

The Working Group's mission is to seek truth and to reveal openly as much truth as can be found.

Mr. Chairman and Members of the Committee, a great deal of work is moving forward. Quite frankly, it is not sensational, headline grabbing activity; rather it is the quiet research inquiry of highly qualified and dedicated men and women of science.

I would like to review briefly some of this research. As you know, the Working Group is currently in the process of preparing a comprehensive, updated catalogue of all relevant Federal research. We hope to have this completed in the near future and will provide it to the Committee and the public as soon as it is ready.

First, I would note that research into possible birth defects in the children of Vietnam veterans is currently being conducted by the Centers for Disease Control. This research is being conducted as a direct result of the Working Group's recommendations and is being funded jointly by the Departments of Health and Human Services and Defense and the Veterans Administration. It is designed to help find answers to one of the most serious questions facing Vietnam veterans and their families.

Second, the National Institute for Occupational Safety and Health of the Centers for Disease Control is continuing its assembly of a registry of workers in the United States

Policy and Policy Development. The congressional Office of Technology Assessment continues as an observer.

On August 28th of this year, the expanded Agent Orange Working Group held its first meeting. At the beginning of that meeting, and speaking as its Chairman, I wished to assure those who had worked so hard and long for the establishment and progress of the Group of the commitment of the Administration and of my position as its new chairman. With your permission, I would like to summarize for the Committee my statement at that meeting.

I said, and I believe, that the concerns of possible long term adverse health effects as a result of exposure to Agent Orange are very real. They demand answers. They demand the kind of deliberate, objective research that will provide as many answers as science can give.

The Working Group will not cave in to the emotional fervor that surrounds this issue. The Working Group has a responsibility to turn aside from the barrage of demands for quick and easy answers based on assumptions rather than facts.

Equally so, the Working Group will not bow to any interests that might seek to sweep this issue under the rug and hope it will go away. This issue will not go away.

Dr. John Doull
Professor
Department of Pharmacology
and Toxicology
University of Kansas Medical Center

Dr. Norton Nelson
Professor and Chairman
Department and Environmental Medicine
New York University
School of Medicine

Dr. Alan Poland
Associate Professor of Oncology
McCardle Laboratory
University of Wisconsin

Dr. Irving Selikoff
Director, Environmental Sciences
Laboratory
Mt. Sinai School of Medicine

The Advisory Committee is scheduled to hold its first meeting in December at Brooks Air Force Base. Following that meeting, two additional scientists will be appointed to serve on the committee. Those scientists will be selected on the basis of their expertise in scientific disciplines deemed desirable by the committee and the Secretary to complement the broad and considerable expertise already represented on the committee.

Fourth, a preliminary protocol for the congressionally - directed Veterans Administration epidemiology study of Vietnam veterans has been received from Dr. Gary Spivey of the UCLA School of Public Health. The material has been reviewed by the Working Group's scientific panel and the panel's comments have been forwarded to the Veterans Administration.

who have been involved in the manufacture of 2,4,5-T, one of the two herbicides in Agent Orange and the one which contains dioxin as a manufacturing contaminant.

This registry is designed to provide a significant data base which can be extremely valuable in supporting studies of the health of workers exposed as a result of their occupation. Thus, the registry holds real promise of providing reliable information about the effects of exposure to dioxins that can be related and cross-referenced to other research underway on the possible adverse effects of Agent Orange exposure in Vietnam.

Third, the Air Force Ranch Hand Study has begun. It is now past the planning stages. The Air Force has begun contacting the approximately 1200 Air Force pilots and maintenance crews who were engaged in spraying herbicides in Vietnam. Also, I would note that a formally chartered Federal Advisory Committee, which includes highly qualified scientists from outside the government, has been formed to provide close monitoring of the study.

The Advisory Committee will be chaired by Dr. John Moore, Deputy Director of the National Toxicology Program. Dr. Moore served with great distinction as Chair of the Interagency Work Group's scientific panel. Other members of the committee appointed by Secretary Schweiker are as follows:

word of caution. All illnesses currently being popularly attributed to exposure to Agent Orange can be caused by a number of factors.

Accordingly, we must keep in mind the possible outcomes of the study of those who served in Vietnam. Vietnam veterans may be at greater risk of suffering serious diseases than other groups. We might also discover that those diseases are not associated with exposure to chemicals involved in defoliating procedures. We may find, on the other hand, that Vietnam veterans are not suffering any more disease than would be expected had they not been in Vietnam.

It should also be borne in mind that absolutes in terms of answers may be beyond the reach of science. It is hoped, at the very least, that interim and final research results will provide enlightened guidance for the development of basic social and legislative policy in this area.

I stress again that the Agent Orange Working Group will not be permitted to fall victim to anything remotely akin to prejudice. We are acutely aware that anything short of our most objective, best efforts would be a grievous disservice to our veterans and to the conscience of our Nation.

I wish to thank the Committee, not simply for the honor of appearing before it, but also for the excellent support that you and your staff have accorded the Agent Orange Working Group and its Science Panel.

Additionally, a comprehensive review of the world's technical publications on herbicides has been completed by J.R.B. Associates, Incorporated, under contract with the Veterans Administration. This literature review provides in one place, for the first time, the currently published scientific information on phenoxy herbicides, their contaminants, and other defoliants used in Vietnam.

These and other research activities planned and underway have been, and will be, discussed before this committee in more detail by individuals closely associated with them. My point in briefly reviewing them is to assure the committee that the Working Group's objectives are being actively pursued.

On a related matter of considerable interest, the full Working Group was recently advised by the Science Panel working with DoD records personnel of a potential new avenue of research relating to possible high dose exposures, particularly incidents of emergency herbicide jettisoning that resulted from spray aircraft malfunctions or battle damage. In some cases, these incidents appear to have occurred directly over or near American military installations.

I would emphasize, regarding the avenues of research that are currently underway and those that are to come, that no one in this Administration, on the Agent Orange Working Group or elsewhere, is prejudging the outcome of this massive inquiry. However, I would be remiss were I to fail to add a

As is obvious from the letter, the Science Panel believes we still have a way to go before we are ready to begin the VA study.

The Science Panel is presently examining how the VA study and other pending research can best be done and how all research can be expedited. In this regard I would like to emphasize again that the Agent Orange Working Group shares Senator Cranston's concern that all federal research activities be as scientifically competent and free from bias as is humanly possible. However, we are dealing with a very difficult and complex issue which will take time to resolve and so will the design and execution of appropriate studies. I would offer for the view a copy of the chronology of Agent Orange Working Group activities which we recently made available (Attachment C).

In closing, I would emphasize that we look forward to continuing and strengthening the close, cooperative working relationship we have enjoyed with the Committee as we move forward. Thank you.

My colleagues and I would be happy to answer any questions the Committee may have.

Attachments

We are honored by the recent communication of support to Secretary Schweiker from you, Mr. Chairman, and you, Senator Cranston. Equally appreciated are your recommendations for priority consideration by the Working Group.

We are also encouraged by the many letters of support we have received from individual veterans and their families, and by the letters and personal thanks of representatives of veterans' organizations, some of whom are in this room today.

I believe these expressions of support are a clear reflection of the progress we are making. They are a credit to the continuing effort of the many people who are supporting the Working Group. And most importantly, they represent a broad -- and I would add -- a bipartisan consensus that we are on the right track.

I believe that all Vietnam veterans can be certain in the knowledge that the Executive and Legislative branches of their government are unified in their dedication to the best interests of those who served their country when called upon to do so.

Earlier in my testimony, I briefly discussed the preliminary protocol for the Veterans Administration's epidemiological study submitted by Dr. Gary Spivey. I would like to offer for the record a copy of Dr. Houk's letter, on behalf of the Science Panel of the Working Group, to Dr. Shepard at the VA regarding the protocol (Attachment B).

available to support the Working Group's continuing efforts. The decision to re-establish and expand the membership of the Working Group and to make it an integral part of the Cabinet Council on Human Resources reflects the President's commitment and accords the highest priority to its mission.

As Chairman Pro-Tem of the Cabinet Council on Human Resources, I am, accordingly, reaffirming by this memorandum the Agent Orange Working Group's mandate of December 11, 1979 and providing specific guidance as to how that mandate is to be carried out in accordance with the Cabinet Council's decisions.

The Department of Health and Human Services shall continue to have lead responsibility for overall direction and management of the Agent Orange Working Group. The Secretary of Defense and the Administrator of Veterans Affairs shall continue to assure that their respective agencies participate fully in all Working Group activities. The Departments of Agriculture and Labor and the Environmental Protection Agency, each of which have until now been observers, shall assume full membership and their respective agency heads shall assure that those agencies participate fully in all Work Group activities.

In addition, ACTION, the Office of Management and Budget, and the Council of Economic Advisers, as well as the White House Office of Science and Technology Policy and the Office of Policy Development, shall assume membership on the Working Group and the heads of those agencies and offices shall assure that the resources of their respective agency or office are fully available to support it.

Also, the congressional Office of Technology Assessment, which has been actively involved in all Working Group activities as an observer, will be invited to continue to participate in that capacity, and the General Accounting Office, which has been extremely helpful to the Working Group in the past, will continue to be kept abreast of developments and invited to advise and assist as appropriate.

The Working Group has initiated research efforts designed to find answers to many of the questions surrounding Agent Orange that have been raised. These efforts include the birth defects study being conducted by HHS' Centers for Disease Control, the Ranch Hand Study being conducted by the Air Force, the epidemiological study being planned by the Veterans Administration pursuant to P.L. 96-151, and the compilation by HHS' National Institute of Occupational Safety and Health of a national registry of workers exposed to dioxins. Each of these research activities, as well as the other important research

THE WHITE HOUSE
WASHINGTON

AUG 21 1981

MEMORANDUM FOR: SECRETARY OF DEFENSE
SECRETARY OF AGRICULTURE
SECRETARY OF LABOR
DIRECTOR, OFFICE OF MANAGEMENT AND BUDGET
ASSISTANT TO THE PRESIDENT FOR POLICY
DEVELOPMENT
CHAIRMAN, COUNCIL OF ECONOMIC ADVISERS
DIRECTOR OF ACTION
ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY
ADMINISTRATOR OF VETERANS AFFAIRS
DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY
POLICY

FROM : *Rich Schweiker*
SECRETARY RICHARD SCHWEIKER
CHAIRMAN PRO-TEM, CABINET COUNCIL
ON HUMAN RESOURCES

SUBJECT : Agent Orange Working Group

The Administration has reviewed the excellent work of the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants and believes that it has made significant progress toward fulfilling its important mandate. By bringing together knowledgeable scientists from the various Federal departments and agencies the Work Group has identified ongoing research activities on phenoxy herbicides and contaminants and begun to develop and organize the means to carry out additional needed scientific research.

President Reagan shares the widespread public and congressional concern over possible adverse health effects among Vietnam veterans exposed to Agent Orange and other substances. The President stated, during his meeting with national veterans organization leaders at the White House on July 17, 1981, that the Administration is giving special consideration to those concerns of Vietnam veterans.

At the White House meeting, the President announced that the administration had re-established an expanded Working Group as the Agent Orange Working Group and raised its status to Cabinet Council level. The President is personally determined to assure that the full resources of the Federal government are

WASHINGTON

July 17, 1981

MEMORANDUM FOR: SECRETARY RICHARD SCHWEIKER
CHAIRMAN PRO-TEM, CABINET COUNCIL
ON HUMAN RESOURCES

FROM: ROBERT CARLSON 
EXECUTIVE SECRETARY OF HUMAN RESOURCES
CABINET COUNCIL

SUBJECT: Agent Orange Working Group

The Secretariat of the Human Resources Cabinet Council has established an Agent Orange Working Group. The lead agency will be HRS, and participating members drawn from:

Department of Defense
Department of Agriculture
Department of Health and Human Services
Department of Labor
Environmental Protection Agency
Veterans Administration
Action
Office of Management and Budget
Council of Economic Advisers
Office of Science and Technology
Office of Policy Development

cc: Martin Anderson
Edwin Gray

activities being conducted under the overall guidance of the Working Group, are to be continued without interruption or delay.

The Working Group has developed an impressive record of scientific objectivity, impartiality and integrity and it is imperative to the success of the Working Group effort that this record and the Group's credibility be maintained. In this regard, regular progress reports to the Cabinet Council, the Congress and the public will continue to be made by the Agent Orange Working Group.

To assure effective leadership of the Working Group, I am hereby appointing James Stockdale, MHS Deputy Under Secretary for Intergovernmental Affairs, as Chair. Also, I am appointing Dr. Vernon N. Houk of the Center for Environmental Health of the Centers for Disease Control as Chair of the Working Group's Science Panel. In addition, I am appointing MHS Legal Counsel Leslie A. Platt, who has served as legal adviser to and staff director of the Working Group since its inception, to continue in those capacities. I know and believe you will find that these individuals share my commitment to carrying out this important mission.

Please review your representation on the Working Group to assure that your agency or office is adequately represented by appropriate technical experts, scientists and policy-level officials. In order to facilitate the Group's effectiveness, it is of course important that each agency's total membership be limited.

The first meeting of the full Working Group has been scheduled for Friday, August 28, 1981 and a meeting of the Science Panel will be scheduled for shortly thereafter. Accordingly, please let Mr. Bart Kull, Special Assistant to the Deputy Under Secretary for Intergovernmental Affairs (245-6156), or Dr. Peter Beach, MHS Director of Veterans Affairs (245-2210), know as soon as possible the name(s) of your designated representative(s) so that briefing materials may be forwarded to them.

Attached for your information is a copy of the memorandum of the Executive Secretary to the Cabinet Council on Human Resources establishing the Working Group.

Attachment

cc: Comptroller General of the United States
Director, Congressional Office of Technology Assessment
Mr. Robert Carleson
Mr. Edwin Gray

HHS NEWS

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Laura Genero--(202) 245-6343
 Richard McGowan--(202) 245-7204

FOR IMMEDIATE RELEASE
 Wednesday, October 21, 1981

HHS Secretary Richard S. Schweiker today made public the attached Chronology of Activities on Agent Orange.

FROM: James S. Stockdale
 Deputy Under Secretary for
 Intergovernmental Affairs

TO : The Secretary

CHRONOLOGY OF ACTIVITIES RE: AGENT ORANGE

The first meeting of the re-established and expanded Agent Orange Working Group was held on August 28, 1981. The first task of the Working Group was to review the status of all ongoing and planned Federal research and related activities.

Each member agency was directed to provide updated reports on the status of its current or planned research activities.

A proposed protocol for the design of the Veterans Administration epidemiological study will be reviewed by the Working Group's Science Panel.

A number of veterans organizations have been briefed on the continuing military records search that is being conducted by the Army Agent Orange Task Force. Preparations are continuing for the Air Force Ranch Hand Study. That study involves pilots and maintenance personnel engaged in the spraying of herbicides during the Vietnam conflict. Concern was expressed that the fullest possible participation by Ranch Hand personnel be obtained for this study of possible health effects related to exposure to Agent Orange. This is critical because the Ranch Hands are a relatively small group of approximately 1200.

A public affairs panel was created and will develop plans for a public meeting of the Working Group to be scheduled later this year.

The Working Group also agreed to establish a resource development panel to assure adequate funding and personnel resources.

Dr. Vernon Houk, Chair of the Working Group's Science Panel, has plans to review all research.

Dr. Houk and several other members of the Working Group visited the Army Agent Orange Task Force Office for a briefing on the status of the Department of Defense records search. During the briefing, it became apparent that a potentially

ATTACHMENT B

FTS 236-4111

October 21, 1981

Dr. Barclay Shepard
Special Assistant to the Chief
Director for Environmental Medicine
Veterans Administration
810 Vermont Avenue, N.W.
Washington, D.C. 20420

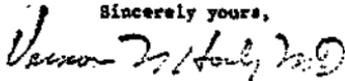
Dear Dr Shepard:

The Science Panel has reviewed the Draft Protocol for Epidemiological Studies of Agent Orange submitted by Gary H. Spivey, M.D., MPH, and Roger Detels, M.D., MS.

A copy of the review and individual comments are enclosed. Basically, the Science Panel had difficulty in providing a meaningful review because the document was not a protocol. Instead it appeared to consist of three parts. The first 19 pages were primarily an introduction. The second 65 pages represented a discussion of the difficulties normally faced in epidemiological studies, and the rest of the document was a literature review covering 141 pages. Every member expressed concern about the lack of details to the point that it was not possible to constructively review the proposal.

The final conclusion was that the present proposal is inadequate and the Science Panel recommends to the VA that a course of action be developed that will not cause any further unnecessary delays in attempting to answer questions about health issues in Vietnam veterans. A specific protocol should be developed. There was substantial discussion at yesterday's meeting of the Science Panel, which you attended, that should help resolve some of these issues.

Sincerely yours,



Vernon N. Houk, M.D.
Chairman, Science Panel
Agent Orange Working Group

Enclosure

cc:

Mr. James Stockdale
Mr. Leslie Platt

2. The Air Force Ranch Hand Study is to be monitored by an independent advisory committee in addition to the Agent Orange Working Group. This advisory committee will meet publicly (probably beginning in November) and will include scientists from inside and outside the Federal government.
3. The Veterans Administration Advisory Committee on Health-Related Effects of Herbicides meets periodically to review all VA herbicide-related research. The committee includes scientists from inside and outside the government as well as representatives of veterans organizations.
4. The Office of Technology Assessment of the Congress has established a scientific review panel to review the proposed protocol for the design of the VA epidemiological study and will provide the VA with its conclusions and recommendations regarding the protocol.
5. There are also a number of State-level Agent Orange commissions charged with undertaking and/or monitoring Agent Orange research.

The report notes in conclusion that a number of veterans organizations, members of the public and Congress have expressed support for the Administration's actions regarding Agent Orange and related research.

Attachments:

- (A) Memorandum of August 21, 1981, Re-establishing the Agent Orange Working Group, from HHS Secretary Richard S. Schweiker in his capacity as Chairman Pro-Tem of the Cabinet Council on Human Resources.
- (B) Opening Remarks of Agent Orange Working Group Chairman James S. Stockdale at the Working Group's August 28, 1981 meeting.
- (C) Report by Dr. Vernon Houk, Chair of the Working Group's Science Panel.

existed

promising new concept/for the identification of people exposed to Agent Orange in addition to the Air Force Ranch Hand personnel or broadly defined units of ground troops. The full research panel was briefed on this new information.

The information may provide the basis for a new approach to finding answers to some of the serious scientific questions before the Working Group. It opens the possibility of an expanded number of potentially identifiable exposures to Agent Orange in addition to those involved in the Ranch Hand study. Further developments regarding the information will be included in the next Working Group report.

The Agent Orange Working Group's predecessor, the Inter-agency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants (IWG), also undertook a number of activities during the transition period between April, 1981, when it transmitted its seventh report, and August, when the expanded Working Group convened.

At the May meeting of the IWG, a status report was given on the birth defects study being conducted by the Centers for Disease Control. It was reported that the Office of Management and Budget had approved the study and preparations for the study were under way, with completion likely in the summer or fall of 1983.

At the same meeting, it was reported that a representative of the Medical Follow-Up Agency of the National Academy of Sciences' National Research Council had been briefed on and had reviewed the Defense Department's records search effort and had concluded it could be difficult to identify a population of ground troops the nature and extent of whose exposure to Agent Orange could be reliably reconstructed and documented.

At its June meeting, the IWG was honored by a visit by the Australian Minister of Veterans Affairs, Senator Anthony Messner. Senator Messner told the Group of his government's Agent Orange-related research and urged continuing cooperation between our countries in the area of research. During the meeting, the IWG was assured of the Administration's strong support for Agent Orange research.

As you know, Agent Orange efforts of the various Federal bodies include research as follows:

1. The Agent Orange Working Group coordinates all Federal Agent Orange research. It does not undertake any research on its own but rather acts as the coordinator and monitor.

available to support the Working Group's continuing efforts. The decision to re-establish and expand the membership of the Working Group and to make it an integral part of the Cabinet Council on Human Resources reflects the President's commitment and accords the highest priority to its mission.

As Chairman Pro-Tem of the Cabinet Council on Human Resources, I am, accordingly, reaffirming by this memorandum the Agent Orange Working Group's mandate of December 11, 1979 and providing specific guidance as to how that mandate is to be carried out in accordance with the Cabinet Council's decisions.

The Department of Health and Human Services shall continue to have lead responsibility for overall direction and management of the Agent Orange Working Group. The Secretary of Defense and the Administrator of Veterans Affairs shall continue to assure that their respective agencies participate fully in all Working Group activities. The Departments of Agriculture and Labor and the Environmental Protection Agency, each of which have until now been observers, shall assume full membership and their respective agency heads shall assure that those agencies participate fully in all Work Group activities.

In addition, ACTION, the Office of Management and Budget, and the Council of Economic Advisers, as well as the White House Office of Science and Technology Policy and the Office of Policy Development, shall assume membership on the Working Group and the heads of those agencies and offices shall assure that the resources of their respective agency or office are fully available to support it.

Also, the congressional Office of Technology Assessment, which has been actively involved in all Working Group activities as an observer, will be invited to continue to participate in that capacity, and the General Accounting Office, which has been extremely helpful to the Working Group in the past, will continue to be kept abreast of developments and invited to advise and assist as appropriate.

The Working Group has initiated research efforts designed to find answers to many of the questions surrounding Agent Orange that have been raised. These efforts include the birth defects study being conducted by HHS' Centers for Disease Control, the Ranch Hand Study being conducted by the Air Force, the epidemiological study being planned by the Veterans Administration pursuant to P.L. 96-151, and the compilation by HHS' National Institute of Occupational Safety and Health of a national registry of workers exposed to dioxins. Each of these research activities, as well as the other important research

APPENDIX A

THE WHITE HOUSE
WASHINGTON

AUG 21 1981

MEMORANDUM FOR: SECRETARY OF DEFENSE
SECRETARY OF AGRICULTURE
SECRETARY OF LABOR
DIRECTOR, OFFICE OF MANAGEMENT AND BUDGET
ASSISTANT TO THE PRESIDENT FOR POLICY
DEVELOPMENT
CHAIRMAN, COUNCIL OF ECONOMIC ADVISERS
DIRECTOR OF ACTION
ADMINISTRATOR, ENVIRONMENTAL PROTECTION AGENCY
ADMINISTRATOR OF VETERANS AFFAIRS
DIRECTOR, OFFICE OF SCIENCE AND TECHNOLOGY
POLICY

FROM : *Dick Schweiker*
SECRETARY RICHARD SCHWEIKER
CHAIRMAN PRO-TEM, CABINET COUNCIL
ON HUMAN RESOURCES

SUBJECT : Agent Orange Working Group

The Administration has reviewed the excellent work of the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants and believes that it has made significant progress toward fulfilling its important mandate. By bringing together knowledgeable scientists from the various Federal departments and agencies the Work Group has identified ongoing research activities on phenoxy herbicides and contaminants and begun to develop and organize the means to carry out additional needed scientific research.

President Reagan shares the widespread public and congressional concern over possible adverse health effects among Vietnam veterans exposed to Agent Orange and other substances. The President stated, during his meeting with national veterans organization leaders at the White House on July 17, 1981, that the Administration is giving special consideration to those concerns of Vietnam veterans.

At the White House meeting, the President announced that the administration had re-established an expanded Working Group as the Agent Orange Working Group and raised its status to Cabinet Council level. The President is personally determined to assure that the full resources of the Federal government are

Agent Orange Working Group
August 28, 1981 Meeting

Introductory Statement by James Stockdale, HHS Deputy
Under Secretary for Intergovernmental Affairs and
Chair, Agent Orange Working Group

Good Morning. I am James Stockdale, HHS Deputy Under Secretary for Intergovernmental Affairs and Chair of the Agent Orange Working Group. As Chair of the Working Group, I wish to express to you my beliefs about the work under way.

Many of you have known frustration in the course of time serving on this project. Occasionally there has been the concern that it would be stuffed away in some dusty corner of official memory and permitted to die of neglect.

Some of you have believed - and in that belief have held firm, and in that firmness have kept the mission and the mechanism of this group intact and alive.

The President of the United States, in his recognition of the trust this nation holds on behalf of those who have served our country in war ... in recognition of the heavy questions that eat at the minds of many who served ... has publicly and forcefully reaffirmed and reinforced the goals this working group seeks to achieve.

President Reagan recently said "we are giving special consideration to the concerns of Vietnam veterans over Agent Orange. Our fiscal year '82 budget will contain a large

activities being conducted under the overall guidance of the Working Group, are to be continued without interruption or delay.

The Working Group has developed an impressive record of scientific objectivity, impartiality and integrity and it is imperative to the success of the Working Group effort that this record and the Group's credibility be maintained. In this regard, regular progress reports to the Cabinet Council, the Congress and the public will continue to be made by the Agent Orange Working Group.

To assure effective leadership of the Working Group, I am hereby appointing James Stockdale, HHS Deputy Under Secretary for Intergovernmental Affairs, as Chair. Also, I am appointing Dr. Vernon N. Houk of the Center for Environmental Health of the Centers for Disease Control as Chair of the Working Group's Science Panel. In addition, I am appointing HHS Legal Counsel Leslie A. Platt, who has served as legal adviser to and staff director of the Working Group since its inception, to continue in those capacities. I know and believe you will find that these individuals share my commitment to carrying out this important mission.

Please review your representation on the Working Group to assure that your agency or office is adequately represented by appropriate technical experts, scientists and policy-level officials. In order to facilitate the Group's effectiveness, it is of course important that each agency's total membership be limited.

The first meeting of the full Working Group has been scheduled for Friday, August 28, 1981 and a meeting of the Science Panel will be scheduled for shortly thereafter. Accordingly, please let Mr. Bart Kull, Special Assistant to the Deputy Under Secretary for Intergovernmental Affairs (245-6136), or Dr. Peter Beach, HHS Director of Veterans Affairs (245-2210), know as soon as possible the name(s) of your designated representative(s) so that briefing materials may be forwarded to them.

Attached for your information is a copy of the memorandum of the Executive Secretary to the Cabinet Council on Human Resources establishing the Working Group.

Attachment

cc: Comptroller General of the United States
 Director, Congressional Office of Technology Assessment
 Mr. Robert Carlsson
 Mr. Edwin Gray

group will not succumb to any effort to stonewall. This issue will not go away. Efforts to stonewall it will fail.

This working group's mission is to seek truth and to reveal openly as much truth as can be found.

All of the truth may be beyond our grasp but we have a moral obligation to reach and even to stretch our reaching beyond the limits we believe imposed upon us by the nature of our finite minds and the current state of science.

On behalf of those who wonder and worry and fear we can do no less.

I am especially pleased, therefore, that we have assembled such an outstanding team for this project.

At this time, I would like to introduce some of the key people in this effort from the Department of Health and Human Services. First, I would like to introduce Dr. Vernon Houk of the Center for Environmental Health of the Centers for Disease Control, who will chair the Science Panel. Next, Leslie Platt, our legal counsel and staff director, and Bart Kull, my special assistant, who will chair the group in my absence. Also, you all know Dr. Peter Beach, the Department's director of veteran affairs who has been and continues to provide overall coordination for this effort. We all welcome you to the Department and look forward to working with you.

increase in funding for the continued study of Agent Orange. In addition to the VA's epidemiological study and the Air Force Ranch Hand Study, we have reestablished an expanded Interagency Work Group as the Agent Orange work group and, yesterday, we raised its status to Cabinet Council level."

If ever there has been a statement of genuine concern for the fears that lurk in the minds of many Vietnam veterans and their families - that was it.

Those fears of possible long term adverse health effects as a result of exposure to Agent Orange are very real. They demand answers. They demand the kind of deliberate, objective research that will provide as many answers as science can give.

There is no fear like the fear of the unknown. It is the mission of this working group to make known the unknown insofar as humanly possible.

This working group will not cave in to the hysteria of emotionalism that surrounds this issue. This working group has a responsibility to turn aside from the barrage of demands for quick and easy answers based on assumptions and fear rather than facts.

Equally so, this working group will not bow to any interests that might seek to sweep this issue under the rug - to pretend it does not exist and hope it will simply go away. This working

REPORT OF SCIENCE PANEL
TO THE
AGENT ORANGE WORKING GROUP

The Science Panel met September 2 and September 15, 1981. A summary of these meetings and other activities is as follows:

Veterans Administration (VA) Draft Protocol for Epidemiological "Studies of Agent Orange"

The Veterans Administration Draft Protocol for Epidemiological "Studies of Agent Orange" received from the University of California at Los Angeles (VA Contract V101(93)P-842) was distributed to the members of the Science Panel. It was agreed that the review would take place in two stages.

The members are to transmit to the Chair by September 18 a general overview and general comments of what needs to be done. By October 16, detailed, specific comments and suggestions for protocol design on what needs to be done, how to do it, and suggestions on who has the capability of doing it should be transmitted to the Chair. The Chair will consolidate the comments and return it to the members of the Science Panel for review with final comments on the proposed study to be submitted to the VA before their committee meeting on this subject in November.

The present VA proposed protocol is scheduled to be reviewed by the Science Panel, the VA Committee, the Congressional Office of Technology Assessment, and the National Academy of Science, National Research Council (NRC). Dr. Honchar suggested that the document was not yet ready for review by the NRC and suggested the VA discuss with NRC that they consider withholding a review until a more detailed and specific document can be made available. The Science Panel members concurred with this suggestion.

Dr. Gough of the Congressional Office of Technology Assessment indicated that their review has been completed.

A Case Control Study of the Relationship Between Exposure to 2,4-D and Spontaneous Abortions in Humans

The Science Panel was asked to review the document "A Case Control Study of the Relationship Between Exposure to 2,4-D and Spontaneous Abortions in Humans" prepared for the National Forest Products Association and the U.S. Department of Agriculture--Forest Service by SRI International. Dr. Kimbrough and a rather large intergovernmental group has reviewed this study in detail during its route to completion. Those comments were made available to the Science Panel. The members of the Science Panel were asked to complete this review process and send written comments to the Chair by the end of October.

APPENDIX C

Memorandum

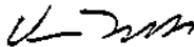
Date September 24, 1981

From Chairman, Science Panel
Agent Orange Working Group

Subject Report of the Science Panel to the Agent Orange Working Group

To Mr. James Stockdale
Chairman, Agent Orange Working Group
Deputy Under Secretary for Intergovernmental
Affairs, HHS

Attached is the Report of the Science Panel.


Vernon H. Houk, M.D.

Attachment

subject material. Dr. Shepard indicated that this was not intended, and anybody with any information was invited to participate.

Attempts will be made to contact the group evaluating soft tissue sarcoma from Sweden to participate. Dr. Honchar was also asked to present her recent study on this subject.

Since the above discussion on the subject symposium, Dr. Lennart Hardell of Sweden asked to present their data on soft tissue sarcoma. He was apparently told by organizers of the conference that there was no room on the program for his paper. The Chair communicated with Dr. Shepard that this was not in accord with the previous agreement and was asked to use his influence with the symposium organizers to have Dr. Hardell's paper included in the formal program.

No governmental agency will formally co-sponsor or otherwise endorse the symposium though many will provide participation by their employees.

Other Groups to be Explored

Major Young suggested that there are other individuals who may have been exposed to Agent Orange in high doses that could be identified and available for study. These include approximately 30 scientists and technicians that were assigned to the Plant Sciences Laboratory, Fort Detrick, Maryland, 1962-70; approximately 200 scientists and technicians involved in the development and evaluation of spray equipment at Eglin Air Force Base, 1962-70; and approximately 200 individuals who were involved in the disposal of Agent Orange (Project PACER-HQ 1977). Major Young was asked to make a presentation at a future meeting of the Science Panel.

After the previous discussion of Data Sets above, Dr. Bricker shared with the Chair information on "aborted missions." An aborted mission is one when for various reasons the intended targeted spraying of the herbicide was not done but the material was dumped from the aircraft. The Chair asked Dr. Honchar to quickly review these data. Her report is attached. Major General Augerson formally notified the Science Panel of these data. That notification and acknowledgment of the Science Panel are attached.

On September 15 a meeting was called for the Science Panel to examine this new information.

Aborted Missions

Dr. Bricker and Mr. Christian presented a briefing on aborted missions. They have identified 90 between 1965-1971 and have reasonable information on 25 (MACV records). It is possible that information could be developed on the other 62 (Air Force printouts). They suggested that major attention be given to the activities at four locations in Vietnam. In addition to exposed personnel in these four areas associated with the aborted missions, there may be other groups that have had extensive exposure. These may include personnel who were involved in base perimeter spraying, by air or by land, sprayers of riverbanks, and any personnel who were used for cleanup activities when there were leaks or disruptions of the storage containers or other significant accidental spills. We would suggest that the Defense Department develop

Mr. Platt indicated that he would send to all agencies involved the list of past, present, and anticipated activities on the subject of herbicides. The agencies will be asked to review and update that document and return to Mr. Platt within 1 month.

Data Sets

There was considerable discussion about additional data sets that may be available. Dr. Shepard was asked to have the VA review and report back to the Science Panel specific information on the VA death certificates, any health information that may be contained in VA life insurance information, and to survey the major VA hospitals for any additional studies or information that may be available.

The Department of Defense (DOD) was asked to report on the status of the Soft Tissue Sarcoma Registry at the Armed Forces Institute of Pathology (AFIP). DOD was asked to investigate and report on the kinds and amounts of herbicides used in non-Vietnam DOD installations in various parts of the United States and the rest of the world.

The Department of Agriculture (DA) was asked to report on any information from their sources (Extension or otherwise) on the use of herbicides in the United States. Dr. Shaw of the DA was concerned that special groups in the United States, such as those involved in spraying the electrical power transmission lines rights of way, could be identified and could contain significant health information on workers involved in this activity. Drs. Rall and Landrigan felt that this information would at best be sketchy. Dr. Shaw was asked to report to the Science Panel on this subject.

VA Mortality Study

Dr. Kimbrough suggested that the VA proceed with the review of the VA death certificates for Vietnam veterans. VA has 95 to 98 percent of death certificates of veterans who died on file in various locations around the country. The study would also include, in cooperation with DOD, individuals who died while still on active duty. Dr. Kimbrough will work with Dr. Shepard and others to explore the feasibility of this being accomplished. It was suggested by several members of the Science Panel that in order to be successful, individuals will have to be identified and trained to extract the specific information needed in a uniform manner from the records. It is unlikely to be successful simply by paying available people overtime to review records in their current installation.

International Symposium on Chlorinated Dioxins and Related Compounds October 23-29, 1981

Dr. Shepard asked the Science Panel to endorse and various agencies to co-sponsor (without commitment of dollars) the subject conference. Dr. Landrigan felt that the speakers listed on the brochure presented only one side of the

DEPARTMENT OF HEALTH & HUMAN SERVICES

Memorandum

Date: September 14, 1981

From: Science Panel Member

Subject: Preliminary Assessment of Epidemiologic Utility of Aborted Ranch Hand Missions

Chairman, Science Panel, Agent Orange Working Group

Through: Director, DSHEFS, NIOSH
Chief, IWSB, DSHEFS, NIOSH

On September 10, 1981, I met with Department of Defense personnel to learn about aborted Ranch Hand missions and to determine whether adequate information about these missions is available to allow identification of a cohort(s) with defined exposure for epidemiologic study. To this end, questions about both the exposure and potential cohorts were explored.

Concerning the exposure, ninety aborted missions have been identified. Of these, some documentation (e.g. date, altitude, agent, gallons, location, etc.) is available for 28, and less complete information on the additional 62 missions is contained in the HERBS tape. It will be important to assemble the original documentation for the additional 62 missions. Based on what is known about the 28, it appears that ultimately documentation for some of the missions will be incomplete. When all available data about these missions is assembled, information such as agent, altitude, gallons, time and date when available can be analyzed to estimate the area contaminated by the emergency dumps. The Army has begun to map the aborted missions, and this activity can and should continue with additional information on the emergencies.

Concerning the population exposed, it appears at this time that it will continue to be difficult to know with absolute certainty from records that a particular individual or unit was located directly under and came in contact with Agent Orange released in an emergency dump. The Army has, from preliminary mapping of the missions, begun to identify military populations in closest proximity to clusters of aborted missions. At this time, four population areas have been identified with from approximately 800 to approximately 12,000 military personnel in residence at the time of the aborted missions in the four areas.

In summary, this evaluation is preliminary. After all available information about the known aborted missions is assembled and evaluated, continued effort can be applied to identify the ground units in closest proximity. At that time, issues of potential cohort size, controls, etc. can be considered. It is very important to note, however, that further information about these aborted missions at best can be utilized to maximize the probability of exposure of a cohort; it will be difficult or probably impossible to define the exposure of each individual in any cohort. Questions of frequency and amount of exposure, and multiple exposures, will remain. And finally, given that the bulk of Agent Orange exposure including the aborted missions occurred in the late 1960's, the issue of inadequate latency must be addressed if a cohort mortality study is proposed.

Pat Honchar
Patricia A. Honchar, M.S., Ph.D.

information on those units that might have had the highest exposure. It is necessary to determine the duration of acute, heavy, and long term exposure to all herbicides used in Vietnam. For the herbicide Agent Orange, it would also be useful if information could be developed on the manufacturer and date of manufacture or at least whether this was one stripe or two stripe Agent. By consensus of the Science Panel, Drs. Honchar and Kimbrough were asked to work with Dr. Bricker and Mr. Christian to develop information from the Army records and other documents. Hopefully, it will be possible to identify units that have had considerable exposure to Agent Orange from these records.

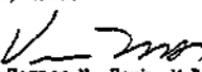
A request regarding this matter was sent to Major General Augerson on September 21. A copy of that letter is attached. The Science Panel recommends that the Chair, Agent Orange Working Group, ask the Resource Panel to explore providing the necessary resources to complete this task. By October 20, we should have a fairly good estimate of what tasks will be needed. DOD should provide a resource estimate. Not only are there groups who may have been acutely heavily exposed to these materials but the surface is likely to be heavily contaminated. It appears that at least some of these incidents occurred in places with significant populations remaining in contact with the contaminated area for a period of time. The Science Panel will explore the possibility of identifying similar non-Vietnamese areas of contamination that would lend themselves to a study of for how long and how much of the TCDD is likely to remain in the soil. It is known that TCDD degrades upon exposure to ultraviolet light. TCDD in soil on the other hand may be extremely persistent. Dr. Kearney of DA has been asked to report on this by October 20 in more detail. Dr. Kearney was also asked to determine what environmental monitoring data is available from Vietnam on 2,4,5T; 2,4D; and TCDD.

Laboratory Quality Monitoring

Dr. Eric Sampson of the Clinical Chemistry Division, GHR, CDC, presented to the Panel some general information on quality control procedures used by the information on new methods developed at CDC for the precise measurement of five reproductive hormones.

The Science Panel recommends for any investigations, including the Ranch Hand Study, that tight quality controls of laboratory tests be incorporated into their studies. This is even more critical when longitudinal observations are being made on groups so the data will be comparable over time.

Respectfully submitted September 24, 1981.


Vernon N. Houk, M.D.
Chairman, Science Panel
Agent Orange Working Group

will consider being sworn to secrecy if the designers deem it necessary to protect the integrity of the study.

The OTA received a letter from Senator Cranston asking that we be especially watchful for any evidence of bias on the part of the study's principal investigator, Dr. Gary Spivey. Dr. Spivey's protocol expresses an intention to keep details about whether or not a veteran is thought to have been exposed and about health outcomes secret from study participants. Part of the justification for this position is concern that participants might behave differently if they are privy to specifics about health exposure and health outcome. Such concerns are common to epidemiologic studies. However, one panel member thinks that the protocol too strongly expresses the opinion that veterans recalling of past events and reporting health effects might be influenced by their knowing details of exposure and health outcomes. The review speaks to these concerns and suggests that the problems can be handled without such emphasis on secrecy. The review suggests that health outcomes be made public and that they be measured as objectively as possible. The review also acknowledges that it may be desirable to withhold exposure information from participants in the early stages of the study. In that case, the designers should provide justification for any decisions made about concealing exposure information and for how long. A clear presentation of the designers' plans to disclose health outcome measures and to disclose or to withhold exposure information will greatly reduce or eliminate concerns that the alleged bias will compromise the study.

The OTA advisory panel remains intact and will review the revised protocol when it is received. OTA appreciates the importance of this study of possible health effects resulting from exposure to agent orange and looks forward to continuing its role in the study.

Senator MURKOWSKI. Thank you very much.

[The prepared statement of Dr. Michael Gough, Project Director, Office of Technology Assessment and the Office of Technology Assessment's review of the VA's "Draft Protocol for Epidemiologic Studies of Agent Orange" follow:]

Senator MURKOWSKI. All right, let's proceed with the witnesses and then we will go into the questions. Mr. Gough, would you proceed with your testimony, please?

Mr. GOUGH. I am Michael Gough and I am employed at the Office of Technology Assessment, U.S. Congress.

The role of the OTA in the agent orange epidemiological study is specified in section 307 of Public Law 96-151:

The epidemiological study shall be conducted in accordance with a protocol approved by the Director of the Office of Technology Assessment and the Director shall monitor the conduct of such a study in order to assure compliance with such protocol.

I am here today because of my responsibilities as Director of the OTA review activity.

OTA assembled an advisory panel to participate in its review of the UCLA protocol. The panel, which is chaired by Dr. Richard Remington, dean of the School of Public Health at the University of Michigan, includes two epidemiologists, two biostatisticians, a neurologist, a biochemist, a lawyer, and a geneticist.

In addition to these experts, the panel also includes representatives of organizations with an interest in possible long-term health effects that may be associated with agent orange. There are representatives from three veterans' groups: The American Legion, the Veterans of Foreign Wars, and the Vietnam Veterans of America; representatives from three industries and one public representative.

The complete roster of our panel appears on page 22 of the OTA review. That has been submitted for the record.

OTA received copies of the protocol prepared by UCLA in August. We mailed copies to the advisory panel and received telephoned or written comments from panel members before the meeting of the panel on September 8. In addition to discussing panel members' analyses and opinions at the meeting, we also heard reports from the Army about their record systems and from the GAO about its agent orange studies.

The draft protocol from UCLA lays out the elements of a large-scale epidemiological study designed to investigate relationships between exposure to agent orange and subsequent health effects.

The large-scale study requires more planning and is seen by the study designers as being some time away. In addition, five smaller studies related to the health experience of Vietnam veterans are proposed.

The overall reaction of OTA to the protocol was one of disappointment, and can be summed up by quoting from Dr. John H. Gibbon, the OTA Director, letter of transmittal that accompanied the review document. It's rather long:

* * * the protocol lacks focus and detail and requires additional work. Current plans call for the study designers to consider reviewers' comments and to submit a revised protocol. The OTA will review the revised protocol, and at that time, I will be able to consider whether or not to approve the undertaking of a study.

The review emphasizes that additional details need to be provided about (1) methods to be used in determining whether a veteran probably was or probably was not exposed to Agent Orange, and (2) how health outcomes that might be associated with exposure to Agent Orange are to be measured. The designers of the protocol express a reluctance to specify details about these items for reviewers, but an adequate review is impossible unless those details are provided. The OTA Review Panel

The 15-person Agent Orange Advisory Panel, assembled in summer 1981, is chaired by Dr. Richard Remington, the Dean of the School of Public Health at the University of Michigan. The membership roster of the panel appears on page 22 of the OTA review document, which has been submitted for the record. The panel includes 2 epidemiologists, 2 biostatisticians, a neurologist, a biochemist, a lawyer, a geneticist, representatives of three veterans groups -- the American Legion, the Veterans of Foreign Wars, and the Vietnam Veterans of America -- three representatives of industry, and one public representative. The public representative, by the way, is a chemical engineer whose farm was the site of the discovery of PBB-contamination of cattle feed. He has, since that discovery was made, been active in toxic chemical control programs in his home state of Michigan.

OTA received copies of the protocol prepared by UCLA in August. We mailed copies to the Advisory Panel and received telephoned or written comments from many members before the meeting of the Advisory Panel on September 8th. In addition to discussing panel members' analyses and opinions at the meeting, we also heard reports from the Army about their record systems and from the General Accounting Office about its Agent Orange studies.

Following that meeting, Hellen Gelband of the OTA staff and I wrote a draft review and distributed copies to the Advisory Panel and to other members of the OTA staff for comments. After that round of review, which was accomplished by telephone, a revised report was delivered to John H. Gibbons, Director of the OTA. Dr. Gibbons made a final review and then submitted OTA's report to the Veterans Affairs Committees and to the Appropriations Subcommittees on HUD and Independent Agencies in both Houses of Congress and to the Veterans Administration.

The draft protocol lays out the elements of a large-scale epidemiologic study designed to investigate relationships between exposure to Agent Orange and

PREPARED STATEMENT OF DR. MICHAEL GOUGH, PROJECT DIRECTOR, OFFICE OF TECHNOLOGY
ASSESSMENT

I am Michael Gough. I am employed as a senior analyst and project director at the Office of Technology Assessment, United States Congress.

The role of the OTA in the Agent Orange epidemiologic study is specified in section 307 of Public Law 96-151: "The epidemiologic study shall be conducted in accordance with a protocol approved by the Director of the Office of Technology Assessment ...[and] the Director shall monitor the conduct of such a study in order to assure compliance with such protocol." I am here today because of my responsibilities as director of the OTA review activity.

The primary function of OTA is preparing technology assessments on a variety of subjects at the request of Congress. Although the protocol approval and study monitoring role that has been mandated for the Agent Orange study is somewhat unusual for OTA, we followed the same basic procedures in carrying out the protocol review that we follow in other assessments. An important component of the process is the Advisory Panel that is assembled for each project. Some members of each panel are technical experts in the study topic, but OTA recognizes that decisions, even decisions about largely technical subjects, frequently have far-reaching effects on large numbers of people. Certainly the conduct of the Agent Orange study will have such far-reaching impacts. To anticipate such effects OTA invites representatives of organizations that have a stake in the outcome to participate in its advisory panels.

"...the protocol lacks focus and detail and requires additional work. Current plans call for the study designers to consider reviewers' comments and to submit a revised protocol. The OTA will review the revised protocol, and at that time, I will be able to consider whether or not to approve the undertaking of a study.

The review emphasizes that additional details need to be provided about (1) methods to be used in determining whether a veteran probably was or probably was not exposed to Agent Orange, and (2) how health outcomes that might be associated with exposure to Agent Orange are to be measured. The designers of the protocol express a reluctance to specify details about these items for reviewers, but an adequate review is impossible unless those details are provided. The OTA Review Panel will consider being sworn to secrecy if the designers deem it necessary to protect the integrity of the study.

The OTA received a letter from Senator Cranston asking that we be especially watchful for any evidence of bias on the part of the study's principal investigator, Dr. Gary Spivey. Dr. Spivey's protocol expresses an intention to keep details about whether or not a veteran is thought to have been exposed and about health outcomes secret from study participants. Part of the justification for this position is concern that participants might behave differently if they are privy to specifics about exposure and health outcomes. Such concerns are common to epidemiologic studies. However, one Panel Member thinks that the protocol too strongly expresses the opinion that veterans' recalling of past events and reporting of health effects might be influenced by their knowing details of exposure and health outcomes. The review speaks to these concerns and suggests that the problems can be handled without such emphasis on secrecy. The review suggests that health outcomes be made public and that they be measured as objectively as possible. The review also acknowledges that it may be desirable to withhold exposure information from participants in the early stages of the study. In that case, the designers should provide justification for any decisions made about concealing exposure information, and for how long. A clear presentation of the designers' plans to disclose health outcome measures and to disclose or to withhold exposure information will greatly reduce or eliminate concern that the alleged bias will compromise the study."

I would like to offer an additional observation that may be of considerable importance to the study of Agent Orange. Deciding what groups of veterans were likely to have been exposed and what groups were likely not to have been exposed depends on access to and knowledge of government records. The experts in dealing with those records are government employees, and it would be difficult and time-consuming for people from outside the government to learn the details of those systems. It may be that government employees are best able to identify likely-to-have-been-exposed and not-likely-to-have-been-exposed groups that can be studied to determine the effects of Agent Orange. If that is the case, a procedure for sharing government-generated information with the study designers and, equally important, a system to review the government's work may be necessary.

The OTA Advisory Panel remains intact and will review the revised protocol when it is received. OTA appreciates the importance of the study of possible health effects resulting from exposure to Agent Orange and looks forward to continuing its role in the study.

subsequent health effects. In addition, five smaller studies related to the health experience of Vietnam veterans are proposed.

The large scale study requires more planning and is seen by the study designers as being some time away. One reason for the delay is problems in determining which veterans were likely to have been exposed and which were likely not to have been exposed to Agent Orange. Such estimates are, of course, essential to answering questions about associations between exposure and health. The five smaller studies are designed to learn about the morbidity and mortality experience of the Vietnam veteran population. Since those five depend on existing records and do not require estimates of exposure, it was proposed that they begin while planning continues for the larger study.

OTA found so few details presented about the large study that it was impossible to evaluate the plan. In general, the OTA review panel found merit in the proposed small scale study of the mortality experience of the Vietnam veteran population. However, the study would be much more difficult to execute than the designers envisioned because of difficulties in obtaining necessary information from available records. Subsequently, we learned that the Veterans Administration has initiated planning of a similar mortality study, but the UCLA researchers had not been informed of that study. One of the morbidity studies proposes inspecting the registry of veterans complaints associated with Agent Orange that has been collected by VA. This effort was judged to be worthwhile for providing information about veterans' health concerns.

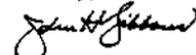
The overall reaction of OTA to the protocol was one of disappointment, and can be summed up by quoting from Dr. Gibbons' letter of transmittal that accompanied the review document.

should provide justification for any decisions made about concealing exposure information and for how long. A clear presentation of the designers' plans to disclose health outcome measures and to disclose or to withhold exposure information will greatly reduce or eliminate concern that the alleged bias will compromise the study.

During the period of the OTA review, Secretary Richard Schweiker of the Department of Health and Human Services announced the existence of newly-found information about exposure to Agent Orange. That information would seem to be of great value to Dr. Spivey in designing an exposure index, and methods to share it with him are worthy of consideration.

Included in the attached OTA review packet is a list of the OTA Review Panel Members, a chronology of the epidemiologic study, a list of OTA staff who participated in the review, and written comments received from each OTA Review Panel Member. Should you or your staff have any questions, please call Mr. Michael Gough at 226-2070.

Sincerely,



John H. Gibbons

Enclosure

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Congress of the United States

OFFICE OF TECHNOLOGY ASSESSMENT

WASHINGTON, D.C. 20510

JOHN H. GIBSON
DIRECTOR

October 2, 1981

Mr. Robert P. Nimmo
Administrator
Veterans Administration
810 Vermont Avenue, N.W.
Washington, D.C. 20420

Dear Mr. Nimmo:

I enclose a copy of the Office of Technology Assessment's review of the protocol for an epidemiologic study of possible health effects resulting from exposure to Agent Orange in Vietnam. The review draws upon written comments received from OTA Review Panel Members (which are appended to the review) and discussions at the September 8 Panel Meeting. Unfortunately, it is our judgment that the protocol lacks focus and detail and requires additional work. Current plans call for the study designers to consider reviewers' comments and to submit a revised protocol. The OTA will review the revised protocol, and at that time, I will be able to consider whether or not to approve the undertaking of a study. This consideration is required of me by the Veterans Health Programs Extension and Improvement Act of 1979 (Public Law 96-151).

The review emphasizes that additional details need to be provided about (1) methods to be used in determining whether a veteran probably was or probably was not exposed to Agent Orange, and (2) how health outcomes that might be associated with exposure to Agent Orange are to be measured. The designers of the protocol express a reluctance to specify details about these items for reviewers, but an adequate review is impossible unless those details are provided. The OTA Review Panel will consider being sworn to secrecy if the designers deem it necessary to protect the integrity of the study.

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4. Two preliminary studies of morbidity among Vietnam veterans that make use of existing records.

The historical cohort study is slated to begin in 1983. The designers propose that the preliminary studies be carried out in the intervening period.

HISTORICAL COHORT STUDY REVIEW

Description of the Study

The contractors propose an historical cohort study to investigate: Is exposure to Agent Orange in Vietnam related to subsequent morbidity and mortality among veterans?

The appropriateness of the historical cohort approach is unchallenged, but the ability to carry out such a study rests on one large unknown and a number of other serious hurdles. The central question is whether or not an acceptable assessment of exposure to Agent Orange can be developed. Without such an assessment, the study is not possible. The other major concerns, discussed in this review, include: determination and specification of health outcomes, participation rates to be expected from veterans, sample sizes necessary for the study, organization and conduct of the study, and maintenance of privacy.

The study design is traditional, and proposes a comparison between the long-term health experience of a group of veterans exposed to Agent Orange and the experience of a similar but unexposed group. The cohorts will include Army and perhaps Marine Corps ground troops, selected to represent various levels of exposure. Active duty and veteran records of each member of the cohorts will be examined for pertinent information. All members of both the exposed and unexposed cohorts will be sent a questionnaire and asked to participate in a physical examination. The cohorts will be followed into the future to detect possible longer-term health effects. Data from all sources will be analyzed to

REVIEW OF THE VETERANS ADMINISTRATION

DRAFT PROTOCOL FOR
EPIDEMIOLOGIC STUDIES OF AGENT ORANGE

INTRODUCTION

An OTA Advisory Panel met and considered the Draft Protocol for Epidemiologic Studies of Agent Orange. The protocol was prepared by the School of Public Health, University of California at Los Angeles, Gary Spivey, MD, MPH, principal investigator, and Roger Detels, MD, MS, and Dean of the School of Public Health, co-principal investigator.

The paucity and in some cases absence of details from the protocol prevented the Advisory Panel from reaching a decision about whether or not a study to answer questions about associations between Agent Orange and health effects can be successfully designed. To some extent the lack of detail is understandable because of the press of time to prepare the draft protocol, and the Panel is sympathetic on that count. The Panel is more concerned about the expressed intention of the study designers to withhold details from reviewers to protect the study's integrity. The Advisory Panel will consider swearing all or a subgroup of its members to secrecy in reviewing a detailed protocol, but it cannot discharge its duty unless those details are provided. Possible methods to deal with privacy and secrecy during conduct of the study are discussed in the body of this review.

The protocol describes:

1. A historical cohort study to assess possible associations between Agent Orange exposure and health effects.
2. A method to estimate Agent Orange exposure and the feasibility of assembling exposed and unexposed groups for the historical cohort study.
3. Three preliminary studies of mortality among Vietnam veterans that make use of existing records.

exposure index allows for the possibility that a satisfactory index cannot be developed. Criteria to evaluate the feasibility study, and the basis for making a decision between success and failure, must be made explicit before the feasibility study is begun. Although a general outline for making an index was provided in the protocol, details which permit making a critical review are lacking.

The panel agrees about the desirability of constructing categories of probable exposures, but does not expect great precision in defining the categories. For instance, the number of times (0, 1, 2, 3, or more) that a soldier may have been exposed as probably sufficient to assign him to an exposure category. It may be that such an exposure index would obviate the need for a control group of veterans who did not serve in Vietnam. Elimination of that control group has advantages:

1. Differences between Vietnam veterans and other Vietnam-era veterans, which could act as confounding variables, and falsely obscure or enhance true associations between exposure and outcome are avoided.
2. The problem of differential response rates between Vietnam veterans and other Vietnam-era veterans is avoided. It is likely that Vietnam-era veterans who did not serve in Vietnam will be less motivated to participate than Vietnam veterans, to whom eventual benefits from the study might accrue.
3. Those who did not serve in Vietnam will be aware of their exposure status (not exposed), while others in the study might not be. This difference could produce biased responses. (The issue of disclosing exposure status to participants is discussed below.)

HERBS Data and Tape

Development of an accurate exposure grid depends heavily on the accuracy of

determine whether certain health outcomes are statistically more common in the exposed group.

General Comments

As the authors have noted, the historical cohort study is described very broadly, with few details. It is not possible, therefore, to either approve or disapprove the plan. Grave doubts were expressed by some panel members that any possible study would produce scientifically credible results. Until more preliminary work is completed, a definitive judgment cannot be made.

The panel favors proceeding with the proposed "Feasibility Test of Exposure Estimation," specification of health outcomes, and determining appropriate methods to measure outcomes (discussed in detail below). Development of the exposure index is seen as the most critical task at this time. If such an index can be developed, a decision can be made about the feasibility of an Agent Orange Study; if it cannot be developed, the study is impossible.

Assuming successful development of the exposure index and identification of outcomes, a pilot testing phase, which would be a scaled-down version of the large study, is recommended. The pilot study will define and standardize procedures and provide an estimate of the rate of veteran participation, another touchstone of the study.

Before any testing of the design is begun, however, decision criteria must be developed for application during and after the feasibility and pilot phases. Failure to meet threshold criteria in critical areas -- in development of an exposure index or in achieving an adequate response rate -- must lead to either abandoning the study or making specific alterations in design.

Exposure

The contractors' proposal to determine the feasibility of constructing an

Participation and Sample Size

The rate of response to invitations to participate in the study is one of the pivot points for deciding whether or not a study should be conducted. The anticipated response rate in the study is not discussed in the draft protocol, but it must be addressed promptly, either in the "feasibility phase," or as part of an initial pilot study. A breakpoint response, leading to alteration or abandonment of the study, should be specified in advance.

The designers should control for bias introduced by proportionately greater participation by veterans who both believe they were exposed to Agent Orange and have health complaints. Some check on this possible bias should be built into the protocol. A suggestion from the Panel is to ask participants what they believe their exposure status to be and then to look for associations between perceived exposures and the results of physical and laboratory testing. A comparison of the associations between health outcomes and perceived exposure and between outcomes and exposure as defined by the study, assuming that there are some differences in the two measures, can be used as an indicator of possible self-selection bias.

The manner of contacting cohort members is critical to the potential success of the study and details of the proposed procedure should be specified. Issues that will bear on the resulting response rate include:

1. Method of contact (personal interview, telephone interview, letter)
2. Contacting body or individual(s) (VA, DOD, contractor, other government officials). The Air Force has carefully considered this issue, and their deliberations are worthy of review by the study planners.
3. The availability and use of supporting statements from veterans' organizations to accompany invitations to participate.

the HERBS data.¹ Validation of these data will improve the credibility of the exposure index. At the panel meeting, a staff member of the House of Representatives Committee on Veterans' Affairs stated that high altitude photographs showing areas of defoliation exist. The time-place coordinates of HERBS records could be matched against the information in the photographs as a measure of HERBS accuracy and possibly to fill in known gaps. Until more is known about these photographs, it is impossible to predict their usefulness. They are highly classified. It is our understanding that a mechanism can be established to allow the defoliation patterns to be interpreted and the information turned over to the study designers. If our information is accurate, this could prove a valuable source of data.

Health Outcomes Measurements

The Panel strongly recommends that health outcomes be specified by the end of the feasibility phase. Sources of information already available or available by the end of 1982 may be sufficient to specify outcomes. These include:

1. Scientific literature already published.
2. Review of the herbicide literature (mandated by the same law PL 96-151 that mandates this epidemiologic study) expected by October 1981.
3. Results from the questionnaires and physical examinations of the Air Force Ranch Hand Study, available toward the end of 1982.

As evidenced by their review of the popular literature, the authors appreciate that veterans have a wide range of complaints that have not been verified by medical science. It is important, in deciding upon which outcomes to measure, that the study look at health effects that veterans believe result from Agent Orange, even if scientific support is weak. The VA's Agent Orange registry provides relevant information.

4. Use of a publicity campaign to precede and coincide with the invitations.
5. The possibility of guaranteeing medical care for conditions detected in study participants.

By the end of the feasibility phase, the study designers must estimate the sample size that will be required. An important consideration in this estimation will be what health outcomes are to be measured. Estimates of the time and resources required for the cohort study will depend on sample size. The organizational structure for the eventual study will also be partially determined by the size of the study.

Physical Examination

The Panel is highly critical of the discussion of physical examinations in the protocol. The use of a general screening examination to detect potential specific, and often subtle, effects of toxic chemicals, is inappropriate. In addition, important areas of concern are not addressed by the physical examination. Neurological, reproductive, and psychological effects, for example, cannot be detected with the proposed exam. Although the examination and laboratory procedures cannot be fully determined until decisions concerning health outcomes are made, there can be no doubt that certain effects, including those mentioned above, must be included.

The lack of discussion of examination procedures disturbed Panel members. Data collection for this study must be carried out systematically and in a highly standardized fashion. To the extent possible, outcome measures should depend on objective measurement.

The proposed physical examination procedure, which apparently allows for ad hoc decisions by physicians to perform additional examinations and to require

additional laboratory tests, is unacceptable. Some mechanism should certainly be devised for study physicians to refer participants to VA physicians or to their own private physicians for additional tests or care, but all participants should receive the same study examination.

The following items might be considered in efforts to standardize both the physical examination and laboratory tests:

1. Physicians administering examinations should undergo training by the organization responsible for the study.
2. The number of physicians administering examinations should be as small as practicable.
3. Criteria should be specified for making decisions to carry out more detailed examinations and tests for particular conditions.
4. The number of centers at which examinations take place should be as small as possible, without reducing the participation rate because of time and travel inconvenience.
5. It is preferable that all laboratory procedures be conducted in a single place, or at least that all of one particular test be analyzed at one place. This is most important for tests known to be difficult to standardize.

Who will conduct the study?

The organizational structure for conducting the study is important but not discussed in the protocol. The structure can seriously influence participation rates. It appears that veterans will be most receptive to a design with minimal involvement of the VA. Veterans' groups believe that the credibility of the VA, with respect to Agent Orange, has been seriously compromised and that an outside

group should run the study.

Some roles for the VA may be possible in a study conducted by an outside group. For example, participants might accept examinations by adequately trained VA doctors in VA-affiliated hospitals if the data are given to a private contractor for analysis. There is universal pessimism that sufficient participation can be achieved if the study is conducted exclusively by the VA.

Some type of monitoring body, either with or without decisionmaking authority, should be considered as part of the study's administrative structure. Such a group might be useful not only for scientific purposes but as an impartial group that would enhance the credibility of the study in the eyes of the public.

Privacy

The issue of privacy has two facets which concern the Panel: withholding of information from review groups, and withholding of information from study participants and the public. The Panel feels strongly that all details of the study protocol must be made available to review groups if these groups are to comment usefully and, in OTA's case, to fulfill the Congressional mandate to approve or not to approve the study design.

The study designers identify some risks involved in making the study plan public, and the Panel recognizes the same risks. However, the Panel believes that these risks must be accepted. Objective measures and standardized examinations can, in part, offset the risks. The following reasons argue for making the health outcomes of the study public.

1. Because of the political and social tension associated with Agent Orange, studies bearing on the question of health effects must, to be credible, be carried out in an open manner.
2. If outcomes are not initially public, but become so only after the

study is completed, the study can be faulted for failing to look for certain health effects. Rationales for including or excluding particular outcomes should be stated initially, and arguments pro and con entertained before the study is begun.

3. Based on information already public, interested parties will know most of the outcomes being considered. As soon as the questionnaire and examination are administered to the first participants, interested parties will be able to determine, at least generally, what outcomes are being assessed. The conspiratorial atmosphere generated by withholding information could have a deleterious effect on the results of the study.

The protocols should discuss the issue of revealing exposure information to participants. To compound the problem of concealment of exposure status, there exist a number of mechanisms whereby veterans can get partial information about potential exposure status:

1. Copies of the HERBS data tape are available for a fee from Department of Defense (DoD). A veteran can place himself in the time-place grid contained in HERBS.
2. The DoD will, upon request, provide veterans with information bearing on the exposure status of their battalion.
3. A private group in Berkeley is selling veterans what they claim to be information about potential exposure to Agent Orange.

Veterans using information from one of these three sources to guess at their exposure status might compromise the study more seriously than if they are told their status by the investigators.

It was suggested by representatives of veterans' groups that as long as

veterans were assured they would be informed of any health problems found and provided necessary medical treatment that revealing exposure status might not be necessary. This contention is supported by a policy of the VA that assumes a veteran claiming exposure to Agent Orange was, in fact, exposed in the absence of positive evidence to the contrary. Thus, exposure status, as determined by the study, will not necessarily bear on any eventual claims made by study participants.

Treatment of the issue of making information available to participants is inadequate in the present protocol. Protection of participants' reasonable rights is as important as protection of study integrity, but it is not discussed. The study designers should discuss an informed consent procedure and should specify the ethical problems they anticipate and how they will deal with them.

REVIEW OF PRELIMINARY STUDIES

General

The proposal outlines three studies of mortality and two of morbidity "to provide a relatively quick look at several questions ... in a reasonable period of time."

Description of Three Preliminary Mortality Studies

1. A proportionate mortality analysis to "determine if there is unusual cause of death or pattern of causes of death among Vietnam veterans or a specific subgroup of Vietnam veterans."
2. A determination and comparison of death rates for Vietnam veterans and Vietnam-era veterans who did not serve in Vietnam.
3. The "frequency of experience in types of military units and of service in geographic regions of heavy defoliant use" will be compared between

each of 2,000 deceased Vietnam veterans (cases) and 2,000 living Vietnam veterans (controls). The cases and controls will be matched for age, race, and educational level at the time of induction into the armed forces.

All of the studies depend on existing records and are to be completed within 14 months. Of the proposed mortality studies, the Advisory Panel supports the proportionate mortality analysis, but doubts that it can be completed in the time allowed in the protocol. The other preliminary mortality studies, as proposed, are unlikely to yield information commensurate with the efforts required to complete them.

A general criticism of the proposed mortality studies is that they do not directly address the possible connection between exposure to Agent Orange and mortality. Because the thrust of the current contract with UCLA is to investigate that connection, the Panel questions undertaking studies that do not bear on that question. While such studies would reveal nothing about Agent Orange, results from them could be interpreted as having something to do with the study of the herbicide, and might be misused in arguments about Agent Orange and health. A related concern deals with the proposal's suggestion that results from the preliminary studies might be used with the exposure index, which will still be under construction at the time the preliminary studies are being conducted. Until the exposure index is firmly established and validated, it should not be used.

Critique of the Proportionate Mortality Analysis

The Advisory Panel generally favors undertaking the proportionate mortality analysis. Such an analysis may reveal unusual causes of death or unusual patterns of causes in Vietnam veterans if they have occurred. However, it appears impossible to complete the study in the 14 months as planned.

The crux of the proposal is that the VA's BIRLS (Beneficiaries Identification and Records Location System) can be used to identify Vietnam veterans and other Vietnam-era veterans, discharged 1965 through 1972, who died during the years 1966 through 1981. BIRLS is a relatively new system, and the completeness of its records has not been evaluated, but the system preceding it included the fact of death for more than 95 percent of all deceased veterans. It is expected that the percentage of deceased veterans identified in BIRLS is nearly as high.

On the negative side, there is no way for the BIRLS system to discriminate between a veteran who served in Vietnam and another Vietnam-era veteran who served somewhere else. (Personal communications, J.F. Bub, VA; S. Jablon, National Academy of Sciences; G. Peterson, VA.) Furthermore, since the emphasis of the proposed study is on ground troops, it is important to note that BIRLS has information about branch of service for only about 75 percent of veterans. Therefore, BIRLS cannot identify those veterans who served in Vietnam, and it cannot provide information about the branch of service on a significant percentage of veterans.

The timetable for the mortality studies allows two months to obtain death certificates for identified deceased veterans. According to the National Academy of Sciences Follow-up Agency, which has had extensive experience with such efforts, about 6 months is usually required to accumulate 2,000 death certificates. The two-month period seems impossibly optimistic, especially if 130,000 death certificates are to be studied.

It is beyond the scope of this review to estimate how long a time will be required to complete the proportionate mortality analysis. Nevertheless, it seems evident that it cannot be completed within 14 months. Whether or not it should be undertaken can be decided only when additional information is presented. A sampling plan which would not require collection and examination of

130,000 death certificates might offer the possibility of a manageable study.

A specific criticism is directed at the protocol's plan to divide the Vietnam veteran population into "subgroups" for the proportionate mortality analysis. No justification is presented for making such divisions, the subgroups are poorly specified, and no criteria for inclusion or exclusion are detailed. Some concern was expressed that certain "subgroups," say "combat units," might be equated with "more likely exposed" while "logistic units" might be grouped into "not likely exposed." Such parallels, even if not drawn by the investigators, might be made by others and be very misleading.

Critique of the Comparison of Death Rates

If, as suggested in the protocol, the Armed Forces Separation One-Percent Sample can be used to provide denominator (population at risk) information, and if the proportionate mortality analysis is completed, calculation of death rates will be an easy exercise. If the One-Percent Sample is not adequate, the calculation becomes more difficult and time-consuming.

Although the Advisory Panel expresses little enthusiasm about this study, arguments have been made in Congress that the Vietnam veteran population is experiencing higher-than-expected death rates. Reliably-calculated death rates would be useful in that discussion. However, a decision to proceed requires better estimates of the time and effort necessary to complete the study.

Critique of the Case-Control Study

The proposed case-control study is not strongly supported by the Panel. A study with 2,000 cases is much too small for a "fishing expedition" to associate particular causes of death with either a geographic location in Vietnam or service in a certain type of military unit. Case-control studies of selected causes of death are viewed more favorably.

Some Advisory Panel members expect that the proposed case-control study would provide very little or no information beyond that to be expected from the proportionate mortality analysis. The case-control study shares a problem with the proportionate mortality analysis. There is concern that information about geographical location and service unit will be transposed into surrogates for Agent Orange exposure and lead to erroneous conclusions by the public.

Morbidity Studies

The protocol describes two preliminary morbidity studies:

1. VA files will be examined to compare claims made before and after widespread publicity about Agent Orange. A proportionate morbidity analysis and a comparison between medical claims filed by Vietnam veterans and Korean War veterans at comparable time periods after the two conflicts is also proposed.
2. The VA's Agent Orange Registry will be used to determine the frequency of different types of complaints associated with Agent Orange by veterans.

Morbidity studies are necessary, as the protocol states, to detect adverse health effects which do not result in death. Furthermore, results from preliminary morbidity studies may be especially useful in developing outcome measures for the planned cohort study. The Advisory Panel supports only the second of the proposed studies.

Results from the Ranch Hand Study physical examinations are expected late in 1982 at about the time that results can be expected from the first proposed morbidity study. The Ranch Hand results in combination with the results of the VA-funded literature review may provide the necessary information to design the questionnaire and physical for the cohort study. If those two studies do not

provide sufficient information, more extensive morbidity studies might be desirable.

Critique of the Morbidity Study Using Claims Files

The investigators intend to sample claims made by veterans during the period 1965 through 1975 and compare those to a sample of claims made during the period 1976 through 1980. The purpose of sampling two periods is to examine claims made before much of the publicity about Agent Orange, and compare those to claims made subsequently. Examination of the two time periods may well reveal a difference in complaint patterns, but interpretation of such a difference will be difficult. As one possible explanation for changing patterns, consider a veteran who had been suffering from a minor complaint. He might not report the complaint to VA until he learned that it had been associated with Agent Orange. Alternatively, another veteran, hearing of a subjective complaint being associated with Agent Orange might report a similar subjective complaint that was either nonexistent or generated by hearsay. In the first example, case finding is improved; in the second, a complaint is generated.

Only about 25 percent of Vietnam-era veterans depend on VA for medical care. A study based on VA records will necessarily be incomplete and the potential bias introduced by such a sample is not discussed in the protocol. The incomplete coverage of veterans in the VA files would decrease the reliability of any results from a proportionate morbidity analysis that depends on those files.

The Panel members find no value in the proposed comparison of claims made by Vietnam veterans against claims made by Korean War veterans. Times, conditions, standards, and practices changed so much during the period between the wars that no useful information is expected from the comparison.

The VA file called "Veterans, Dependents, and Beneficiaries Compensation and Pension Records" has many advantages for a morbidity study as is pointed out in

the protocol. However, it does not differentiate between Vietnam veterans and other Vietnam-era veterans, (T. Preston, National Academy of Sciences), and it includes information only about veterans who have filed claims with VA.

Critique of the Agent Orange Registry Analysis

The investigators propose to determine the frequency distribution of complaints filed by veterans in relation to Agent Orange from the VA's Agent Orange Registry computer file. With some reservations, the Advisory Panel favored going ahead with this analysis, in large part because it appears to be a relatively easy, straightforward task. Should major obstacles present themselves in the undertaking, which would require more time and resources, the question of whether or not it should be completed should be reopened.

Reservations about the study were raised because the registry suffers from a number of shortcomings that reduce its usefulness for a morbidity study. For example the complaints are from a self-selected sample, and the registry was not designed as a research tool.

The VA is currently comparing Agent Orange Registry complaints against VA hospital treatment records, and VA is able to provide the contractors with some information.

RECOMMENDATIONS FOR PROTOCOL REVISION

The OTA Advisory Panel makes the following suggestions for preparing a revised protocol:

1. Highest priority should be placed on:
 - a. construction and validation of an exposure index, and determining the feasibility of associating units or individuals with levels of exposure,
 - b. detailing and justifying the health outcome to be evaluated in the cohort study and developing methods to measure them,
 - c. preparing estimates of the size of study population necessary to study health outcomes.
2. Planning of the proportionate mortality analysis should continue, but neither its planning nor execution should delay beginning the cohort study.
3. Information from inspection of the Agent Orange Registry to learn about veterans' complaints should be considered and evaluated in detailing health outcomes for the cohort study.
4. Decision criteria should be built into the cohort study plan to guide decisions to continue, alter, or discontinue the study. In particular, such criteria should be specified for the following activities:
 - a. the construction of an exposure index and its application to associating units or individuals with exposure levels,
 - b. methods to measure specific health outcomes in such a way as to provide meaningful results,

- c. estimating the size of the study necessary to provide meaningful results,
 - d. insuring an adequate participation rate among all the study cohorts.
5. The study of death rates, the case-control study, and the morbidity study using veterans' claims should either be dropped or more strongly justified.
 6. The Review Panel must be allowed to see details of the exposure index and health outcome measures. Protection of privileged information can be provided as necessary.
 7. Plans for making public or withholding information about exposures and health outcomes should be discussed in the revised protocol.

In whatever manner the VA and the contractor proceed in revising the protocol after receiving comments, the Advisory Panel agrees that it is imperative that each proposed preliminary study and feasibility test be thoroughly justified. Certain minimal criteria must be met, including a clear statement of the hypotheses being tested, a detailed timetable for each aspect of the study, explanations for inclusions and exclusions of groups of veterans and particular outcomes, and the information expected to be gained toward answering the larger question about the health effects of Agent Orange on Vietnam veterans.

If the contractors are severely constrained by time, the VA might consider asking that the contractors concentrate on determining the feasibility of constructing exposed and unexposed cohorts and on specifying health outcomes to be measured. Alternatively, consideration might be given to extending the revision period.

A Chronology of Events in the Congressionally Mandated Epidemiologic Study of Viet Nam Veterans and Projected Dates for the Completion of Various Tasks in the Design of the Study.

- December 1979 Congress passes Veterans Health Programs Extension and Improvement Act of 1979 (PL 96-151). The Act directs (1) the Administrator of the VA to prepare a protocol (plan) for the study of Viet Nam veterans who may be experiencing health effects resulting from exposure to dioxins contained in Agent Orange; (2) the Director of the Office of Technology Assessment to review and approve the study protocol within 180 days after passage of Act (that time period ended about June 20, 1980). If the OTA Director did not approve the plan by then, he was periodically to report to Congress reasons for the lack of approval.
- Dec. 20, 1979 President signs Act into Law.
- December 1979 VA decides to use competitive bid procedure to select an epidemiologist to design the study protocol.
- Feb. 4, 1980 VA publishes its intention to let contract for design of the protocol in the Commerce Business Daily.
- Mar. 19, 1980 VA issues Request for Proposals (RFP).
- Apr. 11, 1980 Conference of potential bidders hosted by VA.
- May 6, 1980 National Veterans Law Center initiates legal action and bid protest about procedures used by VA in soliciting bids.
- May 8, 1980 Last day for receipt of bids.
- May 1980 A selection board of government experts reviews the bids and makes tentative ranking. No further action is taken because of legal suit and bid protest pending against VA.
- Jun. 13, 1980 Judge Harold H. Green of the DC District Federal Court asked that GAO make a ruling about the issues raised in the bid protest.
- August 1980 OTA begins making periodic reports to the Committees of Congress about reasons it has not approved the study protocol. At that time, VA expected to issue contract in September. Subsequent reports kept Congressional Committees informed of continuing legal delays.
- Feb. 2, 1981 GAO finds in favor of VA, and VA can proceed with letting contract.

- Feb/Mar 1981 VA contacts bidders and seeks updated information about their interest in and capability to design the study protocol.
- April 1981 VA reconstitutes selection board of government experts to examine revised bids.
- May 1, 1981 VA selects the School of Public Health, University of California at Los Angeles (UCLA) to design the study protocol.
- May 1981 OTA begins to assemble panel to review the study protocol.
- May 26, 1981 UCLA requests and is subsequently granted a 30-day extension of the contract.
- Aug 18, 1981 OTA receives draft protocol from VA.
- Aug 19, 1981 OTA sends copies of draft protocol to Advisory Panel members.
- Sept 2, 1981 Interagency Work Group on Agent Orange Science Panel receives draft protocol for review.
- Sept 8, 1981 OTA Advisory Panel meeting.
- Sept 23, 1981 Department of Health and Human Services announces newly-discovered military records of aborted Agent Orange defoliation missions, which may provide the basis for identifying heavily exposed veterans.
- Sept , 1981 OTA Director sends review of draft protocol to VA and Congress.

THIS BRINGS US TO THE PRESENT

Following receipt of all official reviews, the VA will forward comments to UCLA for revision of the protocol. The official timetable allows 30 days for UCLA to respond. The revised protocol may require additional review by OTA and others. Events after that step are uncertain.

AGENT ORANGE STUDY PROTOCOL REVIEW

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AGENT ORANGE STUDY PROTOCOL REVIEW

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Senator MURKOWSKI. I have a question that I will pose to the panel. Is it customary that protocols are generally accepted the first time that they are submitted or is this an unusual case because of its complexities?

Mr. KULL. I would defer to Dr. Houk, who was—is the Chairman of the Science Panel and had the opportunity to review that protocol.

Senator MURKOWSKI. Dr. Houk.

Dr. HOUK. I think that very few protocols are bought at first blush in coming through and there is the process of development and peer review to make certain that the result of the study when it is over will meet the needs of the study that the appropriate population groups and et cetera.

The problem that we had, and the science panel, is again, which everybody has discussed I think here today, that there is such insufficient information that the Science Panel did not indeed classify this as a protocol. That we were not able to review constructively and we set out in the charge that I gave to the panel is that we wanted to be as constructive as possible while we were reviewing this to come through, but we were just simply unable to do so.

Senator MURKOWSKI. Is there a consensus among the panel with regard to whether the protocol ought to be redone in its entirety, or are there substantial portions that are acceptable?

Dr. HOUK. To have a study design, one needs to know what is going to be studied and then how to do it. And those two ingredients are basically missing from the design.

Senator MURKOWSKI. They would seem like the very foundation of the study.

Dr. HOUK. Yes. This is the reason, Senator, which we were unable to constructively review the proposal.

Senator MURKOWSKI. It would be helpful to have your opinion as to why this very foundation was not in evidence here.

Dr. HOUK. There are difficulties in establishing a group of people or a cohort who have a high probability of being exposed, and a

group of people, or a cohort, who have a high probability of not being heavily exposed. At the time Dr. Spivey and his colleagues at UCLA were developing the protocol I think there was not sufficient development of the records and understanding of the records that this could be easily done.

Having spent a great deal of time in the last several months with Mr. Christian and the people under him, I remain, or I am convinced that if the epidemiologists, the researchers, would specify very clearly what is exposure and specify very clearly what is not exposure, that is, what is a high risk group and a low risk group, determine the numbers of people they need in each of these groups to address these specific issues that are being addressed so that the results of the study will have sufficient power that they will be valid. Then Mr. Christian and his group could select the units and, therefore, the people doing this kind of a study.

The epidemiologic science is not a laboratory science. It is never designed with everything in place. It is not necessary to know that every individual in the group that is selected that is highly exposed is in fact that highly exposed.

The issues we deal with every day in doing epidemiologic work, do our best to select the groups to meet the criteria that we have and then go on with the study design.

Dr. GOUGH. Senator.

Senator MURKOWSKI. Please go ahead.

Dr. GOUGH. The UCLA document was not intended to be a final product. It is a draft and the contract that VA wrote with UCLA included a time review, and UCLA's subsequent submission of a final protocol. So, to answer your original question, this was always expected to be a preliminary draft.

Senator MURKOWSKI. Tell me, and I will address this to the panel, does the working group have a proposal of its own or suggestion for an exposure index and, if so, is it feasible? Might it be helpful to UCLA to be given a definition of exposure and, if so, is that possible? We seem to have a lack of a starting point here.

Dr. HOUK. Yes, and these data are evolving at the moment. And I think that whoever would do the study, that the Science Panel has enough expertise on it and is familiar enough with the record, work closely enough with Mr. Christian that we could come up with some rather specific definitions of what is a high degree of exposure and what is low probability of exposure.

Senator MURKOWSKI. So, you feel you could come up with an exposure index?

Dr. HOUK. I would not like to call it an exposure index, but I think we would come up with helping whoever did the study to design the groups and to pick the groups that have these characteristics or having been exposed and the absence of these characteristics or not having been exposed.

Senator MURKOWSKI. In light of the fact that the working group seems to have access to most of the available information about developing exposure indexes and the problems involved, should the working group perhaps take the lead in doing so, or in determining that developing such an index is not possible? Well, you have indicated that it is possible. What would be the attitude of the working

group to involve themselves specifically in developing this exposure index, which is what I call it, you call it something else?

Dr. HOUK. The entire effort of the Science Panel since the first of August when it was reinstated has been directed precisely at that effort. To determine if it is possible, indeed, to do a study. It is my opinion that it is possible and that the groups can be chosen and that I would think that by giving the characteristics to Mr. Christian and his people who understand the records so well, the Science Panel could certainly oversee that effort to insure that the appropriate groups were indeed selected.

Senator MURKOWSKI. Do you feel that the UCLA should have additional chances to improve the protocol that they now have?

Dr. HOUK. The development of a protocol, or development of a study; that is, a protocol is a piece of paper, to address an issue as complex as this one, it seems to me that the timeframe originally proposed in the RFP was inadequate. I doubt that anybody in the world in that timeframe could have come up with all the questions answered and with all the details in there that people would like to have seen.

I think that no competent epidemiologic group in the country which I am aware could have met those timeframes specifically.

Senator MURKOWSKI. I assume then the additional time given UCLA, in your opinion, would not be adequate, the additional 30 days?

Dr. HOUK. My—speaking my personal opinion and not of the science panel, yes, it would not be adequate. I would hope that it would be.

Senator MURKOWSKI. How much time would you suggest might be reasonable? Personal opinion.

Dr. HOUK. Personal opinion, something of this complexity and integrity that's been going on for 2 years since the law was passed, it seems reasonable, it would seem reasonable to me to think in terms of 3 or 4 months to design the protocol, to get into the record system, to work with the Science Panel, to do the things that we can help whoever is going to design this with the knowledge that we have gained over the last several months in identifying cohorts of people.

Senator MURKOWSKI. Can you provide, or any of the staff, any further suggestions to help Dr. Detels or Dr. Spivey if they are requested to revise the protocol?

Dr. HOUK. I think the major area that we would be able to help Dr. Detels is sharing with him our knowledge about exposure and groups of people that are probably exposed. The approach that they are taking, once that gets established, in answering this question, the very acceptable and standard approach that most everyone would take to address the issue.

Senator MURKOWSKI. If the design is ultimately not approved, what course of action would you suggest that the VA take?

Dr. HOUK. That is as I understand the legislation, that they are required to produce a study. And if that is not approved, then to issue, or go back, make another assessment of who else would be able to bid, who else would be able to design. I think one of the real difficulties is that it has not been well enough addressed yet of what needs to be done and how it needs to be done. And I think the

"who needs to do it" needs to come after those first two. Who has the capability to do it needs to come after those first two things are answered.

Senator MURKOWSKI. Now, you indicated your personal opinion that a reasonable timeframe or an adequate timeframe might be 3 or 4 months additional time allotted to the present contract. Yet, if the design is not approved, and they have to start again, what is the timeframe in your opinion that would be reasonable to assure thoroughness?

Dr. HOUK. I believe adequate time and the epidemiologic expertise that exists in any well-founded institution such as UCLA and many others in the country would produce a protocol, would produce a study that could answer these questions or give the probability of answering these questions for the Congress, the American people, and for the veterans.

Senator MURKOWSKI. In what timeframe?

Dr. HOUK. I think that within 3 or 4 months—

Senator MURKOWSKI. So, it would be the same then whether they continue with the existing contract or not?

Dr. HOUK. Yes.

Senator MURKOWSKI. That seems a little difficult for me to totally accept because I would assume that if you went out again that there would be a certain leadtime necessary to cite the specifics of what was going to be requested. And in view of the necessity of having this, I am wondering what in the best interest of Federal funding is the best alternative time wise.

Dr. HOUK. The time I gave you, Senator, is my opinion about after you selected who is going to do this. A great—with the literature review done by the VA and recently published, with these things, putting all of these things into one place would make some of the preliminary work much easier than it was before that UCLA went through.

Senator MURKOWSKI. I understand. I think that concludes the questions that I have at this time.

Chairman Simpson has asked me to advise you that evidently this room will not be available soon and the hearing will reconvene at 1:30 in room 412 of the Russell Senate Office Building. That's on the fourth floor.

Is it necessary that you gentlemen be excused at this time or would you be willing to sit initially during the introductory period of the reconvening of the panel?

Mr. KULL. I can't speak for the others, but I would like to continue to be present and I think that—

Senator MURKOWSKI. All right, I would appreciate that and I would ask that the counsel so advise the chairman and I thank you for your excellent testimony and your response to the questions.

Mr. KULL. Thank you very much, Mr. Chairman.

Senator MURKOWSKI. First session is adjourned until 1:30.

[Whereupon, at 1 p.m., the session was recessed, to reconvene at 1:30 p.m. this same day, Wednesday, November 18, 1981.]

AFTERNOON SESSION

Chairman SIMPSON [presiding]. The hearing will come to order. I appreciate your patience as we relocated ourselves, having been tossed out of the other hearing room unceremoniously. And now back to the Veterans' Affairs Committee room.

I believe we are at the agenda item of the Office of Technology Assessment and the Chairman of the Agent Orange Working Group. Senator Murkowski had asked some questions and I now have a very few additional ones. Then we will proceed with the next panel.

Dr. Gough, under Public Law 96-151, which mandated the OTA to review and approve the study protocol or to report to the Congress reasons for lack of approval, you have reviewed the protocol submitted by UCLA. You stated on the first page of your review that due to the absence of details, the advisory panel was prevented from reaching a decision.

Is that a normal occurrence when reviewing protocols? Do these study designs usually lack detail? Can you describe the type of work that is usually anticipated or expected in a protocol?

Dr. GOUGH. I can't respond to the first question about whether or not it's usual, because this is the first time the OTA has participated in a review of an epidemiologic protocol.

I can respond to the second part of the question, which is what kind of detail was expected. The OTA Advisory Panel needs to have details about the construction of the exposure index or indices, and also about what health effects are going to be looked at in the veterans' population. Those details were not provided in the first draft.

Chairman SIMPSON. So it was somewhat unusual from that standpoint?

Dr. GOUGH. Yes, that was an unusual circumstance.

Senator SIMPSON. If the final design of the protocol is not approved, what steps would you recommend the VA take?

Dr. GOUGH. Speaking as an individual?

Chairman SIMPSON. Yes, if you would rather.

Dr. GOUGH. Yes, because we have not discussed that as part of our review.

I think that a year and a half ago the VA made the correct decision to go outside the agency to have this study conducted. If it's decided that UCLA cannot do the study, I think the VA would again have to go outside and look for a group of competent people to carry out the study.

It was clear from our review that veterans would be more likely to participate and more likely to believe in the results of the study if it was conducted with minimal involvement of VA.

Chairman SIMPSON. After hearing the testimony this morning, do you believe that it is possible to establish some kind of statistically valid exposure index for agent orange?

Dr. GOUGH. I think it can be done. As you know, the OTA sits as an observer on the Agent Orange Working Group and there is a division of opinion in that group about whether or not an index can be developed.

Chairman SIMPSON. Even in the face of this morass of undecipherable records that need manual attention, which we heard about this morning?

Dr. GOUGH. The manual attention requires time and manpower. I have heard Mr. Christian say, and I believe him, that the records are not in disarray, but there are a lot of them. I think to characterize them as a morass is incorrect. I think they are difficult to get into, but I think the information is there.

Chairman SIMPSON. Dr. Houk, what is your thought on that?

Dr. HOUK. I would agree with Dr. Gough very much. I have spent time going through those records. I have been privy to a fair amount of them that Mr. Christian has brought to the science panel and I would not characterize them as in disarray. They are going to take time to get through.

I am personally convinced that if the scientists can decide what are the characteristics of an exposed group and what are the characteristics of a group that is going to be called not exposed, that Mr. Christian and his staff, and then the population numbers that are necessary to do the study, Mr. Christian and his staff can come up with the appropriate units to match that request.

Chairman SIMPSON. The Law Center criticized the protocol for focusing too strongly on the causes of death, rather than on current health problems and possible birth defects. Could you please comment on that?

Dr. HOUK. Well, I think that the protocol did mention the mortality part of the study. They did not detail the other health effects that would be adverse, which we felt was a deficiency. I think the mortality study, a proportionate mortality study is very necessary part of answering this question.

The birth defects, we were told this morning that is going to be looked into by the UCLA group, had that planned. And I would very much agree with the comment that was made that that is not duplicative of the CDC effort and their birth defect study because they are going to be addressing quite different issues and quite different kinds of ways. And if both turn out positive, then there is very good evidence that you can say that it had some effect. If they both turn out negative, then that's evidence that you can say that it may not have had an effect.

Chairman SIMPSON. Yes, I recall that response about the difference in methodology. So you do think that a dual approach is very important?

Dr. HOUK. Yes, sir.

Chairman SIMPSON. I have just a couple more questions. Do you feel that the expertise to determine which veterans were exposed and which were not exposed to agent orange lies within the Federal Government? Does it lie with the Science Panel or OTA? Are Federal personnel best equipped to develop this information? What are your recommendations? What are our options as a committee?

Dr. HOUK. Whoever is going to ultimately do the study needs to understand the nature of records and what's included in those records and what is the strength of arriving at probability of exposure or probability of low exposure. I should say probability of high exposure and probability of low exposure. However, I think that we have spent a considerable amount of time and can be very useful to

anybody who ultimately is going to do the study so they don't have to, if I can use the expression "reinvent the wheel," and the Science Panel has spent a great deal of effort over the last 3 months addressing just precisely this issue. You know, how can we design a cohort, expose people in a cohort of probably lesser exposed kinds of individuals.

I think it is unnecessary for another total review of that record system since so much is already known about that record system and it could be pulled out, not easily, with difficulty, but it can be done.

Chairman SIMPSON. One final question. You heard the discussion this morning about expanding the epidemiological study. What are your comments on the recommendations of GAO to expand the feasibility study to general service in Vietnam, rather than limiting the protocol solely to establishing the health effects of exposure to agent orange? What if we come to a position, once we finish a valid study on agent orange, where we have to do another major study on the effects of agent blue, agent white, other herbicides, insecticides, and various other things?

Dr. HOUK. The previous Science Panel, Senator, I believe, and I could be corrected if I am in error, either concluded or was concluding that it was going to be so difficult to get to probability of exposure of individuals, specifically to agent orange, that it would be reasonable to look at the Vietnam experience rather than specifically at agent orange.

Our flurry of activity recently came about, in essence, because we were looking at other ways of looking at exposed groups: Were there other data available, other than just the fixed-wings spraying missions or the other things. Dr. Bricker of DOD and his colleagues began to come in with so-called aborted missions, dumping of the stuff. And we looked at spraying of base perimeters, looking at chemical battalions and this sort of thing.

I think it is possible, this is my personal opinion, there is a division on the Science Panel about this; everybody does not agree. But I think that it is possible to develop a study looking at the overall Vietnam experience and also focusing on a subset to look specifically at the dioxin containing herbicides that were used, or agent orange among others.

Chairman SIMPSON. Yes. Dr. Gough, do you have some response to that please?

Dr. GOUGH. Yes, but I would like to respond to an earlier question first if I may, concerning the criticism of the protocol by the National Veterans Law Center. I have not seen that criticism in writing, but if it is as you characterize it, it's unfair. The large-scale epidemiological study proposed by UCLA would look at health effects among living veterans.

Three of the five proposed preliminary studies would look at what deceased veterans had died from, because death certificates are readily available and may contain valuable information. However, the large-scale study and the other two preliminary studies concentrate on the health effects being experienced by living veterans.

To respond to your last question, I think that it's probably wrong to talk about an agent orange study or Vietnam experience study

as though those two things were incompatible. I think that Mr. Christian and his staff can identify units of troops who were most likely exposed to high levels of agent orange. At the same time, we can identify troops who served in Vietnam, that we think were not exposed. Looking at the health histories of both the exposed and not exposed groups and comparing those histories to those veterans who served in other theaters during the same period of time would result in both an agent orange and a Vietnam study.

I think that both of those studies, the Vietnam experience study and the agent orange study, can be run at the same time. And I think it would be a mistake not to do so.

Chairman SIMPSON. Do you all concur with that suggestion?

Dr. HOUK. I concur with that.

Chairman SIMPSON. Are there any divisions about that suggestion?

Dr. HOUK. There's division on the Science Panel. Some members of the Science Panel do not share that opinion.

Chairman SIMPSON. I thank you. This is all very helpful, and I appreciate your patience and your understanding of our situation. Thank you so much.

Mr. KULL. Thank you very much.

[The responses of the Department of Health and Human Services and the Office of Technology Assessment to written questions submitted by Hon. Alan K. Simpson, chairman of the Senate Committee on Veterans' Affairs and Hon. Alan Cranston, ranking minority member of the Senate Committee on Veterans' Affairs, follow:]

RESPONSE OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO WRITTEN QUESTIONS
 HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS'
 AFFAIRS

Question 1A: Does the Working Group have its own proposal for an exposure index?

Answer: Not at present.

1B. Is the proposal feasible?

Answer: The Science Panel is exploring the feasibility with Working Group members.

Question 2A: As an "Interagency Agent Orange Working Group" how do you find the communication between the various Federal agencies, regarding exchanging information about Agent Orange that is already available?

Answer: The Science Panel is completing a detailed inventory of all Federal activities relating to Agent Orange. This will be completed within 2 weeks and will be periodically updated. In addition, the VA has completed its literature review on herbicides and transmitted it to the Science Panel.

2B. To what extent has there been effective communication between the VA, UCLA, and the Working Group, with regard to Agent Orange and other herbicide studies that have already been completed?

Answer: The Veterans Administration (VA) has transmitted to the Working Group information on Agent Orange research that it has completed. The Science Panel has requested from the VA all Agent Orange research activities that are being conducted within the VA Hospital System. The VA is in the process of providing that information. To do so will require a specific reporting system to be developed between the VA central office and its individual facilities. The Working Group has not transmitted specific information to UCLA nor does it know all of the details of the VA/UCLA dialogue since the contract is between the VA and UCLA.

- 2C. Dr. Spivey's proposed mortality studies replicate the already completed VA mortality study, prepared for the American Public Health Association. and Dr. Spivey's proposed Agent Orange registry analyze the information in the Agent Orange Registry. It appears that Dr. Spivey did not know those efforts had already been made by the VA. Is the Working Group finding this lack of communication to be true with regard to other Federally sponsored Agent Orange scientific efforts?

Answer: The VA has not completed its proposed mortality study. Instead, their presentation, as we understand it, to the American Public Health Association meeting was an outline of the proposed study--not the results. The Science Panel is currently reviewing the preliminary proposed protocol for the mortality study.

As stated above, the Science Panel has not communicated specific information to UCLA.

- 2D. What suggestions do you have to improve this situation?

Answer: The Agent Orange Working Group is making every effort to ensure it is informed of all Federally sponsored Agent Orange activities.

Question 3A: I realize that a large part of the mission of the Work Group is to share information, with regard to Agent Orange, among all Federal Agencies. To what extent are non-Federal agencies contacted or sought after for Agent Orange information?

Answer: The Agent Orange Working Group is seeking to develop mechanisms by which non-Federal activities are made known to the Working Group. In this regard, we have asked the VA as well as all other agencies to inform us of any known non-Federal activities.

The HHS Regional Directors have been asked to keep the Working Group informed of any activities that may be taking place in the States. In this regard, we are concerned that some States are taking separate actions that may not be scientifically justified, are very expensive, and lead to false expectations among the veterans. The industry and veterans organizations are aware of the Working Group's interest, and we are receiving information on some, if not all, of the non-Federal activities. The Centers for Disease Control (CDC) employees stationed in and detailed to State and local health departments have been asked to notify the Chairperson, Science Panel, Agent Orange Working Group (presently Acting Director, Center for Environmental Health, CDC) of any information relating to Agent Orange activities which come to their attention.

- 3B. I understand the State of Wisconsin recently submitted a proposal to develop a series of detailed maps of Vietnam, based on Wisconsin veterans' questionnaires and the HERBS tape data, that will provide visual depiction of the locations and the dates of herbicide spraying missions conducted in South Vietnam. Has the Working Group seen this proposal?

Answer: The Science Panel received the proposal to the VA from the State of Wisconsin approximately 3 weeks ago. That subject will be addressed at a meeting to the Science Panel on December 14, 1981, and will be reported to the Agent Orange Working Group.

- 3C. Is it feasible?

Answer: This cannot be answered until thorough review has been completed. Most members of the Science Panel at the moment feel that although this may be desirable, it is important that the information contained on those maps be factual and useful. The Science Panel has not determined as yet that those two parameters can be met. Information on exposure is needed not only from the HERBS tapes which reflect aircraft spraying missions but also information pertaining to perimeter spraying and the so-called aborted missions. This information must also be displayed in a manner that is understandable. One member who is an expert in this field estimated that this would require over 1500 maps.

- 3D. Are all such proposals relating to Agent Orange, that are non-Federally sponsored, reviewed by the Working Group?

Answer: We do not know. It is highly likely, however, that any proposal submitted to a Federal agency for funding or comment would be made available to the Working Group for its review.

Question 4: In light of the fact that the Working Group seems to have access to most of the available information about Agent Orange, should the Working Group perhaps take the lead in developing an exposure index?

Answer: The Science Panel has spent considerable time in the last 4 months working with the Department of Defense (DOD) in attempting to develop groups of people who are likely to have been heavily exposed and groups of people likely not to have been heavily exposed.

The Science Panel believes that given these exposure characteristics, the DOD working with the Science Panel as oversight can develop these groups. As soon as such an index is developed, we will provide you with the information.

RESPONSE OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES TO WRITTEN QUESTIONS SUBMITTED
BY HON. ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON VETERANS'
AFFAIRS

Question 1A: During the course of this Committee's September 10, 1980, Agent Orange Update hearings, Dr. John A. Moore, then Chairman of the Interagency Work Group's Science Panel, testified that the four Swedish studies of railroad workers, which suggested an increased risk of developing soft-tissue tumors or malignant lymphomas among those exposed to phenoxy acids, could be further strengthened by an independent verification. Dr. Moore further indicated that, rather than making a recommendation regarding verification of a federal agency at that time, the IAG was waiting to see if any of several independent groups that had considered undertaking such a verification would actually do so. Dr. Moore testified that if these groups did not take such action the IAG would strongly consider making a formal recommendation in this regard.

Ques. 1A(i) To date, has any such follow-up study been initiated by an independent group?

Answer: Yes

(ii) (If yes) Who is doing this study, and what is its current status?

Answer: The National Institute for Occupational Safety and Health and the National Cancer Institute are in the process of designing studies independently and collaboratively to answer this question.

Question 2 In Appendix C of your statement, it is noted that the Science Panel is reviewing the Case Control study recently completed by Stanford Research Institute on the relationship between exposure to 2,4-D and spontaneous abortions in humans.

A(i) Has the Science Panel completed its review of this study?

Answer: Yes

(ii) (If yes) Please provide your assessment of the study for the record.

Answer: The assessment is as follows:

1. The estimation of exposure, for instance is very crude.
2. A followup of 48 non-respondents was made to determine why they did not respond. This is a very small sample of the 6,460 non-respondents, namely, less than 1%. Normally such a followup sample should at least represent 5%.
3. It has still not been satisfactorily explained how the controls were chosen or why all normal pregnancy outcomes were not included in the study.
4. At the bottom of page 27 and the top of page 28, it is stated that it was decided to use only the most recent pregnancy in the hope of maximizing the accuracy of the pregnancy and exposure history recall. For the 55 instances in which both live births and miscarriages were reported in the study, only the miscarriage information was used. It is not clear from this or from any other statements in the report whether the pregnancies and the miscarriages were matched in time for the period of conception since fluctuations normally occur during the year in the number of miscarriages, particularly in the lower socio-economic group.
5. It is realized how difficult it is to verify miscarriages. However, a miscarriage verification of only 56% of reported miscarriages makes this a rather inconclusive study. What is particularly disturbing is the discrepancies about the conception date in view of the fact of the seasonal fluctuations of miscarriages.
6. On page 2-9, the first paragraph is not clear and may not be scientifically correct. Spermatogenesis takes place in the testes over a period of weeks. At any point in the development of a sperm starting with

spermatogonia, a chemical could conceivably affect its development. After the sperms have developed, they remain in the epididymis until ejaculation. It is theoretically possible that spermatogenesis may be affected at the level of the spermatogonia or spermatocytes but the sperms that are in the epididymis may be perfectly normal and result in a normal pregnancy. Thus, exposure could have occurred several months before impregnation and could have resulted in a miscarriage while no such effect would occur immediately after exposure.

7. The different groups that were used as cases and controls are so variable and so diversified that we basically feel they cannot really be compared. This is particularly true for the farm group represented by members of the Cattleman's Associations, Feed Council, Wheat Growers' League, and Dairy Association. We doubt very seriously that these people were actually the ones that did any spraying with 2, 4-D. On the other hand, pesticide applicators would probably have been exposed to many other pesticides and so would formulators, utility and transportation workers. The mill workers are not defined at all in the identification of the study population.
8. On page III-8, the possibility of confounding variables is discussed and age mentioned as an example. It is not clear from this report whether other confounding variables were also simultaneously accounted for, such as alcohol, cigarette or marijuana smoking, and socio-economic factors. Since an elevated risk for spontaneous abortion was observed in the 18-25 year age group of forest/commercial subjects, this should be further examined to determine whether there was, indeed, another confounding variable other than the 2, 4-D exposure that might

account for this. The chlorophenols were mentioned as one possibility in the text, but other chemicals such as fumigants or other unrelated factors need to be ruled out as well. Another interesting finding is that there may be an association between spontaneous abortions and the smoking of marijuana. This should also be further investigated.

9. It is not clear from the data presented whether or not an attempt was made to determine if the combination of alcohol and cigarette smoking or alcohol and marijuana smoking affected the incidence of spontaneous abortions.

In summary, because of all the shortcomings of this study, some of which cannot be rectified, no definite conclusions can be drawn from the study.

Question 3(A) What would you estimate to be a reasonable and realistic timetable for the completion of the protocol design and the start of the epidemiological study --

- (i) if the current contractor continues to be involved in the protocol design effort?

Answer: We would estimate between 3 and 6 months.

- (ii) If a protocol designed by the current contractor is not accepted?

Answer: 4 to 9 months.

- B. What is your assessment of the prospects for developing an exposure index in a manner such as is outlined in the so-called draft protocol?

Answer: The Science Panel believes that it is possible to develop a Vietnam cohort with probable heavy exposure to Agent Orange, probable little exposure and a nonexposed non-Vietnam cohort.

C. At the hearing, Dr. Houk discussed a role for the Science Panel to play in the development of exposure data.

(i) Please provide a brief description of how this would be done.

Answer: The Science Panel has spent considerable time in the last 4 months working with the Department of Defense (DOD) in attempting to develop groups of people who are likely to have been heavily exposed and groups of people likely to have had little exposure in Vietnam.

The Science Panel believes that given these exposure characteristics, the DOD working with the Science Panel as oversight can develop these groups. As soon as such an index is developed, we will provide you with the information.

(ii)(I) Have you discussed this with the VA or the contractors?

Answer: The Veterans Administration (VA) has been represented at the Science Panel deliberations on this matter for the past several months. The proposal has not reached the final stages; however, we believe that within the next month, it will be reasonably final. The Science Panel has not discussed the proposal in detail with the contractors as yet since the proposal is still in the evolutionary stages.

(II) (If yes) what has been the response to this proposal?

Answer: We believe that the VA concurs with this proposal.

Question 4 In Attachment C to your statement, the Chronology of Activities RE: Agent Orange, there is a reference to a "promising new concept" for the identification of people exposed to Agent Orange in addition to the Air Force Ranch Hand personnel which became evident when Dr. Houk and several other members of the Working Group visited the Army Agent Orange Task Force Office.

- A. Did this refer to personnel who were exposed when herbicides were dumped by aircraft in aborted spraying missions?

Answer: This proposal refers to personnel exposed not only to the so-called "aborted missions" but also those exposed in base perimeter spraying and other uses and disposal of Agent Orange.

- B. What has been done thus far to develop this particular source of data?

Answer: Please see answer to Question 3 C.

- C. What more needs to be done to develop this or any other source of data?

Answer: Please see answer to Question 3 C.

Question 5. In Dr. Houk's October 21 letter to Dr. Shepard transmitting the Science Panel's review of the draft protocol, provided as Attachment B to your statement, Dr. Houk expresses the panel's concern about the lack of specific detail in the protocol. What are the major deficiencies of the protocol in this regard and what specific improvements should be incorporated in the revised submission to correct these problems?

Answer: Basically, the Science Panel had difficulty in providing a meaningful review because the document was not a protocol. Instead it appeared to consist of three parts. The first 19 pages were primarily an introduction. The second 65 pages represented a discussion of the difficulties normally faced in epidemiological studies, and the rest of the document was a literature review covering 141 pages. Every member expressed concern about the lack of details to the point that it was not possible to constructively review the proposal.

The individual specific comments have been returned to the contractor from the Science Panel, and we believe also from the review by the Office of Technology Assessment and the VA Advisory Committee. Using those comments, a specific protocol should be able to be developed.

Question 6. In your statement, you referred to the Working Group's efforts to prepare "a comprehensive updated catalogue of all relevant federal research."

A. When will this be completed?

Answer: We believe this will be completed within 2 weeks.

B. Will you please provide copies of this catalogue to the Committee and to me directly once it is completed?

Answer: When completed, this will be provided to the Committee and to you directly.

Question 7. With reference to other federal activities related to dioxin, what is the status of the Environmental Protection Agency's regulatory activity directed at the herbicide 2, 4, 5-T?

Answer: The cancellation hearing on 2, 4, 5-T began in the spring of 1980. In the spring of this year Dow Chemical and EPA jointly requested that the proceeding be recessed so that the possibility of a settlement could be explored. Those negotiations are continuing at this time.

Question 8. What role, if any, does the General Accounting Office play in the Working Group?

Answer: The GAO has been invited to attend several meetings of the Working Group and are regularly briefed on all reports. Although GAO is not a member of the Working Group, their input is constantly sought in our activity.

Question 9. Section 307(c) of Public Law 96-151 requires the President (A) to coordinate the VA epidemiological study with all other studies by the federal government pertaining to the adverse health effects of exposure to dioxin and (B) to ensure appropriate coordination and consultation between and among the VA and all other federal entities in the design, conduct, monitoring, or evaluation of all such studies. Has the Working Group been delegated this responsibility by the President?

- (i)(I) (If no) do you know why not?
- (II) Will you recommend to Secretary Schweiker that he recommend to the White House that such a delegation be made?
- (III) At present, what official or agency legally has this responsibility?
- (ii) (If yes) please provide a copy of the delegation for the record.
- (iii) If this delegation is made in the future, please provide me a copy of such delegation.

Answer:

At present there are no plans for formal delegation of the AOWG under P.L. 96-151. However, on July 17, 1981, the President stated during his meeting with national veterans organization leaders that the Administration had re-established an expanded Working Group and raised its status to Cabinet Council Working Group status. The decision to make the Working Group an integral part of the Cabinet Council on Human Resources reflects the President's commitment and accords the highest priority to the mission of the Working Group. If a delegation is made in the future, we will send you a copy.

RESPONSE OF THE OFFICE OF TECHNOLOGY ASSESSMENT TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1. Will you comment on Dr. Detels' opinion that maintaining secrecy of study details is important to remove possible bias?

Answer 1. Maintaining secrecy of certain study details, known in epidemiology as "blinding," is sometimes desirable as a means to maintain the objectivity of participants and researchers. As stated in the OTA review, it may be desirable to keep details of exposure secret from the participants, but probably only for a limited time. However, it is neither possible nor desirable to attempt to keep details about the health examination secret. If details of the physical examination or interview questions are initially withheld, how long after examinations and interviews begin will it be before those details become known? The possible bias introduced through that mechanism would be harder to pin down and account for than the possible bias introduced in the case where everyone knows about the exam and questions ahead of time. If a study is designed and begun under assumptions of blinding, but details are released by, perhaps, sensational means, the study could be irreparably damaged.

Purely scientific consideration might be advanced to support secrecy, but purely scientific issues are not the only consideration. Reasons of public credibility and acceptance argue for a more open study.

Question 2. If UCLA continues to insist on secrecy in their effort, would you be able to approve the protocol?

Answer 2. Our advisory panel feels strongly that it is impossible to review the protocol without knowing all the details. As mentioned in our review of the draft protocol, we would consider swearing the entire panel, or a subgroup of it, to secrecy so that details could be revealed to them.

Question 3. How many chances to improve the protocol should UCLA have?

Answer 3. The VA, in allowing UCLA an additional 35 days to complete a first draft, has, in effect, given UCLA one "chance" more than was allowed in the original contract. When the first draft is completed and reviewed, UCLA should, as stipulated in the contract, be granted additional time to prepare the revision. If the revision is unacceptable, no more opportunities are called for.

Question 4. Can you provide further suggestions to help Dr. Detels and Dr. Spivey as they revise the protocol?

Answer 4. We have provided a number of suggestions for revision of the protocol in our review. The recent progress in records development, of which we have been informed, should also be considered in revising the protocol. Much of the progress in records has come in response to queries of the Department of Defense by the Agent Orange Work Group Science Panel. The Science Panel is in a good position to offer suggestions to UCLA. If a decision is made to share information between the Science Panel and UCLA, some provision might be considered for keeping Science Panel members charged with reviewing the UCLA protocol separate from those who act as advisors.

Question 5. What are your comments on the recommendation of the GAO to expand the feasibility study to general service in Vietnam, rather than limiting the protocol solely to establishing the health effects that result from exposure to Agent Orange?

Answer 5. We believe that the study could be expanded to look at what has been called "the Vietnam experience," while maintaining a specific study of Agent Orange. In the expanded study, the possibility would exist to identify other characteristics of serving in Vietnam that might be associated with subsequent health effects. We differ from GAO in believing that Agent Orange can be examined as an individual risk factor, in the context of a broader study.

Question 6. What alternatives to the proposed historical cohort study might be feasible?

Answer 6. If a study of the long-term health effects of dioxin-containing herbicides is undertaken, the historical cohort design is most appropriate scientifically. Because this type of study becomes less powerful, statistically, as one looks at rarer and rarer health effects, it will not likely answer questions about rarer types of outcomes. For such conditions, certain forms of cancer, for example, case-control studies, which are cheaper and more powerful statistically for rare outcomes, could be considered to supplement the cohort study, but would not replace it.

Question 7. What are your views on the possibility of establishing a statistically valid exposure index for Agent Orange?

Answer 7. It is still too early to say with certainty whether a statistically valid exposure index for Agent Orange can be developed. Judging from the progress made by the Department of Defense in records development, and assuming more will follow, there is a good chance that an index can be developed. A feasibility test of any proposed index still must be anticipated.

Question 8. A. Does the expertise to determine which veterans were exposed and which were not exposed lie within the Federal Government? -- Perhaps within the Science Panel or OTA?
B. Do you believe that Federal Employees are best equipped to develop that information?
C. What are your recommendations?

Answer 8. UCLA, as part of the protocol, has the responsibility to develop the exposure index, which will be essentially the criteria that will be used to assign veterans to "exposed" or "non-exposed" cohorts. These criteria will be important to other aspects of the study design and execution, and it is preferable to have them specified by the study designers. However, the exposure index cannot be developed independently of knowledge of what information is available in Department of Defense records. The expertise to locate the required records does lie within the Federal Government, specifically in the Department of Defense. We believe that the Science Panel of the Agent Orange Work Group would provide an excellent forum for the exchange of information between the Federal Government and UCLA that is essential for development of the exposure index.

Question 9. Does your job include, not only an approval of the design submitted, but responsibility to ensure that certain substantive as well as methodological concerns are included?

Answer 9. We consider that our task includes evaluating the substantive information included or omitted, and the evaluation of methodological aspects of the study design. We have addressed the range of these concerns in our review of the draft protocol.

Question 10. The Law Center criticized the protocol for focusing too strongly on causes of death, and not current health problems, and not including any study of possible birth defects. Would you please comment?

Answer 10. The historical cohort study focuses almost entirely on current health status. We agree that without further detail it is impossible to determine whether health concerns are addressed adequately. We have stressed the importance of such details in our review, including the concern that birth defects were not discussed in the draft protocol.

On the other hand, we feel it highly appropriate that mortality data be used to the fullest extent possible to look for early, unusual patterns of mortality. It would be negligent if some type of mortality study were not done, though it need not necessarily be designed or carried out by UCLA, particularly in light of the VA's own mortality study, which is already under way.

RESPONSE OF THE OFFICE OF TECHNOLOGY ASSESSMENT TO WRITTEN QUESTION SUBMITTED BY HON.
ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON VETERANS'
AFFAIRS

Question 1A. Did you experience any difficulties or delay in receiving the draft protocol submitted by UCLA?

Answer 1A. We understand from the VA that they received the draft protocol from UCLA on August 6, 1981. We received the 25 copies we required for our Advisory Panel on August 18. We had expected to receive them within two or three days of VA's receipt of the document from UCLA, and had telephone conversations expressing our concern almost daily between the 6th and the 18th.

Question 1B. Are you satisfied that the VA recognizes the statutory role assigned by OTA by Public Law 96-151 to review and approve the study protocol?

Answer 1B. In general, there has been good cooperation between the VA and OTA, and we are generally satisfied with working arrangements between the two organizations.

However, the exact nature of the relationship remains unclear. As you know, in his veto of S.2096 on January 2, 1980, President Carter said,

"I viewed the provision in that bill [P.L. 96-151] requiring approval of the study by the Office of Technology Assessment as being constitutionally defective, and I am instructing the VA Administrator not to treat that provision as legally binding."

Not everyone agreed with the President about the defectiveness of the provision: After the veto message, there was an exchange of letters between Senator Cranston, then-Chairman of the Senate Veterans' Affairs Committee and the VA Administrator about the statutory requirements of P.L. 96-151. In addition, two memos from the American Law Division of the Congressional Research Service have stated that the provision is constitutional.

Despite the unsettled nature of the argument about the constitutionality of OTA's role, we interpret P.L. 96-151 to require that the Director of OTA approve any study to be undertaken. Because of the expense involved, VA will require funds to mount any epidemiologic study. Given that the Committee would not likely authorize or allow appropriation of funds for a study that lacked OTA approval, OTA approval will be essential. Those considerations mean, practically speaking, that OTA will, as the statute requires, have to approve or disapprove the protocol. However, the statutory role of OTA remains, so far as we know, unresolved.

Question 2. What would you estimate to be a reasonable and realistic timetable for the completion of the protocol design and the start of the epidemiological study -- (A) if the current contractor continues to be involved in the protocol design effort, and (B) if a protocol designed by the current contractor is not acceptable?

Answer 2. Assuming UCLA continues to design the protocol and a cooperative arrangement between UCLA and the Department of Defense records group, planning could be completed within two to four months. Feasibility testing and pilot testing, including developing procedures for locating participants and testing the questionnaire and physical examination, will require an additional year. The full-scale study could then be launched.

If another contractor takes over the planning process, we estimate that an additional one to three months of actual work time would probably be necessary. This estimate does not include the substantial block of time that would necessarily be spent in contracting procedures. This timetable assumes that all necessary security clearances are completed before the contract period begins.

Question 3A. Do you believe the contractor can revise the so-called draft protocol in 35 days so that it might be acceptable to the OTA reviewing panel?

Answer 3A. We assumed that UCLA had been working on a revision while the first draft was reviewed, and it seemed possible that an acceptable draft protocol could be completed in the 35 days that expire at the end of December. However, we recently learned that Dr. Spivay has been incapacitated and that fact has necessitated a further extension.

Question 3B. (i) What is your assessment of the feasibility of developing an exposure index as outlined in the draft protocol; (ii) how long would it take to develop such an index; (iii) at the hearing, Dr. Houk discussed a role for the Science Panel to play in the development of exposure data--what is your view of this suggestion?

Answer 3B. The description of the exposure index protocol is so sketchy that it is impossible to assess whether or not it could be the basis for the index that is eventually devised. We are, however, encouraged that an index can be developed, especially in light of the progress made by the Department of Defense in records development, and assume that more will follow. The index can probably be developed in one or two months. Selection of individuals meeting criteria for inclusion in the exposed or non-exposed cohort will require additional time.

Mr. Richard Christian estimates that identification of individuals will require nine months to one year. Other aspects of the study, development and testing of questionnaires, physicals, etc., can, of course, go ahead at the same time groups and individuals are being identified.

The Science Panel of the Agent Orange Working Group would provide an excellent forum for the exchange of information between the Federal Government and the contractor that is essential for development of the exposure index. The Science Panel itself could play a more active role by, for example, actually developing the index and offering it to the contractor. The Science Panel contains a wealth of expertise on all aspects of the Agent Orange question and could more easily accomplish this task than any outside contractor.

Question 4A. In your opinion, what are the merits and drawbacks of expanding the scope of the epidemiological study as authorized in Public Law 97-72?

Answer 4A. Expanding the scope of the Agent Orange study to look at the total "Vietnam experience" would have several advantages. Such a study would allow the investigators to look for effects of the overall experience of having been in Vietnam, and, in the same study, to look for effects from some of the individual factors that comprise the Vietnam experience. One factor would be exposure to dioxin-containing herbicides. This study will undoubtedly be one

of the largest ever undertaken in this country, and it would be folly to pass up the opportunity to gather as much information and to answer as many questions as possible.

If the VA decides to expand the scope of the study, that decision should be made soon. The background work done thus far by UCLA will not have been wasted, but further detailed planning toward an Agent Orange-only study might be inappropriate in the context of an expanded study. The expanded study need not include significantly more participants or cost significantly more money than a study solely directed at Agent Orange.

Question 4B. Do you believe that it is feasible to conduct an Agent Orange-only study?

Answer 4B. Yes, assuming an exposure index can be developed, about which we are optimistic.

Question 5. In your opinion, what should be the VA's role in the actual conduct of the mandated study?

Answer 5. Quoting from the OTA review:

"It appears that veterans will be most receptive to a design with minimal involvement of the VA. Veterans' groups believe that the credibility of the VA, with respect to Agent Orange, has been seriously compromised and that an outside group should run the study.

Some roles for the VA may be possible in a study conducted by an outside group. For example, participants might accept examinations by adequately trained VA doctors in VA-affiliated hospitals if the data are given to a private contractor for analysis."

Question 6. In Dr. Gibbons' letter of transmittal that was quoted in your statement, the point is made that the review "suggests that health outcomes [that will be looked for in the study] be made public." Do you have a list of what health outcomes should be looked for in the study?

Answer 6. OTA has not compiled a list of health outcomes that should be looked for in the study. However, animal tests and epidemiologic studies indicate that certain areas should at least be considered. Two such broad areas are neurologic diseases and birth defects, neither of which are mentioned in the draft protocol.

Chairman SIMPSON. The next panel, David Erickson, Birth Defects Branch of the Center for Environmental Health of the Center for Disease Control in Atlanta, and Dr. Nelson S. Irey, Chairman of the Department of Environmental and Drug Induced Pathology of the Armed Forces Institute of Pathology, Paul W. Myers, Lieutenant General of the U.S. Air Force, Medical Corps, Surgeon General, U.S. Air Force. Col. Thomas F. Zuck of the Armed Forces Institute of Pathology is not present.

It is a pleasure to have you gentlemen with us, and if you will proceed under the time limitation, it would be most appreciated.

Dr. Erickson, if you will proceed first.

TESTIMONY OF A PANEL CONSISTING OF DR. J. DAVID ERICKSON, BIRTH DEFECTS BRANCH, CENTER FOR ENVIRONMENTAL HEALTH, CENTER FOR DISEASE CONTROL, ATLANTA, GA.; DR. NELSON S. IREY, CHAIRMAN, DEPARTMENT OF ENVIRONMENTAL AND DRUG-INDUCED PATHOLOGY, ARMED FORCES INSTITUTE OF PATHOLOGY; AND LT. GEN. PAUL W. MYERS, SURGEON GENERAL, MEDICAL CORPS, U.S. AIR FORCE

Dr. ERICKSON. Mr. Chairman, I am Dave Erickson, a scientist with the Center for Environmental Health of the Center for Disease Control in Atlanta. I am the principal investigator for the birth defects study which is underway at CDC, and I am pleased to be here to present testimony on the scope of that study.

CDC's study is based on a registry of babies born with birth defects in the metropolitan Atlanta area. The registry is unique in that it is derived from the only population-based surveillance system in the United States which has reasonably complete ascertainment of babies born with structural congenital malformations.

The registry now contains information on approximately 13,000 babies born with birth defects among more than 300,000 babies who have been born since the surveillance program began in 1968.

From the total of about 13,000 babies born with birth defects, about 7,500 will be included in the study. These 7,500 babies are babies who are born with major or serious malformations, that is, malformations which cause premature death, result in serious handicap or require substantial medical care in those who survive.

The study involves locating the families of these babies and interviewing their mothers and fathers. The interviews will contain questions about military service in Vietnam. In addition, we will ask the babies' parents about a number of other factors which might be connected with the occurrence of birth defects; for example, alcohol and tobacco usage, medicines the mother took during pregnancy, family history of birth defects, and serious chronic diseases in the parents. For comparative purposes we will also interview the parents of 3,000 control babies. These are babies who were born without defects.

The main comparison of interest to this committee in this study will concern the proportion of fathers who served in Vietnam in the case and control groups. A finding of no difference in the proportions will suggest that Vietnam veterans are not, in general, at higher risk of fathering babies with defects. Conversely, a finding

of a higher proportion of Vietnam veterans among the fathers of case babies will suggest that veterans are at increased risk.

You will note, Mr. Chairman, that I have focused on Vietnam service rather than on agent orange. If Vietnam veterans are found to be at higher risk, they may be so for reasons other than exposure to agent orange. In addition to this rather broad focus, we will make use of all exposure, agent orange exposure, data available to us to assess its impact as best we can.

CDC's study will be the largest of its type ever conducted. It will have a very good chance of detecting relatively small increases in the risks of birth defects in babies of Vietnam veterans in general. However, I want to add the caution that the study will not likely be sensitive enough to detect a modestly increased risk if it only occurs among men with very heavy and/or prolonged exposure to agent orange. I state this on the presumption that such heavy or prolonged exposure was infrequent—I may be incorrect in that presumption.

Further, the study will not be particularly sensitive for detecting very small increases in risk or for discerning increased risk for very rare types of defects.

I would like to close by briefly describing the process by which we developed the study procedures and about our anticipated timetable. The basic study protocol and questionnaires were developed by the staff of the Birth Defects Branch of CDC. They were then reviewed by a panel of CDC scientists and also by staff of the State of Georgia Department of Human Resources.

Later, CDC assembled a review panel of four university-based scientists. The protocol was also submitted for review to four veterans' organizations, and a review was made by the Science Committee of the Interagency Work Group on Phenoxy Herbicides.

Finally, the protocol and questionnaires were approved by the Office of Management and Budget. We are now in the early phases of conducting the study. We began about 1 month ago with a pilot study, the purpose of which is to insure that we don't have any major problems with the study procedures and questionnaires. We expect to begin the full-scale study sometime in January. And we anticipate completing a report of our findings in the late summer or early fall of 1983.

Mr. Chairman, that concludes my testimony and I will be pleased to answer any questions you have.

Chairman SIMPSON. Thank you very much. Now, Dr. Irej, please.

Dr. IREJ. Mr. Chairman and members of the committee. This is a report on 408 cases in the agent orange registry of the Armed Forces Institute of Pathology. This registry was formed in 1978, originally jointly with the VA, then with the Air Force and more recently with the Army.

Its purpose: In the first phase to find out what diseases are currently affecting Vietnam veterans as reflected in tissues removed during surgery and in findings at autopsy examination.

In the second phase, to see if these diseases might be related to exposure to agent orange while in Vietnam.

We are presently in the first phase, reviewing materials sent to us by VA and Armed Forces hospitals. The sole criteria for submis-

sion: service in Vietnam, thus, eliminating the bias of local selection of cases on other grounds.

In the detailed report in your hands are tabulations of our findings, demographic data, lists of organs involved, lists of skin and liver diagnoses, and special tabulations of benign and malignant tumors.

Diagnoses of 457 were made on diseases affecting 55 organs or sites. This demonstrates a wide distribution of diagnoses and sites involved. Of special significance would be any of the three following features: (1) Clustering of particular organ diagnosis combinations; (2) clustering of any pathologic changes unusual for a particular site; and (3) clustering of unusual ages for any diagnosis, especially in tumors.

The rationale for the significance of these unusual features is that in past experience with diseases relating to environmental chemicals it has been found that an adverse effect from a particular chemical tends to occur in a limited number of target organs or tissues. Thus, a study of individuals with the same environmental exposure will commonly show a pattern because of this selective targeting. Examples: Asbestos and pleural and lung tumors; vinyl chloride and liver tumors; and vaginal cancer and diethylstilbestrol.

Thus, chemicals tend to have a predilection for their sites of adverse reactions.

Getting back to the tabulations in these 408 cases: (1) Two major clusters were found, lipomas—tumors of fat; and epidermal inclusion cysts—dilatation of the deeper hair structures. Both are benign, both occur in the skin or just beneath it, both are trivial findings with no present or future consequences of any significance. Their numerical frequency may be related to the presentations of the patient as lumps in the skin causing him to seek medical attention.

(2) The liver and benign tumor tabulations show no significant clusters as yet.

(3) The malignant tumor group presents as yet no apparent clustering. There were six cases with unusual features. Details are in your full report, but they are single incidences.

(4) The tabulation entitled "Diagnosis on Remaining Cases" shows a wide scatter pattern and consists of many instances quite unlikely related to agent orange causation such as hernial sacs, torn knee cartilages, and so on.

This type of study has the following capabilities: The identification of clusters relating to residuals of previous acute toxicity and the identification of tumor patterns. Since the latent period for chemically-induced tumors is measured in years or decades, the failure to find them at this point may be because enough time has not yet passed.

This type of study has limitations: It does not address problems of congenital anomalies, genetic changes, decreased fertility or neuro-behavioural consequences of chemical exposures.

In summary, this is a preliminary report. We do not as yet have confirmation of Vietnam service in many of these cases. We lack certain demographic data such as age, sex, and race on some cases. All these missing data we are attempting to obtain.

While this study is initially morphologic, we recognize that statistical and epidemiologic considerations are essential. We plan shortly to meet with representatives of these disciplines to review this data, to further analyze our findings with them, and to make plans for future use of this information. We will continue to receive additional cases and will integrate our studies with the statisticians and the epidemiologists.

This concludes my statement, Mr. Chairman. I would be happy to entertain any questions that the committee might have.

Chairman SIMPSON. Thank you so much, Dr. Irely.

[The prepared statement of Dr. Nelson S. Irely, Chairman, Department of Environmental and Drug-Induced Pathology, Armed Forces Institute of Pathology, follows:]

PREPARED STATEMENT OF DR. NELSON S. IREY, CHAIRMAN, DEPARTMENT OF ENVIRONMENTAL
AND DRUG-INDUCED PATHOLOGY, ARMED FORCES INSTITUTE OF PATHOLOGY

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

I appreciate the opportunity to present to you the findings of the Agent Orange Registry (AOR) that is located in the Armed Forces Institute of Pathology (AFIP) here in Washington.

The Agent Orange Registry was organized in 1978 to learn what diseases Vietnam veterans were currently suffering from, as reflected in biopsies removed during surgical operations, and as reflected in autopsy examinations.

To do this, the AFIP was designated by the Veterans Administration (VA) as a center for the collection and study of these biopsy and autopsy materials. More recently, the AFIP has also been designated by the Armed Forces as a focal point for the study of similar pathologic material on active duty personnel with prior service in Vietnam.

To implement this project, the VA and Armed Forces hospitals were directed to submit to the AFIP case material through their respective pathologists. The sole criterion for the selection of cases to be submitted was: service to Vietnam. The purpose of using this single criterion was to obtain as complete a sampling as possible of the current

medical problems of Vietnam veterans as reflected by a study of their diseased tissues, free of the bias of local selection of cases.

For general orientation, it has been found in past experience with environmental and iatrogenic diseases caused by chemical agents that a particular chemical or drug will tend to affect primarily or predominantly one organ, site, or tissue. Examples: vinyl chloride and hepatic angiosarcoma; carbon tetrachloride and liver necrosis; diethylstilbestrol and vaginal carcinoma; and asbestos and pleural mesothelioma.

While multiple targets for a particular chemical are seen, it does not adversely affect all organs and systems simultaneously, but tends to exhibit its most serious consequence on one "critical organ", or at most several "critical organs".

With this principle in mind, the cases in the AOR are being monitored for the following findings:

1. clustering or peaks in specific organ-diagnosis combinations;
2. clustering of any pathologic changes that are unusual for particular sites;
3. clustering of unusual ages for particular diagnoses.

If, in the initial phase of this cohort-type study, such clustering, peaks, or trends are found, they will constitute a focusing of attention on particular diagnoses and organs that would lead to subsequent epidemiologic (case control) studies with appropriate controls. The assessment of causality of diseases found in Vietnam veterans in relation to their exposure to Agent Orange is in the initial phase of collection and pathologic evaluation in this Agent Orange Registry.

The pathologic findings on the first 408 cases are condensed in a series of enclosed tabulations. Salient features of these tabulations will be discussed in succession under the following categories:

1. Demographic data. (Enclosure #1)
2. Listing of sites or organs. (Enclosure #2)
3. Listing of the skin diseases, (Enclosure #3).
4. The liver diagnoses, (Enclosure #4)
5. The benign tumors, (Enclosure #5)
6. The malignant tumors, (Enclosure #6)
7. Diagnoses on the remaining cases, (Enclosure #7)

More detailed information if desired may be obtained by referring to the attached enclosures.

Demographic data (Enclosure #1):

1. The most frequent age group of the veterans in the AOR at this time is in the 30-39 decade. At the time of these veterans' Vietnam service, they would have been ten or more years younger, which is consonant with the relative youth of our Armed Forces serving in Vietnam.

2. Source of cases was predominantly from the VA hospitals (345 cases). Cases were submitted from 45 States.

3. Race: In 143 of the cases, the race of the veteran was not stated. Of the 265 cases in which the race was stated, 222 were white (83%).

4. Sex: Males dominated (400 of the 408 cases).

Listing of sites or organs (Enclosure #2):

There were 55 different sites or organs involved in these 408 cases. This is a wide dispersion, as 44 of the sites had five or less cases.

The most frequent site of disease was the skin, followed in frequency by: lymph nodes, liver, and lungs.

Listing of the skin diseases (Enclosure #3):

There was a wide scattering of the 60 diagnoses in the skin biopsies. The largest group fell into the chronic dermatitis category, with many of its variants occurring as single instances.

There were three clusters: epidermal inclusion cysts, lipomas, and dermatofibromas. All are benign, all frequently seen, none with serious consequences. The reason for their dominance may well be related to the desire of the patient to seek diagnosis on any abnormality that can be seen or felt in the skin. All of these three lesions are visible and/or palpable.

The carcinomas of the skin in this group were all common varieties, the basal cell type being the most frequent, with no unusual features as to location or age of the patient.

The liver diagnoses (Enclosure #4):

In this group of 31 cases, cancer from other sites metastasizing to the liver was the most frequent finding (7 cases). The remaining diagnoses occurred in low frequency, with no dominant clustering. There was a wide dispersion of diagnoses, all with low frequency. Complicating the interpretation of these cases as to their causes is the fact that eleven of the 31 cases were said to be chronic alcoholics, drug abusers, or both.

The benign tumors (Enclosure #5):

Of the benign tumors in this group, 38 cases were in the category of lipoma or dermatofibroma (previously discussed under skin lesions) and are benign and not of serious import. The remaining tumors listed in Enclosure #5 had wide dispersions as to locality and type, and occurred in low frequency in any one location or diagnosis.

The malignant tumors (Enclosure #6):

This group included 28 diagnoses. Malignant tumors in lymph nodes were the most frequent tumor category. Breakdown into sub-types of Hodgkin's disease and lymphoma revealed that there were no more than two cases in any one of the seven sub-types. The lung tumors had five histologic types in the eight cases, with no clustering of significance. The remaining cancers had a wide dispersion as to location and diagnosis.

Six cases, occurring singly, had features of unusuality, and these are detailed in Enclosure #6. To date, they have occurred in only single instances.

Diagnoses on the remaining cases (enclosure #7):

This group constituted 143 cases, with a very wide dispersion. Many of these cases (74) had a frequency of three or less in any site or organ. The largest single group in this category was labelled as normal or negative, including sputum, pleural fluid, urine smears, and seminal fluid. This group of "other" diagnoses included one suicide by gunshot, and two drug overdose cases.

DISCUSSION

This Agent Orange Registry report is, at this stage, a preliminary one. Certain of the demographic information is as yet unavailable (age, sex, race). In addition, confirmation of service in Vietnam has to be obtained in many instances. However, elimination of any case, because of failure to confirm Vietnam service, would decrease the number of cases in any particular organ-diagnosis combination, and only reduce the clustering in any specific category.

For adequate documentation of these cases, as to Vietnam service, the names and social security numbers on 300 have been turned over to the VA headquarters, in the hope of confirming or denying such service from their records. Demographic data, where missing, has been requested from the contributors.

While this morphologically-oriented cohort-type study is capable of bringing to light unusual findings and features (clustering of similar diagnoses; increased incidence of anatomic sites of disease; unusual ages for particular tumors; or unusual pathologic findings), it has its limitations. This project does not address the following types of problems that might be related to Agent Orange:

1. Teratogenesis.
2. Mutagenesis.
3. Decreases fertility.
4. Neurobehavioural abnormalities.

SUMMARY

1. Pathologic and demographic data has been presented on 408 cases submitted to the AOR of the AFIP as having had service in Vietnam.

2. There were 457 diagnoses made on a total of 55 organs, sites, or tissues in these 408 cases, indicating a broad spread and wide distribution of sites and diagnoses.

3. There were two peaks of relatively high incidence of diagnoses: lipomas and epidermal inclusion cysts. Both are benign. Both lesions are subcutaneous in location, with visibility and palpability to the patient. With the sensitivity of the Vietnam veteran to any abnormality, medical consultation would be sought, with subsequent excision for diagnosis. This may explain their high incidence.

4. There were six single instances of cases with unusual features. These were listed at the end of the tabulation of the malignant tumors. No clustering of these unusual cases was noted.

5. Many of the diagnoses made on this series of cases have little or no possibility of an etiologic relationship with exposure to Agent Orange (examples: deviated nasal septum, hemorrhoids, herniated intervertebral discs, ganglia of tendon sheath, shrapnel fragments, degenerated knee cartilage, etc.). These examples do, however, give evidence of at least a degree of adherence to the directive that cases sent to the AOR should have only one criterion for submission: i.e., service in Vietnam.

SUMMARY (cont'd)

6. Within the limits of the presently available information, there were no clusters or peaks of unusual cases, except of the benign fatty tumors (lipomas), and the epidermal inclusion cysts of the skin (both benign lesions). The cases cited with unusual features in the malignant tumor section were all single instances, without clustering.

7. At this stage of the pathologic evaluation of Vietnam veterans' biopsy and autopsy material, there appear to be no findings yet that would lead to subsequent epidemiologic studies for evaluation of their significance.

8. The findings and evaluations on these 408 cases are not necessarily unchangeable or final, but are subject to possible modification on receipt of additional case information.

This concludes my statement, Mr. Chairman. I will be happy to answer any questions that the committee may have.

ENCLOSURE #1

DEMOGRAPHIC DATA

Age:

20-29:	50
30-39:	218
40-49:	41
50-59:	34
60-69:	11
70-79:	3
80-89:	1
Unknown:	48
Infants:	<u>2</u>
Total:	<u>408</u>

Source of Cases:

VA Hospitals:	345
Civilian :	36
Air Force :	16
Army :	4
Navy :	3
Soldiers & Sailors	
Memorial :	1
Unknown :	<u>3</u>
Total :	<u>408</u>

Sex:

Male :	400
Female :	4
Unknown:	<u>4</u>
Total:	<u>408</u>

Race:

White :	222
Black :	39
Other :	4
Unknown :	<u>143</u>
Total :	<u>408</u>

Geographic sources of cases: 45 States

ENCLOSURE #2
SITE OR ORGAN

	<u>No. of Cases</u>
Skin and Subcutaneous Tissue	-153
Lymph Nodes	-19
Liver	-17
Lungs	-13
Bone & Joint	-9
Hernial Sac	-9
Seminal Fluid	-8
Colon	-7
Prostate	-7
Testis	-7
Sputum	-6
Appendix	-5
Cartilage	-5
Cervix	-5
Fibro Cartilage (Knee)	-4
Inguinal Region	-4
Tendon	-4
Brain	-3
Esophagus	-3
Gall Bladder	-3
Tonsils	-3
Urinary Bladder	-3
Vertebral Disc	-3
Ascitic Fluid	-2
Breast	-2
Kidneys	-2
Parotid Gland	-2
Pleural Fluid	-2
Rectum	-2
Spinal Column	-2
Stomach	-2
Tongue	-2
Veins	-2
Abdominal Wall	-1
Adipose Tissue	-1
Bone Marrow	-1
Conjunctiva	-1
Epididymis	-1
Heart	-1
Jejunum	-1
Larynx	-1
Meninges	-1
Mucosa, oral	-1
Muscle	-1
Nasal mucosa	-1
Nose (septum)	-1
Penis	-1
Perianal Tissue	-1
Peritracheal Tissue	-1
Pleural cavity	-1
<u>Retroperitoneal</u> Tissue	-1
Spinal Fluid	-1
Thymus	-1
Urine	-1
Vas Deferens	-1

ENCLOSURE #3

SKIN DIAGNOSES

<u>DIAGNOSES</u>	<u>No. of Cases</u>
Dermatitis	35
Dermatitis, chronic, non-specific	9
" " with perivasculitis	6
" " with folliculitis	5
" , papulosquamous	3
" , granulomatous	2
" , with atypical lymphohistiocytic infiltration	1
" , chronic, with lichenoid keratosis	1
" , chronic, with lymphohistiocytic inflammation	1
" , chronic, nummular	1
" , chronic, light eruption	1
" , chronic, with pseudoepitheliomatous hyperplasia	1
" , pustular	1
" , chronic, pyogenic granuloma	1
" , chronic, c/w polymorphous light eruption	1
" , seborrheic	1
Total:	<u>35</u>
Epidermal inclusion cyst	22
Lipomas	21
Dermatofibroma	11
Nevus	8
Compound nevus	4
Intradermal nevus	3
Nevus, giant pigmented	1
Total:	<u>8</u>
Scar	7
Angiolipoma	6
Carcinoma	7
Basal cell	6
Squamous cell	1
Total:	<u>7</u>
Perivasculitis	6
Keratosis Seborrheic	5
Condyloma acuminata	4
Inadequate for diagnosis	4
Vasculitis	4
Angiolipoma and lipoma	3
Hidradenitis suppurativa	3
Keratosis	3
Keratosis, actinic	2
Keratosis, lichenoid	2
Lentigo, benign	2
Verruca vulgaris	2
Acne rosacea	1
Acneform lesion	1

ENCLOSURE #3 (cont'd)

<u>DIAGNOSES</u>	<u>SKIN DIAGNOSES</u>	<u>No. of Cases</u>
Angiokeratoma		1
Eccrine acrospiroma		1
Erythema nodosum		1
Hemangioma, Capillary		1
Lichen simplex		1
Lymphoid hyperplasia, reactive		1
Neurofibroma		1
Papilloma, inverted		1
Papilloma, keratotic		1
Papilloma, squamous, hyperkeratotic		2
Parapsoriasis en plaque		1
Parakeratosis & acanthosis		1
Pilar cyst (sebaceous)		1
Plantar wart		1
Polyp, fibroepithelial		1
Scar with foreign body reaction		1
Scar with hemosiderin deposits		1
Steatocystoma multiplex		1
Shrapnel fragments		1
Ulcer (burn)		1
Urticaria, papular		1

ENCLOSURE #4

<u>DIAGNOSES</u>	<u>LIVER DIAGNOSES</u>	<u>No. of Cases</u>
Metastatic Carcinoma		-7
Fatty Metamorphosis		-4
Hepatitis Chronic Persistent		-4
Hemosiderosis		-2
Necroinflammatory Disease		-2
Portal Triaditis		-2
Cholestasis		-1
Cirrhosis		-1
Fatty Metamorphosis & Focal Necrosis		-1
Fatty Metamorphosis & Portal Fibrosis		-1
Hepatocellular Carcinoma		-1
Hepatitis Chronic		-1
Liver Abscess		-1
Necroinflammatory Disease, early cirrhosis		-1
Periportal Fibrosis		-1
Portal Fibrosis		-1

ENCLOSURE #5

BENIGN TUMORS

<u>DIAGNOSES</u>		<u>No. of Cases</u>
Lipoma		21
Dermatofibroma		11
Angiolipoma		6
Polyp		5
Colon	1	
Mouth	1	
Rectum	1	
Skin of neck	1	
Vocal cord	1	
	Total: $\frac{5}{5}$	
Angiolipoma + lipoma		3
Adenoma		3
Colon	2	
Salivary gland	1	
	Total: $\frac{3}{3}$	
Papilloma		3
Skin (squamous)	2	
Nasal cavity (inverted, atypical)	1	
	Total: $\frac{3}{3}$	
Angiokeratoma		1
Eccrine acrospiroma (scalp)		1
Giant cell tumor (tendon)		1
Hemangioma, capillary (hand)		1
Neurilemmoma (retroperitoneal)		1
Neurofibroma (subcutaneous)		1
Steatocystoma multiplex (neck)		1

ENCLOSURE #6

<u>SITES & DIAGNOSES</u>	<u>MALIGNANT TUMORS</u>	<u>No. of Cases</u>
Lymph Nodes		9
Hodgkins Disease	5	
Malignant lymphoma	4	
	Total: 9	
Lung:		8
Undifferentiated large cell carcinoma	3	
Anaplastic carcinoma	2	
Adenocarcinoma	1	
Carcinoma vs lymphoma	1	
Spindle cell carcinoma (? primary)	1	
	Total: 8	
Skin		8
Basal cell carcinoma	6	
Melanoma ?	1	
Squamous cell carcinoma	1	
	Total: 8	
Gastrointestinal tract		5
Colon - Adenocarcinoma	3	
Jejunum - Adenocarcinoma	1	
Stomach - Adenocarcinoma	1	
	Total: 5	
Testis		3
Seminoma	1	
Seminoma + teratoma	1	
Gonadoblastoma + sarcoma (epididymis)	1	
	Total: 3	
Bone		2
Chondrosarcoma	1	
Multiple Myeloma	1	
	Total: 2	
Prostate - Adenocarcinoma		2
Kidney - renal cell carcinoma		2
Bladder - carcinoma, papillary, Grade-1		1
Brain - Glioblastoma multiforme		1
Lip - Squamous cell carcinoma		1
Liver - Hepatocellular carcinoma		1
Mediastinum - Sarcoma		1
Peritoneum - mesothelioma vs lymphoma		1
Pleura - mesothelioma		1
Salivary gland - Mixed tumor		1

Tumor Cases With Unusual Features

1. Colon, adenocarcinoma, mucinous--an unusual type of mucinous carcinoma in the colon.
2. Jejunum, adenocarcinoma with metastases in a 37 year old BM. Site and age are unusual.
3. Lung, large cell undifferentiated carcinoma, probably primary in the lung. Age unusual (age:31)
4. Lung: anaplastic adenocarcinoma (1978); and well differentiated prostatic carcinoma (1980). Metachronous malignancies - of different histologic types. Double tumor in the same case, different sites and different types.
5. Prostate: carcinoma, age 44: unusually young age for this tumor.
6. Testis: Gonadoblastoma, sarcoma of epididymis, and inguinal l. node with metastatic carcinoma, all in the same case.

ENCLOSURE #7

<u>DIAGNOSES</u>	<u>DIAGNOSES ON REMAINING CASES</u>	<u>No. of Cases</u>
Negative or normal		-46
Hernial Sac		-7
Herniated Disc		-6
Hyperplasia Vein		-6
Inadequate for Diagnosis		-5
Appendicitis		-4
Atrophy, Testis		-3
Foreign Body Reaction		-3
Meniscus (Knee)		-3
Cholecystitis		-2
Degenerative Changes (Knee)		-2
Exostosis		-2
Fibrosis, perineural		-2
Ganglion Cyst		-2
Gynecomastia		-2
Hemorrhoids		-2
Oligospermia		-2
Pneumonitis, interstitial		-2
Proctitis		-2
Varicosities		-2
Anal Fissure		-1
Ankylosing spondylitis		-1
Balanitis		-1
Bullae, apical, lung		-1
Bone Fragments		-1
Colitis, chronic		-1
Dequervains Disease		-1
Deviated Septum		-1
Drug Overdose (toxicity)		-1
Embolus		-1
Fistula (Perianal)		-1
Gastritis, chronic		-1
Gangrene (Thumb)		-1
Infection Chronic (Tonsils)		-1
Lymph Node, lipogranulomas		-1
Lymph node, reactive hyperplasia		-1
Lymphadenitis, chronic		-1
Lymphadenitis, Dermatopathic		-1
Lymphoproliferative Syndrome		-1
Necrosis (Lymph Node)		-1
Nephritis Interstitial		-1
Osteoarthritis (femoral head)		-1
Osteochondritis dessicans		-1
Osteomyelitis, mandible		-1
Pancreatitis, Hemorrhagic		-1
Pancytopenia		-1
Parotitis		-1
Pneumothorax		-1
Pneumonitis, granulomatous		-1
Pseudoarthrosis		-1
Pneumoconiosis, anthracosilicosis		-1
Reactive Changes (Bone-Cartilage)		-1
Retained Iron Fragments (Shrapnel)		-1
Sclerosis (Bundle of His)		-1
Spondylolisthesis		-1
Suicide		-1
Toxicity (overdose)		-1
Varicocele		-1

Chairman SIMPSON. General Myers, please.

General MYERS. Thank you, Mr. Chairman, I appreciate the opportunity to give you and the committee members an update on the Ranch Hand study. I will submit a statement for the record. For purposes of brevity I will just touch on milestones and things accomplished.

Why a Ranch Hand study? There are two simple answers: Known heavy exposure among those individuals and the capability of identifying those people with relative ease.

We went through an exhaustive protocol development. It was subjected to extensive scientific review. The University of Texas School of Public Health at Houston, the Air Force Scientific Advisory Board, made up of civilian scientists, the Armed Forces Epidemiological Board, composed of civilian scientists, and the National Academy of Sciences all critiqued the protocol. The last report was received in May of 1980.

We were finally given the go-ahead by the Interagency Work Group after extensive review by that body, including the Science Panel.

We have identified the Ranch Hand group. I have personally spoken to many of those individuals at their national convention. We have accomplished our control group for matching which is on a basis of 10 to 1 overall. That's the match pool. The matching for mortality will be a 5 to 1, for the questionnaire 1 to 1, and for the physical examination 1 to 1; all meeting the necessary epidemiologic criteria.

Our questionnaire has been developed, field tested for its validity, and the contract for its administration has been awarded. That questionnaire is now being applied in the field by the group that was awarded the contract. It consists of a 3-hour personal interview with the interviewer going to visit the interviewee in his home.

If the individual refuses that interview, then an abbreviated questionnaire is given by telephone.

The administration of the questionnaires will be completed by the end of April 1982. The preliminary review of that data will be published within 12 months subsequent to that date.

The physical examination has been developed and standardized. We will include nerve conduction studies and other neurological testing as well as more sophisticated liver studies.

The bid review for a contract to administer the physical examinations is now in Air Force procurement hands. The first examinations will be done after January 1, 1982. All examinations will be completed by September 30, 1982. The peer review committee has been appointed by the Agent Orange Working Group. The examinations will be redone at 3, 5, 10, 15, and 20 years. We do have preliminary data on the mortality study. There have been 58 deaths in the Ranch Hand group since 1962, including 22 killed in action, 16 accident, 3 suicides, 2 homicides, 2 malignant neoplasms, 1 endocrine disorder, 7 circulatory problems, 4 diseases of the digestive system, and 1 from an ill-defined, as yet undetermined condition. That data will continue as more deaths occur. Interim reports are expected to be available in April or June of 1983.

The questionnaire will be completed in April 1982 and we should have some preliminary data by the end of 1982. We should look for-

ward to having some preliminary data on the examinations, which will be completed in September 1982, some 6 to 8 months later.

That concludes my statement, sir.

Chairman SIMPSON. You have some precise figures there to present to us. Could you repeat, General Myers, the total number of deaths from all causes?

Mr. MYERS. Fifty-eight, sir.

Chairman SIMPSON. Fifty-eight out of?

General MYERS. 1,200.

Chairman SIMPSON. 1,200. What was the average age of those deceased?

General MYERS. Well, some of those deaths occurred obviously early on when those people were very young and there has been a gradual—

Chairman SIMPSON. How many were killed in combat?

General MYERS. There were 22 killed in action.

Chairman SIMPSON. Fine. I will be interested in looking at those.

[The prepared statement of Lt. Gen. Paul W. Myers, Surgeon General, Medical Corps, U.S. Air Force, follows:]

PREPARED STATEMENT OF LT. GEN. PAUL W. MEYERS, SURGEON GENERAL, MEDICAL CORPS,
U.S. AIR FORCE

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE

I AM LIEUTENANT GENERAL PAUL W. MYERS, AIR FORCE SURGEON GENERAL. I
THANK YOU MR. CHAIRMAN FOR THE OPPORTUNITY TO PRESENT AN UPDATE ON THE AIR
FORCE EPIDEMIOLOGICAL INVESTIGATION OF RANCH HAND PERSONNEL EXPOSED TO
HERBICIDE ORANGE.

LET ME REDEFINE SOME OF THE TERMS USED IN THIS STATEMENT. HERBICIDE
ORANGE WAS A DEFOLIANT USED IN VIETNAM. IT WAS A 50:50 MIXTURE OF 2,4,-D
{2,4-DICHLOROPHENOXYACETIC ACID} AND 2,4,5-T {2,4,5-TRICHLOROPHENOXYACETIC
ACID}. BOTH OF THESE COMPONENTS WERE REGISTERED BY THE U.S. DEPARTMENT OF
AGRICULTURE. THE COMPONENT 2,4,5-T CONTAINED A CONTAMINANT TCDD (DIOXIN)
PRODUCED DURING THE MANUFACTURING PROCESS. THE NAME HERBICIDE ORANGE CAME
FROM AN IDENTIFYING ORANGE STRIPE PAINTED ON THE DRUM IN WHICH THE HERBICIDE
WAS STORED. RANCH HAND WAS A CODE NAME ATTACHED TO THE AIR FORCE AIRCREWS
INVOLVED IN THE HERBICIDE SPRAYING OPERATIONS BETWEEN 1962 AND 1970.

BECAUSE OF PUBLIC CONCERN ABOUT ALLEGED HARMFUL HUMAN EFFECTS RESULTING
FROM EXPOSURE TO HERBICIDE ORANGE, THE AIR FORCE MADE A COMMITMENT TO THE
CONGRESS AND TO THE PUBLIC TO CONDUCT A STUDY OF THE RANCH HAND GROUP.
THIS GROUP WAS SELECTED BECAUSE OF KNOWN HEAVY EXPOSURE. THESE AIRMEN
COULD ALSO BE READILY IDENTIFIED.

WE DEVELOPED A STUDY PROTOCOL FOR AN INTENSE EPIDEMIOLOGICAL INVESTIGATION
CONSISTING OF THREE INTEGRATED ELEMENTS: (1) A MORTALITY STUDY (DEATH),
(2) A MORBIDITY STUDY (DISEASE, INCLUDING BIRTH DEFECTS IN OFFSPRING), AND
(3) FOLLOW-UP. THE PROTOCOL WAS SUBJECTED TO EXTENSIVE SCIENTIFIC REVIEW.
THE UNIVERSITY OF TEXAS SCHOOL OF PUBLIC HEALTH AT HOUSTON; THE AIR FORCE
SCIENTIFIC ADVISORY BOARD (CIVILIAN SCIENTISTS); THE ARMED FORCES EPIDEMIOLOGICAL
BOARD (CIVILIAN SCIENTISTS); AND THE NATIONAL ACADEMY OF SCIENCES ALL
CRITIQUED THE PROTOCOL. THE LAST REVIEW REPORT WAS RECEIVED IN MAY 1980.

EACH REVIEWING AGENCY RAISED A NUMBER OF TECHNICAL ISSUES ABOUT THE AIR FORCE PROTOCOL. THE NATIONAL ACADEMY OF SCIENCES EXPRESSED CONCERN ABOUT CREDIBILITY IF THE AIR FORCE CONDUCTED THE STUDY. THE INTERAGENCY WORK GROUP TO STUDY THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDES AND CONTAMINANTS MADE THE DETERMINATION AS TO HOW THE STUDY SHOULD BE CONDUCTED AND BY WHOM. THE INTERAGENCY WORK GROUP BEGAN ITS REVIEW ON JUNE 17, 1980 AND A RECOMMENDATION WAS MADE ON AUGUST 1, 1980 TO THE ASSISTANT TO THE PRESIDENT FOR DOMESTIC AFFAIRS AND POLICY THAT THE RANCH HAND STUDY, WITH APPROPRIATE PROTOCOL MODIFICATIONS AND OUTSIDE PEER REVIEW AND MONITORING, BE COMMENCED BY THE AIR FORCE AS SOON AS POSSIBLE. ON SEPTEMBER 16, 1980, THE ASSISTANT TO THE PRESIDENT FOR DOMESTIC AFFAIRS AND POLICY CONCURRED IN THIS RECOMMENDATION. THE SECRETARY OF DEFENSE WAS SO NOTIFIED.

IN THAT SAME MONTH, A CONTRACT WAS AWARDED BY THE AIR FORCE FOR THE DEVELOPMENT OF A MORE EXTENSIVE QUESTIONNAIRE BASED ON THE RECOMMENDATIONS OF THE PEER REVIEW AGENCIES.

WE COMPLETED THE REVISED PROTOCOL BASED ON THE GUIDANCE OF THE INTERAGENCY WORK GROUP IN NOVEMBER 1980.

IN THE INTERIM, THIRTY THOUSAND PERSONNEL RECORDS WERE SCREENED. A MATCHING OF A CONTROL GROUP TO THE 1,264 RANCH HAND MEMBERS WAS COMPLETED AT A RATIO OF 10 TO 1. MATCHES WERE MADE BY AGE, OCCUPATIONAL CATEGORY, AND RACE. A 1 TO 1 MATCH FOR THE PHYSICAL EXAMINATIONS AND 5 TO 1 FOR THE MORTALITY STUDY WAS ALSO DONE.

THE MORTALITY STUDY HAS CONTINUED. TO DATE, WE KNOW OF 58 DEATHS: 22-KILLED IN ACTION; 16-ACCIDENTS (AIRCRAFT, MOTOR VEHICLE, DROWNING); 3-SUICIDES; 2-HOMICIDES; 2-MALIGNANT NEOPLASMS; 1-ENDOCRINE, NUTRITIONAL AND METABOLIC DISEASES; 7-DISEASES OF CIRCULATORY SYSTEM; 4-DISEASES OF DIGESTIVE SYSTEM; AND 1-SYMPTOMS, SIGNS AND ILL DEFINED CONDITIONS. THESE

ARE DISEASE STATES AS GROUPED BY THE BOOK ON INTERNATIONAL CLASSIFICATION OF DISEASES, NINTH EDITION.

THE DRAFT QUESTIONNAIRE AND CONTACT LETTERS WERE APPROVED BY THE OFFICE OF MANAGEMENT AND BUDGET ON MARCH 30, 1981. THE QUESTIONNAIRE WAS PRETESTED BY A CONTRACTOR ON A GROUP OF FORMER AIR FORCE VIETNAM VETERANS. THE RESULTS OF THE PRETEST WERE USED TO REFINE THE QUESTIONNAIRE AND THE FINAL QUESTIONNAIRE WAS PROVIDED TO THE AIR FORCE IN MID-JUNE 1981.

THE CONTRACT FOR ADMINISTRATION OF THIS QUESTIONNAIRE WAS AWARDED ON SEPTEMBER 18, 1981 TO LOUIS HARRIS AND ASSOCIATES, INC. ALL POSSIBLE RANCH HANDERS AND CONTROLS WILL BE INTERVIEWED DURING THE SIX MONTHS SUBSEQUENT TO SEPTEMBER 1981. THE QUESTIONNAIRE WILL IDENTIFY THE HEALTH, MEDICAL, DEMOGRAPHIC, SOCIAL AND PSYCHOLOGICAL CONDITION OF THE STUDY SUBJECTS AND THEIR IMMEDIATE FAMILIES.

STUDY SUBJECTS WILL ALSO BE ASKED TO PARTICIPATE IN AN EXTENSIVE PHYSICAL EXAMINATION. THE STATEMENT OF WORK FOR THAT PHYSICAL EXAMINATION HAS BEEN COMPLETED AND A REQUEST FOR PROPOSAL WAS PUBLISHED ON AUGUST 21, 1981. THREE BIDS HAVE BEEN RECEIVED AND ARE BEING EVALUATED AT THE USAF SCHOOL OF AEROSPACE MEDICINE, BROOKS AIR FORCE BASE, TEXAS. IT IS ANTICIPATED THAT A CONTRACT WILL BE AWARDED DURING THE LATTER PART OF THIS MONTH. THE PHYSICAL EXAMINATIONS ARE SCHEDULED TO BE COMPLETED BY SEPTEMBER 1982.

THE INITIAL CONTACT LETTERS TO RANCH HAND PERSONNEL AND TO CONTROL PEOPLE ANNOUNCING THE STUDY AND ENCOURAGING THEIR PARTICIPATION WERE SIGNED BY THE SECRETARY OF THE AIR FORCE AND MAILING WAS COMPLETED ON OCTOBER 16, 1981. FOLLOW-UP LETTERS FROM ME, PROVIDING A FACT SHEET, AND GIVING DETAILS OF THE STUDY WERE MAILED NOVEMBER 6, 1981.

THE INITIAL ROUND OF QUESTIONNAIRES AND PHYSICALS WILL BE THE BASIS FOR THE REMAINDER OF THE STUDY. FOLLOW-UP EXAMINATIONS WILL BE AT 3, 5, 10, 15, AND 20 YEARS.

THE AGENT ORANGE WORKING GROUP, THROUGH THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, HAS ESTABLISHED AN ADVISORY COMMITTEE TO MONITOR THE RANCH HAND STUDY.

INTERIM TECHNICAL REPORTS FROM THE FIRST ROUND OF QUESTIONNAIRES AND PHYSICAL EXAMINATIONS WILL BE AVAILABLE IN APRIL/JUNE 1983. THE RANCH HAND STUDY SHOULD PROVE TO BE PRODUCTIVE IN DETERMINING THE POSSIBLE LONG-TERM HEALTH EFFECTS OF PHENOXY HERBICIDE EXPOSURES.

THERE HAS BEEN MUCH MISLEADING AND ERRONEOUS INFORMATION PUBLISHED IN RECENT MONTHS CONCERNING ABORTED RANCH HAND MISSIONS AND DUMPING OF HERBICIDES. ALL "ABORTED" MISSIONS DID NOT RESULT IN A "DUMP" OF THE HERBICIDE. THE DEPARTMENT OF DEFENSE IS CURRENTLY REVIEWING THE DATA TO DETERMINE THOSE DUMPS THAT MAY HAVE BEEN NEAR MILITARY INSTALLATIONS. THIS ISSUE WILL BE ADDRESSED BY THE REPRESENTATIVE FROM THE DEPARTMENT OF DEFENSE. MUCH WORK REMAINS TO BE DONE. BOTH THE AIR FORCE AND THE NATIONAL ACADEMY OF SCIENCES HAVE ACKNOWLEDGED THE DUMPING OF HERBICIDES IN VIETNAM AS A RESULT OF SOME ABORTED MISSIONS. THERE HAS BEEN NO COVER-UP OF THIS DATA AS HAS BEEN ALLEGED.

THE RANCH HAND STUDY WILL PROCEED ON SCHEDULE. WE WILL CONTINUE TO WORK CLOSELY WITH ALL INTERESTED AGENCIES IN SEEKING THE ANSWERS TO QUESTIONS CONCERNING THE HEALTH EFFECTS, IF ANY, OF EXPOSURE TO HERBICIDE ORANGE IN VIETNAM.

I WILL BE HAPPY TO ANSWER ANY QUESTIONS.

Chairman SIMPSON. I will not belabor the panel, so I will just bounce around on some questions.

Dr. Erickson, with regard to the birth defects study, has it been difficult to locate the cohorts? How are these veterans contacted? What has been the rate of response or participation there? In your opinion could these same methods be employed on a national scale with regard to the agent orange epidemiological study? Are you familiar with the State of Wisconsin's recent efforts to locate Vietnam veterans in the State of Wisconsin through utilization of the State's selective service documents and discharge papers? Would such a system be feasible on a national scale?

Dr. ERICKSON. Well, with respect to your last question, I am not really familiar with the Wisconsin business. I believe that it somehow revolved around a bonus that was paid to Wisconsin servicemen if I am not mistaken and that's—

Chairman SIMPSON. It deals with maps. I just wondered if you were familiar with the effort.

Dr. ERICKSON. No. In terms of our own study, we are into its very early stages and, of course, we don't have any hard figures on what sort of location rates that we have. We expect it to be a problem because many of the babies in our study were born in the late 1960's and early 1970's and we are starting out with our study with an address, name and address of parents at the time of birth. We think that we can locate fairly easily about 50 percent of them, almost at the drop of the hat.

As you try and increase your location rates to a high level, which we want to do, it becomes more and more difficult. We have a number of methods which we will be using. We had hoped to make use of a public law which permits the National Institute of Occupational Safety and Health to send the Internal Revenue Service the social security number and the Internal Revenue Service returns to NIOSH a relatively current address. We had hoped to use that but the practical application of this procedure is such that IRS requires that the social security number be accompanied by a surname and that if IRS can match the surname with a number, they will return an address.

We are starting out with social security numbers for mothers. We had no access to social security numbers for fathers. And because our society has fairly frequent name changes for women, we expect that process not to be useful and are rather disappointed by that.

Overall, we are still hopeful that we will achieve an acceptably high location and participation rate.

Chairman SIMPSON. We will be interested in your figures on the response rate.

What is the CDC's reaction to the Spivey protocol? Would you please comment on your idea of what a protocol is and how the UCLA product fits within that definition? Do you have any suggestions to the authors that would be helpful to them as they prepare the revised protocol?

Dr. ERICKSON. Well, I can't speak for CDC. I have reviewed the protocol briefly in my capacity as a member of the VA Advisory Committee. And I found the protocol to be lacking, like everybody

else has, lacking in sufficient detail so that the VA could conduct a study.

My idea of a protocol is that it should be in sufficient detail that somebody could begin the conduct of a study.

Chairman SIMPSON. You have heard us again return to the issue of expansion. In your opinion, should the protocol for this epidemiological study be broadened, as is the CDC birth defects study, to include general service in Vietnam rather than just exposure to agent orange? Would broadening the agent orange study make designing the protocol more appropriate?

Dr. ERICKSON. Well, I think that would not necessarily make designing the protocol more appropriate. We designed our study to be a general service study because in our group at CDC we get calls from people wanting to know why their babies were born with birth defects. We were getting calls from women who said, "Well, my husband served in Vietnam, but he doesn't think he was exposed to agent orange, but we are still wondering if something happened to him over there."

And I guess my personal opinion is that a study of the broad issue of Vietnam service in tandem with a study of agent orange is probably what is warranted. That's a personal opinion and not an official CDC position.

Chairman SIMPSON. I appreciate your frankness. It is something we are going to have to pay careful attention to. I know that you are in the early phases of conducting the CDC birth defects study, but are there any initial findings that are of interest? Have you had any problems with the pilot study?

Dr. ERICKSON. No, other than potential problems in locating people, we have had no problems and things are going along fine as anticipated.

Chairman SIMPSON. I see.

[Response of the Department of Health and Human Services to written questions submitted by Hon. Alan K. Simpson, chairman of the Senate Committee on Veterans' Affairs, follows:]

Now, as the questionnaire completion approaches that April 30, 1982 date, we will have an exact idea of how many participants there are. We hope that we will get very high percentages among the ranch handers themselves because of their avowed anxious participation. It might be a little harder to determine out of that large control group, which is a 1-to-1 ratio, just how many we will get at this time.

Chairman SIMPSON. What has been your experience with bias of the cohorts in the Ranch Hand study? Have you found that a high level of secrecy, which Dr. Spivey seems to insist upon in his protocol, is necessary for your study?

General MYERS. The purpose of secrecy is to protect the protocol and the questionnaire because, if they were known publicly there would be an obvious bias. The answers to the questions would be made in an individual's mind before they were even asked. So, we are keeping secret the protocol and the questionnaire.

Chairman SIMPSON. Would you agree that oversight by a peer review committee, such as was implemented for the Ranch Hand study, might be a good idea for the VA's epidemiological study? I would like your views on that.

General MYERS. Yes, sir, I think that's an absolute requirement. It's difficult enough to get individuals to agree on protocol. It's very hard to develop that protocol. Once it is developed and put to test, then there has to be some outside group that monitors the progress of that study the way to make sure that protocol deviations are not occurring, whether there are any new added factors that are considered and put into the study.

Chairman SIMPSON. Who in your command has been most deeply involved in the Ranch Hand study?

General MYERS. We have some 16 people who are currently committed to the Ranch Hand study. Two other people who have been greatly involved are Maj. Alvin Phil Brown from my office and Maj. Alvin Young who is an avowed expert in herbicide orange and who has testified at great length before this committee.

Chairman SIMPSON. Yes. I just wondered what their opinion might be of the protocol based upon their own experience in implementing the plans for the Ranch Hand study.

General MYERS. I wouldn't presume to speak for them, but all of us have worked in concert together to make certain that we had a protocol which would turn out to be scientifically valid. We agreed within the Air Force on the direction in which we wanted to go. We accepted the criticisms from the review groups and incorporated those changes and then left it up to the interagency work group to determine whether or not we should proceed. We got that direction and are off and moving in that study.

Chairman SIMPSON. And you think it is working very well?

General MYERS. I think that we have been able to hit the milestones that we predicted. I am terribly hopeful that we will have fine cooperation and participation and that we will get something out of it. If we could make a prediction on what's happened thus far, then my enthusiasm is very high.

Chairman SIMPSON. Let me ask you about the Ranch Hand group. Apparently they keep in rather close touch with each other. Is that true?

General MYERS. Very much, yes, sir. They wear some distinctive garments at their conventions, a great deal of—oddly enough not orange, green.

Chairman SIMPSON. Green.

General MYERS. I think that's a natural spinoff from aviators who keep in touch with their crews. They had something in common. Now they know that they have an opportunity to make a contribution. And there is quite an esprit de corps in that group. They are working almost as a single individual.

Chairman SIMPSON. I am curious. What would have been the average time of exposure during a period when they would transport this dioxin? I suppose that would differ with a fixed-wing craft versus a helicopter. But did they all remain in constant exposure to it?

General MYERS. Oh, yes, sir. They have, and we have shown this not only photographically but from the recap of the experiences of the individual crewmembers, that their exposure is calculated to be the highest of any group who served in Vietnam. And the example is that the 1,000-gallon tank that needed to be filled and carried aboard the 123 aircraft, was hand pumped. There was a lot of spill. Usually the control operator who handled the spray equipment and other personnel in the aircraft were exposed to the spray. When the mission took place that spraying occurred over 3½ to 4 minutes and that's a relatively short time.

If there was more than one aircraft flying in the formation, there was a lot of contamination from aircraft to aircraft. If you got caught in a crosswind, downwind, or in some kind of maneuver and had the spray blow. Some of the contamination, however, occurred on the ground; that is, from the spray covering the airframe and in the transfer of the agent into the tank and the cleaning of the tanks.

Chairman SIMPSON. I continue asking these questions because my administrative assistant used to do that. I am going to get away from that now, however.

I thank you very much. It has been very helpful to the committee and I thank you for your participation.

General MYERS. Thank you, sir.

[Subsequently, the Department of Defense submitted the following letters for the hearing record:]



DEPARTMENT OF THE AIR FORCE
WASHINGTON, D.C. 20330

OFFICE OF THE SECRETARY

DEC 28 1981

Honorable Alan Cranston
Ranking Minority Member
Committee on Veterans' Affairs
United States Senate
Washington, D. C. 20510

Dear Senator Cranston:

This is in further reply to your letter of December 4, 1981, to the Air Force Surgeon General concerning Herbicide Orange.

The following answers are provided to your questions:

a. Question: How many of the Ranch Hand personnel are currently on active duty? Answer: There are currently 234 Ranch Hand personnel remaining on active duty.

b. Question: How many are employed as pilots or other flight crew members in commercial aviation? Answer: We are unable to determine the number involved in commercial aviation at this date. The questionnaire should provide an answer to this question through collection of the occupational history. We do know that 177 hold current FAA certificates. Not all 177 would necessarily be involved in commercial aviation. Some certificates would cover persons involved in military or private aviation or avocational flying.

c. Question: What have these personnel been told regarding the effects that the results of the exam might have on their current status? Answer: Confidentiality is to be maintained except in two cases: (1) a judicial order to release personal medical data following an Air Force and Justice Department defended lawsuit; and (2) serious medical findings which impact public health and safety. Two examples of situations in which public health and safety would raise the questions of disclosure are: a participant has typhoid fever; a participant who directly impacts the safety of others either in his profession, or as a volunteer, is found to have a serious nerve, heart or mental disorder. In this instance a committee composed of a physician of the individual's choice, a flight surgeon, a judge advocate (lawyer) and a representative from the individual's field of expertise will be convened to review the medical findings. Before any disclosure is made to medical authorities, the committee must determine that the findings jeopardize the public health and safety.

d. Question: Will the physical exams of the Ranch Hand personnel be conducted in a central location? Answer: All Ranch Hand personnel will receive the physical exam at the same location, Kelsey-Seybold Clinic, Professional Association, Houston, Texas.

e. Question: Over what period of time will the exams be given? Answer: Exams are targeted to start in mid-January 1982, and to be completed not later than September 30, 1982.

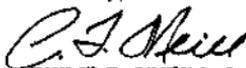
f. Question: I understand that the individual physical exams will be quite extensive—comparable to the exams given to astronauts returning from space. Is that correct? Answer: A very comprehensive research oriented physical exam will be given to each participant. Systems to be covered during the examination include a general medical history, a review of major physiological systems, and detailed medical and laboratory examinations of the heart, liver, kidneys, neurological system, reproductive system, blood, hearing, sight, and skin.

g. Question: How many hours or days is an individual exam expected to take? Answer: The exam is scheduled for 3-4 days.

h. Question: What steps have been taken to ensure that the physical exams will be standardized and that laboratory work will also be analyzed in a standard fashion? Answer: An extensive quality control program has been instituted for this effort. Included will be a full time on-site monitor at the exam facility; stringent laboratory quality requirements; weekly processing of all results to identify possible trends or biases; a limited, stable staff performing the examination; fully certified laboratory facilities; use of a single laboratory for tests; board certified physicians; appropriately certified technicians; and, a standardized examination for all participants.

We are pleased to be of service in providing you this information.

Sincerely,



PHILIP F. O'NEILL, Lt Col, USAF
Deputy Chief, Legislation Division
Office of Legislative Liaison



DEPARTMENT OF THE AIR FORCE
WASHINGTON, D.C. 20330

OFFICE OF THE SECRETARY

FEB 5 1982

Honorable Alan Cranston
Ranking Minority Member
Committee on Veterans' Affairs
United States Senate
Washington, D.C. 20510

Dear Senator Cranston:

This is in further response to your letter of December 4, 1981, concerning Herbicide Orange.

In our letter of December 28, 1981, we set out two examples of when confidentiality is to be maintained on the results of medical examinations. One provision states that confidentiality is to be maintained except in the case of "(1) a judicial order to release personal medical data following an Air Force and Justice Department defended lawsuit ..."

Examples of judicial orders directed at information accumulated during medical exams are:

- a. An order to disclose a participant's home address for use in an action by an ex-wife to collect child support.
- b. An order to disclose medical information regarding pre-existing injury in personal injury litigation brought by a participant against a third party tortfeasor.

The language which reads "... following an Air Force and Justice Department defended lawsuit ..." was included to specifically state that the Air Force does not intend to release any information provided by participants in the medical examination program until all avenues of defense against release have been exhausted.

If we may be of further service, please let us know.

Sincerely,

PHILIP F. O'NEILL, Lt Col, USAF
Deputy Chief, Legislation Division
Office of Legislative Liaison

Chairman SIMPSON. Next, before I go to this classified briefing, I will certainly begin the process to hear from the various veterans' groups. The first witness of the next group is John Sommer, assistant director of the National Veterans' Affairs and Rehabilitation Commission, accompanied by Paul Egan, the assistant director of the National Legislative Commission of the American Legion; and Philip Mayo, special assistant to the director of the National Legislative Service, accompanied by James Davis, claims consultant, National Veterans' Service, and Frederick Mullen, Sr., claims consultant, National Veterans' Service of the Veterans of Foreign Wars of the United States. It is good to have you here and I thank you for your patience. Would you please proceed, Mr. Sommer.

TESTIMONY OF A PANEL OF REPRESENTATIVES OF VETERANS' ORGANIZATIONS CONSISTING OF PAUL S. EGAN, ASSISTANT DIRECTOR, NATIONAL LEGISLATIVE COMMISSION, THE AMERICAN LEGION, ACCOMPANIED BY JOHN F. SOMMER, JR., ASSISTANT DIRECTOR, NATIONAL VETERANS AFFAIRS AND REHABILITATION COMMISSION; AND PHILIP R. MAYO, SPECIAL ASSISTANT, NATIONAL LEGISLATIVE SERVICE, VETERANS OF FOREIGN WARS OF THE UNITED STATES, ACCOMPANIED BY JAMES DAVIS, CLAIMS CONSULTANT, NATIONAL VETERANS' SERVICE AND FREDERICK MULLEN, SR., CLAIMS CONSULTANT, NATIONAL VETERANS' SERVICE

Mr. EGAN. Mr. Chairman, my purpose today is to introduce our witness who you have already recognized, Mr. John Sommer. But before beginning I would like to say that the American Legion has got to view with a considerable sense of foreboding the vagueness of the UCLA study. And that sense of foreboding is underlined by a variety of unanswered questions, two of which have emerged today.

The first one being, Will an additional 35 days be sufficient to produce a methodologically sound and clear protocol. And second, at the end of that 35 days will we be looking at a study of the effects of—a protocol for a study of effects of agent orange or will we be looking at a protocol for a feasibility study of whether or not an agent orange study ought to be produced at all.

After having made those remarks, I will let John go ahead.

Chairman SIMPSON. Thank you.

Mr. SOMMER. Thank you, Paul.

Mr. Chairman, we certainly appreciate the opportunity to appear here today. There are certain factors pertaining to the draft protocol which are of great concern to the American Legion; the first being that the design is incomplete and unacceptable as presently written.

We find it disturbing that the authors are so obsessed with secrecy that information pertaining to symptoms of interest to the study have been withheld. While we can understand their concern, we feel that it is necessary to be specific in spite of their perceived inherent dangers.

For the sake of uniformity of examinations and to be sure that the symptoms sought are complete, it is necessary for this to be known. To withhold such information would only cause added skepticism among Vietnam veterans as to the credibility of the U.S.

Government in determining the effects of exposure to agent orange.

The authors admit that the draft bill is not a complete protocol for a number of reasons, some of which are no fault of their own. For instance, as has been mentioned previously, the investigators were denied access to certain classified military records because of the lack of a security clearance. This does not excuse the fact that the contractor did not employ individuals with a knowledge of tactical military operations in Vietnam or the records pertaining thereto.

The timeliness of reporting study results is also essential. An important phase of the proposed study will track the long-term effects of agent orange exposure, but they are of no instant use to the affected veterans. Immediate effects have been questioned such as chloracne and certain sarcomas and it will be necessary to promptly identify and report any such effects that may be found in order to be of value to Vietnam veterans who were exposed.

We feel that due to the large number of veterans who will be examined, the use of VA medical centers would be the most practical approach. However, we would make such a recommendation only upon the assurance that specific guidelines will be implemented to prevent the specter of conflict of interest from arising. This must require uniformity of examinations, education of the physicians performing the examinations, and the establishment of an impeccable external supervisory board to insure that the examinations are competently carried out and that the results of such examinations are carefully interpreted by the independent scientific body responsible for conducting the study.

The questionnaire to be used with the examination should be made available for review by the groups conducting the peer review prior to conducting the study.

The Legion is opposed to the agent orange study being conducted by the Veterans' Administration. As was the protocol design, we feel the study itself should be contracted to an independent scientific body once the protocol has been completed and approved.

Because of the absence of detail and the need for additional research and development, it is obvious that a period longer than that specified in the contract will be required to complete the draft and implement the recommendations thereon; and we would recommend that an extension of time be provided the contractor by the VA.

In conclusion, it is crucial that the VA cooperate with the contractor to the fullest extent possible by providing all material needed for the satisfactory completion of the protocol.

Further, it is imperative that the contractor retain the services of someone knowledgeable in the area of Department of Defense records.

As mentioned at the outset, the harm to be done in invoking secrecy will exceed the gains to be expected. Confidence rather than distrust in the results is to be sought.

Mr. Chairman, that concludes our statement.

Senator SIMPSON. Thank you very much, Mr. Sommer.

[The prepared statement of John F. Sommer, Jr., assistant director, National Veterans Affairs and Rehabilitation Commission, the American Legion, follows:]

PREPARED STATEMENT OF JOHN F. SOMMER, JR., ASSISTANT DIRECTOR, NATIONAL VETERANS
AFFAIRS AND REHABILITATION COMMISSION, THE AMERICAN LEGION

Mr. Chairman and Members of the Committee:

The American Legion appreciates the opportunity to comment on the draft protocol of the epidemiological study of long-term health effects of Agent Orange exposure mandated by section 307 of Public Law 96-151, and contracted to the U.C.L.A. School of Public Health by the Veterans Administration in May 1981.

We are not epidemiologists, and therefore will not attempt to recommend an alternative protocol for the study or to revise the general methodology that is sketched out in the broad outline that has been presented. However, there are certain factors contained in the draft protocol which are of great concern to The American Legion.

At the outset, it must be said we find it quite disturbing that the authors are so obsessed with secrecy that information pertaining to diseases or symptoms of interest to the study, and details relating to veterans they consider to be in high or low exposure groups has been withheld. While we can understand the authors' concern about the specific symptoms and signs to be sought in the examination we nevertheless feel that it is necessary to be specific in these in spite of their perceived inherent dangers. We believe that this study is no different from other surveys wherein equal problems have been faced without undue hazard to the

study. For the sake of uniformity of examinations and to be sure that the symptoms sought are complete, it is necessary for this to be known.

Further, to withhold such information would only cause added skepticism among Vietnam veterans as to the credibility and sincerity of the United States Government in determining the effects of Agent Orange exposure.

Aside from the failure to disclose the foregoing data, the authors admit that the draft is not a full protocol, for a number of other reasons, some of which were no fault of their own. For instance, the investigators were denied access to certain classified military records because the Veterans Administration had failed to obtain a security clearance for the contractor or his assistants. This, of course, does not excuse the fact that the contractor did not include among the staff of investigators and consultants an individual or individuals possessing knowledge of tactical military operations in Vietnam or the administrative records pertaining thereto.

Documentation of exposure is an extremely important factor and it appears that sufficient information exists in available military records to develop an exposure index. Although it is unlikely that individual exposure data could ever be verified, it is possible to identify battalion or company sized units located in close proximity to sprayed areas. The draft protocol proposes the exclusion of certain individuals from the study, such as battle casualties and military personnel who served more than 13 months

in Vietnam or 3 years in the Armed Forces. However, the justification for such exclusion has not been clarified. It would seem that such individuals might have a greater exposure and thus be more likely to show ill effects as a result.

The timeliness of reporting study results is essential. Granted, an important phase of the proposed study will track the long-term effects of Agent Orange exposure, but they are of no instant use to the affected veterans. Certain immediate effects have been questioned such as chloracne and certain sarcomas. Therefore, it will be necessary to promptly identify and report any such effects that are found in order to be of value to Vietnam veterans who were exposed.

The outline of the proposed historical cohort study contains a sizable discussion relative to the possibility of conducting the necessary physical examinations in VA medical centers, and whether or not such a practice would be acceptable to the Vietnam veterans concerned.

It is the feeling of The American Legion that due to the large number of veterans who will be examined the use of VA medical centers would be the most practical approach. However, we would make such a recommendation only upon the assurance that specific guidelines will be implemented to prevent the specter of conflict of interest from arising. Such controls must require uniformity of examinations, education of the physicians performing the examinations, and the establishment of an impeccable external supervisory board to ensure that the examinations are appropriately and competently carried out, and that the results of such examinations are carefully

interpreted by the independent scientific body responsible for conducting the study.

It is also felt that the questionnaire to be used in conjunction with the examination should be made available for review prior to the onset of the study, particularly so that the groups responsible for peer review may comment thereon.

As has been expressed on many occasions, the Legion is opposed to the Agent Orange study being conducted by the Veterans Administration, not because we doubt the integrity of the VA, but because we are concerned that the end results may be subject to question concerning possible conflict of interest. As was the protocol design, we feel the study itself should be contracted to an independent scientific entity, once the protocol has been completed and approved.

Because of the absence of detail, and the need for additional research and development, it is obvious that a period longer than the 30 days specified in the contract will be required to complete the draft and implement the recommendations thereon; and we would recommend that an extension of time be provided the contractor by the VA.

In conclusion, it is crucial that the Veterans Administration take the steps necessary to secure a security clearance for the contractor in order to ensure access to critical military documents relative to Agent Orange exposure; and cooperate with the contractor to the fullest extent possible by providing all material needed for the satisfactory completion of the protocol. Further, it is imperative that the contractor retain the services of someone

knowledgeable in the area of Department of Defense records, so that a workable exposure index may be developed, and for the interpretation of other important military data relative to the activities of the ground troops who served in Vietnam.

As mentioned at the outset, while we can appreciate the concern of the contractor to avoid premeditated distortion of symptoms, we do not believe the actual findings will be distorted. The harm to be done by invoking secrecy will exceed the gains to be expected. Confidence rather than distrust in the results is to be sought.

Mr. Chairman, that concludes our statement.

Chairman SIMPSON. Phil Mayo, please.

Mr. MAYO. Thank you, Mr. Chairman, for holding this hearing and inviting our views on these matters.

First of all, we would like to commend the committee for its efforts in advancing what is now Public Law 97-72. We believe that this law provides the necessary latitude to resolve the herbicide related issues.

We share the view that we must get on with the necessary actions that would resolve the questions veterans have concerning herbicide exposure. The issue has been widely debated and we believe its resolution should be a matter of highest governmental priority. We believe that current law provides the means to overcome any questions regarding the availability of information for this purpose, and we would urge this committee to exert its influence toward the accomplishment of a timely and accurate investigation of all the herbicide related issues.

We note that no mention of coordination, or interfacing, or review with either the Australian, Vietnamese, or other studies has been made today, and we find this omission ironic. Certainly valuable information could be derived from studies done on those groups and we have repeatedly pointed this out to other groups that have testified before this committee today.

That concludes my remarks.

Chairman SIMPSON. Thank you very much.

[The prepared statement of Philip R. Mayo, special assistant, National Legislative Service, Veterans of Foreign Wars, follows:]



VETERANS OF FOREIGN WARS OF THE UNITED STATES

NATIONAL LEGISLATIVE SERVICE

Office of Director

PREPARED STATEMENT OF

PHILIP R. MAYO, SPECIAL ASSISTANT
NATIONAL LEGISLATIVE SERVICE
VETERANS OF FOREIGN WARS OF THE UNITED STATES

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE

WITH RESPECT TO

MATTERS RELATING TO HERBICIDE EXPOSURE

WASHINGTON, DC

NOVEMBER 18, 1981

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

Thank you for the opportunity to present the views of the Veterans of Foreign Wars of the United States with respect to matters relating to the use of herbicides in Vietnam.

At the outset, Mr. Chairman, we would like to commend this Committee for its efforts in securing the passage of what is now Public Law 97-72, the "Veterans' Health Care, Training and Small Business Loan Act of 1981." As you know, provisions of that law relate to authorizing eligibility for basic health-care services by the Veterans Administration for a veteran's disability if it is found that the veteran, during active duty in Vietnam, may have been exposed to any toxic substance in a herbicide or defoliant.

It also authorizes the Administrator to expand the scope of the Agent Orange epidemiological study mandated by Public Law 96-151 to include additional factors including exposure to other herbicides, chemicals, medications, or environmental hazards or conditions; and that the Administrator shall publish in



Federal Register, for public review and comment, the actions, if any, the Veterans Administration proposes to take with respect to VA programs in light of the results of the study and other available pertinent information. We believe this measure provides the latitude necessary for the federal government to proceed to a timely resolution of this issue.

Mr. Chairman, Public Law 96-151 mandated that the Administrator of Veterans' Affairs conduct an epidemiological study of the long-term health effects on veterans of the herbicide Agent Orange. In complying with that mandate, the Administrator consummated a contract with the University of California, Los Angeles (UCLA) to design a protocol suitable to accomplishing that study.

In that connection, information available to us indicates that those whom the VA contracted with have experienced difficulty in gaining access to records where important information upon which a reasonable recommendation for such a protocol can be based. This is the result of the absence of the appropriate authorization in the contract award. We find such an omission and, particularly, the lack of its resolution, to be untenable; it provides a substantive basis upon which the protocol design may be rejected, thereby constituting a waste of more than \$133,951 of taxpayer's money. Most importantly, it represents a further delay in progress on this issue; we find such unacceptable and respectfully urge this Committee to use its influence to correct this and any other shortcomings which may arise.

Mr. Chairman, it is our position that the resolution of this issue be made a matter of highest governmental priority. This requires that the funding and resources necessary for such be made available and progress toward that end be encouraged by the Congress. It is our conviction that the facilities of the Department of Defense--particularly its Research and Rulemaking Branch--may contribute greatly in these efforts. We stress this point inasmuch as our preliminary review of the recent "Review of Literature on Herbicides, Including Phenoxy Herbicides

and Associated Dioxina" compiled for the VA by JRB Associates has determined that the existence of a substantive relationship between the use of herbicides in Vietnam and health problems suffered by Vietnam veterans is deemed inconclusive. Our view is also supported by our knowledge of a number of criticisms of the proposed protocol, which we believe the VA should review at the earliest possible date. In other words, it appears that the mandated study may be the only means by which this highly controversial issue may be resolved, and we find unacceptable any actions which may delay it. We also believe that this will require the complete support of the Congress and the Executive Branch; and, again, we respectfully request this Committee to exert its considerable influence toward that goal.

Mr. Chairman, in recognizing the need to resolve this issue on a timely basis, the delegates to our most recent National Convention adopted Resolutions Nos. 624 and 716 entitled "Herbicide Exposure." Both are appended hereto for your review.

Mr. Chairman, this concludes my testimony and I would be happy to respond to questions you may have at this time.

Resolution No. 624

HERBICIDE EXPOSURE

WHEREAS, defoliant, the most commonly known being "Agent Orange" were utilized in Vietnam; and

WHEREAS, many of this nation's Vietnam Veterans were exposed, in varying degrees, to these toxic defoliant; and

WHEREAS, some researchers contend that dioxin found in herbicides cause cancerous tumors in test animals in concentrations of as little as five parts per trillion; and

WHEREAS, other researchers contend that exposure to herbicides containing dioxin cause health defects, nervous systems disorders, liver dysfunctions, genetic changes, spontaneous abortions or miscarriages, nausea, dizziness, and skin disease; and

WHEREAS, some experts contend that dioxin concerns are considerably overblown and that no medical evidence exists to substantiate compensatory claims; and

WHEREAS, these factors, as well as several industrial accidents involving dioxin, have brought about one of the nation's most heated and potentially wide-ranging controversies; now, therefore

BE IT RESOLVED, by the 82nd National Convention of the Veterans of Foreign Wars of the United States, that we use every means at our disposal to insure an accurate and timely completion of studies to resolve this question independently of the Veterans Administration; and

BE IT FURTHER RESOLVED, that we endorse and support liberalizing criteria for proper disposition of herbicide related claims; and

BE IT FURTHER RESOLVED, that the VFW continue to utilize its monthly magazine and other publications to inform veterans potentially exposed of recent developments in this area.

Adopted by the 82nd National Convention of the Veterans of Foreign Wars of the United States held in Philadelphia, Pennsylvania, August 14-20, 1961.

Resolution No. 716

HERBICIDE EXPOSURE

WHEREAS, defoliants, the most commonly known being "Agent Orange," were utilized extensively in Vietnam; and

WHEREAS, many of this Nation's Vietnam Veterans were exposed, in varying degrees, to these toxic defoliants; and

WHEREAS, some researchers contend that dioxin found in herbicides cause cancerous tumors in test animals in concentrations of as little as five parts per trillion; and

WHEREAS, other researchers contend that exposure to herbicides containing dioxin causes health defects, nervous system disorders, liver dysfunctions, genetic changes, spontaneous abortions or miscarriages, nausea, dizziness, and skin disease; and

WHEREAS, other health detriments which affect Vietnam Veterans include Agent Blue, an acid which is an organic form of arsenic; Agent Purple and White as well as the experimental malaria drug Dapsone and the physiological effects of psychological stress; and

WHEREAS, some experts contend that dioxin concerns are considerably overblown and that no medical evidence exists to substantiate compensatory claims; and

WHEREAS, these factors, as well as several industrial accidents involving dioxin, have brought about one of this Nation's most heated and potentially wide-ranging controversies; and

WHEREAS, under current law, the VA can provide service connected disability benefits for certain diseases which manifests itself within one year of the veterans date of discharge; and

WHEREAS, over the last two years, thousands of veterans have contacted the VA for treatment and/or filed claims regarding symptoms and maladies they feel were due to their exposure to the defoliant, "Agent Orange"; and

WHEREAS, the vast majority of these veterans left Vietnam before 1970, their skin conditions, lung conditions, cancer and neurological disorders are just now surfacing, and of the many claims acknowledged by the VA for conditions related to Agent Orange, relatively few veterans have received service connected disabilities believed caused by defoliants, in none of these VA decisions were defoliants cited as the cause of disability. The VA was able to grant service connection in all cases without citing a cause of disability, because symptoms appeared while still in military service; now, therefore

BE IT RESOLVED, by the 82nd National Convention of the Veterans of Foreign Wars of the United States, that we endorse and support any pending legislation or other legislation that may be introduced in the future providing for an open-ended presumptive period for any chronic disease or disorder determined through medical research to be the result of exposure to Agent Orange or other toxic substances used in support of the United States military activities in Southeast Asia.

Adopted by the 82nd National Convention of the Veterans of Foreign Wars of the United States held in Philadelphia, Pennsylvania, August 14-20, 1981.

Resolution No. 716

Chairman SIMPSON. I do understand the concerns of the veterans' groups about the importance of getting this study underway in as timely a fashion as possible. I appreciate your remarks about the recent legislation, which I believe is going to have a significant impact on meeting some interim needs of the Vietnam veteran who believes exposure to agent orange is giving some significant diagnostic concern to him or her. And so, the need is timely and I couldn't agree with you more.

However, in light of the problems that you heard portrayed today about this admittedly draft protocol, what are your views on a possible delay while the protocol is being revised?

Mr. MAYO. To include other herbicides and—

Chairman SIMPSON. I will ask that question separately. If you wish to respond to the issue of expansion, you may. But I am talking about your views on whether there should be an additional delay while the present protocol is being revised.

Mr. SOMMER. Mr. Chairman, John Sommer with the American Legion. It will certainly be necessary for a certain delay while the recommendations of the peer review groups are being put into the protocol and that additional research and development is being done. However, I don't feel that this will totally stop anything that is being done in preparation for the study. For instance, the additional work that is being done on the protocol will not stop Mr. Christian's operations in reviewing further military records pertaining to exposure.

Mr. MAYO. I think a modest delay which would improve the study being accomplished on a timely basis and would be certainly in order.

Chairman SIMPSON. What about that issue of expansion? Do you believe we should expand the study into other areas?

Mr. SOMMER. The American Legion would have no objection to the expansion of the study so long as the efforts that are being put forth on the agent orange study are not diminished as a result.

Mr. MAYO. We of the VFW, Mr. Chairman, have suggested that this take place on numerous occasions before this and other committees in the House of Representatives. Our view has not changed on that whatsoever.

Chairman SIMPSON. Would you still object to the VA's continued involvement in the study if the request for proposal is modified and improved?

Mr. SOMMER. The American Legion is mandated to oppose the Veterans' Administration carrying out this study. Of course, the cooperation of the VA is more than necessary in assisting the contractor in carrying out the study satisfactorily, by the provision of information, statistics and so forth. However, we are certainly opposed to the VA carrying out the study itself.

Mr. MAYO. The VFW holds similar views, Mr. Chairman.

Chairman SIMPSON. I thank you. I appreciate your views. It is always helpful to have comments from these two very capable veterans' organizations. Thank you very much.

Mr. SOMMER. Thank you, Mr. Chairman.

Mr. MAYO. Thank you, Mr. Chairman.

[The responses of the American Legion and the Veterans of Foreign Wars to written questions submitted by Hon. Alan K. Simp-

son, chairman of the Senate Committee on Veterans' Affairs and Hon. Alan Cranston, ranking minority member of the Senate Committee on Veterans' Affairs, follow:]

RESPONSE OF THE AMERICAN LEGION TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN K.
SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS' AFFAIRS

Question 1. If UCLA continues to maintain that the use of secrecy is an important element of its protocol, how would you feel about the VA retaining Doctors Spivey and Detels, giving them another chance to complete the protocol?

Answer 1. As was pointed out in our statement, we are quite displeased that the authors are so obsessed with secrecy that a substantial amount of pertinent information was withheld from the draft protocol.

Section 307 of Public Law 96-151 assigns the responsibility of approving the protocol, in accordance with which the Agent Orange study is to be carried out, to the Director of the Office of Technology Assessment. In accordance with the mandate, the OTA Director appointed an Advisory Panel, on which an American Legion representative was invited to serve, for the purpose of reviewing the protocol and recommending revisions thereto. The Advisory Committee met on September 8, 1981, and drafted a report which reflects a great deal of concern regarding the aura of concealment surrounding the protocol, and which suggests that there need not be such an emphasis on secrecy.

The Request for Proposals (RFP) issued by the VA in May, 1980, required that all information regarding the outcomes of the Agent Orange study were to be included in the protocol. And it is our understanding that the VA has recently informally advised the contractor that generally all information regarding the study is to be made public.

Given the assurances that Doctors Spivey and Detels will fully comply with these recommendations and requirements regarding the disclosure of information; and earnestly strive to develop a functional protocol, The American Legion would not object to giving them an opportunity to fulfill their contract.

Question 2. Do you object to the VA's continued involvement in the study?

Answer 2. The American Legion objects to the Agent Orange study being carried out by the Veterans Administration. However, a certain amount of involvement by the VA is necessary for the successful completion of the study.

As was mentioned in our statement, it is our feeling that due to the large number of veterans who will be examined the use of VA medical centers would be practical if certain stringent criteria are adhered to.

A substantial amount of the input needed to conduct the study is only obtainable from the Veterans Administration, such as data from the Agent Orange Registry, and information from veteran's claims folders and clinical records.

Therefore, we would certainly encourage the VA's cooperation in that respect with the independent scientific body ultimately charged with the responsibility of conducting the study.

RESPONSE OF THE AMERICAN LEGION TO WRITTEN QUESTIONS SUBMITTED BY HON. ALAN
CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON VETERANS'
AFFAIRS

Question 1A. During her testimony, Ms. Joan Bernstein, representing Vietnam Veterans of America, recommended that two studies be done -- one that would examine the general health status of Vietnam veterans without any findings of exposure to specific substances and one focusing on the health effects in Vietnam veterans of exposure to dioxin as found in Agent Orange.

What are your views on this proposal?

Answer 1A. It would appear that a substantial amount of information regarding the general health status of Vietnam veterans will be available as the result of the historical cohort study that is prepared in the draft protocol. The question at issue is what are the long-term health effects of exposure to Agent Orange. As we have previously stated, The American Legion would have no objection to expanding the study mandated by PL 96-151 to include a determination of the effects of exposure to other toxic substances that were present in Vietnam, as long as the additional research does not diminish the effort put forth on Agent Orange.

Question 1B. If both studies were to be undertaken, what role, if any, do you see the VA playing in the design and conduct of the studies?

Answer 1B. Regardless of the nature of the study or studies to be carried out, participation by the Veterans Administration to a certain degree will be necessary, as a great deal of the information needed must be secured from that agency. However, The American Legion strongly recommends that the responsibility for the design and conduct of the research be assigned to an independent scientific body.

Question 2. How would you recommend that the VA improve its efforts to alert Vietnam veterans to the agency's activities on the Agent Orange issue, including the provision of physical exams and, in some cases as authorized by Public Law 97-72, health care for disabilities of Vietnam veterans?

Answer 2. The VA has taken some steps to publicize its activities on the issue of Agent Orange, such as the film and pamphlet pertaining to the Agent Orange examination program; news releases announcing the availability of medical treatment as provided by PL 97-72; and briefings for veterans organizations relating to this subject. In order to further this informational effort it would be helpful if public service announcements were prepared by VA and broadcast on radio and television advising Vietnam veterans that the examinations and treatment are available. This information should also be posted in all VA medical centers, Veterans Assistance Offices, Regional Offices, and Vet Centers. Meanwhile, The American Legion will continue to use all of our resources to inform eligible veterans and their families of the availability of these services.

Question 3. Are you satisfied that the VA is soliciting and giving appropriate consideration to the views of veterans' service organizations on the Agent Orange issue?

Answer 3. American Legion representatives are in frequent contact with the VA, particularly with Dr. Barclay Shepard and his staff, regarding various aspects of the matter of Agent Orange. It must be said that although we are not always in agreement on certain issues, due consideration has always been given any recommendation or criticism that we have presented.

RESPONSE OF THE VETERANS OF FOREIGN WARS TO WRITTEN QUESTIONS SUBMITTED BY
HON. ALAN K. SIMPSON, CHAIRMAN OF THE SENATE COMMITTEE ON VETERANS'
AFFAIRS

QUESTION: If UCLA continues to maintain that the use of secrecy is an important element of its protocol, how would you feel about the VA retaining Doctors Spivey and Detels, giving them another chance to complete the protocol?

RESPONSE: We do not believe that a veterans' awareness of his exposure to Herbicides will bias the formulation of a protocol or the results of a study of such. Likewise, we do not consider public knowledge of the elements of the protocol a compromise of its integrity. We are primarily concerned that the general public and Vietnam veterans hold legitimate concerns that must be addressed. We have no objection to the retention of Doctors Spivey and Detels inasmuch as adequate safeguards have been established toward accomplishing a good protocol design in the form of the review process.

QUESTION: Do you object to the VA's continued involvement in the study?

RESPONSE: We do not believe that the VA can be completely eliminated from involvement in the study. The question evolves as to what extent the VA should be involved. We recommend that any physical or laboratory studies, X-ray, or other specialized diagnostic studies be conducted independently of any direct involvement by the VA as long as such is fiscally feasible. We believe such independent efforts would serve to allay many fears concerning biased examinations and study results.

RESPONSE OF THE VETERANS OF FOREIGN WARS TO WRITTEN QUESTIONS SUBMITTED BY

HON. ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON
VETERANS' AFFAIRS

1. QUESTION--During her testimony, Ms. Joan Bernstein, representing Vietnam Veterans of America, recommended that two studies be done--one that would examine the general health status of Vietnam veterans without any findings of exposure to specific substances and one focusing on the health effects in Vietnam veterans of exposure to dioxin as found in Agent Orange. (A) What are your views on this proposal? (B) If both studies were to be undertaken, what role, if any, do you see the VA playing in the design and conduct of the studies?

RESPONSE--(A) The VFW supported adoption of this concept earlier and such was made an element in the development of the current protocol. (B) We do not believe that the VA can be completely eliminated from involvement in the study. The question evolves as to what extent the VA should be involved. We recommend that any physical or laboratory studies, X-ray, or other specialized diagnostic studies be conducted independently of any direct involvement by the VA as long as such is fiscally feasible. We believe such independent efforts would serve to allay many fears concerning biased examinations and study results.

2. QUESTION--How would you recommend that the VA improve its efforts to alert Vietnam veterans to the agency's activities on the Agent Orange issue, including the provision of physical exams and, in some cases as authorized by Public Law 97-72, health care for disabilities of Vietnam veterans.

RESPONSE--The VA has already undertaken outreach through the media and also through veterans' organizations such as the VFW. Continuation of these efforts is in order.

3. QUESTION--Are you satisfied that the VA is soliciting and giving appropriate consideration to the views of veterans' service organizations on the Agent Orange issue?

RESPONSE--Yes, the VA has been very responsive to the recommendations and criticisms of the VFW.

Chairman SIMPSON. Now, the final panel, Ronald Simon, general counsel of the National Veterans Law Center, accompanied by Lewis Milford, director of the occupational health hazards project of the National Veterans Law Center; and John Terzano, director of the Washington office of the Vietnam Veterans of America, accompanied by Joan Bernstein, special counsel of that organization. If you will please proceed, Mr. Simon.

TESTIMONY OF A PANEL CONSISTING OF RONALD SIMON, GENERAL COUNSEL, NATIONAL VETERANS LAW CENTER, ACCOMPANIED BY LEWIS MILFORD, DIRECTOR, OCCUPATIONAL HEALTH HAZARD PROJECT; AND JOHN TERZANO, DIRECTOR, WASHINGTON OFFICE, VIETNAM VETERANS OF AMERICA, ACCOMPANIED BY JOAN Z. BERNSTEIN, SPECIAL COUNSEL

Mr. SIMON. Thank you very much, Mr. Chairman. I would like to enter our full remarks into the record so that I can just briefly summarize.

Let me first indicate that Mr. Furst, the head of the National Veterans Task Force is not here today and let me apologize on his behalf. Mr. Furst is a member of the VA's Advisory Committee. He expected to be here today. The VA regularly pays for his flight here for VA meetings as part of its effort to get veterans' participation. This time Mr. Furst didn't have any money. We asked the VA to advance him his ticket and pay for it in advance. They refused to do so. Mr. Furst asked me to mention the VA's refusal to the committee because there has been a lot of talk about veterans' participation and the veterans' groups that I represent are not satisfied with that participation. The situation with Mr. Furst is one more instance in which the VA did not have the opportunity to get veterans' participation and chose not to. It was within their regulations to authorize the ticket in advance and they simply refused to do it for Mr. Furst.

He wanted me to bring that to the committee's attention. Another point about participation of veterans, which has been the theme that we stressed all along, can be seen by looking at tomorrow's agenda for the VA Advisory Committee meeting. In tomorrow's roster there is supposedly going to be participation by veterans at the Veterans' Administration Advisory Committee. If we look at the agenda for tomorrow, there is only one-half hour in which the veterans can ask questions and there is 3½ hours of presentation by Government officials. Those presentations are mostly by the same officials who are here today. Their presentations could be in writing but they are not and all day will be wasted. And, again, veterans are not satisfied they are getting the participation that they allegedly are getting.

Now, as to where we are in the epidemiological study, I think you already heard the answer this morning. We are nowhere. Up until Dr. Houk and Dr. Spivey looked at the records, no epidemiologist looked at Defense Department records.

People have been very satisfied that the people in the Defense Department have worked very hard in working with these records. People have also said repeatedly, Dr. Houk, Dr. Spivey, others, that the people in the Defense Department needed someone to tell them

what to look for and how to do it. And although this study was ordered by the Congress in December 1979, no one did anything to go over there until Dr. Houk and Dr. Spivey went over there this summer.

And, again, repeating what the American Legion said, veterans' groups do not want the Veterans' Administration to do the study. One issue for this involves the bias of the VA, and a second issue is that the Veterans' Administration simply isn't competent to go forward with the study. And I know that's a harsh conclusion to reach, but I think if the committee looks at the record it would come to the same conclusion.

Since the VA was mandated to do this study, why wasn't somebody over there between December 1979 and this summer to make sure these records came to some order? The conclusion I've reached is quite painful. The agency that's supposed to do the study isn't going forward.

Now, in terms of the bias, I want to thing, bring a few facts to this committee. The Veterans' Administration policy to this day says that there is no evidence of any health hazards except chlor-acne. On the other hand, numerous scientists have talked today of evidence of soft tissue sarcomas, animal experiments; in addition, the Agent Orange Work Group's Scientific Panel last year found and reviewed at great length the European studies found that there was evidence of other health hazards.

When the veterans say that there is bias on the part of the Veterans' Administration, it's not simply an appearance of bias but there is actual bias.

And finally, Mr. Chairman, I just want to say that there has been a lot of talk about delay. I think we have heard this morning that this study is not going to go forward under the most optimistic of predictions for a number of years. Therefore, the demands of the veterans that things be taken away from the Veterans' Administration, and be put in the hands of epidemiologists who know what they are doing, is not really going to cause 1 minute of delay.

Dr. Houk said whether we start with a new contract, or continue with an old one, it's all going to take a number of years. So, at this point there wouldn't seem to be to my clients and veterans around the country any reason not to have some other group look at this matter and take it away from the people who have already had 2 years and gotten nowhere.

Thank you.

Chairman SIMPSON. Thank you very much.

[The prepared statement of Ronald Simon, general counsel, National Veterans Law Center, follows:]

PREPARED STATEMENT OF RONALD SIMON, GENERAL COUNSEL, NATIONAL
VETERANS LAW CENTER

Mr. Chairman and members of the Committee, my name is Ronald Simon. At the witness table with me is Lewis Milford. We are lawyers with the National Veterans Law Center (NVLC) in Washington, D.C. The Law Center is a public interest law firm affiliated with The American University school of law, specializing in the legal problems of veterans. The Law Center is General Counsel to the National Veterans Task Force on Agent Orange, a coalition of veterans organizations concerned with the Agent Orange issue, and counsel on behalf of thousands of Vietnam era and other veterans in numerous federal class action lawsuits and federal administrative hearings.

We are pleased to be before the Committee to discuss the government's actions regarding the herbicide Agent Orange.

We are testifying today on behalf of the National Veterans Task Force on Agent Orange (NVTFO). With us is Jon Furst, Chairman of the Task Force. Since 1978 NVTFO has sought an epidemiological study of Agent Orange. Now, in the fall of 1981, we have a unique opportunity to evaluate the government's study efforts that have begun and to make suggestions about their future direction. Our testimony addresses three points with regard to these efforts: (1) where are we now; (2) who is responsible for our current problems, and (3) what should be done.

The first question is "Where are we?" That is, "What is the current status of the government's study efforts?" Although many technical points about the protocol must be made (our detailed comments are contained in the attached letter to Dr. Shephard) the point is most succinctly made by a

reviewer who said about the protocol: ". . . we aren't much further along than we were several months ago." A single disturbing point permeates all comments made about Dr. Spivey's work--namely, that it is not a protocol. We are repeatedly told by all reviewers that UCLA proposes a traditional, classical, or standard design, but that not enough detail is provided to tell us how any specific scientific work will be done. Most of the protocol consists of background information for nonepidemiologists and very little of it addresses an actual study of Agent Orange that might someday be done. Unfortunately, the government has paid a substantial amount of money for little more than a series of amorphous suggestions about what a still undefined study should be like, not how a specific study or number of studies should be done. We understand that this descriptive approach has proved unsatisfactory and frustrating to almost every person who has reviewed the purported protocol.

Central to the fact that UCLA and the VA have done little to advance the issue, is the underlying problem of defining who was exposed to Agent Orange. In May of 1980 the Task Force challenged the VA's efforts to select a contractor. We pointed out that the VA had not made any indication to a prospective contractor of the difficulties in defining exposure or the data or resources the government had available to make such estimates. At that time NVTAO predicted that the VA solicitation was so inherently defective that a protocol produced in response to the RFP could be no more than a cut-and-paste compilation of generally accepted epidemiological principles that would not be tailored to specific scientific work on Agent Orange. We predicted that an epidemiological cook-book on how to do a health study would be the only result, not a protocol specifically designed for an Agent Orange study. The predictions we made in May of 1980 parallel to an uncanny degree the comments made by the technical reviewers of Dr. Spivey's work.

While it was true that the UCLA failures were predictable, many remedial actions could have been taken by the government to prevent them. First, if UCLA is to be defended, it can be argued that they were not given adequate data. But then one must ask who is responsible for the fact that probably the most crucial government data, that about exposure, was never reviewed by Dr. Spivey. Who is responsible for not planning to obtain and in fact not obtaining in a timely fashion the needed security clearances for UCLA personnel? Is it true that not one official in the federal government realized that the exposure data would be classified and unavailable to the researchers? Mr. Christian of DoD has pointed out that the VA did not even have an account with the DoD office to obtain the information. This raises the disturbing question of whether any VA official has ever reviewed the DoD material. Second, how is it possible that the purported protocol does not even discuss any method that should be used to measure reproductive effects? How is it that this "surprising omission," as noted by a reviewer, was never corrected during the time the VA was working with Dr. Spivey on the design? We understand that the VA personnel met several times with Spivey to discuss his work. Third, who is it that has been collecting data on Agent Orange in the form of a Registry for years, yet has admitted that the data is terribly flawed. Indeed, a reviewer said the Registry had "severe limitations." Fourth, Dr. Spivey expects to rely considerably on the VA's Beneficiary Identification and Records Locator Subsystem (BIRLS). Yet, this system is recognized to contain many irregularities that place its usefulness for health studies in serious doubt. Indeed, no one has ever studied the current system for completeness. Did anyone at the VA ever suggest to Spivey that this data may be seriously flawed and, if not, why not? Many other serious flaws are noted in our attached letter to the VA. Each implicates the failure of the VA to do its job.

Not only did the VA solicit a poor protocol, but it apparently did nothing over the last eighteen months to gather and organize the necessary data for the contractor to do its task. The Congress, and this Committee in particular, must ask how the VA exercised its responsibility under PL 96-151 during the last eighteen months. Indeed, can the VA show it did anything at all during this time to make the contractor's work possible? There is no question that many of the problems encountered are inescapable, but the issue for the Committee is whether the agency charged with carrying out the study anticipated these problems and, more important, what it did to alleviate or at least ameliorate them. The problems of doing a study were obvious before the statute was passed. In fact, the White House Work Group had repeatedly pointed them out. A reviewer poignantly remarked that the problem of exposure, for example, "has been clear to epidemiologists and to the Veterans Administration for several years." With this knowledge, the VA obviously should have been working to obtain and organize this data for the researchers. Congress needs to know what was done to further the work of the protocol.

A second problem underlying the UCLA work is its obsessional concern with bias. (We must add that in light of Dr. Spivey's inappropriate, if not outrageous, statements to the California legislature, it is ironic that he would turn and accuse untold millions of veterans of bias.) Other reviewers have been quite critical of UCLA's point of view about bias. As representatives of veterans we also find the desire for secrecy unacceptable. Looking at the UCLA work, it would be hardly rational for veterans to place their fate in the hands of scientists who find full disclosure so repugnant.

The Task Force would like to emphasize two other serious objections to the UCLA position, which are shared by other reviewers. The first is that despite the fact that the protocol reveals neither disease outcomes nor the exposure status of veterans, information on each of these abounds in the popular press and

in the veterans' community. Potential bias already exists and there are no reasons offered to suggest that revealing information about the protocol will make this situation worse.

We should also stress that UCLA never really made any serious or specific points about bias. The protocol does not point out the kinds of bias it is concerned about, or how withholding information about the protocol will deal with this problem. Government people have told us that bias relates to the possibility that veterans might poison themselves in order to influence the study. This position is not only an affront to veterans with legitimate concerns about their health but it ranks with Spivey's secrecy obsession as an irrational exercise of judgment. In short, UCLA must give details and reasons before its secrecy argument receives any consideration.

More pointedly, we wonder about the audacity and insensitivity of people who argue for secrecy without giving detailed reasons for its use. The potential bias of the people doing the study has been an overriding concern in the Agent Orange issue. Credibility is absolutely necessary. Yet the credibility of this group is hardly deserved where it is hired to produce a protocol, makes public statements that trivialize the health issue before any work is done, does not produce a protocol, insists without justification on its right to maintain absolute secrecy, and then demands an involved role in any future work. Credibility must be earned. Dr. Spivey and his colleagues have squandered it.

Veterans and all citizens want a valid and credible study of Agent Orange. For years we have told this Committee that a study conducted by the VA will not accomplish these goals. The perception by the general public is that agency bias will invalidate a study carried out by the VA.

The second concern about the VA is, of course, technical competence. The VA still has no epidemiologists working on

the issue. The VA did little if anything to make it possible for UCLA to produce the protocol. The group which is in charge of the design and any subsequent study must have the expertise to show the DoD how to best develop the data that is available and be able to use that data to produce a viable study. This is a task at which the VA has failed. The VA's Agent Orange registry is particularly revealing in this area. Reviewers suggest that its data is flawed because it was not designed by people who know how to collect data that will be useful for a health study. On the other hand, reviewers also agree that some preliminary studies should be done with this data because doing this work is so easy. We wonder, as does one of the reviewers, that if this task could be done so easily, why this Committee did not long ago have the results. The answer again is that the VA does not have the expertise to do this work.

Also, it is painfully clear that allowing the VA and Dr. Spivey to continue would be of no benefit to either veterans or the general public. Two arguments against the inevitable conclusion of having independent and competent scientists do this work have been heard. The first is that it would be an insult to the VA to supplant its role. The answer to this, however, is simple. The VA is not an epidemiological center. It has not taken necessary steps to develop data and it is fair to say that it was a mistake in the beginning to believe that the VA could do this work.

The second argument against removing the responsibility from the VA is one of delay, but at this point the argument has no force. Even if things proceed as discussed in the protocol, the study will not begin until 1983. Indeed, little real work has not advanced since Dr. Spivey was hired. Mr. Christian of DoD says that efforts have been continually hampered because of Dr. Spivey's limited knowledge of Defense Department activities. Placing an independent agency in charge of the study would cause no delay. Indeed, it would probably expedite study efforts. The negligible progress made in the last eighteen months is the best evidence to defeat the arguments of those who raise the spectre of more delay. As the efforts stand now, no activity is imminent and none of the actors involved have displayed the expertise to do the assigned tasks. Experience tells us that putting the study in competent hands could only insure the integrity of the study.

National Veterans Task Force On Agent Orange

National Office
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8 October 1981

Dr. Barclay M. Shepard
Special Assistant to the Chief Medical
Director for Environmental Medicine
VA Central Office; Room 938
810 Vermont Ave., N.W.
Washington, D.C. 20420

Dear Dr. Shepard:

This letter represents the comments of the National Veterans Task Force on Agent Orange (NVTFAO) on the submission of Dr. Gary Spivey, dated August 6, 1981. As a member of the VA's Agent Orange Advisory Committee, we feel compelled to comment, despite the fact that the product is not the protocol required by P.L. 96-151 or the VA contract with UCLA.

This letter is divided into three parts. The first is a review of the current status and posture of the epidemiology study ordered by P.L. 96-151. The second is a detailed review of the purported "protocol" designed by Dr. Spivey. The third section is a list of specific recommendations.

Current Status of Study Ordered by P.L. 96-151

P.L. 96-151 was passed in December of 1979. It ordered an epidemiological study of Agent Orange. During the legislative process NVTAO argued that the study should not be done by the VA. NVTAO wanted an independent study for a variety of reasons. The first reason is the bias of the VA, which includes both actual bias and the appearance of bias in the minds of veterans who do not trust the agency. The second reason why veterans want the study done by an independent entity is due to the lack of epidemiological expertise inside the VA. Physicians in the VA department charged with direction and oversight of the study are not epidemiologists. A third reason for seeking an independent entity outside the VA to do the study is the potential lack of cooperation with the VA by veterans that will result because of distrust of the agency. Finally, any study done by the VA will lack credibility because of the general climate of distrust that has been generated by the agency's past performance. These

arguments were accepted by the Senate but not by the House of Representatives and ultimately were not included in the bill reported out by the conference committee. However, the statute provides that the VA may contract out any or all parts of the study and NVTAO continues to believe that the only possible way of generating a study that is both valuable and credible is to have the study completely conducted and supervised by an independent entity. The demand for a study outside the VA has been very widely expressed and is supported by the American Legion.

In May of 1980 NVTAO challenged the process of selecting a contractor in the Federal Court and General Accounting Office. This challenge focused on the issues of bias, the VA's lack of epidemiological expertise, and our prediction that the RFP prepared by the VA would produce an unsatisfactory product. Because of our view that only active participation by veterans would guarantee the success of the study, we tried to end the litigation by asking the VA to seek information from contractors about how they would involve veterans in the planning of the study. Dr. Hobson of the VA flatly rejected the veterans' offer and simply said that it was up to the contractor whether he wanted to involve veterans in any way. (See attached letter.) Our legal challenge was rejected by the GAO because the deficiencies we pointed out were said not to be violations of the technical rules of government contracting.

In the summer of 1981, Dr. Spivey was selected to prepare the protocol for the study ordered by P.L. 96-151. On July 31, 1981, before handing in his protocol, let alone beginning the study itself, Dr. Spivey testified before a committee of the California State Assembly that "fear is the most likely consequence of Agent Orange."

The product submitted by Dr. Spivey has two very different types of limitations. The first is that it is simply not a protocol. Dr. Spivey admits this and offers two reasons. The first is that adequate information was not available to him. This includes both the underlying problem of defining exposure to Agent Orange and the specific failure of the VA not to have obtained security clearances for Dr. Spivey to get the information he needed.

A second reason Dr. Spivey offers for his not providing a protocol is that, if veterans were to know about the protocol, this would bias the study because veterans would lie about their health problems to fit the problems to be studied.

Even though Dr. Spivey did not present a protocol, he closes his submissions by saying this: "We should have a well-defined and strong role in the conduct of these studies. . . . We would have to work closely with a new contractor . . ."

There can be no doubt that a review of Dr. Spivey's work leads to the inevitable conclusion that all of the worst fears of NVTAO about bias and competence have already borne their bitter fruit. Dr. Spivey's submission is not a protocol but an obvious cut-and-paste collection of generalities from standard epidemiological texts which hardly justify the expenditure of \$13,951 of taxpayers' funds. However, the inadequacy of the product cannot be laid at the feet of Dr. Spivey alone. Part of the responsibility falls upon the VA who prepared the RFP and never assembled the necessary data or procured the needed security clearances.

The legal challenge of NVTAO to the RFP focused on the fact that the RFP would produce this useless textbook exercise. Unfortunately, we were correct and now have a useless cut-and-paste version that a competent epidemiologist could have produced in less time and for less money. Unfortunately, the protocol does not address the problem for which the contract was entered. Since part of Dr. Spivey's failure is due to the lack of data, then the blame must fall on the VA which did nothing at all between December 1979 and the summer of 1981 to develop more useful data. The failure to produce more useful data for Dr. Spivey reveals beyond question that the VA does not have the necessary expertise to have a key role in the study that it is responsible for.

We are now faced with a difficult situation. The veterans' lack of confidence in the VA is fed by the damages that have already been caused by its lack of competence. Now we also have a contractor who has not produced a protocol but has gone out of his way to show his own bias on the issue as well as his intention not to involve veterans at all in review of his work. He provides no scientific authority or specific concerns about bias, merely his repeated reiteration that the study would be biased. His frankness and failure to be specific about either details or reasons is quite useful because it makes abundantly obvious how he would approach the problem. Clearly, his statements reveal a bias on his part which is much more troubling than the potential biases he fantasizes that may occur among veterans.

Since the August 6 document clearly is not a protocol and because of Dr. Spivey's bias, the alternatives are simple and obvious. A new contractor must be found. Because of the baldly stated bias, there is no reason to proceed to rehabilitate Dr. Spivey's work since his continuing involvement will produce little of value to overcome the obvious bias with which he has infected developments to this point. Because the VA has refused to disqualify him from further work and because it is clear that Spivey sees his future role in the study as an active one, action must be taken immediately to proceed with a sound and credible study.

Review of Dr. Spivey's Purported "Protocol"

It is impossible to judge this protocol on its scientific merits. There is insufficient factual material in this document to enable a professional epidemiologist to make a critical review. Only the barest traces of substance are permitted by the authors to leak out from beneath a dense fog of concealment of endpoints and technical boilerplate language.

This purports to be a protocol, or plan of study, for assessing the association, if any, between exposure to Agent Orange in Vietnam and subsequent adverse health effects. The usual procedure for reviewing such a proposal involves as a central element answering the questions:

1. Is the exposure well defined for each individual?
2. Are the outcome disease measures well defined?
3. Are confounding factors and other sources of bias adequately controlled either in design or analysis?
4. Are the mechanisms for collecting and validating exposure and outcome data likely to succeed?

The authors of this report appear to be obsessed with eliminating one particular form of bias, that of self-selection and self-reporting of disease outcomes. They seem convinced that this problem has never been adequately dealt with in other studies. This lopsided treatment of a bias, for which no scientific evidence is presented, leaves other, probably more important potential biases barely mentioned. The worst aspect, however, is the authors' decision not to discuss specific endpoints at all. This deliberate concealment is emphasized repeatedly:

- p. 3: "...We believe that full public disclosure of study details at this time and their resultant publicity would prejudice, and thus preclude, any chance of a scientifically valid study ever being conducted."
- p. 37: "The highly inflammatory and emotionally charged climate in which this study is being planned and will be carried out requires additional planning of safeguards against bias which are beyond those normally required in a epidemiological study."
- p. 40: "In the highly emotional climate surrounding this study, we feel that provision of details on which veterans may be in different exposure level groups or on specific disease outcomes of special interest would lead to such serious bias that a valid study could not be conducted."
- p. 46: "At this time no specification of likely outcome measures is being made since the public release of this information would lead to serious potential bias which could eliminate the possibility to conduct a valid study."

Because of the lack of specificity, it is difficult to address the bias with which Dr. Spivey is concerned.

His obsession with bias and secrecy about end-points seems tied to the question of self-selection. Self-selection is a problem when people choose whether or not to be in the study, when they are given the opportunity to concoct subjective symptoms, and when they are the only source of exposure data. However, none of these conditions exist. Veterans will be selected for

participation from a random selection of records, exposure history, will be verified by data such as the Herbs Tapes and outcome will be determined by objective physical examination and medical records.

Even if these unmentionable outcomes satisfied criterion (1) above, there is still insufficient evidence that an epidemiologically sound study can be conducted. In place of an evaluation of sources of data and their relative quality, as would be expected for a historical study, there is a litany of "could nots" representing failed attempts to establish the requisite data bases:

- P. III (Executive Summary): "It is not possible to complete the protocol design at this time because of data limitations."
- P. 3: "A full protocol is not presented at this point. The reasons include the size and complexity of the problem presented to us and the fact that we have not as yet gained access to certain necessary records."
- P. 54: "The sample size for different study groups cannot be specified at this time."
- P. 55: "The exact organization of the study cannot be specified until completion of further planning."
- P. 58: "We believe (identification of groups with different exposures) can be accomplished but have not yet gained access to a sufficient number of army records to be certain."
- P. 63: "We have not yet gained access to a number of the necessary record systems to allow full exploration and documentation of their content and capabilities."
- P. 74: "We have not yet been able to fully investigate all of the necessary record systems because of lack of access."

These problems are not solely the authors' fault. Inexplicably, the authors and the VA never foresaw that security clearances would be needed to review Defense Department records. Therefore, more months of time have been wasted by the government's mistakes and oversights.

The actual protocol begins on page 35. The material preceding this is mostly introductory, with some reviews of the literature on Agent Orange and its chemical constituents as observed in experimental and human studies. There is also a brief description of some epidemiological methods in general, and some discussion of their applicability to this problem. Most of this material has a textbook flavor, and inasmuch as no real epidemiological data on Agent Orange has yet been reviewed or gathered by the authors, it is mainly theoretical.

- P. 35: This is the beginning of the actual protocol section. The protocol is in several parts:

- PP. 39-58 (Authors' B) is an outline for planning (not necessarily carrying out) a historical cohort study. Details on endpoints are deliberately omitted. A major feature of this study is a proposal for a hands-on physical examination which is admittedly of no value to anyone, including the authors or veterans.
- PP. 58-62 (Authors' C) is a proposal to test a method for constructing a cohort with a laborious synthesis of data-finding methods.
- PP. 63-84 is a proposal for a short-term (14-month) study of smaller scope, utilizing existing records only.
- PP. 36-38 comprise a catalog of difficulties encountered so far--that is, early in the planning stage. As outlined above, these related mainly to lack of clearance or access to records, failure of the V.A. to anticipate the need for such security clearance, and the laborious nature of the review of army VA records.

Page 37 says the Ranchhand study took three years to set up, and the Australian study is also taking a long time. What is the purpose of these remarks?

Pages 39-40 contain a summary of the cohort study design. Three criteria are listed for inclusion of subjects: army or marine, no immediate or delayed battle casualties, and limitation to draftees or single-term enlistees.

There are no plausible reasons given for these inclusions, particularly the second and third. Exclusion of battle casualties means loss to the study of those men for whom the VA is likely to have the most extensive medical records. These men furthermore are likely to be among the most heavily exposed. After all, the army sprayed those jungle areas where the enemy was and where it intended to send combat troops, some of whom would be expected to sustain casualties.

Restriction to one-termers means exclusion of men who could have been exposed for more than one year, and further shrinkage of the highest exposure group.

Page 41 contains the only statement of substance concerning disease outcomes, and it is negative:

Thus there is no firm disease outcome established in any human population which could be used for developing a case-control study of the effects of exposure to Agent Orange in Vietnam veterans.

This ignores the studies which have been published by Hardell on soft-tissue sarcomas in Swedish workers occupationally exposed to pentachlorophenols and related compounds, and other case reports by Monchar. This is so well established as an outcome worthy of study that Dr. Peter Greenwald of the New York State Department of Health is conducting exactly this case control study at the behest of the New York State Temporary Commission on Dioxin Exposure.

Page 41: "Because the outcome is difficult if not impossible to define, the case-control approach, dependent on the clear identification of outcomes and persons with those outcomes, is of limited value."

Why do the authors think a cohort study is any less dependent on "clear identification of outcomes and persons with those outcomes"? Are practitioners of cohort studies, which they explicitly view as the favored approach, sloppier than others about what they will accept as a disease endpoint? Does this comment apply to the Framingham study, which has been in progress for over thirty years, or to the M.R.F.I.T. study, which has been funded by N.H.L.B.I. at over \$100,000,000? Aren't the best cohort studies those in which endpoints are as rigorously verified by pathological examination just as in case-control studies?

Page 42-43. Exactly one and a half pages are devoted to the critical issue of defining exposure. Exposure is to be based solely on the herbs tapes. The eyewitness or personal recollections of veterans are to be given no weight at all. But it is well known that the tapes are incomplete, contain known inaccuracies, and have a number of biases in them. They contain records, now unverifiable, pertaining to missions which were aborted in mid-flight or which were never flown, planes which were shot at or shot down, spraying of unauthorized targets, dumping of the Agent Orange tanks at unrecorded locations, do not account for wind-drift or inaccurate flying, and, among others, do not record secret missions into Cambodia or Laos.

Page 45. The authors are to obtain "as much historic and demographic information as possible on those discharged alive." Just what items of information will be obtained? How much information can be expected on the average per Vietnam veteran? (This type of information ought to have been determined in the survey of records sources.)

Page 46. Those who die within one year of discharge are to be excluded because of "possible confounding of deaths due to 'effects of war.'" What is the nature of this confounding? What if these deaths are directly due to exposure to Agent Orange? That would be mistaking the confounder for an actual causative agent, and defeat the entire purpose of adjustment.

Page 55. "We believe that a scientifically valid study can be carried out within the VA system as long as the appropriate validation checks are built into the protocol." The authors have not read their own appendices E and F. The same veterans whom they fear will introduce gross bias if they know in advance the anticipated outcome variables are also the ones who do not trust the VA and who will refuse to participate.

Page 58 has a discussion of the likelihood of obtaining the needed sample size. It is, like the rest of the section, merely textbook generalities. "We anticipate that all suitable areas of South Vietnam will be explored for cohort construction purposes, and that a relatively large sample size will, in fact, be available." A blanket statement like this needs at least some data to back it up, but none is supplied. There is no place stated in the proposal even the broadest estimates of the numbers of men with any health condition or exposure. There is no quantification of any kind, let alone the specific estimates of exposure and outcome needed to estimate sample size.

Page 59. Exposure index. The authors propose a time-place exposure grid. The size of the grid used to "spot" soldiers' locations within Vietnam is a critical issue. The herbs tape coordinates are given to within 100 meters, but to what accuracy can troop or more importantly actual soldiers' locations be specified? Furthermore, if the grid size is taken too large, then practically all soldiers will fall within it, while if it is too fine, then practically none will be. Will some experimentation with various grid sizes be undertaken, and how will an optimum size be chosen?

Pages 60-61. The number of different types of records to be consulted to establish the location of individuals is staggering, and goes well beyond the most ambitious cohort studies done: at least 15 different types of records systems and 3 special groups will be scanned. Most occupational cohort studies use limited personnel records of a single company and even they can be unreliable. It is a great act of faith to believe that reliable personal exposure data can be developed from so many different types of records, given the likelihood of incomplete and probably contradictory information. The cost of reviewing and evaluating the records and then picking out the desired individuals will be astronomical.

Pages 63-82. "Other Studies." These three studies are meant to supplement the "main" prospective study which has been described up to this point. There are three objectives:

1. Are there unusual causes of death in Vietnam veterans?
2. Do Vietnam veterans have unusually high death rates from all causes?

3. Do Vietnam veterans have unusually high rates of non-fatal diseases?

It is incredible that, after all the discussion concerning bias among veterans, and all the theoretical textbook epidemiology, the authors have chosen to concentrate their efforts on cause-of-death studies, and have relegated to the very last the subject that most concerns the veterans, namely, illness, not death. The next most important subject to the veterans, reproductive effects, is not even addressed.

Page 66. The authors intend to abstract each of the 130,000 Vietnam era death records. This may be a good time to consider the relative amount of information this operation will yield compared to its great cost.

Page 67. The UCLA group intends to give the St. Louis record center a form-for recording identification and other data. Given their lack of success in enlisting cooperation so far, how do they know St. Louis will agree to do this, and, even if they agree, what quality controls will the authors be permitted to apply to the coding process?

Page 69 describes a proportional mortality study. References to the epidemiological literature obscure the fact that there is substantial controversy about the meaning and interpretation of the findings in this type of study even if this were a completely acceptable technique. Do the authors seriously expect enough deaths to enable them to control for all the confounding factors they mention by stratification?

Page 71 describes a case-control study. It is very unusual to use "death" as the case, rather than some specific disease, but that is obviously all the authors are willing to do in the absence of discussion of endpoints. It is not clear whether this substudy is meant to confirm the PMR study as an alternative method, or to generate new information.

Page 73. In view of concealment of target diseases and endpoints, the authors have no right to state that "both the case and control groups should contain enough veterans of this subgroup (combat veterans) for adequate analysis." Quantitative specification of sample size requires three elements: disease rate in population, exposure rate in controls, and anticipated relative risk. None of these three factors is given.

Page 76. The authors make it clear here that death is the primary focus of their analysis, and that morbidity is incidental. They have their priorities backwards.

Page 78. The authors propose to study the VA's "Agent Orange Data Tape" in detail. This tape, if it exists at all, was created with practically no planning or quality standards. The

data upon which this tape was based was collected by unprepared, untrained, and unfriendly personnel, often in a hostile environment, in many diverse locations, without coordination, and with professionals encouraged explicitly and implicitly to minimize veterans' complaints.

The bias inherent in this data base is as great/or greater than in any other source named in this protocol. Of all the data sources mentioned, this one is the best candidate to be left out.

RECOMMENDATIONS

1. Terminate all efforts of contractor and pursue recoupment of funds already paid to contractor;
2. Find independent entity with expertise in epidemiology and without bias to design protocol, control and conduct study;
3. Make public the contents of a protocol design;
4. Have review group of veterans work with independent entity to guarantee sufficient input by veterans;
5. Review existing data to:
 - a. see what kind of preliminary inquiries can be done expeditiously; and
 - b. instruct VA about how to make information available to it both useful and usable to scientists and general public including veterans;
6. Secure independent group to work with DOD to assist in expeditious review of records to ensure that they know how to produce useful data.
7. Answer all questions posed in specific comments above;
8. VA should reveal whether it regards submission of August 6 as meeting terms of contract and RFP. If so, why? If not, what steps are planned?

CONCLUSION

The VA refused to do an epidemiological study of Agent Orange until it was ordered to do so by the Congress. While the VA has tried to blame NVTFO for delaying its study, it did virtually nothing in the nearly two years since the study was mandated to develop useful data that could be used to develop a protocol or do a study.

The contractor selected by the VA has not produced the protocol he was paid to produce. Instead we have a cut-and-paste collection of generalities about epidemiologic methods. And while he should have been designing the protocol and consulting with veterans, he was testifying that the most likely result of Agent Orange is "fear." Rather than produce a protocol, for review he warns us to fear the bias and lies of veterans. Yet he cites no reasons; specific evidence or scientific authority to support his proposal to keep veterans ignorant about their exposure or the nature of the study.

The worst fears of veterans about P.L. 96-151 have already occurred. It is essential that we do not continue down this path and "throw good money after bad." Getting a competent and unbiased study is essential. Dr. Spivey and the VA have more than amply demonstrated that they are not up to the task.

The scientific reviewers of this protocol should not be content to rehabilitate this work. The lack of credibility, ethical indifference, and serious scientific flaws evidenced by the work demand a recommendation to relieve the VA and Dr. Spivey from any further involvement with the study.

Sincerely,

John Furst, Chairman
NVTFO

Lewis M. Milford, Esq.

Ronald Simon, Esq.

Counsel for NVTFO
National Veterans Law Center
4900 Massachusetts Ave., N.W.
Wash., D.C. 20016
202-686-2741

Attachment

Veterans
Administration

JUN 5 1980



Counsel for National Veterans
Task Force on Agent Orange
National Veterans Law Center
4900 Massachusetts Avenue, N.W.
Washington, D.C. 20016

Dear Sirs:

Thank you for your letter of May 22, 1980, with its offers of assistance in the design and conduct of an epidemiological study of herbicides. As you can imagine, we have received suggestions from other persons as well. We welcome such contributions even though we cannot act upon all of them.

We feel it inappropriate to amend our Request for Proposal regarding the study design at this time. Our request did not specify the details that a proposer might consider and his failure to mention a single detail, such as the way veterans might be consulted, would not disqualify a bidder.

The successful bidder during the study's design will make his own decisions as to whom to consult. The Veterans Administration will stand ready to assist him and certainly will review work critically when it is prepared. The draft design will also be available for comments by the public and simultaneously for critical review by the groups designated to do so. That time seems most appropriate for any concerned veterans' group to make specific suggestions and a mechanism to do so exists. The VA Advisory Committee which includes veterans' organizations' representatives among its members can receive comments during its review of the draft proposal.

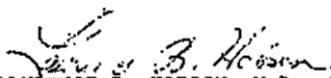
You had, I believe, a representative at the most recent VA's Conference on the Herbicide Orange Program in Bethesda. At that time, I requested the VA staff to suggest ways in which to entice veterans to cooperate, especially those who will be in control groups. We see this as a significant problem. It would seem appropriate for you or any veterans' group to

make suggestions concerning this or similar problems even before the draft design is available. The suggestions should be specific, concrete and submitted in writing. Such an arrangement will allow the VA to pass along the unaltered statements to the contractor as he designs the study.

I realize that this is not precisely what you proposed but I believe that it allows you full opportunity to make your concerns and your proposed solutions known. I am convinced that we will select a qualified and capable contractor. I am certain too that he must be allowed unhampered freedom to prepare his design without too many distractions. His work will be difficult enough under the best of circumstances.

I appreciate your apparent misgivings and trust that you understand that we operate under certain regulatory, scientific and practical restrictions. We are determined to do the best we can.

Sincerely,


LAWRENCE B. HOBSON, M.D., Ph.D.
Deputy Assistant Chief Medical Director
for Research and Development



COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

DEC 29 1980

B-198738

December 23, 1980

The Honorable Ray Roberts
Chairman, Committee on Veterans'
Affairs
House of Representatives

Dear Mr. Chairman:

We refer to your letter of November 21, 1980 regarding the Veterans Administration Agent Orange epidemiological study mandated by Public Law 96-151 and the delay being encountered by the agency in awarding a contract.

The concern expressed in your letter is whether the time-tables projected by John H. Gibbons, Director of the Office of Technology Assessment for the award of this contract in his letter to you dated November 10, 1980, might be advanced; you also ask whether the current lawsuit is the sole cause of the delay.

There are two controversies presently involved in the award of this contract. One is a suit filed by the National Veterans Task Force on Agent Orange in the United States District Court for the District of Columbia, Civil Action No. 80-1162. The court (Judge Harold H. Greene) has retained jurisdiction over the matter, although it has denied the plaintiff's request for a temporary restraining order. The other matter is a bid protest filed in this Office, case No. B-198738. The protest primarily relates to alleged violations of the procurement regulations by the VA in the solicitation for the study. On June 13, 1980, Judge Greene requested that this Office "consider and make a ruling on the issues raised in the protest" since we will not decide matters which are before a court of competent jurisdiction without such a request.

After Judge Greene's letter was received, development of the GAO record, i.e., obtaining reports from the VA, comments from the protester and the conduct of a bid protest conference, was completed on October 28, 1980. Final research, consideration of the factual and legal issues and the preparation of a draft decision commenced thereafter.

ATTACHMENT B

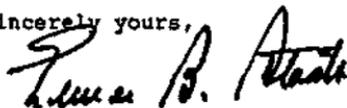
We believe it is reasonable to state that the cases presently in controversy probably have been a contributing factor to the delay in award. We of course are not aware of what, if any, difficulties the VA may have encountered in negotiating a contract under the original solicitation and therefore we do not know when a contract would have been awarded had no controversy arisen.

In addition, the dates contained in Mr. Gibbons' letter regarding the GAO are essentially accurate. However, while we are giving this case the highest priority, we think it will be unlikely that a GAO decision can be reached by mid-December as Mr. Gibbons suggests. We will, nonetheless, make every effort to complete this case in January.

Finally, we are unaware of any steps the VA can now take to advance Mr. Gibbons' projections for contract award. While the Federal Procurement Regulations permit an award under certain circumstances notwithstanding a protest filed with GAO, we are not in a position to say whether the VA could make such an award in view of the pending litigation.

We regret we cannot offer any positive suggestions at this time. We again emphasize, however, that we will attempt to reach a decision on the issues before us as soon as possible.

Sincerely yours,



Comptroller General
of the United States

Chairman SIMPSON. John Terzano, please.

Mr. TERZANO. Thank you, Mr. Chairman. Before I introduce Jodie Bernstein who is accompanying me today, I want to commend you on these hearings. There are serious questions that have to be answered and they have to be answered now. You have raised those questions. Questions whether we should expand the study and even more so on the credibility involved with the UCLA protocol. If we do expand this study, should UCLA get the contract?

For Vietnam veterans across the country, the bottom line is they need answers. And since we are putting so much emphasis and are hanging our hats so much on the VA's epidemiological study, that study has to proceed in the right manner, along the right track. And I think these hearings, as has been shown today, can put everything back in its place and get us going.

At this time I would like to introduce Jodie Bernstein, who is our special counsel for agent orange and phenoxy herbicides. She was a former General Counsel to the Department of Health and Human Services and a former Chair for the Interagency Work Group, which is now known as the Agent Orange Work Group.

Jodie.

Chairman SIMPSON. You used up all her time. Go ahead now. You have been waiting all day.

Ms. BERNSTEIN. Thank you, Mr. Chairman. I am not sure if it is an advantage or a disadvantage to coming last after a very full day but I very much appreciate your having us here. And I, too, would like to have our full statement accepted into the record with your approval.

Chairman SIMPSON. Without objection.

Ms. BERNSTEIN. And only briefly summarize our points.

We in the Vietnam Veterans of America that have watched this so closely and for such a long time are certainly not scientists. We have, nonetheless, tried to review Dr. Spivey and Dr. Detels work and, in fact, we have participated in the OTA review.

We are left and this is the bottomline, I guess, with three concerns that have been talked about today. I will only mention them because I think that they must be considered and answered and resolved before we can all be comfortable with and go forward on the epidemiological study. They are very simply credibility, credibility, and credibility and maybe adding one more, which is exposure.

The first credibility issue, of course, as everybody has mentioned today, is that we do not have a protocol before us. The document was totally inadequate to base decisions upon.

Second, for me the most startling portion of the submission by the authors was what one reviewer of the protocol called the fact that it was cloaked in an aura of secrecy. Now, that secrecy is both unnecessary and is contrary to standard public health investigative procedures and simply left me mystified.

Obviously, it reflects not only upon the submission of the authors but on the authors themselves that they would think such secrecy was necessary.

And last is the issue of whether or not Dr. Spivey, inadvertently I am sure, and not by design, permanently damaged his own credibility by making statements of conclusions to questions that were indeed to be answered by the study itself.

So, collectively or individually, those are our concerns and we are somewhat skeptical at this point about whether the problem can be cured with this design and with these investigators.

On the issue of exposure, we have learned a great deal today wouldn't you say, John, and we were very nicely educated by Dr. Houk and others. It seemed to us that an important consensus emerged today and, if I may just make a note of the fact that I think the most important contribution that the work group has made throughout has been the ability to achieve consensus in these difficult areas.

The consensus that seemed to be emerging today and what we would urge that the committee and the Veterans' Administration seriously consider, was as stated by Dr. Houk and by Dr. Gough, as well as the GAO, that what needs to be done is both studies, both that study which would examine the VA experience—or the Vietnam veterans' experience generally and that which would be connected to exposure of dioxin.

We believe from what we heard today that it can be done and it should be done.

The last point we would like to make is that we would urge the committee, as well as the Veterans' Administration, to explore with the Center for Disease Control, which is, as you heard today, an acknowledge expert and I believe a credible organization, the possibility that it could complete the protocol. With its expertise in the records themselves it would seem to be a very expedient and useful thing to do. And then to actually conduct both the broadened study and the exposure study itself.

I don't believe the law precludes the Veterans' Administration from contracting if it wished to with a unit of Government and it seems to us that based on all we have heard today that that would be a very expeditious way to proceed and would maintain, or perhaps reestablish the credibility that we had earlier and the consensus we had achieved with both the private and governmental groups.

Thank you.

Chairman SIMPSON. Thank you very much.

[The prepared statement of Joan Z. Bernstein, special counsel, Vietnam Veterans of America, follows:]

PREPARED STATEMENT OF JOAN Z. BERNSTEIN, SPECIAL COUNSEL, VIETNAM
VETERANS OF AMERICA

Mr. Chairman and Member of the Committee:

I am Joan Z. Bernstein, Special Counsel to Vietnam Veterans of America. I served as General Counsel of the U.S. Department of Health and Human Services, and Chair of the Interagency Work Group to Study the Possible Long-term Health Effects of Phenoxy Herbicides and Contaminants, during the Carter administration. I appreciate this opportunity to appear before the Committee on behalf of VVA to express our views on the protocol prepared by Dr. Gary Spivey and Dr. Detels, UCLA School of Public Health, for an epidemiological study of the possible long-term adverse health effects on Vietnam veterans exposed to these chemicals. As you know, such a study was mandated by Congress in P.L. 95-151, 38 U.S.C. § 307.

Vietnam Veterans of America was formed in early 1978 and is the only national organization exclusively representing Vietnam veterans. Originally named the Council of Vietnam Veterans, VVA was organized as an activist committee to secure for Vietnam veterans benefits comparable to those offered veterans of other wars.

VVA has broadened this original goal to include securing recognition and treatment of disability peculiar to the Vietnam War and encouraging the American public to recognize the differences between the unpopular war itself and the men who were compelled to wage it.

All of these issues have been surrounded in controversy, none more so than the question of what the government's response should be to those veterans who were exposed to Agent Orange. We have all recognized that a fully reasoned response required the best and most credible analysis the scientific world could produce. Thus, the Congress directed the VA to design and conduct a comprehensive epidemiology study to try to answer that crucial question -- "Was exposure to Agent Orange during Vietnam service harmful to our soldiers?" Everyone touched by this inquiry -- the Congress, the Executive branch, the Vietnam veterans -- agree that above all else the conduct of this study must be credible in every way. Its results must be acceptable and reliable to the scientific community, to the public, and ultimately to the Congress so that it can assess its policy choices against a solidly reliable base of information. It's difficult to recall any other controversy in which so much hinged on reaching consensus about the methodology and conduct of a scientific study. But without that consensus, the time, money and energy devoted to obtaining objectives results will have been wasted.

It is with that essential need for credibility that VVA has tried to review the work submitted so far by the VA's contractor. Drs. Spivey and Detels of UCLA's School of Public. And as it now stands, we have serious reservations about whether the completed study will be able to satisfy the exacting standards intended by Congress

and by the skepticism of affected veterans and their families.

The issue of credibility is two-fold:

(1) The first, as other have said, involves the adequacy of the document . . . whether it is one which will be approved by other scientists in and out of government and not flawed in some methodological way, and

(2) second is the "Caesar's wife standard" . . . in this instance, whether the principle investigator, Dr. Spivey has compromised his credibility by public statements suggesting, at best pre-judgments of questions to be addressed by the study and, at worst, evidence of either personal or professional bias, so that he should not conduct the study.

As to the first, VVA agrees with the conclusion reached by both the OTA and VA Advisory Committees, namely that the "draft protocol" is not by most standards a protocol at all but rather an interim document which describes work in progress. It was described by one reviewer as ". . . a skeleton of a reasonable approach." Col. Richard A. Hoddes, Chairman of the VA's Advisory Committee, in reporting to Barclay Sheppard, said the project

"will need considerable expansion and detailing of the assumptions, methods and proposed analysis to meet the bench marks provided in the RFP."

VVA, while not a scientific organization, did participate in the OTA review, and concurs with the following recommendations for revision:

(1) Highest priority should be placed on:

- (a) construction of an exposure index,
- (b) detailing the health outcomes to be

measured in the cohort study.

(2) Planning of the proportionate mortality analysis continue [sic] only if it seems realistic that it can be completed within one year or so.

(3) Information from inspection of the Agent Orange Registry to learn about veterans' complaints be considered in detailing health outcomes for the cohort study.

(4) Decision criteria should be built into each step of the cohort study plan to guide considerations of whether to continue, alter, or abort the study.

(5) The study of death rates, the case-control study, and the morbidity study using veterans' claims should either be dropped, modified and/or strongly justified.

We especially emphasize the need for decision criteria at each step so to decide whether to continue, alter or abort the study.

VVA is even more concerned with the investigator's explicit recommendations for "secrecy." Most reviewers were startled by those expressions because they are for the most part contrary to standard procedures used in epidemiology studies. The Center for Disease Control, for example, which regularly conducts such studies operates in a fish bowl by comparison.

Both the OTA and VA Advisory Group reviewers who were equally concerned, agreed that there are alternative ways of dealing with Dr. Spivey's legitimate desire to protect the study's integrity and prevent bias. Nonetheless, OTA expressed its concern that lack of openness would prevent it from fulfilling its Congressional mandate to approve the study design.

In addition OTA identified a number of additional reasons for openness in the design and conduct of the study.

(1) Because of the political and social tensions associated with Agent Orange, studies bearing on the question of health effects should be carried out in an open manner. As a result the advisory panel favors a more open design to obtain objective measures and standard examinations for health outcomes.

(2) If "outcomes" are not public, but become so only after the study is well underway or completed, the study may be criticized for failing to look for certain health effects. Rationales for including or excluding particular outcomes should be stated initially, and arguments pro and con entertained before the study starts.

(3) As a practical matter, as soon as the questionnaire and examination are administered to the first participants, interested parties will be able to determine, at least generally, what outcomes are being looked for. Thus, the secrecy would not be effective even for its stated purpose. As one of the reviews put it, it is essential

to find a way to deal with the question of participation bias without "cloaking the protocol in an aura of secrecy." VVA fully concurs with the recommendation that the details of the study not be kept secret.

And finally, we would also note for the record that new exposure data some of which was recently identified must be assimilated into the study's design. "Exposure data" has been a critical and controversial element in the Agent Orange debate . . . and we are pleased to know that more of it exists for use by the investigators. It can add immensely to the ultimate reliability of the study.

As noted earlier, we believe that fully credible study results depend not only on the design of the protocol but on the credibility of the investigator. That does not mean we're questioning his scientific competence. Rather, it is based on the absolute requirement that any investigation must be performed by totally impartial and objective scientists. Without that assurance, the study's ultimate conclusions will be questionable. Indeed, the reason that the VA contracted with an outside entity to design the study, rather than conducting it in-house was to avoid any appearance of partiality or inherent institutional bias.

We are concerned and have reserved on the question of whether Dr. Spivey can repair the damage flowing from his statements and perform a fully credible study. To have expressed conclusions on both the health effects

of Agent Orange and the extent of the exposure prior to beginning the study was shocking. Only he can provide us with an adequate explanation. Whether these concerns are serious enough to impair the total credibility of the study must be answered now. We are grateful that this committee is asking these questions now. Ultimately, the Veterans Administration must decide whether it can fulfill the mandate of Congress with this design and these authors.

At the very least we believe that the concern about the credibility of the investigator -- indeed of any investigator -- can only be responded to effectively by the implementation of an oversight peer review process. Such oversight is standard scientific procedure generally and is especially necessary where any question has been raised.

An issue of bias was similarly resolved by peer review oversight in connection with the Ranch Hand Study. You may recall that the National Academy of Sciences and other peer review groups had been concerned about the credibility of the findings of that study if conducted by the Air Force. The Interagency Work Group, which I chaired, recommended instead that the conduct of the study be overseen for at least the first five years by an independent peer review committee reporting to the White House Office of Science and Technology Policy or some other high level entity. The Committee was to be comprised of representatives of the Work Group, scientists from the private sector

and academia and person with scientific backgrounds nominated by veterans organizations. This recommendation was accepted and implemented. VVA strongly supports establishing such an independent peer review committee to oversee the Agent Orange study to ensure that its conduct is free from any question of bias on the part of the investigator. It can also, of course, continuously advise on the scientific questions.

Conclusion

VVA repeats that a final assessment of the protocol for the Congressionally-mandated Agent Orange study cannot be made without more detail from Dr. Spivey. VVA further believes that certain steps will be essential to ensure that a fully credible study is performed. First, the design of the study must be substantially revised along the lines suggested by the report of OTA's review panel. Most important, we urge that the VA and the investigators adopt a policy of "openness" in the conduct of the study and in its continuing review. Second, a balanced and representative oversight peer review process is needed to assure impartiality. VVA urges that these actions be taken.

I hope that these measures will cure the immediate problems. We all, I'm sure, would despair if we found some months or years from now that these time consuming and expensive efforts do not have general acceptance -- that no concensus can be constructed upon this product and that we're back at square one. The frustration of our members has only been alleviated by their belief that we were all going in the right direction . . . I hope we are not once again in the position of delivering yet another negative message to those who have waited for so long for a deserved and positive response from their government.

Thank you.

Chairman SIMPSON. Do you feel that someone else should design a new protocol? If so, do you have any suggestions regarding who should be engaged to do it? Would the same problems result if the study were contracted to someone else?

Ms. BERNSTEIN. I guess my view would be that it is not a question of whether somebody else should design a new protocol, because I think everybody is in agreement that we do not have one now. Whoever takes the next step, and I would urge that it be either the work group or an expanded work group with representation from outside groups as well should make recommendations as to how to refine the work that has been done so far and do emerge finally with a protocol.

Chairman SIMPSON. What are your comments and suggestions for us with regard to the development of this exposure index? Do you think that with improved Department of Defense record retrieval, it would be possible to develop a statistically acceptable index? Do you have any suggestions to present to DOD, to assist in its efforts to retrieve an index of those records?

Mr. SIMON. Very little work has been actually done so far by epidemiologists. It's my sense from hearing Dr. Houk, GAO, and others, that it is very likely that could be done. We would, I think, advocate exactly what Ms. Bernstein said. That both be done quickly and that it be done with some people with epidemiological expertise. Mr. Christian worked very hard. He needs someone to work with. And in addition, I think the important point is that both studies should be done. I don't think anyone who has been asked the question thinks that a study of a Vietnam experience immediately proceed while they were working on the exposure index.

And I think the important thing to point out is not only does the statute now allow it, but there is nothing in the past that ever prohibited it. I wonder why they didn't do the Vietnam experience study 2 years ago. There is nothing stopping them from doing it. They are the largest medical research institution in the world, I am told, and while we are hung up on the exposure problem, the larger Vietnam experience study could be done. And I am wondering what's stopping them from starting it yesterday.

Chairman SIMPSON. You spoke about the 2-year delay, with some frustration. Could you share with us your views on the reasons for the 2-year delay in beginning the study? What part did the lawsuit, which was filed by your group, play in promoting and continuing that delay?

Mr. SIMON. Yes, sir, I am glad you asked that question. The statute was passed in December 1979. In 1978, I have letters in my file requesting the VA to do an epidemiology study. They refused to do the study. They refused to do the study until they were ordered to by Congress.

When I reviewed the protocol and had a number of scientists look at it, predicted, uncannily, exactly what it would be. Because the RFP was so incomplete, we knew that we would get exactly what we got today, which is a half-baked cookbook product.

Knowing that we went into court, the U.S. District Court, and asked for a temporary restraining order. That temporary restraining order was denied. So, there wasn't 1 minute in time in which

the VA could not have proceeded. The prior General Counsel of the VA came into this committee and said they could have proceeded.

As a matter of fact, any lawyer familiar with Government contracts will tell you that once a temporary restraining order is denied the Government goes ahead and lets the contract; that's the normal operating procedure.

I have a letter attached to my testimony. In it the General Accounting Office makes it clear that their regulations do not prohibit the VA from going forward. The VA itself decided not to go forward. They have continually used the fact that a lawsuit was filed as an excuse. I think using that as an excuse does not wash, it's not persuasive. Every other Government agency lets contracts in the same situation. And in addition, if they were so anxious to do the study, they were legally allowed to, which they absolutely were, they should have gone forward to do it. They continually make references to the GAO, the Justice Department, we don't have a letter anywhere in the files that says the Justice Department told them not to go forward.

And I am very aware in cases like this since I have spent my career litigating against the Government, that if the Justice Department tells them not to go forward, there are letters to that effect. And certainly if I were the General Counsel of the VA and I wanted to do the study and I was told by my lawyers not to, I would have a letter in the file to show people that I didn't want the delay and that I was not allowed to proceed.

So, my response is that at every opportunity the VA has said that that lawsuit is what held them up for 2 years. This is not true. The answer to the question of delay is what did the VA do since December of 1979 when the law was passed to look at those records, to give Dr. Spivey and UCLA something that they could do a study with? What did they do to begin their own Vietnam experience study? And what did they do in response to my 1978 letter that they should do this study in the first place? The answer to all those questions is nothing. So, I think yes, I have been a real whipping boy for their excuses but I haven't been persuaded that I held them up for a second. The record clearly reflects my position, not theirs.

Ms. BERNSTEIN. The fact of the matter is that Ron lost his lawsuit.

Mr. SIMON. In 5 minutes.

Ms. BERNSTEIN. Yes. [Laughter.]

Mr. SIMON. So for at least 5 minutes---

Chairman SIMPSON. But you remained very persistent.

Mr. SIMON. Always.

Chairman SIMPSON. I recall that you did go on to appeal to the General Accounting Office. But, anyway, that is "old laundry." The issue is that there has been delay and there have been many reasons for it. But, I have one final question.

Let's get back to the positive. Do either of you have any suggestions to help improve the communication between UCLA, the Veterans' Administration, and the Agent Orange Working Group, regarding information about agent orange?

Mr. TERZANO. I think, Mr. Chairman, that that communication also has to come from UCLA. And my question is why isn't Dr. Spivey here today.

We try to communicate. They say that we always take it to the press first. But when we have a congressional hearing raising questions about ones own product, Dr. Spivey doesn't show.

Ms. BERNSTEIN. One thing that might be very useful, Mr. Chairman, that I found useful was that we had an open meeting, it was not a hearing, it was an open meeting of the work group and we asked people to come and describe their progress on various things. I don't know whether the work group has currently considered that, but I have often found it very useful to open up the process. If you schedule such open meetings, bring all the parties together, and start to ask some hard questions, then maybe you will get some good answers.

Chairman SIMPSON. I share your opinion about the worth of that type of procedure.

Mr. SIMON. My only suggestion, Senator, would be that I think the ball really lies in your court. I want to make it clear that I met Dr. Spivey in the first week that he signed the contract and I asked him not to make any public statements. I told him this was a very tricky political issue and I advised him to be very, very cautious.

I have never filed lawsuits or made statements with regard to VA actions without telling them first that I thought there were problems. I am long-winded because no one listens to me. And I think perhaps they would listen to you and I would suggest to you if you have any ideas that you tell them because they certainly don't listen to the veterans that I represent.

Ms. BERNSTEIN. But to do so briefly rather.

Chairman SIMPSON. Anyway, we are listening. I hear what you are saying and we will just pursue it on an oversight level in this committee, I assure you of that. And that is the shared view of this chairman and the ranking member, Senator Cranston. I promise that we are going to continue a serious oversight function of the agent orange issue.

I thank you very much for testifying.

[The response of the National Veterans Law Center to written questions submitted by Hon. Alan Cranston, ranking minority member of the Senate Committee on Veterans' Affairs, follows:]

RESPONSE OF THE NATIONAL VETERANS LAW CENTER TO WRITTEN QUESTIONS SUBMITTED BY
 HON. ALAN CRANSTON, RANKING MINORITY MEMBER OF THE SENATE COMMITTEE ON
 VETERANS' AFFAIRS

Question 1. During her testimony, Ms. Joan Bernstein, representing Vietnam Veterans of America, recommended that two studies be done -- one that would examine the general health status of Vietnam veterans without any findings of exposure to specific substances and one focusing on the health effects in Vietnam veterans of exposure to dioxin as found in Agent Orange.

A. What are your views on this proposal?

Answer 1A. We believe that a great number of studies have to be done. The two you mention are important. Studies of other toxic substances, psychological problems, and reproductive problems should be carried out. The question of "expanding" the Agent Orange study creates a misconception that there are only two options. Each epidemiological study is unlikely to produce more than limited information and therefore we seek a variety of studies.

B. If both studies were to be undertaken, what role, if any, do you see the VA playing in the design and conduct of the studies?

Answer 1B. The VA has actual and apparent bias as well as no competence in epidemiology. Studies should not be conducted by VA. Allowing VA to control studies leads to the breakdowns and lack of direction that we are now experiencing. (The process of seeking input can never solve this problem.)

Question 2. How would you recommend that the VA improve its efforts to alert Vietnam veterans to the agency's activities on the Agent Orange issue, including the provision of physical exams and, in some cases as authorized by Public Law 97-72, health care for disabilities of Vietnam veterans?

Answer 2. The VA should develop a medical treatment protocol that is designed to look for the kinds of problems that are most likely to be associated with Agent Orange and that veterans are concerned about. This protocol should be designed by people who are experts in toxicology and environmental medicine and VA personnel should be trained to administer it. (Similar work needs to be done in the psychiatric area with PTSD so that VA personnel are trained to recognize and treat it.)

Question 3. Are you satisfied that the VA is soliciting and giving appropriate consideration to the views of groups and organizations representing Vietnam veterans on the Agent Orange issue?

Answer 3. No. The process of seeking comments is ineffective. VA advisory committee meetings are almost exclusively taken up by reports from people in government agencies. (This work should be written up and sent out.) In addition, the VA does not respond to the suggestions it receives. It merely leaves things in the hands of others such as UCLA. It does not either act upon the input or take the initiative to get things moving forward.

VA refused to issue a pre-paid ticket to Jon Furst of NVTAO the only non-Washington, Viet Nam veterans group on the VA advisory committee. VA acknowledges that they could have done this but they refused to do so.

Chairman SIMPSON. We will be sending further questions in writing to all the witnesses. We would appreciate responses within 10 days so that the hearing record can be closed. That would be very helpful.

And I do very much appreciate the participation of all of you. It has been very helpful. I apologize again for the delays and the relocation. Thank you very much for being present.

That concludes the hearing.

[Whereupon at 3 o'clock p.m., the hearing was concluded.]

[The following written statements and letters were received by the committee for the hearing record:]

VIETNAM VETERANS OF NORTH DAKOTA

324 TETON AVENUE

BISMARCK, N. D. 58501

November 6, 1981

Senate Veterans Affairs Committee
Honorable Alan Simpson, Chairman
United States Senate
Washington, D. C. 20013

Dear Mr. Chairman and Members of the Committee:

This letter is submitted by myself, Robert E. Hanson, as Chairman of the Vietnam Veterans of North Dakota organization.

I want to publicly thank United States Senator Quentin Burdick of North Dakota for submitting this document on our behalf.

This letter is directed to you in regard to your oversight committee's working in the area of the defoliant Agent Orange which was not only sprayed, but also indiscriminately dumped on our troops during the Vietnam War.

The State of North Dakota has, according to the Veterans Administration, 11,000 Vietnam veterans having had service in Vietnam. These 11,000 Vietnam veterans are all potential victims of Agent Orange, as well as the many other chemicals used in that war. The State has a total of 18,000 Vietnam era veterans according to the Veterans Administration.

North Dakota is a state that comprises 70,665 square miles with a total population of approximately 650,000 people. In the minds of some, this does not constitute a large enough population to exert a lot of concern over. However, when one considers that the ratio of Vietnam veterans to Vietnam era veterans of over 61 percent is one of the highest in the nation, one cannot discount the contribution young service people from our state made on behalf of this nation during that very disruptive portion of our country's history.

One must also face the reality that a rural state which has wide open spaces, great distances between our major trade areas, and a relatively small population is confronted with different problems than the more urban states and, therefore, new or different approaches to solve these problems must be adopted. But at the same time we are caught in the same ravaging inflation and interest rate spiral as the rest of the nation.

An excellent Veterans Administration Hospital and Regional Center is located on the eastern border of the State at Fargo. This is

the only VA center in the State. However, our Vietnam veteran population is pretty evenly disbursed with one-half living in eastern North Dakota and the remaining one-half residing in western North Dakota. Obviously, most of our veterans reside in or near the major population centers of our state. Listed below is a chart showing the mileage differences from our major population centers and Indian reservations to the VA center in Fargo.

<u>CITY</u>	<u>MILEAGE</u>
1. Williston	391
2. Crosby	385
3. Bowman	363
4. Stanley	319
5. Dickinson	289
6. Minot	264
7. Ft. Yates	259
8. Bismarck	200
9. Bottineau	268
10. Devils Lake	265
11. Rolla	242
12. Rugby	222
13. Cavalier	151
14. Grafton	116
15. Jamestown	100
16. Grand Forks	80
17. Valley City	60
18. Wahpeton	60

The first eight cities listed above are in western North Dakota. This area is also going through a tremendous change because of the increased energy activity relating to coal, oil, and natural gas exploration and production. This area of our State will undoubtedly have an increase in its Vietnam veteran population because of the increased work activity.

The distances from Indian reservations is substantial as indicated by the distances from Ft. Yates, Devils Lake, Rolla, and Stanley.

My point in presenting this information to this Committee is that in a rural state, like North Dakota, a veteran wanting to take an Agent Orange exam must, in most cases, schedule upwards of three days away from work to do so. This is necessary because of the distances involved. A veteran in North Dakota cannot hop on a transit authority bus, or subway, or other form of mass transit to go across the city to a VA hospital. In North Dakota transportation alone becomes a major burden on a Vietnam veteran to take an Agent Orange physical. This is further complicated because of lack of adequate mass transportation in our State.

The recent cutbacks in Amtrack funding as well as airlines reducing flights or pulling the entire airline out of some of our major cities while many other cities have no airline service at all does absolutely nothing to help veterans find an economical way to get to the VA hospital in our State. Even with this obstacle the Fargo VA center has examined 1,490 individuals from the 15,000 eligible in its service area, which includes a portion of Minnesota. A tremendous feat, and it should be so recognized.

There has also been what I call a lack of information to the Vietnam veteran explaining the Agent Orange problem. There is also not enough information reaching Vietnam veterans on what they should do if they feel they have been exposed to Agent Orange.

I would like to make the following recommendations to this Committee for its consideration on helping solve the Agent Orange problem.

First, an extensive, on-going media blitz using radio, television, and the print media alerting the Vietnam veteran of what Agent Orange is, where it was sprayed and/or dumped in Southeast Asia, some of the alleged symptoms associated with Agent Orange, how they should go about filing for a claim and/or physical, where they must go to take the physical, and how long before they can expect to hear any results.

Secondly, an intensive effort be made by all agencies possible, state and federal, to locate veterans who served in Vietnam so the veteran can take the physical.

Thirdly, all restrictions be removed so that the Vietnam veteran is reimbursed for at least his mileage, if not meals and lodging, to take the exam. We must keep foremost on our minds that it was our own government which did this to our veterans. The very least it can do is defray the related costs of the veteran taking the physical.

Fourthly, no veteran should be subjected to the loss of their job for the time taken to complete an Agent Orange physical. Some type of federal mandate, directive, order, or law should be immediately issued to protect the veteran in this area. I have had several veterans contact me stating that their employer would not allow them to take the time off to take the exam. These veterans were mainly from western North Dakota where jobs are scarce, salaries and cost of living relatively high, and people waiting in line to work. No veteran should ever lose, or be threatened with loss of his job because he wants to take an Agent Orange physical exam.

Fifthly, the VA should consider contracting out to reputable hospitals and medical facilities for the conducting of these examinations in each state. This would provide veterans with more convenient locations at which to take the exam, thus cutting the costs to the veteran. These contracts should be awarded first of all on the basis of ability, professionalism, and performance. Secondly, for states like North Dakota with a large land area and only one VA facility, on a geographic basis.

The Vietnam veterans have had to suffer the burden of an unpopular war for many years. They have had to watch their nation put on ticker-tape parades, lavish parties, White House receptions, and see Congress give substantial amounts of money to the Iranian hostages upon their return to the United States. The Vietnam veteran begrudges the former hostages none of this. But there is a deep feeling of bitterness among the Vietnam veterans that the country they fought for, the country they were ready to die for, and the country so many of their comrades did die for has treated the Vietnam veteran as a second class person. We are tired of this kind of treatment. Nearly 10 years after the end of this war our country has begrudgingly acknowledged the use of such toxic chemicals as Agent Orange in, around, and on our own troops. Yet at nearly every turn of the road the Vietnam veteran has had to fight and claw for rights, benefits, and assistance which other groups appear to be handed on a silver platter.

The Vietnam veteran wants no more than to be recognized for a job well done under the most trying of circumstances. We want only to be treated for the physical and mental injuries resulting from serving our country in time of war. We want the peace of mind accompanying the knowing of what are the real consequences of having been exposed to Agent Orange and the other chemicals used in Vietnam.

We are tired of denials, cover-ups, bureaucratic bunglings, study after study, and self-serving politicians who now find it advantageous to make public statements on behalf of the Vietnam veteran. We now want immediate, positive, meaningful action by the same government that we fought to preserve.

The public is being constantly bombarded with statements that everyone is going to have to sacrifice if this country is to survive economically and politically. To this I say the veteran of any war has sacrificed more than their fair share for all eternity. They have already sacrificed homes, families, jobs, mental and physical portions of their minds and bodies, and in many more cases than we like to discuss, their own lives. They made these sacrifices so that we could live in a free nation. How much more of a sacrifice do these politicians want from people who were ready to give, and in some cases did give, their

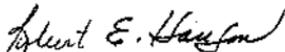
lives in behalf of the defense of America and the principles America stands for?

Those who advocate the reduction of veterans' benefits, as meager as they already exist, are, in reality, weakening our nation's defense. What nation can expect its youth and other citizens to rally to arms when they see the shabby and sometimes disgraceful way it treats its veterans of previous conflicts. How we treat those who have fought for us will be a major factor in the willingness of people to serve in the future. I feel this nation has failed miserably in this area as it relates to the Vietnam veteran.

The majority of North Dakota's Congressional delegation has been working with our organization on an almost daily basis when issues relating to the Vietnam veteran come before Congress. For this we want to publicly thank United States Senator Quentin N. Burdick and United States Congressman Byron L. Dorgan for their unwaivering support of the Vietnam veteran not only with Agent Orange legislation, but also in the other areas, such as Vet Centers and the GI Bill.

Again, thank you, Mr. Chairman and members of the Committee for allowing this testimony to be presented. We anxiously await a solution to the Agent Orange controversy.

Respectfully submitted,



Robert E. Hanson
Chairman
Vietnam Veterans of North Dakota



Malto: "If I cannot speak good of my comrade, I will not speak ill of him."



DISABLED AMERICAN VETERANS

NATIONAL SERVICE and LEGISLATIVE HEADQUARTERS
807 MAINE AVENUE, S.W.
WASHINGTON, D.C. 20024
(202) 654-3501

December 23, 1981

DEC 28 REC'D

Honorable Alan Cranston
United States Senate
Ranking Minority Member
Committee on Veterans Affairs
410 Russell Senate Office Building
Washington, D.C. 20510

Dear Senator Cranston:

Your letter of December 15, 1981, sent to Mr. Norman B. Hartnett, DAV National Director of Services, has been referred to this office for reply.

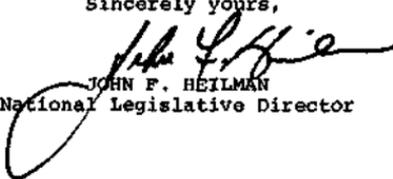
You have requested DAV views on the sentiments expressed by Ms. Joan Bernstein, former General Counsel of HHS and chair of the Interagency Work Group on Dioxin, during the Committee November 18, 1981 oversight hearing on issues relating to Agent Orange. The sentiments were, as one approach to resolving the Agent Orange "controversy," that two studies on the health of Vietnam veterans be conducted: one that would examine the general health status of these veterans without any reference to exposure to toxic substances and one that would focus on the health effect in these veterans of exposure to dioxin (as found in Agent Orange).

In our purely layman opinion, it would appear that such an approach would certainly be helpful in addressing this most complex issue. If a consensus of qualified medical/scientific opinion should concur with Ms. Bernstein, then by all means, her proposal should be implemented.

Regarding the role the Veterans Administration should play in the design and conduct of such studies, we believe the Agency should most certainly not be precluded out of hand. We make this statement in full realization that there are those who believe the VA could not conduct an objective examination of the Agent Orange issue and/or that the Agency's mere "association" with any Agent Orange study would detract from the credibility of results. At the very least, noting that the VA has been giving Agent Orange physical examinations to thousands of Vietnam veterans, we believe the Agency is certainly in a position to identify and provide pertinent medical information on the group of veterans to be examined.

Trusting that your inquiry has been answered, I remain,

Sincerely yours,



JOHN F. HEILMAN
National Legislative Director

JFH:ar