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AGENT ORANGE: STATUS OF THE AIR FORCE RANCH HAND STUDY

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

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AGENT ORANGE: STATUS OF THE AIR FORCE RANCH HAND STUDY

WEDNESDAY, MARCH 15, 2000

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10:05 a.m., in room 2247, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Lee, and Sanders.

Also present: Representative Evans.

Staff present: Lawrence J. Halloran, staff director and counsel; Robert Newman, professional staff member; Jason M. Chung, clerk; David Rapallo, minority counsel; Ellen Rayner, minority chief clerk; and Earley Green, minority assistant clerk.

Mr. SHAYS. Good morning, I would like to call this hearing to order.

This week saw the first visit to Vietnam by a U.S. Secretary of Defense since the war ended. While there, Secretary Cohen cited our "absolute, sacred obligation" to persist in the search for those still missing in action, those long remembered but too long unaccounted for.

The same obligation to those who fought brings us here this morning. The search for long latent illnesses associated with exposure to herbicides in Vietnam demands the same persistence, the same integrity, the same willingness to confront hard truths.

Eighteen years ago, the Air Force began a 25-year, $140 million research program to assess the relative health of 1,300 ranch hands, air and ground crew members who handled and sprayed Agent Orange and other defoliants in Vietnam. The Ranch Hand Study was designed to generate significant scientific data and analysis to be used by the Department of Veterans Affairs [VA], and others in making health care and compensation decisions regarding Vietnam veterans.

But according to a recent study by the General Accounting Office [GAO], requested by our colleague, Representative Lane Evans from Illinois, ranking member on the House Veterans' Affairs Committee, Ranch Hand has been slow to publish findings, unwilling to share data, inconsistent in conveying design limitations, and resistant to congressionally mandated participation by independent parties.

Controversial from the outset, the Ranch Hand study has been consistently criticized for both scientific and administrative shortcomings. Many believe Ranch Hand has so far failed to fulfill its promise as the pivotal longitudinal study of herbicide toxicity. Some conclude it never will. Others believe this research was designed to fail, or manipulated to avoid controversial findings.

Vigilance and independence are needed to resist institutional biases and sustain the pace and rigor of long term research. Today, we ask if the Ranch Hand study meets that test.

It has been said history teaches us the mistakes we are about to make. The history of the Ranch Hand study has much to teach about the mistakes that should not be repeated as the research proceeds, and similar studies are designed for gulf war veterans, anthrax vaccine recipients, and the veterans of future toxic conflicts.

Our witnesses this morning bring a great deal of experience, expertise, and passion to this important discussion. We look forward to their testimony. And we welcome everyone who is here today.

[The prepared statement of Hon. Christopher Shays follows:]

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BERNARD SANDERS, VERMONT
INDEPENDENT

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS,
AND INTERNATIONAL RELATIONS
Christopher Shays, Connecticut
Chairman
Room B-372 Rayburn Building
Washington, D.C. 20515
Tel: 202 225-2548
Fax: 202 225-2382
GROC.NS@mail.house.gov
http://www.house.gov/reform/ns/

Statement of Rep. Christopher Shays
March 15, 2000

This week saw the first visit to Vietnam by a U.S. Secretary of Defense since the war ended. While there, Secretary Cohen cited our "absolute, sacred obligation" to persist in the search for those still missing in action, those long remembered but too long unaccounted for.

The same obligation to those who fought brings us here this morning. The search for long latent illnesses associated with exposure to herbicides in Vietnam demands the same persistence, the same integrity, the same willingness to confront hard truths.

Eighteen years ago, the Air Force began a 25-year, $140 million research program to assess the relative health of 1300 "Ranch Hands," air and ground crew members who handled and sprayed Agent Orange and other defoliants in Vietnam. The Ranch Hand study was designed to generate significant scientific data and analysis to be used by the Department of Veterans Affairs (VA) and others in making health care and compensation decisions regarding Vietnam veterans.

But according to a recent study by the General Accounting Office (GAO) requested by our colleague Rep. Lane Evans (IL), ranking Member on the House Veterans' Affairs Committee, Ranch Hand has been slow to publish findings, unwilling to share data, inconsistent in conveying design limitations and resistant to congressionally-mandated participation by independent parties.

Controversial from the outset, the Ranch Hand study has been consistently criticized for both scientific and administrative shortcomings. Many believe Ranch Hand has so far failed to fulfill its promise as the pivotal longitudinal study of herbicide toxicity. Some conclude it never will. Others believe the research was designed to fail, or manipulated to avoid controversial findings.

Vigilance and independence are needed to resist institutional biases and sustain the pace and rigor of long term research. Today we ask if the Ranch Hand study meets that test.

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Our witnesses this morning bring a great deal of experience, expertise and passion to this important discussion. We look forward to their testimony.

Mr. SHAYS. At this time, I would like to recognize Mr. Sanders, who has really been at the cutting edge of this issue and gulf war illnesses, as well as anthrax. Mr. Sanders.

Mr. SANDERS. Thank you very much, Mr. Chairman.

Let me begin by applauding the chairman for holding this hearing and for saying that he and I and others have been working for a number of years on gulf war illness and on other veteran issues. And for people who think that we are going to disappear and go away and give up the fight, they are wrong. We are going to stay with it, no matter how long it takes to get justice for American veterans.

Agent Orange, as I think everybody knows, is one of the most toxic chemical compounds that has ever been invented. According to Jacqueline Veret of the FDA, it is "100,000 times more potent than thalidomide as a cause of birth defects in some species."

There are many veterans, there are many Members of Congress, there are many Americans who believe the Department of Defense and the Veterans Administration have been less than candid about the health effects that Agent Orange has had on them and on veterans' children. While the Government has acknowledged that some illnesses the Vietnam veterans developed are associated with Agent Orange exposure, and that these vets can receive disability benefits, many veterans believe that the health problems associated with Agent Orange are far more serious and widespread than the Government has acknowledged up to this point.

Also, many veterans believe that the VA and the DOD have been less than effective in developing an outreach program which informs veterans about what benefits they might be entitled to from VA relating to Agent Orange exposure and how they might access those benefits.

In other words, there are two issues. One is the scientific study to determine what health problems are associated with Agent Orange exposure. But the next issue, equally important, is that once you have developed those conclusions, we have the moral obligation to reach out to the veterans and tell them that if they are suffering from this or that disease, they are entitled to benefits.

And I believe that the record that the VA has established in that regard, of reaching out to veterans, of making them aware of what they are entitled to, has been very, very poor.

Some of you may have noticed recently there was an article in the papers throughout this country where the Government of Vietnam has indicated that approximately 1 million people in Vietnam have been hit with health effects as a result of exposure to Agent Orange. And that should wake us up, in terms of the damage that was done to American soldiers who were over there.

The Ranch Hand study, about which the subcommittee will hear today, was supposed to answer many of the questions and concerns that veterans and those of us who support veterans have about the health effects of Agent Orange. This epidemiological study, which was begun by the Air Force in 1982, has been criticized by many years by scientists, Members of Congress, and the veterans community.

So far the study has cost some $100 million, an astronomical sum of money. And while the study looked at the health effects of

Agent Orange on Air Force personnel who sprayed the herbicide, it will not answer the questions about the health effects of Agent Orange on soldiers on the ground in Vietnam who were exposed to Agent Orange differently, including through the ingestion of it in food, swimming in it in the water, or drinking.

So we are not quite convinced that even that those people, who were most exposed to Agent Orange have been fully studied. It is beyond my comprehension that with all the resources of the U.S. Government, we have not been able to track down those people who are most exposed and take an objective look at the health problems that they have suffered.

I would point out that in 1984 a lawsuit was settled, and that it was a very controversial settlement, between Vietnam veterans and the wartime manufacturers of Agent Orange, Dow Chemical, Monsanto, Uniroyal, Diamond Shamrock, et al. What was interesting about that settlement, as many of you know, is that over 200,000 veterans received compensation from the chemical companies for harm resulting from Agent Orange exposure. Meanwhile, and this is an important point, to date according to the VA's own figures only about 7,500 veterans have received service-connected disability compensation from the U.S. Government.

While we acknowledge that the standards were different, I think it should give us some pause for thought as to how 200,000 veterans could get some compensation from the chemical companies, and after all of these years only 7,500 veterans have gotten disability benefits from the Government.

Mr. Chairman, let me conclude by once again thanking you. I look forward to hearing the testimony of our witnesses.

Mr. SHAYS. I thank the gentleman very much.

At this time, I would ask if Lee Terry from Nebraska would have any comments he would like to make?

Mr. TERRY. No, thank you.

Mr. SHAYS. Let me take care of some housekeeping first, and ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record and the record remain open for 3 days for that purpose. Without objection, so ordered.

I ask further unanimous consent that all witnesses be permitted to include their written statements in the record. Without objection, so ordered.

I would ask unanimous consent to insert a statement from James G. Zumwalt, son of the late Admiral Elmo Zumwalt, who long advocated Agent Orange research. He has eight points to make, and we will insert that in the record. We might share some of it later today. Without objection, so ordered.

I will recognize our first panel. It is wonderful to have you gentlemen here. We have Kwai Chan, Director, Special Studies and Evaluations Group, General Accounting Office; accompanied by Mr. John Oppenheim, Assistant Director, National Security International Affairs Division, General Accounting Office; and Dr. Weisueh Chiu, Project Manager, Agent Orange Study, National Security International Affairs Division from the same office.

Gentleman, I would ask you to rise to swear you in, as we always do.

[Witnesses sworn.]

Mr. SHAYS. I would like the record to note that all three of our witnesses have responded in the affirmative.

It is my understanding, Mr. Chan, that you will have the testimony and that you will be assisted by your able colleagues in responding to questions. Thank you.

STATEMENTS OF KWAI-CHEUNG CHAN, DIRECTOR, SPECIAL STUDIES AND EVALUATIONS, NATIONAL SECURITY AND INTERNATIONAL AFFAIRS DIVISION, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY DR. JOHN OPPENHEIM, ASSISTANT DIRECTOR, NATIONAL SECURITY INTERNATIONAL AFFAIRS DIVISION, GENERAL ACCOUNTING OFFICE; AND DR. WEIHSUEH CHIU, PROJECT MANAGER, AGENT ORANGE STUDY, NATIONAL SECURITY AND INTERNATIONAL AFFAIRS DIVISION, GENERAL ACCOUNTING OFFICE

Mr. CHAN. Thank you. Mr. Chairman, members of the subcommittee, it is my pleasure to be here today to discuss the findings of our report examining the Air Force's ongoing Ranch Hand study. This study is one of the most expensive and in depth studies of the long-term health of a small group of Vietnam veterans. Many have described the Ranch Hand study as the definitive health study of Vietnam veterans exposed to herbicides such as Agent Orange.

Before I discuss our findings, let me first provide some background and context surrounding this study. During the Vietnam war, the United States sprayed millions of gallons of herbicide, including Agent Orange, over Vietnam. In the late 1970's, concerns began to emerge over the long-term health problems of the veterans. Although they could have been exposed to many potential hazards, including herbicides, pesticides and infectious diseases, attention focused on herbicides. Several herbicides, including Agent Orange, contain the chemical dioxin. This chemical is known to cause a variety of adverse health effects in animals, but its effects in humans remain controversial.

The Ranch Hand study follows the health and mortality of the so-called Ranch Hands, the almost 1,300 Air Force personnel who sprayed herbicide from the air in Vietnam. The 25-year study began in 1982 and is scheduled to end in fiscal year 2006. It costs over $100 million in then-year dollars to date, and it's projected to cost a total of $140 million by its conclusion.

Since its inception, the Ranch Hand study has been very controversial. Initially, many reviewers expressed concern that the public would not consider this study credible. This was because the Air Force, which conducted the spraying of herbicides in Vietnam, was also given the responsibility to conduct the study. These concerns about the appearance of conflict of interest led to the inclusion of several safeguards intended to ensure scientific rigor and objectivity. Among these measures was the establishment of an advisory committee of outside experts who were responsible for providing independent scientific review.

The Ranch Hand study is one of the few ongoing studies of the health effects of herbicides in human populations. This is of particular importance with regards to the process for determining

whether Vietnam veterans can receive disability compensation for health conditions associated with herbicide exposure. Because, when making compensation decisions, the Department of Veterans Affairs places primary importance on evidence of adverse health from human studies, not on evidence from animal or laboratory studies.

Let me now discuss our key findings. First, though there were high expectations that the Ranch Hand study would help resolve health questions surrounding herbicide exposure, we found that the study has had limited impact on veterans compensation decisions. The most significant impact of the Ranch Hand study so far has been on a decision in 1996 to provide compensation to Vietnam veterans' children born with the birth defect spina bifida. The study has not contributed either positively or negatively to decisions to compensate for any other diseases.

Currently, the Department of Veterans Affairs has recognized a total of 10 diseases, including spina bifida, for which Vietnam veterans can receive compensation.

The study has also led to increased discussion and further study of the association between herbicide exposure and diabetes. This was first reported by the Ranch Hand study in 1991, but currently Vietnam veterans with diabetes are not eligible for compensation.

Let me turn to the implementation of the study. Although the Air Force has conducted many aspects of the study vigorously, we found several past and ongoing problems. Though many of these problems have been resolved, they have led critics to raise questions about the openness and credibility of the study. The problems we found are as follows.

First, delays have occurred in the dissemination of some important study results. For example, although the Ranch Hand study has reported its results periodically in official Air Force reports starting in 1983, publications of the study's health findings in peer-reviewed scientific journals did not begin until 1990.

Also, a key update to the study findings on reproductive outcomes and birth defects was delayed for 8 years and not released until 1992. This was because the Air Force conducted additional data verification and analysis without releasing any interim information. We found that the degree of verification was highly unusual and virtually unprecedented for a study of its size.

Second, public access to data remains limited. Currently, the public can only access the 1987 physical examination data which was released in 1995. Data from 1982, 1985, 1992, and 1997 have not been released.

We recommended in our report that the Air Force establish and publicize a timetable for the release of all study data and release the data through a medium that is easily accessible to the general public. The Air Force concurred with our recommendation. They have since posed a timetable for the release of study data on their website. In addition, they are investigating ways to release the data in a more accessible format.

Third, communication of key study limitations by the Air Force has been inadequate. The study has difficulty detecting increased risk of rare diseases, including many forms of cancer. This is because of the relatively small size of the Ranch Hand population.

Furthermore, the study's findings cannot be generalized to all Vietnam veterans. This is because the Ranch Hands and ground troops were exposed to different levels of herbicide in Vietnam in different ways. For instance, while Ranch Hand appear to have been exposed to herbicide primarily through skin contact, ground troops report exposure through contaminated food and water, as well as contaminated clothing worn for extended periods of time. Little is known about the potential impact of these differences.

Despite these limitations, early study press releases and executive summaries contained language that may have been misinterpreted to mean that the study showed herbicide were safe. More recent press releases and executive summaries still do not clearly communicate the study limitations to the public.

We recommended in our report that the Air Force include more information on the study's limitations in its press releases and executive summary. The Air Force concurred with our recommendation.

Fourth, in the early years of the study, two measures intended to ensure that it was conducted independently and without appearance of bias were not carried out as planned. One of these measures, specified in the study's protocol, was that the Air Force scientists in charge of conducting the study have primary responsibility over the scientific aspects of the study. However, in 1984 and 1985 the Air Force management and the White House tried to direct certain aspects of the Air Force scientists' research.

In addition, the protocol specified that the study's advisory committee include scientists nominated by veterans organizations. However, the committee did not include veterans' representatives until 1989.

Finally, the advisory committee's outreach to veterans is still an issue. Better notification of committee meetings and vacancies would help ensure that veterans groups perceive the committee as fulfilling its role as an independent and unbiased oversight body. The Food and Drug Administration concurred with our recommendation and stated that it has begun to work to ensure that veterans organizations are notified of the committee's activities in a timely manner.

Mr. Chairman, this concludes my statement. Thank you.

[The prepared statement of Mr. Chan follows:]

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at 10:00 a.m.
Wednesday,
March 15, 2000

AGENT ORANGE

Persisting Problems With Communication of Ranch Hand Study Data and Results

Statement of Kwai-Cheung Chan, Director,
Special Studies and Evaluations,
National Security and International Affairs Division

GAO/T-NSIAD-00-117

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the findings of our report examining the Air Force's ongoing Ranch Hand study,[1] an expensive and in-depth epidemiological study[2] of Vietnam veterans. The study was designed to investigate whether exposure to herbicides, including Agent Orange,[3] in Vietnam led or would lead to adverse health effects. The study follows the health (morbidity) and mortality rates of the so-called Ranch Hands—the almost 1,300 Air Force personnel who sprayed herbicides from the air in Vietnam.

Since its inception in 1982, the Ranch Hand study has been controversial. Initially, official government and nongovernment reviewers of the study's design expressed concern that the public would not consider the study credible because the Air Force, which conducted the spraying of herbicides in Vietnam, would also conduct the study. Because of these concerns about the appearance of conflict of interest, the design of the study protocol included several safeguards intended to ensure scientific rigor and objectivity. Among these measures was the establishment of a monitoring group, which currently consists of an Advisory Committee (administered by the Food and Drug Administration) responsible for providing independent scientific review.

Our testimony today summarizes the results of our investigation of the Ranch Hand study. We assessed (1) what impact the study has had on veterans' compensation decisions and (2) how the study disseminated results and data, communicated its limitations, and implemented measures to ensure that it was conducted with scientific independence and appropriate outside scientific oversight.

The extent to which most Vietnam veterans were exposed to herbicides is not well known, and one reason the Ranch Hands were selected for the study was that the Air Force believed that they were heavily exposed to herbicides. The study compares the Ranch Hands with a comparison group of Air Force personnel who served in Southeast Asia but who were not involved in the spraying. The comparison group was matched to the Ranch Hands in terms of age, race, and military occupation. Results of the

[1] *Agent Orange: Actions Needed to Improve Communications of Air Force Ranch Hand Study Data and Results* (*GAO/NSIAD-00-31*, Dec. 17, 1999).

[2] A scientific study of the incidences, distribution, or control of diseases in human populations.

[3] Several herbicides, including Agent Orange, contain the chemical 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin. This chemical, often referred to as dioxin, is known to cause a variety of adverse health effects in animals.

study, along with those of other scientific studies of veterans and other populations, are used by the Department of Veterans Affairs to determine whether veterans are eligible to receive disability compensation for conditions believed to be connected to service in Vietnam.

Summary

To date, the Ranch Hand study has had limited impact on decisions affecting veterans' compensation. Its most significant impact so far has been on a decision by the Department of Veterans Affairs to provide compensation to Vietnam veterans' children born with *spina bifida*,[4] but it has not contributed either positively or negatively to decisions to compensate for any other diseases. The study has also led to increased discussion and further study of the association between herbicide exposure and diabetes, an association that was first reported by the Ranch Hand study in 1991. Currently, Vietnam veterans with diabetes are not eligible for compensation. The relatively small size of the Ranch Hand population limits the study's ability to detect increases in risks of rare diseases, including many forms of cancer.

Although the Air Force has conducted many aspects of the study rigorously, we found several past and ongoing problems, including delays in the dissemination of some results, limited public access to detailed data, inadequate communication of the study's limitations, failure to implement some measures to ensure rigor and independence, and insufficient outreach to veterans. Though many of these problems have been resolved, they have led some critics to question the openness and credibility of the study.

In our December 1999 report, we recommended several actions to improve the communication of study results and data. Both the Air Force and the Food and Drug Administration agreed with our recommendations and indicated they were taking steps to address them.

Background

The Ranch Hand study is one of the few ongoing studies of the health effects of herbicides on human populations. This is of particular importance because when it makes compensation decisions, the Department of Veterans Affairs places primary importance on evidence of an association between herbicide exposure and adverse health in humans, not on evidence of adverse health from animal or laboratory studies. The Ranch Hand study is also important because relatively high exposure to a

[4] *Spina bifida* is a birth defect in which the vertebral column (backbone) fails to close, possibly allowing herniation of the spinal cord.

substance may be necessary in order for a scientific study to detect adverse health effects. The 25-year Ranch Hand study, which began in 1982 and is scheduled to end in fiscal year 2006, has cost over $100 million so far and is projected to cost a total of over $140 million. To date, the Air Force has conducted all scheduled phases of the Ranch Hand study, including up to five full physical examinations of each participating member of the Ranch Hand and comparison groups. It has periodically reported study results in official Air Force reports.

In 1984, and again in 1991, Congress revised the process used by the Department of Veterans Affairs to determine whether Vietnam veterans are eligible to receive compensation for health effects from exposure to herbicides.[5] Since 1991, the Department has been required to contract with the National Academy of Sciences to perform reviews of scientific literature, including published reports from the Ranch Hand study, on the association between diseases and herbicide exposure. Largely on the basis of these reviews, the Department determines which diseases show a positive association between herbicide exposure and the disease. Vietnam veterans with such diseases are then eligible for disability compensation.

Study Has Had Limited Impact on Compensation Decisions

The most significant impact of the Ranch Hand study to date has been on the Department of Veterans Affairs' decision to provide compensation to Vietnam veterans' children with the birth defect *spina bifida*. On the basis of Ranch Hand birth defects findings, released in a report in 1992 and published in a scientific journal in 1995, the National Academy of Sciences decided in 1996 to upgrade its evaluation of evidence for association between herbicide exposure and *spina bifida* in Vietnam veterans' children. Subsequently, the Department of Veterans Affairs requested, and Congress approved, legislation allowing the Department to provide compensation to Vietnam veterans' children with the disease.

In part because of its statistical limitations, the study has not contributed either positively or negatively to the Department's decisions concerning compensation for any other disease, including nine (in addition to *spina bifida*) for which Vietnam veterans are currently eligible to receive compensation.[6] The study's relatively small sample size provides limited

[5] P.L. 98-542 (1984) and P.L. 102-4 (1991).

[6] The 10 diseases for which veterans are currently eligible for compensation benefits are: chloracne, Hodgkin's disease, multiple myeloma, non-Hodgkin's lymphoma, prophyria cutanea tarda, respiratory cancers (lung, bronchus, larynx, and trachea), soft-tissue sarcoma, acute and subacute peripheral neuropathy, prostate cancer, and *spina bifida* in offspring.

potential for addressing possible links between herbicide exposure and many forms of cancer. For instance, in order to detect a statistically significant increase in the risk of non-Hodgkins lymphoma (for which veterans can receive compensation), the study would have to find an incidence of the disease among Ranch Hands more than twice as high as among members of the comparison group. A finding of a possible association between herbicide exposure and diabetes was first reported by the Ranch Hand study in 1991. This finding led to further review of the issue by the National Academy of Sciences and further scientific investigation by the Air Force and others.[7] However, the Department of Veterans Affairs has not yet determined whether Vietnam veterans with the disease are eligible for compensation, though in 1999 it did request that the Academy issue an interim report on diabetes, currently due in March or April 2000.

Problems Have Led Critics to Question the Study's Credibility

The Air Force has conducted many parts of the Ranch Hand study in a rigorous manner. But we found that a number of problems experienced early on damaged the study's credibility. Many of these initial problems have been corrected, although some persist. Past problems included delays in and limits on dissemination of study results, limited public access to detailed study data, inadequate communication of study limitations, failure to implement measures to ensure that the study was conducted rigorously and independently, and insufficient outreach to veterans' organizations. Communication of the study's data and limitations and outreach to veterans remain problem areas.

Publication of Study Results and Update of Birth Defects Report Were Delayed

Delays occurred in the publication of morbidity and mortality findings in scientific journals during the study's early years. No journal articles on these findings were published until 1990, even though the first mortality and morbidity reports were issued in 1983 and 1984, respectively, and even though the Advisory Committee had repeatedly recommended that such articles be published in peer-reviewed journals as soon as possible. The importance of publishing journal articles is illustrated by the fact that even though the Air Force's report on reproductive outcomes was released 1992, compensation for veterans' children with *spina bifida* was instituted only in 1996, after a journal article was published in 1995. The pace of journal article publication has increased in recent years.

[7] For instance, the Academy stated in its 1994 report that additional information on characteristics of dioxin metabolism, particularly with regard to total body fat, was necessary to interpret the observed association.

A detailed report on reproductive outcomes was also delayed. Although it reported preliminary findings in 1984, the Air Force did not release the more detailed update until 8 years later, in 1992. The delay was caused by the Air Force's decision to verify birth defects data extensively and to perform additional data analyses without releasing any interim findings. The amount of data verification was highly unusual and virtually unprecedented for a study of this size. Although these additional efforts ultimately strengthened the scientific basis of this portion of the study, the length of the delay and the decision not to release an interim report led to concerns by some veterans and scientists that the study was being purposely delayed to suppress information. One scientist told us that preliminary findings could have been useful for making decisions affecting veterans' family planning or prenatal care. Others stated that earlier reporting might have led to an earlier decision to compensate for *spina bifida*.

Public Access to Study Data Remains Limited

Although the number of published reports has increased in recent years, some scientists and veterans' groups want full and ready access to all the study's data so they can verify the findings and perform additional analyses. However, only a relatively small amount of data is currently available, and its storage format (magnetic tape) is difficult to use. Currently, the public can access only data the Air Force analyzed in 1987 and released in 1995. Air Force officials have told us that they intend to make all other data available by the end of 2000. This should help increase the credibility of the study's results.

Study Limitations Have Not Been Clearly Communicated to the Public

Like all epidemiological studies, the Ranch Hand study has a number of inherent limitations. However, the Air Force has not clearly or effectively communicated these limitations to the public. The study has two major limitations: it has difficulty in detecting low to moderate increases in risks of rare diseases because of the relatively small size of the Ranch Hand population, and its findings cannot be generalized to all Vietnam veterans because Ranch Hands and ground troops were exposed to different levels of herbicides in different ways. Blood measurements of dioxin (a chemical in some herbicides that is known to cause adverse health effects in animals) suggest that the Ranch Hands' exposure levels were significantly higher than those of many ground troops. But ground troops may have been exposed in ways (such as through contaminated food and water) that Ranch Hands were not, and little is known about the potential effects of such differences.

As far back as 1980, a government working group emphasized that the public needed to understand clearly the limitations created by the study's sample size. However, in its first two morbidity reports, the Air Force described the study's lack of findings as "reassuring" because they detected few statistically significant increased risks of disease. The use of such language could have led to the misinterpretation that the study showed herbicides were safe. The Air Force stopped using this type of language in 1990, and while communication of study limitations to the public has improved over the years, additional improvements are possible. The Air Force still reports the study's findings through press releases and executive summaries that do not make the study's limitations clear.

Implementation of Oversight Measures Had Problems

During the study's first several years, two measures intended to ensure that the study was conducted independently and without any appearance of bias were not carried out as planned. The study's protocol (published in 1982) mandated that (1) Air Force scientists, subject to review by an independent scientific monitoring group (the Advisory Committee), have primary responsibility over the scientific aspects of the study and (2) the monitoring group (currently consisting of nine scientists) include scientists nominated by veterans' organizations. These requirements were not fully implemented until 1989. According to documents we reviewed dating from 1984 and 1985, Air Force management and the White House at the time tried to direct certain aspects of the scientists' research. These attempts deviated from the protocol's requirement that Air Force scientists retain primary responsibility over the study's scientific conduct. In addition, the White House's actions bypassed review by the Advisory Committee. Furthermore, the Advisory Committee did not include any veterans' representatives, as required, until 1989.

Problems Remain With Advisory Committee's Outreach to Veterans

Although many early problems were resolved through executive and congressional actions, the Committee's outreach to veterans is still an issue. For example, although the Committee's public meetings are announced in the Federal Register, the Committee has not routinely informed veterans' organizations directly of these meetings. In addition, the Committee's informal process for soliciting nominations has resulted in some interested veterans' organizations not being notified of opportunities to nominate Committee members. Better notification of Committee meetings and vacancies would help ensure that veterans' groups perceive the Committee as fulfilling its role as an independent and unbiased oversight body.

Recommendations

We recommended in our report that the Secretary of Defense direct the Air Force scientists in charge of the Ranch Hand study to establish and publicize a timetable for the release of all study data and release the data through a medium (such as CD-ROM or the Internet) that is easily accessible to the general public. We also recommended that the Air Force include more information on the study's limitations in its press releases and executive summaries of study reports. In particular, we recommended that it provide clear information on the limited applicability of study results to other Vietnam veterans and on the study's limited ability to detect small to moderate increases in risks of rare diseases. The Air Force concurred with our recommendations and indicated that it was taking steps to address them.

In addition, we recommended that the Advisory Committee's Executive Secretary at the Food and Drug Administration provide direct and timely notification to veterans' organizations of scheduled Committee meetings and of opportunities for nominations of Committee members. The Food and Drug Administration concurred with our recommendation and stated that it has begun working to ensure that veterans' organizations are notified of the Committee's activities in a timely manner.

Objectives, Scope, and Methodology

To examine the conduct and findings of the Ranch Hand study, we obtained and reviewed the study protocol, various study memoranda and correspondence, published study reports and peer-reviewed journal articles, executive summaries and Air Force press releases, and other available documents related to the study. In addition, we interviewed Ranch Hand study investigators, Advisory Committee members, Air Force program officials, Department of Veterans Affairs officials, veterans' representatives, and scientists involved in research on the health effects associated with exposure to herbicides and dioxin. We also visited Brooks Air Force Base, San Antonio, Texas, to interview members of the Ranch Hand study team and to review data collection and reporting procedures.

This concludes our formal statement. If you or other members of the committee have any questions, we will be pleased to answer them.

For future contacts regarding this testimony, please contact Kwai-Cheung Chan at (202) 512-3652. Individuals making key contributions to this testimony included Dr. John Oppenheim and Dr. Weihsueh Chiu.

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Mr. SHAYS. Mr. Chan, thank you.

At this time, I would ask Lee Terry if he has any questions.

Mr. TERRY. Thank you, Mr. Chairman.

I want you to expand on the third point of the credibility issues, which was the limitations of the study. And the reason I want to focus on that is because obviously this is an oversight committee. We need to make informed opinions as to the credibility of the study. And obviously, if the limitations are such that the credibility is questioned, then I think we have to ask the question should we continue.

So let us go back to the study and the limitations. You raised a couple of points, but I would appreciate it if you would go over those limitations to the Ranch Hand study and discuss them in a little bit more detail and then I am going to ask some of the follow-up questions.

Mr. CHAN. We raised two points in terms of the—one is that of the sample size and the second is the representativeness of the Ranch Hands themselves. Let me talk about the sample size first.

Basically, the Ranch Hands consist of about 1,300 people, and that's all you have. You are limited by this small population.

Mr. TERRY. And who are those folks?

Mr. CHAN. They are Air Force pilots and ground crews where they handle and sprayed the herbicides in Vietnam. The majority of the spraying was done by this group of people. So in the early stage, it was believed that this is a likely group of people who might be exposed to the herbicide in the greatest quantity-wise, in terms of exposure. The opportunity for exposure is much greater. That is the belief they have.

But the sample size itself, basically what they did is they picked the entire population of the Ranch Hands. And then, because it was a study looking for Agent Orange, the effect of Agent Orange, they picked the control group in various sizes as a ratio of one to five to as many, so that they can replace those people. So currently we have about 1,200 Ranch Hands versus about 1,800 of the control size for comparison.

These people were also in Vietnam doing—in the war, but they were not supposedly exposed to Agent Orange. So the control group is not really sort of like the Vietnam-era veterans who did not go to Vietnam who were never exposed to anything.

Let me clarify that point right away. That's how the comparison is being done.

Mr. TERRY. Is there difficulty, from a scientific point of view, of that being a credible control group for a scientific study?

Mr. CHAN. Let me give you my own opinion then, since we did not address that in our report. In a way, you would love to have three groups. One is those supposedly exposed to the Agent Orange, those who were there and supposedly have not been exposed, and those who never went. Because that one actually would not have any exposure to pesticide, to drinking the water, to taking showers, to eating food and all those things that possibly could affect them, as well.

But the intent of the study is really to look for the affect of Agent Orange, not on anything else. This is not a general health study,

per se. So therefore, the third group was not included in that study. That's the first point.

Now when you have a comparison of 1,300 as the treatment group, it's statistically extraordinary to detect any kind of rare disease where let's say it happens 1 out of 100,000 subjects, once in 100,000 and so on. Because statistically, out of these 1,300, it's very difficult to find these rare diseases, as we stated.

So as a result of that, since you cannot expand the size of this group like an accordion, it's difficult to have rare disease showing up for comparison purposes because of the sample size. I mean, we can go through a statistical way to analyze this, but clearly the larger the sample size, the more likely you would find people with those rare diseases. So that's one problem with it.

The second problem is really that of representativeness. I think in our statement we did say that this is solely represented by the Air Force personnel. They are not the people who were on the ground, such as the Marines, exposed to the spray at the time when they're out in the open as the spraying is being done, or maybe exposed to the dioxin in a different manner than this. There are different medium by which they may have been exposed.

So those are two major problems that we note.

Mr. TERRY. Can you help me work through the latter part, because I am having difficulty understanding. The representatives in this group are just Air Force. You said others that may have been exposed, Marines, are not part of the representative group?

Mr. CHAN. That's true.

Mr. TERRY. But talking about the credibility of the study, whether it is scientifically based, explain to me how that may create some issues of its credibility? Do you understand what I am saying? Just because some of the Marines were excluded, to me it is not clicking why I should be concerned.

Mr. CHAN. It is really the medium of exposure. One clearly is the following, I think, to think of logically. The spraying is done through an aircraft so therefore, the handling of the dioxin of itself, the herbicide. The other way is the soldier may have been exposed while the spraying is going on by our own people. And water could be contaminated where they may be drinking from it or taking showers and so on and intake of food, and so on.

So what I'm saying as well as the possibility of the soldiers, particularly some of them told us they were out there in the jungles for a long period of time where their clothing may be contaminated and they couldn't wash, unlike the pilots. They can finish spraying, go back to their place, and then take a shower and have clean clothing and so on. So there are different ways that you might be exposed to the herbicide. That's what we're saying.

Mr. TERRY. So in this representative group, has the Air Force at least identified the types of exposure that the sample size, the group would have, whether it has been on clothes, from the ground, water, drinking? Have they gone through the steps that you just laid out?

Mr. CHIU. They have investigated, through surveys, different ways in which the ground crew and the pilots were exposed. And they were able to correlate that with measurements of dioxin in those people's blood. They found that most of the exposure from the

Ranch Hands was through handling, bare skin contact, being sprayed in the face when a valve was opened.

I guess my feeling is that the problem with credibility is more in the communication of those limitations not necessarily the fact that they exist. Because all studies will have limitations. Just making sure that you have a balanced communication of what the study can tell you and what it can't tell you. If for instance, we did find some adverse health effect, then you need to make clear whether the finding is more or less representative of other veterans. Especially of negative results. If they don't find anything, then there are limitations as to what that says. That doesn't necessarily mean that something isn't happening in other veterans.

Mr. TERRY. And that is a great point, and that is ultimately the goal of this study. So my question to you is based on the sample size and the representatives in this group. Can we scientifically make conclusions that we can communicate the details that you just stated, Doctor? Or do we question whether we can credibly communicate specifics to various veterans groups or types of representatives that are involved?

Mr. CHIU. I think it is possible to effectively communicate the study's findings and its limitations.

Mr. TERRY. Well, can we rely on those? Reliably? We can communicate anything. It doesn't have to be reliable, as I'm learning in my first 13 months in Congress.

Mr. OPPENHEIM. Mr. Terry, part of the problem, too, is in the early reports that came out of the study. There are some statements in there that, as Mr. Chan mentioned, had the potential to be misinterpreted. Terms such as reassuring were used in one report when no adverse health effects were found.

And I think that gets to the communication issue. The limitations weren't communicated to the public in particular. I think the scientific community recognized the limitations.

Mr. TERRY. And that goes to another issue of how people are going to perceive the study and whether they believe it. That is the next phase, I think, for us. But right now, we have to determine if we find it to be a credible study.

Thank you, Mr. Chairman.

Mr. SHAYS. I thank the gentleman.

Mr. Sanders, you have the floor for 10 minutes.

Mr. SANDERS. Thank you, Mr. Chairman.

Let me begin by asking the panelists, I think most lay people, most citizens, would say spending $100 million to study 1,300 people, and then coming up with the conclusion that the study has not contributed either positively or negatively to the decisions to compensate for any other diseases, that is a hell of a lot of money to be spent. How did they manage to spend so much money with so little results, Mr. Chan?

Mr. CHAN. First of all, it's a 25 year longitudinal study. So if each year you spend an average of a few million dollars, it adds up. And also, the actual physical examination of individuals was extraordinarily detailed and very complete, and it costs money to do that.

Mr. SANDERS. I appreciate that, but $100 million. Do you think that that is—that sounds to me like it is quite inflated. It seems

to me you could do a heart transplant for each of these people for probably less money.

Mr. CHAN. $100 million averages what, about $5 million a year?

Mr. SHAYS. $5.6 million each year.

Mr. CHAN. And these are in then-year dollars, let me say that, too. It's a very detailed scientific endeavor and we are quite impressed with what they've done. But you're right, also, it's very expensive but they expected up front that it would cost this amount of money.

Mr. SANDERS. Let me just switch gears and pick up on a point that Mr. Terry was making, and tell me what I am missing here. Common sense would suggest that those people who were most exposed to Agent Orange might suffer the most serious consequences. That is what common sense would suggest.

We know that there were groups of soldiers who were really in the midst of this thing, who were in the areas that were sprayed for week after week, wearing the same clothes, drinking water. I talked to guys in Vermont, they were drinking the water from the rivers. They were eating food in the area. They were really living in this stuff.

How did the Department of Defense manage not to take a hard look at those people? Would not common sense have suggested let us look at those people who were most exposed and see the health impact that that exposure might have had on them. What is wrong with that approach?

Mr. CHAN. I believe they did consider the other possible candidates for this study and they ultimately dismissed them. I might add that as far back as 1979 GAO issued a report that basically said that the United States ground troops in South Vietnam were an area sprayed with herbicide Orange where we found that Marines to units in sprayed areas can be identified.

Mr. SANDERS. Can be?

Mr. CHAN. Yes, but the Army personnel in the sprayed areas cannot be identified because Army records are incomplete. But 10 of 13 major Army units reviewed, report having Agent Orange in their area of operation. So we do have some ideas of those exposed from our previous studies that we have done, back in 1979. But they did consider and they found that this is the most credible group to study.

Mr. SANDERS. What do you think? Why would we not look at those folks who were most exposed and just, I would be curious to see. I mean, we hear anecdotally what people tell us, my child was born with birth defects, this one died of cancer. That is anecdotal. Why was it so difficult, if we are prepared to spend so much money, why was it so hard to get better information on the epidemiology of those people most exposed, in your judgment?

Mr. OPPENHEIM. Mr. Sanders, when they started planning the study back in the late 1970's, I think there was the belief that this Ranch Hand population was a heavily exposed population. Second, I think there was some logistical concerns. One issue was that the Ranch Hand group was a very defined population and it was a very reachable population. So it was an easy study to—not an easy study, but it was a study which could be developed without too much difficulty and you could reach that population.

Mr. SANDERS. I appreciate that and that is not unreasonable. But tell me your views if somebody would argue that the life experiences and the type of exposure of somebody on the ground, who was wearing the same clothing week after week, was swimming in this stuff, is a different type of exposure. I am not opposed to looking at a group of Air Force people, but it seems to me to be somewhat incorrect to ignore those who were most exposed.

What am I missing in that analysis?

Mr. OPPENHEIM. I think that the other piece of it was that when the Ranch Hand study was started, there was an understanding that there would be other studies conducted at the same time.

Mr. SANDERS. Has that happened?

Mr. OPPENHEIM. Which may have covered the ground troops.

Mr. SANDERS. Has that happened?

Mr. OPPENHEIM. There's been some to a limited extent. There's a Chemical Corps study that the VA is conducting, but it's much smaller and a much less in-depth study, I would say, than the Ranch Hand study.

Mr. SANDERS. Is there any study being done right now involving the health of those people who were most exposed to Agent Orange, to your knowledge?

Mr. OPPENHEIM. I think this Chemical Corps population was another population believed to be heavily exposed, so that's one study.

Mr. SANDERS. What are the results? Do we have any published results on that?

Mr. OPPENHEIM. Help me out a little bit here, Weihsueh.

Mr. CHIU. Not to my knowledge.

Mr. SANDERS. So what kind of study is it, that we do not have any results. The war did not end yesterday, we are a few years down the line.

Mr. CHIU. The Chemical Corps study, Mr. Sanders, was initiated after the National Academy of Sciences recommended that such a study be done in 1993. In the 1980's, there were several other studies done, one of which was the Vietnam Experience study, which studied—basically compared people who went to Vietnam to people who didn't go to Vietnam. There was an attempt to conduct a study relating to exposure to Agent Orange, but the CDC decided, after conducting a pilot study, that they couldn't develop a methodology for exposure assessment. There was some hearings in the late 1980's on that study.

Mr. SANDERS. Mr. Chairman, I would just say, and I am going to get to another question in a moment, that after so many years it really seems to me that the kind of information that we would like is sorely lacking. We have spent a hell of a lot of money, a lot of years have gone by, and I think that we do not have the kind of information that we need.

Let me ask our panelists one other question. Mr. Chan, your report indicates that the VA asked the National Academy of Sciences to evaluate the scientific literature on the association between exposure to herbicides and adult onset diabetes. Based on your review, what do you think the likely result of that review be? Will diabetes be one of the diseases listed as having been caused by Agent Orange?

Mr. CHAN. Let me say that the Air Force Ranch Hand study issued a report in 1991, I believe, and observed this finding in terms of high risk of diabetes for the Ranch Hands. And we were quite impressed that, in fact, it's a rather strong study, if anything, I thought.

But as we stated in our statement, it's still being considered by VA as of today. I really don't know how it's going to come out, to be honest with you. But they plan to issue a report next month, in the year 2000. So I think——

Mr. SANDERS. So in other words, what you are saying is the Ranch Hand study suggested that diabetes might be caused by exposure to Agent Orange but the VA has not done anything with that information?

Mr. CHAN. They've been asked to further review, obtain more information, and so on. The decision has not been made as of today, as to whether the veterans should be compensated for diabetes.

Mr. SANDERS. Just say a word or two on a point that you made, and that is that veterans were concerned that for many years the scientific community and their representatives were not able to get the information. Why did that occur? And what would be the effect of opening up that information to the general population?

Mr. CHAN. As we stated, the only available data that has been given to the public is the 1987 data, and there were total of five sets of data, I think. The Air Force is planning to release the information hopefully by this year, but it's taking a long time. Even the 1987 data was not released until 1995, so it's taking them quite a while.

Mr. SANDERS. Maybe they need more money. Maybe $100 million was not enough.

My last question is recently, on March 3rd, the Vietnamese Government released a report that an estimated 1 million victims of Agent Orange exist in Vietnam. Obviously, that is an unscientific statement, I am sure. But that is a heck of a lot of people in a fairly small country. What might that do to our whole discussion about Agent Orange and the problems that some of our own soldiers have had?

Mr. CHAN. Well, I think from a science point of view, more information is needed to understand this relationship between herbicide and health. I do not know, as you said, it's a very large number of people exposed and with health problems. So whether in fact one can verify that or not. I still see it as a very promising area.

Mr. SANDERS. Then my last question leads us to this point. It would seem that if, in fact, so many Vietnamese are suffering health effects from exposure to Agent Orange, then that is something the United States Government would want to learn about, if for no other reason than to see how it affects American soldiers. Has the U.S. Government done enough to understand the impact of Agent Orange on the Vietnamese people?

Mr. CHAN. I think some private efforts have been devoted to that.

Mr. SANDERS. There was a study done by some Canadians, and the Vietnam Veterans of America have been interested. What about the U.S. Government. Is that not an area that we should be studying, in your judgment?

Mr. CHAN. Yes, I believe so.

Mr. SANDERS. Thank you, Mr. Chairman.

Mr. SHAYS. I thank the gentleman. In my opening statement, I made reference to Lane Evans, who had requested this study, the ranking member on the House Veterans' Affairs Committee, and someone I deeply respect, and a very good friend.

I would like to invite you to make a statement that you would like to make for the record, and this time would be very appropriate.

Mr. EVANS. Thank you, Mr. Chairman. I appreciate your leadership on this issue and I am glad we are holding a joint hearing. I think this is a more economical use of our time, our witnesses' times, so I appreciate that. This may be a rare occurrence in Congress, but I am following my tenant. I am Bernie's landlord, so I hope to do as well as you did, Bernie.

I have had a longstanding interest in the effects of herbicide exposure on veterans and their dependents. I introduced legislation that served as the catalyst for providing compensation to America's veterans from the Vietnam era for conditions arising from herbicide exposure.

I also have worked to ensure that the DOD and the VA make use of existing medical evidence to make the right decisions about what conditions should be service-connected and compensated. We must remain vigilant and your scheduling this important subcommittee hearing, Mr. Chairman, assures me that you are willing to join on this watch.

25 years after the official end of the Vietnam war, veterans are still questioning the effect of their exposure to herbicides, including Agent Orange, which contains the contaminant dioxin on their health. The Ranch Hand study was to lay a scientific groundwork that the Government would use to identify conditions to which veterans might be compensated. It has been the target of much of the criticism in the veterans community and they have been very vocal about it.

Because of the new and ongoing allegations, in the fall of 1998, I requested GAO to examine the Ranch Hand study. As Mr. Chan will attest, GAO found that there are continuing problems with effective communications with our veterans. In addition, many of the valid concerns veterans initially had about the Ranch Hand study still remain.

This January, Senator Tom Daschle and I sent letters to Secretary Shalala of the Department of Health and Human Services, and to Defense Secretary Cohen. I requested that they provide detailed plans to address the problems reported in the GAO report.

Secretary Cohen has indicated that Brooks Air Force Base would make the newest data from the Ranch Hand study available to the Government Printing Office on CD-ROM for a nominal fee, as GAO has recommended. I am happy to provide a copy of this letter, along with Secretary Cohen's response, to your hearing, Mr. Chairman.

I will certainly continue to monitor this issue to assure that interested parties can make use of the complete information. I understand a response from Secretary Shalala is forthcoming.

While I believe that the Ranch Hand study should continue, the long-standing concerns about its integrity must also be quickly and

fully addressed. The bottom line is that veterans want and deserve to be informed about the process and the results of an important study.

Chairman Shays, Ranking Member Blagojevich, I appreciate the opportunity to be with you this morning. Again, thank you for asking me to attend.

[The prepared statement of Hon. Lane Evans follows:]

STATEMENT OF THE HONORABLE LANE EVANS
BEFORE THE
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS
OF THE COMMITTEE ON GOVERNMENT REFORM

HEARING ON "AGENT ORANGE:
Status of the Air Force Ranch Hand Study"
MARCH 15, 2000 at 10:00 AM
2247 Rayburn House Office Building

Mr. Chairman, thank you for inviting me to participate in your Subcommittee hearing today. As you know, I have a long-standing interest in the effects of herbicide exposure on veterans and their dependents. I introduced legislation that served as the catalyst for providing compensation to America's veterans from the Vietnam era for conditions arising from herbicide exposure. I also have worked to ensure that the DOD and VA use existing medical evidence to make the right decisions about what conditions should be service-connected and compensated. We must remain vigilant and your scheduling this important Subcommittee hearing assures me that you are willing to join on this watch.

Twenty-five years after the official end of the Vietnam War, veterans are still questioning the effect of their exposure to herbicides, including Agent Orange, which contains the contaminant, dioxin, on their health. Veterans rightly demanded action and answers about the possible effect of their exposure to herbicides during their military service and have been critical of the seemingly slow and sometimes, insensitive, response from the Federal Government.

The law, which mandates that VA compensate veterans for conditions that are associated with herbicide exposure, requires scientists to determine the conditions with which herbicide exposure during the War could be associated. VA is then to review the medical evidence and the scientists' recommendations and decide for which of these conditions it will compensate veterans on a "presumptive" basis. The Ranch Hand Study, which actually began in 1980 prior to the mandate for service-connected disability compensation, was to help lay the scientific groundwork the government would use to identify conditions for which veterans might be compensated.

The Ranch Hand Study, because of its expense and because of the promise it purported to hold in finding answers, has been a target of much of the criticism

veterans have expressed about the Government's response. In the beginning, many veterans were concerned about the apparent conflict of interest brought about by Air Force scientists conducting the Ranch Hand Study. Advocates have charged that science was influenced by military leaders and Administration officials. They charged that veterans had been given misleading and inaccurate information about the Study and its findings and that there had been unreasonable delays in receiving any information.

Ranch Hand is an on-going research project being conducted to assess the long-term effects of herbicide exposure on veterans' health. It is named for the Air Force veterans who conducted Operation Ranch Hand. This unit was responsible for loading defoliants onto planes and manning the flights that released the aerosolized herbicides. Even though more than a thousand Operation Ranch Hand veterans, plus an equal number of "controls", have participated in the research, this Study is considered too small to draw conclusions about rare diseases associated with exposure to dioxin. It has also been suggested that being exposed to herbicides in aerosolized forms for short time periods may have had different consequences than being exposed to the agents that have contaminated food and water or soaked uniforms over longer periods of time. These limitations have not been well publicized.

At the very least, communications with veterans about the process and results of the Ranch Hand Study have been far from ideal. The Air Force continues to fuel veterans' perceptions that the Air Force is being evasive and that there is an active cover up about how Agent Orange has affected veterans' health, and even the health of their children.

In the fall of 1998, I requested the General Accounting Office (GAO) to examine the Ranch Hand Study. American taxpayers have literally invested millions of dollars in this Study. Ranch Handers and other veterans have donated countless hours to travel, clinical evaluations and medical follow up. Yet there are still many questions about whether Ranch Hand has addressed the key issues it set out to evaluate.

As Mr. Chan will attest, GAO found that there are continuing problems with effective communication with veterans. In addition, many of the valid concerns veterans initially had about the Ranch Hand Study still remain.

This January, Senator Tom Daschle and I sent letters to Secretary Shalala of the Department of Health and Human Services and to Defense Secretary Cohen. We

requested that they provide detailed plans to address the problems reported in the General Accounting Office report. Specifically, we have asked Sec. Shalala to develop an aggressive outreach plan to achieve more participation and opportunities for veterans to monitor the process. We want HHS to make a concerted effort to solicit nominations for vacant positions on Ranch Hand's Scientific Advisory Committee from many veterans' groups that believe they have a stake in the outcome of the Ranch Hand Study and to inform veterans about open meetings of Ranch Hand's Advisory Committee.

We have also called on Defense Secretary Cohen to ensure the Air Force makes its vast clinical database readily accessible to other scientists, veterans and the general public. This will give others an opportunity to examine the Study's finding and a chance to develop and test alternative hypotheses about dioxin exposure. This is necessary to increase the public's confidence in the reported Study findings.

While we have not yet heard from Secretary Shalala, Secretary Cohen has indicated that Brooks Air Force Base will make its latest database from Cycle 4 examinations of the Ranch Handers and their "controls" available through the Government Printing Office on CD-ROM for a nominal fee, as GAO recommended. He also explains that earlier databases have been provided to the National Technical Information Services. While this assertion is true, I understand that these expensive and outdated tapes which contain the other datasets have been extremely difficult to access and manipulate. I will continue to press to ensure that this information is made available to interested parties.

While I will call for quick action to address the problems GAO and others reported, I am not recommending that Defense "throw the baby out with the bath water". This important study must continue, but the long-standing concerns about its integrity must also be addressed quickly and fully. The bottom line is that veterans want and deserve to be better informed about the process and results of this study. Chairman Shays, Ranking Member Blagojevich, I appreciate the opportunity to be here with you this morning. Again, thank you for asking me to attend.

Mr. EVANS. I would like to ask that those letters be part of the record.

Mr. SHAYS. Without objection, so ordered.

[The information referred to follows:]

LANE EVANS
17TH DISTRICT, ILLINOIS

RANKING MEMBER
HOUSE COMMITTEE ON
VETERANS' AFFAIRS

MEMBER
HOUSE COMMITTEE ON
NATIONAL SECURITY

Congress of the United States
House of Representatives
Washington, DC 20515–1317

WASHINGTON OFFICE:
2335 RAYBURN BUILDING
WASHINGTON, DC 20515–1317
(202) 225-5905

DISTRICT OFFICES:
1535 47TH AVE., #5
MOLINE, IL 61265
(309) 793-5760
TOLL FREE: 800-322-6210

261 N. BROAD, #5
GALESBURG, IL 61401
(309) 342-4411

January 21, 2000

The Honorable William S. Cohen
Secretary
Department of Defense
The Pentagon 20301-1155

Dear Secretary Cohen:

The General Accounting Office (GAO) has recently completed a report requested by Representative Evans to investigate recurring problems with the Ranch Hand Study being conducted by the Air Force. As you know, this study is examining the effects of exposure to Agent Orange, other herbicides and their contaminants such as dioxin, on veterans' health.

GAO has reported, among other flaws, that the Air Force has not effectively shared information and data with veterans or other scientists. While this was particularly true during the early years of the study, to our knowledge, the Air Force has still prepared only a few magnetic tapes containing the study data.

The GAO has recommended that the Department of Defense (DOD) make Ranch Hand study data readily accessible to other scientists. It has been specifically recommended that DOD "establish and publicize a timetable for the release of all study data and provisions to release the data in a format (such as compact disc or the Internet) that is easily accessible to the general public".

The Air Force has created a valuable resource containing the wealth of data it has collected from hundreds of veterans. The Air Force plans to make its Ranch Hand data available to the public in 2000. We are certain that you join us in wanting to ensure that this data is readily accessible as soon as possible. Once data is open to external review, other scientists and veterans will be better able to assess its true value.

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Hon. William S. Cohen
January 21, 2000
Page 2

We are sure you will agree that veterans who participated in the Ranch Hand study did so to give scientists the chance to find answers regarding the effects of exposure to dioxin on behalf of all of the veterans with whom they served. We have a responsibility to honor their contribution by making the study data accessible to anyone who might advance the science on Agent Orange exposure and for other meaningful purposes. Science will undoubtedly have many uses for this important resource.

We appreciate your prompt attention to this matter. At your earliest convenience please advise us of the means the Department and the Air Force will use to ensure Ranch Hand study data is readily accessible to the public.

Sincerely,

Lane Evans

LANE EVANS
U.S. House of Representatives

Tom Daschle

TOM DASCHLE
U.S. Senate

LANE EVANS
17TH DISTRICT, ILLINOIS

RANKING MEMBER
HOUSE COMMITTEE ON
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MEMBER
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WASHINGTON OFFICE:
2335 RAYBURN BUILDING
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DISTRICT OFFICES:
1535 47TH AVE., #5
MOLINE, IL 61265
(309) 793–5790
TOLL FREE: 800–322–6210
261 N. BROAD, #5
GALESBURG, IL 61401
(309) 342–4411

January 21, 2000

The Honorable Donna E. Shalala
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Shalala:

The General Accounting Office (GAO) has recently completed a report prepared at Rep. Evans request on recurring problems with the Ranch Hand Study being conducted by the Air Force. This study is examining the effects of exposure to Agent Orange and other herbicides containing contaminants such as dioxin, on veterans' health.

Although the law requires one-third of the scientists appointed to the Ranch Hand Advisory Committee to be nominated by veterans' organizations, this requirement has not always been satisfied. We understand several major veterans service organizations such as the Vietnam Veterans of American and the Disabled American Veterans have never been invited or requested to nominate a scientist to serve as a member of the Advisory Committee. GAO has also reported that veterans were not even adequately apprised of Advisory Committee meetings.

Clearly the intent of the law is for concerned veterans and their representatives to be able to actively participate in the oversight of this important study. Based on the record, the Food and Drug Administration (FDA), which you have charged with ensuring veterans' representation on the Advisory Committee and communicating about open meetings with Ranch Hand's advisors, must improve its efforts to fulfill these responsibilities.

As you are aware, the Ranch Hand Study has been the subject of controversy in part because of problems with communications to veterans, Congress, and other interested parties. Continued problems with communication

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Hon. Donna E. Shalala
January 21, 2000
Page 2

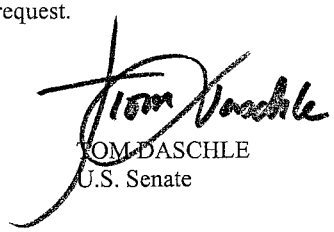
perpetuate veterans' concerns that information is not being fully disclosed to them. Particularly in this matter, openness and candor with veterans and their representatives are paramount considerations.

FDA has indicated that it will now work with the Office of Veterans Affairs and Military Liaison to improve communications with veterans. We would welcome and request receiving a specific plan for outreach to veterans and their representatives. This plan should include specific information describing efforts to provide veterans timely information about planned meetings, apprising veterans and particularly major veterans' service organizations of vacancies on the Advisory Committee and the process for selecting individuals to serve on the Advisory Committee in the future.

We appreciate your attention to this request.

Sincerely,

LANE EVANS
U.S. House of Representatives



TOM DASCHLE
U.S. Senate

cc: FDA Commissioner

THE SECRETARY OF DEFENSE
1000 DEFENSE PENTAGON
WASHINGTON, DC 20301-1000

MAR 0 9 2000

Honorable Lane Evans
House of Representatives
Washington, DC 20515-1317

Dear Lane:

Thank you for your joint letter regarding the Ranch Hand Study. I share your interest in ensuring that Ranch Hand Epidemiological Study data are readily accessible to the public and other interested scientists. The General Accounting Office (GAO) report largely identified problems that occurred early in the study and that, as the report stated, have been corrected since 1989. We agree with the GAO recommendation for the data release to take place as soon as possible and have already been working to that end.

The Ranch Hand Study data sets are acknowledged as a national asset containing life-long medical information about U.S. veterans. The Air Force recognized the value of having these data available for other scientists to review, and in 1994 began release of all the analytical data sets to the National Technical Information Service (NTIS). The first data released were from the Cycle 3 physical examination as these were the most recent health data available. These data also contained serum dioxin measurements, a key parameter for estimating exposure to Agent Orange. The reproductive outcome analytical data sets have also been released to the NTIS and are available to the public as well as portions of the Cycle 4 physical examination data. In all, some 79 files with their corresponding data dictionaries are available, representing about 30 percent of the total.

As they complete the Cycle 4 physical examination data and the rest of the physical examination data sets throughout the coming months, the scientists at Brooks Air Force Base, Texas, will send all Ranch Hand Study reports as viewable files and corresponding supporting data sets to the Government Printing Office (GPO). The GPO will incorporate this information onto CD-ROMs to be readily available to the public for a nominal fee. We hope to have this process completed this year.

The Department of Defense and the Air Force look forward to completing this significant epidemiological study regarding the effects of exposure to dioxin. I appreciate your continued interest and support. A similar letter is being provided to Senator Daschle.

Sincerely,

Mr. SHAYS. Again, thank you for requesting the study and thank you for all the work you have done over all the years.

I would like to use some of my time to just put on the record and ask Mr. Chan, Mr. Oppenheim and Dr. Chiu, if you have any response to this. This is a statement from James G. Zumwalt, the son of Admiral Zumwalt. I will just read his eight points but not the details.

He said I believe Agent Orange research should not be undertaken by the U.S. Government, especially when research on humans is involved.

He said I believe the Air Force Ranch Hand study contains several major methodological flaws.

He then says data such as the reproduction and development data collected by the Ranch Hand researchers must be turned over to trained university-based researchers for evaluation.

He then says published studies, when negative, should always point out their weaknesses, such as small sample size where rare events would not be expected to be found because of the limited numbers, i.e., a group of only 600 exposed men or their children.

He says to be balanced, a scientific study should include a wide range of expertise.

Point six, the issues raised by the recent GAO report conclude communications is not good between the Ranch Hand researchers on the one hand, and the veterans community, the general public, and other dioxin research on the other. It must be addressed.

We now know dioxins cause increases in the number of various cancers and cancer related deaths, heart disease related deaths, diabetes, even at general population levels, health problems in children whose mothers experience high dioxin levels, et cetera.

And finally he said, as my father did before his death, I too support dioxin research in other countries where Agent Orange was sprayed and populations have been exposed, including Vietnam, Cambodia, and Laos.

I would like you to respond to any of those points that he made.

Mr. CHAN. Generally, I think I have very little disagreement with what he said. Basically, the only issue he raised is the first one, which is research should not be done by the Government. I can certainly understand this perspective, given the past history of the so-called lack of trust.

I am not quite sure what he's talking about in terms of the methodological flaw. Maybe it's because of the generalizability, sample size issues, and so on. But I don't—we didn't address that part.

But certainly, the others I would agree with him. And if indeed, the last point that's made about supporting dioxin research, particularly in humans, I think that's a very important area because, quite frankly, industry has basically used less and less dioxins for industrial use. So as a result, you really don't have a lot of data out there, people who have been exposed to dioxins, per se, except our Vietnam veterans, as well as the Vietnamese people.

Mr. SHAYS. Thank you. Dr. Chiu, or Mr. Oppenheim, would you like to make any comments on anything?

I wrote next to your point one, Mr. Chan, unbelievable. Particularly this statement, also a key update to this study's findings on

reproductive outcomes and birth defects was delayed for 8 years and not released until 1992.

I am going to read it again. Also, a key update to the study's findings on reproductive outcomes and birth defects was delayed for 8 years and not released until 1992. I mean, if you had said 8 months, I would have said that is pretty bad.

Would you comment on why you think that happened?

Mr. CHAN. For various reasons, I think. If you look at it on a case-by-case, that seems to be a rather egregious problem, in terms of issuing it. At the time, I think, there were a lot of reasons why they felt they shouldn't release the information from the Air Force perspective. One is because it was not part of the protocol, they were not required to release the information. They were asked to look into it more carefully, verify in fact that the birth defects, in fact, were true because the data collection instrument they used was basically collected through a questionnaire.

At the same time, given the sensitivity of this information and the high level of interest there's really a need to communicate to the veterans in a timely manner.

So we sort of look at it and wish the interim report was released.

Let me say it in a very different way.

If one designed a research study to gather information in this manner, then it seems to me that once one receives the results and determine that where the study requires further examination, suggests that the study itself wasn't designed well up front. Because either you have a good study or you don't have a good study. But by having a study out there, releasing some of the information, I think was important.

And indeed, as we said, the checking and verification of the reported birth defects was extraordinary at that time. And in our report, we list a couple of examples where, similar studies did not go through that kind of checking. We were surprised by it, but it's also a very solid way to approach it if you're interested in research methods.

Mr. SHAYS. What did we gain? Tell me one thing we gained by waiting 8 years?

Mr. CHAN. You gain by having a much more solid scientific study. What you lose is basically, in a different way, the people, the veterans, if they knew about it, they can in fact use the information in preventive ways, to make sure that their health is OK and if they plan to have children to take steps to provide the right kind of care before the child is born. So there is the positive and negative.

I think in here this is pursing the study as an end rather than pursuing the study as the means toward an end, if I may say it that way.

Mr. SHAYS. Say that last sentence again.

Mr. CHAN. I said this appears to be a study that becomes an end in itself. That is, we want to make sure we're right. We want to make sure we check everything. First we check the people who have live births and then you want to make sure that those kids are OK up to the year 18 years old, and so on. All those are really the right thing to do.

But in a different way, as I said, it's an end in itself rather than the means toward and end. The means toward the end is to allow the veterans to know that——

Mr. SHAYS. It strikes me as somewhat arrogant to think that you could not release this information and put qualifiers on it, and then let other people, who happen to be intelligent, and happen to have knowledge, to look at this information. It strikes me as extraordinarily arrogant that somehow adults could not deal with this information and recognize there was some limits to it.

Mr. CHIU. If I might comment, the advisory committee at that time was one that pressed for the Air Force not to release their draft update until they had done the additional verification. So it wasn't solely an Air Force——

Mr. SHAYS. You know, additional research, another year, another 2 years. Another 8 years?

One thing we are going to do is we are going to be paying close attention on what data is being released and so on. I mean, that is your biggest objection. I think there are others there, and I realize you were not asked to do everything we might have wanted you to do, but this has been helpful.

Does any other Member have a question, before we get to the next panel? Do any of the three of you? And Mr. Oppenheim, you do not lose your job by responding. I can guarantee you, Mr. Chan is a very good man.

I sometimes believe that the people who accompany the person who gives the testimony sometimes have more enlightened comments to make. No offense, Mr. Chan. Any other comments?

Mr. OPPENHEIM. I would just add the one comment that I think Kwai has sort of touched on. And that seems to be this conflict that exists between the needs to do really credible in-depth research versus what the needs of the public and the veterans community are. I think there are a number of steps along the whole sequence of this research study in which there could have been greater effort on the part of the Air Force to really communicate what was going on and to create a really more open kind of research environment that would engage outside input into the research itself, either through putting data out that's accessible to the public, providing greater opportunities for the veterans to participate in the advisory committee, and so forth.

So I don't know how you really deal with that conflict, but it's just something that's existed in this study, and I'm sure it exists in other studies like this, as well.

Mr. SHAYS. I think we should expunge from the record my comment more enlightened, just additional great comments, in addition to what Mr. Chan has said.

Mr. CHAN. I would like to raise an issue which I always felt all along, in doing this study and the work that we've done in gulf war illnesses, is that to me there's a fundamental problem between the gathering of the scientific evidence and research in general, versus policymakers in terms of their intent.

On one hand in science we really want to understand if there's a relationship, an association, or correlation. If we find there's a correlation, we then want to make sure that there is a statistically significant relationship. Once we have that, we want to make sure

there's a linear dose response. That means the more stuff you have the worse you get, in terms of your physical well-being. And ultimately, we want to establish cause-and-effect.

Now what we do here, is keep on raising the bar to achieve that end goal and it's a very, very important part of science to pursue in research.

Over time the science wants to establish sort of a beyond a reasonable doubt we are doing the right thing.

On the other hand, I think, Congress, through various legislation including Public Law 102–4, basically suggests that we wanted to give the benefit of the doubt to the veterans. That is, if they are sick, but we can't clearly establish cause and——

Mr. SHAYS. We just do not want to wait until they die before we help them.

Mr. CHAN. I understand.

But my point is that the science doesn't quite support that approach. Giving them the benefit of the doubt means that the risk for the people exposed is higher for than the normal population. So the risk means that the percentage of people who are exposed sick, versus those who were not exposed but sick of the same illness, is greater than one.

Science doesn't work that way. It emphasizes in a statistical significance of I want to make sure that 19 out of 20 times I'm correct in this decision. So as a result then what happens is that scientific information that——

Mr. SHAYS. I would feel more comfortable though, Mr. Chan, if this scientific research was being done by a party that was not a major player, and I would have a greater comfort level. And I believe that, as a policymaker, I have the right to determine that even there's not a shadow of a doubt, there's every indication that, I'm happy to move forward and commit dollars to helping people. I just think you give the benefit of the doubt.

I hear your point.

Mr. CHAN. Then what happens is that when the Academy looks at scientific information what they're seeing are so-called the——

Mr. SHAYS. They found flaws in the——

Mr. CHAN [continuing]. Beyond a shadow of a doubt. Because if you have a piece of paper that actually shows that the risk is only a little higher, you can't publish that article. It's not even in the data base for consideration. Do you see the problem?

Mr. SHAYS. You do not think that information can be shared without certain caveats that there may have been a flaw here or there? That they cannot let other researchers look at it and come to certain conclusions?

Mr. CHAN. I agree with that.

Mr. SHAYS. I need to move on here. Did you want to make a comment, Dr. Chiu?

Mr. CHIU. I just have one short comment and this has to go back to the very beginning, the inception of this study. It has to do with scientific credibility versus public and veterans credibility, credibility to the public and veterans.

In 1980, no one questioned the Air Force's scientific ability to carry out the science of the study. All the questions were about whether they could maintain public credibility. What we found, in

sum, in our report is that many small actions, each of them justifiable in itself. But when you add them all up, it erodes the credibility of the study.

And so I guess, as a lesson for future studies, especially if the decision is for the Government to conduct them, is to have constant attention over the lens of public credibility that is going to be focused on every decision in the conduct of that study.

Mr. SHAYS. Thank you. I would like the record to show we are spending $140 million. That is an average of $5.6 million a year. We are not seeing much to show for this at this point.

I would like to call the next panel. Thank you.

Dr. Joel Michalek, who is Senior Principal Investigator, Ranch Hand Study, Department of Defense; Robert J. Epley, Director, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, accompanied by Susan Mather, Chief Public Health and Environmental Hazards Officer, Department of Veterans Affairs; Ronald Coene, Executive Secretary, Ranch Hand Advisory Committee, Food and Drug Administration; and Dr. David Butler, Study Director, Veterans and Agent Orange Reports, Institute of Medicine.

If you would stand, I would like to swear you all in.

[Witnesses sworn.]

Mr. SHAYS. I would note for the record that our five witnesses have responded in the affirmative. We have four testimonies and we will start as I called you and go down the row. Dr. Michalek.

STATEMENTS OF DR. JOEL MICHALEK, SENIOR PRINCIPAL INVESTIGATOR, AIR FORCE HEALTH STUDY ON EXPOSURE TO HERBICIDES, DEPARTMENT OF DEFENSE; ROBERT J. EPLEY, DIRECTOR, COMPENSATION AND PENSION SERVICE, VETERANS BENEFITS ADMINISTRATION, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY DR. SUSAN MATHER, CHIEF PUBLIC HEALTH AND ENVIRONMENTAL HAZARDS OFFICER, DEPARTMENT OF VETERANS AFFAIRS; RONALD COENE, EXECUTIVE SECRETARY, RANCH HAND ADVISORY COMMITTEE, FOOD AND DRUG ADMINISTRATION; AND DR. DAVID BUTLER, SENIOR PROGRAM OFFICER, VETERANS AND AGENT ORANGE REPORTS, INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES

Dr. MICHALEK. Members of the committee, panel members and guests, thank you very much for inviting us here today. I'm Joel Michalek, principal investigator of the Ranch Hand study. I'm always pleased to have an opportunity to tell people about the study.

I want to emphasize that our first concern is the veterans. I've been a part of the study since 1978. We have spent countless hours with over 2,000 veterans during the physical exam cycles in San Diego and Houston. We have developed close relationships with many veterans who risked their lives for their country in an unpopular war. So believe me, we will leave no stone unturned to find any connection between exposure to Agent Orange and adverse health effects.

For that reason, we welcome the GAO study and we welcome any recommendations you may have to help us toward that goal.

As our reviewers have described it, due to its size, scope, data quality, and the use of a biomarker, the Ranch Hand study is one of the best epidemiological studies ever conducted. Every effort has been made to adhere to the protocol, collect complete and accurate data, and obtain unbiased interpretations of the results.

By design, the study has benefited from an independently administered advisory committee of experts in medicine, toxicology and statistics, biannual review by the National Academy of Sciences, and submission of all results to peer-reviewed scientific journals.

Peer-reviewed articles in the areas of birth defects and immunological function have resulted from collaboration with national experts from the Centers for Disease Control and Prevention and Northwestern University and Evanston Hospital in Illinois.

Research in diabetes, peripheral neuropathy, cardiovascular disease and fertility is being co-authored with faculty from the University of California at Davis, the University of Arkansas, the University of Michigan, Yeshiva University of New York, the University of Southern California and the University of Texas.

My point is that interpretations are made by individuals outside of the study recognized as experts in their fields. The peer-review process itself provides an additional level of quality assurance and rigor. The publication process is long but the effort is focused and the end result is the best achievable.

In November 1998 an article appeared in the San Diego Union Tribune that was critical of the study alleging management interference and coverup. I wrote a rebuttal and presented it to the professional staff of the Senate and House Veterans' Affairs Committee that same month. At the end of the presentation a House staff member asked me if we would be willing to undergo a GAO audit. I said yes. Personally, I'm always happy to invite review and critique because I know that is the best way to display the quality and thoroughness of our work.

Subsequently, through most of last year we gave GAO investigators unlimited access to all documents, including medical records, electronic data, correspondence, reports and articles. We hosted them twice at our facility. We produced a randomized and blinded sampling plan for their review of medical records in their check of our files against our electronic data bases.

The end result was what we regard as a comprehensive and positive report. The GAO report recommended that we improve our communication of the limitations of the study and establish a time table for the release of data to the public. We concur with their conclusions and have made their recommendations our No. 1 priority.

We now highlight study limitations in our reports, report summaries, and press releases, and have established a timeline for the release of all data to the public by the end of this calendar year.

We are planning to provide data in easily accessible formats on compact disks. In an effort to increase communication and available information with veterans and the public we have already placed executive summaries of morbidity reports, abstracts of our published articles, all annual reports to Congress and target dates for the release of our data on our webpage.

This ends my prepared statement. We would be happy to answer any questions you may have.

[The prepared statement of Dr. Michalek follows:]

PRESENTATION TO COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS
AND INTERNATIONAL AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES

SUBJECT: GAO Report on Agent Orange

STATEMENT OF: Dr. Joel Michalck
Senior Principal Investigator
Air Force Health Study on Exposure to Herbicides

15 March 2000

NOT FOR PUBLICATION UNTIL RELEASED
BY THE COMMITTEE ON GOVERNMENT REFORM
UNITED STATES HOUSE OF REPRESENTATIVES

Mister Chairman, members of the Committee, panel members and guests, thank you very much for inviting us here today; I am always pleased to have an opportunity to tell people about our study. I want to emphasize that our first concern is for the veterans. I have been a part of this study since 1978 and we have spent countless hours with over 2000 veterans during the physical exam cycles in San Diego. We have developed close relationships with many veterans who risked their lives for their country in an unpopular war. So believe me, we will leave no stone unturned to find any connection between exposure to Agent Orange and adverse health effects. For that reason, we welcomed the GAO study and we welcome any recommendations you have to help us toward that goal.

As our external reviewers have described it, due to its size, scope, data quality, and use of an exposure biomarker, the Ranch Hand Study is one of the best epidemiological studies ever conducted. Every effort has been made to adhere to the protocol, collect complete and accurate data, and obtain unbiased interpretations of the results. By design, the study has benefitted from an independently administered advisory committee of experts in medicine, toxicology and statistics, bi-annual review by the National Academy of Sciences, and submission of all results to peer-reviewed scientific journals. Peer-reviewed articles in the areas of birth defects and immunological function have resulted from collaboration with national experts from the Centers for Disease Control and Prevention, and Northwestern University and Evanston Hospital in Illinois. Research in progress on diabetes, peripheral neuropathy, cardiovascular disease and fertility is being co-authored with faculty from the University of California at Davis, the University of Arkansas, the University of Michigan, the University of Southern

California and the University of Texas. My point is that interpretations are made by individuals outside of the study recognized as experts in their fields. The peer-review process itself provides an additional level of quality assurance and rigor. The publication process is long, the effort is focused, but the end result is the best achievable.

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disks. In an effort to increase communication and available information with veterans and the public, we have already placed executive summaries of all morbidity reports, abstracts of published articles, all annual reports to Congress, and target dates for data release on our web page [www.brooks.af.mil/AFRL/HED/hedb/afhs/afhs.shtml].

This ends my prepared statement.. We would be happy to answer any questions the committee may have.

Mr. SHAYS. Thank you. Mr. Epley.

Mr. EPLEY. Mr. Chairman and members of the subcommittee, thank you for the opportunity to testify today on the Air Force Ranch Hand study and its impact on veterans benefits.

The VA agrees with the recent assessment by the General Accounting Office that the Ranch Hand study has had limited impact on benefits determinations. Our written statement summarizes VA's past use of Ranch Hand study data and the general framework within which we make determinations for service-connected compensation benefits, so I won't repeat that information verbally right now.

Public Law 102–4 directed the Secretary of Veterans Affairs to seek to enter into an agreement with the National Academy of Sciences to review and summarize the scientific evidence concerning the association between the exposure to herbicides used in support of military operations in Vietnam and specific diseases. The NAS has submitted three reports as a result of Public Law 102–4. Those three reports have resulted in a determination that several diseases are associated with exposure to herbicides in Vietnam.

The Ranch Hand study has been considered in each of the NAS reviews but numerous other studies have also been considered and have minimized the impact of Ranch Hand findings.

The recent GAO report concluded that the Ranch Hand study has had almost no impact on VA determinations on which diseases warrant presumptive service connection because of the small size of the Ranch Hand population and the relative rarity of the many cancers. The Department agrees that these and other limitations in the Ranch Hand study noted by NAS over the years have made its impact on our determinations very limited.

We believe the review process outlined in Public Law 102–4 has provided an effective basis for identifying diseases associated with herbicide exposure. Clearly, the work in this area is not done.

We understand that this committee is concerned about information dissemination to Vietnam veterans and we're working to improve our outreach efforts.

We look forward to working with NAS and with this committee to assure that we provide the best possible service, the most informed decisions, and all appropriate benefits to the veterans of our Nation.

This concludes my statement. Dr. Mather and I will be pleased to answer any questions.

[The prepared statement of Mr. Epley follows:]

Statement of Robert J. Epley

Director, Compensation and Pension Service

Veterans Benefits Administration

Department of Veterans Affairs

Before the House Committee on Government Reform

Subcommittee on National Security, Veterans Affairs,

and International Relations

March 15, 2000

Mr. Chairman and Members of the Subcommittee, thank you for the opportunity to testify today on the Air Force Ranch Hand study and its impact on veterans' benefits. You have asked that our testimony include information on the impact of the study on determinations of diseases for which Vietnam veterans are eligible to receive compensation benefits. The Department of Veterans Affairs (VA) agrees with the recent assessment by the General Accounting Office, that its impact on these determinations has been limited. My testimony will summarize VA's past use of Ranch Hand and other herbicide study data, and our intentions for using such data in the future.

Delays in Publication of Ranch Hand Findings

In 1984, Congress passed the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, Pub. L. No. 98-542. Pursuant to that Act, VA adopted regulations on how VA would evaluate scientific studies to determine

which diseases are related to veterans' Agent Orange exposure. VA conducted this ongoing evaluation process throughout the 1980's.

As noted by the General Accounting Office (GAO) in its December 1999 report entitled "Agent Orange: Action Needed to Improve Communications of Air Force Ranch Hand Study Data and Results" (GAO/NSIAD-00-31), no Ranch Hand study results were published until 1989, more than seven years after the study began. While this obviously delayed VA's opportunity to consider this data in reaching our Agent Orange compensation decisions, VA did obtain and analyze a significant amount of other research on the health effects of herbicide exposure during this time.

The Agent Orange Act of 1991

Section 3 of the Agent Orange Act of 1991, Pub. L. No. 102-4, directed the Secretary to seek to enter into an agreement with the National Academy of Sciences (NAS) to review and summarize the scientific evidence concerning the association between exposure to herbicides used in support of military operations in the Republic of Vietnam during the Vietnam era and each disease suspected to be associated with such exposure. Congress mandated that NAS determine, to the extent possible: (1) Whether there is a statistical association between the suspect diseases and herbicide exposure, taking into account the strength of the scientific evidence and the appropriateness of the methods used to detect the association; (2) the increased risk of disease among individuals

exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and (3) whether there is a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the suspect disease.

Section 3 of Pub. L. No. 102-4 requires that NAS submit reports on its activities every two years (as measured from the date of the first report) for a ten-year period.

Section 2 of Pub. L. No. 102-4 provides that whenever the Secretary determines, based on sound medical and scientific evidence, that a "positive" association, (i.e., as defined in the Act, the credible evidence for the association is equal to or outweighs the credible evidence against the association), exists between exposure of humans to an herbicide agent used during the Vietnam War and a certain disease, the Secretary will publish regulations establishing presumptive service connection for that disease. Although Pub. L. No. 102-4 does not define "credible," it does instruct the Secretary to "take into consideration whether the results [of any study] are statistically significant, are capable of replication, and withstand peer review." Section 2 of Pub. L. No. 102-4 also requires that the Secretary's determinations be based on consideration of the NAS reports and all other sound medical and scientific information and analyses available to the Secretary. If the Secretary determines that a presumption of service connection is not warranted, he must publish a

notice of that determination, including an explanation of the scientific basis for that determination.

VA's Reliance on National Academy of Sciences Reports

NAS issued its initial report, entitled "Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam," (VAO) on July 27, 1993. The Secretary subsequently determined that a "positive" association exists between exposure to herbicides used in the Republic of Vietnam and the subsequent development of Hodgkin's disease, porphyria cutanea tarda, multiple myeloma, and certain respiratory cancers (of the lung, bronchus, larynx, or trachea). The Secretary also determined that there was no "positive" association between herbicide exposure and any other condition, other than chloracne, non-Hodgkin's lymphoma, and soft-tissue sarcomas, for which presumptions already existed. VA promulgated regulations implementing its determination.

NAS issued its second report, entitled "Veterans and Agent Orange: Update 1996" (Update 1996), on March 14, 1996. The Secretary subsequently determined that a "positive" association exists between exposure to herbicides used in the Republic of Vietnam and the subsequent development of prostate cancer and acute and subacute peripheral neuropathy in exposed persons. The Secretary further determined that there was no "positive" association between herbicide exposure and any other condition, other than those for which

presumptions already existed. VA promulgated regulations implementing its determination.

Also based on Update 1996, the Secretary determined that a "positive" association exists between exposure to herbicides used in the Republic of Vietnam and the subsequent development of the birth defect spina bifida in the offspring of exposed persons. Based on this finding, the Secretary and the President sought legislation providing VA benefits for these children. In October 1996, Congress passed Pub. L. No. 104-204, which provides health care, a monthly monetary allowance, and vocational rehabilitation benefits to these children.

Veterans and Agent Orange: Update 1998

NAS issued its third and most recent report, entitled "Veterans and Agent Orange:Update 1998" (Update 1998), on February 11, 1999. The focus of this updated review was on new scientific studies published since the release of Update 1996 and updates of scientific studies previously reviewed. In Update 1998, NAS assigned hepatobiliary cancers, nasal/nasopharyngeal cancer, bone cancer, breast cancer, female reproductive cancers, urinary bladder cancer, renal cancer, testicular cancer, leukemia, abnormal sperm parameters and infertility, motor/coordination dysfunction, chronic peripheral nervous system disorders, metabolic and digestive disorders (including diabetes mellitus), immune system disorders, circulatory disorders, respiratory disorders (other than

certain respiratory cancers), and skin cancer to a category labeled inadequate/insufficient evidence to determine whether an association exists. This is defined as meaning that the available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association with herbicide exposure.

Also in Update 1998, NAS assigned gastrointestinal tumors and brain tumors to a category labeled limited/suggestive evidence of no association. This is defined as meaning several adequate studies do not show a "positive" association with herbicide exposure.

As he did after the release of the prior NAS reports, the Secretary again formed a VA task force to review the report and pertinent studies and to make recommendations to assist him in determining whether a "positive" association exists between herbicide exposure and any condition. The task force completed that review and submitted its recommendations to the Secretary.

In the Secretary's judgment, the comprehensive review and evaluation of the available literature which NAS conducted in conjunction with its report has permitted VA to identify all conditions for which the current body of knowledge supports a finding of an association with herbicide exposure. Accordingly, the Secretary determined that there is no "positive" association between exposure to herbicides and any other condition for which he has not previously determined

that a presumption of service connection is warranted. (However, as noted below, the Secretary requested that NAS conduct an additional review of diabetes mellitus.)

On November 2, 1999, as required by law, VA published a notice in the Federal Register that the Secretary of Veterans Affairs, under the authority granted by the Agent Orange Act of 1991, had determined that a presumption of service connection based on exposure to herbicides used in the Republic of Vietnam during the Vietnam era was not warranted for the following conditions: Hepatobiliary cancers, nasal/nasopharyngeal cancer, bone cancer, breast cancer, female reproductive cancers, urinary bladder cancer, renal cancer, testicular cancer, leukemia, abnormal sperm parameters and infertility, motor/coordination dysfunction, chronic peripheral nervous system disorders, metabolic and digestive disorders (other than diabetes mellitus), immune system disorders, circulatory disorders, respiratory disorders (other than certain respiratory cancers), skin cancer, cognitive and neuropsychiatric effects, gastrointestinal tumors, brain tumors, and any other condition for which the Secretary had not specifically determined a presumption of service connection is warranted.

This notice also conveyed the Secretary's determination that a new study concerning the possible association between exposure to herbicides and diabetes mellitus that was published since NAS completed Update 1998, is

potentially significant. The Secretary has requested NAS to review that new study and, after reviewing NAS' response, will determine whether a "positive" association exists between herbicide exposure and diabetes mellitus.

NAS's Analysis of the Ranch Hand Study

As noted by the General Accounting Office (GAO) in its December 1999 report entitled "Agent Orange: Action Needed to Improve Communications of Air Force Ranch Hand Study Data and Results" (GAO/NSIAD-00-31), the three NAS reports on Vietnam veterans and Agent Orange, including their conclusions on specific diseases, were based on numerous studies besides Ranch Hand. This fact alone has limited the impact of Ranch Hand on the NAS' conclusions.

Moreover, to the extent NAS has relied on the Ranch Hand study, NAS has carefully analyzed both the strengths and weaknesses in the study and publication of study results. The NAS has included this critical analysis in all three of its reports. For example, NAS included such analysis in *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam* (1993), at pages 231-232, 279-280, 722-724 and 757-763 (this last section was an appendix entitled, "Methodological Observations on the Ranch Hand Study"). NAS also included such analysis of the Ranch Hand study in *Veterans and Agent Orange: Update 1996* at pages 293-296. NAS also included such analysis in *Veterans and Agent Orange: Update 1998* at pages 447-449, 453, 457-458, and 498-500.

VA's Recognition of Ranch Hand's Strengths and Weaknesses

As stated in the GAO report, "reports and articles by the Ranch Hand study comprise only a small fraction of the information the National Academy of Sciences reviews and the Department of Veterans Affairs then considers when weighing scientific evidence." The Department agrees with this GAO assessment.

In the same report, GAO concluded that "the Ranch Hand study has had almost no impact" on VA determinations on which diseases warrant presumptive service connection, "because of the small size of the Ranch Hand population and the relative rarity of many cancers." The Department agrees that these, and other limitations in the Ranch Hand study noted by NAS over the years, have made its impact on these determinations very limited.

VA recognizes that simply comparing the number of studies which found an association between herbicides and a certain disease, to the number of studies which did not find an association, is not a valid method for concluding whether there is a "positive" association between herbicides and that disease. Differences in statistical significance, confidence levels, control for confounding factors, bias, and other pertinent characteristics, make some studies less credible than others. For example, some studies did not explicitly address the issue of smoking, a potential confounding factor which may have skewed their results. Therefore, the Secretary has given the more credible studies more

weight in evaluating the overall weight of the evidence concerning specific diseases.

VA's Future Use of Ranch Hand and Other Herbicide Study Data

NAS has informed VA that it expects its report on Agent Orange and diabetes to be issued this spring. After reviewing the report, the Secretary will determine whether to add diabetes to the list of diseases for which VA allows a presumption of service-connection. Similarly, when NAS issues its next comprehensive biennial report, which is expected in 2001, the Secretary will review it to determine which, if any, health effects should be considered for presumption of service-connection. As required by law, the Secretary will continue to consider not only the NAS report, but also all other sound medical and scientific information and analyses available. Also as required by law, the Secretary will continue to take into consideration whether the results of any study are statistically significant, are capable of replication, and withstand peer review.

Conclusion

In summary, we believe that NAS has done a very credible job of pointing out the strengths and weaknesses of the Ranch Hand study, as well as the other research NAS has reviewed. The Department has paid close attention to these strengths and weaknesses in making its determinations on which diseases warrant presumptive service connection. We believe that this process has

proven to be effective in forming a solid basis for compensation for Vietnam veterans.

While we still have work left to do, we feel that over the past decade, the Department has made significant progress in the compensation of Vietnam veterans for diseases related to Agent Orange exposure. Mr. Chairman, as I have said before, we owe veterans and their families the best service we can provide in the most sensitive, caring way possible to ensure that they receive benefits in a manner befitting their service to our Nation.

This concludes my prepared statement. My colleagues and I will be pleased to answer any questions Subcommittee members might have.

Mr. SHAYS. Thank you, your statement was concise and right to the issue, and I thank you for that. I also wanted to thank Dr. Michalek. Your statement was helpful, as well, and it will enable us to have a good dialog.

I just want to clarify one thing and then we will get right to you, Mr. Coene. Did you say you started this study in 1968, Dr. Michalek? When did you start?

Dr. MICHALEK. Actually, talk about the protocol and its design stage began, I think, in 1976, was when I was originally hired at Brooks Air Force Base.

Mr. SHAYS. So you started in 1976?

Dr. MICHALEK. Yes, sir.

Mr. SHAYS. So this is something that you have worked long and hard on, and I thank you for that work. I know you have been very devoted.

Whatever else happens in this hearing, I want that to be part of the record. Mr. Coene.

Mr. COENE. Mr. Chairman, members of the committee, my name is Ron Coene and I'm the Deputy Director for Washington Operations of the National Center for Toxicological Research. I serve as the executive secretary to the advisory committee known as the Ranch Hand Advisory Committee. I'm pleased to be here to discuss my role as executive secretary to that committee.

The committee, as chartered, advises the Secretary and the Assistant Secretary for Health concerning its oversight of the Ranch Hand study being conducted by the Air Force, as well as providing oversight to the Department of Veterans Affairs Army Chemical Corps Vietnam Veterans Health Study. The committee is made up of nine members, including the chair, and members are appointed for overlapping 4 year terms.

My written testimony, which has been submitted for the record, describes in more detail my role as executive secretary. Let me get to the substance of the GAO report and concerns of this oversight.

The General Accounting Office report on Agent Orange examined the Ranch Hand study and recommended that improvements be made in communication between the advisory committee and veterans organizations. In managing the committee, we utilize the Federal Register the legal requirement to notify the public, including veterans organizations, of its activities, namely meeting times, dates, places and preliminary agendas.

In maintaining and assuring the proper mix of committee appointees among veterans organizations, we utilize the Secretary's Office of Veterans Affairs to obtain nominations of qualified veterans to fill vacancies on the committee. But we acknowledge that these informal practices could possibly lead to the perception that the committee was not fulfilling its role as an independent, unbiased oversight body.

I would like to discuss the steps the Department has taken to ensure that, both in perception and practice, veterans organizations are being involved in the conduct of the advisory committee's activities. While the GAO investigation was underway this past summer, these issues became known to us. We took steps to use the Department's Office of Veterans Affairs and Military Liaison to identify and intensify outreach and contact the veterans organiza-

tions concerning the committee's planned meeting in October of this past year.

In January of this year, that office began sending letters requesting nominations for vacancies that currently exist on the committee. To date 13 veterans service organizations have been contacted. Six organizations have expressed a desire to participate in the nomination process. The Department has received two nominations each from the American Veterans Committee, the Ranch Hand Vietnam Association, one nomination from the American Legion, and three draft nominations from the Vietnam Veterans of America. The Veterans of Foreign Wars also has indicated an intention to submit nominations.

Additionally, the Disabled Americans Veterans have expressed the desire to participate by reviewing the list of nominees and providing their endorsement. The Vietnam Era Veterans Association did not make a nomination but indicated they planned to send observers to the advisory committee meetings. Finally, the American Ex-Prisoners of War also responded to our outreach but did not make a nomination.

The Department is continuing to followup with the remaining organizations, seeking their input to this process.

I foresee closing out the nomination process by veterans representatives by early next month and, in consultation with the chairperson of the committee, we will select two individuals from each of the three veterans organization vacancies that exist from the nominations that we have received from the VSOs and forward them to the Secretary for a final selection. The new members should be on board in 90 days from the time the Secretary selects the panel members.

We also are beginning to recruit for other vacancy positions that exist on the panel. We expect the next meeting of the full advisory committee will be in late summer to discuss the scope of work of the contract for the physical examinations of the Ranch Hand study which will occur in 2002.

Similarly to what we have done for the nomination process, we will also ensure the veterans organizations are provided, by letter, logistical and agenda information of advisory committee meetings. These letters should go out around the time we place the meeting notice in the Federal Register.

This ends my testimony, Mr. Chairman, and I look forward to answering any of your questions.

[The prepared statement of Mr. Coene follows:]

Testimony of Ronald Coene
Executive Secretary
Ranch Hand Advisory Committee
Food and Drug Administration

Before the

Subcommittee on National Security, Veterans Affairs, and International Relations
Government Reform Committee
Rep. Christopher Shays
Chairman

"Agent Orange: Status of the Air Force Ranch Hand Study."

March 15, 2000

For Release on Delivery
Wednesday, March 15, 2000
10:00 am

Introduction

Mr. Chairman, Members of the Committee, my name is Ronald Coene, I am the Deputy Director for Washington Operations, National Center for Toxicological Research (NCTR), Food and Drug Administration (FDA or Agency). I serve as the Executive Secretary to the Advisory Committee on Special Studies Relating to the Possible Long-term Health Effects of Phenoxy Herbicides and Contaminants, better known as the Ranch Hand Advisory Committee. I am pleased to be here today to discuss my role with the Ranch Hand Advisory Committee.

Background

As you may know, this Advisory Committee is the result of an inter-agency workgroup established by the Assistant to the President for Domestic Affairs and Policy in December 1979. In December 1980, this group recommended that the Air Force conduct epidemiological studies of the Ranch Hand personnel and that an independent monitoring committee oversees the study. Accordingly, in January 1981, the Secretary of Health and Human Services (HHS or the Department) established the Ranch Hand Advisory

Committee (the Committee). The Committee operates under the authority of the Public Health Service Act and is guided by Title XII of Public Law 100-687 as it relates to the make up of the Committee. Specifically, Public Law 100-687 requires that one-third of the membership be made up of members nominated from veterans' organizations.

The Committee, as chartered, advises the Secretary and Assistant Secretary for Health, concerning its oversight of the Ranch Hand Study being conducted by the Air Force, as well as providing oversight of the Department of Veterans Affairs Army Chemical Corps Vietnam Veterans Health Study. The Committee is made up of nine members, including the Chair. Members are appointed to serve overlapping four-year terms.

FDA's Role as Executive Secretary

During the late 1980's, NCTR was involved in a Department-wide Committee on Agent Orange. Dr. Louis Sullivan, former Secretary, HHS, asked the Director of NCTR, FDA to support the Ranch Hand Committee. As the Deputy Director for NCTR, I was asked

to assume the Executive Secretariat function for the Committee, and have served in that role since 1989.

In this role, I am responsible for administrative and logistical support of all meetings and the appointment of all members to the Committee. The Air Force Project Officer for the Ranch Hand Study and the Department of Veterans Affairs Project Officer for the Army Chemical Corps Vietnam Veterans Health Study provide agenda items for consideration by the Committee. Then the Committee Chairperson and I set the agenda for the meeting. My office is responsible for publishing that agenda in the *Federal Register* 30 days prior to the meeting. My staff and I develop minutes of the meetings which are available in the FDA dockets room. Starting with the August 1999 meeting we began having complete meeting transcripts recorded and these are also available in the FDA dockets room. Since 1989 we have supported twelve meetings of the Ranch Hand Advisory Committee. Two of these meetings were site visits to Brooks Air Force Base, San Antonio, Texas, where the Air Force project is based, and one was a site visit to the

Scripps Clinic in La Jolla, California, the Air Force's contractor that performs the physical examinations of the study participants.

Over the last ten years I have worked through the Secretary's Office of Veterans Affairs and more recently its successor organization, the Office of Veterans Affairs and Military Liaison, in the Office of the Assistant Secretary for Health, in maintaining contacts with veterans groups and obtaining recommendations for nominations of members to the Committee. The Office of Veterans Affairs and Military Liaison maintains direct contact with veterans groups.

On an annual basis I prepare a report of the Committee's activities, membership, and actions taken during the previous year. This report ultimately becomes a part of the "President's Report on Federal Advisory Committees" sent to Congress.

General Accounting Office Report

The General Accounting Office (GAO) report on Agent Orange, that examined the Ranch Hand Study recommended that improvements be made in communications between the Advisory Committee and veterans' organizations.

In managing the Committee we utilized the *Federal Register*, the legal requirement, to notify the public, including veterans' organizations of its activities, namely meeting times, dates and places, and a preliminary agenda. In maintaining and assuring the proper mix of committee appointments among veterans' organizations we utilized the Secretary's Office of Veterans Affairs to obtain nominations of qualified veterans to fill vacancies on the Committee. We acknowledge that these informal practices could possibly lead to the perception that the Committee was not fulfilling its role as an independent, unbiased oversight body.

I would like to discuss the steps that the Department has taken to ensure that both in perception and practice veterans' organizations are being involved in the conduct of the

advisory committee's activities. While the GAO investigation was underway, this past summer, and these issues became known to us, we took steps to use the Department's Office of Veterans Affairs and Military Liaison to intensify outreach and to contact veterans organizations concerning the Committee's planned meeting in October of this past year. In January of this year, that office began sending letters requesting nominations for vacancies that currently exist on the Committee. To date, thirteen veterans' service organizations have been contacted, and six organizations have expressed a desire to participate in the nomination process. The Department has received two nominations each from the American Veterans Committee and the Ranch Hand Vietnam Association, one nomination from the American Legion, and three draft nominations from the Vietnam Veterans of America. The Veterans of Foreign Wars also has indicated the intention to submit nominations. Additionally, the Disabled American Veterans have expressed the desire to participate by reviewing the list of nominees and providing endorsements. The Vietnam Era Veterans Association did not make a nomination, but indicated that they plan to send observers to Advisory Committee meetings. Finally, the American Ex-Prisoners of War also responded to our outreach, but

did not make a nomination. The Department is continuing to follow up with the remaining organizations seeking their input to this process. Once again I would like to reiterate that FDA, in carrying out its executive secretariat functions, will work closely with the Department's Office of Veterans Affairs and Military Liaison to ensure that veterans' organizations are notified in a timely manner regarding Committee meetings and Committee vacancies.

We look forward to a more proactive relationship with veterans' organizations in carrying out the oversight function of the Secretary for these studies.

Mr. Chairman, thank you for the opportunity to discuss my role as the Executive Secretary to the Ranch Hand Advisory Committee. I would be happy to answer any questions the Committee may have.

Mr. SHAYS. Dr. Butler.

Mr. BUTLER. Good morning, Mr. Chairman, Mr. Sanders. My name is David Butler. I am Senior Program Office in the Institute of Medicine, a private non-profit organization that provides health policy advice under a congressional charter granted to the National Academy of Sciences. The Institute of Medicine has three ongoing studies related to the evaluation of the health impacts of herbicide and dioxin exposure on Vietnam veterans.

I serve as study director for all three studies, which include the third biannual update of the "Review of the Health Effects in Vietnam Veterans of Exposure to Herbicides;" the "Review of Evidence Regarding a Link Between Exposure to Agent Orange and Diabetes; and Phase Three of the Historic Exposure Reconstruction Model for Herbicides in Vietnam."

In response to the request of the subcommittee, I will review the status of these studies, what's been learned to date, and future study plans.

As Mr. Epley stated, the Agent Orange Act of 1991 directed the Secretary of Veterans Affairs to request the National Academy of Sciences to do an independent comprehensive review and critical evaluation of the scientific studies and medical evidence concerning the health effects of herbicide exposure. This act prompted the first of the three research efforts I will briefly review.

A committee convened by the Institute of Medicine conducted an initial investigation and in 1994 published the report "Veterans and Agent Orange." The Agent Orange Act also called for subsequent reviews every 2 years for a period of 10 years from the date of the first report.

The committees responsible for these studies evaluate epidemiologic and toxicologic data on exposures to the types of herbicides used in Vietnam and the contaminant dioxin. The epidemiologic studies comprised three primary categories: occupational studies, such as those conducted by NIOSH; environmental studies, like those conducted in the aftermath of an industrial accident in Seveso, Italy; and veterans studies, including the Ranch Hand studies. Information from all of these sources is considered in drawing conclusions.

Based on their evaluation of the scientific literature for Update 1998, the committee found sufficient evidence of a statistical association between exposure to herbicides and dioxin and four conditions: chloracne, soft tissue sarcoma, non-Hodgkin's lymphoma and Hodgkin's disease. The committee found limited or suggestive evidence of an association with respiratory cancers, prostate cancer, and multiple myeloma. They also found limited or suggestive evidence that exposure may be associated with porphyria cutanea tarda, the acute transient form of peripheral neuropathy, and the congenital birth defect known as spina bifida in the children of fathers who were exposed to herbicides.

For most of the other cancers, diseases and conditions reviewed by the committee, the scientific data were not sufficient to determine whether an association exists.

The third biannual update is presently underway and is scheduled to be completed by the end of this year. The future plans for

this research effort are to complete the mandate specified by the act.

A second Agent Orange research effort being conducted by the National Academies was prompted by the 1999 request from the Department of Veterans Affairs to call together a committee to conduct an interim review of the scientific evidence regarding one of the conditions addressed in the "Veterans and Agent Orange" series of reports, Type II diabetes.

The committee convened for this review examined studies published since the deliberations of the Update 1998 committee in light of the whole of the literature on the subject. Their draft report is presently under review. It is expected to be released in May of this year.

The third research effort underway addresses one of the greatest problems encountered by the Agent Orange committees in their work, a severe lack of information about the exposure of Vietnam veterans to herbicides. In response to this information gap, the Department of Veterans Affairs requested that the National Academies help facilitate the development and evaluation of models of herbicide exposure for use in studies of Vietnam veterans.

For this effort, a committee developed a request for proposals for research and invited interested individuals and organizations to submit responses. Committee members thoroughly evaluated the technical and scientific merit of these responses and unanimously concluded that a proposal submitted by Professor Jeanne Stellman of the Columbia University School of Public Health and colleagues merited funding.

In the present phase of the project, the research proposed by the Columbia University group is being conducted with the continuing oversight of the committee. Most recently, in December 1999, the researchers reported on the progress in developing a data base of military units that served in Vietnam, improving the data base of herbicide spraying missions, developing models of troop movement and otherwise establishing the information foundation for their modeling work. Present plans call for this research to be completed by the end of 2001.

These three research efforts comprise the work on the Agent Orange issues presently being supported at the National Academies. Thank you.

[The prepared statement of Mr. Butler follows:]

THE STATUS OF THE NATIONAL ACADEMY OF SCIENCES RESEARCH EFFORTS REGARDING THE HEALTH EFFECTS OF EXPOSURE TO AGENT ORANGE AND OTHER HERBICIDES USED DURING THE VIETNAM WAR

Statement of

David A. Butler, Ph.D.
Senior Program Officer
Institute of Medicine
National Academy of Sciences

before the
Subcommittee on National Security, Veterans Affairs and International Affairs
Committee on Government Reform
U.S. House of Representatives

March 15, 2000

Good morning, Mr. Chairman and members of the Committee. My name is David Butler. I am Senior Program Officer in the Division of Health Promotion and Disease Prevention of the Institute of Medicine (IOM). The Institute of Medicine is a private, non-profit organization that provides health policy advice under a congressional charter granted to the National Academy of Sciences. I am happy to be here to discuss the status of IOM's Agent Orange investigations, what has been learned to date and what the future study plans are. The IOM has three ongoing studies related to the evaluation of the health impacts of herbicide and dioxin exposure on Vietnam veterans. I serve as the study director for all three studies, which include:

- the third biennial update of the Review of the Health Effects in Vietnam Veterans of Exposure to Herbicides;
- the Review of Evidence Regarding Link Between Exposure to Agent Orange and Diabetes; and
- Phase III of the Historic Exposure Reconstruction Model for Herbicides in Vietnam.

In response to the request of the committee, I will review the status of these studies, what has been learned to date, and future study plans.

For Vietnam veterans and their families, the issue of Agent Orange exposure has been a source of great anguish. To address these concerns, Congress passed the Agent Orange Act of 1991, which directed the Secretary of Veterans Affairs to request the National Academy of Sciences to do an independent, comprehensive review and critical evaluation of the scientific studies and medical evidence concerning the health effects of herbicide exposure.

This Act prompted the first of three research efforts I will review. The goal of this effort was to establish an agreed-upon base of information from which to proceed to answer specific questions about the health impacts of exposure to herbicides and dioxin. For each disease examined, the committee was asked to determine, to the extent that available data permitted meaningful determinations: 1) whether a statistical association with herbicide exposure exists, taking into account the strength of the scientific evidence and the appropriateness of the statistical and epidemiological methods used to detect the association; 2) the increased risk of the disease among those exposed to herbicides during Vietnam service; and 3) whether there is a plausible

biological mechanism or other evidence of a causal relationship between herbicide exposure and the disease.

A committee convened by the Institute of Medicine conducted this review and in 1994 published a comprehensive report entitled *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam*. The Agent Orange Act also called for subsequent reviews every two years for a period of ten years from the date of the first report. These reviews were to be comprehensive evaluations of the evidence that had become available since the previous report and reassessments of the committees' determinations. On completion of the 1994 report, successor committees were formed that produced *Veterans and Agent Orange: Update 1996* and *...1998*. The third biennial update, which is presently underway, will result in the publication of *Veterans and Agent Orange: Update 2000*. That report is scheduled to be completed by the end of this year. The future plans for this research effort are to complete the mandate specified in the Act.

The committees responsible for these studies evaluate epidemiologic and toxicologic data on exposures to the types of herbicides used in Vietnam, and the contaminant dioxin. The epidemiologic studies comprise three primary categories:

- occupational studies — research on individuals who were exposed as a result of their jobs in for example the chemical industry or agriculture;
- environmental studies — research on individuals who were exposed as a result of some contact in the environment — for example, because of a nearby industrial accident; and
- veterans' studies — research on the health on Vietnam veterans themselves.

Information from all of these sources is considered in drawing conclusions.

In conducting their work, the committees operate independently of the Department of Veterans Affairs and other government agencies. They were not asked to and did not make judgments regarding specific cases in which individual Vietnam veterans have claimed injury from herbicide exposure. The committee was charged with reviewing the scientific evidence rather than making recommendations regarding policy, and their findings are not intended to imply or suggest any policy decisions. Instead, these studies provide scientific information for the Secretary of Veterans Affairs and others to consider as they exercise their responsibilities to Vietnam veterans.

The committees have followed a common approach established by the first committee to summarize their evaluations of the evidence. They have classified diseases into four categories: the first category is "sufficient evidence" of a statistical association between the disease and

exposure to herbicides or dioxin; the second, "limited or suggestive evidence"; the third, "inadequate or insufficient" evidence to determine whether an association exists; and the fourth category, "limited, suggestive evidence of *no* association." Consistent with the mandate of the Agent Orange Act, the distinctions between categories are based on *statistical association*, not on *causality*. As a result, the committees have not applied the standard criteria epidemiologists use when judging whether a causal relationship exists between an exposure and a health outcome.

The most recent set of conclusions developed by these committee are contained in the 1998 update of the report series. I am submitting a copy of the Executive Summary of the report as a supplement to the testimony and ask to be included in the record[1].

Based on their evaluation of the scientific literature, the committee found sufficient evidence of a statistical association between exposure to herbicides or dioxin and three types of cancer: soft tissue sarcoma, non-Hodgkin's lymphoma, and Hodgkin's disease. The committee also found sufficient evidence of an association with chloracne, a skin condition.

The committee found limited or suggestive evidence of an association between exposure to herbicides or dioxin and three other types of cancer: respiratory cancers, prostate cancer, and multiple myeloma. They also found limited or suggestive evidence that herbicide or dioxin exposure may be associated with three other conditions: porphyria cutanea tarda, which manifests as a skin disorder; the acute, transient form of peripheral neuropathy, a nerve disorder that can lead to pain, numbness, and weakness in the limbs; and the congenital birth defect called spina bifida, in the children of fathers who were exposed to herbicides. For most of the other cancers, diseases, and conditions reviewed by the committee, the scientific data were not sufficient to determine whether an association exists.

A second Agent Orange research effort being conducted by the National Academies was prompted by a 1999 request from the Department of Veterans Affairs to call together a committee to conduct an interim review of the scientific evidence regarding one of the conditions addressed in the *Veterans and Agent Orange* series of reports: Type II diabetes. This disease is also referred to as *non-insulin dependent diabetes mellitus* and as *adult-onset diabetes*. The committee convened for this review conducted a workshop and meeting to hear current researchers in the field present

[1] The Executive Summary is available on the web at http://books.nap.edu/html/update98/. The entire *Update 1998* report may be accessed at http://www.nap.edu/books/0309063264/html/.

information on their ongoing investigations and to review material published since the deliberations of the *Update 1998* committee. Although limited to one health outcome, this committee adhered to the format of the update series described above. Their draft report is presently under review. It is expected to be released in May, 2000.

The third research effort underway regarding herbicide exposure in Vietnam was prompted by an observation in the original *Veterans and Agent Orange* report. The committee responsible for that report observed that one of the greatest problems it encountered in its work was a severe lack of information about the exposure of individual Vietnam veterans to herbicides. Except for particular groups, such as those involved in Operation Ranch Hand and other groups directly involved in spraying operations, information on the extent of herbicide exposure among veterans is practically non-existent. This lack of data is one reason why the National Academies' committees were compelled to focus largely on epidemiologic studies of groups *other* than Vietnam veterans. They concluded that not enough was known about the exposures of individual veterans to determine to what degree they were or are at risk. Although most veterans probably experienced lower levels of exposure than those who worked with herbicides over long periods in occupational or agricultural settings, it is difficult to determine precisely which veterans may have encountered higher levels.

In 1996, in response to the original committee's observation, the Department of Veterans Affairs (DVA) requested that the National Academies help facilitate the development and evaluation of models of herbicide exposure for use in studies of Vietnam veterans. Specifically, this effort was to: 1) develop a Request for Proposals (RFP) for herbicide exposure research and subject it to external peer review; 2) disseminate the RFP, evaluate the proposals received in response to it, and select one or more academic or other non-governmental groups to develop a model or models; 3) provide scientific oversight of the work of the subcontractor; and 4) evaluate the model(s) developed.

Phase I of the project—development of the Request for Proposals—was completed in 1997. It was comprised of a statement of work, selection criteria, and background information for potential respondents. For Phase II, the National Academies circulated the RFP and invited interested individuals and organizations to submit responses. Committee members thoroughly evaluated the technical and scientific merit of these responses, based on the criteria set forth in

the RFP. In March of 1998, they unanimously concluded that a proposal submitted by Professor Jeanne Stellman of the Columbia University School of Public Health and colleagues merited funding. The National Academies and Columbia University subsequently entered into a contract to conduct the work.

The present phase of the project—III— is underway. The research proposed by the Columbia University group is being conducted with the continuing oversight of the committee. Approximately every six months, public meeting are held where reports of research progress are presented. Most recently, in December 1999, the researchers made their eighteen-month progress report. Among their accomplishments, they have assembled a database that is the first easily accessible and cross-referenced comprehensive list of all Army units that were stationed in Vietnam, and the numbers of troops actually assigned to them in Vietnam. The researchers have also created a military unit database that contains the locations of tens of thousands of military units during the war, and have begun to develop and test algorithms and programs for describing and analyzing the movement of mobile battalions and their elements. They are continuing the work of compiling data on airborne and ground spraying of herbicides, and of developing models for estimating exposure to herbicides. Present plans call for the research to be completed by the end of 2001.

These three research efforts comprise the work on Agent Orange issues presently being supported at the National Academies.

As was said in the first report on veterans and Agent Orange, the committee's responsible for these research efforts know their reports will not end the controversy over the health effects. But we hope these additional findings will lead to better understanding of the questions that remain, and the steps we must take to answer them.

Thank you for your attention. I would be happy to answer your questions.

Mr. SHAYS. Thank you very much. Again, I want to say that I know that every one of you is a dedicated public employee and wants only the best for our veterans. I just want to establish that for the record. And I know that you all have lots of responsibilities and you are doing your best to fulfill them well.

When I ask some of these questions, they are going to basically relate to my sense that you are players in a bigger picture. And you may play out your part, but in the end, do we get what we need from what happens?

I also acknowledge that this study basically was fairly limited and that there is a general consensus that the GAO findings are accurate and there will be efforts to comply with their recommendations. Frankly, their recommendations are fairly limited and center primarily on communications.

But let me first ask you, Mr. Coene, I am unclear. This study has gone on from 1982 and it will be concluded in the year 2006. It is a 25 year study.

Mr. COENE. Correct.

Mr. SHAYS. You became the director of the advisory group when?

Mr. COENE. In 1989.

Mr. SHAYS. In 1989, and you work for the Food and Drug Administration?

Mr. COENE. Correct.

Mr. SHAYS. This is, in a sense, one of your assignments?

Mr. COENE. It is.

Mr. SHAYS. This is not your primary assignment?

Mr. COENE. No, sir. I'm the deputy director of NCTR, National Center for Toxicological Research. It was an assignment that the Secretary asked us to take on.

Mr. SHAYS. I get the sense that the facts support, and you kind of concede, that this advisory group has not been all that active and that it has had vacancies?

Mr. COENE. We have vacancies at the moment, but we have always had a quorum at any of our meeting?

Mr. SHAYS. What is a quorum?

Mr. COENE. A quorum would be five, sir.

Mr. SHAYS. And how large is the committee?

Mr. COENE. Nine.

Mr. SHAYS. How often have you met?

Mr. COENE. We have met 12 times over the period since 1989, since I have taken the responsibility.

Mr. SHAYS. Just say that again and then tell me what you think about that?

Mr. COENE. We have had 12 meetings over the last 10 years, approximately one a year. And we responded to the need to review information that the Air Force was producing and also oversighting the scope of work for the next round.

Mr. SHAYS. The sense I get is that you view yourself more as a responder rather than a catalyst.

Mr. COENE. That would be a correct characterization. We responded to the need to oversight information and, at least during the period that I have been executive secretary to the committee.

Mr. SHAYS. I do not want to dwell on this, sir, too much but I will tell you that I find that sad because it would strike me that

veterans deserve a catalyst in an advisory group. I think your view of your responsibility is very different than mine or most veterans. And I think it points out to some of the reason we are in this mess.

Dr. Michalek, you have been working, the reason I interrupted the flow is I just thought I was not hearing right and I wanted to ponder. You have been working on this project since when?

Dr. MICHALEK. Actually, I was hired at the School of Aerospace Medicine in 1976. I was, prior to that, an assistant professor at Syracuse University in upstate New York.

Talk about the Agent Orange issue and the possibility of writing a protocol began in 1977, shortly after I was hired. I co-authored the protocol. I was involved with the planning stages and during the protocol review. The protocol was reviewed by the Armed Forces Epidemiologic Board, for example, the National Academy of Sciences, the Air Force Scientific Advisory Board during the period 1978 roughly to 1980.

During that period, all of the issues that we have talked about today were talked about in great detail. For example, should the Air Force do the study at all? What about this limited sample size and the limited power? What about this possibility of using other control groups? What about the exposure metric? All of those things were discussed in great detail. And there's an audit trail showing all of these discussions in minutes of the meetings.

Many of the resolutions of those discussions were described in the protocol. All of the concerns that we mentioned today actually are discussed in the protocol. So we have visited these issues many times.

Mr. SHAYS. Which is to say we were forewarned?

Dr. MICHALEK. We ourselves were faced with a daunting scientific issue, as to how to study—how to apply an epidemiologic template in an unprecedented setting, where we did not know the disease outcome and we did not know clearly who was exposed among the Ranch Hand unit. We knew that the best scientific method was to isolate that group which we could identify and which we could be reasonably assumed to be heavily exposed, namely the Ranch Hand unit.

The prerequisites were already satisfied. We had military records to show us who was in the Ranch Hand unit. We could identify them. And we believed, from standard epidemiologic and industrial hygiene concepts, that this group would be candidates for the most exposed cohort in the entire Vietnam—or one of the most exposed in the entire Vietnam population. Not that there are not others. In fact, we've talked about those today already. For example, the Army Chemical Corps veterans.

So yes indeed, all of the principles that we've talked about today were mentioned and clearly argued out back in the late 1970's.

Mr. SHAYS. So would it be your conclusion that this was a mistake for us to begin this study?

Dr. MICHALEK. It was not a mistake to begin the study. In fact, it has been an unprecedented and noble effort on the part of the Government to launch a study of this magnitude in a situation where there was widespread fear about the possible consequences of exposures.

We launched a study without knowing what we were going to find. We committed funds, we committed resources, and we committed people to a long-term epidemiologic effort, not knowing what the outcome was going to be. That was a very noble effort on the part of our Government and I'm proud of it.

Mr. SHAYS. But what do you think the outcome is?

Dr. MICHALEK. The outcome is that we have an unprecedented wide data base and collection of data of unprecedented scope and quality to address the issue. If you're asking me about findings, that's a different question.

Mr. SHAYS. So right now the outcome so far is that we have a data base and the data base is not being shared very willingly with the rest of the scientific community.

Dr. MICHALEK. I'd like to address that, for a minute. You're talking about data release.

Certainly, the concept of data release has evolved over the last 25 years. In fact, 1977–1978 the issue of data release was never mentioned by any of our review bodies during the time that we were writing the protocol. Data release was not mentioned in the protocol specifically.

In fact, the idea of data release has evolved in the entire scientific community since the middle 1970's, to the current time where I actually attended a National Academy workshop in December on the gulf war. The prevailing attitude there is that in all federally funded studies from this point forward, data will be released to the public immediately. That's an unprecedented decision. And that illustrates the evolution of attitude and philosophy that has taken place since the middle 1970's.

So to take you back to the middle 1970's, in 1978, 1979, certainly the intent of the study and of the principal investigators and of the advisory committee was to conduct a credible and scientifically defensible effort in this direction, although data release itself was not specifically mentioned.

Among the principal investigators, of which I am one, and by the way I was appointed principal investigator in 1985, our attitude has been No. 1, we will release to the public that data which we are sure is correct. And No. 2, we will not change any data. When we receive data from the clinics, such as in Houston or in San Diego, the data bases remain untouched. If we find mistakes, data in the computer which doesn't match with data on the records, we make fixes or corrections in our computer code. So that our attitude there was that this was as much a legal investigation as it is a medical investigation.

So with those two constraints that we had self-imposed ourselves back in the early 1980's, we have already made data release very difficult. It can't be done quickly.

On top of that, we have privacy concerns with the veterans themselves. The immediate release of data, if not carefully done, would certainly violate privacy because names and Social Security numbers and other private information are in many of these datasets.

And when you speak about data you need to realize that there are many different kinds of data that are in our possession at Brooks Air Force base, not just computer data files. We have approximately 4 million documents collected on the medical records

from the men themselves, their children, and their wives. And we have approximately 50,000 specimens of biological materials such as serum, adipose tissue, urine, and semen in our institutional freezers. We have an archive of information on these individuals that's very extensive. Data release has to be done very carefully.

Another constraint on data release that you may not be aware of is that when this study began our emphasis was on carefully auditing data release such that it could be made official. That meant we would release data through the National Technical Information Service in Virginia. At that time, in 1978, 1979 and early 1980's, the prevailing computer technology was far different from what it is today. Computers were—datasets were in very crude what are called flat file format, where they had to be individually documented. That was the requirement for the National Technical Information Service, that they receive what are called flat files.

The other constraint is that once an agency such as us releases data to the National Technical Information Service, it can never be retrieved. Meaning that whatever we give out, we can never get back. That puts a constraint on what we release, because we want to release data that contains no mistake. In other words, data that can be item-by-item verified as being the same as what is in the medical record.

So the data release concept is as difficult and perplexing for us as it is for you.

Mr. SHAYS. I want to be clear for the record. The record is I want to be clear that I am understanding, Mr. Epley, what you said. Basically, your testimony is to date the Ranch Hand study has not been a factor one way or the other in decisions made on compensation to veterans, in terms of their general health care? That is the essence of what I got.

Mr. EPLEY. That's correct.

Mr. SHAYS. So really where we are right now, in my judgment is——

Mr. EPLEY. With one exception, Congressman, if I may. In the issue of spina bifida, that was material.

Mr. SHAYS. OK. Dr. Michalek, what I still wrestle is you are basically saying that we were told things would turn out the way they have. I am not quite sure I am comfortable with that. In other words, everything we are talking about now was talked about when we began this study. All the concerns about data release and so on.

I get the sense that, in a way, that this is turning out to be a study that will be great for scientists and great for someone who follows maybe years from now, so I do not belittle that part in that sense, our solders to come. But in terms of the Vietnam veterans, by the time we are going to get some solid information from the data that is still not being disseminated and still being developed, that they are almost—I do not want to say guinea pigs in a bad sense, but they have provided all of this information but they may not benefit from it. That is the sense I am getting.

Dr. MICHALEK. I think the conflict has been described already by Dr. Chan from the GAO. There's definitely a conflict here between expectations and reality, as far as science is concerned.

When we say, for example, that our first published article occurred in 1990, you need to know that work on that paper began in 1986, only 1 year after the second physical.

Mr. SANDERS. Excuse me for interrupting, you are really not answering the Congressman's question. I think basically what he was saying is we are spending $120 million. There are a whole lot of interesting scientific questions out there. Although neither of us were in Congress when this process began, we presumed that what Congress wanted to know and wanted to learn was how Agent Orange affected the men and women who served in Vietnam. That is what they wanted to learn.

And what Mr. Epley has just told us, what Mr. Chan has told us, is basically we have learned very, very little from Operation Ranch Hand in terms of how that affects our soldiers who were over there and how we can provide compensation to them.

So it may be the world's greatest scientific and epidemiological study, but in terms of what the U.S. Congress wanted, I would agree with the chairman that apparently we have not gotten a whole lot for that.

Mr. SHAYS. I am going to give you a chance to respond. I guess the bottom line is my sense is that that was what, an unrealistic hope? An unrealistic expectation?

Dr. MICHALEK. All I am saying is that the timelines in science are much longer than the timelines in public health policy. It takes up to 7 years to get an article published in a peer-reviewed journal, for example. It took us——

Mr. SANDERS. Let me jump in and say something. You know, we are talking about people who believe that they are dying, that their kids are being affected. And it takes 7 years to get a peer-reviewed article accepted? Well, do something about it.

In other words, this gets back to the point. We are not dealing with some academic exercise. You are dealing with the lives of Americans who suffered in that war. And to say well, it takes 7 years for us to get it peer-reviewed is unacceptable.

Can you respond to that?

Dr. MICHALEK. Yes, I can. Of course, we have two different kinds of products from the study. We have un-peer-reviewed Government reports that we put out subsequent to every physical examination, each numbering in the thousands of pages. We've produced approximately 20,000 pages of reports, all of them available through the Government Printing Office. They're all official Government reports summarizing every single physical examination.

So that all of the data you've just mentioned has been described already in those reports. Separately, we intend and are publishing the data from those reports in a distilled form in research articles published in scientific journals. So that the immediate timelines you're talking about are met by the Government reports, not by the journal articles themselves which come out many years later.

Mr. SHAYS. Go ahead, Mr. Sanders.

Mr. SANDERS. Thank you, Mr. Chairman.

The advantage, in some respects, for scientists testifying before a congressional hearing is that Congressman do not necessarily know a whole lot about science. But you know what we do know

about? Do you know what we are the world's greatest experts about? It is outreach.

Because if we were not good in outreach, we would not be here. Whether it is Mr. Shays, myself, Mr. Bush and Mr. Gore, they have to reach out to the people or else they do not get elected. Right? That is what politics is all about.

So we know a whole lot about outreach. We spend a whole lot of money on outreach, et cetera.

Now I would like to ask Mr. Epley to describe, and I want to thank him and Dr. Mather for joining me last week in my office to go over some of these issues. After all is said and done, we have about 7,585 men and women who are receiving benefits for health effects due to Agent Orange. Is that a correct number? That is the number you gave me, and I am presuming it is.

Mr. EPLEY. That number is accurate in reflecting the Vietnam vets who are receiving service-connected compensation due to the presumptive conditions.

Mr. SANDERS. I have nine diseases listed, I guess spina bifida is not here, so maybe there are some more.

We had approximately 3 million men and women over there; is that correct? And probably nobody in the world knows how many of them were exposed to Agent Orange and so forth?

Mr. EPLEY. That is the best number I've heard, sir.

Mr. SANDERS. Off the top of my head, would you agree with me or disagree with me, Mr. Epley, it would seem to me that 7,585 folks receiving compensation is a pretty small number. Would you agree or not agree?

Mr. EPLEY. Relative to the number of veterans that served in Vietnam, it is a low number. If I may, I would add to that, though, the number of people who are receiving compensation who asserted disability from Agent Orange is higher. Let me explain that, if I may.

We have about 99,000 vets, a few more than 99,000 veterans from Vietnam who have claimed service-connected benefits and asserted that their disability related to Agent Orange.

Mr. SANDERS. 99,000.

Mr. EPLEY. Right. The 7,500 comes out of that population. But also out of that population, about 65,000 of those veterans are service-connected for one or more disabilities. They're not the disabilities on the presumptive list. But that number certainly is a more representative figure.

Mr. SANDERS. So 99,000 came forward requesting benefits?

Mr. EPLEY. Yes, sir.

Mr. SANDERS. 66,000 are receiving benefits?

Mr. EPLEY. About, yes.

Mr. SANDERS. And 7,500 are getting——

Mr. EPLEY. I need to add to that. Some of those veterans may be service-connected and at the zero percent. We did a data run to determine how many of the 99,000 have one or more service-connected conditions. That's the 65,000-plus. Some of those could be zero, so they may not all be receiving money, but certainly the vast majority of the 66,000 are receiving compensation.

Mr. SANDERS. Explain to us why, if 99,000 came forward, understanding that people are receiving benefits for other things, only

7,500 approximately are receiving benefits from exposure to Agent Orange?

Mr. EPLEY. That 7,500 represents the number of Vietnam veterans who have one of the presumption conditions, the 9 or 10 on your list. It is a low number, but we did a quick check based on the Agent Orange studies and our informal discussion on expectations. And the 1993 study, the Agent Orange study did do some estimations of what populations they would expect to see by the year 2000 to have contracted the conditions.

The numbers are not that different from what we have in our 7,500 list. By example, the 1993 study said the expected cancer cases among male Vietnam vets in the year 2000 for non-Hodgkins lymphoma would be 494. We're paying 1,464. For prostate cancer, their expectation in 1993 was 855 and we're paying 1,441.

Mr. SANDERS. But if I can interrupt you, that's an interesting statement. But in fact, these prostate cancer and the other illnesses are on this list because we have concluded that exposure to Agent Orange causes these problems. And so the real question to be ask is, given the fact that *X* numbers of people were exposed, is the numbers that you have here a reasonable response to those numbers? Do you understand what I am saying?

Mr. EPLEY. Yes, sir.

Mr. SANDERS. So we are not talking about the general population, we're talking about those who, in fact, have been exposed to Agent Orange, which is a cause of these illnesses.

Off the top of my head, I would say that is not a particularly high number.

Mr. EPLEY. I understand.

Mr. SANDERS. Mr. Epley, let me ask you this, we held a town meeting in Vermont a couple of weeks ago and the question I asked the veterans who were there is they really have not heard a whole lot about this issue. They do not know what they are entitled to. And you can disagree with me if you want, please.

I would say if we did a poll of Vietnam vets and we said to them do you know what particular illnesses the Government has determined were caused by exposure to Agent Orange, of which you are entitled to benefits, would you think a large number of the vets would know that?

Mr. EPLEY. I think that a large number would not be able to recite the conditions.

Mr. SANDERS. I know that. I do not mean as an exam. But I mean to say if I was a Vietnam vet, which I am not, and if I had prostate cancer, do you think I would automatically say geez, I read something and I know that that is something that might be caused by Agent Orange? Do you think the average vet would know that?

Mr. EPLEY. I think there is a general understanding that it's an issue to be pursued and I think that's indicated by the number of vets who have filed claims. It's indicated by the number of vets who, at least initially, applied to the Agent Orange lawsuit that you referred to earlier.

I think there's a sense that hey, I can go somewhere and pursue this. Maybe not much more than that.

Mr. SANDERS. Would you be willing to guess, and we do not have the information, that there are perhaps thousands of veterans who served in Vietnam who were exposed to Agent Orange who have prostate cancer and have no idea that they are entitled to benefits from the United States Government? Would I be right or wrong, do you think?

Mr. EPLEY. I think there are some.

Mr. SANDERS. Some?

Mr. EPLEY. Yes.

Mr. SANDERS. Do you want to broaden that; 1, 2, 5,000, how many? I know you do not know.

Mr. EPLEY. I don't know.

Mr. SANDERS. Let me ask you this question, and we discussed this last week. You gave me, and I appreciate you giving me this, some pretty good publications. How many of these do you publish, and who reads them?

These are publications, for the record, Agent Orange: Information For Veterans Who Served in Vietnam, general information. And also, there is an ongoing publication called Agent Orange Review. How many of these do you publish? Does the average veteran get this? Or is this really for the scientific community or the veterans organizations?

Ms. MATHER. The Agent Orange Review, which is the newsletter that comes out several times a year, goes to all of the veterans who have signed up for the Agent Orange registry exam. And as of February 24th, that was 298,234 veterans. So that many goes out.

Also, copies go to the veterans service organizations who are our strongest ally in outreaching to veterans. The Vietnam Veterans of America do a wonderful job of outreaching, as does the American Legion and the VFW and the DAV.

Mr. SANDERS. So approximately 300,000 of these go out.

Ms. MATHER. Those go out to individuals.

Mr. SANDERS. Right, that is a lot, and that is good. The problem is we had about 3 million men and women over there. What effort are you making to reach out to the others, A. And B, I am a great fan of the service organizations, and I think they do a very good job, and obviously they must be involved. The Vietnam Veterans of America, VFW, American Legion, DAV must be involved in this effort.

But the fact of the matter is that we have 27 million veterans in the United States and less than 3 million of them belong to the service organizations. And some of them belong to more than one organization. That leaves about 25 million veterans who are not in contact with the service organizations.

What effort is being made to reach out to those people? For example, and you and I discussed it, how many town meetings have you had on this issue? How many PSAs have gone out? How many press conferences have you had around the country? How would the average veteran, who is not associated with the VSO, know what he or she might be entitled to?

Mr. EPLEY. We do do regular town meetings through the regional office system that we have. This year we have scheduled 59 standdowns, which is a process that we do at various locations around the country to provide general benefits dissemination. It's not

geared specifically to Agent Orange, but general benefits dissemination, general medical——

Mr. SANDERS. How do you advertise those meetings? How many people come to those meetings? How do you advertise them?

Mr. EPLEY. They're advertised locally, basically through the medical system.

Mr. SANDERS. How many folks might attend those meetings?

Mr. EPLEY. At the ones that I've attended, it has ranged from 150 to 300.

Mr. SANDERS. And you are explaining the benefits that veterans are entitled to?

Mr. EPLEY. Yes, in a very informal way, but it's set up to allow the vets to come in and look for what they need.

Mr. SANDERS. I am going to invite you to Vermont to do that.

Mr. EPLEY. I think I knew that was coming.

Mr. SANDERS. But in addition, I have to tell you something. I have been working on an issue of prescription drugs and veterans. As you know, of course, that if a doctor examines a veteran, that veteran is entitled to prescription drugs at, I think, $2 a prescription which is an enormous saving for many veterans.

Do you know what? In the State of Vermont many, many veterans did not know that that benefit existed. I am sure that that is true all over America. I sent out a newsletter. We probably had 300 veterans respond to it.

If veterans do not know that they are entitled, going through the VA, to get inexpensive drugs, I have my doubts about how many of them are going to know about the benefits that they are entitled to through Agent Orange. Would you agree with me?

Mr. EPLEY. It's hard to know. If you don't know, you just don't know. You don't know where to go.

Mr. SANDERS. I heard Mr. Coene talk about the service organizations, but I am concerned about your being overly dependent on the service organizations. In other words, how are you going to get to the vast majority of the veterans who are not members of service organizations? What is your plan?

Mr. EPLEY. We do have a toll-free number available to veterans, on which we receive about 10 million phone calls a year for general benefits information.

Mr. SANDERS. When people call what do they get? A human being? Do they get a tape recorder? What do they get?

Mr. EPLEY. They get a human being. They get an opportunity to go to the team that manages their case, if they have an active case. They do, in some instances, get an interactive voice response if they're looking for general information. They can do that automatically.

Mr. SANDERS. You got 10 million calls.

Mr. EPLEY. About 10 million a year is what we respond to.

Mr. SANDERS. For information about veterans benefits?

Mr. EPLEY. We do the stand-downs, as I mentioned. As Dr. Mather mentioned, we do the newsletters. We also notify veterans on the registry when there are results from the NAS reviews. We let them know that there's potential change in the benefits, and those are to the 300,000.

Mr. SANDERS. Would you agree with me that if we have about 10 percent of the folks who were over there on the registry, yes? That is not a particularly high number is it?

Mr. EPLEY. No.

Mr. SANDERS. What are we doing to increase the number of people? I mean, it sounds to me like you are trying. Dr. Mather indicated that you are trying to do a good job in communicating with the folks who are on the registry. The concern is the 90 percent of the vets that are not on the registry.

Mr. EPLEY. One of our main focuses or foci recently, in terms of outreach, has been to separating servicemen. I know that that does not apply directly to this population. But we have initiated a project under transition assistance where we are trying to reach out and give full orientation of benefits to departing servicemen before they leave the service, so they get an understanding of the full range of benefits.

Last year we conducted about 80,000 personal interviews in that effort and we're expanding to the point now where we have VA personnel either permanently or itinerantly at about 60 of the major separationsites.

Mr. SANDERS. I think that that is, by the way, a very good idea.

I was told by at least one veteran so I do not know if it is the God's truth or not, that this information is not often seen at VA hospitals. Are these publications available? Are they on the racks?

Ms. MATHER. They are sent out. They have been very popular. I think the fact that they may not always be available is just our inability to keep up with the demand. That just did come out this year, however.

Mr. SANDERS. But what I mean is do you make, in terms of trying to get the word out, do you send this to every VA hospital in the country?

Ms. MATHER. We do send these, yes.

Mr. SANDERS. And you will insist that they put in a place where veterans can pick it up?

Ms. MATHER. Yes.

Mr. SANDERS. Let me just ask Dr. Michalek a question. How do you respond to the recent information that came out from the Vietnamese Government that they estimate that there are 1 million victims of Agent Orange in Vietnam, suggesting that it is a very serious health problem over there. They suggest they have a million victims, and I know that that is totally unscientific and an estimate. And we have 7,500 men and women who are collecting Federal benefits from exposure to Agent Orange.

What do we learn from the serious problems that may be existing in Vietnam? Does that mean anything to you?

Dr. MICHALEK. Yes, it's meaningful to me because, of course, if you're going to look for people who were exposed, that would be the place to go. And to see evidence of concern over there and a counting of individuals with adverse effects should motivate more research. In my opinion, I'm not saying agency policy here.

Mr. SANDERS. But you said that might be the place to go?

Dr. MICHALEK. Yes.

Mr. SANDERS. Have we gone?

Dr. MICHALEK. I understand that certain individuals have visited. We've seen video of Dr. Arnold Schecter, for example, visiting Vietnam. We know the Canadians are there, taking very systematic sampling.

Mr. SANDERS. But what about the U.S. Government?

Dr. MICHALEK. I have not seen any official—personally, I haven't seen any official evidence of United States involvement in Vietnam.

Mr. SANDERS. Again, I am not a scientist but it would seem to me that if I wanted to learn about the impact that exposure to Agent Orange might have on human health, I might want to go to that place where people were most exposed.

Now whether the Vietnamese Government is right or not that there are 1 million victims, I do not know. We have heard, and I am sure you have heard anecdotally and probably seen photographs, of children who were born with birth defects and other problems.

I do not quite understand how people who are studying the impact on Agent Orange on human health have not quite made it over to the country where the exposure seems to be most great. Anyone want to comment?

Dr. MICHALEK. Personally, I agree with you completely.

Mr. SANDERS. Thank you.

Mr. SHAYS. Dr. Butler, I would like to draw you in here a bit, and I think that Congressman Sanders has made an obvious statement. This is not our expertise, but the value of this is that if you can explain it to us, then the rest of the world can understand it.

Mr. Chan kind of introduced this in talking about the certainty of scientific research versus our needs and policy. In your testimony, you talked about how you are basically in charge of three epidemiological studies in three areas: the occupational studies, environmental studies, and veterans studies.

Excuse me, you are doing three studies: the review of the health effects of Vietnam veterans exposure to herbicides; review of evidence regarding link between exposure to Agent Orange and diabetes; and phase III of the historic exposure reconstruction model for herbicides in Vietnam?

Mr. BUTLER. That's correct.

Mr. SHAYS. You are looking at the occupational studies, environmental studies, and veterans studies?

Mr. BUTLER. Yes, sir.

Mr. SHAYS. You then make the point, you say the committees have found a common approach established by the first committee to summarize their evaluation of the evidence. They have classified disease into four categories. The first category, sufficient evidence of a statistical association between the disease and exposure to herbicides or dioxins. The second, limited or suggested evidence. The third, inadequate and insufficient evidence to determine whether an association exists. And the fourth category, limited suggested evidence of no association.

Mr. BUTLER. That's correct.

Mr. SHAYS. When we have to look at what you do to determine compensation, what level should we be at?

Mr. BUTLER. That's a policy rather than a scientific decision. What the committees were tasked with doing was doing a com-

prehensive review of the scientific information and presenting a consensus opinion, if you will, looking at——

Mr. SHAYS. That it would be one of the four categories you described?

Mr. BUTLER. That's right. In trying to summarize a vast amount of scientific literature on this subject, scientific groups in the past have used general categories like this to try to give a general feel for where the consensus of the science is.

This particular set of categorizations was one that was first used by the International Agency for Research on Cancer and was subsequently borrowed by this committee.

Mr. SHAYS. Well, you did not really answer the question, but I will come back to it because this is helpful. I guess what I am trying to come to grips with is, in your work, have you relied on data from Ranch Hands? Are you basically waiting for information?

Tell me how you would like to utilize the information from this 25 year study.

Mr. BUTLER. Ranch Hands is one of the studies that is carefully examined by National Academy of Sciences committees when they reach their conclusions. It isn't the only piece of information, though.

For example, there is also information available from the Australian Commonwealth Department of Veterans Affairs on their Vietnam veterans population.

Mr. SHAYS. I understand you are not going to just wait for this, but we are spending on an average $5.6 million a year. We are hoping that this study has more than just outcomes on more than just data. I am just trying to ask you, it has not been very helpful to date to the Department of Veterans Affairs.

I guess we could do the inverse and say well, it could be helpful in one sense, we could take the inverse and say well, we are not feeling we have to compensate anyone yet, or many people. So it has not put many people on our list. And some could interpret it to say that so far there is nothing that has caused us a proactive effort to do that.

Now from my standpoint I may not be pleased with that, but that would be one potential result. But I guess what I am asking you is has this been very helpful to you?

Mr. BUTLER. The Ranch Hand study is a helpful study as part of our examination of the whole of the literature. There's no one study that's going to be determinative.

Mr. SHAYS. I accept that, but my sense is, and correct me if I am wrong, but my sense is there has not been much information disseminated.

Mr. BUTLER. We have reviewed a number of reports over the years in the three Veterans and Agent Orange studies. I'm afraid I don't have an exact number, but we carefully examine any information that is published by the Ranch Hand researchers.

Mr. SHAYS. I feel like I am playing chess with you here. The reality is we have got a fairly concise comment from VA that, to date, it has not resulted in their finding many people to compensate as a basis of this report. I am asking you if you have gotten much information here? And did you expect that you would get more sooner?

Let me just say, I do not want you to carefully consider your words here. Just as you do not rely on this for the total basis for all your studies, your answer is not going to be the total on my conclusions. I just need to get an answer.

Mr. BUTLER. It is a helpful study. I can tell you that Dr. Michalek has always been forthcoming in providing information requested by the National Academy of Sciences committees, and has been mindful of the observations committee members have made, the suggestions for future work, and for ways to improve the study.

Mr. SHAYS. Let me ask you this question. Did you have an expectation that you would get more information and you would get that information sooner?

Mr. BUTLER. The Academy does not form any expectations of any study of this sort.

Mr. SHAYS. That is not what I asked. They have information that has not been released, they have studies that have not yet been released. Did you expect you would get information and studies sooner? It is a simple question.

Mr. BUTLER. We expect that we will get the information from the studies, yes, as quickly as it's available. We want as much information as possible to consider in making our decisions.

Mr. SHAYS. I am going to ask it again and we will have a long time here, because it is really a simple question and it is a waste of time for you to be here if you are not going to answer basic simple questions. It is a yes or no.

Am I am not saying I am going to like your answer. Did you expect that you would get information sooner? And did you expect to get more information than you have received to date?

Mr. BUTLER. Did we expect to get information sooner?

Mr. SHAYS. And did you expect to get more information than you have received to date?

Mr. BUTLER. No, I don't believe we expected to get information sooner and no, we don't have any expectation about getting specific information in the future, except that we are hoping to get as much as possible as soon as possible.

Mr. SHAYS. So your expectations were pretty low, frankly. They certainly were lower than our expectation.

Mr. BUTLER. In our job, in reviewing all the information, we can only deal with what's out there. We don't have the ability to initiate specific studies or to drive the pace at which others provide information for the committee's consideration.

Mr. SHAYS. I understand that. That is not really what I said. I know you cannot force the information sooner, but you might have had an expectation you would get it sooner. And your answer is no. You had really no expectation that you would get it any sooner than you have. And that is helpful information, and I thank you for finally answering the question.

I am going to ask you the first question again. You shared the fact that you classify diseases into four categories. I am asking you to give me your opinion, and that is the way I accept it, as your opinion.

At what level do you think Government should consider compensation? Should we have a no shadow of a doubt? The reason why I am asking the question is I have come to the conclusion,

based on our work that we have done on gulf war illnesses, based on our review of Agent Orange, that I have to be honest with our veterans. By the time we will know the scientific data, you are dead. You will either have died early or you will have died in your old age in pain, but you will not get help from the Federal Government.

That is the honest answer that I have to give people, if in fact we have to wait until we have 99 percent certainty. What Mr. Chan said in the beginning, I think, is very helpful to me and it explains, Dr. Michalek, your approach. You are a statistician and an expert in your field and you are doing your job as best you see. And you have already said that a lot of these questions we have raised were discussed early on.

But it is an eye-opener to me because my view is that I do not want to wait until you have 99—maybe I would like to be 70 percent certain and then I am willing to go to my taxpayers and say you are going to pay more to help veterans who were sent to war. And maybe I am saying it because when my colleagues were in Vietnam I was in the Peace Corps. Maybe a whole host of factors are coming into play.

You are a scientist, I am a politician. I am asking you to step aside from your position as a scientist now and say is there some solution short of being 99 percent certain where we can say it trips over and, you know, the odds are, and why do we not compensate? Is there any solution to this mess I find myself in, of having to wait until we are 99 percent certain?

Mr. BUTLER. The Academy gives its opinions on the scientific information.

Mr. SHAYS. I understand that.

Mr. BUTLER. The policy decisions are very clearly outside of the mandate for the committees, and the committees have never offered an opinion on the policy decisions which are made on the basis of that.

Mr. SHAYS. And so you choose not to offer an opinion?

Mr. BUTLER. I don't feel it's my role as a study director to offer a policy opinion.

Mr. SHAYS. Now you have an opportunity to make a contribution separate. That is not unusual. We get witnesses here and we say my God, you have worked on this for years. You are restrained by your science and you are going to follow that, you have an opportunity.

And you refuse to give an opinion?

Mr. BUTLER. I appreciate the opportunity, Mr. Shays. In my role as the person who facilitates this study, it's my belief that I do that job best if I act as a neutral, unbiased conduit of information to the expert committees that are formed by the National Academy of Sciences who come to the decisions that are made in these reports.

Mr. SHAYS. And therefore, you have decided not to answer that question?

Mr. BUTLER. That's correct.

Mr. SHAYS. So who do we turn to? Let us go to the VA. What I am trying to do is I am not going to wait until we are 99 percent certain. You are going to do your science and you will be in your nice rooms and you will do it and the veterans will be guinea pigs

because they will be there and they will provide all your wonderful data. And we have this outcome, all this data, and they literally grow older. Some of their children are raised and they are not well.

And maybe they should have been compensated by us, but we are not 99 percent certain. Is there any scientific level that we could turn to, short of 99 percent, that would give us some way to come to a conclusion here?

Ms. MATHER. I believe that the Congress gave the Secretary of Veterans Affairs that charge in the legislation, in which he took the reports that the National Academy of Science and Institute of Medicine gave him, and then made a policy decision as to what diseases should be service-connected.

In reality, we've accepted all the diseases for which the National Academy of Sciences found there was sufficient evidence of an association, and limited or suggestive evidence of an association.

Mr. SHAYS. That is the top category, is it not?

Ms. MATHER. The top two categories.

Mr. SHAYS. So you have to meet sufficient evidence of a statistical association or limited or suggested evidence? I do not think that is true.

Ms. MATHER. That is, in fact, what the Secretary has decided over time, over the 3 years.

Mr. SHAYS. Now do you release reports, Dr. Michalek, that would come to a conclusion? Do you grade according to these four categories?

Dr. MICHALEK. No, sir, and I'm not aware of any other study that does. That's an activity carried out by the National Academy of Sciences for reviewing all studies.

Mr. SHAYS. So when you release your studies, what do you have to be certain of?

Dr. MICHALEK. We're not really certain of anything when we release a study, except for the fact that we've done the best job we can. We render an opinion at the end of any article or report suggesting an interpretation of the data, as to whether we think this indicates a relation between exposure and disease or whether it does not. Those interpretations are read by the National Academy of Sciences and all of our reviewers.

So yes, we do offer an opinion about whether or not there is a relation between herbicides and exposure in every article and every report.

Mr. SHAYS. And how do you grade those opinions? What are the levels? How do you grade them? Do you say yes, no, or maybe?

Dr. MICHALEK. Well, the language that's used in these reports is not conversational. For example, a statement in an article or report that the data suggests an adverse relation between herbicides and health is, in the scientific literature, a very strong statement. And that's about as strong as it gets in any scientific article or report.

Mr. SHAYS. Suggested evidence?

Dr. MICHALEK. Yes, suggested. And that's the material that the NAS uses to render an opinion that's ultimately used by the VA.

Mr. SHAYS. And is suggested evidence one level below, in your opinion, sufficient evidence?

Dr. MICHALEK. I think it's—yes, second level up.

Mr. SHAYS. Do you have any questions you want to ask?

Mr. SANDERS. Mr. Chairman, one thing occurs to me, based on this discussion, especially with Mr. Epley, that we as a committee—and it is your decision of course—but at some point we, as a committee, might want to take a look, a general look, at how well the VA does in terms of its outreach for veterans benefits in general, beyond Agent Orange.

Mr. Epley, veterans have told me that it is sometimes a very difficult process, in terms of filing a claim for a service-connected compensation regarding Agent Orange, in terms of not receiving a fair hearing. Is that true, in your judgment?

Mr. EPLEY. No, I don't think so. The filing of the application is a fairly simple procedure. The adjudication of the claims for the presumptive conditions should be very simple. That is the intent of it. If the veteran served in Vietnam and if the veteran has contracted one of the diseases on the presumptive list, they should be service-connected. Then we're only dealing with the level of evaluation.

Mr. SANDERS. But I am told by some knowledgeable people that, in fact, that is the case in some of the offices. But in fact, in other offices there is a great deal of foot dragging, denying claims, and making spurious requests. Do you think you have an across-the-board process where all of your offices are responding well?

Mr. EPLEY. I think we have a process that is clear and understood. I would suggest that there is not a level of consistency that we need in the administration of it day-to-day.

Mr. SANDERS. Doctor, you indicated a moment ago what I think is common sense, that you think that the U.S. Government should probably go to Vietnam to start studying the situation. When will we expect that study to be done?

Dr. MICHALEK. First of all, I've offered to go myself and that's still under discussion in our group. As to when it should begin, that will require a mandate on the part of the Government to provide the resources and the apparatus to get something started. I would say as soon as possible, because the longer we wait, the more difficult it would be.

Mr. SANDERS. Require a mandate. Small groups without a whole lot of money, like the Vietnam Veterans of America could send over a group of people.

Dr. MICHALEK. It's not enough.

Mr. SANDERS. I agree with you. So what kind of mandate? That is your job, is it not? You are studying this issue.

Dr. MICHALEK. The mandate would be similar to the mandate that established this study, to set up an advisory panel, to write a protocol, to define the concepts.

Mr. SANDERS. Let me tell you something, based on what I have heard about this study, that would be precisely the last thing that I would suggest that we do. It would be another 20 years before anyone got there.

Dr. MICHALEK. It does not have to be a 20 year study.

Mr. SANDERS. Mr. Epley, maybe you and I could speak later.

Mr. EPLEY. May I add one comment? You mentioned outreach and we are undertaking a study of the outreach efforts in VA, VBA specifically, to determine whether or not we're meeting the statutory intents for outreach and if there are gaps what we need to do

to pursue them. As soon as they're available, we'll be glad to talk with anyone who's interested.

Mr. SANDERS. I would be very curious to see that. Thank you, Mr. Chairman.

Mr. SHAYS. Thank you very much. I appreciate all of the witnesses. Your testimony was helpful, very helpful, and very educational. So that was appreciated.

At this time, I would like to call the next panel. Thank you.

Our first witness is Dr. Richard Albanese, Senior Medical Research Officer, U.S. Air Force; Dr. Linda Schwartz, associate research scientist, Yale University School of Nursing, consultant, Veterans Health Care; and Dr. Ronald Trewyn, dean of graduate school and vice provost of research, Kansas State University, former member, Ranch Hand Advisory Committee.

I would invite the panel to stand and I will swear you in.

[Witnesses sworn.]

Mr. SHAYS. I appreciate all of you being here for the other panels. It helps us because you have heard from them and you can make comments.

For the record, all three of our witnesses have responded in the affirmative and we will start with you, Dr. Albanese.

STATEMENTS OF DR. RICHARD ALBANESE, SENIOR MEDICAL RESEARCH OFFICER, U.S. AIR FORCE, FORMER RANCH HAND PRINCIPAL INVESTIGATOR; DR. LINDA SCHWARTZ, ASSOCIATE RESEARCH SCIENTIST, YALE UNIVERSITY SCHOOL OF NURSING, CONSULTANT, VETERANS HEALTH CARE; AND DR. RONALD TREWYN, DEAN OF GRADUATE SCHOOL AND VICE PROVOST OF RESEARCH, KANSAS STATE UNIVERSITY, FORMER MEMBER RANCH HAND ADVISORY COMMITTEE

Dr. ALBANESE. Thank you. I am an Air Force medical research officer whose travel here has been funded by the Air Force. However, my testimony does not necessarily reflect Air Force policy.

I was a principal investigator in the U.States . Force health study, the Ranch Hand study, from 1978 through 1984. I am one of four authors of record primarily responsible for writing the protocol, with Colonel George Lathrop, Colonel William Wolfe, Colonel Patricia Moynahan and myself. We're the four authors of record of the study protocol.

During my time with the Ranch Hand program, I observed two protocol violations. These were the lack of veteran representation in the science review process and command influence.

Mr. SHAYS. What was the second?

Dr. ALBANESE. Command influence.

In my opinion, the lack of Vietnam veteran representation denied veterans and their families a fair assessment of health effects associated with Vietnam service. Important on-the-ground operational dimensions, and critical study limitations were missed.

The command influence directly altered report content. In my opinion, this also denied veterans a fair assessment of their health status.

Protocol violations, in my opinion, are quite serious. We advertised to the veterans who came and allowed themselves to be examined that they would have their interests protected by representa-

tives in the science review process. We violated their right of informed consent when we failed to do that. And command influence is effectively scientific misconduct.

These issues were addressed in the 1980's. The legislation passed after the 1988 hearings apparently did not fully correct the problems in the Air Force health study. Public Law 100–687 requires the study monitoring group to conform to the study protocol with one-third veterans representation.

The December 1999 GAO report to the Honorable Lane Evans relates that veterans participation has been incomplete or erratic, despite the public law. As you read in the report, there were individuals who were representing veterans who didn't know they were representing veterans. Similarly, the December 1999 GAO report indicates that study limitations have not been fully and clearly communicated to the public.

In my opinion, the effects of limited veterans representation and poor communication are apparent in the scientific reports issued by the Ranch Hand study. Of very great concern to me are birth defects and cancer in this group involved with spraying herbicides. Also, I perceive seriously inadequate data flow to veterans concerning heart disease, vascular disease, neurological ailments, endocrine disturbances and hematological difficulties.

Timely full clear reporting can assist medical personnel to better care for veterans. And it is my definite medical opinion that the men in this study need care today. And what they need today relates also to what other veterans need today.

The hierarchical structure of the military organization, which is excellent to conduct war, can compromise scientific and medical research. I am concerned that the recent failures to report the Ranch Hand study properly are institutionally influenced. I recommend that the Air Force adapt integrity programs such as the Office of Scientific Integrity in the NIH and the FDA program to improve the way they clear research and other papers for publication.

I personally have experienced management changing a concluding sentence in an article even after that article was cleared by the Air Force and accepted in the open literature. This is not an every day matter, but there are no protections, that I'm aware of. About 10 percent of my medical articles have been thus changed. How can I view Dr. Michalek and his people as free, intellectually free, when I know that I am not and my other senior colleagues are not?

Clearance processes may be OK when you're building missiles, but it makes no sense in medical research. It makes no sense in medical research.

For nearly 20 years, the Ranch Hand study has been unable to properly include veterans in the scientific review process. And for nearly 20 years this study has only reported part of the truth. Real veterans' representation can occur and reporting can improve in this effort if GAO recommendations are energetically and scrupulously followed.

I concur with the GAO recommendation on data release to the general public, but I advocate full, full, full data release to individuals who are qualified to protect subject confidentiality, individuals at medical schools and university who would sign a document agreement to protect confidentiality.

And there's no issue about letting data go that has error. You publish the data that you've used to write your report and you earmark it as such, and every scientist knows the limitations of such data. I am concerned that full data publication will not occur.

I strongly advocate funded replication and analysis of Ranch Hand work by independent and qualified individuals. I would like to think the data itself will attract professors, but if it doesn't I think funded studies to replicate are necessary.

If integrity programs are not strengthened and if veterans are not included, and if data are not really shared, then at the risk of loss of time and data—and remember, my medical judgment is these men are ill—I recommend study transition to another agency.

Thank you.

[The prepared statement of Dr. Albanese follows:]

Testimony of Richard A. Albanese, MD, to the Committee on Government Reform, Subcommittee on National Security, Veterans Affairs and International Affairs, 15 March 2000.

I am an Air Force Medical Research Officer whose trip here has been funded by the Air Force. However, my testimony does not necessarily reflect Air Force policy. I was a Principal Investigator in the United States Air Force Health Study, the Ranch Hand study, from 1978 through 1984. I have since stayed abreast of Agent Orange research through Air Force Office of Scientific Research activities and outside personal research activities.

Peer review group meetings during my time with the Ranch Hand program did not have the protocol required Vietnam veteran representation. In my opinion, this departure from the study protocol denied Vietnam veterans and their families a fair assessment of health effects associated with Vietnam service. Important operational dimensions were missed and critical study limitations were not appreciated.

Also during my tenure, in violation of the study protocol, one letter from above the Air Force chain, and one letter from Air Force management, was provided to the principal investigators. My local commander provided one additional letter directly to me stopping my dioxin toxicological research. These letters influenced report content. In my opinion, these actions further denied veterans a fair assessment of their health status by inappropriately incorporating institutional biases. It is clear to me that there was limited intellectual freedom in the Air Force Agent Orange research program in its early years. In the setting of an American university, a scientist is permitted to report his or her scientific findings uninhibited by material university interests. This was not the case in the Air Force in 1984.

The legislation passed after the 1988 hearings evidently did not fully correct the problems in the Air Force Health Study.

Public Law 100-687 requires the study-monitoring group to conform to the study protocol with one-third veterans' representation. The December 1999 GAO report to the Honorable Lane Evans relates that veterans' participation has been incomplete or erratic despite Public Law 100-687.

Similarly, the December 1999 GAO report indicates that study limitations have not been fully and clearly communicated to the public. The GAO concerns with sample size limitations and evaluation criteria are, in my opinion, directly on target.

In my opinion, the effects of limited veterans' representation and poor communication practices are apparent in the scientific reports issued by the Ranch Hand study as I have reviewed them through to the present time.

Of very great concern to me are the reports addressing birth defects and cancer. The National Academy of Sciences Institute of Medicine scientifically criticized the birth defects report released in 1992 but the Institute's recommendation for an independent re-analysis of the birth defects data has not been fulfilled.

Further, I am concerned with the current use of serum dioxin levels to estimate Agent Orange exposure in the absence of a proper analysis of inferential error. Also, I perceive inadequate data flow to veterans concerning heart disease, vascular disease, neurological ailments, endocrine disturbances and hematological difficulties. Timely, full, clear, reporting can assist medical personnel to better care for veterans.

Two protocol-mandated analyses involve time-in-Vietnam correlation and the comparative evaluation of over-reporting, overt and sub-clinical illness. I perceive these analysis schemes have been insufficiently exercised.

The hierarchical structure of the military organization can compromise scientific and medical research. I am concerned that the recent failures to report study limitations were institutionally influenced. I recommend that integrity programs be strengthened in the Air Force to include improving the process of clearing research papers and other communications. I have experienced management changing a concluding sentence in an article even after the article was accepted for publication in the open literature. This is not an every day matter, but there are no protections that I am aware of at this time.

For nearly twenty years the Ranch Hand study has been unable to properly include veterans in the scientific review process, and this study has reported only part of the truth. Real veterans' representation can occur and reporting can improve in this effort if the GAO recommendations are followed. I concur with the GAO recommendation on data release to the general public. I advocate full data release to individuals who are qualified to protect subject confidentiality. I additionally strongly encourage funded replication and extension of Ranch Hand data analyses by independent and qualified individuals. If integrity programs are not strengthened, Veterans not included, and data not really shared, then, at the risk of loss of time and data, I recommend study transition to another agency.

Mr. SHAYS. Thank you very much. Dr. Schwartz.

I am assuming that you work at the West Haven Hospital as a consultant? But you are at that facility or not?

Ms. SCHWARTZ. No, I am not attached to the VA. I am a consultant to the Secretary of Veterans Affairs in several areas, mostly women veterans. And I am myself, of course, a veteran. And my work, my research has been——

Mr. SHAYS. But the important thing is you come from Connecticut.

Ms. SCHWARTZ. But I do not come from your district, I'm sorry.

Mr. SHAYS. That is all right. I am magnanimous, it is a great State. Welcome. I was trying to be positive.

Ms. SCHWARTZ. First of all, you are positive. By having this hearing you are positive. You and Mr. Sanders have done an excellent job and you have done a service for the veterans of our Nation.

Let me explain that yes, I am retired from the U.S. Air Force Nurse Corps. I have had the opportunity to several times speak to the National Academy of Science groups when they were considering their reports. I have completed a study on women veterans, the health needs of women veterans who were stationed in Vietnam. And I have just returned from Vietnam and can address some of the issues that you have raised about research in that country.

I would first of all like to say that one of the issues that has been raised earlier this morning, the cost of this study, is somewhat ironic given the fact that it costs approximately $140 million. And when you talk about the class action suit which was done to help the veterans, the cost of that suit was $180 million. That's how much chemical companies gave veterans to assist them with the needs that they had.

I would also add that the Vietnam Experience study, which has been noted earlier today, was 8 years in the making and $43 million. And at the end of all that time and all that money, they decided they could not do the study. So that's what we're dealing with here.

I would just like to refer to some of the more important issues that I brought out in my written testimony.

There is no doubt that the dioxin TCCD, which was very evident in Agent Orange is a carcinogen. In a recent discovery of a case in New Brunswick, Canada, evidence made public during the litigations between the Sprayers of Dioxin Association and Dow Chemical Co. and Uniroyal clearly shows that in 1965 the manufacturers of TCCD knew that it was dangerous, it was a potent carcinogen, but decided to make a pact to keep that information secret not only from our Government but from any people that purchased the chemicals.

In the GAO report, the one thing that I would like to stress is the fact that we have paid a great deal for this study and we have used very little of the data. And although the GAO report refers to the fact that we could be looking at what Air Force has already done, from a scientific point of view I say that this is a very rich field of information that has not completely been analyzed.

And so, with that in mind, and to build on my own work of looking at women veterans, the Yale School of Nursing, where I am an associate in the research department, has become a repository for

information on the Ranch Hand study acquired from several sources. I would just like to say that while Dr. Michalek said that these reports are available, you indeed can get those reports that he has talked about. But it will cost you about $1,500 to get them. So that's the cost of getting those reports. And they are not readily available, nor are they easily understood by the average veteran.

However, we did go ahead and try to—we did acquire the 1987 dataset which was the variables from the physical examination which was made available in the public domain. The cost was $454. At the time we made the order, it was for the cartridge format. When we got the cartridge format at Yale, we took it to all of our computer laboratories and we even went to some of the commercial sources in the area, and some of the businesses in the area to try to access that data.

So yes, you can buy it. You can't read it. When we made that order, I would like you to know that when we made the order we said well, we'll have to make a copy, we don't keep this in stock. How would you like it? We said we would like it on CD-ROM. But that was denied. And so we got these rather antiquated formats for the information. And now, we are going to try a second try at an additional fund to that.

I also would like to say that when I read the GAO report and it talked about the reporting in 1992 of the study of birth defects, I checked the U.S. Air Force Health Study Internet and found that—I said how did I miss that, 1992? Well, it was published in Helsinki, Finland. And if I wanted a copy of that article, I would have had to write to the Health Institute of Finland. Not knowing that, I was not aware until the summer of 1998, when the Air Force actually did put forth that report, that there was a report on the birth defects that were studied in 1984.

One of the greatest limitations that has escaped the public and many veterans are the fact that findings from the Ranch Hand study are not applicable to all Vietnam veterans. The stated purpose of this study was to determine of Ranch Hand personnel were adversely affected by their proximity and handling of Agent Orange. And I have heard Dr. Michalek on several occasions at the advisory committee meetings reiterate that.

In other words, the question was are Ranch Handers sicker than other Air Force personnel who served in Vietnam? If you look at the study from that aspect, then some of this falls into place. However, many of us did not know this, and I did not know this until I heard Dr. Michalek say that for sure.

However, the stature of the U.S. Air Force and the fact that very few other studies could afford to perform serum dioxin levels—and just so you know, if you want to have a serum dioxin level done by our CDC it costs $1,000 per person. So you can see right away that there are many studies that could not afford, and many would not be funded if they asked for funding for this. So Air Force had the gold standard in many respects, because they had the capacity to access serum dioxin levels.

Another point of potential bias is the fact that all the subjects and the controls in this study were in Vietnam at one time. And although the control group did not actually handle and spray Agent Orange, there is reason to believe that they did have a dispropor-

tionately larger exposure to the dioxin than other military personnel.

As I said, I have just returned from Vietnam where we received a briefing from the Hatfield Consultants of Vancouver, British Columbia. The Hatfield Consultants have been working in Vietnam since 1969, specializing in environmental assessments of the human and ecological consequences of large dioxin contaminations.

I want to tell you that they really shocked us. They reported that, and I am going to tell you that my statement must be amended at this juncture where I referred to this. Because in my statement I say some of the most barren spots the dioxin level was 1,000 points per trillion. That was not true. It was on the site of a former United States base, military base in Vietnam that the 1,000 points per trillion soil dioxin 25 years later was obtained. And so you must realize that that is not a barren spot. That is where our troops were working on a daily basis.

In addition, I wish to also amend my statement after talking with Mr. Hatfield last night. What they found in the food that people eat, even to this day, in a place called the Aloui Valley, which many Marines will remember, is their finding that in the food it's 65 points per trillion in the ducks and the fish that they are getting from there. And it's 30 points per trillion these many years in the blood and breast milk of people who live in the Aloui Valley.

Another point of potential bias that is not widely known is the fact that in this study limited confidentiality extended to the active duty personnel that participated in the study. Unlike most research, confidentiality of answers and information obtained during the study is a sacred covenant between the researcher and the subject. However, in this particular instance, the Ranch Hand protocol stated that active duty personnel would not be given complete confidentiality. Instead, they were told that the DOD would be notified if any of the information they provided was a risk to public safety or national defense.

In essence, this limited confidentiality proviso could have threatened the promotion potential, the flying status, and retention in the Air Force of the active duty personnel who participated in the study and should challenge the validity of the responses given by these individuals.

Last year, in addressing the issue of the study's conduct to prevent improper influences, last year I attended two meetings of the Ranch Hand Advisory Committee which reviewed the findings prior to the publication of the findings of the last round of examinations. The notice of the first meeting was indeed published in the Federal Register, under the FDA, probably the last place a veteran would look for a meeting about the Ranch Hand study.

Thoughtful suggestions for improvements in presentation of the data, concerns about the interpretations of the findings, and suggestions about the protocol were made by members of the advisory committee. However, I have to say that one of the things that came up over and over again was Air Force researchers repeatedly countered that it would be difficult and costly to carry some of these suggestions out.

Mr. SHAYS. If you could bring it to a close.

Ms. SCHWARTZ. I will. Let me just say this.

The Agent Orange Act of 1991 authorizes presumed service connection disability for diseases from certain herbicides. One of the things it says, and maybe you don't have to fix this, is that an association of a disease in human and exposure to herbicide is considered to be positive of the credible evidence of an association is equal to or outweighs the credible evidence against the association. With these parameters in mind you can see that the fact that the Ranch Hand data has not completely been made available, and not all of their associations, only the statistically significant associations. This means that there may be data there that could help us understand more about what the exposure is about.

I just would like to say, in closing, that war, like any other human catastrophe, must be acknowledged as an important occupational epidemiological event. And you, Mr. Shays, has certainly pioneered the way for gulf war veterans and Vietnam veterans. And I would just like to say that by continuing to have Government entities with a vested interest in the outcome of science to be allowed to continue to do research is not the way to go because there are too many questions about the credibility.

And the idea has been put forth as a freestanding institute of military medicine and I think it is something that as we progress we must take a very good look at and consider for the future.

I thank you for your time.

[The prepared statement of Dr. Schwartz follows:]

Testimony of

Linda Spoonster Schwartz RN, MSN, DrPH
Associate Research Scientist
Yale University School Of Nursing

Before the
United States House of Representatives
National Security, Veterans Affairs and Intergovernmental Relations
Subcommittee

Regarding

GAO's December 1999 report: AGENT ORANGE – Actions Needed to Improve Communications of Air Force Ranch Hand Study Data and Results (GAO/NSIAD-00-31)

March 15, 2000

Linda Spoonster Schwartz, RN, MSN, DrPH

GAO's December 1999 report: AGENT ORANGE – Actions Needed to Improve Communications of Air Force Ranch Hand Study Data and Results (GAO/NSIAD-00-31)

Thank you Mr. Chairman, for your leadership in holding this hearing, and for allowing me to offer my comments here today. With your and the committee's permission, I will read my prepared statement, and answer and questions.

My name is Linda Spoonster Schwartz RN, MSN, DrPH. I am the Associate Research Scientist at Yale University School of Nursing and a retired Major United States Air Force Nurse.

It has been almost 25 years since the last US military personnel left Vietnam, questions about the long-term health consequences associated with the use of herbicides during the war remain unanswered. Not only is this a major concern for the men and women, who served in Vietnam, the release of the US Department of Veterans Affairs "Women Vietnam Veterans Reproductive Outcomes Health Study" now extends the question to the health of the children and grandchildren of these veterans.

The U.S. Army and Joint Services Environmental Support Group have reported that 15 different herbicides were used in Vietnam. However public and professional attention has centered on the Herbicide or Agent Orange, "a 1:1 mixture of the n-butyl esters of 2,4-dichlorophenoxy acetic acid (2,4-D) and 2,4,5- trichlorophenoxy-acetic acid (2,4,5-T). A by-product contaminant of the manufacturing process for 2,4,5-T is 2,3,7,8-tetrachloro-dibenzo – p-dioxin (TCDD) commonly referred to as dioxin. Dioxin has been referred to as the most toxic substance on earth. Accelerated manufacture of the herbicides resulted in the production of higher levels of TCDD, than those found in the pesticides made for civilian use in the United States. Herbicide Orange was sprayed undiluted in Vietnam at the rate of 3 gallons (containing 12 pounds of 2,4-D and 13.8 pounds of 2,4,5-T per acre". These chemicals were used to defoliate the thick jungles of Vietnam to hinder enemy operations, clear perimeters of US and allied field installations and outposts.

Despite the high concentrations of the herbicides used in Vietnam, manufacturers maintained that the defoliants were harmless to humans and animals. The failure to inform the US military of the potential caustic effects of these chemicals promoted a rather apathetic attitude about the handling and disposal of the herbicides. Troops used them to clear vegetation around living quarters, hospitals and base facilities. There are numerous reports that when the barrels containing Agent Orange were empty, military personnel used them as outdoor grills. In 1970, while spraying missions continued in Vietnam, the Surgeon General of the United States warned that the use of Agent Orange was hazardous to health and the Department of Agriculture suspended the use of these chemicals in America.

Since the end of the Vietnam war, there has been an increasing body of evidence to suggest that dioxin causes cancer in animals and humans. Dioxin is one of the few harmful substances capable of crossing the placental barrier risking the development of the unborn and is passed to infants through the breast milk of exposed mothers. In New Brunswick Canada, evidence made public during litigation, between the Sprayers of Dioxin Association (SODA) and Dow

Chemical, Chipman Inc. and Uniroyal clearly shows that in 1965 manufacturers knew that TCDD was "dangerous", "most toxic compound ever experienced" and "a potent carcinogen". Unfortunately the Chemical Companies elected to withhold this information from the public. In 1979, the Environmental Protection Agency (EPA) noted an "overwhelming surge of miscarriages" during the months following the use of 2,4,5-T in Alsea, Oregon. The VA has recognized the association of dioxin exposure to Soft Tissue Sarcoma, Non-Hodgkin Lymphoma, Hodgkin Disease and other cancers for the purpose of disability compensation to veterans who served in Vietnam. The 1997 International Agency for Research on Cancer (IARC) "Evaluation of Carcinogenic Risks to Humans" Vol. 69 classified TCDD as "carcinogenic to humans". Furthermore in 1998, the National Toxicology Program of the US Department of Health and Human Services moved to upgrade TCDD from the "Reasonably Anticipated To Be A Human Carcinogen" to " Known To Be A Human Carcinogen".

THE AIR FORCE HEALTH STUDY

The Department of Defense (DOD) estimates that approximately 3.4 million American military personnel served in Vietnam during the war. From an environmental and clinical point of view, Vietnam was an extreme. American military personnel were exposed to an array of occupational risks: tropical diseases, environmental toxins, primitive living conditions and the stress of a combat zone which all had the potential for harmful long-term health effects. As more information about the toxic nature of dioxin became known, veterans returning from Vietnam began to associate their increased rates of rare cancers, debilitating diseases and the birth defects of their children to exposure to Agent Orange. When veterans began pressing these claims for disability compensation, Congress began to investigate the use of Agent Orange in Vietnam.

Establishing exposure to Agent Orange was considered to be difficult to document. However there was no question that the US Air Force (USAF) personnel responsible for Agent Orange spray missions in Vietnam, handling and loading the herbicides, ground personnel responsible for aircraft maintenance and aircrews participating in spray missions had all been in close proximity and could indeed be considered as exposed. The idea of investigating the health of "Operation Ranch Hand" veterans was thought to be the best approach to assessing the effects of Agent Orange on human health. In 1978, the Surgeon General of the Air Force at the request of Congress began to investigate the health of Ranch Hand personnel. The Air Force Health Study (AFHS), design and history have been disputed from the beginning, a controversy that persists now these many years after the war. My comments are focused on the four specific areas queried in the December 1999 GAO Report "Agent Orange: Actions Needed to Improve Communications of Air force Ranch Hand Data and Results".

1. <u>Assess if study's findings have been properly and promptly reported and disseminated.</u> There is no question that public access to the data is limited. The AFHS represents one of the largest sources of longitudinal data on a group of military men. Additionally, we have the added luxury of having baseline of information on all of the subjects in the study. Each of the

subjects in the Ranch Hand Study had to successfully pass a rigorous physical exam before entering the Air Force, qualifying for Pilot Training and maintaining Flying Status. Unlike other studies, we know that these men were healthy with no disabilities or chronic illnesses when they came into the military. The physical health criteria makes the data in the AFHS especially valuable for learning more about trends in health status of military and flying personnel. Who is healthy? Who is not well? What makes the difference? In fact, the bulk of the information on the hundreds of lab tests, physical exams and diagnostic tests has not been used or made public. Recently, we learned that USAF has 53,000 frozen biological specimens obtained from Ranch Hand Study subjects. It is imperative that decisions made about the use and disposition of these samples of blood, semen and tissue be in accordance with the consent given by subjects who participated in the study.

Because USAF researchers have limited their area of inquiry to only one herbicidal agent, dioxin, the majority of the information they have collected has gone unanalyzed and unknown. The GAO Report noted making the data available to the public for additional analysis would validate the present findings by Air Force. From a scientific point of view, the unavailability of the data for additional analysis by other investigators has not maximized the considerable investment of time and resources allocated to this study.

Mention is made in the Report that "analyzed data from one physical examination is currently available". As you may know, Yale University School of Nursing has become a repository for information on the Ranch Hand Study acquired from several sources including the National Technical Information Service (NTIS). Orders for the "Variable Name Dictionary for the Air Force Health Study: 1987 Physical Examination (Operation Ranch Hand) (Raw Data File) were made in November 1999 at a cost of $454.00. At the time the order was placed, there were two formats available, Magnetic tape 6250bpi and 3480 cartridge. As the order was being processed, we learned that NTIS would have to make a copy from the original tape since this was not a stock item. We requested that the copy be made in CD-ROM, which is a much more usable form. After several weeks we were told that the CD-ROM could not be made and chose the cartridge format. Upon receiving the cartridge, we found that this format is so antiquated that none of the resources or computer personnel at Yale University and area commercial sources could access the data. We returned the materials on February 19, 2000 with a request to change the format to the magnetic tape, which has more of a possibility for successfully accessing the data. At this time, we have had no word on the progress of this exchange. It is important to note that although the 1987 cycle of the Ranch Hand data listed as being available, it is not easily accessible.

Although Air Force explains that publication of findings in professional journals may take 3-5 years, there is a concern about the way in which these findings are reported. Because the results are crafted to fit the format of profession journals, important findings that are suggestive but do not achieve statistical significance go unreported. For example, the Report on Reproductive Outcomes was delayed for several years while investigators opted to expand the verification of medical records on birth defects to children 18 years of age. Although GAO

reports that the results were available in 1992, "An Epidemiologic Investigation of Health Effects in Air Force Personnel Following Exposure to Herbicides: Reproductive Outcomes Update" was not released to the public until 1998. This was in response to the repeated requests from veteran's organizations. The urgency of this report was due to the fact that VA had released the findings from a study of the " Women Vietnam Veterans Reproductive Outcomes Health Study" that included an assessment of birth defects in children born to women who had served in Vietnam. The results of that study had prompted Secretary of Veterans Affairs West to announce that legislation would be drafted to assist and compensate the women Vietnam veterans and their children.

It is important to stress that articles in professional journals do not include all the information needed to understand the study findings. In the case of the Ranch Hand Reproductive Outcomes several items in the protocol are especially troubling and suggest potential sources of bias when considering the findings. For example, only one birth defect per child was considered in the analysis. If a child born had more than one birth defect, USAF researchers elected to only include what they considered to be the most serious defect in the analysis.

2. Study Limitations have not been clearly communicated to the Public. In addition to the issue of the number of subjects noted in the GAO report, Ranch Hand researchers have subdivided the already small number of exposed subjects into even smaller groups (high exposure, low exposure, background exposure) which further compromises the statistical power required to detect significant findings. Additionally it has recently been reported that the number of original subjects willing to participate in the study continues to decline, which further questions the reliability of the findings and the future of the entire study.

One of the greatest limitations that have escaped the public and many veterans are the fact that findings from The Ranch Hand Study are not applicable to all Vietnam veterans. The stated purpose of the study is "to determine if Ranch Hand Personnel were adversely effected by their proximity and handling of Agent Orange." In other words, "Are Ranch Handers sicker than other Air Force personnel who served in Vietnam?" However the stature of the USAF and the fact that there are very few other studies of the health of Vietnam veterans has cast this study in the role of the "gold standard" for decisions about health problems which can be associated with exposure to Agent Orange. This is due to the longevity of the study and the capacity to include serum dioxin levels in the analysis. Most researchers and agencies cannot afford the cost of an adequate number of serum dioxin levels to make meaningful statistical conclusions. The cost of a serum dioxin level is approximately $ 1,000 per sample. Because serum dioxin is measurable, Air Force has chosen to use dioxin as the proxy measure for all herbicides used in Vietnam. Presentations of study results are often confusing and convoluted because the terms herbicides, Agent Orange and dioxin are used interchangeably in various Ranch Hand reports.

Another point of potential bias is the fact that all of the subjects and controls in the study were in Vietnam at one time. Although the "control group" did not actually handle or spray Agent Orange, there is reason to believe that they did have a disproportionately larger exposure to

dioxin than military personnel who never served in Vietnam. I recently returned from Vietnam where I attended a briefing by Hatfield Consultants LTD of Vancouver BC, Canada. Hatfield Consultants have been working in Vietnam since 1996 specializing in environmental assessments of the human and ecological consequences of large dioxin contamination areas. Their work is financed in part by the Canadian Government in the hope that lessons learned in Vietnam may be of some help to the areas of Canada effected by dioxin residues. Although the formal report will not be available until the end of April, Chris Hatfield, President of the firm has given me permission to share some of their findings with you.

It is important to note that the major thrust of the work of the Hatfield Group is environmental rehabilitation and health promotion. As a first step, areas of concentration of dioxin must be identified and the human and ecological aftereffects assessed. Utilizing random soil samples and blood and breast milk samples from Vietnamese citizens in the Aloui Valley, they have determined that there is irrefutable evidence that the highest concentration of dioxin are not in the spray areas but on the sites of former US bases. In some of the more barren spots, the concentration of soil dioxin is as high as 1000ppt. In blood and breast milk, the average dioxin level is 110 ppt., which infers an inconsistency to the assumption that the control group of the Ranch Hand Study was not disproportionately exposed to dioxin.

Another limitation of the study is the practice of excluding the most relevant baseline data on subjects with serum dioxin levels below 10 ppt. This essentially excludes important information on truly unexposed individuals from the analysis and makes it difficult to identify positive statistical relationships. The Environmental Protection Agency (EPA) 1991 Symposium on Dioxin Report noted that it is impossible to estimate exactly how individuals who have been disproportionately exposed to higher than ordinary every day levels of dioxin will respond. But the "margin of exposure (MOE) between background levels and levels where effects are detectable in humans… is considerably smaller than previously estimated." This suggests that all levels of serum dioxin should have been included in the Ranch Hand analysis.

The importance of preserving the serum dioxin levels as they are reported is illustrated by the AFHS that examined TCDD concentrations among Ranch hand Ground Crews. Although the serum dioxin median measurement for the 397 subjects was 26 pp., over 25% of the subjects had TCDD levels above the maximum cut off point of 150ppt, some as high as 500ptt. Individuals with higher serum levels are not well represented by the artificial ceiling imposed by the researchers. While these study design decisions may be within the purview of researchers, delays in publishing reports, and the suggestion of bias in the study design are interpreted by veterans as a "Slight of Hand" designed to deprive them of a fair hearing of their health concerns and those of their children.

Another potential source of bias not widely known is the "Limited Confidentiality" extended to the Active Duty participants in the study. Unlike most research, confidentiality of answers and information obtained during the study is a sacred covenant between the subjects and the researchers. Most Internal Review Boards tasked with granting permission on research

involving 'Human Subjects" have stringent protocols for assuring the highest standards of confidentiality of the data during all phases of the research including securing the information after the study is concluded. This did not happen here. The Ranch Hand protocol stated that Active Duty personnel would not be given complete confidentiality. Instead they were told that DOD would be notified if any of the information they provided was a "risk to Public Safety or National Defense" In essence the "Limited Confidentiality" proviso threatened the promotion potential, flying status and retention in the Air Force of the Active Duty participants and challenge the validity of responses given by these individuals.

3. Measures established to monitor the study's conduct to prevent improper influence, particularly those involving the Advisory Committee. Last year, I attended two meetings of the Ranch Hand Advisory Committee, which reviewed the findings prior to the publication of the findings of the last round of examinations. The notice of the first meeting was indeed published in the Federal Register. However is was buried under meetings of the Food and Drug Administration (FDA). Someone just happened to know my interest in Agent Orange Research and e-mailed me the details of the meeting. I was surprised that the Advisory Committee would come under the aegis of the FDA.

Through out the meeting the interest and professionalism demonstrated by members of the Advisory Committee was impressive. Thoughtful suggestions for improvements in the presentation of the data, concerns about the interpretation of the findings and suggestions about the study protocol were made by members of the Advisory Committee. However, the USAF researchers repeatedly countered these recommendations by saying the proposed changes would be too costly or difficult to implement. Subsequently most of the advice from the Advisory Committee was lost as the meeting progressed.

I was also surprised at the uncertainty as to whether or not the Advisors could vote on issues and where any recommendations they had should be forwarded. It is important to note that while the Committee has existed for some time, prior to the 1999 meetings, there had been several years in which the group had not met. It was obvious from the four days that I attended these meetings that funding for the very important work of oversight of the Ranch Hand Study was insufficient for the charge made to the Advisory Committee. Although expenses for travel to the meetings are reimbursed, members serve without remuneration.

While the entire report of the AFHS was being reviewed, all members of the Committee did not see the document in its entirety. Members had been assigned to review specific Chapters of the report but did not have the opportunity to see the complete report. As you might guess, this situation is less than ideal and does not inspire confidence in the review process. I also noted that members of the Committee were not well versed in the Air Force Mission and Organization, the metabolism of dioxin or the long range effects findings from this study have on the lives of the men and women who served in Vietnam. I am most appreciative that Dr. Harrison, Chairman of the Advisory Committee, permitted me and other observers to provide additional information when these issues were raised. Having more members familiar with the

United States Air Force, service in Vietnam and the physiological dynamics of dioxin would definitely strengthen the oversight responsibility of this Committee.

4. **Impact of the study on determinations of diseases for which Vietnam Veterans are eligible to receive compensation benefits.** The Agent Orange Act of 1991 (Public Law 102-4) authorizes presumed service connection for diseases associated with certain herbicide agents. The definition of herbicide agent is defined as "a chemical in an herbicide used in support of the United States and allied military operations in the Republic of Vietnam during the Vietnam era." Further, an association of a disease in humans and exposure to herbicides is considered to be positive if the "credible evidence of an association is equal to or outweighs the credible evidence against the association." With these parameters in mind, I must argue that the Ranch Hand study has had an impact on the determination of compensation benefits for Vietnam veterans.

For reasons cited earlier, the practice of only publishing and presenting statistically significant findings, limited analysis of the available data and the reliance on serum dioxin levels to determine exposure, Ranch Hand has severely restricted the range of diseases that are considered to be associated with herbicide use in Vietnam. It is important to note that from the beginning, USAF has maintained that this study is of Air Force personnel. Perhaps it is a fault of the government, the public sector and science that results from this study have been used extensively to determine the health effects for all men and women who served in Vietnam. Perhaps the most prominent omission is that women were not Ranch Handers or Aircrew members and could not be included in the study. Not only is the AFHS constrained by the number of subjects in the study to detect rare cancers and diseases, there is the question of the relationship of the Vietnam experience of Air Force personnel and other US military troops operating in Southeast Asia.

Emphasis on exposure to dioxin as the causative agent for illnesses and disabilities reported by veterans has severely limited the discussion of the health consequences that can be associated with service in Vietnam. Ranch hand was initiated before Congress authorized presumptive disability for all veterans who served in Vietnam. Therefore the question that should be asked is "Are veterans who served in Vietnam more disabled or suffer from more health problems than veterans who did not serve in Vietnam?" Relying on the Air Force Health Study to answer these questions does a disservice to the researchers and participants. We need to accept this study for what it is and realize that is does not encompass the entire Vietnam veteran experience.

Ranch Hand has relied heavily on the serum dioxin levels of study subjects. However the National Academy of Science (NAS) Committee tasked with reviewing the "Effects of Herbicides on Vietnam Veterans" has noted that serum TCDD measures are helpful in epidemiological studies but they should not be considered the "gold standard" for exposure determination. In the 1998 NAS Report to Congress on this issue stated emphatically that the subject of herbicides and Vietnam veterans remains poorly studied and more research is needed

before substantive conclusions can be made about the health effects of these exposures. What is needed is a comprehensive investigation of the health problems of the men and women who served in Vietnam that takes into account all environmental and war zone stressors.

SUMMARY

War, like any other human catastrophe, must be acknowledged as an important occupational and epidemiological event that deserves a full and complete exploration and scientific review. The sophistication of modern warfare with the threats of terrorism and chemical and biological agents require more concentrated and coordinated investigations than in the past. Lessons to be learned from Ranch Hand and other studies conducted in the post Vietnam period indicate that agencies with a vested interest in the outcome of a study will always be questionable. Thought should be given to the recent proposals for a freestanding agency "Institute of Military Medicine" dedicated to providing an unbiased, comprehensive scientific inquiry in support the men and women we send to war. This endeavor is as vital to National Defense as any weapons system.

Mr. SHAYS. Thank you very much. We have a vote. I am going to go vote and we are going to come right back and, Dr. Trewyn, you will get to have your say.

You were kind to your comments to me at the end. I just want to say that Mr. Sanders has actually done more than I have in this area, and it has been wonderful to work with him.

I will convene you all and I will be right back after I vote.

[Recess.]

Mr. SHAYS. I will call the hearing back to order.

Mr. Trewyn, you have the floor. Doctor, excuse me. You spent many years getting that doctor, did you not?

Mr. TREWYN. I did, more than I would like to talk about, sir.

I want to thank you for the opportunity to provide a few brief comments here today. I will try to be brief. I know this has been a long day.

Most of my comments are in my written testimony. It gets into a lot of science but I was sort of inspired by Representative Sanders to maybe try a couple of common sense sorts of arguments here.

Mr. SHAYS. Common sense is not allowed.

Mr. TREWYN. OK, I will rethink that and go back to the other thoughts.

Mr. SHAYS. No, common sense is allowed, we will take it.

Mr. TREWYN. What I'd like to talk about are briefly scientific problems, administrative problems which have been alluded to before. To just let you know how I got involved in this, I did spend 4 years on the Ranch Hand Advisory Committee from 1995 through 1999.

Mr. SHAYS. As a doctor not a veteran? No, you said you were on the advisory committee. Were you appointed as a veteran or as a doctor?

Mr. TREWYN. Well, I've never been quite sure. It was, in fact, Admiral Zumwalt who got me appointed.

Mr. SHAYS. I am not looking for a long answer, I am looking for the short answer.

Mr. TREWYN. And I don't know the true answer.

Mr. SHAYS. That tells me something.

Mr. TREWYN. I was asked that by the GAO and I didn't know the answer and I don't know if they ever found it when they went through the paperwork.

But I did spend 20 years of my life doing cancer research and most of that with a focus on chemical carcinogenesis, so I do have some scientific background in the area.

What I want to just briefly mention, and this is outlined in my written material, are three scientific hypotheses that one can look at here. The first one that started this whole thing is that Vietnam veterans are suffering from excessive health problems and those health problems are service-connected, connected to their service in Vietnam. That is what launched all of this, and that really remains the most important question or the questions that underpin that remain the most important ones to answer.

But somebody figured out that, you know, we sprayed a lot of herbicides in Vietnam. Those have some nasty things in them, so maybe the herbicides sprayed in Vietnam caused adverse health outcomes in veterans who served there. And that, in fact, is more

the question that the Ranch Hand study is designed to test, is that it was a causal relationship of herbicides.

But because Agent Orange, the major herbicide sprayed in Vietnam, contains dioxin—and we've heard a lot about that today, TCDD, it moved to a third hypothesis and that is that dioxin, a minor contaminant found in some of the herbicides sprayed in Vietnam, caused adverse health outcomes in the veterans exposed to herbicides.

If I could just give a quick example that will maybe illustrate I think where our problem is with this whole thing right now, and it's a forest and trees argument. If you were standing in the middle of a redwood forest and some of the trees are sick. We've gotten to the point where it's no longer an issue that you can't see the forest for the trees. People aren't even seeing the trees anymore in this study.

We've focused down on, in my hypothetical, a small beetle burrowing into the bark of some of those sick trees. We'll call it a dioxinite beetle, just for something novel. And you invest 25 years, $140 million and come up with the assessment at the end, you know, that little beetle caused some problems for those trees.

But when you step back and look around, you realize there are no more trees. There's no more forest. We have lost sight of what the original issue here was, which was health effects, and sir, some of your predecessors in Congress have to bear some of the blame here, because I truly believe the Air Force is doing what they were mandated to do, what they were charged to do, to study a possible, at the point in time, a probable cause.

Now because they may not be finding as many adverse health outcomes as we would like to see doesn't mean if we were examining the right population, the veterans who were there on the ground in general, this might not show up.

I could go into a lot of discussions about synergy, something you've probably encountered in your discussions of the Persian Gulf situation, mixtures of chemicals, biological agents. I spent a lot of time in my career studying those things. Where a couple of small effects can become a huge effect when you put things together.

There are lots of suspects in Vietnam beyond dioxin, that may have caused adverse health outcomes.

To just mention briefly a couple of administrative items, from my role as a member of the oversight committee. In my view, the advisory committee lacks authority, it lacks appropriate reporting lines. For example, the committee never files a report with the Secretary of Health and Human Services which is then provided to Congress. There's nothing like that. We talked to the Air Force and for the most part, or did when I was involved and it still goes on. And for the most part, they listened to our comments and recommendations on that committee.

But also, I believe the advisory committee lacks sufficient resources to function properly. The first meeting I attended after being appointed in 1995, the committee voted, as a body, very busy people, a number of MDs and other experts on this committee, voted as a body that we needed to meet every 6 months to really monitor this effectively, both the Ranch Hand study and the later congressionally mandated Army Chemical Corps study.

When we next got together 3 years later, we were informed that well, you know, there really is no budget. The FDA does not have a budget to do this job. It's just been passed down, an unfunded mandate. They're supposed to call this group together as need be and well, we didn't have the money and there weren't pressing issues.

And I don't blame Ron Coene or the other people in the FDA. It's a fact of life. They don't have—he has a job, a regular job, and this has been passed down without the resources to get the group together to adequately monitor the study.

I do believe that there are studies going on that could be fixed and made better. The Army Chemical Corps study has some great potential to yield positive results, hopefully in a relatively short period of time. I'd be a lot more comfortable with that if the VA wasn't involved in it. I'm a combat wounded veteran with a service-connected disability. I stay as far away from the VA as possible. I'm not on the registry for exposure.

The Vietnam Experience study, that group, if the study was structured properly, the records are there, could still be looked at.

And this is more than a veterans affairs issue. It is, in fact, a national security issue. Because if the country continues to treat their veterans poorly and, in some cases, abominably as has been the case with the veterans suffering from adverse health outcomes from Vietnam, from the Persian Gulf, we're not going to meet the recruitment and retention needs in this new era of needing highly educated, highly technically proficient people. They aren't going to stay in because why should they, when they know what's going to happen going out the other end?

So I really do believe this is an opportunity for Governmental reform and some oversight on this, and trying to tie it to, at least as I read the mission of this group, of looking at how to address these needs. And hopefully, something can be done about this. Thank you for this opportunity.

[The prepared statement of Dr. Trewyn follows:]

HOUSE OF REPRESENTATIVES: **Committee on Governmental Reform**

SUBCOMMITTEE: **National Security, Veterans Affairs, and International Affairs**

HEARING: **Air Force Ranch Hand Study on the Health Effects of Agent Orange**

DATE: **15 March 2000**

TESTIMONY BY: **R.W. Trewyn, Ph.D.**
Vice Provost for Research and
Dean of the Graduate School
Kansas State University
President, KSU Research Foundation

Two major problems exist with regard to health effects studies of Vietnam veterans: (1) scientific problems and (2) administrative problems. Both of these difficulties are alluded to in the GAO report of December 1999 entitled "Agent Orange: Actions Needed to Improve Communications of Air Force Ranch Hand Study Data and Results." However, the severity of the problems is not fully delineated, especially in the case of the scientific shortcomings.

The scientific deficiencies can be illustrated most effectively by first addressing some general issues, prior to discussing the Ranch Hand study specifically and then mentioning some additional problems with the congressionally mandated study of Army Chemical Corp workers. The basis for the scientific deficiencies can be best described in relationship to the following three hypotheses: (1) Vietnam veterans are suffering from excessive, service-connected health problems. (2) Herbicides sprayed in Vietnam caused adverse health outcomes in veterans who served in Vietnam. (3) Dioxin (TCDD), a minor contaminant in some of the herbicides sprayed in Vietnam, caused adverse health outcomes in veterans exposed to herbicides.

Clearly, the possibility that Vietnam veterans were suffering from service-connected health problems was the reason most studies were undertaken, and the questions raised by hypothesis #1 are those most important to answer. If military veterans – the 10% of U. S. citizens who have served their country in uniform – are suffering from severe service-connected health problems, they should be provided with first-rate health care for those problems. Identifying a causal agent may prove helpful in defining treatment regimens, but that may not be possible if multiple causal agents were involved.

With multiple agents and the potential for synergistic activities among them, there may be no way to sort out the relative importance of different levels of exposure to individual components in veterans with different genetic backgrounds and susceptibilities. And synergy is a well-known phenomenon in chemical carcinogensis and other disease progressions. However, if an inordinate number of Vietnam veterans are sick and dying, does it matter whether a causal agent or agents are identified definitively or not? Do we owe veterans with service-connected illnesses and death warrants any less just because

we don't know why? Obviously, not! Therefore, the most important studies would be those designed to establish whether service-connected health problems exist in Vietnam veterans.

Unfortunately, the Ranch Hand study was not designed to test hypothesis #1. It was designed to examine hypothesis #2, and it will only answer the questions that underpin the hypothesis for Ranch Hand personnel, not Vietnam veterans in general. Of course, positive findings with Ranch Handers may help in extrapolating to other veterans, but the findings may not if there were multiple causal agents for any of the adverse health effects. And negative findings prove absolutely nothing for non-Ranch Hand veterans with regard to either hypothesis #1 or hypothesis #2. There are far too many variables (routes of exposure, hygiene practices, types of herbicides, chemical cofactors, biological cofactors, etc.) to derive any conclusive results for non-Ranch Handers from negative findings in the Ranch Hand study.

Moreover, it was not discovered until the most recent Ranch Hand advisory committee meeting that some of the controls in the Ranch Hand study were stationed in Vietnam and some were stationed in other parts of Southeast Asia. Therefore, the controls may have been differentially exposed to potential complicating variables, thereby further compromising the integrity of the study's findings.

To make matters worse, the Ranch Hand study has actually shifted in primary focus to testing hypothesis #3. Because dioxin can be used as an indicator of exposure to Agent Orange (the major herbicide sprayed in Vietnam), it is easy to become convinced that the only significant adverse health outcomes are those that show a direct correlation to dioxin. However, the levels of dioxin contamination varied in different production runs of Agent Orange (or, more accurately, production runs of 2,4,5-T, which along with equal parts 2,4-D, made up the herbicide known as Agent Orange), and not all herbicides sprayed in Vietnam contained dioxin. Yet, the draft Ranch Hand report reviewed at the last two advisory committee meetings was filled with examples arguing the importance of dioxin causal relationships (hypothesis #3). The congressional mandate was to evaluate hypothesis #2.

Furthermore, some of the other herbicides contained hazardous agents and contaminants (e.g., cacodylic acid and hexachlorobenzene) which, like dioxin, have been subjected to EPA exposure restrictions and bans.[1] These could have contributed to service-connected health problems, while showing no relationship to dioxin exposure. And that still doesn't take into account exposure to Chlordane (now banned by the EPA) and other insecticides sprayed around base camps in Vietnam or how any of these agents interacted with the Chloroquine/Primaquine and Dapsone[2] the troops were required to take. So, there are many scientific shortcomings with the Ranch Hand study, which preclude making generalizations about health effects for non-Ranch Hand veterans.

The congressionally mandated study of Army Chemical Corp personnel in Vietnam also deserves brief mention. This study is intended to establish whether Chemical Corp workers in Vietnam who sprayed herbicides (and who, presumably, were exposed to other potential hazardous cofactors) are suffering from an enhanced level of health problems. Sounds reasonable. Of course, as currently structured by the VA, increased

health problems are compared exclusively to Army Chemical Corp workers not stationed in Vietnam. While the pilot study suggests that measurable health differences do exist between these two groups, one could argue that the baseline for Chemical Corp workers might be well above the norm for the general citizenry who have not been exposed routinely to hazardous chemicals. As a result, this study is flawed as well (see Attachment 1 for additional information). Perhaps congressional intervention and oversight could still salvage additional information from this ongoing investigation.

With regard to the administrative problems with the Air Force Ranch Hand study (and the Army Chemical Corp study as well), these involve mainly oversight issues that can also be corrected. These problems are best illustrated with examples involving the Ranch Hand advisory committee appointed by the Secretary of Health and Human Services (the Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants). Essentially, the advisory committee lacks authority, appropriate reporting lines, and sufficient resources to function properly.

At the first advisory committee meeting I attended after being appointed in 1995, it was decided by the membership that we needed to meet twice a year in order to oversee and advise the Air Force Ranch Hand and Army Chemical Corp studies effectively. Our next meeting was three years later. We were informed at the meeting in 1998 that the FDA had no budget to hold any Ranch Hand advisory committee meetings, much less meetings every 6 months. Moreover, it was clear from the meetings that were held that we had no authority to impose changes in study protocols. We reviewed findings of the studies, provided editorial comments on reports generated, and made suggestions to the Air Force and Veterans Affairs personnel conducting the studies. And while they did follow many of our suggestions voluntarily, that was by no means universal.

Although it may be too late to resolve the controversies about service-connected health problems for Vietnam veterans, it would be nice to prevent similar fiascoes for tomorrow's veterans. The federal investigative debacle has already been duplicated with Persian Gulf War veterans (with far too many similarities to Vietnam veterans), so it may be necessary to step up the level of congressional oversight and changes are needed in the way veterans' health studies are conducted.

First and foremost, the studies should be contracted in a peer-review process to non-federal entities for implementation. Although the Air Force seemed to be doing a reasonable job with the Ranch Hand study during the four years I was on the advisory committee, they can hardly be viewed as a neutral party. And I know of no veteran who believes that the Department of Veterans Affairs serves and advocates for veterans. The opposite appears to be more accurate. Yet, the VA has been charged with conducting the Army Chemical Corp study. That does not bode well for a believable outcome.

And finally, the matter of how the nation treats its veterans is becoming an issue of national security, not just veterans' affairs. How is the military going to attract and retain the top quality, technically proficient service members needed in this new millenium when America treats its veterans so abominably? The time for governmental reform of the system is now!

BIOGRAPHICAL SKETCH

R.W. TREWYN was a Staff Sergeant in the US Army Infantry in Vietnam in 1969, serving in III Corps where he earned the Combat Infantry Badge and Purple Heart. Trewyn obtained a Ph.D. from Oregon State University in 1974, specializing in cellular and molecular biology. After four years of cancer research at the University of Colorado Medical Center, he joined the medical school at Ohio State University, attaining the rank of Professor of Medical Biochemistry in 1988. During his tenure at Ohio State, Trewyn brought more than $3.5 million in cancer-related grant support to the university. Trewyn was inducted into the Ohio Veterans Hall of Fame in 1994, an honor bestowed for his efforts to overcome employment discrimination against veterans on college campuses. That same year he assumed the positions of Associate Vice Provost for Research and Professor of Biology at Kansas State University. He currently holds the positions of Vice Provost for Research and Dean of the Graduate School at K-State along with that of President of the KSU Research Foundation. Trewyn is the author or co-author of numerous published articles and studies related to veterans' employment rights. Based on his expertise in cancer etiology, he was named by the Secretary of DHHS to the Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants in 1995 and served until 1999.

Army file photo of herbicide spraying of a riverbank near a fire support base in Vietnam.[3]

FOOTNOTES:

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(1) For an informative review of the potential problems these less studied herbicides might have caused, see the article written by LTC Patrick H. Dockery, USAR (Retired) entitled "Agents Orange, White, and Blue – New Disclosures: A Combat Soldier's Research" (JOURNAL OF THE VIETNAM VETERANS INSTITUTE 6: 5-29, 1997). Although LTC Dockery is not a scientist, he has rigorously researched the topic and uncovered critical information about the hazards the ignored herbicides Agents White and Blue may have posed. Why have federal studies to date ignored the potential contributions of cacodylic acid, hexachlorobenzene, and other hazardous agents to which Vietnam veterans were exposed?

Additionally, the statistics LTC Dockery has collected with regard to his battalion in Vietnam are, as he states, "staggering." With less than 15% of the surveys returned at the time the article was written, he had found 19 cancer deaths, 3 heart disease deaths, 19 active cancer cases, 45 miscarriages, 27 children with birth defects, and 6 suspected sterilities. If a non-scientist can gather this type of information, why can't the VA collect meaningful statistics on health outcomes?

(2) The information LTC Dockery uncovered and presents about Dapsone, the daily "anti-malarial" pill we took in Vietnam, is also of interest. It is used in the treatment of leprosy, but in non-leprosy cases, it sometimes causes peripheral neuropathy – a problem for many Vietnam veterans. Dapsone can cause "male infertility, drug-induced lupus erythematosus, and an infectious mononucleosis-like syndrome." It can cause blood disorders that may result in fatalities. Why have questions not been raised in federal studies about the role Dapsone may have played in causing adverse health outcomes?

(3) Note that the individuals (presumably Army Chemical Corp workers) spraying the herbicide were not wearing respirators or other protective gear. According to the notes with the National Archives photo, the soldiers in the boat were spraying Agent Blue – cacodylic acid, an arsenic-based herbicide. As noted in LTC Dockery's article, "cacodylic acid is toxic by inhalation." Why did the Army not provide better training for those exposed routinely to potentially hazardous chemicals, and why has the VA not considered these hazards in assessing health outcomes for Vietnam veterans?

Vice Provost for Research
Dean of Graduate School
108 Anderson Hall
Manhattan, KS 66506-0113
785-532-5110
Fax: 785-532-6507

Attachment 1

DATE: 4 January 1999

TO: Ranch Hand Advisory Committee

FROM: R.W. Trewyn
Interim Vice Provost and Dean
Professor of Biology
President, KSU Research Foundation

RE: Army Chemical Corps Vietnam Veterans Health Study

As an overdue follow-up to the last Ranch Hand Advisory Committee meeting, I would like to provide to the full committee some of my concerns with the Army Chemical Corps Vietnam Veterans Health Study. Most of my comments will focus on the issue of control groups for the study, since I am still concerned about this aspect even though the majority of the committee members in San Antonio were not similarly inclined.

First, I would like to reiterate a point made at the last meeting: it had been recommended at the first committee meeting reviewing the Army Chemical Corps Study that the number of control groups in the Phase I, pilot study should be expanded to include non-Chemical Corps service personnel. I am unaware of the committee approving otherwise prior to the meeting in San Antonio. However, only Vietnam and non-Vietnam cohorts of Army Chemical Corps personnel were evaluated in the pilot study.

Among the material provided at the meeting in San Antonio was a 10-page statement, including references, entitled "Responses to the October 25, 1995 Ranch Hand Advisory Committee Meeting Minutes," signed by Han K. Kang and Nancy A. Dalager, two of the study's principal investigators. This response includes their arguments for *not* including non-Chemical Corps service personnel in the study, and there is an indication that the 10-page statement had been distributed to the Ranch Hand Advisory Committee in 1996. Although I do not recall seeing this material prior to San Antonio, seeing it would still not equate to the committee affirming its contents and endorsing a change in the study protocol as approved at the meeting in 1995. However, the pilot study has been completed without non-Chemical Corps controls, so my point in rehashing the matter is that I still believe Phase II of the study will fail to resolve the actual health outcomes if only Vietnam and non-Vietnam cohorts of Chemical Corps personnel are examined.

Since I'm not an epidemiologist, I posed these concerns to a scientist with such training and expertise who has conducted health studies at the CDC. She concurred that the inclusion of a non-Vietnam, non-Chemical Corps control group (and, perhaps, others) would be highly appropriate for comparison, since Chemical Corps workers, whether in Vietnam or not, might be expected to have had more exposure to hazardous chemicals than the general population. Therefore, the "normal health" baseline could be skewed significantly. Her bottom line: "The study is seriously flawed, and can, at best, only provide partial answers to questions that are answerable."

It was contended at the meeting in San Antonio that neither the congressional mandate for the study nor the National Academy of Sciences committee recommendations authorized the inclusion of non-Chemical Corps controls. I would argue that it is our responsibility, and charge, to sanction what we believe is appropriate for a heath effects study of this type. And while the results from Phase I suggest that significant health differences may, in fact, be seen between the Vietnam and non-Vietnam cohorts, that does not preclude even greater differences being established for other reference cohorts. I don't recall anyone arguing at either Ranch Hand Advisory Committee meeting that the inclusion of non-Vietnam Army Chemical Corps personnel as a control group in the study is inappropriate; it certainly is appropriate. But, why limit the study by including only a single control group? Why fail to establish a normal health baseline?

Kang and Dalager noted in their 10-page response statement that "members of (the) Army Chemical Corps would have handled chemicals that others who were not members of the Corps were not required to handle regularly." They use this as an argument for not having non-Vietnam, non-Chemical Corps veterans as a control group, and state that "this will further complicate an interpretation of any positive findings." I disagree. Non-Vietnam Chemical Corps workers could be suffering from adverse health effects precisely because they "handled chemicals that others who were not members of the Corps were not required to handle regularly." Without a non-Vietnam, non-Chemical Corps control group, there will be no way of determining whether or not that is the case. Furthermore, failing to include an additional, non-chemically exposed control group may obfuscate the potential for synergy between various chemicals in eliciting adverse health effects.

It was also argued in the response statement by Kang and Dalager that the inclusion of other non-Vietnam veterans was problematic "because of their potential for being significantly different from members of (the) Army Chemical Corps with respect to pre-service and post-service characteristics." However, no evidence was provided to indicate that personnel in the Chemical Corps are any less "poorly defined" with respect to these characteristics than non-Chemical Corps workers. Without such evidence, it might seem equally (or more) plausible that the MOS assignment for enlisted personnel during the Vietnam War had more to do with military "need" than "pre-service characteristics" of those inducted. Moreover, when one considers that the average age of those who served in Vietnam was 19, selection criteria based on "pre-service characteristics" would appear minimal, at best.

Considering all of the above, I would summarize by saying that I still believe a non-Vietnam, non-Chemical Corps control group should be included in Phase II of the Army Chemical Corps Study. In my opinion, the study is flawed without it. And, while I'm expressing my concerns, let me add a few other points regarding the study.

Based on the materials presented in San Antonio regarding Phase I of the study, the Vietnam cohort appears to differ significantly from the non-Vietnam cohort in a number of ways. (1) The number of veterans age 45 or younger is less in the Vietnam cohort. (2) The number of veterans age 55 or older is greater in the Vietnam cohort. (3) The number of individuals who entered military service in 1964 or before is greater in the Vietnam cohort. (4) The number of individuals who entered military service between 1970 and

1973 is less in the Vietnam cohort. Because age is a crucial parameter when assessing health effects, the age constraints within the Vietnam and non-Vietnam cohorts should be examined thoroughly in Phase II. It's also possible that the pre-service and post-service characteristics of those entering military service in 1964 or before and those entering military service between 1970 and 1973 could be quite different. Since the Vietnam cohort is slanted toward the former timeframe and the non-Vietnam cohort toward the latter, this should be reexamined in Phase II as well.

With additional time to review the materials provided to us in San Antonio, I would also like to question the value of doing more serum TCDD analyses on Army Chemical Corps workers. This aspect is being well covered by the Ranch Hand Study of Air Force personnel, and the significant limitations associated with these measurements are well documented. It would seem not to justify the excessive expense in the Army Study just to have additional marginal data, derived near the limits of detection, that tell us little if anything about the herbicide exposure one received 25-35 years ago. It might be more beneficial to consider other serum analyses (e.g., liver enzymes and other indicators of adverse health effects) as indicated by Ranch Hand, the preliminary survey, the earlier CDC study, IOM, etc.

Lastly, it's clear that the Air Force sprayed more Agent Orange in Vietnam than any other herbicide. What documentation is available regarding which herbicides the Army sprayed? It would seem feasible that the herbicides most efficacious at defoliating trees might be different from those used on other foliage. Therefore, the preferred agents in the Delta might have differed from those in the Highlands. Was it Agent Orange or some other herbicide that the Army generally sprayed around base camps? If it were something other than Agent Orange, there would be little reason for doing any additional TCDD measurements with either cohort of Army Chemical Corps workers.

Thanks for reviewing my concerns.

RWT/rt

Mr. SHAYS. Thank you. I think you were more than generous to the advisory committee because frankly, there are people who would serve at their own expense. They would come at their own expense. And the fact that you do not know whether you were a veteran appointee or appointed in terms of your medical expertise tells me something. I suspect you were not a veterans appointee.

And it raises questions in my own mind, and I should have asked Dr. Coene, when he said he had a quorum of five, can I make an assumption that the five who were usually there were not veterans because we had not been filling the spots with veterans? Which also says somethings to me about the veterans organizations, that they were not pushing this organization.

But I chose not to dwell on that, because I think it is pretty evident.

Mr. TREWYN. I was told that it was the American Legion who recommended my name, but I do not believe the GAO ever found any record of it, and I never had anything official that indicated that.

Mr. SHAYS. Then you may have been an appointee of the veterans. The bottom line is not to meet for 3 years just boggles the mind. It certainly was different than what we anticipated.

Dr. Albanese, would you elaborate on your concerns about the 1992 IOM reports on birth defects and cancers?

Dr. ALBANESE. Yes, sir. When you compare the Ranch Hand sprayers with their control group, there's a more than 50 percent excess in the group that has sprayed. Now that birth defects excess, using current analytical techniques, does not regress linearly on dioxin. But that group difference exists.

I am one of four authors of that protocol. The purpose of this study was to determine whether Agent Orange is associated with problems. There's also a portion in the protocol which says we're concerned about the Vietnam experience.

We have sitting on the table a greater than 50 percent increase in the birth defects. And because it doesn't have a linear regression with dioxin, which is not the only dangerous contaminant in Agent Orange, we've ruled it out. And in the IOM report we have a statement which says let there be an independent analysis of this data because they severely criticized this.

Mr. SHAYS. Does this relate to, Dr. Trewyn, your comment on your first page on the bottom, with multiple agents and the potential for synergistic activities among them, there may be no way to sort out the relative importance of different levels of exposure to individual components in veterans with different genetic backgrounds and susceptibilities. And synergy is a well-known phenomenon in chemical carcinogenesis and other disease progressions?

Mr. TREWYN. That is correct. And in Agent Orange, 2,4-D being essentially 50 percent of the mixture, which has been shown to cause problems. Weed-B-Gone is how it's currently marketed. But that has problems. You put dioxin, which came in in the other component, 2,4,5-T, you put those together and I don't know that anyone has ever scientifically studied the potential for synergy that these two things together could cause a much greater effect than either alone.

And those are just a couple of possibilities.

Mr. SHAYS. Ms. Schwartz, do you have any comment?

Ms. SCHWARTZ. I think the thing is that Ranch Hand was designed to look at Ranch Handers. What happened was because they honed in on the ability to be able to measure dioxin, that became the coin of the realm when indeed it should not be the coin of the realm. And statistical significance should not be the way in which you decide what things are compensable disabilities.

So that's why I'm saying if you could look into the Ranch Hand data, you could probably see if there were any other things that had a greater than 50 percent chance——

Mr. SHAYS. Do you have access to that data?

Ms. SCHWARTZ. There is no access to the data at this time. As I said, we have the tapes. We just don't have—we cannot read the data.

Mr. SHAYS. If we spent an average of $5.6 million a year, and I should probably ask this to others, but it would strike me that the relative cost of transferring that onto manageable equipment would allow so many people to look at this data and we might come up with some other conclusions.

Ms. SCHWARTZ. That was the intention of the Yale School of Nursing, to transfer it to CD-ROM and then to say if anybody wants this data, you have to pay for the CDs but we'll make the copies for you.

Mr. SHAYS. So one thing that this committee could do that would make a contribution would be what would the cost be to convert this data to a consumable?

Ms. SCHWARTZ. Right.

Mr. SHAYS. You know, Doctor, if you do not mind coming up now, you could just respond to that. There me things and you are more than welcome to come down.

One, I appreciate you staying here. It is appreciated.

Ms. SCHWARTZ. I think, just to answer and I probably shouldn't steal Dr. Michalek's thunder, but the idea of making that data available and something that can be used has been on the Internet for quite some time. The delay, we don't see that.

Mr. SHAYS. Doctor.

Dr. MICHALEK. I understand your frustration. We are preparing a series of CD-ROMs to be released to the public this year. Each CD-ROM will contain the full report and all supporting data bases and they will be in there as both flat files and as sass files. We promise to have all this out by the end of calendar year 2000.

Mr. SHAYS. Thank you. Will that be a help, Dr. Schwartz?

Ms. SCHWARTZ. I will be eagerly awaiting this, especially if it's in a sass file.

Dr. MICHALEK. Absolutely. For example, we've already released the birth defect data. Everything that has been published is now released. The dataset itself is out there at NTIS. I would invite anyone who wants to have access to the data and it's inconveniently formatted, just send me a message and I'll send you a sass dataset.

Ms. SCHWARTZ. I don't think that the birth defect data is there. If you sent it there, it's not there and it is not available to the public.

Mr. SHAYS. This dialog is helpful because we can, by the fact that we have a public dialog about this, we can do our job as a committee and just make sure it happens the way it should.

Ms. SCHWARTZ. I would just like to say, as a way of informing everyone, that the VA did complete a study of the birth defects associated with women veterans. Agent Orange was not in the—was not considered in that because of the presumption that if you served in Vietnam you would be eligible for this, and that the Secretary of Veterans Affairs found that the high rates of birth defects in women and the children of women who served in Vietnam was so high that he did make an announcement that they would be making efforts to compensate these women and their children.

And as much of a women's advocate as I am, I see that we really need to proceed as soon as we possibly can——

Mr. SHAYS. Do you think that is happening?

Ms. SCHWARTZ. Yes, it is happening.

Dr. ALBANESE. Congressman Shays, I think it's very important for me to say, based on what Dr. Schwartz just said, I studied that report on the birth defects to female veterans. The pattern in the Ranch Handers is nearly identical to the pattern in that study. But because they didn't meet the standard of a linear increase with dioxin, the fact of that difference hasn't been further pursued. That's the tragedy of it.

Mr. SHAYS. Let me just say, Doctor, you might be tempted to jump in. I will just ask questions of the three panelists, but I do want to give you the opportunity to come back to the panel here and respond to anything that you have heard. We like everything out on the record, and again I thank you for being here. Let me just focus on the three of you a second and then we will conclude.

Dr. Albanese, I would like you to give me examples of the Ranch Hand study of how the hierarchical structure of the military organization can compromise the work. Tell me how it becomes compromised, in your judgment?

Dr. ALBANESE. I'm not going to give you a hypothesis. I'm going to report on what happened.

Perhaps the most overt effect was a letter from Commander Mosher who wrote in the name of the Surgeon General Chesney. And in the mortality report we were directed to use five controls for every exposed Ranch Hand instead of the 8 to 10 that we had available. We were to put that as a secondary analysis.

Mr. SHAYS. You would do that based on what? On someone's directive?

Dr. ALBANESE. Surgeon General Chesney perceived that to be in the peer-review's interest. We had no way of verifying that. And I want to remind you that this was an improperly constituted peer-review at that time. There were no scientists representing veterans.

So we received this letter saying highlight the one to five analysis, not the stronger, more powerful statistical one to eight analysis. And report percentages, mortality percentages rather than numbers.

Now I was the lead statistician at the time. My desire was to go with the strongest statistical analysis, one to eight, and feature that. I felt that there were some indications of a mortality blip.

And furthermore, when men and women are young, in their 40's and early 50's, percentages are small. But numbers are people, numbers are real. And the thing to do is actually publish both. General Chesney intervened directly and changed our report.

Now we have a very small sample size. Very small. A 1 in 1,000 disease is not a rare disease, as the GAO claimed. That's like leukemia and I wouldn't view leukemia as a rare disease. If we have 1 in 1,000 extra leukemias, we have 25,000 of them in the Vietnam veterans. Ranch Hand can't detect 1 in 1,000. It can't detect 2 in 1,000 excesses. These are the limitations that haven't been described.

So how can you amplify the size of the study? You can understand how dioxin affects the metabolism. You can augment your analysis with models of the toxicology. Now that's what I was doing as a statistician. And there's a letter in the record, which the GAO has, which absolutely terminates that line of research, written by Commander Mosher.

Mr. SHAYS. Let me ask you, though, it sounds to me that you were making a determination that you were going to go beyond the size of the study. Was that your prerogative?

Dr. ALBANESE. No, no, I was going to augment.

Mr. SHAYS. Now in your judgment, that is your professional license to be able to do that?

Dr. ALBANESE. No, that was part of the protocol, sir, to use toxicological data. I wrote that protocol and that protocol says—with Moynahan, Lathrop and Wolfe. And that protocol says we were going to look at the relationship of Agent Orange to disease. Not dioxin, Agent Orange to disease.

And we were going to look at the Vietnam experience. There are two other aspects of the protocol that haven't been fulfilled. There's an entire time in-country analysis that has not been featured in any publication that I've been able to time. And there's been a second analysis. I was just fulfilling the protocol.

Mr. SHAYS. I hear you. Thank you.

Dr. Schwartz, would you expand on your testimony that results of the Ranch Hand study are used to determine health effects on all Vietnam veterans, especially women?

Ms. SCHWARTZ. The statement is that it does not, it should not be applicable to all veterans because, first of all, there aren't any women and that's not the Ranch Handers fault nor the Air Force's fault. Women just weren't in that.

Mr. SHAYS. Thank goodness. Thank goodness that they were not part of Ranch Hand.

Ms. SCHWARTZ. But I think some of the recent findings about the levels of dioxin in the soil of our bases really casts another challenge to us about what happened to the folks that were on those bases, and there were women.

There has not been, to this date, a health study of the women who served in Vietnam. My own dissertation, it was the beginning. And the reproductive outcomes has been done by the VA. But what I am saying is this, that I have heard Dr. Michalek say, and I understand perfectly, that this study was about Air Force Ranch Handers and that's the way we should look at it.

And perhaps it has been too convenient to lean on the results of this study, to cast the wide net and say that this involves all of the veterans who served in Vietnam.

Mr. SHAYS. Just based on that comment, do you think that the study should continue? One, should the study continue? And second, should it continue in the Air Force's hands? Should it be given independently?

Ms. SCHWARTZ. This is a hard question but I feel that if we put it in the correct perspective, that the work that Dr. Michalek and all the others have done, that this is probably the longest longitudinal picture we have of men who were in the military and the after effects. If we want at that and looked at that as a way in which we could use the data which has already been collected, then I say yes, the study should be continued.

But for us to continue to hang our hat on the fact that this is the absolute gold standard of what is happening to the health of veterans who served in Vietnam, no.

Mr. SHAYS. Do you think it being held up as the gold standard?

Ms. SCHWARTZ. Yes, it is. I think that when the National Academy of Science reviews, even though they do mention in their reports some of the things about Ranch Hand's protocol and study design, that if it's not statistically significant, Ranch Hand does not publish it. Therefore, we are not getting all of the information.

If Ranch Hand is publishing, crafting their reports to fit into professional journals, then we are not seeing the things that probably are greater than a 50 percent chance. So we are denying veterans, or maybe we are denying veterans some compensation and disability for the facts that we have not really looked at all.

And also, I think the thing is that the subjects who have participated in the Ranch Hand study deserve, deserve to know if there is anything else. Dr. Albanese raised an excellent point, that the study is of herbicides. There were 15 herbicides used in Vietnam. Agent Orange was one of them.

Mr. SHAYS. Thank you. Dr. Trewyn, if you were to take the study out of the hands of the Air Force, the DOD, who would you give it to?

Mr. TREWYN. I'm not sure that I would take this study out of the hands of the Air Force, to be honest. During the 4 years I was on the advisory committee, I found the personnel involved to be very responsive to any questions, any materials that we asked for. In their reports they use a number of different statistical models, some of which provide useful information, more useful information for making some of the determinations that this group is interested in here, the health things that may not sustain the scientific scrutiny that a publication in a peer-review journal would.

But those things are in the report. And I think the material is there.

Dioxin, and some of the associations that they're finding with that, truthfully it's—well, it's not found in chemical processes like it used to be. There is an environmental burden of dioxin that we all have to deal with. I used to live in Columbus, OH and if you were anywhere near the trash-burning power plant there, your dioxin levels were going to be very high because they were putting a lot of it out the stack. And that was not that many years ago.

So there are sources of dioxin. I think as a study of effects of dioxin, granted this is a herbicide study and the data is there for that. There's going to be valuable information that's going to come out of this. But negative findings in this study mean nothing for any other Vietnam veteran because of all of these other possible routes of exposure, other things involved in everything.

And so this really should not be held up for a cure-all thing, solve-all answer for Vietnam veterans. This isn't the study to do that. And I believe at the time they started it, the belief was that it was going to be. It hasn't turned out that way and I don't think it's necessarily through the fault of the people involved.

New studies I would put elsewhere.

Mr. SHAYS. Your analogy of the forest and the trees, and the description that a lot of the trees are dying, it implies that even if we cannot identify the cause to Agent Orange, we know that there are sick veterans who need help.

Do the other two of you agree with that analogy? Are the trees dying?

Ms. SCHWARTZ. I would just like to say that the fact that we have not been able to come to conclusions about the rare diseases and the cancers that are suffered by the veterans, about the birth defects that they are seeing in their children and their grandchildren is a great sorrow. It's a great sorrow.

But the fact is that the lag time between the exposure to Agent Orange and the appearance of symptoms is upon us now. And I have buried too many friends in the last few years, women especially, who had never even thought that they had been exposed to Agent Orange. But I will tell you this, that the only comfort they got about hearing that their diseases might be related to Agent Orange is the fact that they could consider that they were dying for their country.

Mr. SHAYS. That is a pretty powerful statement. My general feeling is if I were to ask the VA, they would tell me, and I would be happy to have them disagree, but they would tell me that it has not been established that more people are dying who served in Vietnam.

Mr. TREWYN. I would agree with that, that it has not been established. And that's one of the flaws in the system. That's the study, long-term studies of outcomes, morbidity and mortality, are the sorts of things, tracking a group of individuals who were involved in the conflict. And so I'm using this in terms of Vietnam, Persian Gulf, Kosovo, wherever. Tracking the long-term outcomes to a normal population, a group that was not subject to the same levels of exposure——

Mr. SHAYS. You have made your case, I think clearly, that to compare our soldiers who fought in Vietnam who may not have had direct contact with Agent Orange to those who had direct contact would be flawed, because they would have indirect contact.

But it would seem to me, and I do want to complete here, but from my simple-minded approach to this, I would want to determine are more people dying who served in Vietnam, are more people suffering illness and birth defects. I would want to know that kind of information, and whether or not we knew the exact cause—

I mean, obviously we want to know the cause for cures and so on. But at least we could reach out and lend a helping hand to them.

And I would make an assumption that some would have gotten this illness for other reasons or died for other reasons. But so what? We gave them additional help. They did serve in Vietnam. That is kind of the way my simple mind works.

If you all can help steer me in that direction, I would love some help.

Dr. ALBANESE. May I respond to your first question? I think it's beyond a reasonable doubt that there is a birth defects excess in the Ranch Hand group. I think the preponderance of the evidence is that there has been an excess of cancer. I think it's beyond a reasonable doubt that there are some neurological effects. And I think there's a preponderance of the evidence that there are endocrinological effects in the Ranch Hand group.

Having said that, the issue of how these extrapolate or if they extrapolate to the veterans as a whole is an open and interesting question.

Ms. SCHWARTZ. I would just like to address that. In my particular study we had three groups. We had women who served in Vietnam. We had women who were in the military but never served in Vietnam. And we had a cohort of civilian women who were matched for age and occupation, being nurses. I find that that design has a lot of strengths to it, because you are then able to see, because there are other exposures to dioxin now in our atmosphere.

My data came from the National Vietnam Veterans Readjustment Study, which was commissioned by the Congress to look at the readjustment problems of Vietnam veterans. I know that there has been several proposals that we go revisit this same group that we studied in 1985, because you have the three groups and you can see where they are now.

Mr. SHAYS. Dr. Michalek, would you like to make any comments?

Dr. MICHALEK. Just a couple of things. They are fairly technical and I feel inadequate to respond to some of the statements that——

Mr. SHAYS. Let me just say this to you, I am not suggesting that you have the burden of responding to every testimony here. So if something is said here and you have not responded, I will not assume your silence means you agree.

Dr. MICHALEK. Thank you. I just feel sorry and sorrowful myself, after listening to Linda talk, and I hate to talk technicalities after hearing her statements.

Mr. SHAYS. I understand.

Dr. MICHALEK. In the area of mortality, we mentioned the one to five and the one to eight design. You should know that those analyses were carried out many different ways and in duplicate in many of our reports. For example, in 1987, we used a reduced mortality cohort and then we used all mortality study subjects, up to 19,000. And we showed the results side-by-side.

In fact, every step of the way in this study, whenever we've changed our models or changed our ideas about statistics, we do everything twice or three or four times. And so everything is there, it just takes time to find it.

In the area of data release, yes, we have released the birth defect data and I'm sorry about its format. That has to do with NTIS and the way they handle data and we'll certainly fix that with CD-ROMs. With anybody who would approach me for that, I'd certainly hand it out right away.

On the birth defect issue, as we've said, we have the most comprehensive data available. It's been analyzed independently by the Centers for Disease Control, and that led to the published article in 1995. That conclusions in that article were drawn by the Birth Defects and Developmental Disabilities Branch at CDC. They received the data from us, they interpreted it, and they wrote the conclusions to that paper.

So what you're seeing here today is a disagreement between medical doctors on how to interpret data. That would be Dr. Albanese against the physicians at CDC. The data is now available and I would encourage anyone who has any ideas on reanalyzing that to go ahead. And if you need extra help, call me and I'll send you what you need.

Mr. SHAYS. Thank you. Thank you very much.

Good things can happen from the effort of the GAO and there will be some blessings in this and there will be some silver lining. And I think when you have devoted as much of your life, Doctor, as you have, it is tough to have this kind of dialog. I am sure we could have witnesses that would say things are not exactly this way, so I understand we can also do it that way.

But I think we are all people of good will and I am absolutely convinced that you care as much as anyone else about the welfare of our veterans.

So I thank all of you. You all have made a contribution here.

Let me just allow anyone to make a completing comment if they want.

Dr. ALBANESE. One concluding comment would be, I believe, since you are the Government Reform Committee, that a reform is needed in the Air Force with respect to medical research. Medical researchers need the opportunity to compete in the open literature without having a policy review on their papers.

Mr. SHAYS. I think that is fair. Dr. Schwartz?

Ms. SCHWARTZ. I would just reiterate that as the technology of the battlefield becomes more complex and that the idea that VA may have to look at compensation, that the military may have to validate or not validate what's going on with their soldiers that they send to war, that thought should be given to a freestanding institute of military medicine.

Mr. SHAYS. Very good, thank you. Dr. Trewyn.

Mr. TREWYN. I would just say that I do think that in the future, using the existing sort of NIH peer-review process, a lot of these studies could be done long-term in a mechanism involving the medical schools and experts around the country to do this. And I do think that the Congress can have an impact on some of these existing studies.

Because Congress did not mandate, in the Chemical Corps study and the National Academy did not mandate in that study that there be a non-chemically exposed group included, a normal control baseline, there is no normal control baseline. There are Chemical

Corps workers in Vietnam compared to Chemical Corps workers in other parts of the world. So you don't have, you have probably already set the baseline too high.

And there are other studies out there. The old Vietnam Experience study, whether there are things that could be—if that could be pulled back in and analyzed and the group studied at this point to see if there are now significant difference, could be an important thing to do.

Mr. SHAYS. Thank you. I appreciate the VA still having representatives here. Dr. Mather, do you have any, or anyone else? Or are we all set?

Ms. MATHER. Only that I would hate for people to go away from the hearing feeling that VA doesn't do anything for Vietnam veterans who don't have service connection. In fact, Vietnam veterans who think their illnesses are due to exposures or service in Vietnam can get treatment in VA hospitals, and they have a priority for that.

Mr. SHAYS. Dr. Michalek?

Dr. MICHALEK. Just one more thing. I think one thing that we've all heard today, and we've said many times, is the committee itself, the advisory committee, I wish you could find funding to strengthen the committee, to make it proactive instead of reactive, and to encourage more frequent meetings.

Mr. SHAYS. I honestly think if they had been more proactive, they would have been a help to you rather than a hindrance, because they would have been coming from the perspective that would be important. I think that that will be one of the findings of this committee, and we will try to come out soon with that, and you have made some suggestions on how we proceed.

So we have learned a lot and you have all been very helpful. I thank you so much. I have to run off to a budget hearing, so I will just say thank you.

This hearing is closed.

[Whereupon, at 1:37 p.m., the subcommittee was adjourned.]

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