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# AGENDA

## SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

## MAY 6, 1981

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|---|---|
| LIEUTENANT GENERAL PAUL W. MYERS | SURGEON GENERAL<br>UNITED STATES AIR FORCE |
| DOCTOR WILLIAM J. JACOBY, JR. | DEPUTY CHIEF MEDICAL DIRECTOR<br>VETERANS ADMINISTRATION |
| AND | |
| DOCTOR BARCLAY M. SHEPARD | SPECIAL ASSISTANT TO THE CHIEF MEDICAL DIRECTOR<br>VETERANS ADMINISTRATION |
| DOCTOR MICHAEL GOUGH | SENIOR ANALYST, HEALTH PROGRAM<br>OFFICE OF TECHNOLOGY ASSESSMENT |
| MR. RONALD SIMON | NATIONAL VETERANS LAW CENTER |

STATEMENT

OF

WILLIAM J. JACOBY JR., M.D.

DEPUTY CHIEF MEDICAL DIRECTOR

DEPARTMENT OF MEDICINE AND SURGERY

VETERANS ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

COMMITTEE ON VETERANS' AFFAIRS

U.S. HOUSE OF REPRESENTATIVES

MAY 6, 1981

Mr. Chairman and Members of the Committee:

Good morning. I wish to express my appreciation for the opportunity to appear before you today for the purpose of providing an update of the Veterans Administration Agent Orange-related activities. In particular, I wish to address the status of the epidemiological study and literature analysis, both mandated by P.L. 96-151 as responsibilities of this Agency.

With me today is Dr. Barclay M. Shepard, Special Assistant to the Chief Medical Director for Environmental Medicine. Dr. Shepard, who is charged with the task of coordinating all VA Agent Orange activities within the Department of Medicine and Surgery, has demonstrated a keen awareness of the many facets of the Agent Orange issue. He will continue to play a key role in this Agency's efforts and serve as our liaison with other Federal and non-federal agencies and institutions who are also working toward a better understanding of this complex issue.

Mr. Chairman, we have testified on a number of occasions before various Congressional committees on the Agent Orange activities of the Veterans Administration. The Administrator's testimony before the House Veterans Affairs Committee on February 25, 1980 and before the House Interstate and Foreign Commerce Committee on September 25, 1980, as well as the General Counsel's statement before the Senate Veterans Affairs Committee on September 10, 1980, provided an overview of the history of the use of herbicides in Vietnam and of major Agent Orange activities in which the VA has been actively engaged. It

is my intention today to describe our progress since our appearance before this committee on September 25, 1980.

Mr. Chairman, I wish to state at the very outset that from the time this issue first began to emerge, the VA has taken a leading role in the government's efforts to keep abreast of the problem. It is largely because of this visible, and therefore perhaps vulnerable position, that the VA has at times come under heavy criticism. I would submit, however, that despite perceptions to the contrary, this agency has remained faithful to its primary mission as the true advocate of the veteran. Within the body of the law that governs its operations, the VA has made every effort and has embarked on a series of bold initiatives in an attempt to respond to the many and varied concerns of our Vietnam veteran beneficiaries as they relate to the issue of Agent Orange.

I would also like to emphasize once again that it is established VA policy that no veteran seeking medical advice or evaluation for possible ill effects from exposure to Agent Orange be denied this opportunity. It is also our policy that any eligible veteran who needs medical attention can receive this care at a VA facility regardless of the cause of his illness. Further we are firmly committed to the policy that all veterans reporting for examination and participation in our Agent Orange Registry will be treated with the dignity and respect to which they are entitled. Every effort is made to ensure that from the time the veteran first enters a VA facility, to the conclusion of the physical examination, the experience is one which affirms our commitment to allaying

unfounded fears and which responds to medical or other needs in a compassionate manner. We fully accept this responsibility as a privilege of service. My testimony today will emphasize the steps we are taking to fulfill our responsibilities to veterans and their beneficiaries.

## VETERANS ADMINISTRATION EPIDEMIOLOGICAL STUDY

As you are aware, Mr. Chairman, almost a year and a half has passed since the Congress mandated that the Veterans Administration conduct a long-range epidemiological study of the possible health effects among Vietnam veterans exposed to Agent Orange. Since that time this Agency has expended considerable effort to implement the design of such a study. The process of selecting a contractor for the study design was significantly delayed by factors external to the VA, factors which were so well described in your statement which appeared in the Congressional Record on February 19, 1981. I wish to express the appreciation of the Veterans Administration to you, Mr. Chairman, for your awareness of the circumstances surrounding this regrettable delay, and of the need to be objective concerning the ability of the VA to fulfill the mandate of P.L. 96-151 in light of those delays.

Following its detailed review of the contracting procedures, the General Accounting Office on February 2, 1981, rendered a decision favorable to the VA. This allowed us to initiate final procedures for award of the contract. Because of this long delay, however, we were concerned that changes in personnel, cost factors, or other changes,

would place some of the bidders in a position of being unable to satisfy the terms of their original proposals. Contact was made with the bidders to determine whether or not they were still interested in competing for the contract and to permit them to amend their proposals. Amended proposals were received from each of the original bidders, and these were reviewed by the Selection Panel, which has reached a concensus. I am pleased to inform you that the contract for the design of the epidemiological study mandated by P.L. 96-151 has been awarded to University of California at Los Angeles on May 1, 1981.

It is hoped that a proposed design will be submitted to the Veterans Administration on or about July 1, 1981. It is anticipated that the design will then undergo a detailed peer review by a number of agencies, including the Office of Technology Assessment, the Science Panel of the Interagency Work Group, and the VA Advisory Committee on the Health-Related Effects of Herbicides and the National Academy of Sciences - National Research Council. It is anticipated that part of this review process will include discussions relative to whether the study should be performed in-house by the VA or by contract to a non-government organization, or a combination of these. At some point during the process of review of the study design it will be incumbent on the Veterans Administration to estimate the resources which will be required to complete the study and to report these findings to this committee.

At this point, Mr. Chairman, an important factor should be emphasized. Although the study design is not yet com-complete, I believe it is safe to assume that information

resulting from the study will be obtained in two broad phases. The first phase will most likely be an assessment of the past and present health status of the veterans being studied, including the control group or groups. The information from this phase should be available approximately 18 months following the actual start of the study. The second phase should be a prospective evaluation of the health of these individuals over a period of several years in order to look for evidence of more subtle or latent effects. We therefore, should have some results within a relatively short period of time following the start of the study. On the other hand answers to questions relating to the long-term effects will require many additional years of observation and study. Even then, we cannot expect that this study, or any other single study, will provide all the answers we seek. It is quite likely that many persons will be frustrated by the inability to provide immediate answers to their questions. In the interests of scientific truth, however, and in the ultimate interest of these individuals, it is vitally important that we do not respond to the dictates of public pressure in a fashion counterproductive to our ultimate goal of finding verifiable answers to this issue. Hopefully, as the results from various research efforts become available, the Veterans Administration will be able to etablish new policies as needed to best serve the interests of this group of veterans. If new legislation is required, we will not hestitate to make the appropriate recommendations to the Congress.

## LITERATURE ANALYSIS

The contract for the Literature Analysis entitled "A Proposal to the Veterans Administration to Review Literature on Herbicides, Including Phenoxy Herbicides and Associated Dioxins." was awarded on December 15, 1980, to JRB Associates Inc., of McLean, Virginia, one of the largest and most widely recognized environmental and occupational health and safety consulting groups in the nation. On December 16, the first meeting between representatives of JRB Associates, VA Supply Service and the Office of Environmental Medicine, was held at VA Central Office. Since that time, Dr. Shepard has met periodically with the contractor to discuss the progress of the analysis. We anticipate a completion date of September 15, 1981.

This review began with a thorough search of the world's literature on phenoxy herbicides and the toxic contaminant known as TCDD or dioxin. This portion of the contract has been completed and JRB scientists and a panel of expert consultants, have now initiated a detailed review, scientific analysis, and a critical appraisal of the literature. A comprehensive annotated bibliography will be included. Although the literature search concentrated primarily on the two phenoxy herbicides in Agent Orange, 2,4-D and 2,4,5-T and the contaminant 2,3,7,8-tetrachloro-dibenzo-para-dioxin (TCDD), other herbicides used in Vietnam will be included. Areas of review will include the method of environmental transport and fate, as well as potentials for delayed toxicity, prolonged chronic toxicity, carcinogenicity, and birth defects.

I wish to emphasize to the committee that the contractor has been directed to conduct an independent and objective review and analysis of the available literature. The VA has been most careful to avoid directing the efforts of the contractor towards any particular findings or conclusion. We will, of course, provide this committee with copies of the document when completed.

## VETERANS ADMINISTRATION COMMITTEE ACTIVITIES

Our efforts to resolve the issue of Agent Orange have been greatly aided by a group of agency and interagency committees. The work of these committees has been a major contributing factor in providing support to this agency in its continuing search for answers to many perplexing questions.

### Policy Coordinating Committee (PCC):

Within the VA, the Policy Coordinating Committee (PCC), continues to serve as this agency's central coordinating point for major policy decisions and recommendations concerning the Agent Orange issue. It is this committee which generally oversees the activities of the Office of Environmental Medicine and develops policy for ultimate review and approval by the Administrator. I believe this committee will continue to be an valuable internal agency mechanism for responding to the many concerns of Vietnam veterans as they relate to possible health effects of herbicide exposure.

Advisory Committee on the Health-Related Effects of Herbicides:

Mr. Chairman, on April 3, 1981, the General Services Administration Committee Management Secretariat and the Office of Management and Budget (OMB) approved a 2-year extension of the charter for the VA Advisory Committee on the Health-Related Effects of Herbicides. This committee continues to meet quarterly at VA Central Office for the purpose of analyzing significant scientific and other information which the VA needs to formulate appropriate policies and procedures. We are very gratified that the action by OMB in approving the renewal of the committee's charter will enable this knowledgeable body of individuals to continue its factfinding and advisory role to the Administrator. Representation and attendance of the public, including individual veterans and veteran representatives, has been most encouraging. Some of the more significant activities of the committee during the past two meetings have included discussions of:

1. A follow-up of workers at the Mansanto Chemical Company plant in Nitro, West Virginia
2. The Armed Forces Institute of Pathology (AFIP) Agent Orange Registry
3. A proposed soft tissue sarcoma study to be conducted jointly by the AFIP and National Cancer Institute (NCI)
4. A review of the most recent data on the industrial exposure in Seveso, Italy
5. A report of a study on the environmental fate of TCDD observed at Egland Air Force Base, Florida
6. The status of the Center for Disease Control (CDC) study of birth defects.

In compliance with the provisions of the Federal Advisory Committee Act, a formal transcript of these meetings is prepared and made available to various government offices and interested individuals. The Department of Medicine & Surgery insures that copies of the transcripts are promptly forwarded to our field facilities in order to provide information to key staff personnel including facility Directors, Chiefs of Staff, Chiefs of Ambulatory Care and Environmental Physicians.

The Advisory Committee will continue to serve as a focal point for discussion of those scientific studies and activities with possible implications for understanding or resolving the many complex problems raised by Agent Orange or the other herbicides used in Vietnam.

Interagency Work Group (IWG):

The role and history of the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants was described in some detail in our previous hearings. The Veterans Administration views this committee and its Science Panel as the key interagency body which effectivly monitors and coordinates all Federal research efforts regarding the possible health effects of phenoxy herbicides. It is an invaluable forum for reporting to the public the results and implications of this research. Since its establishment by the White House in December 1979, the IWG has met monthly at the Department of Health and Human Services (DHHS). These meetings have been well attended and the group's efforts and purpose have been enthusiastically supported by the attendees and the agencies they represent. In particular, the Science Panel has made a significant contribution

to the overall efforts of the IWG through its close monitoring and scientific review of a number of research studies relative to Agent Orange and other phenoxy herbicides. Among its many efforts, the Science Panel has reviewed in detail and supported the design of the Air Force Ranch Hand Study and the Birth Defects Study to be conducted by the Center for Disease Control in Atlanta. The work of the IWG has added immeasurably to the overall understanding by the Federal government of the possible adverse health effects of phenoxy herbicides and has established an enviable reputation among members of Congress, scientists, and the lay public for objectivity and credibility in its handling of this very sensitive issue. The Veterans Administration is most grateful for the many significant accomplishments of this work group.

Agent Orange Registry and Data Analysis Task Force (DATF):

Since the initiation of the Agent Orange Registry in 1978, approximately 45,000 examinations of veterans concerned about the possible adverse health effects of Agent Orange have been conducted by the VA utilizing a special examination protocol. The information on over 25,000 of these veterans is now contained in the special Agent Orange Registry data bank. The Registry continues to serve as an important vehicle for:

1. Identification of concerned Vietnam veterans
2. Serving as a basis for follow-up contact with Registry participants.
3. Providing general medical information concerning these individuals.
4. Possible identification of significant health trends in the population of examined veterans

In response to concerns of veterans that they were not being fully informed of the results of their Agent Orange examinations, special instructions have been sent to all of our medical facilities directing that each registry participant will be advised by a physician of the results of the examination and that a follow-up letter explaining the findings will be sent to each veteran. It further directed that each veteran be provided with a copy of the pamphlet "Worried About Agent Orange?" at the time of the initial examination.

The Data Analysis Task Force meets on a regular basis within the Office of Environmental Medicine to continue the work of evaluating the information in the Agent Orange Registry. In addition, the DATF is in the process of developing a data retrieval system which will provide a systematic approach towards describing some of the health problems being experienced by those veterans who are enrolled in the Registry.

In addition to other uses of the Registry, its data base is currently assisting us in reviewing the consolidated medical records, including the Agent Orange examinations, of those Vietnam veterans identified as having "evidence of neoplasia."

Our efforts to develop an effective nationwide Registry reflect our awareness of the need to identify, counsel and assist that segment of the Vietnam veteran population which views Agent Orange as a potential or real threat to their health and general well-being.

Chloracne Task Force (CTF):

The VA continues to be served by the activities of a Special Chloracne Task Force which was established to review the causes, diagnosis, and treatment of chloracne, a skin condition which may result from exposure to TCDD, a contaminant of Agent Orange. As regards our efforts in this area, I am pleased to report that we are making good progress. Some of our accomplishments in this area include:

1. Forwarding of educational and informational materials to all VA dermatologists.
2. Development of a draft chloracne examination protocol, which is currently being circulated for review and comment by VA dermatologists in the field. When completed, this protocol will serve as an objective and uniform basis for diagnosing possible cases of chloracne.

The Department of Medicine and Surgery has examined the rating decision forms of some 3,500 claims for damage from Agent Orange. In about 350 instances, "skin conditions" were claimed but not described in sufficient detail to establish any diagnosis. In another 350, the described condition had some potential resemblance--usually remote--to chloracne. We are is now planning a more detailed review of the actual claims folders of these 700 veterans Any veteran whose skin condition may resemble chloracne will be asked to be re-examined by a dermatologist who is particularly familiar with the diagnostic criteria of chloracne.

## VA AGENT ORANGE INFORMATION AND EDUCATION ACTIVITIES

The Department of Medicine and Surgery is cognizant of the need to provide significant and timely information to those veterans and individuals who are concerned about the potential health effects of Agent Orange. Equally important is our responsibility to provide information and guidance to our VA health care professionals and administrative staff who are most involved with assisting these individuals.

In our previous testimony before this committee, we outlined several of our efforts to provide information and education to the 180 Environmental Physicians currently serving as our Agent Orange coordinators in each of our medical centers. The special educational conferences held in the Washington, D.C. area in September 1979, and May 1980, were described. In addition, we have instituted a series of ongoing conference calls, held every other month, with key staff personnel including our Environmental Physicians, Chiefs of Ambulatory Care, and Chiefs of Medical Administration Service. The Office of Environmental Medicine and other VA Central Office personnel serve as agency resources for these conference calls.

The pamphlet "Worried About Agent Orange?" has been widely distributed to all VA medical centers, independent outpatient locations, Vet Outreach Centers, VA regional offices, members of Congress, State Veterans Affairs Offices, Veterans Service Organizations and other concerned agencies and individuals.

On January 23, 1981, the videocassette "Agent Orange - A Search for Answers" was mailed to each of the 58 regional offices, 172 medical centers, 7 independent outpatient clinics, 91 Vet Outreach Centers, and 13 Information Service Area Directors. All facilities were directed to provide for a showing of this videocassette to all VA employees, service organizations and to provide special showings on a regular basis, or upon request, to veterans, service organizations, the media, and the general public. The response to the information conveyed by this audiovisual has been encouraging. We have asked each of our facilities to provide viewers with the opportunity to comment on the content of this tape. Future plans include a second videocassette for the further education of our medical staff and administrative personnel.

The inaugural issue of the Agent Orange Bulletin was released to the field during December 1980. The purpose of this bulletin is to provide our physicians and medical staff with information regarding recent developments concerning herbicide orange and other related matters. This bulletin will be issued on a periodic basis as an unofficial means of communicating to our staff new developments regarding Agent Orange and other phenoxy herbicides.

## CONCLUSION

In conclusion, Mr. Chairman, I wish to reaffirm the Veterans Administration's commitment to resolving the Agent Orange issue as expeditiously as possible consistent with sound scientific and administrative principles. We view the epidemiological study and literature analysis together including the Air Force Ranch Hand Study and the CDC Birth Defects Study with other research efforts as critical and necessary elements to our continuing search for answers. Although we can provide no guarantee that these activities will answer all the questions on this issue, we can reasonably expect that they will materially assist us in developing policy relative to providing assistance to concerned Vietnam veterans. In the meantime it is our firm policy that no eligible veteran will be denied medical care by the Veterans Administration regardless of the cause of his or her problem, and that all veterans will be provided the full range of medical benefits to which they are entitled by law.

Testimony of
Michael Gough, Ph.D.
Office of Technology Assessment
Congress of the United States

Before the
Subcommittee on Oversight and Investigations
Committee on Veteran's Affairs
House of Representatives

May 6, 1981

I am Michael Gough. I am employed as a senior analyst and project director at the Office of Technology Assessment, United States Congress. Congress mandated that OTA review the design and monitor the conduct of the Veterans Administration epidemiologic study of possible long-term health effects resulting from exposure to dioxins in Viet Nam. I am here today because of my responsibilities as director of that project. As is well known, dioxins, in particular 2,3,7,8-tetrachlorodibenzo-para-dioxin or TCDD, contaminated mixtures of 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-trichlorophenoxyacetic (2,4,5-T) acids. A 50:50 mixture of 2,4-D and 2,4,5-T, called Agent Orange, was used extensively in Viet Nam, and individuals exposed to it were, at the same time, exposed to TCDD. Concern about possible health effects resulting from exposure to dioxins was responsible for Congress directing VA to investigate whether or not adverse health effects are now being borne by Viet Nam veterans.

The role of the OTA in the study is straightforward. As 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.... The Director shall monitor the conduct of such a study in order to assure compliance with such protocol.

Organizationally the OTA is well suited to review the study protocol. In preparing each of its assessments for Congress, OTA assembles an advisory panel of non-Federal employees to comment on the work of its staff and contractors. OTA will assemble such a panel to review the VA protocol. The panel will consist of 12 to 14 people of diverse backgrounds. About half will be biomedical scientists from academic, medical and private research organizations. They will include 2 epidemiologists, 2 biostatisticians or experts in experimental design, 1 dermatologist, 1 neurologist, 1 geneticist, 1 environmental health scientist, and a public health expert. These individuals will provide the careful technical scrutiny that this important protocol deserves.

OTA recognizes that decisions, even decisions about largely technical subjects, frequently have farreaching effects on large numbers of people. Certainly the conduct of the dioxin study will have such farreaching impacts. To anticipate such effects and to represent people who have a stake in the outcome studies, OTA invites stakeholders to participate in its advisory panels. We expect to include 2 representatives of veteran's groups, 1 or 2 individuals from industry, 1 labor representative, and 1 public interest or environmentalist representative on the panel. Selection of these panel members will be made carefully. They will, in order to be effective, have to have sufficient technical background so that they will not be buffaloed by the technical experts.

In addition to the actual panel members, we will call upon other experts to review particular parts of the design if the panel members or staff think such additional review is necessary. Such additional review will be sought and the persons chosen in consultation with the advisory panel.

The chairman of this panel has been selected. He is Dr. Richard Remington, Dean of the School of Public Health at the University of Michigan. We have discussed potential panel members with Dr. Remington, the National Academy of Sciences, several other organizations, and many people, but all the discussions have been tentative. Reading and criticizing an experimental design of the complexity and importance of the VA study will require a solid block of time. When we receive the study plan, we expect to distribute it to the panel members, allow them about two weeks for review, and then have a meeting of one or two days duration to discuss the review. We decided to wait until we had a firm idea of when we will require people's time before approaching them to serve. This week we learned that we can expect the study plan in early July, and we will now fill out our panel.

P.L. 96-151 directed that the OTA should report to Congress reasons why it had not approved the study protocol if approval had not been granted within 180

days after passage of the law. Those 180 days elapsed about June 20, 1980, and OTA has written to the appropriate Committees periodically since then to inform Congress about why approval had not been forthcoming.

The VA decided that a contract was necessary because it did not have inhouse staff experts to develop the protocol. VA published a Request for Proposals (RFP) in the Commerce Business Daily on March 19, 1980. The RFP was an invitation to organizations that wanted to design the protocol to submit a statement of their staff capabilities and a short description of their ideas about the design of the study. A month later, on April 11, VA held a meeting of potential bidders, and the Agency accepted bids through May 8.

On May 6, 1980, the National Veterans' Law Center took two actions in protest of the procedures used by the VA in issuing the RFP. It filed a suit in the United States District Court for the District of Columbia, Civil Action No. 80-1162. It also filed a bid protest, Case No. B-198738, with the General Accounting Office (GAO). On June 13, 1980, Judge H.H. Greene of United States District Court asked the GAO to make a ruling about the issues raised by the National Veterans' Law Center. The suit, bid protest, and subsequent GAO investigations and considerations of factual and legal issues were not settled until January of this year. During those 9 months, from May through January, no progress could be made in issuing a contract.

GAO found in favor of the VA, and VA contacted the bidders to determine if they remained interested in competing for the contract, if personnel were still available, and if changes were necessary in their estimated costs. All bidders remained interested. To choose among the bidders, VA sent the original bids plus the revisions to a panel of Federal experts. These same experts reviewed the bids last year, and VA has just completed the second review. One of the members of the VA panel was Dr. Joyce Lashof, an Assistant Director of OTA.

The VA selected the bid from the University of California at Los Angeles and a preliminary draft of the study is to be submitted to VA 60 days after the day UCLA receives the contract. Soon after that, OTA will begin its review. We see no reason that we will be unable to execute the review in the time alloted to us.

During the last year, OTA has participated in the Interagency Workgroup to Study the Possible Long-Term Health Effects of Phenoxyacid Herbicides and Contaminants, generally called "the Interagency Workgroup" and has provided reviews of technical papers about herbicides and chronic disease to the Senate Veterans' Affairs Committee. We have also, as I mentioned, made reports to Committees of Congress about the state of the VA study. OTA appreciates the importance of this undertaking and looks forward to making the study as good as possible.

D E P A R T M E N T  O F  T H E  A I R  F O R C E

PRESENTATION BEFORE THE VETERANS AFFAIRS COMMITTEE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

HOUSE OF REPRESENTATIVES

MAY 6, 1981

SUBJECT: STATUS OF HERBICIDE ORANGE STUDIES

STATEMENT OF: LIEUTENANT GENERAL PAUL W. MYERS, USAF, MC
SURGEON GENERAL

NOT FOR PUBLICATION UNTIL RELEASED
BY THE COMMITTEE ON VETERANS AFFAIRS
HOUSE OF REPRESENTATIVES

His military decorations and awards include the Distinguished Service Medal, Legion of Merit, Air Force Commendation Medal, Air Force Outstanding Unit Award Ribbon with one oak leaf cluster, and the honor decoration for the Causa de la Fuerza de Chile.

General Myers is married to the former Virginia Carman of Schenectady, New York. They have four children: Peter Paul, Michelle Lynne (Biasiolli), Debra Ann (Lawrence), and Joan Harriet (Carter).

He was promoted to the grade of lieutenant general effective August 1, 1978, with date of rank July 31, 1978.

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. This issue plus the other peer review observations was referred to the Interagency Work Group to Study the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants for a determination of how the study should be conducted and by whom. The Interagency Work Group began its review on June 17, 1980. A recommendation was made on August 1, 1980 to the Assistant to the President for Domestic Affairs and Policy.

It was finally recommended 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 then 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.

The following additional actions have been taken or are underway:

controls are to be interviewed during the twelve months subsequent to August 1981. The questionnaire will identify the health, medical, demographic, social and psychological condition of the study subjects.

Study subjects will also be asked to participate in an extensive physical examination to be conducted at a national medical center. The Statement of Work for that physical examination is currently in preparation. The initial physical examinations are planned to start in September 1981 with completion in September 1982. The first 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 cost for this study is estimated at $35 million in today's dollars.

The Interagency Work Group, through the Department of Health and Human Services, is in process of establishing the advisory committee to monitor the Ranch Hand Study.

The Veterans Administration and the Internal Revenue Service have been of great assistance in identifying and locating the individuals in the study. We are appreciative. I wish to sincerely thank the Interagency Work Group and the Office of Management and Budget for their expeditious review of the study material. Their cooperation has enabled us to move forward with the study.

The Ranch Hand Study should prove to be productive in determining the possible long-term health effects of phenoxy herbicide exposures.

I will be happy to answer any questions.