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TESTIMONY BY MR. RICHARD S. CHRISTIAN

DIRECTOR

U.S. ARMY AND JOINT SERVICES

ENVIRONMENTAL SUPPORT GROUP

BEFORE THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

COMMITTEE ON VETERANS' AFFAIRS

of the

HOUSE OF REPRESENTATIVES

July 31, 1986

Not for Publication until Released by the Hospitals and Health Care Subcommittee, House of Representatives

Statement Record Version

Mr. Chairman and Members of the Committee:

I am Richard S. Christian, Director of the U.S. Army and Joint Services Environmental Support Group (ESG), Department of the Army. I am pleased to appear before the Committee to provide, in response to your request, ESG's research missions in support of the Agent Orange Epidemiological Study, mandated by Public Law 96-151.

The Army became actively involved in the Agent Orange issue early on because we recognized its importance to operational readiness.

As the major Service involved in the subject, the Army is The Executive Agent for all the Services on this issue.

Two point four (2.4) million Americans served in Vietnam from 1961 to 1973. These men and women served their country admirably. They deserve our care.

The Army is keenly aware of its obligation and is dedicated to help Vietnam veterans. The American Soldier, Sailor, Airman and Marine is intelligent and wants frank answers to his concerns, and that is ESG's purpose: to provide such answers.

In the last six years ESG has led in research, assistance, and providing information to Vietnam veterans.

Over 20,000 inquiries have been answered regarding veterans issues. Eighty-Five percent(85%) of these inquiries related to the issue of exposure to Agent Orange.

Mr. Chairman I will outline the record of ESG involvement in various Agent Orange studies.

First I must state the obvious in order to avoid the hope of easy answers. Unfortunately, but not unpredictably, combat operations were not designed as an epidemiological laboratory. Combat does not contribute to anyone's health, nor does it favor scientific review that is based on the correlation of statistics. Yet, the records generated during military conflicts can serve many uses. I will briefly describe our efforts in reviewing the records from Vietnam.

Our first study involved Birth Defects. In December of 1983 ESG provided the Centers for Disease Control (CDC) exposure opportunity scores on 536 Vietnam veterans. This required ESG to develop a procedure to identify a unit's area of operation for each participant in the study. In addition, ESG established a board of military experts to evaluate each case.

Another phase of ESG operations involved assistance to veterans and the Department of Justice. Hundreds of documents were provided in connection with the civil class action lawsuit involving the Vietnam veterans, chemical companies and the U.S. Government. The claim against the U.S. Government was later dismissed, except for wives and dependents claims. This was a major undertaking, as our job involved records support for all parties. It meant examining and cataloging the 40,000 linear feet of combat unit records from the Vietnam conflict.

ESG provided additional exposure opportunity scores on Vietnam veterans for the Veteran Administration's Chloracne and Adipose Tissue Studies.

We are currently doing military research on eight other VA studies concerning Agent Orange.

As to the current interaction with the CDC, CDC was provided personnel data for over 20,000 study subjects for what is termed the Vietnam

Experience Study. This study covers all those factors, including Agent Orange that may have contributed to potential ill health of the military personnel who served in Vietnam. Despite the requirements of abstracting 73 personnel data elements for each study subject, this task was completed ahead of schedule. To supply this information 43,000 personnel files had to be analyzed.

In 1983, the Science Panel and Office of Technology Assessment approved ESG's portion of the Agent Orange Epidemiological Study protocol.

On 1 April 1984, we began the research for both the Vietnam Experience Study and the major Agent Orange Study.

Changes were frequently made in battalion tracking for the Agent Orange Epidemiological Study and personnel data abstraction, for both the Agent Orange and the Vietnam Experience Study. This required frequent adjustment of research to add, check, refine, assess and massage the data.

In July 1984, we were informed that eleven CDC contracts were signed, resulting in new time tables for ESG. We adjusted to meet the new deadlines. Time tables and numbers of subjects and disqualification factors repeatedly changed over the ensuing months.

In November 1984, a major change in workload required ESG to research an additional 15 battalions, and revise the selection process for Agent Orange study subjects. Concurrently for both the Agent Orange and the Vietnam Experience Studies, CDC requested more documents for deceased veterans.

In January 1985, CDC assigned new time frame deadlines and again increased the amounts of personnel data required.

Differences in quality control between the military and the investigators occurred. Nonetheless, these issues were resolved after mutual education of the scientists and military experts in military operations,

language, procedures and scientific techniques.

Due to lack of agreement on assumptions, government scientists never approved an exposure model crucial to the study.

On September 12, 1985, ESG completed the only record of documented military spraying by helicopter, backpack, ground spraying, aborts and leaks. This document, now known as the "Services Herbs Tape," provided a second source, other than the Air Force Operation Ranch Hand, for the matching of units to Agent Orange spraying.

Defoliation spraying may have occurred at main base camps, fire support bases and landing zones. Unfortunately, the records are not complete enough to substantiate the magnitude of these operations. Whether or not these bases were sprayed by Orange, Blue, White or diesel fuel is not known to us since complete documents are not contained in the units' records. In the 9th Infantry Division's area alone there were about 365 such locations that might or might not have been sprayed. Yet, the records only show a total of 478 perimeter sprays for all of Vietnam during the entire war, although there were 11 plus U.S. Divisions, 2 Korean Divisions, 1 Thai and 1 Australian Division in Vietnam.

The Chairman of the Science Panel, Agent Orange Working Group then tasked ESG to conduct a decisive Pilot Study on unit/troop exposure.

Accordingly, ESG researched and completed grid coordinate locations for all companies of seven combat battalions covering the period 1 October 1966 to 31 March 1969. ESG then matched the grid coordinate locations of each company by date against the Ranch Hand and "Services Herbs Tape" to produce an exposure opportunity score for each company. ESG then provided unit exposure opportunity scores on 700 individuals from these units using varying time and distance criteria.

The Pilot Study results revealed the dispersion of combat companies on one-half the given days and that the units had little contact with Agent Orange herbicide spray missions.

These were startling discoveries by even my own staff and the White House Agent Orange Working Group Science Sub Panel, charged with evaluating all available data. We had anticipated higher numbers of exposure than what were actually recorded.

It should be clearly understood that ESG can identify a combat company's locations on a given day. However, records do not permit the location of individual sub-elements or individual troops within these sub-elements at each location. ESG is not qualified to answer the scientific problems this creates. This is an issue the scientists must address. ESG can only report what is contained in the records.

The Military Services performed all this work without outside funding. Over the past six years we have expended 6 million dollars for these efforts.

In summary: over the past three years the Military Services have been scrutinized, scrubbed and critically examined by distinguished groups of experts, such as the National Academy of Science, The Science Panel of the White House Agent Orange Working Group and most recently the Science Subpanel on Agent Orange assessment. The records do not support continuance of the Agent Orange Epidemiological Study, that is, a study based solely upon the use of military records to select cohorts on men potentially exposed to Agent Orange. We are proud of our exhaustive work.

I shall be most pleased to answer any questions.

NEWS

FOR IMMEDIATE RELEASE

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Statement of the Hon. Bob Edgar
Chairman of the House Veterans Affairs
Subcommittee on Hospitals and Health Care
July 31, 1986

Hearings on Agent Orange Studies

Thirteen times since 1978 the House Veterans Affairs Committee and its Subcommittees have held hearings on the subject of Agent Orange. Here we are again.

Being one of the original members of this committee to call for those first hearings in the late 1970's I have to admit that this nine-year process has been one of the most frustrating experiences in my tenure on this committee.

Every time we think we have made a step forward in resolving the Agent Orange question something always happens to push us two or four steps backward.

Sometimes science and scientists have been the stumbling blocks. Sometimes policy and policymakers have been the problem. And sometimes the two get so mixed up that it is impossible for us to tell whether Agent Orange is really an unsolveable problem ---- or a problem nobody really wants to solve.

Over the past few months we have been hearing consistent reports that the major Agent Orange Study mandated by this committee and the Congress in 1979 was in serious trouble. We heard that a recommendation from a White House Science panel had been forwarded to the Agent Orange Working Group declaring the protocol for the study scientifically unfeasible.

Then we heard nothing...and heard nothing...and heard nothing.

So we called for these hearings to get a straight answer from the Administration for the sake of all those Vietnam veterans who expect and deserve that answer.

We asked to hear from Dr. Alvin Young, Past Chair of the White House science subpanel that made the recommendation to the working group. Dr. Young, who has testified many times before this committee, declined to testify.

We asked to see a copy of Dr. Young's report. And we were told that the White House or OMB would not let us have a copy of that report.

We invited Don Newman, Under Secretary of the Department of Health and Human Services and Chairman of the Agent Orange Working Group, to

testify today to tell us what policy decisions are to be made based on the science panel's recommendations. If the protocol for the study is unworkable, then how does this Administration propose to fulfill the mandate of the Congress and complete the study. But, Mr. Newman declined to testify.

No one expected the study to be easy. We did expect, however, that the major players would keep us informed of its problems and its progress. The Congress authorized this study in 1979. It's now 1986. It appears that we are no further along after all this time and all these dollars spent in getting this study underway than we were eight years ago.

The Vietnam veterans of this country deserve better efficiency on the part of their government than that. They deserve a better show of good faith than this.

I remember, in 1982 sitting in this hearing room in similar circumstances. It wasn't the Department of Health and Human Services, or the Centers for Disease Control who had dropped the ball on the study. It was the Veterans Administration that had the initial "shot at it". There was a question about who was dragging their feet on the Agent Orange question then.

The response ironically came from one of our witnesses today. On September 12, 1982 Dr. Vernon Houk of the Centers for Disease Control responded this way:

"If I were responsible for the development of the protocol, I would get a group of people, epidemiologists, laboratory people, the necessary ones from our own shop, and outside help if we had to have it....put them in a room and tell them not to come out until they had one done....that would take, in my estimation, maybe a couple of weeks."

That was four years ago.

After four years there are still a lot of people locked up in a room somewhere downtown with nothing to show for it. . Hopefully, in this hearing we will open up that door.

RECENT CHRONOLOGY OF EVENTS IN CDC AGENT ORANGE STUDY

JANUARY 1983 CDC GETS RESPONSIBILITY TO DESIGN AND CONDUCT STUDY WITH REVIEW BY OFFICE OF TECHNOLOGY ASSESSMENT

SUMMER 1985 HVAC STAFF HEARS OF PROBLEMS IN STUDY DESIGN REGARDING EXPOSURE ASSESSMENT AND THAT CDC IS WORKING WITH A "RADICALLY DIFFERENT DESIGN" THAN THE ONE CONDITIONALLY APPROVED BY OTA; TROUBLED WORKING RELATIONSHIP BETWEEN CDC AND ARMY ENVIRONMENTAL SUPPORT GROUP; TROUBLED WORKING RELATIONSHIP BETWEEN CDC AND OTA.

FALL 1985 HVAC STAFF CALLS MEETING OF SENATE AND HOUSE COMMITTEE STAFF, CDC, ESG, OTA TO DISCUSS PROBLEMS. SERIES OF WORKING MEETINGS AMONG VARIOUS ACTORS OCCURS BUT EXPOSURE ASSESSMENT PROBLEM IS NOT SOLVED.

JANUARY 1986 CHAIRMAN AND RANKING MEMBERS OF HOUSE AND SENATE VETERANS COMMITTEE WRITE SECRETARY OF HHS REQUESTING INFORMATION ON STATUS OF AGENT ORANGE STUDY; TIMETABLE FOR THE PROTOCOL AND STUDY; STATING THAT NO IMPLEMENTATION OF A STUDY CAN GO FORWARD UNTIL A PROTOCOL HAS BEEN REVIEWED BY OTA.

FEBRUARY 1986 RESPONSE FROM HHS SAYING THAT THEY ARE WORKING ON THE PROBLEM AND WILL LET US KNOW WHEN THEY'RE DONE.

MAY 1986 FOLLOWUP LETTER TO HHS FROM CHAIRMAN AND RANKING MEMBER OF HVAC AGAIN REQUESTING TIMETABLE AND STATUS OF STUDY.

APRIL 1986 ACTING ASSISTANT SECTRETARY FOR HEALTH (HHS) WHO IS VICE-CHAIRMAN OF AGENT ORANGE WORKING GROUP DIRECTS FORMATION OF SPECIAL SCIENCE SUBPANEL ON EXPOSURE ASSESSMENT. THE SUBPANEL DOES TWO THINGS: RESEARCH LITERATURE FOR INFORMATION ON WHAT MAKES SENSE IN TERMS OF EXPOSURE TO AGENT ORANGE AND RUNS A PILOT TEST OF ESG RECORDS OF PERSONNEL IN VIETNAM (MORNING REPORTS, ETC) AND HAS THEM REVEIWED BY RECORDS EXPERT (MAJOR GENERAL MURRAY).

MAY 28 SUBPANEL REPORT FINISHED AND SENT TO SCIENCE PANEL OF AGENT ORANGE WORKING GROUP.

JUNE 17 SCIENCE PANEL VOTES TO SEND SUBPANEL REPORT TO FULL WORKING GROUP.

JUNE 23 INTERIM RESPONSE TO MAY 7 LETTER SAYING HHS IS AWAITING RESULTS OF SUBPANEL REPORT.

JULY 15 AGENT ORANGE WORKING GROUP MAKES NO DECISION ON RECOMMENDATION OF REPORT.

TESTIMONY OF HELLEN GELBAND
OFFICE OF TECHNOLOGY ASSESSMENT
U.S. CONGRESS
BEFORE THE SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE
OF THE HOUSE COMMITTEE ON VETERANS' AFFAIRS

Review of OTA Activities Related to Exposure Assessment for the Agent Orange Study

July 31, 1986

I am Hellen Gelband, Director of Special Projects and Agent Orange Project Director in the Health Program of the Office of Technology Assessment. OTA was given responsibility for reviewing and approving study protocols, and monitoring the conduct of studies, under the mandates of Public Laws 96-151 and 97-72. I'd like to relate briefly OTA's involvement specifically related to Agent Orange exposure assessment in one of the three studies planned by the Centers for Disease Control in response to Congress's mandates. I will not chronicle the history of the study before the time CDC gained responsibility for it.

The Agent Orange study was proposed to examine the question of whether ground troops exposed to Agent Orange in Vietnam are more likely to be dying at a faster rate or are in poorer health than are similar men who served in Vietnam but were not exposed to Agent Orange. The study hinges on an ability to assemble groups of men that are <u>different</u> with respect to exposure, but similar in as many other ways as possible. This difference may be expressed in several ways: high and low levels of "exposure opportunity," and high and low "probabilities of exposure" are the types of terms applied. In the end, however, whatever names are used, it is critical that there be a high degree of certainty that the groups actually <u>are</u> different in their exposures to Agent Orange. That does not mean that every man in the high exposure group

was actually highly exposed, or that each man in the high exposure group was exposed to more than any man in the low exposure group. It does mean, however, that the groups should be clearly different and that we should be able to characterize, at least roughly, what the difference is in logical terms. Today, seven years after the Agent Orange study was mandated, after much effort, there is still no clear answer about whether groups of ground troops that differ in their exposure to Agent Orange can be identified.

From the outset, in the protocol outline produced in February 1983, CDC recognized the difficulties of obtaining good information about Agent Orange exposure. The feasibility of using military records that contained information about troop movements together with other records that contain Agent Orange spray locations had been shown in 1979 by the General Accounting Office, and it is that strategy that has been the focus of CDC's attempts to devise a scheme for exposure assessment. The intent was always to select study participants on some records-based measure of proximity in time and space to Agent Orange applications.

In June 1983, OTA reviewed protocols for the three studies planned by CDC, one of which is the Agent Orange study. Because of the great uncertainties concerning the records--particularly how complete they were and how accurate they were considered to be--no final decisions could be made about the study as a whole. As OTA stated in its review of that document, "it is still possible that studying associations between health effects and Agent Orange exposure may not be possible because the records will not provide information for meaningful exposure classification." In their revised protocol, which OTA received in January 1984, CDC stated: "Since many of the proposed procedures are untested, modification, indeed even a recommendation not to proceed with an Agent Orange study, may be required after pilot study

assessments." In February 1984, OTA approved the general structure of CDC's revised protocols, while noting that the details of a method for classifying men according to Agent Orange exposure had yet to be worked out. As CDC stated in their document, final decisions about the feasibility of the study would have to await results of pilot studies of the methods and consideration of their results. OTA agreed that this was an appropriate way to proceed.

The general approach outlined by CDC was to select 50 battalions from a heavily sprayed area during a time of heavy Agent Orange use, and rank each company (about 250 companies in total) according to a cumulative Agent Orange exposure "score" based on some combination of time and distance measures. The area chosen was the area designated "III Corps" during the period 1967 through 1968. The one-third of companies with the greatest opportunities for exposure would supply the exposed group, and the one-third with the fewest opportunities would supply the unexposed group. OTA believed at the time that CDC needed to set the requirements for the necessary records research and pilot tests so they could be implemented by the U.S Army and Joint Services Environmental Support Group.

CDC transmitted its first report about exposure assessment to OTA in February 1985, two years after CDC took control of the study. At that time, data from battalion daily journals, the main source of grid coordinates for companies and battalions, were available for 21 battalions for the two-year period. Because grid coordinates were not recorded each day for each company, gaps existed. CDC described two types of information that could be used to fill gaps: battalion and brigade-level records that might contain additional grid coordinates, and geographic names or name codes that appeared in some records in lieu of grid coordinates for unit locations. Many of the place names could be located at specific grid coordinates by use of a gazeteer. ESG

used these additional sources of information to fill gaps, where possible, for nine of the 21 battalions whose records had been abstracted. According to the data presented by CDC in their report, even with the additional data, there were too many gaps for companies to be used as the unit for characterizing Agent Orange exposure. As stated by CDC:

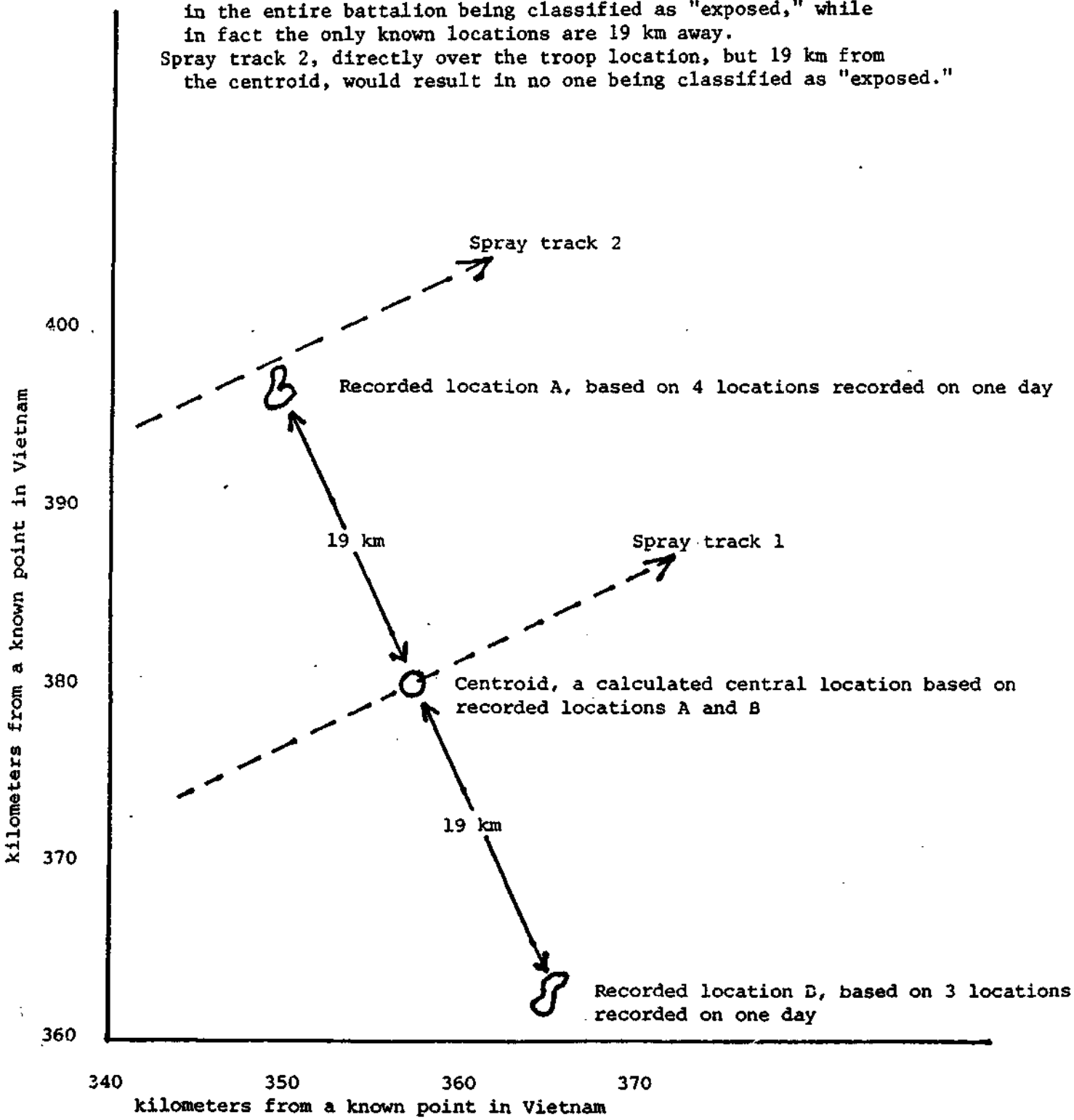
> For these reasons battalions rather than companies or batteries will be the units whose locations form the basis for ranking individual men's likelihood of exposure to Agent Orange.

The shift from considering exposure based on a company to exposure based on battalion locations constituted a major change from the original protocol. The second major change presented in the February 1985 report was that men would not be selected into the study by units, but by individual rankings. CDC reported that high transfer rates of men among battalions necessitated this change.

The OTA advisory panel met in February 1985 to review these changes, and OTA produced a report in April. The first change is of far greater importance than the second. A company contains about 100 to 150 men, while a battalion is five times as large, upwards of 500 men. Battalions are spread out over much larger areas than are the individual companies that make up the battalion. CDC presented data showing multiple reported locations for a single battalion on a single day. The different locations represent the positions of individual companies or other subunits of the battalion. Using those locations, CDC calculated a "centroid," an "average" point which was assigned, for the purposes of the study, as a uniform location of each man in the battalion. According to the data supplied in CDC's report, a reported location could be nearly 20 kilometers from the centroid, and in fact, there might not be one person actually at the centroid (see Figure). The degree of

An Example of Recorded Positions of a Battalion's Subunits and the Calculated "Centroid" of those Locations.

The spray tracks represent hypothetical Ranch Hand missions.
Spray track 1, passing directly over the centroid would result in the entire battalion being classified as "exposed," while in fact the only known locations are 19 km away.
Spray track 2, directly over the troop location, but 19 km from the centroid, would result in no one being classified as "exposed."



misclassification that would be introduced by this approach appeared extremely high.

To quote from OTA's April 1985 report:

> These are serious problems, but OTA comes to no conclusion about their impact on the study at this time. We expect to hold another meeting in about six months to hear from CDC about any improvements that can be made. If there are no improvements, OTA may decide that the problems of deciding on exposure are so overwhelming that it is impossible to study the possible effects of Agent Orange.

As a followup to our February panel meeting, OTA staff met with Mr. Richard Christian and his colleagues of the ESG to discuss the problems CDC had raised about the lack of information in the records for determining locations for companies. It appeared that, in fact, ESG was able to locate companies, if CDC would agree to using different types of information. OTA staff urged that CDC and ESG hold a meeting to discuss that question, which they did successfully, and ESG began to develop what has been called the "contextual approach" to filling gaps in location data.

In late September 1985, Dr. Gibbons wrote to the Congressional committees, expressing concern that no new information about CDC's exposure assessment activities had come to OTA, but that CDC had not changed their plans for interviews of study participants to begin in January. Discussions between CDC and OTA resulted in CDC's agreeing to provide a revised plan for exposure assessment before the scheduled interviews. OTA received relevant documents between November 18 and December 13, and held an advisory panel meeting on December 14 to review the material with the hope that the plan would be far enough advanced to allow undertaking the interviews with confidence that the study would proceed on a sound footing. Unfortunately, what we found was to the contrary. Quoting from the letter sent by Dr. Gibbons (December 19) to the committees as a result of that meeting:

> In sum, the recent reports from CDC outline an Agent Orange Study of radically different design than the one that was initially reviewed and approved by OTA. The changes are of sufficient magnitude to require interruption of any plans for initiating interviews or examinations of study subjects.

CDC did finally have data on a company level and some on an individual level, but for no companies had all the gaps been filled, so the information was still incomplete. CDC did not comment on the unexpectedly low level of exposures seen in the data, and evinced no skepticism about the viability of the study. OTA did, however. The serious problems still existing led to OTA's recommendation that "no major new phase of the study should be undertaken before the new design and exposure assessment method are found acceptable."

Dr. James Mason, Director of CDC, wrote to the committees on January 6, 1986, responding to OTA's assertions. About exposure assessment, the letter states:

> We have a model for assessing exposure/nonexposure for persons selected...This is one of the most comprehensive models for possible exposure to an environmental contaminant thus far devised. What remains to be done is to develop methods of record reviews to locate as accurately as possible the placement of these men on each day they were in Vietnam.

The letter also stated that the design changes noted by OTA had been presented to the AOWG Science Panel and that the Science Panel "supported the design changes." It goes on to say, "We are currently preparing a more extensive statement, as requested by OTA, which we believe will clarify and substantiate the design change." The report was to be submitted to OTA "in time for a March-April 1986 review." The letter clearly states CDC's intent to proceed with the interviews as planned, continuing for at least three

months, but stopping short of performing physical examinations, which would be scheduled for late May or June 1986. To quote, "It is at that point that the study can be aborted if available information is inadequate to distinguish between nonexposed and exposed Vietnam veterans."

Both the House and Senate Veterans' Affairs Committees responded to Dr. Mason's letter with letters to HHS Secretary Bowen (January 10, 1986) expressing their concerns about the study. Both letters stated that, by law, no new major phase of the study could go forward until a protocol, including a method of exposure assessment, was approved by OTA. The letter from the Senate stated that interviews should not be conducted until such time as a protocol was approved. While CDC based its decision to go ahead with interviews on fiscal considerations, the Congress voiced its concern about "the implications of interviewing subjects for the study only later to advise them that the study is not going forward." Such an action could be interpreted as an attempt to cover up early findings. To quote again, "Such a result would be particularly unfortunate and undesirable." In response to the Committees' letters, further interviewing was not carried out. We do not know how many interviews actually took place.

At the same time that letters were sent to Secretary Bowen, the Senate Committee wrote to the President, reminding him of his responsibility, as laid out in PL 96-151, of assuring that "studies of the Federal Government with respect to adverse health effects in humans of exposure to dioxins are scientifically valid and conducted with efficiency and objectivity."

To date, OTA has not received a new protocol for the Agent Orange study from CDC. The major activity that we are aware of is the undertaking of the AOWG and ESG in assembling a set of complete location data for the study period for 7 combat battalions, and examining the potential use of the data,

along with information about Agent Orange applications, to identify individuals with high and low probabilities of Agent Orange exposure. OTA was not directly involved in this activity, which was undertaken by a subpanel of the AOWG Science Panel, under the chairmanship of Dr. Young, the representative from the Office of Science and Technology Policy. The first official OTA involvement came at the time of the Science Panel review of the Subpanel report, in our role as observer. We have not received the report officially, and our advisory panel has not met to discuss it. I believe, also, that the report has not yet been made a public document. It is therefore inappropriate for me to comment on the substance or recommendations contained in that report.

OTA's most recent involvement came in the form of a June 26 letter from HHS Under Secretary Donald Newman, chair of the AOWG. That letter requested OTA's permission for CDC to prepare a protocol for a validation study to explore a possible correlation between dioxin in blood with a records-based definition of Agent Orange exposure. OTA Director Gibbons responded (July 11) by stating that "OTA's statutory role is limited to approving protocols and monitoring the conduct of studies" under the mandates of PL 96-151 and 97-72. OTA does not have the authority to grant such approval. To my knowledge, CDC has not been prohibited from preparing such protocols, only from embarking on the studies themselves without protocol approval.

Thank you for the opportunity to report on OTA's mandated activities related to exposure assessment for the Agent Orange study. I will be happy to answer any questions you may have.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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FOR RELEASE ONLY UPON DELIVERY

Testimony of

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Director, Centers for Disease Control
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

before the

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON VETERANS AFFAIRS

SUBCOMMITTEE ON
HOSPITALS AND HEALTH CARE

Hon. Robert Edgar, Chairman

Thursday, July 31, 1986

9:00 a.m.

Room 334, Cannon House Office Building

INTRODUCTION

Good morning, Mr. Chairman, I am Dr. James O. Mason, Director, CDC. I am honored to be here to represent Secretary Bowen and Under Secretary Newman, who is Chairman of the Domestic Policy Council Agent Orange Working Group (AOWG). I welcome this opportunity to appear before the Subcommittee to describe the progress of studies of the health of Vietnam veterans being conducted by the Centers for Disease Control (CDC) especially the status of the Agent Orange Exposure study.

With me this morning are Mr. Ed Weiss who is here as acting Executive Secretary of the AOWG; Dr. Vernon Houk, Director of CDC's Center for Environmental Health; and Dr. Carl Keller, who has served as Chairman of the Agent Orange Science Panel.

BACKGROUND

Public Laws 96-151 and 97-72 directed the Veterans Administration (VA) to conduct investigations of Vietnam veterans' health. The first of these laws, signed in January 1979, dealt with the health effects of veterans' exposure to Agent Orange. The second, signed in November 1981, expanded the scope of the study to allow for the inclusion of other environmental hazards associated with service in Vietnam. CDC was assigned responsibility for design and conduct of the studies in January 1983 by an Interagency Agreement with the VA.

In May of 1983, CDC completed and submitted a draft research protocol for scientific review and comment by four groups: the Office of Technology Assessment (OTA), the Science Panel of the Agent Orange Working Group (AOWG), the HHS Advisory Committee on Special Studies Relating to the Possible Long Term Effects of Phenoxy Herbicides and Contaminants (the "Ranch Hand Panel"), and CDC's own independent Ad Hoc Review Panel.

The format for these studies was published in November 1983. It incorporated modifications suggested by the scientific reviewers and included three independent but related studies that together comprise the Agent Orange Projects. These studies are:

1) The Vietnam Experience: a study of the long-term health effects of military service in Vietnam, including reproductive effects.

2) The Agent Orange: a study of the long-term health effects of exposure to herbicides in Vietnam.

3) The Selected Cancers: a study to determine the risks of specific cancers among Vietnam veterans.

These three studies represent a comprehensive approach to evaluating the health of Vietnam veterans.

The Office of Management and Budget (OMB) gave preliminary approval for conduct of the studies in May 1984. By August CDC awarded the first of what would eventually be 15 major contracts for data collection. The first health interviews of Vietnam veterans --a test of systems to identify, locate, and collect data for the Vietnam Experience Study-- were begun in September 1984.

Data collection for the Vietnam Experience and the Selected Cancers studies were begun on the effective date of OMB's final approval in January 1985 and are continuing. Data collection for the Agent Orange exposure study was originally planned to begin in January 1986 but has been put on hold. I will briefly provide information on how the Vietnam Experience and the Selected Cancers studies are proceeding before reviewing the Agent Orange Exposure study in greater detail.

SEQUENCING OF STUDY COMPONENTS

Selection of veterans to participate in the Vietnam Experience study was begun first because identifying men for this study could be accomplished easily. Further work was necessary to establish criteria with respect to herbicide exposure for the selection of participants in the Agent Orange exposure study. The Selected Cancers study follows a separate schedule which does not interact with the other two studies.

Data collection procedures for both the Vietnam Experience and Agent Orange exposure studies were designed to be used by the same competitively selected contractors. This approach was taken because it was less expensive and would ensure the integrity of the study design and uniformity of results. The contractors have recruited and trained professional staffs and purchased equipment to conduct extensive health interviews and medical, psychological, and laboratory examinations of participants. The contracts were based on the premise that, as the last of the interviews and examinations of Vietnam

Experience study participants were being completed, the first Agent Orange exposure participants would have been identified. Thereby the interview and examination phases of both studies would continue essentially without interruption.

The delay in starting the Agent Orange exposure study has not had any direct effect on the Vietnam Experience and the Selected Cancers studies. Both have been proceeding on schedule.

STATUS OF THE SELECTED CANCERS STUDY

The Selected Cancers study will determine if Vietnam veterans are at increased risk of developing certain cancers which have been identified in the scientific literature as possibly associated with industrial or occupational exposure to phenoxy herbicides and their dioxin contaminant. The cancers are: lymphoma, soft tissue sarcoma, nasal and nasopharyngeal cancer, and primary liver cancer. This case-control study was proposed because the sample size of the two cohort studies is not large enough to provide answers about these relatively rare cancers. The cases are those reported from December 1984 through November 1988 to eight tumor registries. The controls are selected through a random digit dialing process. As cases and controls are identified, it is not known whether they are military veterans and, if they are veterans, whether they served in Vietnam.

Data for the Selected Cancers study will be collected from approximately 2000 cases and 1300 controls. As of June 30, 1986, data have been collected from 552 cases and 357 controls. The collection of data on new cases as they occur is proceeding on schedule and the ascertainment of new cases will continue until November 1988. Therefore, the conclusions of this study are planned to be published in 1989.

STATUS OF THE VIETNAM EXPERIENCE STUDY

The Vietnam Experience study was designed to evaluate possible health effects of the overall Vietnam "experience" by comparing the health status of a cohort of male U.S. Army veterans who served in Vietnam with a cohort of male U.S. Army Vietnam-era veterans who served elsewhere. This study examines a wide range of health outcomes (e.g., psychological, neurological, medical, etc.) and has three substudies: a mortality assessment, a health interview, and a medical examination. I will briefly describe the status of each of these.

Mortality Assessment

The Mortality Assessment study investigates the causes of death of 446 veterans who were among the 18,313 men selected as participants but were found to have died after leaving active military service. CDC has received and reviewed death certificates and other reports covering 437 (98 percent) of these deaths. The collection of these data was completed in April of this

year. Analysis of these data is currently underway. A report of the findings from the Mortality Study is being peer reviewed and is expected to be published this fall.

Health Interviews

The first part of the data collection phase of the Vietnam Experience study —the health interviews— has been completed on schedule, thanks to the exceptional cooperation of individual veterans and the support of veterans service organizations who have encouraged veterans to participate.

It was a challenge to locate the over 17,000 subjects from among the men CDC selected as candidates for the Vietnam Experience Study almost two decades after most had been discharged from the service. The CDC contractor responsible for tracing and interviewing veterans, Research Triangle Institute, Inc. (RTI) has been successful in tracing more than 92 percent of these veterans, and of the men contacted by RTI for interviews, 92 percent (15,310 veterans) have participated in the study. That is an exceptionally high participation rate.

Medical Examinations

A stratified random sample of 6,452 veterans who have been interviewed were selected for medical examinations and their names given to another contractor, the Lovelace Medical Foundation, Inc. Lovelace has contacted these men and asked each to undergo comprehensive physical and psychological examinations at

their facility in Albuquerque, New Mexico. In participating a veteran agrees to interrupt his life for several days of travel, tests, and examinations. As of July 9, Lovelace had completed examinations of 4,048 veterans, and another 497 have been scheduled to be done between now and the end of September. Then this phase of data collection for the Vietnam Experience study will be completed.

The community of veterans has also been extremely cooperative during this more personally demanding medical examination phase. The more than 4,500 examinations already completed or scheduled represent just over 70 percent participation by veterans contacted by Lovelace. Considering the investment in time and effort required by participating veterans, we think this is an excellent response.

One goal of this phase of the data collection process has been to ensure that the experience is as pleasant and "hassle free" as possible for the veterans. The contractor has asked each participant to evaluate every step of the examination process; from travel arrangements and hotel accommodations, to how they feel that they have been treated by medical and support staffs. The veterans' evaluations have been very positive: over 90 percent have rated the overall experience as "excellent." A member of the COC Agent Orange Project staff is on permanent assignment in Albuquerque to work with the contractor.

Findings from the health interview and the medical examination will be published simultaneously and are currently planned for May 1987.

STATUS OF THE AGENT ORANGE EXPOSURE STUDY

The Agent Orange Exposure study was designed to evaluate possible health effects of exposure to Agent Orange herbicides by comparing the health of an exposed cohort of male U.S. Vietnam veterans with an unexposed cohort. The two cohorts should differ in their exposure to herbicides in Vietnam while all other health risk factors remain constant. Existing military records—developed many years previously for military purposes— are all there is available to separate individuals into a cohort who were most likely heavily exposed to these agents and into a cohort who were most likely to have been unexposed. In the original approved study protocol, numerous problems were identified regarding the categorization of veterans with respect to herbicide exposure. The protocol indicated that since the proposed categorization procedures were untested, verification through pilot testing would be needed before a final decision to proceed with the full scale study could be made.

The U.S. Army and Joint Services Environmental Support Group (ESG) has worked diligently and effectively in abstracting location data to identify potentially exposed and unexposed individuals for inclusion in the study. Using this information, CDC prepared and submitted to the Office of Technology Assessment (OTA), two reports on exposure assessment and for the Agent Orange Exposure study, one in February 1985 and another in November 1985. These reports indicated that it was possible to identify relatively few veterans with probable heavy exposure using information available to ESG. Initially, however, before the military records were evaluated, it had been anticipated

that the difficulty would be in finding unexposed individuals. This exposure assessment problem led CDC to consider treating exposure as a continuous variable; however, this idea was rejected after review by the Agent Orange Working Group (AOWG) Science Panel and OTA. OTA recommended that the initiation of the Agent Orange Exposure study be delayed until a totally revised study protocol was developed and approved. The problem, however, is defining a reliable exposure index when data are not sufficiently detailed or nonexistent. CDC has revised the protocol with the exception of those portions relating to selecting the study cohorts.

Let me emphasize that the difficulties in assessing exposure are related to the scope and the content of the military records, not the manner in which these military records were abstracted by ESG. The records were designed for military purposes not for the purpose of doing epidemiologic studies. All available information from military records is being used and was abstracted appropriately by ESG.

Beginning in January 1984 and continuing until just weeks ago, an intensive effort to separate exposed from unexposed veterans has been underway by the ESG, the Science Panel of the AOWG, and CDC; the conclusion of this effort is that by using military records alone, it is not possible to distinguish between exposed and unexposed cohorts. Records indicate that only a small proportion of men in the seven pre-test battalions had a likelihood of significant exposure to recorded Agent Orange sprays. A Subpanel of the Agent Orange Science Panel was established specifically to look at these issues.

The recommendation of the Subpanel was that "Any study of ground troops which is dependent upon military records for the ascertainment of exposure to herbicides, not be conducted without an additional method to verify exposure." The basis for this recommendation was that the pilot study confirmed a potential for considerable misclassification of an individual's exposure to herbicides or dioxin as estimated from the military records alone.

Two issues were specifically confirmed by the pilot study as influencing the degree of misclassification.

- Unit dispersion – On a substantial number of days, personnel in combat units eligible for the study were not located together as a unit; rather they were dispersed geographically up to 20 kilometers that same day.

- Incomplete spray records – Expert opinion suggested that an unknown but apparently large proportion of fire-base perimeter spray operations were never recorded and the degree to which these unrecorded operations may have influenced exposure is unknown. The record of aerial sprays, i.e., the Ranch Hand missions on the so-called HERBS Tapes, are thought to be complete and without question.

CDC has suggested a method for verifying whether exposure to dioxin actually occurred in a cohort of Vietnam veterans classified as potentially exposed to Agent Orange by military records. This verification would compare the actual level of 2,3,7,8-tetrachlorodibenzodioxin (TCDD) found in veterans' fat or blood with the military record exposure estimate. Using these fat samples in conjunction with military records had been considered and rejected in 1983 during the development of the original protocol because of these factors:

- At that time it was believed that the half life of residual dioxin in previous exposed persons was too short (about 1 year) to be of use in a study done 15 or 20 years after exposure.

- The estimation of body burdens would require the use of fatty tissue for analysis. Twenty grams of fat, or a specimen about the size of a man's thumb, were required. It was not felt feasible to use this procedure in a large number of veterans because a surgical procedure was required.

Recent evidence indicates a much longer half life of dioxin in man. It is now known to be more than 5 years, so a study done 15 years after exposure (2-3 half lives) would still be able to detect residual dioxin in those who had been highly exposed. In addition, recent advances in technology indicate that it may now be possible to measure TCDD levels in blood rather than fat. CDC has been independently evaluating a method for measuring TCDD levels in blood. This evaluation will correlate TCDD levels in fatty tissue and in

blood in individuals with little or no exposure and those with high levels of exposure to TCDD. The evaluation of the blood/fat level relationship will be completed and peer reviewed by September. If there is a correlation in this relationship, it may be possible to conduct a validation study to determine whether military records can be used to produce the two cohorts necessary for a scientifically sound Agent Orange Exposure study. Again, if the correlation is positive, CDC and ESG will develop a protocol for this validation. It is expected that the protocol, its review and final action by AOWG and OTA, will be completed by the end of this year.

If the validation study indicates that it is scientifically possible to separate exposed from unexposed veterans, then the method for identification of the two cohorts will be included in the Agent Orange Exposure study protocol to be evaluated by OTA and AOWG. An Agent Orange exposure study cannot be done if the validation study demonstrates that it is not possible to use military records to identify exposed from unexposed veterans.

The budget is the final area I will address. The total in-house costs for FY 1983-1986 for personnel, equipment, etc. are approximately $11.5 million which have been allocated across the three studies. This figure is an estimate since FY 1986 is not yet complete. The contractual costs/obligations are broken down by the specific study. The vast majority of the contractual obligations were made in FY 1984 when the funds were made available. For the Selected Cancers Study, the total contractual obligations to date are approximately $4.3 million; the Vietnam Experience study contractual

obligations are approximately $17.3 million; and the contractual obligations for the Agent Orange Exposure study are about $26.0 million. These funds for the Agent Orange Exposure study have not yet been spent since this component has not yet started. In addition to these costs/obligations, it will be necessary to pay the contractors about $2.0 million for costs associated with keeping the Agent Orange Exposure study on hold through September. It will be necessary to negotiate final settlement costs with the contractors if this study cannot be conducted. All the funds have been provided by the Veterans Administration.

In concluding the summary of CDC's studies, the Vietnam Experience and the Selected Cancer studies are proceeding well and on schedule. The Agent Orange Exposure study's difficulties are due to inability to document exposure from existing military records. Verification of the exposure assessment by blood analysis may make it possible to do a scientifically valid study.

In addition to the ongoing work by the Centers for Disease Control, I should mention that this Administration has committed resources for over ten Federal agencies in addressing health issues of concern to Vietnam veterans. For example, the Veterans Administration has two studies about to be released (their mortality study and their soft tissue sarcoma study) and the U.S. Air Force has just completed another round of physical examinations as part of their continuing Ranch Hand Study. The combined efforts of these agencies under the guidance of AOWG represent an extensive commitment to resolving the health concerns of Vietnam veterans.