AGENT ORANGE: STATUS OF THE AIR FORCE RANCH HAND STUDY

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HEARING

before the

SUBCOMMITTEE ON NATIONAL SECURITY,
VETERANS AFFAIRS, AND INTERNATIONAL
RELATIONS

of the

COMMITTEE ON
GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

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Albanese, Dr. Richard, 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.

Chan, Kwai-Cheung, 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.

Michalek, Dr. Joel, 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.

Letters, statements, et cetera, submitted for the record by:

Albanese, Dr. Richard, Senior Medical Research Officer, U.S. Air Force, former Ranch Hand Principal Investigator, prepared statement of.
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:]

[GRAPHIC] [TIFF OMITTED] T7153.001
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
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 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:]

[GRAPHIC] [TIFF OMITTED] T7153.003

[GRAPHIC] [TIFF OMITTED] T7153.004

[GRAPHIC] [TIFF OMITTED] T7153.005

[GRAPHIC] [TIFF OMITTED] T7153.006

[GRAPHIC] [TIFF OMITTED] T7153.007

[GRAPHIC] [TIFF OMITTED] T7153.008

[GRAPHIC] [TIFF OMITTED] T7153.009

[GRAPHIC] [TIFF OMITTED] T7153.010

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. 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:]
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
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.

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 cover-up. 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 timetable 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:]
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
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 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 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 follow-up 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:]

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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 database 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:]
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. 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 oversighting 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 stand-downs, 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 separation sites.

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
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 comprehensive 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 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
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.
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.S. 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 representatives 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:]

[GRAPHIC] [TIFF OMITTED] T7153.048

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 if 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 disproportionately 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:]

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[GRAPHIC] [TIFF OMITTED] T7153.056

[GRAPHIC] [TIFF OMITTED] T7153.057

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:]

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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 something 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 sas 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. 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. {Comment by our Nations Veterans and Widows… What a crock of VA BS as they stall and deny even today’s known associated compensations until the Veteran is dead: while they lay down gauntlet after gauntlet to the many more illness from DoD Herbicide usage that should be added with their stall to the death of the Veteran processes and procedures.} 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.]