NATIONAL ACADEMY OF SCIENCES REPORT ON HEALTH EFFECTS OF AGENT ORANGE

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS

HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

AUGUST 4, 1993

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NATIONAL ACADEMY OF SCIENCES REPORT ON HEALTH EFFECTS OF AGENT ORANGE

WEDNESDAY, AUGUST 4, 1993

HOUSE OF REPRESENTATIVES,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The committee met, pursuant to call, at 10:38 a.m., in room 334, Cannon House Office Building, Hon. G.V. (Sonny) Montgomery, chairman, presiding.

Present: Representatives Montgomery, Evans, Penny, Rowland, Kennedy, Baesler, Bishop, Clyburn, Kreidler, Stump, Smith, Bilirakis, Ridge, Hutchinson, Everett, Buyer, Quinn, Linder, Stearns, King.

OPENING STATEMENT OF CHAIRMAN MONTGOMERY

The CHAIRMAN. The full committee will come to order.

Today, we will receive the report of the National Academy of Sciences study on health effects of Agent Orange. We are going to hear first from Senator Tom Daschle of South Dakota, a former member of this committee. Tom did excellent work as a member of this committee for Vietnam veterans, and we are glad to have you back, Tom.

After we hear from Tom, I will make my opening statement.

Mr. Stump.

Mr. STUMP. Thank you, Mr. Chairman. I just want to welcome Senator Daschle back over to the committee. It is nice to see you again. We are glad to have you here.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Tom, we do appreciate your being here, and the floor is yours.

STATEMENT OF HON. THOMAS A. DASCHLE, A UNITED STATES SENATOR FROM THE STATE OF SOUTH DAKOTA

Senator DASCHLE. Mr. Chairman, thank you very much for your introduction, and for holding this hearing. I have fond memories of my times on this panel. I started out where Mr. Bishop is right now and worked my way up a little bit to the top here. But I have always admired the work of this committee and appreciate very much your willingness to allow me a couple of minutes.

I want to be very brief because you have a lot of good witnesses today. I have a full statement, and I, with your permission, would like that submitted for the record.

The CHAIRMAN. Without objection.

Senator DASCHLE. Let me just begin by commending the 16-member NAS panel. As everyone on this committee knows, they worked for no compensation. They didn't get a penny, and I think that needs to be emphasized. That they did this because they believe in what they are doing. We chose them because we wanted to ensure that there was no charge of some kind of subjectivity here in the analysis. And I think under the circumstances and given the time they had, they did an extraordinary job.

The report, as most of the members, I am sure, know, confirms the association between exposure to Agent Orange and other herbicides used in Vietnam and five specific diseases, and suggests that there may be a relationship with additional diseases. The NAS scientists indicate that more research is necessary, and, as the chairman so well knows, that is the reason why we called for the series of bienniel reviews over the next 10 years.

Contrary to the Centers for Disease Control, the Agent Orange Working Group, and the Office of Technology Assessment, the National Academy of Sciences suggests an epidemiologic study of American veterans can be done and makes specific recommendations on how to do it right. I think that has been a critical part of what they have proposed, and I commend them for it and certainly hope the committee will look into these recommendations very carefully.

Appropriately, I think, the report has been highly critical of the Ranch Hand study. The NAS has recommended that an independent, nongovernmental panel review and approve a new protocol, and reanalyze the data to clarify some of the misinformation in the Ranch Hand study.

In my view, the NAS report is a true milestone. It is a milestone because I think it emphasizes again what many of us know.. We struggled with the facts for a long period of time. We struggled to try to analyze the data and come to some conclusion about that data—what it means in the most objective sense—and I think the NAS more than anybody else has been able to contribute in that struggle to ascertain the facts.

Veterans, as this committee knows so well, want to be told the truth. They want their government to take responsibility for the truth. It has been a long, difficult, and, unfortunately, unnecessary struggle with the Government in that regard. The NAS has now verified how right those of us who called for greater collection of data and a more honest assessment of the science, were. This should put to rest once and for all the claims that Agent Orange never hurt anybody. The fact is that we now know it has.

So let us continue the research. Let us continue to bring the NAS before us and analyze their work, and let us, during that process ensure that veterans receive the benefit of whatever remaining doubt there may be.

Again, Mr. Chairman, I appreciate the opportunity to share some thoughts with you, and I appreciate very much the work the NAS has done in bringing us to this point this morning.

[The prepared statement of Senator Daschle appears at p. 75.]

The CHAIRMAN. I thank my good friend for his testimony.

For the newer members on the committee, Tom Daschle pushed long and hard to see that we got a full report on the Agent Orange

issue, and he never backed off from it. He and I would talk many hours over this situation, and finally we did come up with the solution for the National Academy of Sciences to look into it and give us this factual report. Many times we get reports from commissions that don't spit it out—you didn't gain much from the report. But I think this report did that.

And, again, thank you, Tom.

Do any other members have comments?

Dr. ROWLAND. Yes, Mr. Chairman.

The CHAIRMAN. Dr. Rowland.

Dr. ROWLAND. Senator, it is good to see you. I recall in 1983, I had only been here about a month, we met in a room right down the hall here. You called a meeting and I think there were two or three other House members that came to discuss this issue, and you excited my interest in it at that time. I want to thank you for that and tell you how much I appreciate the hard work that you have done over the years.

Senator DASCHLE. Thank you.

The CHAIRMAN. Lane Evans.

Mr. EVANS. Thank you, Mr. Chairman. I have an opening statement that I would ask to be entered into the record without objection.

The CHAIRMAN. Without objection.

[The prepared statement of Congressman Evans appears at p. 67.]

Mr. EVANS. And I associate my remarks with Senator Daschle who did serve very well here in the House. I, basically, picked up his legislation when he moved over to the Senate. I doubt that we would really be here today if Senator Daschle as a House Member and as a member of the Senate hadn't pushed so hard.

So I appreciate, Tom, very much your hard work all these years. And we are not out of work yet. We still have work to do, and I look forward to working with you in the future.

Senator DASCHLE. Thank you.

Mr. EVANS. I appreciate all your leadership on this issue. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you. If there are no further comments, thank you, Senator Daschle, for being here this morning.

Senator DASCHLE. Thank you, Mr. Chairman.

The CHAIRMAN. This morning we will receive the views of the National Academy of Sciences on possible health effects resulting from exposure to Agent Orange and other herbicides used in Vietnam. In addition to the witnesses from the Academy, we also will hear from the Secretary of Veterans Affairs, Jesse Brown, also several veterans' service organizations, and a number of other important witnesses.

In veterans' affairs, few issues have generated as much controversy as the questions surrounding the long-term health effects of exposure to Agent Orange. There have been numerous studies and much work by the Congress on the subject, and I believe that the Congress has demonstrated its commitment to making certain that veterans are treated fairly and that the VA's compensation decisions are just and reasonable. That is why we asked the Academy

to do this study in February of 1991 when we enacted Public Law 102–4.

This particular assessment of the effects of exposure is very important. Not only were the scientists and physicians who conducted this assessment highly qualified, greatly respected and fully independent, they considered the results of thousands of studies in reaching their conclusions.

We are pleased to have Dr. Kenneth Shine, President of the Institute of Medicine, here with his colleagues to brief us on the results of this study. On behalf of the Veterans' Committee, I want to thank all of the members of this special committee for the many hours they have spent on the review, all of it without pay.

One of the committee's conclusions is that there is sufficient evidence to suggest a link between exposure to herbicides and five other conditions. The Institute of Medicine found that for some conditions there is limited or suggestive evidence of an association with herbicide exposure, and for a number of others the committee has concluded that a connection is not suggested by the information which it considered.

Secretary Brown will review these findings and make further decisions within the next 60 days. Based on his announcement to grant service-connected conditions for two of these herbicides, PCT and Hodgkin's disease, on the same day that the Academy announced its finding that they appear to be related to herbicide exposure, I am confident he will complete this further review in a timely manner.

Clearly, some important questions have at long last been answered. Other important questions, however, still remain. To help answer the remaining questions, the Institute of Medicine committee has recommended additional scientific research.

I said when we passed the law authorizing this review that I would support the Academy's findings and recommendations. I stand by that statement today and urge all members to support their recommendations.

The chair would like to yield to Mr. Stump.

Mr. STUMP. Thank you, Mr. Chairman. Thank you for calling this meeting. I would like to thank also the panel that worked so tirelessly on this difficult task for the past year, and in particular, Dr. Shine, Dr. Fallon and Dr. Tollerud. We appreciate it very much.

It appears that, on preliminary, examination at least, that this would confirm the report, or the action rather, that Ed Derwinski took back in 1990. Also, as you mentioned, Secretary Brown is to be commended for taking swift action.

And, once again, I would like to personally thank all those members of the committee for the hard work they have done. Thank you, Mr. Chairman. I do have a statement for the record.

The CHAIRMAN. Thank you. The statement will be put in the record. All members' statements and other statements will be put in the record.

[The prepared statement of Mr. Stump appears at p. 68.]

OPENING STATEMENT OF HON. LANE EVANS

Mr. EVANS. Thank you, Mr. Chairman. I appreciate this opportunity to speak.

I want to pick up just where Bob Stump left off. I think the change in attitude occurred when Secretary Derwinski took a second look at Agent Orange. It has been followed up by Jesse Brown. I think these are important steppingstones to a full resolution of this issue, and I believe that we now have a new beginning in our government's relationship with Vietnam veterans.

After fighting the Government for 3 decades, it appears that Vietnam veterans may finally get the respect and the treatment that they deserve. The NAS study proves that Vietnam veterans were right all along. That Agent Orange is harmful and that the Government studies were flawed.

I also want to join with Senator Daschle in congratulating the NAS panel that worked without compensation and has given us the data that we have got in this report. It has been very helpful. I think they have done great service to this country.

I appreciate the opportunity to speak.

The CHAIRMAN. I want to thank Lane Evans. He has certainly been working in this area for a number of years. Thank you for your help.

Dr. Rowland.

Dr. ROWLAND. Thank you, Mr. Chairman. I do have a statement that I want to submit to the record.

The CHAIRMAN. Without objection.

Dr. ROWLAND. I just want to commend the National Academy of Sciences for the wonderful job that they have done on this. I have always felt that any information that would relate the harmful effects of chemicals, whatever they may be or whether it is in the water or the air, should be based on scientific findings, and that is what has taken place here. And I think we can move forward and do those things that need to be done to address the problems that veterans are having who were exposed to this herbicide and it would be based on scientific evidence, and that is what is so important.

The CHAIRMAN. Thank you.

Mr. Bilirakis.

OPENING STATEMENT OF HON. MICHAEL BILIRAKIS

Mr. BILIRAKIS. Well, thank you, Mr. Chairman. Just very briefly, I certainly associate myself with your remarks and the remarks of the others.

Mr. Chairman, we hear and oftentimes have used the phrase "the cost of war does not end with the end of the war," and I guess this is certainly a perfect illustration of that, and well it should be. Almost 20 years after the end of the Vietnam War, we are finding out additional costs to that war, which had been there all along, I suppose.

Mr. Chairman, Lane used words, something about learning process or words to that effect. Well, when we got together regarding the Persian Gulf veterans and some of the mysterious ailments that we are running into there, I think this experience with Agent Orange has helped us to basically accept that a heck of a lot quicker than ordinarily we would. And we didn't use words such as "causation" and "tying things together" and that sort of thing

when we discussed that legislation, so we have learned an awful lot.

Thank you.

The CHAIRMAN. Thank you, Mr. Bilirakis.

The chair would like to recognize the first panel led by Dr. Ken Shine, President of the Institute of Medicine.

Dr. Shine, will you introduce those with you today?

Dr. SHINE. Yes, Mr. Chairman, I would be delighted to do that.

STATEMENTS OF KENNETH I. SHINE, M.D., PRESIDENT, INSTITUTE OF MEDICINE; AND DAVID TOLLERUD, M.D., M.P.H., VICE CHAIRMAN, INSTITUTE OF MEDICINE'S COMMITTEE TO REVIEW THE HEALTH EFFECTS IN VIETNAM VETERANS OF EXPOSURE TO HERBICIDES, ACCOMPANIED BY GRAHAM COLDITZ, M.D., DR.P.H.

STATEMENT OF KENNETH I. SHINE, M.D.

Dr. SHINE. Mr. Chairman, and members of the committee, I am pleased to have the opportunity to testify before the House Committee on Veterans' Affairs on the Institute of Medicine's report prepared by the Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides. I will provide a brief summary of the background on the committee's report and the Institute of Medicine. The Vice Chair of the committee, immediately to my left, Dr. David Tollerud, will present a brief overview of the committee's findings and recommendations. Also seated with us is Dr. Graham Colditz, a member of the committee, who is prepared to answer questions.

In response to decades of concern surrounding the possible long-term health consequences of exposures to herbicides and the contaminant dioxin, Congress directed the Secretary of Veterans Affairs, in Public Law 102–4, signed on February 6, 1991, to request the National Academy of Sciences to conduct a comprehensive review and evaluation of the available scientific and medical information regarding the health effects of exposure to Agent Orange and other herbicides used during the Vietnam conflict.

The report from the Institute of Medicine's Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides, entitled "Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam," reviews and evaluates the available scientific evidence regarding the association between exposure to dioxin and other chemical compounds in herbicides used in Vietnam and a wide variety of health effects, and provides the committee's best assessment of this body of knowledge for the Secretary of Veterans Affairs to consider as the Department of Veterans Affairs exercises its responsibilities to Vietnam veterans.

The report also describes areas in which the available scientific data are insufficient to determine whether an association exists and provides the committee's recommendations for areas in which future research is likely to be most productive.

The National Academy of Sciences was created by an Act of Congress which was signed into law in 1863 by President Lincoln. It is dedicated to the furtherance of science and technology and to their use for the promotion of the general public welfare. The Insti-

tute of Medicine was chartered by the National Academy in 1970 to serve as an adviser to the Federal Government on issues that affect the public's health, as well as to act independently in identifying important issues of medical care, research and education.

The Institute of Medicine brings to this mission more than 2 decades of experience in conducting independent analyses of pressing health problems that involve Federal policy decisions.

The Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides includes 16 members representing a wide range of expertise. As noted by you and by Senator Daschle, members serve voluntarily and without compensation. The report which they have submitted is unanimous. They reached full consensus with regard to its recommendations. It was chaired by Harold Fallon, M.D., Dean of the Medical School at the University of Alabama, Birmingham, and Dr. Tollerud, Director of Occupational and Environmental Medicine at the University of Pittsburgh, served as vice chair. Committee member Norman Breslow, a professor in the Department of Biostatistics at the University of Washington, served as liaison to the rest of the Institute of Medicine.

I should emphasize that a number of members of this committee, although they are experts in their field, they are individuals who had not previously worked on Agent Orange. This was a deliberate attempt to provide an opportunity to give a fresh look by experts in this area. All of them were selected because they are leading authorities in their scientific fields, well respected by their colleagues and peers, have no conflicts of interest with regard to the matters under study, and indeed have taken no public positions concerning the potential health effects of herbicides in Vietnam veterans or related aspects of herbicide or dioxin exposure.

The committee thus has provided a fresh analysis of this issue, which is both scientifically complex and emotionally charged, and this report reflects the committee's thorough and unbiased scientific judgments. As with all reports from the Institute of Medicine, the committee's work before completion was reviewed by an independent panel of distinguished experts who critiqued it prior to its final publication.

I would now like to introduce Dr. David Tollerud, Vice Chairman of the committee, to brief you on the contents of the report.

The CHAIRMAN. Dr. Tollerud.

STATEMENT OF DAVID TOLLERUD, M.D., M.P.H.

Dr. TOLLERUD. Thank you, Dr. Shine. Mr. Chairman, and members of the committee, I am pleased to have the opportunity to testify before the House Committee on Veterans' Affairs on the Institute of Medicine's report prepared by our committee to review the health effects in Vietnam veterans of exposure to herbicides. I will provide a brief overview of the committee's findings and recommendations.

A bitter legacy of the Vietnam War has been the decades of concern over the health effects of Agent Orange and other herbicides. More than 19 million gallons of herbicides were sprayed over South Vietnam in the years between 1962 and 1971 before reports of health effects in laboratory animals ended herbicide spraying. Most large-scale spraying took place from the air, but a considerable

amount of spraying was also done from boats and ground vehicles and by soldiers carrying back-mounted equipment.

Since that time some of the 3 million Americans who served in or near Vietnam have come to suspect that their wartime exposure to herbicides caused them to develop cancer or their children to have birth defects. This concern has helped initiate literally thousands of scientific studies on the health effect of herbicides and of dioxin which contaminated about two-thirds of the herbicides used in Vietnam. Yet the issue remains shrouded in controversy and mistrust.

This issue has been a source of great anguish for veterans, for their families, and for the Nation at large. Vietnam veterans made great personal sacrifices in serving their country, yet they have faced continuing uncertainties about whether exposure to herbicides has led to past health problems or could lead to problems in the future. Some of these veterans and their families feel that their pain and suffering have been ignored, and that these questions have not been adequately addressed.

Recognizing this uncertainty, the U.S. Congress passed the Agent Orange Act of 1991. That legislation asked the National Academy of Sciences to do a comprehensive review and evaluation of the available scientific and medical evidence regarding this issue. The task was undertaken by a committee under the Institute of Medicine. Our committee released its report to the public on July 27, 1993.

To gather information for this report the committee held three public hearings to allow veterans and other interested individuals to voice their concerns and opinions. In addition, members of the committee and the staff sought and received information from a broad array of individuals and organizations, including veterans' groups, Congressional committees, Federal agencies, scientific experts, and the public. This wide-ranging dialogue contributed substantially to this report.

We studied both the toxicological and the epidemiologic data on herbicide exposure. After reviewing literally thousands of studies, we focused on approximately 230 epidemiologic investigations for detailed review and analysis. Most of these studies did not involve Vietnam veterans. Rather, they were studies of people who were exposed to herbicides as a result of their jobs or as a result of contact in the environment; for example, because of a nearby industrial accident.

Three types of exposures often were at high levels for long periods of time. Getting a clear picture of the health risks for Vietnam veterans is not so straightforward because the levels of exposure were extremely wide-ranging. Indeed, while most veterans probably had lower exposure levels, some may have experienced levels as high as that of occupational or agricultural exposures. What is uncertain is how many veterans may have been exposed at those higher levels and who those individuals are.

Based on the evaluations of the studies we reviewed our committee found sufficient evidence of a statistical association between exposure to herbicides or dioxin and three types of cancer: soft tissue sarcoma, non-Hodgkin's lymphoma and Hodgkin's disease. We also

found sufficient evidence of an association with two skin conditions: chloracne and porphyria cutanea tarda, or PCT.

We found limited or suggestive evidence of an association between exposure to herbicides used in Vietnam and three other types of cancer: respiratory cancers, prostate cancer, and multiple myeloma. For most of the other cancers, diseases and disorders reviewed by the committee, the scientific data were not sufficient to determine whether an association exists. These include such cancers as bone cancer and leukemia, and disorders ranging from birth defects to nervous system disorders.

However, for a small group of cancers, including gastrointestinal cancers and brain tumors, the committee found limited or suggestive evidence to conclude there is no association between these cancers and herbicide exposure.

The greatest problem that we encountered in our study was a severe lack of information about the exposure to individual Vietnam veterans to herbicides. Except for particular groups such as the individuals directly involved in spraying operations, information on the extent of herbicide exposure among veterans is practically nonexistent.

New biochemical techniques can detect low levels of dioxin in the blood, but we did not find that these measures are useful for arriving at individual exposures. People metabolize dioxin at different rates and almost all Americans have some background exposure to dioxin. Furthermore, not all of the herbicides used in Vietnam contain dioxin.

This lack of data is why we were compelled to focus largely on epidemiologic studies of groups other than Vietnam veterans. We simply do not know enough about the exposures of veterans to determine to what degree they were or are at risk.

We do feel, however, that it is possible to develop better methods to determine exposures among individual veterans. Rather than relying on measures of dioxin in the blood, we recommend that exposure evaluations draw on historical reconstructions. These reconstructions take into account such factors as troop movements, ground and perimeter spraying, herbicide shipments to various military bases, the type of terrain and foliage typical of the location sprayed, and the military missions of the troops located there.

Historical reconstructions require substantial professional judgment. Therefore the committee recommends that a nongovernmental organization be commissioned to develop and test models of herbicide exposure for use in studies of Vietnam veterans. These exposure models should, in turn, be evaluated by an independent scientific panel to determine their usefulness. The independence of these scientific groups would allay the public's concern about impartiality and scientific credibility.

If a better model of exposure can be developed, a number of important epidemiologic studies become possible. Highest priority should be given to those studies that could change the balance of evidence for or against an associated health effect. Research on reproductive effects should also receive priority.

In addition, the committee recommends that a study of the Ranch Hand cohort which has been looking at individuals involved in the Air Force's spraying program be continued and expanded. A

similar study should look at the members of the Army Chemical Corps and an appropriate comparison group. Both the Ranch Hand and the Chemical Corps veterans are known to have had significant exposures to herbicides.

The committee also believes that an expanded reanalysis of existing Ranch Hand data may contribute significantly to answering some of the pressing questions that remain regarding the health effects of herbicides used in Vietnam.

Our committee was not asked to make judgments regarding individual injuries or the appropriate compensation for Vietnam veterans, and we did not do so. Rather we were asked to provide information that the Secretary of Veterans Affairs could use in exercising the responsibilities of the Department of Veterans Affairs to Vietnam veterans.

Over the years extreme views have evolved over this issue: on one extreme is the view that Agent Orange and dioxin cause a wide range of diseases; on the other is the suggestion that exposure to Agent Orange has not led to health problems. Our committee has determined through an extensive review of the scientific literature that, indeed, there does appear to be a link between exposure and certain diseases.

We believe that our report is a comprehensive, unbiased scientific review of the available evidence concerning this issue. This report will not end the controversy, but we hope that it will provide an agreed upon base of information from which we can proceed to answer the questions that remain.

I would like to submit the Executive Summary of the committee's report for the record.

That concludes my testimony. My colleagues and I are prepared to answer any questions that you and other members of the committee may have. Thank you.

Mr. EVANS [presiding]. Without objection, the Summary will be entered into the record.

[The Executive Summary appears at p. 83.]

Mr. EVANS. Before we go to questions to this panel, I would like to recognize the gentleman from Michigan, the distinguished Majority Whip, to come forward, Dave Bonior.

STATEMENT OF HON. DAVID E. BONIOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. BONIOR. I thank my colleagues and the chairman, and I commend them. And I apologize for the intrusion, but I was asked by Mr. Evans to come and give a little recap of the history of the Agent Orange issue and how it has evolved historically here. And given the importance of this hearing, I would ask your indulgence, if I could proceed for about 5 minutes to do just that.

First of all, I want to thank you, Lane, for asking me to be a part of this important day for Vietnam veterans. I want to applaud the efforts of the committee in holding this hearing and the National Academy for producing a well thought out report.

The NAS study validates what many of us have known for years. That exposure to Agent Orange is deadly. For nearly 2 decades, veterans, their families, and many of us in the Congress have been making this point over and over and over again. Lane asked me to

share with some of the new members of the committee some of my historical perspectives on the issue.

When I was first elected to the Congress back in 1976 I believed along with others were just coming in that year that we needed to do something on a variety of issues that affected Vietnam veterans, issues not only affecting Agent Orange but issues that dealt with post-traumatic stress syndrome, education issues, tax issues. We felt it was an important part of the healing process to make the country aware of what went on and what was needed in terms of binding the country back together.

I joined with several of my colleagues at that time in founding what was known then, and still is, the Vietnam-era Veterans in Congress. We had 11 of us at that time and we proceeded to enact the legislation that I have just talked about.

The fight for Agent Orange victims has lasted longer than the use of the herbicide lasted during the war itself. The first hearings, as I recall, were held by Senator Phil Hart from my State of Michigan back in 1970, and in 1978, I believe, because we were having difficulty with the Veterans' Committee, the then chairman, getting this legislation out, we asked other committees and members of our caucus to work on specific issues.

Vice President Gore was a member, was elected with me at that time and was a member of the Energy and Commerce Committee, and because of an inability to get things out of the then Veterans' Committee, different certainly than this committee, we were able to get our first action on Agent Orange in, I believe, 1978 when Vice President Gore was able to put something together in the Committee on Energy and Commerce.

From 1981 to 1984, under the leadership of Tom Daschle and yourself, Mr. Chairman, we gradually were able to include Vietnam veteran issues more and more among this committee's priority. In 1981, this committee adopted legislation advanced by then Representative Daschle to mandate health care for Agent Orange problems. In 1983, this committee pushed Agent Orange compensation legislation for Vietnam veterans which was later adopted by the full House in 1984, but there was still more to be done.

In order to cut the red tape at the Veterans' Administration, Congress passed the Agent Orange Act of 1991. We passed that bill to codify the presumption that all in-country Vietnam veterans were exposed to Agent Orange, and those with chloracne, soft tissue sarcoma, and non-Hodgkin's lymphoma deserved benefits. The 1991 legislation also promoted the National Academy of Sciences study and, of course, just last Wednesday they released their findings which concluded that there is sufficient evidence that exposure to Agent Orange causes three cancers: soft tissue sarcoma, non-Hodgkin's lymphoma, Hodgkin's disease, as well as chloracne.

The study also shows that there is a growing body of evidence that Agent Orange is directly responsible for other illnesses in Vietnam vets and that further research is necessary. The study is, to date, the culmination of our legislative efforts, but not the end. The study reminds us all of how much more there is to do. It is only the first step.

Now is the time to redouble our efforts to ensure that the National Academy of Sciences' recommendations for new research are

taken seriously and that the research is completed quickly. We owe that to the Vietnam veterans, their families, their children, and now, of course, their grandchildren.

We owe it to veterans like Jim Weir, who is from my hometown of Mount Clemens' district and he is the vice president of the Macomb County Vietnam Veterans of America, Chapter 154, which I am also a member of. He had a hard time, Mr. Chairman, letting his children know that his exposure to Agent Orange has infected them, but he did.

Jim has two children and both have hearing impediments. His daughter is getting married soon and every day he asks, "Do I encourage her to have children?" To Vietnam veterans like Jim, his children, and his grandchildren, we owe them these answers.

While this committee, my fellow colleagues and the Veterans' Administration have made, I think, tremendous progress in helping to heal the wounds of the Vietnam War, the families of these vets still suffer. And, while the pain continues, we must continue to help and to heal.

I look forward to working with the committee as we continue to research the consequences of Agent Orange and to fight for the answers that have for so long eluded us, but for so long that this committee and members of this committee have pursued with a steadfastness and a passion that meets the obligation that we owe these veterans.

I thank my colleagues. And I thank my colleagues at the table for their indulgence at this moment.

Mr. EVANS. Thank you, Dave. We appreciate your leadership on this issue as a founding member of the Vietnam-era Veterans in Congress Caucus, your help to us as you progressed up the ladder here in Congress, and your continuing support means very much to Vietnam veterans across the country. We appreciate your leadership.

Mr. BONIOR. Thank you.

Mr. EVANS. We have a Journal vote pending. We would like to recess for that?

We will now recess for about a period of 10 or 15 minutes.

[Recess.]

Mr. EVANS. We apologize to this distinguished panel for the delays in the question and answer period, and appreciate their patience.

Because of the numerous questions I have, I would like to yield to other members first and then come back to the questions that I, hopefully, will still have by the time that this round is done.

Let me recognize Dr. Roy Rowland from Georgia.

Dr. ROWLAND. Thank you, Mr. Chairman. And I want to thank you very much for your testimony here this morning and all the hard work that you have put into this.

Let me ask if there has been some confusion and maybe not the kind of recognition this problem should have received early because there may be some genetic differences in individuals that would make a condition manifest in one instance when it may not be manifest in another instance? Am I making myself clear in what I am saying?

Dr. SHINE. There is one condition, porphyria cutanea tarda, in origin—for which there is a genetic predisposition, and in that particular case only those individuals who are genetically predisposed are going to get the condition.

In the case of other kinds of conditions, I don't think we know enough about all of the contributing factors with regard to the background illnesses to be able to determine that there are certain individuals who are genetically predetermined with regard to their exposure to these agents.

I think it is important to recognize that one of the reasons that the committee repeatedly emphasized the notion of association is that it is not clear to what extent in some cases the presence of one of these agents accelerates some predetermined condition as opposed to initiating an activity in someone who is not likely or prone to get it. And those are some of the dilemmas that one gets into in terms of answering these questions.

Dr. ROWLAND. That is a point that always has been to me what makes it difficult to make a determination. Joe Kennedy and I were discussing this just a little bit ago. If there is a genetic predisposition to developing lung cancer and an individual smokes, that individual is more likely to get lung cancer than someone who does not have that predisposition.

I guess what I am trying to say is that there may be some veterans who have problems that are not covered by what you determined here that are linked to the exposure to this herbicide and that genetic variation can make the difference, and there is not enough evidence based on the way you conducted this study, the way you had to conduct this study, to determine that.

Dr. TOLLERUD. Yes. I think that is a safe statement.

Dr. ROWLAND. Thank you. Let me ask you, you recommend additional epidemiological studies if a valid exposure reconstruction model can be developed, and urge that highest research priority go to conditions where further study is likely to change the balance of evidence for or against an association. For what specific conditions is it likely that exposure data will alter the case for or against an association?

Dr. TOLLERUD. It is the nature of scientific investigation that that is the kind of question that is difficult to answer. I think the committee in the report outlined a strategy for assigning priorities to specific diseases or outcomes where we thought—I am not sure we can say with certainty that the questions will be answered by these proposed studies, either the questions are sufficiently compelling in the case of, for example, birth defects and those conditions which are of great concern to veterans, or there is some information in the literature which could be bolstered by additional studies, and these are particularly the cancers in this limited or suggestive area. There are also a group of cancers and other conditions for which there really isn't sufficient evidence in humans to know whether diseases exist or not, but there are some intriguing scientific evidence from other sources which lend what we call biological plausibility to an association, and those are all areas where additional research may, in fact, sway the balance one way or the other.

And I guess I would like to emphasize also that it is not at all certain that additional investigation is going to—first of all, is going to answer the question; second, it is the nature of scientific investigation that you can't predict whether it is going to prove or disprove an association. And it is important, I believe, for your committee and for others to understand that this category of limited or suggestive evidence where we believe additional research is warranted it is not in any way concluded or the committee is not in any way saying that additional research is going to necessarily move them up or move them down. We don't know how that outcome will be.

Dr. ROWLAND. Mr. Chairman, I guess the point that I would want to make is the point that he just talked about and that, while they have been able to scientifically establish these five diseases, that there may well be other diseases that could have been caused by exposure to Agent Orange and we don't know at this point. So this needs to be ongoing.

Dr. SHINE. It should be pointed out that the Category III, which is this very large category, is exactly that group. A very large number of disorders where the committee simply felt the data wasn't there either because it hadn't been studied or because there wasn't enough power in the research.

Dr. ROWLAND. Right. I understand that. Thank you all very much for that. Thank you, Mr. Chairman.

Mr. EVANS. I believe he was here earlier, and we would just go in the order of original appearance.

Congressman Kennedy from Massachusetts.

OPENING STATEMENT OF HON. JOSEPH P. KENNEDY II

Mr. KENNEDY. Fist of all, Mr. Chairman, I appreciate the timing of this particular moment, but I want to—because I didn't have a chance to make an opening statement, and although I have mentioned it to you personally, I want to just state for the record how really delighted I am with the new results that have come in, not only for the veterans who themselves are so, I think, in many ways relieved at the information the NAS has provided and it gives them a sense of their own, that their contributions and the complaints that they have had are finally being officially recognized by our government.

And I think, to the three doctors, that all of you should get a real sense of accomplishment because you have provided such a tremendous relief to so many veterans who for so long have felt that their country really has not stood by them in their long days and months and years of need.

But I also want to pay particular thanks to the chairman of this subcommittee, Mr. Evans. Without Lane Evans' leadership, my sense is that this issue in all likelihood would never have been developed along the lines that you gentlemen have been able to pursue. Really, for so many years that I have served on this committee, Lane's has been the lone voice that has often stood out against almost every other person on this committee, calling for a continuation of government-funded research, trying to debunk studies in the past that have been full of holes, trying to provide the impetus to get this committee to continue to look out for what we heard

from so many of our veterans as anecdotal information that just was all too convincing in the stories that were put forward.

So I just really want to thank you, Lane. I think you should consider this development one of your great achievements of your career here in the Congress, and I just want to say how proud I am to serve with you and what a great job I think you do for this committee. So often, whether it is homeless veterans or black veterans or victims of Agent Orange, you are always picking up those people that would normally fall through the cracks.

Well, anyway, as one member I just want to thank you. You do a good job.

Mr. EVANS. Well, thank you. And you were always with me, so I appreciate your help as well.

Mr. KENNEDY. Having said all that, I am interested in getting into a couple of the details of what has gone on. We heard—although as you can probably tell, I was inclined to side with those that were indicating that there were direct links between the Agent Orange exposures and the cancers and sicknesses that they felt, and incidentally I still have concerns that the birth defects that a lot of their children are having could possibly be linked as well. I would like to get your opinion on that one, or the possibility of linkage, number one.

And, number two, I would like to hear a little bit more—you refer to the Ranch Hand study. Maybe I could just check with the chairman, briefly.

The study that we had here where the fellow came from the Pentagon and said that they had checked with literally hundreds of thousands of people that had served in Vietnam and there was no difference between those that had sprayed or had Agent Orange sprayed upon them is that what we are referring to here as the Ranch Hand study?

Mr. EVANS. I believe so.

Mr. KENNEDY. Okay. Now, we heard this fellow from the Pentagon—I can't remember what the guy's name was—anyway, he came in, kind of a tough guy, and he said that they had taken into account hundreds of thousands of troops, and that they took hundreds of thousands of troops that were in the vicinity in Vietnam where Agent Orange had been sprayed and then they took hundreds of thousands of troops in places in Vietnam that hadn't been sprayed, and that there was absolutely no difference in cancers' increases between the two groups.

Are you familiar with what I am referring to? And if you are, could you comment on why that study should not be listened to?

Dr. COLDITZ. In terms of the Ranch Hand study, we are referring in particular to the relatively small number of the Air Force who were involved in doing the spraying, rather than the troops on the ground who may or may not have been exposed. So in that report Ranch Hand is a specific subgroup of servicemen.

Mr. KENNEDY. Are you familiar with the other study?

Mr. EVANS. That, I believe—if the gentleman would yield—would be the CDC Selected Cancers.

Dr. COLDITZ. Okay. That is the key I was looking for, which of the numerous studies—Selected Cancers study. We certainly refer to it in here and note that for some of the cancers that are in our

category of sufficient evidence the Selected Cancers study supports the findings that we have. So, if we look cancer by cancer, I don't think we are going to be saying across the board that there is no association. And we break out that study site by site for cancer to show where there is——

Dr. SHINE. Let me respond to two or three elements of your question. One, Ranch Hand is a relatively small group of highly exposed individuals for which there is actually some very good data that have been collected. The committee's concern there had more to do with the nature of the analysis of that data and it would like to see some additional outside scientific expertise work with them because there are some potential clues in that material. The committee thought there was a real probability that one could get some additional information, perhaps, particularly with regard to birth defects. That is one of the areas that they particularly wanted to look at in that population.

They felt that the strength of the analysis would be increased if an additional study which involved the Army Chemical Corps, again people who had a high probability of handling material, could be included.

The second point is that one of the most important developments over the last 5, 6, 7 years has been a new burst of understanding of how you do research in occupational exposures. Historically, one thought that one had to know exactly who was at a particular place at a particular time on a particular day in order to make meaningful data, and some of the conclusions which were reached with regard to the CDC study were before this large development in occupational health—this kind of research didn't develop to study herbicides in Vietnam. It developed in looking at industrial kinds of exposures, that methodology has evolved enormously over the last decade.

The committee felt that the developments of that methodology made the possibility—not the certainty—the possibility of an exposure model much more likely now than it might have been a decade ago or 8 years ago. What you are hearing to a certain extent is the notion that the science has progressed that would allow an analysis that might not have been possible.

The third issue is an issue which Dr. Tollerud referred to, and namely, looking at large populations of veterans for dioxin levels. As you have heard, the committee didn't believe that that was a useful way of making a distinction as to whether being inside or outside Vietnam helped you because of the difficulties with dioxin levels since it is so ubiquitous.

I think that is being responsive.

Mr. KENNEDY. Yes, you are being responsive. It actually leads me to a different set of questions that I want to pursue for a brief minute.

Dr. Shine, this committee has also been very concerned with Persian Gulf veterans and some of the illnesses that they have faced, and certainly complained about having difficulties with what has now become known as Persian Gulf syndrome. Are you familiar with this at all?

In any event, not to get into all of the details of it, but one of the problems that I think we have seen on this committee is be-

cause that has not been known or recognized by the scientific and medical community as an illness that develops as a result of multiple chemical exposures, we have had difficulty having the VA provide health benefits as a result.

In order to have the medical community recognize these linkages to chemical exposures and disease, is it necessary to have organizations such as the NAS or—and who are the other bodies in the medical community that have to give this sort of the imprimatur to allow regular treatment and recognition by the Government and the medical community to understand and feel that these linkages are, in fact, legitimate?

Dr. SHINE. I don't think there is any single source of all wisdom in these regards, but I would point out that the Congress has mandated a Persian Gulf Registry.

Mr. KENNEDY. Sure.

Dr. SHINE. That the Institute is working closely with both the VA and the Department of Defense both in the development of that registry, and also with OTA, in the development of that registry, and that we in fact are constituting a group with the purpose of asking the question, "What are the kinds of issues that ought to be addressed using that information?"

I can't prejudge what those conclusions will be, but I think the point that you make is a very good one; namely, we would like to see the Persian Gulf Registry used in a prospective way with regard to a variety of the issues that you are concerned about, rather than to be in the position 20 years from now of having to argue backwards. And we intend to try to do that in collaboration with OTA, VA and DOD.

Mr. KENNEDY. Would the chairman allow me just one question as a follow-up to that? Thank you, Mr. Chairman.

What I am really driving at, however, is a slightly different point, which is that you have done yeoman's work in trying to legitimize a concern that many members of this committee have had for years. You have to take on, we have to take on—some of us more than others—the medical scientific community which has had a, you know, what we would refer to as kind of keeping its left hand hidden, a kind of sense of a lot of this might be not verifiable, and so there is a sense that Agent Orange is in the heads or the minds of those that have gotten sick that they would have gotten sick anyway. And the same thing is true with Persian Gulf syndrome.

So what I am trying to ask is what is it that you would recommend when we are looking at sort of a new guinea pig generation that for the first time is exposed—as the first generation of human beings that is exposed to all of these chemicals, what is it that we can do to try to legitimize the very symptoms that these individuals, particularly in the military because they get exposed to much more than ordinary civilians do—what is it that we can do to give some legitimacy to the kinds of concerns that they have?

You are saying that there isn't any single study? I mean do we have to go through these 20-year periods of questioning? Despite the fact of what you say, we can already see it starting to take place with the Persian Gulf syndrome, and there isn't going to be

any single study that debunks all of that either. You know, it will go on.

Dr. SHINE. Well, again I would argue that if, for the sake of argument, in the case of the Persian Gulf Registry, we can identify a cohort of individuals who were exposed, a cohort of individuals who clearly were not exposed, and put in place the kind of analysis which would likely give some statistical validity to the two different populations, you could come to some conclusion at a relatively earlier, much earlier stage. I am not suggesting we have to wait 20 years. That is one of the reasons why we would like to see this kind of thing go on prospectively.

So, I think our whole intent is to try to work with these agencies to design exactly the kind of analysis that you are talking about. There may be some other things that could be done—we have not formally examined them—including the questions of how and in what way the military as they go into a new area with a new campaign of any kind sets up methodologies to examine even within that theater the way in which illness develops, and there may be some opportunities to do that as well.

But, again, our intent is to try to address the Persian Gulf issue in the most comprehensive way that we can and in a prospective way that is likely to yield data as time goes on rather than to have to wait and do a long retrospective.

Mr. KENNEDY. Maybe we could get together sometime privately. Thank you very much, Mr. Chairman.

Mr. EVANS. The gentleman from Georgia, Mr. Bishop.

Mr. BISHOP. Thank you very much, Mr. Chairman. I didn't have an opportunity to do an opening statement either, but I would just like to associate myself with the remarks of Mr. Kennedy with regard to the chairman and the work of the committee, but particularly your leadership with regard to this issue and Vietnam veterans as a whole.

I come from a district in Georgia in which Fort Benning is wholly contained. There are many, many Vietnam veterans who have for many years complained about the residual effects of exposure to Agent Orange. In my other life as an attorney I was involved in the class action litigation involving Agent Orange which involved several hundreds of soldiers from the Columbus area.

And so I want to commend the committee, commend your leadership in exploring this. And, of course, our distinguished panel, I want to thank them for the much work that they have done.

I would like to ask Dr. Tollerud a question—and I hope I pronounced your name correctly——

Dr. TOLLERUD. Yes, sir.

Mr. BISHOP [continuing]. Regarding compensation benefits. It seems that the questions regarding compensation benefits have implications for VA health eligibility. And could I get you to comment from a scientific perspective on the strengths or weaknesses of using a test that would permit the VA to provide treatment to Vietnam veterans for any conditions except those found to have resulted from a cause other than exposure to a toxic substance? What are the implications of that in terms of our eligibility standards for treating our veterans for conditions that may be service-related, that kind of exclusionary language?

Dr. TOLLERUD. Okay, I am not—we could maybe come back because I am not sure I quite understand the middle part of your question. But I would like to make a couple of statements for background information on how these kinds of studies are done, the limitations of the data and how the results are presented, because I think it helps to explain why the report doesn't contain the kind of numbers that many people would like to see that would assist in these kinds of policy decisions.

The nature of these kinds of scientific investigations, particularly what we call epidemiological studies, studies of populations of people who are exposed to, perhaps, environmental or occupational or other kinds of conditions, and these are studies done of infectious diseases, a whole variety of conditions. The nature of those studies is that it is rarely possible to assign something as cleanly defined as cause and effect. What we find is associations. We find that this population which has on average a higher exposure than this population, in the exposed population there appears to be more disease than in the unexposed population.

The fact of the matter is that for any disease, almost any disease you want to think of both exposed and unexposed people have those diseases. There is a section in the report, for example, which outlines, based on U.S. population data gives numbers for all of these conditions, including the ones that we put in the strongest evidence category. I mean we can come up with a number of expected cases of non-Hodgkin's lymphoma in a population of men that are the age of Vietnam veterans today that could have lived their entire lives in Denver or Houston or New Jersey, have never been exposed to Agent Orange, to our knowledge, never been exposed to these conditions, and yet based on population rates there are going to be several hundred of X, Y, Z cases of this disease in that population as well.

So we are very limited in any of these studies in assigning cause and effect, and that is just a fundamental problem that we have from the science.

The second point concerns the concept of statistical association and what these significance values mean. When a study like this—studies like the ones that we looked at, are published and when we look at the results, there are kind of two parts to the results. One is whether there is a statistical association between an exposure and a disease, and that we use probability theory, we use some fancy computer programs to come up with a statistic that tells us whether it is likely that this observation was due to chance or not chance.

Our ability to say that has a lot to do with the dose of exposure, whether it was a high exposure or a low exposure. It has a lot to do with how big the populations were. You know, if you take two people who smoke and compare them with two people who don't smoke and try to answer the question does smoking cause lung cancer, you are going to be up a tree because it is a coin toss. If you take a thousand people who smoke and a thousand people who don't smoke, now you are in a lot better situation for being able to answer the question.

So the limitations to many of these studies has nothing to do with whether the investigators were good or the questions were

asked properly. It is just they may not have been large enough. The exposure wasn't sufficient.

And the last point is that, just because there is a statistical association, that doesn't in and of itself say anything about the level of risk. There are very large studies, and Dr. Colditz is an expert in this area from some studies that he is involved with, where you look at literally hundreds of thousands of people where you can detect a statistical association between a condition or an exposure and a disease but the risk of that disease in somebody who has the exposure may be only 10 percent, 20 percent, 30 percent higher than somebody who doesn't have it. But it is statistically significant.

There are other diseases where the risk may be 500 percent higher or 600 percent higher in an exposed and unexposed but there is no statistical association because we can't get a big enough population to make the science work out.

So, for all those reasons the committee spent a great deal of time. We read the legislation. We understood the policy implications of what we were doing. But we stuck to the science. We called balls and strikes as they were. We pushed—as Dr. Kriebel, one of the other committee members said at the earlier hearings, we pushed the data as far as they would go and then we called it like we saw it.

And we just simply are not able scientifically to make the kinds of statements that policymakers would like to see to make their very difficult decisions easier.

Mr. BISHOP. But the bottom line as you see it is what in terms of the relationship?

Dr. TOLLERUD. Well, I think it is well spelled out in the report. The bottom line is that we have three cancers and two other conditions which are statistically—where there is sufficient evidence to link them with exposure to herbicides. It is important to note that nowhere in there does it say "in Vietnam veterans." It says exposure to herbicides, and that is based on—that is just data on people in general, and then the other categories follow on that.

I think particularly for some of the conditions in other categories which are very common conditions, like lung cancer, like prostate cancer, we really are very limited in our ability to make specific comments about Vietnam veterans, and the hope is that with this additional research those very thorny issues can be addressed.

Mr. BISHOP. But the scientific conclusions you reached were that there is a statistical relationship, but you cannot establish on your own from your studies whether or not certain bodies of individuals were exposed or not exposed, and that is a factual determination that will have to be made by someone else, the VA or the Department of Defense, or someone else in some other fact-finding body; is that what I understand?

Dr. TOLLERUD. Well, not quite. Fact-finding won't do it at this point because the facts aren't out there. The point is there is additional work that needs to be done. There are additional studies that need to be done to answer those kinds of questions.

If the facts were out there, we believe we could have sorted it out. So that there are—with some limitations, there are some analyses of data that exist that will help.

Mr. BISHOP. Your answers have been somewhat long, so I haven't been able to do very much follow-up questions. If the chair would indulge me just a moment.

Let me just ask you if you could describe for me in layman's terms the proposed methodology of your new study and how you are going to use it, and then give a guesstimate of what your timetable will be when we can expect some definitive results and the report?

Dr. COLDITZ. The committee didn't draw up a time line. The aim of exposure reconstruction is to draw on data from multiple sources, not only spraying records from the air but around camps and so on, and the recommendation from our report is that this exposure reconstruction be developed and reviewed by an independent body before it is then applied more generally in studies.

So we would be talking years, rather than weeks, if you say the extremes, in terms of going through the process of having a group develop an exposure reconstruction for Vietnam and then having that reviewed by independent scientists before the next step of applying it to data that in fact are already available for servicemen in terms of cancers and so on.

Mr. BISHOP. So what you are suggesting is that we may not even be at a point where we can make any definitive policy recommendations for years, is what you are suggesting; is that correct?

Dr. TOLLERUD. I don't know that we can say about policy decisions because frequently my understanding is that policy decisions need to be made whether there is adequate information to make you comfortable with those decisions or not. I think what we are saying is that these research recommendations, some of them can be done fairly quickly. I mean a look at the current Ranch Hand data can be done in a matter of months, I think. But some of the other steps that are required to look at that are in months to years for their completion, to really come up with a study.

I think it is important, though, not to appear to throw cold water on this. These are specific recommendations about studying Vietnam veterans. One of the personal observations that I had, and I am one of the people that Dr. Shine referred to who, although I have done research in areas closely related to this—why I was asked to be on the committee—I have not followed the Agent Orange scientific literature closely. Frankly, when I started the committee, I knew the issue wasn't dead but I thought the science was pretty much moldy. That what was known was known and that it was just a matter of going through, you know, some old papers and coming up with a scientific statement.

There was a paper published in March of this year that had a substantial impact on putting diseases in these categories. Much of the data that we looked at has come out just in the last couple of years. There are studies ongoing which will come into print this fall. New studies coming out every year that are not necessarily in veterans but bear directly on these remaining questions.

So I think you should not be pessimistic about this. I think there is a great deal of scientific interest, a great deal of scientific activity. I think the questions will continue to be answered by the work that is going on.

Mr. BISHOP. I guess my frustration is that as we wait for these studies we are having thousands of Vietnam veterans who will continue to suffer and die without having had their conditions properly adjudicated.

Dr. SHINE. I would emphasize that the committee in their public hearings heard from veterans. They heard their anguish. As I have mentioned in a couple of other settings, I was impressed when I met with the committee after those exposures how shaken they were. This is not a committee that didn't care about those issues.

At the same time it is important that they bring to you the best analysis they can. They didn't get into compensation issues, not only because it wasn't their charge, but because compensation goes to individuals and, as Dr. Tollerud has said, these kind of studies deal with populations.

It is important to note that the legislation called for a biennial look at the data, and we know that this fall there may be some important additional research published. We are very hopeful that if there is a biennial look that this is a baseline. Thus, data provides a floor. It is not a ceiling. And, to the extent that that data comes forward and there is a biennial review, there will be an opportunity to address a lot of those issues in a much more timely way.

Mr. EVANS. The gentleman from Louisiana, Mr. Buyer.

Mr. BUYER. Thank you, Mr. Chairman. I also want to begin by thanking you, Chairman Evans. I have not been on the committee long but I have appreciated your leadership and willingness to step forward along with Mr. Kennedy, what you do in the Persian Gulf. And I appreciate also Sonny Montgomery and Mr. Stump, and also Chris Smith, and their leadership. So I wanted to take a moment to say that.

Let me make some comments because I didn't have an opportunity to make an opening statement.

Mr. EVANS. Without objection, members' opening statements in their entirety will be included in the record.

Mr. BUYER. All right. Thank you, Mr. Chairman.

Mr. EVANS. But you may make a statement at this time.

Mr. BUYER. I want to, first of all, yield to Mr. Smith.

OPENING STATEMENT OF HON. CHRISTOPHER H. SMITH

Mr. SMITH of New Jersey. I thank very much my friend for yielding. I, unfortunately, will have to leave. We have a hearing going on on Bosnia and I am ranking on the Helsinki Commission, so it requires my attendance.

But just let me very, very briefly—and I thank the gentleman for yielding—note that back in 1984 former Congressman—now Senator—Tom Daschle and I offered an amendment in this committee to H.R. 1961 which would have required the kind of study that was finally authorized and mandated in 1991. Nine years later we have got the study. As Dr. Shine has pointed out, it is not a ceiling, it is a floor. It provides, I think, one of the most comprehensive studies we could have hoped for, but it becomes a working document that, if necessary, will be expanded as the science would require.

I would also ask that approximately six or so questions I have of the VA be made a part of the record because I will have to get back to that other hearing.

I thank the gentleman for yielding. Thank you.

[The prepared statement of Congressman Smith of New Jersey appears at p. 71.]

Mr. EVANS. Without objection, the questions and answers will be made a part of the record.

(See p. 260.)

OPENING STATEMENT OF HON. STEVE BUYER

Mr. BUYER. Thank you. Reclaiming my time, the comments I would like to make is when Mr. Kennedy commented not only about today discussing Agent Orange, but you can't also but not mention the Persian Gulf, because we are talking about exposures to chemicals not only from the Vietnam era but also presently of the Persian Gulf War.

I can't help but boil things down and how basic life gets. I have an older brother and, doggone it, if older brothers don't sometimes break wake for you in life. I look at the Vietnam veterans and look at what wake they have broken for members of my generation who served in the Persian Gulf War. A minute doesn't go by that I don't recognize what they have done, because it was their leadership and also the leadership of the senior NCOs and senior officers in the Persian Gulf who, even on the battlefield, remembered a lot from the Gulf War and refused to relive that. But also it relates to Agent Orange and the frustrations that both of you have mentioned, the testimonies you received and their complaints about the residual effects.

Many of us all across this country have recognized that there is a potentiality of causal linkage, the causal effects, with the exposure of these chemicals with many different soldiers, and that being very real. Sometimes we as humans—I may not have the medical expertise that this panel may have, but sometimes we are granted a God-given instinct, and that instinct, even those of us who have served in the military, learn a lot about. That is, if it doesn't smell right, look right, feel right, you better rely upon your instinct—stop, look, listen and learn. And that is part of this learning curve, and this learning curve for Agent Orange has taken so many years.

But I am glad that through the years of the learning experience there has been a tremendous benefit. Number one, you have come forward and you have a causal linkage of some kind. I think it is a beginning. Number two, for the Persian Gulf War veterans, it was immediate action in this Congress to set up a Gulf War Registry, but not only the Gulf War Registry, but to set out the diagnostic criteria to get the ball rolling.

Is that going to be it for the Gulf War vets? No, it is only the beginning.

One thing that I have, my question relates not only to what we are doing here with the Gulf War vets, more particularly to the Agent Orange veterans. Is this model that you are talking about, a study of an environmental unit to recreate exposures of the Persian Gulf so we can set out diagnostic criterias? Now one of the recommendations is also the development of an exposure reconstruction model for Vietnam veterans.

So not only does my question pertain to Agent Orange, but there are some questions I have heard about in trying to do this for the Persian Gulf also. What is the integrity of such a model? One of you mentioned that science has moved forward so much that we can do those kinds of things.

Give me the detail. Why should I feel comfortable that we can have a model that will produce and have the integrity result that will lead us to a cause and effect linkage?

Dr. TOLLERUD. Well, I am not sure you should be comfortable with that. We are not comfortable with going as far as your statement was, which is that development of this model will ultimately lead to a cause and effect linkage and answer many other questions. We don't know that.

I think what Dr. Shine referred to before is in the past what has made scientists comfortable or epidemiologists comfortable was being able to identify an individual and make a measurement in the atmosphere around their face and say, Okay, that was the exposure. Now we will use that and we will look for disease.

There are now statistical ways and more powerful computer programs and a variety of other methodologies to say, Yes, well that is great if you have got it, but, you know, for a work force that was near a chemical plant explosion, 20 years ago for Vietnam veterans and for other groups where the exposure happened and we really didn't understand the impact of it until much later, isn't there something we can do about that.

There are now methods to not necessarily know what each person was exposed to or even in a quantitative sense what groups were exposed to, but to reconstruct from a variety of informal information sources what the likelihood of exposure was and to build into the model some understanding, if you will, of those likelihood estimates.

Basically, what a good model, a perfect model that uses that kind of information may in fact not be powerful enough to do what you say, is to establish cause and effect. But at least if it is well done it won't give you red herrings. It won't tell you the wrong answer in terms of linking that exposure with a disease that in fact is not linked with that exposure.

It is 20 years later. We may well come up with an answer that says either there is not enough information or there doesn't appear to be an association when, you know, if the study had been done 20 years ago there could have been association. We can't say that.

Mr. BUYER. I do not know what you mean when you say a likelihood estimate. I don't know what you mean by that statement. Does it mean when you put together a model we are going to have a percentage of possibilities or probabilities? I don't know what you mean by likelihood estimate.

I am trying to play this out.

Dr. TOLLERUD. I understand.

Mr. BUYER. You say we go ahead and we have a model, and we have got questions on whether or not we can have direct causal linkage. I don't know what that means.

Dr. COLDITZ. In a simplistic sense, the model is trying to let us rank people. People at one end will have been exposed and people at the other end clearly shouldn't have been exposed, and we want

to be able to have categories from no exposure through to the highest exposure. And at some level we know that we cannot get everyone who served in Vietnam 100 percent correct in order, but we don't want a model that puts the most highly exposed in the least exposed category, which would be a major error in the model.

Mr. BUYER. So these findings are going to be on percentage probabilities in the end?

Dr. COLDITZ. No. Reference has already been made to the advancing methods dealing with this type of classification, and we would typically be looking at the top end, be it 5 percent or 20 percent, as the troops who were most highly exposed and the bottom 10 percent as no exposure at all, and we can with statistical techniques look at the difference in risk between those extremes of exposure.

Mr. BUYER. I know that you don't have to deal with the compensation issues, but we are going to have to deal with them at some point in time, and the types of criteria need to be established based on medical science. So, if we have a person that is at the low end, say at the 5 percent end, but he comes down with one of your three—boom!—I mean we have to take a good look at that. That might have been one of the exceptions to the rule type thing.

Dr. COLDITZ. My sense is that while we would focus on or envision a model focusing on the ranking of people it may well be that part of the review of that model focuses on the probability that people are misclassified, so that there is some quantification of the error. We refer to that misclassification as error in the model if it is putting people at the wrong extremes, and that should also be quantified if possible.

Dr. TOLLERUD. But let's be clear. Nothing that we have proposed is going to make your life any easier. Compensation is never—I mean decisions about compensation are not going to be easy ones. My reading of the legislation and the way compensation is currently decided is that it doesn't relate very much to the science of these kinds of studies. They are just very difficult questions.

The science will never say with certainty whether John Smith's soft tissue sarcoma was caused by exposure in Vietnam. It is beyond us to say that. I am a physician. I can't say that—I mean somebody comes into my office, they have been smoking for 40 years and they get lung cancer. I mean I say pretty convincingly to them, Yes, smoking caused your lung cancer. But I know there is a 1 in 100 chance that they would have gotten lung cancer if they never touched a cigarette.

Mr. BUYER. All right. I have one last question. I know you have come in and you have recommended the development of an exposure reconstruction model. Let's just remove that and put it aside. Are there other bases that you could use for further epidemiological studies other than a reconstruction model? I don't know. I am throwing this out. Are there other processes which you could use?

Dr. TOLLERUD. Possibly. We don't know yet. One of the other recommendations relates to what we call biomarkers of which currently serum dioxin level, blood dioxin level, is an example. You know science is evolving everyday, and there may conceivably be some measure that is developed at some point which would suggest damage which was specifically caused by dioxin or a chemical like

that which would allow you to look at an individual and say, you know, based on our evidence this really looks like this was linked to that. It is not available now. We have suggested that in concept that kind of research be supported, but we have no idea where it might lead.

Mr. BUYER. All right. But we want to remain open in that process of study. Thank you.

Thank you, Mr. Chairman.

Mr. EVANS. You are welcome. The gentleman from Pennsylvania.

OPENING STATEMENT OF THOMAS J. RIDGE

Mr. RIDGE. Thank you, Mr. Chairman. It goes without saying, Mr. Chairman, I, too, appreciate your longstanding leadership on this and other issues related to Vietnam veterans.

Gentlemen, listening to what I think, is a very thoughtful discourse between my colleagues and yourselves points out what I consider to be, not a clash, but a classic comparison between two cultures: a political culture that looks for very quick, and justifiably so, looking for immediate answers to resolve problems; and a scientific culture where by virtue of training, by virtue of the profession, by virtue of the culture, you are looking for very precise information upon which you can draw conclusions which take, in many instances, extraordinary time.

My colleague from Massachusetts talked about frustration. I think he is right. There is a lot of political frustration with the inability to come to some resolve with regard to Agent Orange, particularly in the whole area of cause and effect, I know that there is even as much frustration as we may have politically and as much frustration you may have scientifically there is even more frustration among those men and women who served who have in their minds, and justifiably so, decided that there is a relationship between the malady that they have experienced or their offspring have experienced and their exposure to Agent Orange.

There has been an evolution, at least before this committee, in terms of how we are looking at the problem. I can recall 5 or 6 years ago, even longer than that, 10 years ago, cause and effect was what everybody was really looking for. Again, the scientific community was pressured in that direction. Having a little experience with service in Vietnam myself, and knowing relatively the impossibility of putting together, I think a virtually impossible effort to put together individuals in areas of exposure and saying to you as scientists that they were exposed for this period of time, intensity of the exposure was this type for this long—I don't think there are military records available to do that.

And so over the years we have in a way an understanding of the logistical problems when you get into your studies. Given the nature of the war, the nature of the spraying, the fact that we move troops in and we move them out, chopper them in, chopper them out, in monsoons, not in monsoons—you've got all kinds of scientific problems to come up with the kind of evidence, hard evidence you need, the hard exposure, so you can take this group of people and say they were exposed for this long to these kinds of dioxins and these people weren't and compare.

So we have kind of gotten away from that, and I think you are taking us into, with your model that you want to work, probably an area where Chris Smith wanted to go and we should have gone, a lot of us should have gone a long time ago where you can draw some statistical associations because we can't—the absolute cause and effect just isn't going to be there, I don't think, because the records are not complete. We will never have that for you.

I guess what I am interested in determining, you have looked at 230 studies and you have drawn some conclusions, and it wasn't based on exposure of Vietnam veterans, it is just basically exposure of people to dioxins, and you have drawn some conclusions. And based upon this wonderful effort—and it is, I think, a wonderful effort—there will be some adjustments made, I think, by the Secretary of VA to add a couple of these conditions to the list for compensation purposes.

We are getting to the point where we are going to have to resolve policy questions on the back of incomplete scientific responses. And, if we don't have cause and effect, then are you with your exposure reconstruction model trying to prepare for us a statistical baseline to make policy recommendations based upon probabilities? Is that where we are going? And, as scientists, are you comfortable with that?

Dr. SHINE. Two or three comments. First, just to give you a sense of the magnitude, the committee actually reviewed over 6,400 studies. They eventually focused on 230 as being contributory. But it is a massive kind of effort and it is still continuing.

Secondly, I understand your frustration——

Mr. RIDGE. Not with you.

Dr. SHINE. We do much better doing what we do well and you do what you do well.

Mr. RIDGE. Yes.

Dr. SHINE. The third point——

Mr. RIDGE. By no means is that criticism. It is a difference in culture.

Dr. SHINE. I understand. But we can only go as far as we think the data goes at the present time.

The third observation I would make is that in terms of some of the points you made prostate cancer is very common. A large number of Vietnam veterans are coming into the age range in which prostate cancer will occur. We know that a certain amount of it would have occurred independent of that because it is a very common cancer, and yet there is data now that suggests that there may be an association. The kind of statistical probability that we are talking about would be very powerful if it turned out that in relationship to statistical kinds of exposures, groups of exposures, knowing that in a particular area the foliage was right so that there was a fair amount of ground spraying, that there was air spraying in that area. If one can create that kind of model and then look at, throughout this sequence from very low probability of exposure to high probability of exposure that there clearly is more prostate cancer, particularly if it is occurring at a younger age group, then that becomes a very powerful bit of information to help you make those kinds of decisions.

So, yes, there is a very strong element of probability, and that is why Mr. Bishop is frustrated in the sense that when we talk about probabilities the question is how do you attach that—how do you connect that with an individual veteran coming forward looking for compensation? All we can do is give you the probability data. We can't give you the individual data.

Mr. RIDGE. I think it is appropriate for you to highlight that distinction. Then it becomes our responsibility to take the probability data and turn it into policy decisions as to whether or not we want to extend compensation based on that probability, that group of veterans who fit into your reconstructive model. I appreciate that.

Are you confident from the material that you have reviewed in any relationship or discourse you have had with the Department of Defense that you will have adequate military information with regard to troop locations, spraying, length of stay, et cetera, to come up with a model that meets the minimal scientific requirements that you have?

Dr. TOLLERUD. I think that what we can say is that the committee was impressed that all of the agencies that we dealt with were really forthcoming, providing us with information, providing us with background information on that information, if you will, so that we could understand the limitations of it. You know data are just numbers and you have to understand how they were put together to know whether they are good numbers or bad numbers.

So I think we were all very impressed that to the extent that it is known, all of that information is available or will be made available.

Mr. RIDGE. That is quite a caveat, though—to the extent that it is known. Is there a point in time where——

Dr. TOLLERUD. Well, sure.

Mr. RIDGE [continuing]. It is not known sufficiently enough? I mean that the baseline of that information would not be adequate enough for you even to construct the model?

Dr. TOLLERUD. Yes. I think that is possible. I think that—in fact, the reason why the recommendations are written rather carefully to have a series of steps to look, to get the best experts available anywhere around to put their heads together and to come up with a model or several models, to then test those models, and there are a variety of ways of sort of validating those models—the committee suggested some ways, but we think that an expert committee could come up with additional ways to look at exactly—that is a superb question—to look at exactly what you are asking, Is this model going to add anything? Is this model likely to help us? And only if the model itself passes these several hurdles would the committee feel comfortable recommending that at that point the resources be made available to do what would be by any standards a very large, complex, long-lasting study.

We are really not at all recommending that huge resources or a great amount of time and energy be put into these studies yet. We don't know whether a model could be made. It appears to us, though, that—10 years ago it really looked like such a model could not be put together. We think that with the development of the field there is at least that possibility out there now.

Dr. SHINE. I should emphasize we are not talking about the Institute doing the model. There are, for example, academic institutions which have developed these models for use in a variety of other occupational kinds of exposures that could be asked to formulate a model, and then having had them develop the model, having a careful critique of that.

Part of the whole issue in this whole debate has been the concern about the objectivity of the players in terms of how they evaluate what is going on, and I think what the committee keeps coming back to is creating methodologies which assures everybody that if the data is not there or if the data is inconclusive that at least it has been looked at by people who have no axes to grind. I think that is why the 2-step proposal which was suggested is rather important.

Mr. RIDGE. Well, I don't think anyone has anything but high praise for your independence and your good work, and I very much appreciate it. I would like to think that you have in your own mind, or within the scientific community, the baseline of both evidentiary and scientific information that is needed as a minimum to structure the model; hopefully, to give us then the probabilities from which we would extract, if we chose to do so, the different policy options as to whether we should or should not grant compensation.

But again, my hat is off to you. I think you have done a wonderful job, and I thank you very much for it.

Mr. EVANS. Thank you. One of the problems the committee has pointed out is that military records were not flagged for Vietnam service. It was a research problem, trying to go through all the different files. I am very pleased to tell the committee represented by these people here today that legislation in the armed services authorization bill would require that of the Department of Defense. So you had an impact. That happened the same day that the study came out, so you have had an immediate impact in that regard.

Thank the gentleman for bringing up those questions.

I would like to start a round now and I may go on. If Congressman Penny wants to interrupt anytime, please let me know.

Admiral Zumwalt, who is testifying later today, concluded 32 health effects are "as likely as not" to result in exposure to Agent Orange. In his submitted statement he suggests the committee didn't reach the same conclusion because it considered studies that had been deliberately manipulated so the results would appear inconclusive.

I am quoting him. He goes on to say: "Therefore any reviewing panel examining all available studies found the overall weight of evidence less conclusive than is the true case because of the consideration given to manipulated studies and thus the dilution of the accurately done studies." Now, this is in regards to studies found to be manipulated by the Government Operations Committee.

How would you respond to the suggestions that the committee's conclusions may understate the health effects of exposure to Agent Orange because the committee considered studies which have been accused of being deliberately manipulated to have inconclusive results?

Dr. TOLLERUD. Well, at a couple of levels. First of all, even the studies which you may have referred to from government agencies, I think it is important to note, as Dr. Shine mentioned, we didn't look at just a few studies. We looked at a great number of studies, and in the balance of—as you balance scientific information from a variety of studies looking for the best thread of truth that runs through all of those, as a scientist you consider a whole number of aspects of the studies. You look at the design. You look at the collection of information. And, while I am sure it is true that we can't tell everything about every study, most of us have been in this business long enough to know a bad study when we see it, to look at the presentation. And we had—through the course of our analysis over the year, we had individuals from many of these larger studies come and give personal testimony—some open, some closed—and I will say that committee members asked some quite pointed questions and were very satisfied with the results.

So I am not going to address in a concrete way the issue of validity of studies or not validity of studies, but I can tell you and harken back to, again, for many of these areas of evidence the most powerful information out there is available from studies that did not deal with veterans. There are many very good studies where there is a range of doses and a range of exposures where the information remains inconclusive either because there is not association or because there are problems with the studies or because there aren't enough studies.

So I think the committee looked at all of the available evidence. I think to an enormous degree was extremely critical, I mean particularly the key studies. They were not read by a single individual. They were read by multiple individuals very carefully and criticized very carefully and individually and the evidence falls where it will.

Mr. EVANS. I think you have done a good job. But I guess my question would be did committee members realize that the Government Operations Committee had accused certain studies of being deliberately manipulated to be inconclusive or rigged to fail?

Dr. TOLLERUD. I think it is safe to say that we were, I mean we heard from Admiral Zumwalt on at least one occasion. We heard from numerous other individuals who provided us with comments, with statements, with both oral testimony and written testimony in a variety of ways. I think the committee was well aware of the controversy. The committee became aware of many specific charges that were levied against specific studies.

So we certainly didn't do this in a vacuum. We were aware of the controversies. We evaluated each study extremely critically, and weighed the evidence accordingly.

Mr. EVANS. All right.

Dr. TOLLERUD. Dr. Shine, do you have a——

Dr. SHINE. The only other comment I would make is that the committee had a responsibility to look at the data and not to conduct an investigation in terms of what was potentially manipulated or not. That it simply was not their responsibility.

They were aware of the allegations. They were aware of the controversy, and they tried to look as carefully as they could at the data.

Mr. EVANS. Well, I don't know that this has been thoroughly resolved, for that matter, and in this committee's eyes, whether these studies were manipulated or not. But wouldn't it within the mix of things if it is a fact that a study had been manipulated isn't it possible, if not likely, that the committee would have been concluded there is evidence of an association between herbicides and other health conditions if it had been aware of that? In other words, in the mix of things wouldn't this study, these kinds of studies, if they were manipulated, be discounted in the overall assessment?

Dr. TOLLERUD. Well, you know, something may clarify it. Let me read you from how we assigned associations. For example, in the sufficient evidence of an association, which is the most strongly worded category where there really is very strong evidence for an association between herbicide exposure and the example that is given, if several small studies that are free of bias and confounding—show an association that is consistent in magnitude and direction, there may be sufficient evidence.

Another example of that is if one or two large powerful studies showed an association that link would not be substantively diluted if another large study showed no association. I mean the lack of an association can be attributable to many different things, and I think it is not accurate to say that if one study, even a fairly large study, did not show an association that that was going to throw cold water on a bulk of evidence that came from other well done associations, that it would result in one of these diseases being moved into a different category.

I think Dr. Colditz may want to make a comment on that.

Dr. COLDITZ. I would add that we specifically did not take an average of all the studies. If we had averaged the results of the studies, then, in fact, we would have been more likely to dilute the overall estimate of an association. But as Dr. Tollerud pointed out, we really did look for the presence of a number of studies showing the association. And other studies addressing the same cancer or other health outcome may not have shown the association, but if we could identify sources of bias and so on, then the fact that the study didn't show the association didn't move our sense that we could identify strong studies that showed the association.

Dr. TOLLERUD. With the chairman's indulgence, I would like to make one more comment which I think bears very specifically on your question. And that is, remember that our charge in the legislation was threefold, and the first was to look for a statistical association between exposure and disease, and the wording of that charge said nothing about Vietnam veterans. It talked about herbicides and disease. And then the second charge was in Vietnam veterans, and the third charge was biological plausibility.

Scientifically, we understand all of the studies of Vietnam veterans to date have great limitations. Irrespective of your concern about the integrity of the data, even the very best studies, if they were done perfectly, have great limitations compared to some of the occupational studies simply because the doses available on occupational studies or environmental studies, high dose, long period of time. And we were very free to make statistical association based on those other studies of a very high dose and a very long period

of time regardless of whether that level of exposure was even plausible in Vietnam.

We weren't asked about—we were asked about an association between herbicide and disease. If we had been limited to looking at Vietnam veterans studies, then I would say, yes, this dilution issue is a major one. We looked at studies where the most information was available.

Mr. EVANS. The gentleman from Pennsylvania.

Mr. RIDGE. Would the gentleman yield just briefly? Might I understand then that in arriving at the 230 studies that you basically focused on after you screened thousands and thousands that most of them did not involve a Vietnam veteran population which gave you probably from a scientific point of view a much stronger protocol because you had fewer variables, I mean you could see that? And that, secondly, you had internally an eye toward looking to those studies that showed some relationship between exposure and disease, in those 230 studies?

Dr. TOLLERUD. There are two halves to your question.

Mr. RIDGE. Correct.

Dr. TOLLERUD. The first part of the question, it is true that not only were most of the studies but the studies with most of the information were in populations other than Vietnam veterans and that is where most of the useful statistical associations that bore on placing these diseases in categories of evidence came from. That is absolutely correct.

The second question concerning the integrity of the data, if you could repeat that.

Mr. RIDGE. Yes. I was wondering as you were looking at those 230 studies given the primary purpose to try to relate exposure to disease, and I thought it was something I may have heard Dr. Colditz say, and maybe I misinterpreted what was said, but actually internally you looked at studies that found in some way a relationship between exposure and disease and tried to be as inclusive of those regardless of whether they involved the Vietnam veteran population, or as you said earlier, most of them involved a non-Vietnam veteran population.

Dr. COLDITZ. I agree with your statement there. We did look, you know, through each of the studies, and we would look at studies individually and then as a group. So having gone through all the studies on prostate cancer, we would go back and say now that we have got 15 studies on prostate cancer do we see a pattern? What do we see in the ones that are showing something? What do we see in the ones that aren't showing anything? Are there reasons why there are differences between the studies?

Mr. RIDGE. It just seems to me, Mr. Chairman, that the methodology that they used probably minimized the impact of these more controversial studies on their conclusions because they chose studies more often related not to Vietnam veterans and they were looking for studies that did actually show a link between exposure and disease, which again is one more reason to thank you for your work.

Mr. EVANS. All right. Thank you.

Let me switch gears here and move on to another area. For respiratory and prostate cancers and multiple myeloma, the commit-

tee concluded that the evidence it considered suggest an association with herbicide exposure but all other factors couldn't be ruled out confidently. If our guiding principle as legislators here on this committee was to give the veterans the benefit of the doubt, why shouldn't we consider respiratory and prostate cancers and multiple myeloma as being service-connected?

Dr. TOLLERUD. I will answer as an individual, and representing the committee, I think I would like to get other responses. What you have asked again is a policy question. Why shouldn't you do that or not is a matter for discussion which includes a whole variety of issues that aren't related to the science. We have been asked repeatedly on the committee, and we grappled with this question because, you know, we are not totally naive to the implications of the report and we knew the questions were coming, and we actually struggled mightily to see if we could come up with an answer to the as-likely-as-not question, and after substantial internal debate we admitted that we couldn't based on scientific literature. That is simply not the way science is done. It is not the way the data are done. As likely as not it comes down to questions that are not answerable, I think, by the information that we have available.

The only thing I would say in addition to that that may be useful to you as legislators is a concept which was alluded to earlier that Dr. Colditz knows better than I. It is something we call attributable risk, which is that we know that some cancers like multiple myeloma, like lung cancer are very common. Some of them like lung cancer we think have other exposures which increase risk substantially, and ultimately some of these statistics come out and might say, for example, of all of cancer X, we would estimate that a certain exposure, for example, being exposed to radiation or whatever, might account for 10 percent or 20 percent of those cancers, being an attributable risk in a population, and that is as far as the science can take us.

That may be useful information to you, or it may not.

Mr. EVANS. If you were a Congressman from Pennsylvania or Illinois and met a Vietnam veteran who you understood from talking to his doctors was dying of lung cancer, or had died in my case, wouldn't you feel on a personal level that probably we should go ahead and award compensation and treatment?

Dr. TOLLERUD. I really can't answer that question. I am a physician. I am a lung specialist as well as an occupational specialist. I deal with, I have dealt with many people dying of lung cancer and other conditions. It is a gut-wrenching experience. There is never a satisfying answer. We all want to do the right thing for everyone. Whether that happens to involve compensation or not is just not a matter that I, in my current position can voice a personal statement on.

Mr. EVANS. I have numerous other questions, and I will submit them in writing to you. I would like to ask just one real quick one.

Congressman Don Edwards has for years recommended something that now the Vietnam Veterans of America are recommending; that we actually try to study herbicide exposure in Vietnam because of the exposures in the people there. Would you have any opinion about possibly good data coming out of some study in Vietnam?

Dr. COLDITZ. We actually include in our recommendations a statement that for some conditions it may in fact be appropriate to consider studies in Vietnam, and it will vary by condition. But we certainly were open to that as a committee as one possible source of future information that will help us understand.

Mr. EVANS. We thank this panel very much. We do have additional written questions, and the responses to those questions will be made part of the record. Thank you very much.

We do again want to thank the NAS for their excellent work done and helping us make these associations and helping veterans. Thank you very much.

Mr. EVANS. At this time the committee calls forward the Secretary of Veterans Affairs, the Honorable Jesse Brown, and ask him to come forward now and to introduce the members of his administration that are joining him today.

Mr. Secretary.

STATEMENT OF HON. JESSE BROWN, SECRETARY, U.S. DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY SUSAN MATHER, M.D., ASSISTANT CHIEF MEDICAL DIRECTOR, ENVIRONMENTAL MEDICINE AND PUBLIC HEALTH; MARY LOU KEENER, GENERAL COUNSEL; R.J. VOGEL, DEPUTY UNDER SECRETARY FOR BENEFITS

Secretary BROWN. Good morning, Mr. Chairman. How are you?

Mr. EVANS. Good.

Secretary BROWN. Appearing here with me this morning is Mr. Vogel, Deputy Chief Benefits Director; our Assistant Chief Medical Director, Dr. Mather; and our General Counsel, Ms. Keener.

Mr. Chairman, I would like to begin by expressing the appreciation of the veterans community and my personal admiration for the leadership you and this committee have shown in addressing this very, very difficult issue. We are here, Mr. Chairman, in part because of you, and for that, sir, I thank you very much.

We have reached a milestone in the search for the truth about Agent Orange. Since 1978 when the issue first surfaced, Vietnam veterans and their families have been waiting for answers to their many questions about Agent Orange. As a member of a veterans' service organization, I was aware of the fears and the frustrations of my fellow Vietnam veterans. As Secretary of Veterans Affairs, I am committed to taking a fresh look at the issue and to do the right thing. Vietnam veterans deserve no less.

As you know, one of the principal sources of frustration has been the inability of the scientific community to provide us with definite answers about the health effects of exposure to Agent Orange. The conclusions reached in the scientific research were often conflicting and confusing. Every side of the controversy could point to some study to support their position. As the controversy dragged on, positions hardened and the dialogue became passionate and emotional. This is, in part, why the Congress mandated VA to contract with the National Academy of Sciences to perform an unbiased review of the scientific literature and offer its assessment. I must acknowledge the task was not an easy one for the Academy.

We are now reviewing their report and will, within the time mandated by the Agent Orange Act of 1991, make the necessary

decisions. There are some decisions, however, that need not wait the full 60 days the Congress gave us in that law. I am prepared to act right now on some of the Academy's recommendations. I am referring to those conditions for which they found scientific evidence sufficient to conclude that there is a positive association between exposure to a herbicide agent in Vietnam and some diseases.

I have directed the Veterans Benefits Administration to begin the rule-making process to recognize Hodgkin's disease and porphyria cutanea tarda, also known as PCT, as being associated with exposure to herbicides used in Vietnam. We do not need to take any action on soft tissue sarcoma and chloracne since VA already recognizes that these are associated with exposure. VA's rule regarding non-Hodgkin's lymphoma will be revised to reflect its association with herbicide exposure.

I have also directed the Veterans Benefits Administration to identify Vietnam veterans on the Agent Orange Registry who suffer from these five diseases. We will contact those who have not filed for compensation to urge them to apply. I will ask the service organizations to assist us in this outreach effort. I believe this prompt action is appropriate, indeed even mandatory.

I am not prepared today to render judgment about the Academy's report as it relates to other conditions. It is imperative, in my view, to fully analyze the implications of this report and then to expeditiously act on the recommendations from that review.

I therefore have established an internal high-level panel to review the report and to solicit comments on it from other medical and scientific authorities, representatives of veterans' service organizations and other interested parties. Dr. Susan Mather, VA's Assistant Chief Medical Director for Environmental Medicine and Public Health, will chair this panel. Membership will include top-ranking officials of the Veterans Health Administration, Veterans Benefits Administration, and General Counsel. The panel will advise me of their findings in time to make decisions within the 60-day time period.

I am also acting now to accept key recommendations of the Academy with respect to future research. I am keenly aware that Vietnam veterans have been waiting too long, and too often have been told to wait for more research. But I am persuaded by the Academy that more research is needed if we are to put this issue behind us.

I think the recommendations of the Academy are well presented and they appear to be soundly based. I have therefore asked the Under Secretary for Health to prepare an action plan that will implement the research recommendations in a timely manner. I would like to comment about several of those recommendations.

Perhaps the fourth recommendation is the most important: the Academy recommended exploring the feasibility of developing a method for historical herbicide exposure reconstruction for Vietnam veterans. I have accepted this recommendation.

There are many conditions for which the Academy was unable to give definitive recommendations. In large measure, this was due to inadequacies in the scientific literature, particularly with respect to verified exposure. If a method for determining exposure with greater certainty can be devised, we would be able to better focus our research and arrive at more supportable conclusions. Indeed, this

may serve as a way to answer whether Vietnam veterans are at risk for adverse health due to Agent Orange exposure. Because of its potential importance I have asked that this be given the highest priority for implementation.

The Academy also recommended that the Air Force Ranch Hand study be continued with an external review by an independent, non-governmental scientific panel. I have written to the Acting Secretary of the Air Force to urge serious consideration of this proposal.

The Academy additionally recommended that members of the Army Chemical Corps and an appropriate comparison group be followed in a study similar to the Ranch Hand study with oversight from an independent, non-governmental scientific panel. VA is presently conducting a mortality and morbidity study of Chemical Corps personnel who served in Vietnam. Study results were reported on this group in 1990, and no unusual findings were noted at that time.

VA researchers are currently working to expand the study to include Army Vietnam-era veterans with chemical occupational specialties who did not serve in Vietnam. The Department will seek to have this research project reviewed by outside experts to determine if improvements can be made and we will, of course, submit the results to the independent panel for their review.

The Academy recommended that military personnel records be modified to include a marker for Vietnam service. We agree, and I noted the comments you made to the panel previously before you, Mr. Chairman. VA will, of course, explore the feasibility of accomplishing this, and as you so rightly pointed out, it will require a coordinated effort between several departments and agencies.

I want to assure you and the Vietnam veterans community that I am approaching this issue with an open mind. In those areas where I believe the Academy has made definitive findings, I have acted to implement them. As to remaining areas, I will take the time provided by statute to satisfy myself that the action the Department takes is the right action, and that it puts veterans first.

I also want to note that I intend to pursue further discussion of this issue with the members of this committee and the Senate Committee on Veterans' Affairs. I am certain that working together we can achieve a just resolution.

Mr. Chairman, I know everyone will not be satisfied. However, I hope sincerely that our actions and intentions will allay the doubts of many who, hopefully, will acknowledge that a good faith effort is being made to addressing this issue and their concerns.

Mr. Chairman, that concludes my prepared statement, and we, of course, are available to respond to any questions you may have, sir.

Mr. EVANS. Thank you, Mr. Secretary. First of all, I want to say I am very pleased that you took such quick unprecedented action on the very day that this report was released in service-connecting Hodgkin's disease and PCT, and you also promised to identify and reopen the claims of Vietnam veterans who have had these conditions.

But I have a question relating to the effective date that the VA may assign to these cases. In the class action lawsuit *Nehmer* v.

U.S. Veterans' Administration the VA agreed to a consent order that requires, except in a few situations, that the effective date be the date that the Agent Orange claim was filed even if it was filed in 1982. However, prior to your taking office the VA finalized a soft tissue sarcoma regulation that appears to be inconsistent with this consent order because it prohibits an effective date prior to September 25, 1985, even though veterans had filed Agent Orange claims prior to this date.

VA's Assistant Secretary for Congressional Affairs, Ed Scott, has informed my office that the VA General Counsel is currently reconsidering this effective date and discussing it with veterans' organizations. Can you give us an assurance that the VA will fully honor the provisions in the consent order requiring that the effective date be the date of filing?

Secretary BROWN. The majority of cases will be effective the date of the law. However, there are a number of cases, a maximum of approximately 30,000, that will involve retroactive entitlement.

Now, I would like to ask our General Counsel to share with us the details of that retroactivity.

Ms. KEENER. We have looked at the issue of retroactivity and concluded that these claims generally fall into one of four categories. As you know, awards based on any original claims that are filed subsequent to these new regulations that will be issued may be effective no earlier than the date of the new regulations. Going back then to May of 1989 when the Nehmer case was decided, for pending claims that were filed after May of 1989 and prior to the issuance of the new regs, awards will be retroactive back to the date of claim.

The third category of claims are those that were filed and then denied between September of 1985 and May of 1989. Claims that were denied during that period are still in abeyance waiting to be decided. Those claims will be retroactive back to the date of claim.

Now, for claims that were filed prior to September of 1985 but denied after September of 1985 and before May of 1989, awards will be retroactive back to the date of claim, so there may be some of those claims that will be retroactive back to dates prior to September of 1985.

If there were claims that were filed and denied prior to September of 1985, their decision was not based in any way on those regs that were determined to be void by the court. For those individuals, whether they refile their claims or VA reviews the prior decisions on its own, awards will be subject to the date of the new regs that will be issued in accordance with this law.

Is that clear?

Mr. EVANS. Well, I have a better understanding, not a complete understanding. But we will follow up on that.

VA's statutory authority that provide priority health care to Vietnam veterans exposed to herbicides expires on December 31st of this year. While the final NAS report on the health care effects of exposure to Agent Orange will be released in 2003, I think we both feel that ill veterans must be cared for immediately.

Accordingly, based on these NAS conclusions and its research recommendations, would you support the extension of the VA authority to provide this priority health care through the year 2003?

Secretary BROWN. Not at this point. We do support and we are aggressively moving forward to provide this up through 1995. At that time we will certainly get a chance to revisit exactly where we should go.

Mr. EVANS. You stated, Mr. Secretary, that the Under Secretary for Health is developing an action plan to implement the NAS research recommendations. Do you know when this plan will be ready?

Secretary BROWN. As you know, there was no time limit imposed on the research aspect of the law. However, we have imposed a 60-day time frame on ourselves with respect to research, and the panel will make recommendations within that 60-day period, which began on July 27.

Mr. EVANS. And would you submit those recommendations to this committee?

Secretary BROWN. Absolutely, sir.

Mr. EVANS. Thank you.

Will additional funding be necessary to carry out the research, and will the VA seek that additional funding?

Secretary BROWN. At this point we don't think so. If you are talking about the contract for 1994, we have already identified $156 thousand to continue the research and we will look at it each year thereafter. We have not signed the contract but we are fairly close. I think within a matter of days we will work out the final details.

Mr. EVANS. Can you describe how the VA will go about contacting veterans on the registry that either have PCT or Hodgkin's disease?

Secretary BROWN. I would like to just make a general observation. Then I would like to ask Mr. Vogel to respond.

We have approximately 227,000 names entered into our Agent Orange Register, and within each file there is a diagnostic code or—what is that, Doctor?

Dr. MATHER. The ICD-9 codes.

Secretary BROWN. ICD-9 code—let's just for my reference call it a diagnostic code—that will tell us exactly what that particular veteran was suffering from, so we can ask the computer to give us the names of all individuals who suffer from any of these five diseases. Then we will run those names by our compensation files to see if they are already receiving compensation. Those that do not match would receive a letter to inviting them to file a claim. Of course, we are also going to ask the service organizations to help us identify them.

But I would like for Mr. Vogel to clarify that.

Mr. VOGEL. Thank you, Mr. Secretary. The only thing I would like to add to what the Secretary has already said is that in addition to running the names against the Agent Orange Registry file, we are now determining just exactly how to do it against the patient treatment file. Then we will take those records and run them against our computer files on compensation and pension master records and the pending disability claims. We have the systems well identified.

The role then is to identify any Vietnam veteran who has contracted a disease and is not yet service-connected for it. Any vet-

eran that we so identify will be contacted by us. The pending claims that we identify in the match will be expedited.

All of those efforts will yield, we think, great results. We fully realize that there are some that we could miss who don't come forward. Our encouragement is that everybody here help spread the word. The Secretary has a meeting tomorrow with the veterans' service organizations. That will be one of the things he will ask them to help us to do.

Mr. EVANS. All right. Mr. Secretary, I am going to ask you the same question I asked the panel earlier. For respiratory and prostate cancers and multiple myeloma the committee concluded that the evidence it considered suggest an association with herbicide exposure but all other factors could not be ruled out confidentially.

Again, in determining whether or not these conditions should be service-connected, shouldn't we be guided by giving the principle of the benefit of the doubt to the veterans themselves?

Secretary BROWN. Before I respond to that, when you asked about the contract we were entering into with the National Academy of Sciences I said $156 million. I meant $156,000. So please correct the record, unless you are going to provide the difference for us. We could use it.

To respond to your question at this point, sir, we have set up a panel to advise me. These are very distinguished people from the benefits side, from the health care side, and from the legal side, and we are going to be getting a lot of other smart people involved in the process. Out of that will come some recommendations on exactly how we will proceed on those issues—on Category 2, 3 and 4.

Mr. EVANS. Mr. Secretary, give us your opinion of the VVA's recommendation and Congressman Edwards' longstanding recommendation that the Government fund research in Vietnam on the effects of herbicide exposure given the fact that Vietnam would be the best site for research on this issue, on dioxin and other herbicides?

Secretary BROWN. I did not understand that question, sir. Will you ask it again, please?

Mr. EVANS. Sure. What would be the VA's position on the recommendation of the Vietnam Veterans of America and Congressman Don Edwards that we conduct research on Agent Orange exposure and other herbicides exposure in Vietnam, it being the best possible site for that kind of research to be done?

Secretary BROWN. At this point in time I have not formulated an opinion but I——

Dr. MATHER. You mean on the people who live in Vietnam?

Mr. EVANS. Yes.

Secretary BROWN. Yes. At this point in time I have not formulated an opinion for the Department. But as soon as we do, we will advise you accordingly, sir.

Mr. EVANS. All right. Thank you.

If scientific data show that children of Vietnam veterans were adversely harmed by their parents' exposure to Agent Orange, would you support the treatment of these children in VA medical facilities or the provision of compensation for their illnesses?

Secretary BROWN. As you know, under present law that is prohibited. There is no provision in law that would allow us to compensate the children even if it was proven beyond a reasonable doubt that their diseases resulted from the exposure of the parents. That will require legislation, and at that time we will be happy to take a look at it.

Mr. EVANS. I have numerous other questions, but I understand the President is calling you to a Cabinet meeting very shortly, and we appreciate your appearance under those conditions.

And unless Minority Counsel has any other questions, thank you very much for your attendance here with us today.

Secretary BROWN. Thank you.

Mr. EVANS. Our next witness is Admiral Zumwalt. The Admiral served as Commander of U.S. Naval Forces in Vietnam. More recently, he answered the call to serve as a Special Assistant to former VA Secretary, Ed Derwinski. He is currently chairman of the Agent Orange Coordinating Council. He has testified before our committee and, as a former marine who served under him when he was CNO, we very much look to him as a role model on so many things and issues.

I will recognize you now for your statement, Admiral.

STATEMENT OF ADM. E.R. ZUMWALT, JR., USN (RET.), CHAIRMAN, AGENT ORANGE COORDINATING COUNCIL

Admiral ZUMWALT. Thank you, Mr. Chairman. I appreciate the invitation to appear. You have already outlined the three capacities in which I appear.

As Commander of U.S. Naval Forces, Vietnam, I requested and obtained Agent Orange defoliation along the rivers and canals in Vietnam. I did so at a time when the average young man had about a 70 percent chance of being killed or wounded during his year tour in the naval craft. The defoliation rapidly reduced casualties to less than 1 percent a month.

At that time, no one in Vietnam was aware that Agent Orange could have harmful health effects on humans. In the light of subsequent knowledge, I have a very special responsibility to the courageous young men who served under my command to see that justice is done with regard to providing compensation for the ill health effects of those Vietnam veterans who were exposed to Agent Orange and their families.

As Special Assistant to the Secretary of Veterans Affairs, I conducted a review of the hundreds of available studies, as did the panel today, and other government documents relating to this issue. I concluded that there were 31 health effects that meet the required test that they are "as likely as not" the result of exposure to Agent Orange. My written statement cites the Congressional hearings and report establishing the deliberate policy at the bureaucratic level of our government for many years to seek to avoid any conclusion that the use of Agent Orange and related herbicides could cause undesirable health effects. It cites the consequent studies manipulated to be inconclusive and other evidence, all of which would result in any reviewing panel such as the one subject to today's hearing examining all available studies in finding the overall weight of evidence to be less conclusive than is the true case.

I was able to recommend to Secretary Derwinski that the many diseases mentioned in my report should be approved for compensation because I, as a non-scientist, did what I believe the law allows the Secretary of Veterans Affairs to do; that is, to discount the proven manipulated studies.

In my capacity as Chairman of the Agent Orange Coordinating Council, which includes approximately 20 veterans and veterans' service organizations listed in an attachment to this testimony, let me comment as follows on the report.

I consider it to be the first objective and honest report on the Agent Orange issue emanating from government or quasi-government sources. The fact that the committee affirmatively links five diseases, including two that have not previously been approved as capable of being caused by exposure to Agent Orange and other defoliants, is a significant step forward. It is my view that the diseases listed under the reports category "Limited/Suggestive Evidence," namely, respiratory cancers, prostate cancer and multiple myeloma, should also be added by statute to those currently listed.

The Institute of Medicine report fails to include any conclusions regarding the ability of dioxin to cause or be associated with an overall increase in the cancer rate. The following information came to my attention since I submitted my original statement. EPA recently reviewed the same studies on chemical production workers summarized by the IOM and came to a definite conclusion as part of its ongoing effort to evaluate the risks of dioxin. After undergoing extensive public and expert review and after open workshop meetings, the EPA's Second Draft Report on Human Epidemiology states:

"Other TCDD related hormonal effects including immune suppression may result in multi-organ sensitivity and may contribute to the overall increased mortality from all malignancies combined seen in four cohort production worker sub-cohorts with higher estimated TCDD exposures:" These increased relative risks, while not large, 10 percent to 70 percent, are consistent and are either statistically significant or of borderline significance. While no one tissue site can account for this observed increase, lung cancer is also increased in three of these."

In view of this fact, I now recommend that this committee move to amend existing legislation to authorize compensation to Vietnam veterans experiencing any form of cancer or to their families in the case of deceased Vietnam veterans.

As a separate matter, the Institute of Medicine did not list peripheral neuropathy as a disease associated with exposure to Agent Orange or other herbicides used in Vietnam.

Since the Committee on Environmental Hazards, before it was disestablished by Congressional statute, recommended to the Secretary of Veterans Affairs the addition of that disease as one for which there should be compensation, and in view of the fact that the relatively modest number of veterans who are affected have been expecting that disease to be compensated in the near future, I strongly urge that it not be removed from the diseases for which the Vietnam veterans will be provided compensation.

Finally, there is another aspect of this issue I would like to address that should interest members of this committee concerned

about justice for those Vietnam veterans who were injured by Agent Orange. I earnestly solicit that each of you consider becoming sponsors in your individual capacities of a bill which I shall now discuss.

I am speaking of the Federal courts' repeated invention of any new law necessary to deny veterans the opportunity to place before a jury their personal injury claims against the Agent Orange manufacturers. The 1984 class action settlement, whereby lawyers nominally representing the class took more than $13 million in fees, and Judge Weinstein became the head of a $52 million foundation, had the result that only veterans with death or total disability claims received much of anything, on average, a mere $3,200 each.

In the case of *Ivy* v. *Shamrock,* veterans whose injuries arose after the 1984 settlement have had their search for a fair trial of their claims similarly short-circuited by the Federal courts, who removed the case from Texas State court over the opposition of 21 State Attorneys General, who in their legal brief in *Ivy* called the court's actions, and I quote, "an illegitimate judicial amendment of Congress' removal statute, . . . an invasion of State judicial independence and an insult to State courts throughout the Nation." The Federal courts then compounded the problem by transferring *Ivy* directly to Judge Weinstein on legal grounds that were also unprecedented and again seemed to defy the intent of Congress.

The reason for the courts' invasion of States' rights in order to have only Judge Weinstein hear *Ivy* was clear. Both Judge Weinstein and the Federal Court of Appeals proceeded to make unprecedented decisions holding that the 1984 settlement included veterans' claims that did not exist in 1984, since they had no injury at that time, even though these veterans had no notice or knowledge of the 1984 case and were not separately represented by any lawyer who agreed to such a settlement.

By the Federal courts' invention of a class settlement of these "future" claims that did not even exist at the time, their violation of all existing law concerning participation in and settlement of class actions, and most importantly, their exercise of extraordinary powers to deny the State courts their ordinary authority to hear such claims, the Federal courts have destroyed the veterans' claims which are now worth far more than the average $3,200 some of them might have been able to get from Judge Weinstein.

Judge Van Graafeiland of the Court of Appeals for the Second Circuit, on June 24, justified these unprecedented and even bizarre rulings denying veterans a jury trial in an unbiased State forum on the grounds that in his view, "despite continuing research, the crucial issue of 'general causation,' i.e., whether any injuries are attributable to Agent Orange, remains unsettled." Juries are supposed to make such findings of causation, not judges.

Here Federal judges are making scientific findings that directly contradict today's NAS study which has now found that there is "sufficient evidence of an association" between Agent Orange and a number of the kinds of diseases experienced by Vietnam veterans exposed.

I am submitting with this testimony a draft law which I support to correct this systematic denial of justice by the New York Federal

courts. It would give clear instructions to these courts to enforce existing law and to keep the New York Federal judges' obviously biased hands off the Agent Orange litigation so that the *Ivy* case may go to trial.

Our veterans are entitled to a better quality of justice. The courts have done sufficient damage by inventing their own rules to apply to Vietnam veterans. It is now up to Congress, by passing the law I propose, to insist that courts enforce the laws written by Congress and the Constitution. Otherwise this episode will go down as one of the most egregious denials of justice by the Federal courts in our national history, and a shameful betrayal by Federal institutions of those who fought and sacrificed for this country.

In conclusion, I believe the IOM panel's study has given the Vietnam veterans and their families the first significant scientific support for the condition of ill health effects due to Agent Orange. This report confirms the wisdom of Congress in its decision last year to authorize by statute compensation for three of these ill health effects. I hope this report will lead the Secretary of Veterans Affairs, at a minimum, to authorize compensation for respiratory cancers, prostate cancer, multiple myeloma, and that Congress will do so statutorily for these as well as Hodgin's and PCT.

I hope that future review panels will be instructed to discount manipulated studies. I urge the implementation of the IOM recommendations so that the additional diseases included in my report can be added for compensation as soon as possible. It would be even more responsive to the facts, in view of EPA's review, which is consistent with my study, to authorize compensation for all cancers in Vietnam veterans.

Thank you, Mr. Chairman.

[The prepared statement of Admiral Zumwalt, with attachments, appears at p. 138.]

Mr. EVANS. Thank you, Admiral. First of all, I would like to tell you that your letter submitted to Chairman Montgomery will be made a part of the record in this proceeding today.

Admiral ZUMWALT. Thank you, sir.

Mr. EVANS. Besides the fact that you think the committee relied on manipulated studies, and you may respond to their response to your allegations, do you at least find the work and the findings and recommendations of this committee to be as free of bias as possible?

Admiral ZUMWALT. I do, sir.

Mr. EVANS. I guess you have seen it all.

Admiral ZUMWALT. I do. I think that this committee is the first one that has tried to be objective. Previous committees, the Committee on Environmental Hazards of which I was a member, clearly had been infiltrated by some scientists responsive to corporations and was cognizant of the directives not to come up with a causation relationship.

Mr. EVANS. My frustration, being on this committee over 11 years, is that we have spent about $63 million studying these problems with studies that, as Ted Weiss concluded looking into this, were either rigged to failed or manipulated or just not conducted properly. That money could have been better spent on these veterans all these years.

Admiral ZUMWALT. That is correct, Mr. Chairman. The panel did not respond to the fact that in addition to the Government manipulated studies there have been studies manipulated by chemical companies. The Monsanto series of studies by Zack and Suskind and others for years were considered the reference studies by which scientists began to denigrate the results of the more honest studies that came along from the Swedish scientists. So that the impact that I have cited is very clearly there both with regard to outside studies and with regard to government studies.

Mr. EVANS. Would you have an opinion about research being conducted in Vietnam?

Admiral ZUMWALT. Yes, sir. I strongly have recommended it to Chairman Natcher, and I do recommend it here, sir.

Mr. EVANS. How do you think it might be structured?

Admiral ZUMWALT. I think it would have to be done by non-government agencies, as the panel here has recommended as the case for all research. I think it would have to be done in league with the Vietnamese scientists who are very good but have not had money to do the rigorous kinds of studies that are required, and that we have some very good people, including Dr. Arnold Schechter, who has been there many times and is ready and eager to do the studies.

Mr. EVANS. You have met with 1,080 Committee people, as it is called in Vietnam, the Vietnamese scientists?

Admiral ZUMWALT. I have met with one the members who came here, sir.

Mr. EVANS. And you feel that some of their approaches are at least valid for following up?

Admiral ZUMWALT. I do, sir.

Mr. EVANS. Well, Admiral, thank you so much for your testimony today, and we look forward to working with you on this issue in the future.

Admiral ZUMWALT. Thank you, Mr. Chairman. I am deeply grateful to you for your contribution to this effort over the years.

Mr. EVANS. Thank you very much.

Mr. EVANS. Our next witnesses are Dr. Bryan Smith and Betty Mekdeci.

Dr. Smith is project director, National Information System for Vietnam Veterans and Their Families, Center for Developmental Disabilities, Department of Pediatrics, School of Medicine, University of South Carolina.

Betty is executive director of the Association of Birth Defect Children.

Well, you are seated already. Dr. Smith, we will start with you.

STATEMENTS OF BRYAN C. SMITH, ED.D., PROJECT DIRECTOR, NATIONAL INFORMATION SYSTEM FOR VIETNAM VETERANS AND THEIR FAMILIES, CENTER FOR DEVELOPMENTAL DISABILITIES, DEPARTMENT OF PEDIATRICS, SCHOOL OF MEDICINE, THE UNIVERSITY OF SOUTH CAROLINA; AND BETTY MEKDECI, EXECUTIVE DIRECTOR, ASSOCIATION OF BIRTH DEFECT CHILDREN

STATEMENT OF BRYAN C. SMITH, ED.D.

Mr. Bryan C. SMITH. Mr. Chairman, members of the committee, I am delighted to be here and have the opportunity to express my thoughts with you. I am on the faculty of the Center for Developmental Disabilities at the University of South Carolina. I am the Director of a project entitled the National Information System for Vietnam Veterans and Their Families. This project is a central information and referral system designed to connect Vietnam veterans with services that exist in their communities.

This project is sponsored by the Agent Orange Class Assistance Program. I am here today not as a representative of that program, but in my role as the University of South Carolina faculty member. I am also representing over 14,000 Vietnam veterans, their children and family members whom we have helped over the last 4 years. During this time we have amassed a unique set of data on more than 10,000 veterans' children that now enables us to offer testimony to this committee on the effects of the Vietnam War on veterans' children.

The main function of the NIS is to provide outreach to and be a central information and referral service for Vietnam veterans who have children with disabilities. Our challenge and task is to connect these children and families with community or national resources that can meet their needs. Examples of the services we provide to these veteran families include simple problems as referring a family to a disability-related support group for more information on cerebral palsy and working with parents to explain the rights guaranteed by the Individual's With Disabilities Education Act, and assisting them in getting the appropriate education their child needs and is entitled to receive.

Frequently, our work becomes extremely complex. For example, it may require coordination of a full range of services for a family who has a 6-month-old little girl who has never left the hospital and now must travel across six States to have a liver transplant in order to survive. In this case, the NIS would work with the family and the service providers to coordinate air transportation for the child and family, investigate Medicaid reciprocity between the States, if necessary work with programs like Ronald McDonald House to arrange housing, and perhaps involve other philanthropic organizations to provide financial support for things not covered through insurance, Medicaid or other family resources.

Our information specialists use a database of over 114,000 services from programs that include Medicaid, Title V programs, special education programs, early intervention services, private resources such as parent support groups, disability-related organizations, and pharmaceutical foundations.

I am here today to share what we have learned from working with these families and encourage you to sanction the research that will provide the answer to the question that so many veterans have asked us: Are my kids' disabilities caused by my exposure to Agent Orange? Less common but associated questions are those that relate to risks in the outcomes of future pregnancies and why genetics counselors and other medical professionals are unable to give them a straight answer related to those risks.

I support the conclusions of Chapter 9 of the report and recognize that there is no alternative to an epidemiological study to show a possible cause and effect relationship. However, there is another area of research that may provide the indicators needed to encourage such a study and to help build a model. The area is the review of clinical records.

The most common conditions that we have seen in veterans' children are learning disabilities and attention deficit disorders. A little over 36 percent of the children who needed help from the NIS had these conditions: skin abnormalities, 24 percent; immune deficiencies, 20 percent; birth defects, almost 18 percent; and asthma, almost 11 percent. Many of these conditions can be grouped into the area of immune response disorders. These disorders include persistent skin rashes, respiratory infections, chronic fevers, allergies and asthma.

We have observed that these immune dysfunctions which may sound minor in relationship to the impact of a birth defect or disability, either physical or mental, are very serious and are often disabling themselves. They occur in many members of the same family constellation and persist for many years. In fact, many veterans report that their children have never lived a day without these conditions.

I have brought a list of these conditions that has a tally showing the number of family members with each diagnosed condition. This list has more than 900 diagnostic entities. I will be happy to leave that list with you for your scrutiny.

The average age of veterans' children helped by the National Information System was 15.1 years in this last year, with actual ages ranging from birth to 28 years of age. Comparing average ages for each of the 5 successive years shows an annual increase of only 8/10 of a year, which is 9½ months, in the ages of children that have been helped.

The question this raises is why don't the ages increase one year in one year's experience? The answer lies in the number of new babies coming into the Vietnam veteran population, and these children already have problems that have caused one of their parents to initiate a search for help. The number of children in the birth through 3 is 4 percent of the children helped by the National Information System. Although Vietnam veterans' average age is around 45, they are still having children and their children are still having disabilities.

Vietnam veterans' families, like all families, vary in the ways that they meet the challenges of parenting children with disabilities. Some pursue lead after lead to locate community resources to cover their informational, material and support needs. Others discover inner resources they had not previously tapped. Sometimes

members of extended families rally to support them during a crisis or stressful situation.

Many families are very successful in responding to problems or special concerns that they must address. Other veteran families are far less efficacious in their coping with immediate and long-term needs. Generally, Vietnam veterans are not seeking disability compensation for their children; they are seeking help with their medical expenses and they are seeking services to improve the lives of their children.

Vietnam veterans with children face the usual issues that all families face in raising their children. Just like any family with a member who has a disability, they have the additional challenge of dealing with their children's special needs. These may include solving financial burdens of medical care, finding special equipment, learning about the condition and what the child needs, and identifying the services to meet those needs.

Problems for Vietnam veterans become even more complex than those of other parents because of the difficulty the veterans' service system has in addressing the issues of family health problems. For a number of reasons, many veterans have acquired a distrust of the institutional service system created to help them. Of the veterans calling the national information system for help with their own problems, 36.8 percent of them were seeking help for post-traumatic stress disorder.

We have operated four national information referral programs over the last 10 years. The one most comparable to the National Information System for Vietnam Veterans and Their Families was the National Information System serving families with children from birth to 21 with disabilities and special health care needs. While there are many similarities between the families and children in these two groups, several differences and unique characteristics are apparent.

The magnitude of these differences provide some indicators of the relationship between the Vietnam experience and disabilities and health conditions which are manifested in the children of those veterans. In our efforts to help Vietnam veterans we observed these unique characteristics:

Fifty-five percent of the veterans' children have multiple disabilities with an average of 9.5 conditions per child.

Thirty percent of the families have more than one child with disabilities. It is not uncommon for a veteran to have six or seven children, all having severe disabilities.

Most Vietnam veteran parents also have disabilities, usually service-connected.

Occasionally, a veteran will report having one or more children without disabilities born before the war and two or three children with disabilities born after the Vietnam experience.

Divorce is high in this population. With remarriage and subsequent families, these children too have disabilities.

The cause and effect questions are questions that should have been answered before the herbicides were used in Vietnam and they still need to be answered today. They need an answer to relieve the guilt and to direct the frustration carried by many families. They need an answer so that genetics counselors can do their

jobs by giving people an indicator of risk in their prediction on birth outcomes. They need an answer because it is a moral and ethical issue that will not go away, and most importantly because Vietnam veterans deserve the answers.

Twenty years ago family members could predict that cigarette smoking by a family member would cause a premature death. They were so certain of their prognosis that many of them referred to cigarettes as coffin nails and that each one smoked would reduce life expectancy by 14 minutes. When a death of a smoker occurred, the cigarettes were blamed. Yet another 15 years would pass before there was enough scientific evidence accumulated that demonstrated a cause and effect relationship existed. When it was finally concluded, the evidence was so strong that even secondary smoke was implicated.

Vietnam veteran family members believe that something in the Vietnam experience contributed to the next generation's health problems. Unlike smoking, which has a longitudinal exposure, the Vietnam veterans and the Agent Orange exposure was time limited, and hopefully there will never be another large group of people exposed that would provide a comparison group. We cannot wait another 15 years before we formally look at whether a cause and effect relationship exists.

The issue of cause is multi-dimensional. One dimension is due to the multiple factors that cause the conditions. Another is that the conditions are not unique to this population. When a child has a traumatic event, such as a bicycle accident resulting in a broken arm, we can directly associate the single cause with the outcome; that is, the broken arm was caused by the fall. But the conditions the Vietnam veterans' children have, such as cancer, learning disabilities or birth defects, do not have a single potential cause. For many of them the cause is still unknown.

What makes the interpretation even more difficult is trying to connect the outcome with something in the parent's lifestyle or something teratogenic that the parent may have been exposed to many years ago. Another complication is that Vietnam veterans were exposed to a variety of hazards ranging from arthropod vectors, anti-malarial drugs, Agent Orange, fungal infections and the stress of combat. Which of these or their combinations may have contributed to the increase in the incidence of child health problems in subsequent generations may never be determined. What can be determined is that the Vietnam experience did or did not result in generational effects.

From a scientific standpoint, there are a number of issues that cry out for investigation. Once this research is completed, if the findings indicate a relationship, as I suspect they will, this committee will have assisted Vietnam veterans in obtaining access to appropriate and quality health care and a range of supportive services needed by their families.

Mr. Chairman, this concludes my prepared statement.

[The prepared statement of Mr. Smith appears at p. 146.]

Mr. EVANS. Thank you, Mr. Smith.

Because of a pre-existing obligation, we are going to have to take a 10-minute break here before we get to Betty.

And I am really sorry to make you wait longer, Betty, but give us about 10 minutes.

We will stand in recess until that time.

[Recess.]

Mr. EVANS. We will come back to order.

Ms. Mekdeci, after everyone is seated, you may proceed.

[Pause.]

Mr. EVANS. Betty, you may proceed.

STATEMENT OF BETTY MEKDECI

Ms. MEKDECI. Oh. I may proceed?

Good morning, Mr. Chairman, and members of the committee that are still here. I would like to thank you for inviting me here to speak today. My name is Betty Mekdeci, and I am the Director of the Association Birth Defect Children, a national non-profit organization that is involved with research and public education about environmental birth defects, and by that I mean birth defects associated with the mother or the father's exposure to drugs, chemicals, pesticides, lead, mercury, dioxin, and other substances that are potentially hazardous to the unborn baby.

Our organization first became involved with the Agent Orange issue in 1988 when we were contacted by a special master appointed by Judge Weinstein to determine a distribution plan for the Agent Orange settlement funds. We were asked to recommend projects that would offer the greatest benefit to Vietnam veterans' children who had been born with birth defects and developmental disabilities.

After an extensive review of animal and human studies involving Agent Orange or its components, we recommended setting up a birth defects registry. We believed that a registry could address the two most important parts of this issue at that time: (1) whether there was a unique pattern of birth defects or disabilities occurring in the children of Vietnam veterans, and (2) if so, what range of services should be funded to meet the greatest needs of this population.

Although we were encouraged to develop this proposal, we discovered at the last minute that such a project could not be funded because of restrictions the chemical companies had placed on the Agent Orange settlement funds barring the funding of any research that might connect Agent Orange to any adverse health outcomes.

Our organization decided to proceed with the registry through other funding sources. We also expanded the scope of the registry to collect data on all kinds of environmental exposures. The pilot phase of our National Environmental Birth Defects Registry was launched in 1991 with two seed grants from the National Coalition Against the Misuse of Pesticides here in Washington, DC.

We continued to discuss the feasibility of using the registry to collect information about the children of Vietnam veterans with veterans' organizations and the New Jersey Agent Orange Commission. In 1992, we received a contract from the New Jersey Agent Orange Commission and a grant from the American Legion Child Welfare Fund to start the Vietnam Veterans Birth Defects/Learning Disabilities Registry as a subproject of our national registry.

The National Environmental Birth Defects Registry offers a different approach to birth defect epidemiology. We use the registry to look for unique patterns of disability that may be associated with the same or similar environmental exposures. Every major teratogen, that is, cause of birth defects, can be identified by such a pattern much like every human can be identified by a unique fingerprint. In fact, this is how all the major causes of birth defects were first identified, and that includes thalidomide, fetal alcohol syndrome, rubella, dilantin, DES, radiation, and so forth. It is a mechanism we call the "alert practitioner." That means that doctors seeing a pattern of birth defects in children looked in the prenatal histories for some common etiological factor.

The National Environmental Birth Defects Registry is designed to function as an alert practitioner on a grand scale by looking for the fingerprints of environmental teratogens.

We use an 11-page questionnaire to collect comprehensive data on more than 300 birth defects and developmental disabilities as well as occupational, health, genetic and environmental exposure histories for both the mother and the father. All of this information is hand entered into multiple fields in the database where they can be interrelated in many, many ways for pattern and cofactor analysis.

During the last year our organization and the New Jersey Agent Orange Commission started gathering data from Vietnam veterans. In April, we produced a report of our first analysis of this data for the National Academy of Sciences to facilitate their review of the Agent Orange/birth defects question.

At the time of this report, we compared data from approximately 500 Vietnam veterans with 300 controls. In their comments about this report, the National Academy noted that our data had shown increases in certain categories of disabilities. But they were concerned because our data are self-reported and is therefore subject to memory recall bias.

Memory recall bias means that parents of children with birth defects or disabilities are more likely to remember events and exposures during pregnancy than parents of children without disabilities. Since all of the children in our database, both Vietnam veterans and our controls, have children with disabilities, we believe that the memory recall bias deficiency is equalized.

We currently have 1,200 cases in the database—800 from Vietnam veterans and 400 from nonveterans. In our analysis of these data, we are finding a unique pattern of disabilities that includes statistically significant increases in the following: all areas of learning and attention deficit disorders; allergic conditions, including severe asthma; persistent skin disorders; emotional/behavioral problems; chronic infections, particularly urinary tract and upper respiratory; growth hormone deficiency; early puberty; prolapsed heart valve; benign tumors and cysts; and a range of symptoms that may be consistent with dysfunction of the immune system.

This pattern of disability is similar to symptoms reported in children with chronic fatigue immune dysfunction syndrome. Discrete immunological defects have been noted in recent studies of chronic fatigue immune dysfunction syndrome patients at the National Institutes of Health.

In addition, two new studies of children at Times Beach who were exposed prenatally to dioxin have all shown statistically significant increases in immune and neuro-cognitive defects. Although most veterans do not have the financial resources to have their children tested, some of those who have had comprehensive testing have shown similar markers for immune dysfunction.

There is evidence from recent research that prenatal exposure of the developing immune system to toxic agents like dioxin may result in long-term immune dysfunction after birth. In addition, the cellular events responsible for immune processes are also involved in the process through which the embryo becomes a fetus. Therefore many immunotoxic agents would also be expected to cause birth defects. And I will just insert here that thalidomide, which is kind of the great-granddaddy of all teratogens, is such an effective immunotoxic agent it has been used recently in transplant therapy to prevent organ rejection.

I believe that we may be seeing a new pattern of birth defects in the children of Vietnam veterans, birth defects of the immune system. There may be structural damage as well since recent studies have indicated that children with learning and attention problems like those we are seeing in Vietnam veterans' children have differences in size and symmetry of certain areas of the brain. These studies suggest that something interferes with the normal growth patterns in the brain's cortex during fetal development.

Most of the studies evaluated by the National Academy of Sciences in the review of the possible reproductive effects of Agent Orange did not monitor for learning and attention problems or immunological disorders. And even our data may not be showing the most severe effects of Agent Orange exposure yet.

Recently, I was in Washington where I met with researchers from several large environmental organizations. Their studies of wildlife populations exposed to dioxin and similar chemicals suggest that these agents have hormone-like effects and actually may cause the most severe problems during adolescence and early reproductive life. Since many Vietnam veterans' children are just moving into this age group, no one has monitored for these effects at all.

The National Academy of Sciences has recommended that a reanalysis of the Ranch Hand data may help to resolve the Agent Orange birth defects question. While this would be an important addition to the information about major structural birth defects, I don't believe it will address the questions raised by our data collection, and I do not believe that the reanalysis of a single government study even by an independent group will be sufficient to resolve the concerns of the families of Vietnam veterans who have children with disabilities. While this is a difficult time to ask any government body to recommend appropriations for costly studies, I believe there are cost-effective ways to address this issue by utilizing systems that are already developed.

For example, this committee could implement the following recommendations that would address both the cause and effect issue and the immediate needs of the children of Vietnam veterans. And I want to insert that because it really doesn't matter in the final analysis whether these children's problems were caused by Agent

Orange or something else. The fact is that the veterans' children have something important going on and something needs to be done about it, and they don't have 20 years to wait.

The committee could vote to (1) provide a more comprehensive evaluation of the full reproductive effects question through an expanded outreach into the Vietnam veterans community through a project such as our National Environmental Birth Defects Registry. This would be a cost-effective decision since the questionnaire and database have already been developed and tested for more than a year, and according to experts in the field information from this database can be utilized for random sampling and appropriate statistical analysis when sufficient numbers are reached.

A second recommendation is that we could test a subset of children of Vietnam veterans with this pattern with the same immunological and neurocognitive tests used in the recent Times Beach study.

If similar markers are found, then diagnostic and treatment protocols could be implemented right now to help these children long before any cause and effect questions may be resolved. The most economical method to accomplish this would be to set up a board of expert consultants—this was Bryan's suggestion, so I will give it to him—that would make diagnostic and treatment information available to the treating doctors working with Vietnam veterans in their own communities.

And finally, since the VA by, I guess by mandate is not allowed to compensate families for their children's problems, I have a suggestion that may be something that could be implemented. My suggestion is that in an effort to offer Vietnam veterans financial assistance with the cost of diagnosis and treatment for their children, this committee could call together large national insurance companies for the purposes of setting up a high-risk insurance pool for Vietnam veterans and their families. Participation could be on a sliding scale according to the ability to pay by the veterans or the VA—Veterans Department could elect to pay the premiums for those who could not afford any contribution to the system.

In closing, I would like to say that in addition to doing the registry I have worked with the National Information System doing casework for the last 5 years, and the one question that we hear from families every day, no matter how sick the father may be, is not "What will happen to me?" but "What will happen to my children?"

I believe that at the very least we owe those who honored their call to serve our country an answer to the question "Did Agent Orange leave a toxic legacy?" Thank you very much.

[The prepared statement of Ms. Mekdeci, with attachments, appears at p. 161.]

Mr. EVANS. Thank you, Betty. We appreciate your testimony, and we appreciate you waiting so long.

Both of you have observed a pattern of immunological and cognitive defects in children of Vietnam veterans. Compared to their age mates whose parents did not serve in Vietnam, the children of Vietnam veterans exhibit an abnormally high incidence rate of physical and mental disorders?

Mr. Bryan C. SMITH. Let me respond to that first. First of all, I am not in the business of conducting research, and I would be unable to answer that question because our data can only reflect the population that we have been helping, the 10,000 children that we have helped. If we were able to do a comparison—we are blocked. As Betty suggested, we are blocked from doing research based on our funding resource which has resulted from the litigation money. Consequently, we can't do any research that is going to lead to any more litigation.

What I am sharing with you are the indicators of the need for more research and the numbers of problems in this area that you are describing we have come up with independently. We don't work together on this issue—Betty through her research and the fact that the number of calls that we have received. We don't have a comparison group to make that comparison.

So it is a very common condition. Granted, learning disabilities are a common condition in the population. So the question that we are looking at is how does it compare to the general population. You would expect to see some parallels. But the types of conditions, as I stated in my statement, the number of children with multiple disabilities is unprecedented.

When we ran other systems we were getting something like 1 to 2 percent of the families calling having children with multiple disabilities. We have over 50 percent with Vietnam veterans. So something is happening.

Ms. MEKDECI. In our data, we do compare. Our organization reaches—well, last count our mailing list is 6,000—no, 7,000. We go to every State and I think 17 different countries. We have sent out questionnaires to every single person on our mailing list, so our control group is of other families who have children. All of the children in our database have disabilities. We have a big outreach into the groups who represent national learning disabilities organizations, and I have worked with those for many years.

So the skewing that we see—I brought a single set of color charts because they are very expensive to run. But the skewing that we see and the increases in learning disabilities are just extraordinary, and you would expect that children with disabilities, structural disabilities, might also have learning disabilities. But we are seeing it in veterans. It is so increased that when we run the charts we scratch our heads and go back, and we have looked at this many different ways.

We have gone in—I thought perhaps there might be a problem because maybe the veterans' children were older and that we were comparing them to younger children in the database. We can go in with this and we can stratify many different ways. We went in and stratified by age. We only compared children from age 7 up because that would be, probably, the earliest you would have a diagnosis, and it still was highly skewed.

Also, we have the ability—because we go out to toxic dump sites, we go out to hazardous waste sites, we will be as things grow having other populations with similar exposures where we can compare and see if similar things are going on. We already know this anecdotally, but we don't have it in our database yet.

Mr. EVANS. All right. You are looking at children of Vietnam veterans, not necessarily Vietnam veterans exposed to herbicides?

Ms. MEKDECI. We have on our questionnaire, when New Jersey started participating in the project, we have a whole page related to area of service, place of service, some ways to determine corps and all of that. We haven't started analyzing that yet. New Jersey will be doing that part of the analysis as far as determining some type of exposure model.

Mr. EVANS. The Agent Orange Act of 1991 requires the Secretary of DVA—the Department of Veterans Affairs—to provide VA benefits, including medical care and compensation, to those veterans whose illnesses meet the following standard: "An association between the occurrence of a disease in humans and exposure to a herbicide shall be considered to be positive for the purposes of this Act if the credible evidence for the association is equal to or outweighs the credible evidence against such an association."

Have the disorders in children of Vietnam veterans satisfied this standard of proof? And, if so, what actions should the VA take to care for those children?

Ms. MEKDECI. Do I get to go first? Okay.

I believe that what we are seeing does represent something important happening, but what we are dealing with is state-of-the-art research. This is cutting edge stuff, brand-new. A lot of the information I shared with you today was based on a brand-new report from the National Research Council called "Biologic Markers In Immunotoxicology."

It is new to me. When I became involved with this, I didn't think there was any association between the fathers and what is going on with the children, and I have changed my mind radically.

I believe that we are seeing something important. I hate to say more study is needed, but I do think more study is needed. I think at the very least a subset study to see if you are getting similar markers to what happened in Times Beach could clarify it very quickly and reasonably economically, if such things can be done.

We are not at this point in our data collection seeing associations with major structural birth defects such as the neural tube defects, spina bifida and things like that. We have done a big outreach. I would think if they were there we would see them. But perhaps there is a veteran population that is still skeptical, that is not willing to participate yet.

I would be happier if we had 2,000 veterans and 2,000 controls.

Mr. Bryan C. SMITH. The statement you read relates to Vietnam veterans. It does not relate, I don't think, to the children, and I think that is the critical issue as we heard earlier.

My concern is the VA has provided services which have helped families in the past. Vet centers provide family counseling, for example. I do believe that the VA could consider family centered approaches and might resolve many of these conflicts.

We are going to spend a lot of money coming up with cause and effect, and it may take a long time to get that evidence. But in the meantime, there is a great deal of suffering going on, a lot of difficulty, a lot of anguish and a lot of anger that Vietnam veteran families have.

And I think at this point I too have to resolve the research issue. There are some—in building this model, I hope we are looking at children as well.

Mr. EVANS. And just one final question, and one that I have asked virtually everybody. Would you support—have you looked at the possibility of doing research in Vietnam as an effective way of conducting research, particularly insofar as birth defects are concerned?

Mr. Bryan C. SMITH. Absolutely. That has been reported in the literature. Admiral Zumwalt referred to the fact that they did not have the funds to do some of the more elaborate manipulations, and the question on possible exposure I think can be resolved by looking at the data of those studies.

Ms. MEKDECI. My opinion is a little different on that. You are looking at two different things. When you are looking at a woman exposed during pregnancy and a father's exposure, you might get two different sets of problems. I think that if you look at the women who were exposed to Agent Orange during pregnancy in Vietnam, you probably are going to see more structural birth defects, molar pregnancies and such. So I am not sure the two groups are absolutely comparable.

But let me just add one other thing. One of the reasons that I work so hard on this issue is because I know there are diagnostic and treatment modalities available right now for immunological problems. These children aren't getting these because they cost a lot of money. These treatments could be made more widely available.

I know this because I have immune problems secondary to a chemical exposure, and just by fate, went to a research doctor who diagnosed me quite quickly. I have been on state-of-the-art treatment, and I don't have cancer and I, hopefully, am not dying. So when I tell you there are ways to treat these children I know what I am talking about.

There are ways to treat them, ways to diagnose them. But they need to be treated now. We don't have—if we keep waiting, if we are correct and their immune systems are affected, the longer we let this go the more serious the long-term outcomes will be—cancer, autoimmune disease, et cetera, et cetera.

Mr. EVANS. All right. Thank you very much for your testimony before us today.

Mr. Bryan C. SMITH. Thank you.

Mr. EVANS. Appreciate your time.

Our final witness panel is comprised of John Hanson, Dave Gorman, Dennis Cullinan, and Paul Egan.

John is Director of Veterans Affairs and Rehabilitation Commission, the American Legion. Dave is the Assistant National Legislative Director for Medical Affairs with the Disabled American Veterans. Dennis is Deputy Director, National Legislative Service, Veterans of Foreign Wars of the United States. And Paul is the Executive Director of the Vietnam Veterans of America.

Once you are seated, we will start with John.

STATEMENTS OF JOHN HANSON, DIRECTOR, VETERANS AFFAIRS AND REHABILITATION COMMISSION, THE AMERICAN LEGION; DAVID W. GORMAN, ASSISTANT NATIONAL LEGISLATIVE DIRECTOR FOR MEDICAL AFFAIRS, DISABLED AMERICAN VETERANS; DENNIS M. CULLINAN, DEPUTY DIRECTOR, NATIONAL LEGISLATIVE SERVICE, VETERANS OF FOREIGN WARS OF THE UNITED STATES; PAUL S. EGAN, EXECUTIVE DIRECTOR, VIETNAM VETERANS OF AMERICA

STATEMENT OF JOHN HANSON

Mr. HANSON. Thank you, Mr. Chairman, for this opportunity. I will summarize our full statement and ask that the entire one be put in the record.

The American Legion commends this committee on the speed with which this hearing on the Institute of Medicine's report on the effect of herbicides in Vietnam veterans was scheduled, and we commend you for your steady leadership on this issue over the years.

For far too many years, The American Legion has been asking questions about a number of health problems faced by Vietnam veterans and demanding action with few tangible results. Beginning with the release of the IOM study last week, we reached a place we should have been more than a decade ago, and we feel that the clash of cultures Representative Ridge talked about earlier has been a tremendous barrier to the truth. But that is no reason for us not to proceed.

You know that we have funded and conducted our own study of the health of Vietnam veterans when the Government refused to act. The Legion and the Vietnam Veterans of America joined in a lawsuit against the Federal Government on this issue over 3 years ago. That is the only lawsuit The American Legion has ever filed against the Government in 75 years.

The position of The American Legion on Agent Orange today is no different than it was in the late 1970s and throughout the 1980s. We sincerely believe that for some reason this government has consistently ignored legitimate medical complaints of Vietnam veterans and their families for so long that even modestly good news, such as we heard last week, provides little comfort.

While we have speculated about the reasons for the delays and false starts, we know that what is important now is not why there were no studies done earlier, but rather that there must be additional studies conducted now. We sincerely hope that the lessons learned from the Agent Orange experience will be applied to research conducted for Desert Storm veterans as well.

And, of course, we were relieved to see a panel of experts say that it is indeed possible for at least five medical conditions to be associated with exposure to chemicals in Vietnam. But we also know that this group of scientists was not charged with the job of finding cause and effect, but rather with a review of the literature on herbicide and dioxin exposure. As Drs. Fallon and Shine said last week, much work is yet to be done, and The American Legion is reinforcing its appeal for this government to get on with the work.

We cannot lose sight of the fact that every year a good, solid, independent and scientifically valid epidemiological study is delayed more veterans and their families are affected by the impact of their exposure to defoliating agents in Vietnam.

The Institute of Medicine report offers new evidence which supports action that will lead to an independent epidemiological study of the people who served in Vietnam. We do not ask this committee or this government to recommend any action that can't be justified, and we know that many questions are still unanswered. We are simply asking for the delays to cease so we can once and for all put the remaining issues of Vietnam behind us.

As The American Legion worked on the issue of the effects of herbicide spraying we knew then that we were walking into a complicated area. But the more we interviewed concerned veterans with rare diseases we knew we had to act. Optimistically, we felt certain at that time that this government would agree, but, of course, that didn't happen. We faced interference from at least one administration and saw scientific studies become so truncated that they were useless.

The American Legion is tired of the gamesmanship. We are tired of the lies and the double talk. If Vietnam veterans were not bitter for other reasons, they surely must be disgusted with what they saw their government do and how it behaved on this one issue.

It is important to remember no study has yet declared that exposure to Agent Orange was harmless. So Congress and VA are starting a new chapter now, and we hope that this may be the beginning of the epilogue. We are urging this committee and this Congress to move forward and finally agree that an independent, scientifically powerful study be done so we can put the doubts to rest.

Thank you, Mr. Chairman.

Mr. EVANS. Thank you, John.

[The prepared statement of Mr. Hanson appears at p. 243.]

Mr. EVANS. Mr. Gorman.

STATEMENT OF DAVID W. GORMAN

Mr. GORMAN. Thank you, Mr. Chairman. Mr. Chairman, today we believe is a landmark day, for it can now be said that Vietnam veterans and those other caring individuals involved in and dedicated to ensuring Vietnam veterans and their families receive what they believe they are entitled to from the VA finally have received answers to questions that have long alluded reasonable and acceptable resolution.

Also present, in our view, is an atmosphere of optimism that we are close to finding additional answers to additional questions. Mr. Chairman, our optimism today is derived basically from three sources:

First, the persistence of Congress in pursuing meaningful legislation, oversight and action regarding Agent Orange. Second, the independence, credibility, devotion and commitment of the Institute of Medicine in pursuing this study in a timely fashion. And third, the commitment of the Secretary of the VA, Jesse Brown, to do what is right and in the best interest of veterans.

As we understand the IOM's report and its recommendations, the DAV is supportive of Secretary Brown's immediate decisions. We

support the decision to have the Veterans Benefits Administration begin the rulemaking process to recognize Hodgkin's disease and PCT as being associated with exposure to herbicides. We also support Secretary Brown's decision to establish a panel to review and solicit comments on the report from other medical and scientific authorities and interested parties regarding an association between exposure and respiratory cancer, prostate cancer and multiple myeloma.

The report also recommended certain actions be undertaken regarding future research activities and that a non-governmental organization be commissioned to develop and test models of herbicide exposure relating to Vietnam veterans. Mr. Chairman, we support both those recommendations.

We also agree with the decision directing the Under Secretary for Health to prepare an action plan that will implement the research recommendations made by the committee and agreed to by the Secretary. We would urge that this plan be prepared in the most timely manner possible and that it be shared with the Veterans' Affairs Committees, the veterans' service organizations and other appropriate parties with an interest in this interest.

Mr. Chairman, the DAV is in agreement with the decisions up to this point made by the VA based on the IOM's recommendations. Also, our belief is that we are now beginning to see a resolution to the major questions involved in the Agent Orange debate. We would urge, however, in the strongest possible terms that the VA continue to pursue as expeditiously as possible all available avenues attendant to this issue. Only by doing so will the VA have met its commitment to Vietnam veterans and their families.

Mr. Chairman, that concludes my testimony. Thank you.

Mr. EVANS. Thank you, Dave.

[The prepared statement of Mr. Gorman appears at p. 247.]

Mr. EVANS. Mr. Cullinan.

STATEMENT OF DENNIS M. CULLINAN

Mr. CULLINAN. Thank you, Mr. Chairman. Speaking on behalf of the 2.2 million members of the Veterans of Foreign Wars, I wish to express our deep gratification in having been provided this opportunity to comment on the report prepared by the National Academy of Sciences concerning the health effects of Agent Orange and other herbicides on Vietnam veterans. The VFW is proud to include among its membership approximately 600,000 Vietnam veterans, many of whom were exposed to dioxin and other chemical toxins which were present in Agent Orange as well as other herbicides used in Vietnam.

Additionally, the VFW has long championed the cause of providing VA health care on a service-connected basis to Vietnam veterans suffering from Agent Orange related disabilities as well as the provision of VA compensation to such veterans where there is any evidence of a causal relationship between a given disability and a toxic herbicidal agent. Thus it is truly a privilege for me to be here today to speak before this committee, and I would also like to commend the activities of this committee and your own efforts on behalf of Vietnam veterans, and especially in this area of Agent Orange.

The VFW will now take this opportunity to thank and congratulate the Secretary of Veterans Affairs, Jesse Brown, for showing himself to be a true and committed Secretary for veterans affairs by establishing two additional diseases to be compensable Agent Orange-related, service-connected disabilities. This was done immediately upon release of the study and goes a long way toward demonstrating that the time of hesitancy and vacillation on this most important veterans' issue is finally over. It presents a victory of compassion and common sense over bureaucratic inertia and intractable skepticism.

The VFW also notes that the report establishes limited or suggestive evidence that respiratory cancers, prostate cancer, and a bone disorder called multiple myeloma may also be linked to exposure to toxic agents found in herbicides. In this regard, the VFW again offers its support of Secretary Brown, who has indicated that he intends to make a determination on these additional disabilities within 60 days.

Vietnam veterans have already had to wait far too long for the answers to their often terrifying questions regarding their herbicide-related disabilities, and the VFW strongly believes that prompt action is more than warranted in this case. We would only ask that the determination as to whether these three additional disabilities are service-connected be made with the utmost compassion and with all reasonable doubt resolved in this Nation's veterans' favor.

While the VFW acknowledges the growing body of evidence that, as a group, Vietnam veterans did not suffer a substantially high exposure to herbicides, it is also clear to us that certain Vietnam veterans, such as those who participated in Operation Ranch Hand and those who served in the most heavily sprayed areas, suffered extremely high exposure levels. Since the deadly nature of dioxin as well as certain other toxic agents found in herbicides is now a well-documented scientific fact, the VFW holds that any veteran who demonstrably suffered significant exposure to toxic agents incidental to his or her military service be awarded service-connected compensation and care for his or her disabilities on the most liberal basis.

The Institute of Medicine's report under discussion today clearly states that the "existing epidemiologic data basis is severely lacking in quantitative measures of individual exposure to herbicides and dioxin." And the report goes on to state that the "intensity and duration of individual exposures is a key component" in ascertaining whether specific disabilities are attributable to exposure to dioxin or other toxins found in the herbicides used in Vietnam.

It is clear from the report that the available data is clearly lacking in this regard. The VFW further notes that while even very sound epidemiologic studies are quite effective at establishing a connection between exposure to a certain agent and a particular health outcome affecting a large number of people, they are totally inappropriate and inadequate for discerning health effects for only a small number of people.

The available Agent Orange data, therefore, would totally overlook the ill health effects of certain highly susceptible veterans for

whom only relatively minimal herbicide exposure resulted in diseases or disability. We believe this lends force to our view that whenever exposure is established, the concerned veterans should be granted service-connected for any disability which is not clearly the result of some other factor.

The VFW also places special emphasis on the finding that additional research is highly warranted in order to resolve areas of continuing scientific uncertainty concerning the health effects of the herbicides used in Vietnam. Based on the paucity of reliable data with respect to the ill-health effects of herbicide exposure, especially in Vietnam veterans, the panel concludes that a series of epidemiologic studies of veterans could yield valuable information if a new, valid exposure reconstruction model could be developed.

Further, this panel goes on to recognize the value in continuing the existing Ranch Hand study and expanding it to include Army Chemical Corps veterans. The VFW urges that this recommendation be heeded and that such ongoing research be authorized and funded by the Congress.

In conclusion, Mr. Chairman, the VFW is highly supportive of all of the panel's specific recommendations urging the furtherance of scientific investigation and understanding of individual herbicide exposure. And I would include in this remark that this should pertain to children of Vietnam veterans as well.

Thank you, Mr. Chairman.

Mr. EVANS. All right, Dennis, thank you.

[The prepared statement of Mr. Cullinan appears at p. 250.]

Mr. EVANS. Mr. Egan.

STATEMENT OF PAUL S. EGAN

Mr. EGAN. Thank you, Mr. Chairman. I would like to begin with just a couple of comments about the report of the Institute of Medicine. The results of this report, I think, demonstrate that there is an affirmative answer to two questions that have been troubling in this whole issue for a long, long time, and the first of those questions is whether or not it is possible to assemble a scientific entity to review information on the issue of Agent Orange and come up with findings that are free from interference by government policymakers looking for an inexpensive outcome.

And the second question is is it possible for a panel, a scientific panel to reach conclusions that are free from interference from chemical companies with an obvious interest in outcomes?

And this report seems to demonstrate that yes, indeed, it is possible for a panel to be assembled that can give objective results based on a thorough review of the science, that, of course, assuming that there was no obvious reliance by this particular panel on any of the studies that have been pretty roundly discredited; studies in many cases, which I think we are all familiar with, that were underwritten in large part by the chemical companies.

So we are gratified that it is possible that this report can come forward and that its results can be objective. And it provides I think for veterans, Vietnam veterans a significant sense of vindication. What veterans have been saying for many years turns out to be absolutely right. Agent Orange exposure causes specific diseases and that previous statements by government entities that have at-

tempted to speak on the issue of Agent Orange have consistently said improperly that veterans should be considerably relieved at the fact that Agent Orange is essentially harmless. So vindication is an important part of what comes from this report.

However, I think it is important to underscore this is not the end of the Agent Orange issue, not by a long stretch. This is the beginning.

The NAS report offers a variety of suggestions on further science. It offers the guidance that further science needs to be undertaken by non-governmental entities. It says that the protocols and the methodologies for the conduct of that science too should be undertaken by non-governmental entities.

We can't simply rest on the laurels of what this report has recommended, however. We have to assure that what is recommended is carried out. And, to that extent, I think it is important to find a way to construct, perhaps, some authorizing legislation to codify these recommendations to assure that they are fulfilled as this ongoing NAS process consistent with the 1991 law goes forward.

Finally, with respect to the report and its recommendations on the first two tiers of disabilities for which evidence was found to support an association between exposure and disease, the sufficient evidence category, we are certainly pleased that Jesse Brown has added Hodgkin's disease and PCT to the list of those that will be compensated at this point. But the second tier, the tier including limited/suggestive evidence of an association, those respiratory cancers, prostate cancers and multiple myeloma, we think that those also should be added.

Now, naturally the VA is going to take its 60 days and review that topic. But certainly the first tier's diseases ought to be codified right away. The second tier's diseases probably should be codified even if only an interim basis, and we certainly we understand that if there are intercurrent reasons why someone might have come up with a, for example, lung cancer, perhaps they were heavy smokers, perhaps they shouldn't be eligible for compensation. But if someone was a nonsmoker and had lung cancer, they certainly ought to be—compensation ought to be available to them.

Some would say, Well, does limited/suggestive evidence means that the test of reasonable doubt has been met? Well, several years ago, the former chairman of the Board of Veterans Appeals was asked to define what was meant in the statute by resolving reasonable doubt in favor of the veteran, and he said very simply and succinctly that ties go to the runner. And it would seem from our standpoint, from Vietnam Veterans of America's standpoint that limited/suggestive evidence would constitute a tie which should be given to the runner, and even if it is only on an interim basis, perhaps authorized for a limited period of time until the additional science is completed to provide a more definitive answer.

As you have referenced in a variety of your questions to some of the previous witnesses, Mr. Chairman, we have indeed recommended that research be conducted in Vietnam. It may very well be one of the most perfect research laboratories available. It is a country where in the north Agent Orange and other herbicides were not used at all. In the south herbicides were used heavily. So you have two populations, one exposed and one not exposed, and

you also have the additional advantage of having a country that is not an industrialized country, meaning that you don't have an accumulated background presence of dioxin as the rest of the industrialized world has.

And so we have recommended to the Senate Appropriations Committee that they allocate some money for that purpose, and in our testimony we detail what we think is an appropriate way to go about pursuing that kind of research.

I will conclude, Mr. Chairman, by saying that the Secretary of the Department of Veterans Affairs has indeed demonstrated that he is a Secretary for veterans in acting quickly as he has done. Having said that, however, we have some concerns that we will express to him at the first available opportunity about the committee that he is assembling to take a look at this report and what to decide within the next 60 days. He is going to assemble some people from the benefits side and the medical side and the legal side, and we, from experience, even though we are fully confident in the Secretary and in the General Counsel we are not nearly so confident, and again based on history, in the senior career bureaucrats in the agency who will be relied upon to do the staff work and who will undoubtedly be relied upon to staff the decision-making options that will be presented to the Secretary for a final decision.

In many instances we would anticipate that these same individuals would be people who have over the last 12 and more years had sufficient opportunity to develop clear and unmistakable biases on this topic, and we are not sure what can be done to satisfy a need that the Secretary ought to be entitled to, which is a need for objective recommendations. But it is a concern and it certainly bears watching, and I would certainly recommend to this committee that that concern be borne in mind as the Secretary goes forward with this process.

Mr. Chairman, that concludes my remarks.

Mr. EVANS. All right. Thank you, Paul.

[The prepared statement of Mr. Egan appears at p. 255.]

Mr. EVANS. Let me ask all of you, given the fact that the NAS says that effective studies will have to be continued into the next century to the year 2003, would your organization support the continuation of the authorization set to expire at the end of this year to give priority health care to Vietnam veterans exposed to Agent Orange?

Mr. GORMAN. The DAV would, Mr. Chairman.

Mr. EVANS. To the year 2003?

Mr. GORMAN. I think we would prefer to have it go, I think, for 3 years until the next stage of the NAS comes to be, and certainly at that time if there are still unresolved issues to continue it again.

Mr. CULLINAN. Mr. Chairman, from the VFW's perspective we wouldn't see any reason to discontinue the special authority until there is proof showing, some sort of evidence showing that it should be. So we would stand behind the extension.

Mr. HANSON. The American Legion feels the same way.

Mr. EGAN. We support the further extension.

Mr. EVANS. If I understand, the VFW and the VVA support inclusion of the so-called third tier of illnesses into a category—well,

being compensated and treated. Is that the position of the DAV and the Legion as well?

Mr. HANSON. Yes, sir. The American Legion concurs. In fact, Mr. Egan and I were talking about this last week. Ties certainly should at least go to the veteran in this case, and that as long as there is any benefit of the doubt it should go to the veteran.

Mr. GORMAN. Certainly, Mr. Chairman, for treatment purposes we would. For compensation—I think you are referring to the lung cancer, the prostate and the multiple myeloma—we would prefer to wait out the 60 days and see what the panel's recommendations are on the findings. And if at that time, as we say, there is a reasonable doubt present, then we would also give it to the veteran, obviously.

Mr. EVANS. And let me finally ask you the question I think I have asked everybody. Would your organization support some form of research in Vietnam itself to study Agent Orange and herbicide exposure and the impact on those populations?

Mr. CULLINAN. Mr. Chairman, again the VFW's perspective, it seems to us that that would be a good source of information. Now exactly how the study would be carried out, and there was a scientist speaking earlier about the problems associated with the study of women versus men, these are things that have to be worked out by doctors and scientists. But it seems to us that there would have to be some good information to be garnered out of Vietnam itself.

Mr. HANSON. The American Legion has long supported studies in Vietnam, and we think that is a critical element in finding an answer to this question.

Mr. GORMAN. We haven't given that subject a whole lot of thought, Mr. Chairman. I am starting to think about that today as the witnesses talked about it and you asked these questions.

I would think also, as Mr. Cullinan has responded, that if there is a suitable protocol that could be made and it is scientifically thought to have some value, then we would certainly think it should be pursued if there is going to be a conclusion reached to this question.

Mr. EVANS. All right. I want to thank you all for your continued advocacy for America's veterans. I know it is unusual for veterans' organizations to go to court to sue the Federal Government. If we hadn't had that suit, though, we might not be here today. So thank you all very much.

And with that we conclude the start of a new beginning, you might say, with this issue. I think the bipartisan concern shown by the members today indicates that our work has just begun. So thank you all for attending here today.

And we are now concluded.

[Whereupon, at 1:25 p.m., the committee was adjourned, to reconvene subject to the call of the chair.]

APPENDIX

HONORABLE G. V. (SONNY) MONTGOMERY
FULL COMMITTEE HEARING
HOUSE COMMITTEE ON VETERANS AFFAIRS
ON THE NATIONAL ACADEMY OF SCIENCES STUDY
ON HEALTH EFFECTS OF AGENT ORANGE
AUGUST 4, 1993

The Committee will be in order.

This morning we will receive the views of the National Academy of Sciences on possible health effects resulting from exposure to Agent Orange and other herbicides used in Vietnam. In addition to the witnesses from the Academy, we also will hear from Secretary of Veterans Affairs Jesse Brown, several veterans service organizations and a number of other important witnesses.

In veterans' affairs, few issues have generated as much controversy as the questions surrounding the long-term health effects of exposure to Agent Orange. There have been numerous studies and much work by the Congress on the subject. I believe that the Congress has demonstrated its commitment to making certain that veterans are treated fairly and that VA's compensation decisions are just and reasonable. That is why we asked the Academy to do this study in February 1991 when we enacted Public Law 102-4.

This particular assessment of the effects of exposure is especially important. Not only were the scientists and physicians who conducted this assessment highly qualified, widely respected, and fully independent. They considered the results of thousands of studies in reaching their conclusions.

We are pleased to have Dr. Kenneth Shine, President of the Institute of Medicine, here with his colleagues to brief us on the results of this review. On behalf of the Veterans Committee, I want to thank all of the members of this special committee for the many hours they spent on this review, all of it without pay.

One of the Committee's conclusions is that there is sufficient evidence to suggest a link between exposure to herbicides and five conditions: chloracne, non-Hodgkin's lymphoma, soft-tissue sarcomas, Hodgkin's disease and PCT, a liver disorder.

The Institute of Medicine Committee found that for some conditions, there is limited or suggestive evidence of an association with herbicide exposure, and for a number of others the Committee has concluded that a connection is not suggested by the information which it considered. Secretary Brown will review these findings and make further decisions within the next 60 days. Based on his announcement to grant service-connection for two conditions (PCT and Hodgkin's disease) on the same day that the Academy announced its finding that they appear to be related

to herbicide exposure, I am confident he will complete this further review in a timely manner.

No one can legitimately say that the Congress has not been attentive to the concerns of our Vietnam veterans who believe their medical conditions are related to herbicide exposure in Vietnam. Since 1978, our committee alone has conducted 18 oversight and legislative hearings on the matter.

In 1979, the Congress enacted Public Law 96-151 which commissioned a broad, multi-million dollar epidemiological study which, to the applause of veterans' organizations, it later took from the VA and placed in the hands of the Centers for Disease Control (CDC). Further, we've mandated independent reviews of CDC findings.

In 1981, in Public Law 97-72, the Congress established priority hospital care, and in 1988, in Public Law 100-322, priority outpatient care, for any veteran who might have been exposed to Agent Orange while serving in Vietnam, unless the VA finds the veteran's disability resulted from a cause other than herbicide exposure. The original provision for health care eligibility has been extended three times.

In 1984, Public Law 98-542, the Congress indicated its intent that determinations regarding disabilities related to Agent Orange exposure be made on the basis of sound scientific and medical evidence. We directed the Department, through an advisory committee on environmental hazards, to review, compile and apply the best available evidence to decisions regarding service-connected compensable conditions. This law also provided compensation benefits on an interim basis for Vietnam veterans suffering from chloracne and porphyria cutanea tarda (PCT).

Finally, with the enactment of Public Law 102-4 in February 1991, we established the mechanism for the comprehensive literature review to be conducted by NAS and codified the presumption of service connection for three disabilities: chloracne, non-Hodgkin's lymphoma, and soft-tissue sarcomas.

Clearly, some important questions have at long last been answered. Other important questions, however, still remain. To help answer the remaining questions, the Institute of Medicine Committee has recommended additional scientific research. I said when we passed the law authorizing this review that I would support the Academy's findings and recommendations. I stand by that statement today and urge all members to support their recommendations.

Statement of Congressman Lane Evans
House Committee on Veterans' Affairs

August 4, 1993

Mr. Chairman:

Thank you for convening today's hearing.

Let me begin by welcoming Senator Daschle and Congressman Bonior. Without their assistance, the Agent Orange Act of 1991 would not have become law and we would not be here today. On behalf of both myself and our Vietnam veterans, I thank you.

Today marks a new beginning in our government's relationship with Vietnam veterans After fighting the government for 3 decades, it appears as if Vietnam veterans may finally get the respect that they deserve. The NAS study proves that Vietnam veterans were right all along -- Agent Orange is harmful and the government studies were flawed.

These men and women returned from battle only to find an unappreciative public and a government that denied responsibility for its actions. Rather than welcoming these men and women home and caring for their injuries, Vietnam veterans were made to prove their illnesses were service-connected instead of being given the benefit of the doubt.

Given this history, the NAS must be commended. For eighteen months and without compensation, the sixteen scientists on the NAS panel reviewed and evaluated the research on the health effects of Agent Orange. Their report, which was issued last week, is the first credible government sponsored report on Agent Orange. For this, I thank the panelists and their staffs.

I believe that the comprehensiveness and quality of this report should ensure that the problems facing veterans exposed to Agent Orange are taken seriously. And I think it can lead to further recognition of illnesses and problems related to exposure.

In fact, on the day the report was released, Secretary Brown moved to provide compensation benefits to Vietnam veterans with either Hodgkin's disease or PCT (porphyria cutanea tarda). The Secretary's decision was admirable and I thank him for his quick action. The VA's action, however, will not solve all the problems facing Vietnam veterans and so I look forward to hearing the Secretary's views on where we go from here.

This report is not the end, but the beginning. It is the first of six NAS reports that the NAS will issue during the next decade on the possible health effects of exposure to Agent Orange and other herbicides used in Vietnam. In the meantime, however, we should move immediately on the NAS recommendations by pushing for new research and deciding what illnesses should be added to the list of those presumed service-connected.

I am looking forward to working with both the new members of this committee as well as my old friends as we move on NAS' recommendations and ensure that Vietnam veterans get the benefits that they deserve.

Prepared statement of Congressman Stump

THANK YOU MR. CHAIRMAN.

I APPRECIATE YOUR CALLING THIS HEARING TODAY TO RECEIVE THE REPORT OF THE NATIONAL ACADEMY OF SCIENCES' INSTITUTE OF MEDICINE CONCERNING THE HEALTH EFFECTS OF HERBICIDES USED IN VIETNAM.

I JOIN YOU IN WELCOMING OUR COLLEAGUES, TOM DASCHLE AND DAVE BONIOR.

LET ME TAKE THIS OPPORTUNITY TO CONGRATULATE THE ACADEMY'S 16-MEMBER PANEL FOR COMPLETING A TASK AS DIFFICULT AS EVALUATING THE SCIENTIFIC LITERATURE ON THIS SUBJECT. PARTICULAR RECOGNITION NEEDS TO BE PAID TO DRS. FALLON, TOLLERUD AND SHINE FOR THEIR OUTSTANDING LEADERSHIP IN THIS EFFORT.

HOPEFULLY, THE VETERANS' COMMUNITY WILL ACCEPT THIS REPORT AS THE MOST OBJECTIVE

SCIENTIFIC REVIEW POSSIBLE. I ALSO HOPE THAT THE VETERANS SERVICE ORGANIZATIONS WILL NOTIFY VETERANS OF ALL THE NATIONAL ACADEMY OF SCIENCES' FINDINGS.

VETERANS AND POLICY MAKERS NEED TO USE THE NAS REPORT AS THE BENCHMARK FOR MAINTAINING A SCIENTIFIC PERSPECTIVE IN RELATION TO WHAT REMAINS A VERY EMOTIONAL ISSUE.

IT WOULD APPEAR THAT THIS REPORT CONFIRMS THE ACTION TAKEN BY VA SECRETARY ED DERWINSKI IN MARCH OF 1990.

IN ADDITION, SECRETARY JESSE BROWN IS TO BE COMMENDED FOR TAKING SWIFT ACTION BASED ON THE NAS REPORT.

AGAIN, I WISH TO PERSONALLY THANK ALL THE MEMBERS OF THE NAS/IOM COMMITTEE WHO SERVED SO TIRELESSLY AND WITHOUT COMPENSATION ON THIS VERY DIFFICULT PROJECT -- AND LOOK FORWARD TO TODAY'S TESTIMONY.

STATEMENT OF JOSEPH P. KENNEDY II
HEARING ON THE HEALTH EFFECTS OF AGENT ORANGE
AUGUST 4, 1993

Mr. Chairman, I want to thank you for calling today's hearing -- this has been more than a decade in coming -- despite the efforts of a number of us in Congress and the Vietnam veterans community. In particular, I want to commend Lane Evans for his unmatched leadership on this issue. He has championed the concerns of Vietnam veterans and fought tirelessly for passage of the Agent Orange Act of 1991 that brings us this National Academy of Sciences (NAS) study. I am proud to have worked with him on this matter and look forward to moving ahead to address the needs that are so apparent from this report.

After 20 years, we finally have some answers about the illnesses that have been plaguing Vietnam veterans who were exposed to Agent Orange. Upon returning from Vietnam, our vets had to fight an unwilling government for two decades to get answers and VA health care and benefits.

The NAS Report is the first independent review of the scientific evidence surrounding exposure to Agent Orange and confirms that five diseases [soft tissue sarcoma, non-Hodgkin's lymphoma, Hodgkin's disease, chloracne, and PCT-a liver disorder] are caused by Agent Orange. It finds suggestive health implications for additional illnesses, including respiratory cancers, prostate cancer, and bone marrow cancer.

We cannot rest until we have the answers to the medical questions that need further research. I am committed to moving forward with recommended research in key areas and to ensuring that all Vietnam veterans receive compensation for illnesses that resulted from Agent Orange exposure.

Congress must extend the law which provides priority health care to veterans who were exposed to Agent Orange or ionizing radiation, which is due to expire on December 31, 1993. I have cosponsored H.R. 2375, which would extend care for 10 years through 2003, and call for its quick consideration.

This report does not close the book on Vietnam, but rather it opens a new chapter -- hopefully a more cooperative chapter. The swift action of Secretary Jesse Brown in adding Hodgkins disease and PCT as compensable illnesses should be commended. I hope his actions will turn the page on the legacy of past government indifference under previous Administrations to a kinder VA, more responsive to the medical concerns of Vietnam veterans.

I look forward to the testimony of our distinguished witnesses.

STATEMENT OF CONGRESSMAN CHRIS SMITH
FULL COMMITTEE ON VETERANS' AFFAIRS
AUGUST 4, 1993
THE INSTITUTE OF MEDICINE REPORT ON AGENT ORANGE

Mr. Chairman, in January of 1984, then-Congressman Tom Daschle and I offered an amendment during this Committee's markup of H.R. 1961. Our amendment would have substantially expanded the research on the effects of exposure to Agent Orange. While that long-ago amendment failed, I am pleased that today, we are seeing the organs of our government move in concert to recognize the health effects of Agent Orange exposure and to appropriately compensate Vietnam veterans.

I am encouraged to finally see the long-awaited report of the National Academy of Sciences (NAS) on the health effects of Agent Orange and other herbicides. This landmark study, originated in the "Agent Orange Act of 1991" (Public Law 102-4), has given new hope to veterans who may have given up on their government's willingness to acknowledge the illnesses caused by dioxin exposure. The report may also, I sincerely hope, put other veterans' minds at ease.

The report of the NAS Institute of Medicine is immensely comprehensive. It is also an evaluation -- according to the testimony of our witnesses -- praised for its scientific competence and its unquestioned impartiality. Mr. Chairman, to review 6,420 abstracts of medical investigations and to perform detailed analysis of 230 epidemiological studies truly demonstrates a commitment to thoroughness and objectivity. In fact, the New Jersey Agent Orange Commission's work was cited in this report six times.

Mr. Chairman, I applaud Secretary Jesse Brown for acting so swiftly to recognize the two additional conditions found by the Institute of Medicine as being linked to use of defoliants -- Hodgkin's Disease and the liver disorder porphyria cutanea tarda (PCT). The Institute of Medicine found there was "sufficient evidence of an association" with these particular outcomes and exposure to herbicides. I understand the VA will publish its final regulations on compensation for these new conditions in February of 1994. Of course, the VA is already paying compensation for soft-tissue carcinoma, non-Hodgkin's lymphoma, and chloracne which

also were found to have a link with Agent Orange.

The report's finding that there was "inadequate/insufficient evidence to determine whether an association exists" for tragedies like birth defects, nonetheless, should put some Vietnam veterans at ease. I certainly hope that no connection is found, but I hasten to add that further study of the birth defects question is imperative.

Finally, the finding of "limited/suggestive evidence of no association" for conditions such as skin cancer, brain tumors or various gastrointestinal tumors should also greatly ease the concerns of veterans.

Mr. Chairman, it is important to put into perspective the scope of the Agent Orange issue. During the Vietnam conflict, roughly 2.6 million U.S. military personnel served in South Vietnam. Up until 1970, when it was concluded that Agent Orange caused birth defects in laboratory animals, 11.2 million gallons of Agent Orange had already been applied to the jungle canopy of South Vietnam. One of the herbicides used in Agent Orange, unfortunately, was contaminated during the manufacturing process with dioxin.

While Vietnam veterans may indeed have lower levels of exposure to dioxin than certain industrial or agricultural workers, the capacity for significant exposure is enormous.

Mr. Chairman, that fact underscores the importance of following up on the Institute of Medicine's recommendation to develop valid exposure reconstruction models We must take the next step and arrange for the design and testing of models of herbicide exposure to properly evaluate epidemiological studies of Vietnam veterans. However, we must work immediately. This cannot wait another twenty years.

This Committee has already conducted 22 hearings on the issue of Agent Orange exposure. I suspect we will call further oversight hearings on this issue and may never reach a conclusion satisfactory to everyone. Nevertheless, I look forward to a more complete resolution of this matter -- perhaps further review of the some 80 federal studies presently

underway regarding dioxin exposure.

I deeply appreciate the hard work of the National Academy of Sciences and I welcome the Secretary and the other witnesses to this morning's hearing. I look forward to hearing from you.

Statement of The Honorable Jack Quinn
August 4, 1993
Full Veterans' Affairs Committee Hearing on
NAS Report - "Health Effects of Herbicides Used in Vietnam"

Mr. Chairman - We are all well aware of the gravity of this issue and the great source of distress that it has caused our fine veterans and their families.

Vietnam veterans served this country with distinction - unfortunately they were let down in many ways. The Vietnam War was extremely divisive - and the men and women who made tremendous sacrifices often didn't receive the support of many of their fellow citizens.

Mr. Chairman - I have been contacted by Vietnam veterans in my district who have suffered from debilitating illnesses and whose children have birth defects and emotional disabilities.

Their lives have been effected in immense ways - and they feel that they have been let down by the government and the VA system for not recognizing that some of these problems stem from exposure to Agent Orange and other herbicides during their tour of duty in Vietnam.

The use of dioxins and herbicides in Vietnam and its effects on veterans may not have been adequately addressed to date.

However - it is my hope that the evidence presented in this study will be taken and built upon so that we can properly care for these veterans.

Once again, Mr. Chairman I am pleased to be here. I look forward to hearing the testimony this morning.

I would like to thank everyone involved for their hard work and dedication to this issue.

THOMAS DASCHLE
SOUTH DAKOTA

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Testimony of Senator Tom Daschle
Before the House Veterans' Affairs Committee
August 4, 1993

Mr. Chairman, thank you for inviting me to testify today on the significance of the report released last week by the National Academy of Sciences on the health effects of exposure to Agent Orange and other herbicides used in Vietnam. It is an honor to be before this Committee to discuss what may be the single most important contribution to the long struggle to address the concerns of Vietnam veterans exposed to Agent Orange.

This impressive report is the work of a 16-member panel of independent scientists chosen by the National Academy of Sciences to review the existing scientific literature related to the health effects of exposure to Agent Orange, including its contaminant dioxin, and other herbicides used in Vietnam. The panel members worked without compensation and were screened for any potential conflicts of interest.

The Agent Orange Act of 1991, which mandated this NAS review, passed both houses of Congress unanimously because people on all sides of the issue agreed that a committee of independent, unbiased scientists should do their best to tell us the truth as clearly as it can be known at this point. This independent review of the evidence confirms that there is an association between exposure to herbicides used in Vietnam and the development of five diseases. It suggests that there is a relationship between exposure and several other health effects, and identifies still others for which additional research is needed to understand their relationship with exposure.

Contrary to the conclusions of the Centers for Disease Control, the now-defunct White House Agent Orange Working Group, and the Office of Technology Assessment, the National Academy of Sciences suggests that epidemiologic studies of Vietnam veterans *can* be done. The committee recommends a series of scientific steps, including development of an historical exposure reconstruction model, toward that end.

The report is highly critical of the Air Force's handling of the Ranch Hand Study of veterans who handled and sprayed Agent Orange, and recommends that "an independent, nongovernmental scientific panel . . . be established to review and approve a new, expanded research protocol" and that the Ranch Hand data be reanalyzed. Although many have cited the Ranch Hand Study as "negative," the NAS committee cites problems with exposure misclassification and data analysis that could be hiding adverse health effects in the Ranch Hand veterans and their children.

The release of the NAS report marks a true milestone in the long struggle for justice for Vietnam veterans. It marks a milestone in the struggle for the facts. And I want to stress that point. Most people understand that Vietnam veterans have struggled for compensation. What many people may not understand is that, even more than compensation, the struggle has been to get the facts.

Veterans have wanted to be told the truth. They also have wanted their government -- the government that sent them to war -- to take responsibility for the truth. Unfortunately, until recently, the government had done just the opposite. Through delays, through misinformation, through a lack of commitment to resolving the issue, the federal government successfully hid the truth.

There is a long history to this issue. Much of the government's role in it is documented in speeches, hearing records, and court records. It is a painful story that I hope will never be repeated.

Sadly, the NAS report provides independent verification of much of that historical record. It also validates the work of many experts in the field of dioxin and herbicide research who have been subjected to intense efforts by powerful interests to discredit them.

This report from the National Academy of Sciences does not answer all our questions. But it should put to rest the chants of those who have claimed that Agent Orange never hurt anyone or that we will never be able to answer these questions. It should also give us a base from which to continue our efforts to understand the health effects of exposure to Agent Orange and to ensure that Vietnam veterans are given the treatment and compensation they deserve.

Testimony by David E. Bonior

8/4/93
on

Agent Orange

I would like to thank Lane Evans for asking me to be a part of this important day for Vietnam veterans.

I applaud the efforts of the Committee in holding this hearing and the National Academy of Sciences for producing a well thought-out report.

The NAS study validates what many of us have known for years --- exposure to Agent Orange is deadly

For nearly two decades veterans, their families and many of us in Congress have been making this point over and over again.

Lane has asked me to share with the newer members of the Committee some of my historical perspective on this issue.

When I was first elected to Congress in 1976, I believed that we must heal the wounds of the Vietnam war, bring torn generations together and raise the consciousness of the American people so that a war like that would never be fought again

Back then, I joined with several of my colleagues in founding the Vietnam-Era Veterans in Congress

It was just a handful of us, but we were determined to get health and retirement benefits for Vietnam vets, help for victims of Agent Orange and for victims of post traumatic stress syndrome, and, above all, bring some sense of dignity to those who came back from an unpopular war.

When the war was over there was a rush to forget not only the war, but those who fought in Vietnam

The fight for Agent Orange victims has lasted longer than the use of the herbicide lasted during the war.

From 1981-84, under the leadership of Tom Daschle and Lane Evans, we gradually were able to include Vietnam veterans issues more and more among this Committee's priorities.

In 1981, this Committee adopted legislation advanced by then Rep. Daschle to mandate health care for Agent Orange problems.

In 1983, this Committee pushed Agent Orange compensation legislation for Vietnam veterans which was later adopted by the full House in 1984

But there was still more to be done.

In order to cut the red tape at the Veterans Administration, Congress passed the Agent Orange Act of 1991

We passed that bill to codify the presumption that all in-country Vietnam veterans were exposed to Agent Orange and those with chloracne, soft-tissue sarcoma or non-hodgkins lymphoma deserved benefits.

The 1991 legislation also prompted the National Academy of Sciences study.

Just last Wednesday they released their findings, which concluded that there is sufficient evidence that exposure to Agent Orange causes three cancers: Soft tissue sarcoma, non-Hodgkin's lymphoma, Hodgkin's disease as well as chloracne.

The study also shows that there is a growing body of evidence that Agent Orange is directly responsible for other illness' in Vietnam vets and that further research is necessary.

The study is, to date, the culmination of our legislative efforts --- but not the end.

The study reminds us all of how much more there is to do.

It is only the first step.

Now is the time to redouble our efforts to ensure that National Academy of Sciences recommendations for new research are taken seriously and that this research is completed quickly.

We owe that to the Vietnam veterans, their families, their children and their grandchildren.

We owe that to veterans like Jim Weir from my home area.

He is the Vice-President of Macomb County's Vietnam Veterans of America Chapter #154.

He had a hard time letting his children know that his exposure to Agent Orange has affected them.

Jim has two children --- both have hearing impediments.

His daughter is getting married soon. Every day he asks, "do I encourage her to have children?"

To Vietnam veterans like Jim, his children and his grandchildren we owe the answers.

While this Committee, my fellow colleagues and the Veterans Administration have all made tremendous progress in helping to heal the wounds of the Vietnam war, the families of these vets still suffer.

While the pain continues, we must continue to help and to heal.

I look forward to working with the Committee as we continue to research the consequences of Agent Orange and to fight for the answers.

Testimony of
Kenneth I. Shine, M.D.
President
Institute of Medicine

Before the
Committee on Veterans' Affairs
U. S. House of Representatives
August 4, 1993

On the Report of the National Academy of Sciences' IOM Committee to Review the Health Effects of Vietnam Veterans of Exposure to Herbicides

Mr. Chairman and members of the Committee:

I am pleased to have the opportunity to testify before the House Committee on Veterans' Affairs on the Institute of Medicine's report prepared by the Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides. I will provide a brief summary of the background on the committee's report and the Institute of Medicine. The vice-chairman of the committee, Dr. David Tollerud, will present a brief overview of the committee's findings and recommendations. Also seated with us is Dr. Graham Colditz, a member of the committee, who is prepared to answer any questions.

In response to decades of concern surrounding the possible long-term health consequences of exposures to herbicides and the contaminant dioxin, Congress directed the Secretary of Veterans Affairs, in Public Law 102-4 signed on February 6, 1991, to request the National Academy of Sciences to conduct a comprehensive review and evaluation of the available scientific and medical information regarding the health effects of exposure to Agent Orange and other herbicides used during the Vietnam conflict. The report from the Institute of Medicine's (IOM) Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides, Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam reviews and evaluates the available scientific evidence regarding the association between exposure to dioxin or other chemical compounds in herbicides used in Vietnam and a wide range of health effects, and provides the committee's best assessment of this body of knowledge for the Secretary of Veterans' Affairs to consider as the Department of Veterans' Affairs exercises its responsibilities to Vietnam veterans. The report also describes areas in which the available scientific data are insufficient to determine whether an association exists and provides the committee's recommendations for areas in which

future research is likely to be most productive.

The National Academy of Sciences was created by an act of Congress and signed into law in 1863 by President Abraham Lincoln, and is dedicated to the furtherance of science and technology and to their use for the promotion of general public welfare. The IOM was chartered by the National Academy of Sciences in 1970 to serve as an adviser to the federal government on issues that affect the public's health, as well as to act independently in identifying important issues of medical care, research, and education. The IOM brings to this mission more than two decades of experience in conducting independent analyses of pressing health problems that involve federal policy decisions.

The Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides' 16 members represent a wide range of expertise. The members voluntarily participated on the committee and served without compensation. The committee was chaired by Harold Fallon, M.D., Dean of the Medical School at the University of Alabama, Birmingham. David Tollerud, M.D., M.P.H., Director of Occupational and Environmental Medicine at the University of Pittsburgh, served as vice-chair. Committee member Norman Breslow, Professor of the Department of Biostatistics of the University of Washington, served as a liaison to the IOM Board on Health Promotion and Disease Prevention, which was responsible for overseeing this study.

All committee members were selected because they are leading authorities in their scientific fields, are well-respected by their colleagues and peers, have no conflicts of interest with regard to the matters under study, and, indeed, have taken no public positions concerning the potential health effects of herbicides in Vietnam veterans or related aspects of herbicide or dioxin exposure. The committee thus has provided a fresh analysis of this issue--which is both scientifically complex and emotionally charged--and this report reflects the committee's thorough and unbiased scientific judgments. As with all reports from the IOM, the committee's work was reviewed by an independent panel of distinguished experts.

I would now like to introduce Dr. David Tollerud, vice-chairman of the committee.

# # #

Testimony of
David Tollerud, M.D., M.P.H.
Vice-Chairman
Institute of Medicine's Committee to Review
the Health Effects in Vietnam Veterans of Exposure to Herbicides

Before the
Committee on Veterans' Affairs
U. S. House of Representatives
August 4, 1993

Mr. Chairman and members of the Committee:

I am pleased to have the opportunity to testify before the House Committee on Veterans' Affairs on the Institute of Medicine's report prepared by our Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides. I will provide a brief overview of the committee's findings and recommendations.

A bitter legacy of the Vietnam War has been the decades of concern over the health effects of Agent Orange and other herbicides. More than 19 million gallons of herbicides were sprayed over South Vietnam in the years between 1962 and 1971, before reports of health effects in laboratory animals ended herbicide spraying. Most large-scale spraying took place from the air, but a considerable amount of spraying was also done from boats and ground vehicles and by soldiers carrying back-mounted 2equipment.

Since that time, some of the 3 million Americans who served in or near Vietnam have come to suspect that their wartime exposure to herbicides caused them to develop cancer or their children to have birth defects. This concern has helped initiate literally thousands of scientific studies on the health effects of herbicides and of dioxin, which contaminated about two-thirds of the herbicides used in Vietnam. Yet the issue remains shrouded in controversy and mistrust.

This issue has been a source of great anguish for veterans, for their families, and for the nation at large. Vietnam veterans made great personal sacrifices in serving their country. Yet they have faced continuing uncertainty about whether exposure to herbicides has led to past health problems or could lead to problems in the future. Some of these veterans and their families feel that their pain and suffering have been ignored and that these questions have not been adequately addressed.

Recognizing this uncertainty, the U.S. Congress passed the Agent Orange Act of 1991. That legislation asked the National Academy of Sciences to do a comprehensive review and evaluation of the available scientific and medical evidence regarding this issue.

The task was undertaken by a committee under the Institute of Medicine. Our committee released its report to the public on July 27, 1993.

To gather information for the report, the committee held three public meetings to allow veterans and other interested individuals to voice their concerns and opinions. In addition, members of the committee and the staff sought and received information from a broad array of individuals and organizations, including veterans' groups, congressional committees, federal agencies, scientific experts, and the public. This wide-ranging dialogue contributed substantially to this report.

We studied both the toxicological and the epidemiologic data on herbicide exposures. After reviewing thousands of studies, we focused on approximately 230 epidemiologic investigations for detailed review and analysis. Most of these studies did not involve Vietnam veterans. Rather, they were studies of people who were exposed to herbicides as a result of their jobs or as a result of contact in the environment -- for example, because of a nearby industrial accident. These types of exposures often were at high levels and for long periods of time. Getting a clear picture of the health risks for Vietnam veterans is not so straightforward because the levels of exposure were extremely wide ranging. Indeed, while most veterans probably had lower exposure levels, some may have experienced levels as high as that of occupational or agricultural exposures. What is uncertain is how many veterans may have been exposed to those higher levels and who those individuals are.

Based on the evaluations of the studies we reviewed, our committee found sufficient evidence of a statistical association between exposure to herbicides or dioxin and three types of cancer: soft tissue sarcoma, non-Hodgkin's lymphoma, and Hodgkin's disease. We also found sufficient evidence of an association with two skin conditions: chloracne and porphyria cutanea tarda, or PCT.

We found limited or suggestive evidence of an association between exposure to herbicides used in Vietnam and three other types of cancer: respiratory cancers, prostate cancer, and multiple myeloma.

For most of the other cancers, diseases, and disorders reviewed by the committee, the scientific data were not sufficient to determine whether an association exists. These include such cancers as bone cancer and leukemia and disorders ranging from birth defects to nervous system disorders.

However, for a small group of cancers, including gastrointestinal cancers and brain tumors, the committee found limited or suggestive evidence to conclude that there is no association between these cancers and herbicide exposure.

The greatest problem that we encountered in our study was a severe lack of information about the exposure of individual Vietnam veterans to herbicides. Except for particular groups, such as the individuals directly involved in spraying operations, information on the extent of herbicide exposure among veterans is practically nonexistent.

New biochemical techniques can detect low levels of dioxin in the blood, but we did not find that these measures are useful for arriving at individual exposures. People metabolize dioxin at different rates, and almost all Americans have some background exposure to dioxin. Furthermore, not all of the herbicides used in Vietnam contained dioxin.

This lack of data is why we were compelled to focus largely on epidemiologic studies of groups other than Vietnam veterans. We simply do not know enough about the exposures of veterans to determine to what degree they were or are at risk.

We do feel, however, that it is possible to develop better methods of determining exposures among individual veterans. Rather than relying on measures of dioxin in the blood, we recommend that exposure evaluations draw on historical reconstructions. These reconstructions take into account such factors as troop movements, ground and perimeter spraying, herbicide shipments to various military bases, the type of terrain and foliage typical of the locations sprayed, and the military missions of the troops located there.

Historical reconstructions require substantial professional judgment; therefore, the committee recommends that a nongovernmental organization be commissioned to develop and test models of herbicide exposure for use in studies of Vietnam veterans. These exposure models should in turn be evaluated by an independent scientific panel to determine their usefulness. The independence of these scientific groups would allay the public's concern about impartiality and scientific credibility.

If a better model of exposure can be developed, a number of important epidemiologic studies become possible. Highest priority should be given to those studies that could change the balance of evidence for or against an associated health effect. Research on reproductive effects should also receive priority.

In addition, our committee recommends that the study of the Ranch Hand cohort, which has been looking at the individuals involved in the Air Force's spraying program, be continued and expanded. A similar study should look at the members of the Army Chemical Corps and an appropriate comparison group. Both the Ranch Hand and the Chemical Corps veterans are known to have had significant exposure to herbicides.

Our committee was not asked to make judgments regarding individual injuries or the appropriate compensation for Vietnam veterans, and we did not do so. Rather, we were asked to provide information that the Secretary of Veterans Affairs could use in exercising the responsibilities of the Department of Veterans Affairs to Vietnam veterans.

Over the years, extreme views have evolved over this issue. On one extreme is the view that Agent Orange and dioxin cause a wide range of diseases; on the other is the suggestion that exposure to Agent Orange has not led to health problems. Our committee has determined through an extensive review of the scientific literature that, indeed, there does appear to be a link between exposure and certain diseases.

We believe that our report is a comprehensive, unbiased scientific review of the available evidence concerning this issue. This report will not end the controversy. But we hope that it will provide an agreed-upon base of information from which we can proceed to answer the questions that remain.

I would like to submit the Executive Summary of the committee's report for the record. That concludes my testimony. My colleagues and I are prepared to respond to any questions you and other members of the committee have.

# # #

EXECUTIVE SUMMARY
PREPUBLICATION COPY

Veterans and Agent Orange:
Health Effects of Herbicides Used in Vietnam

Committee to Review the Health Effects in
Vietnam Veterans of Exposure to Herbicides

Division of Health Promotion and
Disease Prevention

INSTITUTE OF MEDICINE

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NOTICE: The project that is the subject of this report was approved by the Governing Board of the National Research Council, whose members are drawn from the councils of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine. The members of the committee responsible for the report were chosen for their special competences and with regard for appropriate balance.

This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

The Institute of Medicine was chartered in 1970 by the National Academy of Sciences to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. In this, the Institute acts under the Academy's 1863 congressional charter responsibility to be an adviser to the federal government and its own initiative in identifying issues of medical care, research, and education. Dr. Kenneth I. Shine is president of the Institute of Medicine.

Support for this study was provided by the Department of Veterans Affairs (contract no. V101(93)P-1331).

This Executive Summary is available in limited quantities from the Institute of Medicine, Division of Health Promotion and Disease Prevention, 2101 Constitution Avenue, N.W., Washington, DC 20418.

The complete volume of *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam*, from which this Executive Summary is extracted, is available for sale from the National Academy Press, 2101 Constitution Avenue, N.W., Box 285, Washington, DC, 20055. Call 800-624-6242 or 202-334-3938 (in the Washington Metropolitan Area).

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The image adopted as a logo-type by the Institute of Medicine is based on a relief carving from ancient Greece, now held by the Staatlichemusseen in Berlin.

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Foreword

In response to decades of concern surrounding the possible long-term health consequences of exposures to herbicides and the contaminant dioxin, Congress directed the Secretary of Veterans Affairs, in Public Law 102-4 signed on February 6, 1991, to request the National Academy of Sciences (NAS) to conduct a comprehensive review and evaluation of the available scientific and medical information regarding the health effects of exposure to Agent Orange and other herbicides used during the Vietnam conflict. This report from the Institute of Medicine (IOM) Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides is hereby submitted in compliance with Public Law 102-4.

Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam reviews and evaluates the available scientific evidence regarding the association between exposure to dioxin or other chemical compounds in herbicides used in Vietnam and a wide range of health effects, and provides the committee's best assessment of this body of knowledge for the Secretary of Veterans Affairs to consider as the Department of Veterans Affairs exercises its responsibilities to Vietnam veterans. The report also describes areas in which the available scientific data are insufficient to determine whether an association exists and provides the committee's recommendations for areas in which future research is likely to be most productive.

That Congress would ask the NAS--a nongovernmental organization--to conduct this study reflects a time-honored tradition. Created by an act of Congress and signed into law in 1863 by President Abraham Lincoln, the NAS is dedicated to the furtherance of science and technology and to their use for the promotion of general public welfare. A private, nonprofit society of distinguished scholars engaged in scientific and engineering research, the NAS has a mandate to advise the federal government on scientific and technical issues of pressing importance. Its members, drawn from universities and the private sector, are elected by their peers on the basis of exemplary professional achievement. Members, along with other leading experts, voluntarily participate in National Research Council and IOM studies and serve without compensation.

The IOM was chartered by the NAS in 1970 to serve as an adviser to the federal government on issues that affect the public's health, as well as to act independently in identifying important issues of medical care, research, and education. The IOM brings to this mission more than two decades of experience in conducting independent analyses of pressing health problems that involve federal policy decisions.

As described in more detail in Chapter 2 of this report, the NAS has a history of

involvement with the Agent Orange issue. A major study in 1974 focused primarily on the possible ecological consequences of herbicides used in Vietnam, but an individually authored component of that report published eight years later reviewed its possible reproductive effects among the Vietnamese. In the early 1980s, two committees reviewed protocols for large, epidemiologic studies of the health effects in veterans. Between 1986 and 1990, an IOM committee reviewed protocols and the analytical methods of a series of epidemiologic studies of Vietnam veterans carried out by the Centers for Disease Control, though it did not contribute to the final conclusions reached in those studies. Thus, while the NAS and the IOM have been aware of the controversy surrounding the military use of Agent Orange and other herbicides in Vietnam, these past activities are quite different from the current study, of which the primary purpose is to determine whether there are health effects related to exposure to herbicides.

The 16-members of the Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides represent a wide range of expertise including occupational and environmental medicine, toxicology, epidemiology, pathology, clinical oncology, psychology, neurology, and biostatistics. The committee was chaired by Harold Fallon, M.D., Dean of the Medical School at the University of Alabama, Birmingham, and a member of the IOM. David Tollerud, M.D., M.P.H., Director of Occupational and Environmental Medicine at the University of Pittsburgh, served as vice-chair. Committee member Norman Breslow, Professor of the Department of Biostatistics of the University of Washington and also a member of the IOM, served as a liaison to the IOM Board on Health Promotion and Disease Prevention, which was responsible for overseeing this study. Biographical sketches of the other committee members and the professional staff appear in Appendix D.

All committee members were selected because they are leading authorities in their scientific fields, are well-respected by their colleagues and peers, have no conflicts of interest with regard to the matters under study, and, indeed, have taken no public positions concerning the potential health effects of herbicides in Vietnam veterans or related aspects of herbicide or dioxin exposure. The committee thus has provided a fresh analysis of this issue--which is both scientifically complex and emotionally charged--and this report reflects the committee's thorough and unbiased scientific judgments. As with all reports from the IOM, the committee's work was reviewed by an independent panel of distinguished experts.

Kenneth I. Shine
President, Institute of Medicine

Preface

The use of Agent Orange and other herbicides in Vietnam has stimulated concern and controversy ever since the U.S. began the military herbicide program in 1962. Questions regarding the effects of herbicides on health and the environment have persisted over several decades. Many veterans, who served their country in Vietnam at great personal sacrifice and hardship, face continuing uncertainty about whether a myriad of diseases and health effects are associated with exposure to the herbicides used in Vietnam. Some of these veterans and their families feel that their pain and suffering have been ignored and that these questions have not been adequately addressed.

In response to the concerns voiced by Vietnam veterans and their families, Congress called upon the National Academy of Sciences (NAS) to review the scientific evidence on the possible health effects of exposure to herbicides. The creation of the NAS Institute of Medicine's committee underscores the critical importance of approaching these questions from a scientific standpoint, yet the committee realized from the beginning that it could not conduct a credible scientific review without a full understanding of the experiences and perspectives of veterans. Thus, to supplement its standard scientific process, the committee opened several of its meetings to the public to allow veterans and other interested individuals to voice their concerns and opinions, to provide personal information about individual exposure to herbicides and associated health effects, and to educate the committee on recent research results and studies still under way. This information provided a meaningful backdrop for the numerous scientific articles that the committee reviewed and evaluated. The committee appreciates the efforts of everyone who presented information to it and acknowledges this valuable addition to the study process.

As the study progressed, two separate but interdependent themes became evident to the committee. First, this report is a scientific investigation of the potential health effects of exposure to the herbicides that were used in Vietnam and to dioxin (2,3,7,8-tetrachlorodibenzo-*para*-dioxin; TCDD), an unintentional contaminant of some of those herbicides. This theme is discussed first in Chapter 2, which provides a context for the investigation by relating the history of national concern about TCDD and herbicides and of efforts to address this concern. Chapter 4 reviews the toxicological data (based on laboratory studies and animal investigations) on these chemicals, with a focus on the TCDD contaminant because this area has been the object of more substantial scientific research. Most of the committee's work, however, focused on the review of epidemiologic studies. Chapters 8 through 11 analyze and present the committee's conclusions regarding the relationship between herbicide/TCDD exposure and 44 specific diseases and disorders. These diseases and disorders include different forms of cancer,

reproductive and developmental effects, neurobehavioral disorders, and other health effects, including chloracne and porphyria cutanea tarda. In order to understand the committee's approach to these reviews, Chapter 5 lays out the general methodological considerations that the committee used in evaluating this evidence, and Chapter 6 addresses the question of how to assess the nature of exposure to the substances in question, a critical element in evaluating the epidemiologic studies that were reviewed. Many of these studies addressed the health effects of people who were occupationally or environmentally exposed to TCDD or the herbicides in question, and many of the studies investigated more than one health outcome. Rather than summarize the methods of these studies each time they are considered, the committee's review and summary of the health effects are preceded by a complete and thorough methodologic description of all the studies under review–organized by the nature of the population exposed and by study methods–in Chapter 7.

The second theme in this report relates to the use of herbicides in Vietnam, the effects of exposure on Vietnam veterans, and the direction of future research efforts toward learning more than is currently known about these issues. The discussion of this theme also begins in Chapter 2, but the history of military operations in Vietnam, with a special focus on the herbicide program, is described in detail in Chapter 3. In addition to addressing exposure assessment in general, Chapter 6 discusses the methods that have been used to assess exposure to herbicides in studies of Vietnam veterans and summarizes what is currently known about the nature and extent of that exposure. Chapter 6 also proposes a new method of historical exposure reconstruction in studies of Vietnam veterans, a topic that is the focus for the committee's research recommendations in Chapter 12. In addition, Chapter 12 comments on existing studies of Vietnam veterans and makes recommendations about four specific programs mandated in Public Law 102-4.

CONDUCT OF THE STUDY

The committee worked on several fronts in conducting this study, always with the goal of seeking the most accurate information and advice from the widest possible range of knowledgeable sources. Consistent with procedures of the Institute of Medicine (IOM), the committee met in a series of closed sessions and working group meetings in which members could freely examine, characterize, and weigh the strengths and limitations of the available evidence. Given the nature of the controversy surrounding this issue, the committee deemed it vital to convene open meetings as well. Three public meetings were held during the course of the study, which provided timely forums for veterans and veterans service organizations, researchers, policymakers, and other interested parties to present their concerns, review their research, and exchange information directly with the committee members.

The first open meeting was held in September 1992. To solicit broad participation, the IOM committee sent announcements to nearly 1,000 persons known to have an interest in this issue. Names were gathered from veterans service organizations, scientific organizations, labor unions, environmental groups, government agencies, and numerous other sources, and news of

the meeting was circulated to approximately 1,500 media outlets nationwide. During this day-long public meeting, 25 persons made oral presentations. Because some individuals were unable to attend the public meeting, written statements were given equal weight to oral presentations; by April 15, 1993, 28 additional individuals had submitted written statements. Besides these statements, the committee received specially prepared analyses from several groups. All of this material was carefully considered by the committee over the course of the study. The oral presentations and written statements submitted to the committee are described in detail in Appendix B.

The second public meeting, a "Scientific Workshop on Exposure Assessment," took place in December 1992. The committee assembled 17 experts in various scientific fields--drawn from universities, veterans service organizations, federal agencies, and health groups--to discuss how exposure to Agent Orange, other herbicides, and TCDD is assessed in epidemiologic studies. Participants discussed records-based methods, as well as more recent biomedical research in which current dioxin levels are measured in the blood and tissue of individuals to estimate previous levels of exposure to TCDD (see Appendix B).

A third public meeting, held in February 1993, focused on the "Vietnam Experience." The committee heard from veterans who had served in the U.S. Marines, Navy, Army, and Air Force. Some of these individuals experienced extensive combat, frequently in areas sprayed with herbicides. Others had been directly involved in spraying herbicides from aircraft or "brown water" river patrol boats. The committee also heard from the Vietnam Veterans of America on the wartime experiences of women, thousands of whom served in Vietnam, primarily as military nurses.

In addition to its formal meetings, the committee actively and continuously sought information from, and explained its mission to, a broad array of individuals and organizations with interest or expertise in assessing the effects of exposure to herbicides. These interactions included frequent meetings with representatives of veterans service organizations, congressional committees, federal agencies, and scientific organizations. The committee heard from the public through several hundred telephone calls and letters, each of which received a response from the IOM staff.

The committee also benefited from the expert advice and reviews of consultants in toxicology, environmental health, neurotoxicology, autoimmune disorders, reproductive effects, and dermatological disorders, including porphyria cutanea tarda. A list of the background papers, their authors, and the experts consulted appears in Appendix B.

During the course of the committee's work, the Environmental Protection Agency (EPA) has been in the process of carrying out an open scientific reassessment of the health risks of dioxin to guide its regulatory policy. The committee has benefited from this effort by being able to read and consider draft scientific reports prepared for the EPA by independent scientists as part of this process, and by IOM committee members' and staff's attendance at the EPA's public meetings. However, the congressional charge to the IOM committee is substantially different than the EPA's review in at least two important ways: (1) the EPA is concerned only with dioxin, whereas the IOM is concerned with all of the herbicides used in Vietnam, and (2)

because of its regulatory focus, the EPA is more concerned with defining a dose-response relationship than the IOM committee felt was either necessary or feasible for Vietnam veterans.

The value of this continued, open, and wide-ranging dialogue between the IOM committee and the scientific community, veterans, policymakers, and citizens proved itself many times over and ultimately contributed to a more comprehensive report.

Most of the committee's work involved reviewing the scientific literature bearing on the association between herbicides or dioxin and various health outcomes. The committee or its staff read approximately 6,420 abstracts of scientific or medical articles which were then entered into a computerized bibliographic data base. From these, approximately 230 epidemiologic studies were chosen for detailed review and analysis. These included studies of people exposed to the herbicides in question in occupational and environmental settings, as well as studies of Vietnam veterans. The committee relied on the original publications themselves rather than on summaries or commentaries. Such secondary sources were used to check the completeness of the review. The committee also reviewed the primary and secondary literature on basic toxicological and animal studies related to dioxin and other herbicides in question. Appendix A describes the committee's literature review strategy in detail.

Controversy has surrounded the study of Agent Orange since the first questions of herbicide-related health effects in Vietnam veterans were raised more than 20 years ago. In the course of its work, the committee heard allegations of scientific misconduct and claims of a government conspiracy to suppress information on health effects, as well as serious disagreements among scientists about the interpretation of laboratory and clinical data. The committee was not charged with investigating or resolving these controversies, and it did not attempt to do so. The committee took these issues into consideration only to the extent that they had a direct bearing on the scientific results that are the subject of this review.

We believe that the committee has produced a comprehensive, unbiased scientific review of the available evidence regarding potential health effects of exposure to herbicides in Vietnam veterans. Although the conclusions and recommendations presented here will not end the controversy surrounding this issue, it is the committee's hope that this report will crystallize the current scientific information on this important topic and prompt further research to answer the remaining questions being asked by veterans and their families, the Department of Veterans Affairs, and Congress.

The committee wishes to acknowledge that this study could not have been done without the assistance of a number of people, many of whom are listed in Appendix B. A special acknowledgement is extended to Donald Whorton and Albert Munson, both of whom served for a brief period with the committee. The work of the Institute of Medicine staff deserves high praise. Thanks are extended to the professional staff, Susan Rogers, Diane Mundt, Cynthia Abel, Catharyn Liverman, Gail Charnely, and Jane Durch, for their input, advice, and support. Thanks are also extended to Catherine Wesner, the study's project assistant, who planned travel and meeting arrangements and provided assistance with editorial changes to the manuscript; Jana Katz, the committee's student intern, who assisted with literature searches and in compiling the literature data base; Thomas Burroughs, who worked with IOM staff members in drafting several sections of the report; Zoe Schneider who aided in the preparation of the final

manuscript; Andrea Posner, who proofread the final changes in the manuscript; and Florence Poillon, who provided excellent editorial skills. Finally, the committee wishes to recognize the major contributions of the study director, Michael Stoto. It is through his expert leadership that this report has come to fruition.

Harold Fallon, Chairman
David Tollerud, Vice-chairman

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Executive Summary

INTRODUCTION

Between 1962 and 1971, U.S. military forces sprayed nearly 19 million gallons of herbicides over approximately 3.6 million acres in Vietnam. The preparation known as Agent Orange accounted for approximately 11.2 million gallons of the total amount sprayed. Herbicides were used to strip the thick jungle canopy that helped conceal opposition forces, to destroy crops that enemy forces might depend upon, and to clear tall grass and bushes from around the perimeters of U.S. base camps and outlying fire support bases. Most large-scale spraying operations were conducted using airplanes and helicopters, but considerable quantities of herbicides were sprayed from boats and ground vehicles, as well as by soldiers wearing back-mounted equipment. Spraying began in 1962 and increased greatly in 1967. After a scientific report in 1969 concluded that one of the primary chemicals used in Agent Orange, namely, 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) could cause birth defects in laboratory animals, U.S. forces suspended use of this herbicide in 1970 and halted all herbicide spraying in Vietnam the next year.

As the decade wore on, concern about possible long-term health consequences of Agent Orange and other herbicides heightened, fueled in particular by reports from growing numbers of Vietnam veterans that they had developed cancer or fathered handicapped children, which they attributed to wartime exposure to the herbicides. Along with the concerns of Vietnam veterans, public awareness increased because of reports of health concerns surrounding occupational and environmental exposure to dioxin--more specifically, 2,3,7,8-tetrachlorodibenzo-*p*-dioxin (2,3,7,8-TCDD), informally known as TCDD--a contaminant of 2,4,5-T. Thousands of scientific studies have since been conducted, numerous government hearings have been held, and veterans organizations have pressed for conclusive answers, but the question of the health effects of herbicide exposure in Vietnam remains shrouded in controversy and mistrust. Indeed some veterans organizations, researchers, and public interest organizations remain skeptical that the issue has received full and impartial consideration by the Department of Veterans Affairs (DVA; formerly the Veterans Administration) and other federal agencies.

Faced with this lingering uncertainty and demands that the concerns of veterans be adequately addressed, the U.S. Congress passed Public Law 102-4, the "Agent Orange Act of 1991." This legislation directed the Secretary of Veterans Affairs to request that the National

Academy of Sciences conduct a comprehensive review and evaluation of available scientific and medical information regarding the health effects of exposure to Agent Orange, other herbicides used in Vietnam, and their components, including dioxin.

In February 1992, the Institute of Medicine (IOM) of the National Academy of Sciences signed an agreement with the DVA to review and summarize the strength of the scientific evidence concerning the association between herbicide exposure during Vietnam service and each disease or condition suspected to be associated with such exposure. The IOM was also asked to make recommendations concerning the need, if any, for additional scientific studies to resolve areas of continuing scientific uncertainty and to comment on four particular programs mandated in Public Law 102-4.

To carry out the study, the IOM established the Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides. In conducting its study, the committee operated independently of the DVA and other government agencies. The committee was not asked to and did not make judgments regarding specific cases in which individual Vietnam veterans have claimed injury from herbicide exposure; this was not part of its congressional charge. Rather, the study provides scientific information for the Secretary of Veterans Affairs to consider as the DVA exercises its responsibilities to Vietnam veterans.

ORGANIZATION AND FRAMEWORK

The framework for this report reflects the size and complexity of the committee's task. The committee felt that an evaluation of the health effects of exposure to herbicides in Vietnam veterans would not be complete without a historical review of the Agent Orange controversy. The report begins in Chapter 2 by tracing more than two decades of public concern about the military use of herbicides during the war in Vietnam, in addition to public concern over various environmental and occupational exposures to herbicides and dioxin that arose in parallel to veterans' concerns, and describes federal and state responses to this national dilemma.

Chapter 3 provides background information on the nature and extent of potential exposure of Vietnam veterans to herbicides, based on information about the military herbicide program. Some 3 million military personnel served in or near Vietnam, and as one historian notes, "there was no 'typical' U.S. soldier in Vietnam . . . Americans who served there went through many varied experiences--partly because the quality of the war varied in different areas of the country, and partly because the nature changed over time" (Karnow, 1991). Individual experiences also varied by branch of service, military occupation, rank, and type of military unit. As reflected in military records, the use of herbicides was varied as well. Starting in 1962 and peaking in the late 1960s, seven different herbicide formulations were used in varying quantities for a variety of purposes in different parts of the country; approximately 65 percent of these herbicides were contaminated by TCDD, in varying concentrations. Aerial spraying of herbicides by Operation Ranch Hand accounted for approximately 86 percent of all spraying and was well documented; other spraying by helicopters and from trucks or backpacks was poorly documented.

Chapter 4 provides toxicological background on the biologic plausibility of health effects that may occur in humans after accidental or occupational exposure to herbicides and TCDD components. This chapter describes the biological and chemical properties of the compounds in question as determined by basic research and animal studies. TCDD administered to laboratory animals interacts with an intracellular protein called the Ah receptor. This interaction appears to play a role in a number of health effects observed in animals. Because humans also have intracellular proteins that have been identified as Ah receptors, it is plausible that interactions between TCDD and these receptors could play a role in human health effects. In contrast to TCDD, the effects of the herbicides do not appear to be mediated through interactions with intracellular receptors. TCDD has also been shown to have a wide range of effects in laboratory animals on growth regulation, hormone systems, and other factors associated with the regulation of activities in normal cells. In addition, TCDD has been shown to cause cancer in laboratory animals at a variety of sites. If TCDD has similar effects on cell regulation in humans, it is plausible that it could have an effect on human cancer incidence. In contrast to TCDD, there is no convincing evidence in animals of, or mechanistic basis for, carcinogenicity or other health effects of any of the herbicides, although they have not been studied as extensively as TCDD.

In fulfilling its charge of judging whether each of a set of human health effects is associated with exposure to herbicides or dioxin, most of the committee's efforts concentrated on reviewing and interpreting epidemiologic studies. The committee began its evaluation presuming neither the existence nor the absence of association. It has sought to characterize and weigh the strengths and limitations of the available evidence. These judgments have both quantitative and qualitative aspects. They reflect the nature of the exposures, health outcomes, and populations at issue; the characteristics of the evidence examined; and the approach taken to evaluate that evidence. To facilitate independent assessment of the committee's conclusions, Chapter 5 describes as explicitly as possible the methodological considerations that guided the committee's review and its process of evaluation.

In reviewing the literature, the committee discerned that the existing epidemiologic data base is severely lacking in quantitative measures of individual exposure to herbicides and dioxin. Assessment of the intensity and duration of individual exposures is a key component in determining whether specific health outcomes are associated with exposure to dioxin or other chemicals found in the herbicides used in Vietnam. Although different approaches have been used to estimate exposure in Vietnam veterans and in others exposed occupationally or environmentally, each approach is limited in its ability to determine precisely the degree and level of individual exposure. The problems associated with each of these approaches are discussed in detail in Chapter 6. New biochemical techniques that can detect small amounts of TCDD in the blood many years after exposure have some merit, especially for detecting *group* differences. However, because of common background exposure of all Americans to TCDD, poorly understood variations among individuals in TCDD metabolism, and relatively large measurement errors, *individual* TCDD serum levels are usually not meaningful. Furthermore, because not all herbicides used in Vietnam contained TCDD, serum TCDD levels are not good indicators of overall exposure to herbicides. Chloracne has been used in epidemiologic studies

as a biomarker for TCDD exposure, but the data indicate that it is neither sensitive nor specific. It is usually not long lasting, is difficult to diagnose, and is not at all sensitive to exposure to herbicides that are not contaminated with TCDD.

Although definitive data are lacking, the available quantitative and qualitative evidence about herbicide exposure summarized in Chapter 6 suggests that Vietnam veterans as a group had substantially lower exposure to herbicides and dioxin than the subjects in many occupational studies. The participants in Operation Ranch Hand are an exception to this pattern, and it is likely that others among the approximately 3 million men and woman who served in Vietnam were exposed to herbicides at levels associated with health effects. Thus, in the committee's judgment, a sufficiently large range of exposures may exist among Vietnam veterans to conduct a valid epidemiologic study for certain health outcomes (see research recommendations below).

Due, in part, to the uncertain validity of exposure measurements in many of the studies of veterans, the committee decided to review studies of other groups potentially exposed to the herbicides used in Vietnam and TCDD, especially phenoxy herbicides, including 2,4-dichlorophenoxyacetic acid (2,4-D) and 2,4,5-T, chlorophenols, and other compounds. These groups include chemical production and agricultural workers, residents of Vietnam, and people exposed heavily to herbicides or dioxins as a result of residing near the site of an accident or a toxic waste dumping area. The committee felt that considering studies of other groups could help address the issue of whether these compounds might be associated with particular health outcomes, even though these results would have only an indirect bearing on the increased risk of disease in veterans themselves. Some of these studies, especially those of workers in chemical production plants, provide stronger evidence about health effects than studies of veterans because exposure was generally more easily quantified and measured. Furthermore, the general level and duration of exposure to the chemicals were greater and the studies were of sufficient size to examine the health risks among those with varying levels of exposure.

Because the committee relied on many of the same epidemiologic studies when assessing potential associations with various health effects, Chapter 7 provides a framework for the methods used in the epidemiologic studies on which the committee based its report. The nature of the exposure to herbicides and herbicide components varied substantially for each; therefore, both the organization of the chapter (which is structured to reflect similarities and differences in the populations studied) and the methodologic issues that are summarized for each study emphasize exposure.

CONCLUSIONS ABOUT HEALTH OUTCOMES

Chapters 8 through 11 provide a detailed review of the epidemiologic studies evaluated by the committee and their implications for cancer, reproductive, neurobehavioral, and other health effects. The committee's specific mandate was to determine, if possible,

1. whether there is a statistical association between the suspect diseases and herbicide use, taking into account the strength of the scientific evidence and the appropriateness of the methods used to detect the association;
2. the increased risk of disease among individuals exposed to herbicides during service in Vietnam; and
3. whether there is a plausible biologic mechanism or other evidence of a causal relationship between herbicide exposure and a disease.

As detailed in Chapter 5, the committee addressed the first part of this charge by assigning each of the health outcomes under study into one of the four categories listed in Table 1-1 on the basis of the epidemiologic evidence that it reviewed. The specific rationale for each of the findings summarized in this table is given in Chapters 8 through 11. The second part of the charge is addressed at the end of this section. The committee's response to the third part of the charge is summarized in general terms in Chapter 4, and specific findings for each health outcome are also given in Chapters 8 through 11.

The definitions of the categories and the criteria for assigning a particular health outcome to them are described in Table 1-1. Consistent with the charge to the Secretary of Veterans Affairs in Public Law 102-4, the distinctions between categories are based on "statistical association," not on causality, as is common in scientific reviews. The committee was charged with reviewing the scientific evidence, rather than making recommendations regarding DVA policy, and Table 1-1 is not intended to imply or suggest any policy decisions, which must rest with the Secretary.

Health Outcomes with Sufficient Evidence of an Association

The committee found sufficient evidence of an association with herbicides and/or TCDD for three cancers: soft tissue sarcoma, non-Hodgkin's lymphoma, and Hödgkin's disease. For cancers in this category, a positive association between herbicides and the outcome must be observed in studies in which chance, bias, and confounding can be ruled out with reasonable confidence. The committee regards evidence from several small studies that are free from bias and confounding, and show an association that is consistent in magnitude and direction, as sufficient evidence for an association.

Soft tissue sarcomas are a rare but diverse group of tumors that share a common International Classification of Diseases code but have a wide variety of forms and causes. The strongest evidence for an association between STS and exposure to phenoxy herbicides comes from a series of case-control studies involving a total of 506 cases conducted by Hardell and colleagues in Sweden (Hardell and Sandstrom, 1979; Eriksson et al., 1981; Hardell and Eriksson, 1988; Eriksson et al., 1990) that show an association between STS and exposure to

TABLE 1-1 Summary of Findings in Occupational, Environmental, and Veterans Studies Regarding the Association Between Specific Health Problems and Exposure to Herbicides

Sufficient Evidence of an Association

Evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between herbicides and the outcome in studies in which chance, bias, and confounding could be ruled out with reasonable confidence. For example, if several small studies that are free from bias and confounding show an association that is consistent in magnitude and direction, there may be sufficient evidence for an association. There is sufficient evidence of an association between exposure to herbicides and the following health outcomes:

Soft tissue sarcoma
Non-Hodgkin's lymphoma
Hodgkin's disease
Chloracne
Porphyria cutanea tarda (in genetically susceptible individuals)

Limited/Suggestive Evidence of an Association

Evidence is suggestive of an association between herbicides and the outcome but is limited because chance, bias, and confounding could not be ruled out with confidence. For example, at least one high-quality study shows a positive association, but the results of other studies are inconsistent. There is limited/suggestive evidence of an association between exposure to herbicides and the following health outcomes:

Respiratory cancers (lung, larynx, trachea)
Prostate cancer
Multiple myeloma

Inadequate/Insufficient Evidence to Determine Whether an Association Exists

The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association. For example, studies fail to control for confounding, have inadequate exposure assessment, or fail to address latency. There is inadequate or insufficient evidence to determine whether an association exists between exposure to herbicides and the following health outcomes:

Hepatobiliary cancers
Nasal/nasopharyngeal cancer
Bone cancer
Female reproductive cancers (breast, cervical, uterine, ovarian)
Renal cancer
Testicular cancer
Leukemia
Spontaneous abortion
Birth defects
Neonatal/infant death and stillbirths
Low birthweight
Childhood cancer in offspring
Abnormal sperm parameters and infertility

TABLE 1-1 (continued)

Inadequate/Insufficient Evidence to Determine Whether an Association Exists (continued)

Cognitive and neuropsychiatric disorders
Motor/coordination dysfunction
Peripheral nervous system disorders
Metabolic and digestive disorders (diabetes, changes in liver enzymes, lipid abnormalities, ulcers)
Immune system disorders (immune modulation and autoimmunity)
Circulatory disorders
Respiratory disorders

Limited/Suggestive Evidence of No Association

Several adequate studies, covering the full range of levels of exposure that human beings are known to encounter, are mutually consistent in not showing a positive association between exposure to herbicides and the outcome at any level of exposure. A conclusion of "no association" is inevitably limited to the conditions, level of exposure, and length of observation covered by the available studies. *In addition, the possibility of a very small elevation in risk at the levels of exposure studied can never be excluded.* There is limited/suggestive evidence of *no* association between exposure to herbicides and the following health outcomes:

Skin cancer
Gastrointestinal tumors (stomach cancer, pancreatic cancer, colon cancer, rectal cancer)
Bladder cancer
Brain tumors

NOTE: "Herbicides" refers to the major herbicides used in Vietnam: 2,4-D (2,4-dichlorophenoxyacetic acid); 2,4,5-T (2,4,5-trichlorophenoxyacetic acid) and its contaminant TCDD (2,3,7,8-tetrachlorodibenzo-*p*-dioxin); cacodylic acid; and picloram. The evidence regarding association is drawn from occupational and other studies in which subjects were exposed to a variety of herbicides and herbicide components.

phenoxy herbicides, chlorophenols, or both. Although these studies have been criticized, the committee feels that there is insufficient justification to discount the consistent pattern of elevated risks, and the clearly described and sound methods employed. These findings are supported by a significantly increased risk in the NIOSH study (SMR=9.2, CI 1.9-27.0) for the production workers most highly exposed to TCDD (Fingerhut et al., 1991), and a similar increased risk in the IARC cohort (SMR=6.1, CI 1.7-15.5) for deaths that occurred between 10 and 19 years after the first exposure (Saracci et al., 1991). These are the two largest, as well as the most highly exposed occupational cohorts. Some studies in other occupational, environmental, and veterans groups showed an increased risk for STS, but the results were commonly nonsignificant possibly because of small sample sizes related to the relative rarity of STS in the population. Because of difficulties in diagnosing this group of tumors, the epidemiologic studies reviewed by the committee were inconsistent with regard to the specific types of tumors included in the analyses. The available data did not permit the committee to determine whether specific forms of STS were or were not associated with TCDD and/or herbicides. Therefore, the committee's findings relate to the class as a whole.

Non-Hodgkin's lymphoma includes a group of malignant lymphomas, that is, neoplasms derived from lymphoreticular cells in lymph nodes, bone marrow, spleen, liver, or other sites in the body. One large, well-conducted case-control study in Sweden by Hardell and colleagues (1981) examined NHL and Hodgkin's disease together and found an odds ratio of 6.0 (CI 3.7-9.7) based on 105 cases for exposure to phenoxy acids or chlorophenols, and these results held up under further investigation of the validity of exposure assessment and other potential biases (Hardell, 1981). A more recent case-control study by Persson and colleagues (1989) showed increased risk for NHL in those exposed to phenoxy acids (OR=4.9, CI 1.0-27.0), based on a logistic regression analysis of 106 cases. Other studies of farmers and agricultural workers are generally positive for an association between NHL and herbicides/TCDD; however, only some are significant. All of the studies of U.S. agricultural workers reviewed showed elevated relative risks (although none were significant), and two NCI studies of farmers in Kansas and Nebraska (Hoar et al., 1986; Zahm et al., 1990) show patterns of increased risk linked to use of 2,4-D. The CDC Selected Cancers Study found an increased risk of NHL in association with service in Vietnam; other studies of veterans, generally with small sample sizes, are consistent with an association. In contrast, studies of production workers, including the largest, most heavily exposed cohorts (Fingerhut et al., 1991; Saracci et al., 1991; Zober et al., 1990; Manz et al., 1991) indicate no increased risk. Thus, unlike most of the other cancers studied by the committee for which the data do not distinguish between the effects of herbicides and TCDD, the available epidemiologic data suggest that the phenoxy herbicides, including 2,4-D, rather than TCDD may be associated with non-Hodgkin's lymphomas.

Hodgkin's disease, also a malignant lymphoma, is a neoplastic disease characterized by progressive anemia and enlargement of lymph nodes, spleen, and liver. Fewer studies have been conducted of HD in relation to exposure to herbicides or TCDD than have been conducted of STS or NHL, but the pattern of results is strikingly consistent. The 60 HD cases in the study by Hardell and colleagues (1981) were later examined by Hardell and Bengtsson (1983),

who found odds ratios of 2.4 (CI 0.9-6.5) for low-grade exposure to chlorophenols and 6.5 (CI 2.7-19.0) for high-grade exposures. Persson and colleagues' study (1989) of 54 HD cases showed a large, but not statistically significant, OR=3.8 (CI 0.5-35.2) for exposure to phenoxy acids. Furthermore, nearly all of the 13 case-control and agricultural worker studies show increased risk for HD, although only a few of these results are statistically significant. As with NHL, even the largest studies of production workers exposed to TCDD do not indicate an increased risk. The few studies of HD in Vietnam veterans tend to show elevated risks, all but one are not statistically significant.

When these three cancers (STS, NHL, and HD) are considered as a whole, it is noteworthy that the strongest evidence for an association with exposure to phenoxy herbicides is the series of case-control studies conducted by Hardell and colleagues and the cohort studies of herbicide applicators and agricultural workers. Studies in other countries are sometimes positive, but not as consistently. Whether this reflects higher typical exposure levels in workers in the countries studied, genetic differences in susceptibility to these diseases, the fact that more intensive studies have taken place, or other risk factors is not known. With regard to STS, the study of Woods and colleagues (1987) suggests that both exposure levels and genetic differences are at play. However, although there may be differences from population to population in the increased risk associated with exposure to herbicides and TCDD, the committee regards the available evidence as sufficient to indicate that there is a statistical association between the herbicides used in Vietnam and STS, NHL, and HD.

The other two health outcomes for which the committee found sufficient evidence of an association with herbicides or TCDD are both skin conditions (see Chapter 11). Chloracne is a specific acne-like skin disorder characterized by exposure to TCDD or related chemicals (but not herbicides). Porphyria cutanea tarda (PCT), which is characterized by thinning and blistering of the skin in sun-exposed areas, is an uncommon disease in which porphyrins are abnormally metabolized. Only genetically predisposed individuals have been shown to develop PCT after TCDD exposure. Both chloracne and PCT have been shown in animal and human studies to be associated with TCDD per se. The clinical evidence for these conditions suggests that onset occurs soon after exposure to TCDD; however, the conditions subside (although perhaps slowly) after exposure ceases.

Health Outcomes with Limited/Suggestive Evidence of An Association

The committee found limited/suggestive evidence of an association for three other cancers: respiratory cancers, prostate cancer, and multiple myeloma. For outcomes in this category, the evidence must be suggestive of an association between herbicides and the outcome, but may be limited because chance, bias, or confounding could not be ruled out with confidence. Typically, at least one high-quality study indicates a positive association, but the results of other studies may be inconsistent.

Among the many epidemiologic studies of respiratory cancers (specifically cancers of the lung, larynx, and trachea), positive associations were found consistently only in those studies in

which TCDD or herbicide exposures were probably high and prolonged, especially the largest, most heavily exposed cohorts of chemical production workers exposed to TCDD (Zober et al., 1990; Fingerhut et al., 1991; Manz et al., 1991; Saracci et al., 1991) and herbicide applicators (Axelson and Sundell, 1974; Riihimaki et al., 1982; Blair, 1983; Green, 1991). Studies of farmers tended to show a decreased risk of respiratory cancers (perhaps due to lower smoking rates), and studies of Vietnam veterans are inconclusive. The committee felt that the evidence for this association was limited/suggestive rather than sufficient because of the inconsistent pattern of positive findings across populations with various degrees of exposure and because the most important risk factor for respiratory cancers--cigarette smoking--was not fully controlled for or evaluated in all studies.

Several studies have shown elevated risk for prostate cancer in agricultural or forestry workers. In a large cohort study of Canadian farmers (Morrison et al., 1993), an increased risk of prostate cancer was associated with herbicide spraying, and increasing risk was shown with increasing number of acres sprayed. For the entire cohort, the relative risk for prostate cancer and spraying at least 250 acres was 1.2 (CI 1.0-1.5). When the analysis was restricted to the farmers most likely to be exposed to phenoxy herbicides or other herbicides, and those with no employees, no custom workers to do the spraying for them, and age between 45-69 years, the test for trend over increasing number of acres sprayed was significant. The risk was elevated a study of USDA forest conservationists (OR=1.6, CI 0.9-3.0) (Alavanja et al., 1989), and a case-control study of white male Iowans who died of prostate cancer (Burmeister et al., 1983) found a significant association (OR=1.2) that was not associated with any particular agricultural practice. These results are strengthened by a consistent pattern of nonsignificant elevated risks in studies of chemical production workers in the United States and other countries, agricultural workers, pesticide applicators, paper and pulp workers, and the Seveso population. Studies of prostate cancer among Vietnam veterans or following environmental exposures have not consistently shown an association. However, prostate cancer is generally a disease of older men, and the risk among Vietnam veterans would not be detectable in published epidemiologic studies. Because there was a strong indication of a dose-response relationship in one study and a consistent positive association in a number of others, the committee felt that the evidence for association with herbicide exposure was limited/suggestive for prostate cancer.

Multiple myeloma, a cancer of specific bone marrow cells, has been less extensively studied than other lymphomas, but a consistent pattern of elevated risks appears in the studies that have been conducted. Ten studies of agricultural and forestry workers provide information on MM risk in relation to herbicide or pesticide exposure. All demonstrated an odds ratio or SMR greater than 1.0; seven did so at a statistically significant level. This finding is made more specific for herbicide exposure by subanalyses in four of these studies (Burmeister et al., 1983; Cantor and Blair, 1984; Alavanja et al., 1989; Boffetta et al., 1989) that suggest higher risks for those exposed to herbicides, and higher risks for the studies of herbicide applicators (Riikimaki et al., 1983; Swaen et al., 1992). The committee determined that the evidence for this association was limited/suggestive because the individuals in the existing studies--mostly farmers--have, by the nature of their occupation, probably been exposed to a range of

potentially carcinogenic agents other than herbicides and TCDD. Multiple myeloma, like non-Hodgkin's lymphoma and Hodgkin's disease for which there is stronger epidemiologic evidence of an association, is derived from lymphoreticular cells, which adds to the biologic plausibility of an association.

Health Outcomes with Limited/Suggestive Evidence of No Association

For a small group of cancers the committee found a sufficient number and variety of well-designed studies to conclude that there is limited/suggestive evidence of *no* association between these cancers and TCDD or the herbicides under study. This group includes gastrointestinal tumors (colon, rectal, stomach, and pancreatic), skin cancer, brain tumors, and bladder cancer. For outcomes in this category, several adequate studies covering the full range of levels of exposure that human beings are known to encounter are mutually consistent in not showing a positive association between exposure to herbicides and the outcome at any level of exposure, and which have relatively narrow confidence intervals. A conclusion of "no association" is inevitably limited to the conditions, level of exposure, and length of observation covered by the available studies. In addition, the possibility of a very small elevation in risk at the levels of exposure studied can never be excluded.

The data on colon cancer exemplify the situation that led the committee to say that there was evidence of no association between a cancer and exposure to herbicides and/or TCDD. Colon cancer is relatively common, so an increase in the risk of these cancers would be relatively easy to detect in occupational studies. The epidemiologic studies reviewed by the committee that address colon cancer include a mixture of occupational studies of various types, environmental studies, and studies of Vietnam veterans. Some of the studies such as the NIOSH (Fingerhut et al., 1991) and IARC (Saracci et al., 1991) cohorts are large and have relatively high exposures. The number of studies with estimated relative risks above and below 1.0 are roughly evenly distributed, and a number of studies have tight confidence intervals that include 1.0. The NIOSH study, for instance, based on 25 exposed cases, finds an odds ratio of 1.2 with a 95 percent confidence interval of 0.8 to 1.8. The IARC study finds an odds ratio of 1.1 (CI 0.8-1.5) based on 41 cases. Thus, this pattern suggests that there is no association between herbicides/TCDD and colon cancer, at least in the situations represented in the available studies.

Health Outcomes with Inadequate/Insufficient Evidence to Determine Whether an Association Exists

The scientific data for the remainder of the cancers and other diseases reviewed by the committee were inadequate or insufficient to determine whether an association exists. For cancers in this category, the available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association.

For example, studies fail to control for confounding or have inadequate exposure assessment.

This group includes hepatobiliary cancers, nasal/nasopharyngeal cancer, bone cancer, female reproductive cancers (breast, cervical, uterine, ovarian), renal cancer, testicular cancer, and leukemia. For example, there are relatively few occupational, environmental, or veterans studies of liver cancer, and most of these are small in size and have not controlled for life-style-related risk factors. One of the largest studies (Hardell et al., 1984) indicates an increased risk for liver cancer and exposure to herbicides, but another study of Swedish agricultural workers (Wiklund, 1983) estimates a relative risk that is significantly less than 1.0. The estimated relative risks from other studies are both positive and negative. As a whole, when bearing in mind the methodological difficulties associated with most of the few existing studies, the evidence regarding liver cancer is not convincing about either an association with herbicides/TCDD or the lack of an association.

The epidemiologic evidence for an association between exposure to herbicides and leukemia comes primarily from studies of farmers and residents of Seveso, Italy. The observed overall relative risk for leukemia mortality and incidence in Seveso was elevated, but not significantly. A number of studies of farmers that the committee found convincing for NHL, HD, or MM also show a consistently elevated risk of leukemia, but these results are not necessarily due to herbicide use because confounding exposures were not controlled for adequately in the analyses of these studies and because when farmers are stratified by suspected use of herbicide, the incidence of leukemia is generally not elevated. Some studies of chemical workers found an increased risk of leukemia, but the number of cases was small in all of these studies. The available data on Vietnam veterans are generally not conclusive because the exposure data are inadequate for the cohort being studied. Small sample sizes weaken the studies of the Ranch Hands or Chemical Corps, where excesses are not likely to be detected.

A number of occupational, environmental, and Vietnam veteran studies were available for assessing the association between herbicide and TCDD exposures and reproductive outcomes. These studies generally reported no association with any of the reproductive outcomes examined by the committee--spontaneous abortion, birth defects, stillbirth, neonatal and infant death, low birthweight, childhood cancer, or altered sperm parameters and infertility. However, given the small sample sizes, the lack of consistent findings, and inadequate exposure classification in most studies, the evidence is considered inadequate for determination of an association.

Studies of neurotoxic effects of herbicides or TCDD were also inadequate for determining whether an association exists between exposures and chronic cognitive or neuropsychiatric disorders, motor/coordination dysfunction, and peripheral nervous system disorders. As a group the studies have not applied uniform operational definitions of neurobehavioral disorders. Information on individual exposure was often inadequate and complicated by exposure to multiple chemicals, and only a limited number of studies provided sufficient comparison group data. Reported abnormalities have ranged from mild and reversible to severe and chronic. While the chances of detecting subtle central nervous system disorders 20 years after exposure are small given the assessment tools currently available, the committee recognized that it may be possible for subtle changes that occurred earlier in life to manifest themselves in later adult

life when compounded by the normal aging process. Therefore, while the currently available evidence is insufficient, study of the interactive effects of exposure to herbicides and TCDD with age on neurobehavioral functioning are encouraged. In addition, observations from followup of veterans and some environmental studies warrant further investigation of motor/sensory/coordination problems in exposed persons.

Other health effects examined by the committee for which the evidence was determined to be insufficient included several metabolic and digestive disorders (diabetes, changes in liver enzymes, lipid abnormalities, and gastrointestinal ulcers), immune system disorders, and circulatory and respiratory disorders. Assessment of these disorders in association with herbicides and TCDD involved the medical evaluation of a wide array of critical signs and symptoms, laboratory parameters, and other diagnostic tools. Studies of these health effects were limited by poor exposure measures, generally small sample sizes, and the lack of assessment of independent risk factors for certain outcomes, such as smoking and certain circulatory and respiratory disorders, or alcohol use and ulcers.

Increased Risk in Vietnam Veterans

Although there have been numerous health studies of Vietnam veterans, most have been hampered by relatively poor measures of exposure to herbicides or TCDD, in addition to other methodological problems. In Table 1-1, most of the evidence on which the findings are based comes from studies of people exposed to dioxin or herbicides in occupational and environmental settings, rather than from studies of Vietnam veterans. The committee found this body of evidence sufficient for reaching the conclusions about statistical associations between herbicides and health outcomes summarized in Table 1-1; however, the lack of adequate data on Vietnam veterans per se complicates the second part of the committee's charge, which is to determine the increased risk of disease among individuals exposed to herbicides during service in Vietnam. To estimate the magnitude of risk for a particular health outcome among herbicide-exposed Vietnam veterans, quantitative information about the dose-time-response relationship for each health outcome in humans, information on the extent of herbicide exposure among Vietnam veterans, and estimates of individual exposure are needed. Given the large uncertainties that remain about the magnitude of potential risk from exposure to herbicides in the studies that have been reviewed (Chapters 8-11), the inadequate control for important confounders, and the uncertainty about the nature and magnitude of exposure to herbicides in Vietnam (Chapter 6), none of the ingredients necessary for a quantitative risk assessment are available. Thus, it is not possible for the committee to quantify the degree of risk likely to be experienced by veterans because of their exposure to herbicides in Vietnam. The available quantitative and qualitative evidence about herbicide exposure among various groups studied suggests that Vietnam veterans as a group (except those with documented high exposures, such as participants in Operation Ranch Hand) had lower exposure to herbicides and TCDD than the subjects in many occupational and environmental studies. However, individual

veterans who had very high exposures to herbicides could have risks approaching those in the occupational and environmental studies.

RESEARCH RECOMMENDATIONS

The committee was also asked to make recommendations concerning the need, if any, for additional scientific studies to resolve areas of continuing scientific uncertainty concerning the health effects of the herbicides used in Vietnam. Based on its review of the available epidemiologic evidence and a consideration of the quality of exposure information available in existing studies, especially of Vietnam veterans, the committee concluded that a series of epidemiologic studies of veterans could yield valuable information if a new, valid exposure reconstruction model could be developed. The committee also sees value in continuing the existing Ranch Hand study and expanding it to include Army Chemical Corps veterans. The committee's research recommendations emphasize studies of Vietnam veterans, rather than general toxicologic or epidemiologic studies of occupationally or environmentally exposed populations. A substantial amount of research on the toxicology and epidemiology of herbicides and herbicide components is already under way in the United States and abroad. Indeed, many of the studies on which the committee's conclusions are based have been published since 1991. Although not targeted specifically to Vietnam veterans, it is likely that this research will also contribute to the knowledge of potential health effects in this population.

Epidemiologic Studies of Vietnam Veterans

The committee makes the following recommendations regarding epidemiologic studies of Vietnam veterans.

Recommendation 1. The committee endorses continued follow-up of the Air Force Ranch Hand cohort and its comparison group, and recommends that members of the Army Chemical Corps and an appropriate comparison group be followed in a similar study. An independent, nongovernmental scientific panel should be established to review and approve a new, expanded research protocol for both study populations, and to commission and direct a common analysis of the results.

Much can be learned by reanalysis of existing data or more in-depth analysis of data expected from current research programs investigating the health of Vietnam veterans, including the Air Force Ranch Hand study and DVA studies of other highly exposed Vietnam veterans such as members of the Chemical Corps. Priorities for specific health outcomes are

discussed after recommendation 6. Public perception of the federal government's interest in the outcome of these studies suggests the need for studies of the health of Vietnam veterans to be conducted by a nongovernmental organization. Ranch Hand's excellent participation rate argues that components of the Department of Defense or the DVA continue to conduct follow-up examinations of the Ranch Hand and Army Chemical Corps cohorts. However, an independent, nongovernmental scientific panel is needed to oversee the analyses of resulting data in order to satisfy the public's concern about impartiality and scientific credibility.

As discussed in Chapter 6, one of the major problems with the interpretation of existing studies is the frequent lack of appropriate measures of exposure to herbicides or TCDD; however, the committee finds that it may be possible to develop better exposure measures for Vietnam veterans. In particular, Chapter 6 proposes measures that are not dependent on serum TCDD levels (which the committee finds inappropriate for the full range of herbicide exposures) but instead recommends the use of less formal sources of historical information about base perimeter spraying and other relevant exposures, as discussed below in Recommendation 4. Thus, the committee concludes that certain further research efforts using new measures of exposure to herbicides in Vietnam are both necessary and potentially feasible. However, each of the possible measures that the committee has considered involves some degree of nondifferential misclassification bias, and the effect of this bias on risk estimates would likely be to underestimate true effects if they existed, possibly to the point that they would not be detected. In particular, the committee recommends that the following steps be taken prior to undertaking new epidemiologic studies of Vietnam veterans, for the reasons described below.

Recommendation 2. The Department of Defense and the Department of Veterans Affairs should identify Vietnam service in the computerized index of their records.

Chapter 3 notes that Vietnam service is not a "flagged item" on the computerized index of military personnel records archived at the National Personnel Records Center, which is maintained by the General Services Administration, under an agreement with the Department of Defense, in St. Louis, Missouri. Therefore, the computerized index of the record system does not allow for searches or selection of records of individuals who have served in Vietnam. The lack of an indicator of Vietnam service complicates every epidemiologic study of veterans based on military records and leads to methodologic inconsistencies among studies in defining the population under consideration. Adding this indicator to the computerized data base would facilitate future mortality studies based on computerized records, thereby increasing accuracy and decreasing cost, and would also simplify other epidemiologic studies of health outcomes in Vietnam veterans. All servicemen and women who were stationed in Vietnam or in the Vietnam theater during the Vietnam era should be identified in the records.

Recommendation 3. Biomarkers for herbicide exposure should be developed further.

Considerable uncertainty remains about the use of current or future serum TCDD levels as indicators of past exposure to dioxin in Vietnam veterans. Further research on the toxicokinetics of TCDD (2,3,7,8-tetrachlorodibenzo-*p*-dioxin) is needed to permit more accurate extrapolation from current serum TCDD measurements to past exposures. Development of new biomarkers for exposure to herbicides, per se, also would be useful.

Recommendation 4. A nongovernmental organization with appropriate experience in historical exposure reconstruction should be commissioned to develop and test models of herbicide exposure for use in studies of Vietnam veterans.

Exposure assessment has been a weak aspect of most epidemiologic studies of Vietnam veterans. The military reports and personal testimony reviewed by the committee suggest that a sufficient range of exposure to herbicides may exist among Vietnam veterans for valid epidemiologic studies of certain health outcomes, and the committee believes that it is possible to develop valid exposure reconstruction models for such studies by using the methods of historical exposure reconstruction. Historical exposure reconstruction requires substantial professional judgment, and the results might be questioned if developed by a government agency; therefore, the committee recommends that the DVA arrange for a nongovernmental organization with appropriate experience in historical exposure reconstruction to develop and test potential models of herbicide exposure for use in studies of Vietnam veterans.

Recommendation 5. The exposure reconstruction models developed according to Recommendation 4 should be evaluated by an independent, nongovernmental scientific panel established for this purpose.

Herbicide exposure reconstruction models for Vietnam veterans must be thoroughly evaluated before epidemiologic studies based on these models proceed. The committee has identified three possible approaches to such an evaluation, which are discussed in more detail in Chapter 6: (1) internal consistency checks, (2) comparisons of exposure measures based on the reconstruction model with actual serum dioxin measurements, and (3) assessments of the association between exposure reconstruction measures and health outcomes shown in occupational or environmental studies to be associated with herbicides. Scientific judgment is required in interpreting the results of such an evaluation, so the committee cannot specify explicit criteria for acceptance or rejection of the new exposure reconstruction models in advance of their development and testing. Thus, the committee recommends that an independent, nongovernmental scientific panel be established to review the results of the proposed evaluation studies and to judge the validity and feasibility of the exposure reconstruction models. This panel should have expertise in historical exposure reconstruction

and in epidemiology. In order to maintain the public and scientific credibility of the study, the panel members should be nongovernmental and independent of the organization that develops the exposure reconstruction models.

Recommendation 6. If the scientific panel proposed in Recommendation 5 determines that a valid exposure reconstruction model is feasible, the Department of Veterans Affairs and other government agencies should facilitate additional epidemiologic studies of veterans.

A number of possible epidemiologic studies could provide additional information on the health effects of exposure to herbicides in Vietnam beyond what is already known. Highest research priority should be given to those health effects for which additional study is likely to change the balance of the evidence for or against an association. This includes

a. health outcomes for which current evidence is limited/suggestive of an association (lung and respiratory cancers, multiple myeloma, and prostate cancer);
b. health outcomes for which current evidence is insufficient or inadequate to determine whether an association exists, but which, in the committee's judgment, are plausible based on animal toxicologic data (such as nasal/nasopharyngeal cancer) or for which there are known associations with related chemical compounds in humans (such as liver cancer and polychlorinated biphenyls; Nicholson, 1987);
c. health outcomes for which the typical age at onset has not yet been reached by members of the Vietnam veteran cohort (such as prostate cancer).

The committee also recommends that priority be given to additional research on reproductive effects that would help clarify the possible effects of herbicides. In particular, the committee believes that extensive reanalysis of the Ranch Hand reproductive data could shed additional light on these questions (see Chapter 9 and Appendix C).

Although there is sufficient evidence of an association between occupational or environmental exposures to herbicides and non-Hodgkin's lymphoma, Hodgkin's disease, and soft tissue sarcomas, the existing information on dose-response relationships is incomplete, especially with regard to Vietnam veterans. If a valid exposure reconstruction method can be developed, it might be applied to the exposure data available from existing case-control studies to provide additional dose-response evaluations. Additional refinement of the clinical and pathological definitions of soft tissue sarcomas in epidemiologic studies would also help to determine which of the specific cancers in this class are associated with herbicides or TCDD.

The committee recognizes that the recommendations for development of a historical exposure reconstruction model and its use in epidemiologic studies might seem at variance with the Centers for Disease Control (CDC), White House Agent Orange Working Group (AOWG), and Office of Technology Assessment (OTA) conclusions made in 1986 with regard to the congressionally mandated Agent Orange Study. The committee has come to a different conclusion for four reasons: First, the CDC-AOWG-OTA conclusions were based in large part

on serum TCDD measurements, which the committee feels are insufficient for validating exposure to herbicides used in Vietnam, as explained in Chapter 6. Second, the arguments underlying the earlier conclusion that individuals in combat units were widely dispersed and that troop movement data are incomplete imply that exposure measurements may be imprecise, not that they are invalid. However, these arguments do suggest that historical reconstruction of exposure will have nondifferential misclassification errors that will lead to underestimates of the relative risk of health outcomes if an association is in fact present. Third, the committee is proposing the use of more, but less formal, information on exposure than was considered in 1986. This includes the development and use of informal information on perimeter spraying, which might account for more meaningful herbicide exposure than the aerial spraying documented on the HERBS tapes. Finally, the committee does not know whether the approach it proposes will prove valid or whether new methods will identify a sufficient number of highly exposed Vietnam veterans for an epidemiologic study. In the committee's judgment, however, the likelihood that this approach will be successful is sufficient for it to be recommended.

Mandated Research Efforts

For the purposes of further research on the health effects of Vietnam service, Public Law 102-4 mandates that the DVA establish four specific programs that are subject to initiation, continuance, or discontinuation, depending on the findings of this IOM report, and the committee is charged with making recommendations about these specific mandates. The DVA has no specific plans for any of these research efforts beyond the minimal descriptions given in the law, so the committee is able to comment on them in only the broadest terms.

The committee's recommendations speak to its legislative mandate to determine "the feasibility of conducting additional scientific research on" health hazards resulting from exposure to dioxin and herbicides used in Vietnam, the research mandate in section 8 of Public Law 102-4. As previously stated, the committee feels that a series of epidemiologic studies of veterans could yield valuable information if a new, valid exposure reconstruction model can be constructed.

Section 6 of Public Law 102-4 requires the DVA to "compile and analyze, on a continuing basis, all clinical data" that (1) are obtained in connection with DVA examinations and treatment of Vietnam veterans, and (2) are likely to be scientifically useful in determining the association between disabilities experienced by these veterans and exposure to dioxin or herbicides. Such a system, called the Agent Orange Registry (see Chapter 2), currently exists. Section 7 of the law calls for the establishment of a system for the collection and storage of voluntarily contributed samples of blood and tissue of veterans who served in Vietnam. Balancing the strengths and weaknesses of stored biological samples and clinical data for research purposes, the committee feels that systems of this sort have scientific value, but only to the extent that they are components of specific, well-designed studies; see, for instance, National Research Council (1991). In the absence of a clear study design to guide such activities, and without resolution of important design, quality control, and ethical issues

regarding tissue banks, the committee does not recommend the establishment at this time of the clinical data and tissue archiving systems described in sections 6 and 7 of the law.

The final mandate in Public Law 102-4 on which the committee must comment calls for the testing of serum of Vietnam veterans who apply for medical care or file a disability compensation claim for TCDD (section 9). The purpose of this mandate is not stated in the legislation. If research purposes are contemplated, the committee's discussion about tissue archiving systems applies, and such a program would not be recommended at this time. It is also possible that this program is intended to provide information on individual exposure to dioxins or herbicides to aid in individual compensation decisions. The committee cannot make recommendations for DVA policy, but notes that the finding in Chapter 6 that individual TCDD serum levels in Vietnam veterans are usually not meaningful (because of common background exposures to TCDD, poorly understood variations among individuals in TCDD metabolism, relatively large measurement errors, and exposure to herbicides that did not contain TCDD) might apply to this mandate.

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Prepared Statement
The Honorable Jesse Brown
Secretary of Veterans Affairs

Before the
House Committee on Veterans' Affairs
Hearing on Agent Orange

August 4, 1993
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Mr. Chairman, I would like to begin by expressing the appreciation of the veteran community, and my personal admiration, for the leadership that this committee has shown in addressing this difficult issue.

We have reaced a milestone in the search for the truth about Agent Orange. Since 1978 when the issue first surfaced, Vietnam veterans and their families have been waiting for definitive answers to their many questions about Agent Orange.

As a member of a veterans service organization, I was aware of the fears and frustrations of my fellow Vietnam veterans. As Secretary of Veterans Affairs, I am committed to taking a fresh look at the issue and to doing the right thing. Vietnam veterans deserve no less.

As you know, one of the principal sources of frustration has been the inability of the scientific community to provide us with definitive answers about the health effects of exposure to Agent Orange. The conclusions reached in the scientific research that has been done were often conflicting and confusing. Every side of the controversy could point to some study to bolster their position on whether exposure to Agent Orange produced an adverse health impact. As the controversy dragged on, positions hardened and the dialogue became impassioned and emotional.

It was at least partially in response to this stalemate that the Congress mandated VA to contract with the National Academy of Sciences to perform an unbiased review of the scientific literature and offer its assessment. I must acknowledge the task was not an easy one for the Academy.

We are now assessing what they have said and will, within the time mandated by the Agent Orange Act of 1991, make the necessary decisions. There are some decisions, however, that need not await the full 60 day time period the Congress gave us in that law.

I am prepared to act right now on some of the Academy's recommendations; specifically, concerning those conditions for which they found scientific evidence sufficient to conclude that there is a positive association between exposure to a herbicide agent in Vietnam and subsequent adverse health.

I have directed the Veterans Benefits Administration to begin the rule-making process to recognize Hodgkin's disease and porphyria cutanea tarda as being associated with exposure to herbicides used in Vietnam. No action need be taken with respect to soft-tissue sarcomas and chloracne, as VA has already recognized these as being associated with exposure. VA's rule regarding non-Hodgkin's lymphoma will be revised to reflect this disease's recognized association with herbicide exposure.

I have furthermore directed the Veterans Benefits Administration to contact Vietnam veterans on the Agent Orange Registry who have the newly recognized diseases, and have not filed for compensation -- to urge them to apply. I believe that this prompt action is appropriate, indeed, even mandatory.

I am not prepared today to render judgment about the Academy's report as it relates to other conditions. It is imperative, in my view, to fully analyze the implications of this report, and then to expeditiously act on the recommendations that arise from that review.

I therefore have established an internal, high-level panel to review the report and to solicit comments on it from other medical and scientific authorities, representatives of veterans service organizations and other interested parties. Dr. Susan H. Mather, VA's Assistant Chief Medical Director for Environmental Medicine and Public Health, will chair this panel. Membership will include top-ranking officials of the Veterans Health Administration, Veterans Benefits Administration and General Counsel. The panel will advise me of their findings in time for me to make decisions within the 60 day time period.

I am also acting now to accept key recommendations of the Academy with respect to future research. I am keenly aware that Vietnam veterans have been waiting too long, and too often have been told to wait for more research. But I am persuaded by the Academy's reasoning that more research is needed if we are to ever be able to finally put this issue behind us.

I think the recommendations of the Academy are well presented and they appear to be soundly based. I have therefore asked the Under Secretary for Health to prepare an action plan that will implement the research recommendations in a timely manner.

I would like to comment specifically about several of the recommendations.

Perhaps the fourth recommendation is the most important: the Academy recommended exploring the feasibility of developing a method for historical herbicide exposure reconstruction for Vietnam veterans. I think this is a worthwhile proposal, and I have asked that steps be taken to accomplish this recommendation.

There are many conditions for which the Academy was unable to arrive at definitive recommendations. In large measure, this was due to inadequacies in the scientific literature, particularly with respect to verified exposure. If a method for determining exposure with greater certainty can be devised, we would be able to better focus our research and arrive at more supportable conclusions. Indeed, this may serve as a way to answer whether Vietnam veterans are at risk for adverse health due to Agent Orange exposure. Because it does have such potential importance, I have asked that this be given high priority for implementation.

The Academy also recommended that the Air Force Ranch Hand study be continued with an external review by an independent, non governmental scientific panel. I have written to the Acting Secretary of the Air Force to urge serious consideration of this proposal.

The Academy additionally recommended that members of the Army Chemical Corps and an appropriate comparison group be followed in a study similar to the Ranch Hand Study. The recommendation said that this Chemical Corps study also should have oversight from an independent, non governmental scientific panel. VA is presently conducting a mortality and morbidity study of Chemical Corps personnel who served in Vietnam. Study results were reported on the mortality and morbidity experience of this group in 1990. No unusual findings were noted at that time.

VA researchers are currently working to expand this study to include Army Vietnam era veterans with chemical occupational specialties who did not serve in Vietnam. The Department will seek to have this research project

reviewed by an outside panel to determine if improvements can be made and we will submit the results to the panel for their review.

One Academy recommendation will require greater consideration: the suggestion that military personnel records be modified to include a marker for Vietnam service is a worthwhile one. VA will explore the feasibility of accomplishing this. It will require a coordinated effort among several departments and agencies.

I want to assure you and the Vietnam veteran community that I am approaching this issue with an entirely open mind. In those areas where I believe the Academy has made definitive findings, I have acted to implement them. As to the remaining areas, I will take the time provided by statute to satisfy myself that the action the Department takes is the right action, and that it puts veterans first and foremost.

I also want to note that I intend to pursue further discussion of this issue with the members of this Committee and of the Senate Committee on Veterans' Affairs. I am certain that working together we can achieve a just resolution.

Testimony of
Admiral E.R. Zumwalt, Jr. USN (Ret.)
Chairman
Agent Orange Coordinating Council

Before the
House Veterans Affairs Committee

August 4, 1993

Mr. Chairman and members of the Committee:

I appreciate the invitation to appear before this Committee to discuss my views on the Report by the Institute of Medicine of the National Academy of Sciences concerning the health effects of Agent Orange and other herbicides.

I do so in three capacities: 1) as a former Commander of the U.S. Naval Forces, Vietnam (the "Brown Water" Navy) from September 1968 until May 1970, 2) as a former unpaid Special Assistant: Agent Orange Issues to the Secretary of Veterans Affairs, the Honorable Edward Derwinski from October 1989 until May 1990 and 3) as current Chairman of the Agent Orange Coordinating Council.

In the first of these capacities, as Commander of U.S. Naval Forces, Vietnam, I requested and obtained Agent Orange defoliation along the banks of major and minor rivers and canals in Vietnam. I did so at a time when our casualties were running at the rate of about 6% per month, which meant that the average young man had about a 70% chance of being killed or wounded during his year's tour in the naval craft. The defoliation rapidly reduced casualties to less than 1% per month. At that time, to the best of my knowledge, no one in the Vietnam theatre was aware that Agent Orange could have harmful health effects on humans. In the light of subsequent knowledge, I consider that I have a very special responsibility to the courageous young men who served under my command -- that is, to see that justice is done with regard to providing compensation for the ill-health effects of those Vietnam veterans who were exposed to Agent Orange and their families.

In my capacity as Special Assistant to the Secretary of Veterans Affairs (at his request), I conducted a review of the hundreds of available studies and other government documents relating to this issue. I am submitting, separate from this testimony, a copy of that report. In it you will note that I concluded that there were 31 health effects that, as of May 1990, meet the required test that they are "as likely as not" the result of exposure to Agent Orange. Since that time, additional studies have convinced me that at least one other disease, diabetes, should be added to that list. One of the things that I learned in the course of this review is the unfairness of the requirement that the "as likely as not" decision be based on scientific studies. That unfairness results from the following factors:

1) It was the deliberate policy at the bureaucratic level of our government for many years to seek to avoid any conclusion that the use of Agent Orange and related herbicides could cause undesirable health effects. Hearings by the Human Resources and Intergovernmental Relations Subcommittee of the Committee on Government Operations in the House of Representatives conclusively proved that the government

maneuvered to evade its responsibility to be objective in determining possible health effects of defoliants used in Vietnam. Those hearings are the following:

June 26, 1990: Links Between Agent Orange, Herbicides, and Rare Diseases
July 11, 1989: Oversight Review of CDC's Agent Orange Study
July 26, 1990: CDC Interference in Dioxin Water Standards
June 10, 1992: Health Risks of Dioxin
Twelfth Report: The Agent Orange Coverup: A Case of Flawed Science and Political Manipulation

The results of the manipulated studies were made to be inconclusive. Therefore, any reviewing panel examining all available studies found the overall weight-of-evidence less conclusive than is the true case because of the consideration still given to the manipulated studies and thus, the dilution of the accurately done studies.

2) Anecdotal evidence, which in some cases ought to be sufficient for establishing the "as likely as not" relationship are disregarded in the scientific method. Let me give a specific example. In 1977, 47 railroad workers were exposed to dioxin while cleaning up spillage of dioxin-containing fluid from a railroad tank car in St. Louis. Within a relatively short time, among that group, there were 2 suicides, 41 cases of continuous fatigue, 23 cases of continuous muscle aching and 22 of the 45 living workers suffered cognitive impairment, among other effects. This was considered sufficiently determinative that in August, 1982, an Illinois jury ordered $5.8 million to the disadvantaged civilian workers. Numerous scientific studies give evidence of similar symptoms among other people exposed to dioxin, yet, to date, none of those difficulties survive the so-called scientific method to provide compensation for Vietnam veterans who show similar problems.

3) In addition to the manipulated government studies, some of the studies sponsored by chemical companies have been similarly manipulated.

I was able to recommend to Secretary Derwinski that the many diseases mentioned in my report should be approved for compensation because I, as a non-scientist, did what I believe the law allows the Secretary of Veterans Affairs to do, i.e., to discount the proven manipulated studies.

In my capacity as Chairman of the Agent Orange Coordinating Council, I believe I speak for the member organizations, although the sudden requirement for me to appear before this Committee has not made it possible for me to check definitively in that regard. The Agent Orange Coordinating Council includes approximately twenty veterans' and veterans' services organizations and are listed in an attachment to this testimony.

With that background, let me comment as follows on the Report which is the subject of today's hearing:

1) I consider it the first objective and honest report on the Agent Orange issue emanating from government or quasi-government sources.

2) The fact that the Committee affirmatively links five diseases, including two that have not previously been approved as capable of being caused by exposure to Agent Orange and other defoliants, is a significant step forward. This association confirms the frequently stated views of those members of Congress in both Houses who have looked into the issue in depth, as well as those of us on the outside who have done

so. That the report calls for additional studies due to the continuous accumulation of scientific information, reinforces the views of those of us who believe that a number of additional health effects should be added.

I applaud the prompt decision of the current Secretary of Veterans Affairs to initiate rules to add PCT and Hodgkin's disease to the list of compensable diseases and recommend that Congress add them by statute. It is my view that the diseases listed under the Report's category "limited/suggestive evidence" (namely, respiratory cancers, prostate cancer, and multiple myeloma) should also be added by statute to those currently listed. I believe it is the reasonable conclusion (particularly because of the dilution problem that this objective panel faced having to consider the manipulated studies along with the honestly done studies) that it is "as likely as not" that the diseases listed under "limited/suggestive evidence" are the direct result of exposure to Agent Orange.

For the same reason, it is my view that Congressional guidance should be given to the National Academy of Sciences that, in doing future reviews, those studies which have been proven by Congressional investigation to have been manipulated, should be suitably discounted so that a more objective weight-of-evidence conclusion could be reached. In future reviews, a significant number of the diseases for which the IOM panel could not find sufficient evidence at this time, will emerge as much more significantly related to exposure to defoliants.

I strongly endorse the IOM panel's recommendations for future research. It is significant and will be helpful in guarding against future government manipulation that the IOM panel recommends: an independent, nongovernmental scientific panel to review and approve a new, expanded research protocol and to commission and direct common analysis of the results in future Ranch Hand/Army Chemical Corps studies; a nongovernmental organization to develop and test models of herbicide exposure; evaluation of such models by independent, nongovernmental scientific panel.

Finally, there is another aspect of this issue I would like to address that should interest members of this committee concerned about justice for those Vietnam veterans who were injured by Agent Orange. It may not concern you as members of this particular Committee, but I earnestly solicit that each of you consider becoming sponsors, in your individual capacities, of a bill which I shall discuss. I am speaking of the federal Courts' repeated invention of any new law necessary to deny veterans the opportunity to place before a jury their personal injury claims against the Agent Orange manufacturers.

We have probably all heard of the general dissatisfaction of veterans with the 1984 class action settlement in which the veterans had little or no say, but whereby the lawyers nominally representing the "class" took more than $13 million in fees, and Judge Weinstein became the head of a $52 million foundation. As a result of that settlement, only veterans with death or total disability claims received anything, and that was, on average, a mere $3200 each. In the case of Ivy v. Diamond Shamrock, veterans whose injuries arose after the 1984 settlement have had their search for a fair trial of their claims similarly short-circuited by the federal courts. The federal courts removed the case from Texas state court over the opposition of 21 State Attorneys General who in their legal brief in Ivy called the court's action, and I quote, "an illegitimate judicial amendment of Congress' removal statute, ... an invasion of state judicial independence and an insult to state courts throughout the nation." The federal courts then compounded the problem by transferring Ivy directly to Judge Weinstein on

legal grounds that were also unprecedented and again seemed to defy the intent of Congress.

The reason for the federal courts' invasion of states' rights in order to have only Judge Weinstein hear Ivy was clear. Both Judge Weinstein and the federal Court of Appeals proceeded to make unprecedented decisions holding that the 1984 settlement included veterans' claims that did not exist in 1984 (since they had no injury at that time) even though these veterans had no notice or knowledge of the 1984 case and were not separately represented by any lawyer who agreed to such a settlement. By the federal courts' invention of a class settlement of these "future" claims that did not even exist at the time, their violation of all existing law concerning participation in and settlement of class actions, and, most importantly, their exercise of extraordinary powers to deny to the state courts their ordinary authority to hear such claims, the federal courts have destroyed the veterans' claims which are now worth far more than the average $3200 some of them might be able to get from Judge Weinstein. Judge Van Graafeiland of the Court of Appeals for the Second Circuit on June 24, 1993, justified these unprecedented and even bizarre rulings denying the veterans a jury trial in an unbiased state forum, on the grounds that, in his view, "despite continuing research, the crucial issue of 'general causation', i.e., whether any injuries are attributable to Agent Orange, remains unsettled." My understanding, in accordance with the constitutional right to jury trial, is that juries are supposed to make such findings of causation, not judges. Here federal judges are making scientific findings that directly contradict the NAS study which has now found that there is "sufficient evidence of an association" between Agent Orange and a number of the kinds of diseases experienced by Vietnam veterans exposed to Agent Orange.

I am submitting with this testimony a draft law which I support to correct this systematic denial of justice by the New York federal courts. This new law would not really change current law so much as give clear instructions to these courts to enforce existing law and to keep the New York federal judges' obviously biased hands off the Agent Orange litigation so that the Ivy case may go to trial. Our veterans are entitled to a better quality of justice than they have received from the federal courts in the course of the Agent Orange litigation. The courts have done sufficient damage by inventing their own rules to apply to Vietnam veterans. It is now up to Congress, by passing the law I propose, to insist that the Courts enforce the laws written by Congress and the Constitution. Otherwise this episode will go down as one of the most egregious denials of justice by the federal courts in our national history, and a shameful betrayal by federal institutions of those who fought and sacrificed for this country.

In conclusion, I believe the IOM panel's study has given the Vietnam veterans and their families the first significant scientific support for the condition of ill-health effects due to Agent Orange. This report confirms the wisdom of Congress in its decision last year to authorize by statute the compensation for three of these ill-health effects. I hope this report will lead the Secretary of Veterans Affairs to authorize compensation for respiratory cancers, prostate cancer, and multiple myeloma and that Congress do so statutorily. I hope that future review panels will be instructed to discount manipulated studies. I urge the implementation of the IOM recommendations so that the additional diseases concluded in my report can be added for compensation as soon as possible.

Attachments

AGENT ORANGE JUDICIAL REFORM ACT OF 1993

SECTION 1. The immunity from liability known as the Government Contractor Defense, which has been extended to private parties by judicial interpretation of "federal common law," is hereby abolished.

SECTION 2. Section 1407(a) of Title 28 of the United States Code, first sentence, shall be amended by adding the word "simultaneously" before the word "pending."

SECTION 3. Section 1407(e) of Title 28 of the United States Code shall be amended by adding the following sentence: "The Court of Appeals shall issue a mandamus when necessary to confine the panel to a lawful exercise of its prescribed jurisdiction."

SECTION 4. Section 1407(f) of Title 28 of the United States Code shall be amended by adding the following sentence: "No proceedings for transfer shall be initiated unless an Act of Congress has conferred jurisdiction of the action upon the District Courts."

COMMENT

A) Section 1 is intended to reverse Boyle and other cases which have created a "federal common law" defense which preempts or "displaces" substantive state law under certain circumstances, Congress has not delegated such law-making authority to the federal courts, and has expressed no intent to make such wholesale changes in, the common law tort remedies traditionally provided under state law for regulating private conduct in matters raising no question under the Constitution, or under any Act of Congress.

B) Sections 2, 3 and 4 are intended to reverse rulings in Ivy v. Diamond Shamrock Chemical Co., 901 F.2d 7 (2d Cir. 1990) pertaining to the jurisdiction of the multidistrict litigation panel.

Section 2 provides that the transfer of a prior case that is no longer pending or in pretrial proceedings shall not be grounds for transferring a subsequent pending case. This section clarifies the intent of Congress that there must be two or more pending actions, in pretrial proceedings, and arising in different districts, in order to justify a transfer of one of the cases for the purpose of achieving the convenience and efficiency of "coordinated" conduct of such actions.

Section 3 provides that the Court of Appeals shall exercise its powers of review by extraordinary writ under Section 1407(e) in conformity with the Supreme Court's definition of "[t]he traditional use of the writ ... to confine an inferior court to a lawful exercise of its prescribed jurisdiction." Roche v. Evaporated Milk Ass'n. 319 U.S. 21, 26 (1943)

Section 4 provides that the multidistrict litigation panel is subject to the same jurisdictional constraints as other inferior federal courts, and possesses no jurisdictional powers other than those granted by an Act of Congress.

The purpose of these changes is to assure that the transfer statute is not abused to assign particular cases to particular judges whose views are known, and to clarify that jurisdictional issues should be addressed at the earliest opportunity in order to avoid litigation over transfer issues where federal jurisdiction is lacking.

SECTION 5. Section 1442(a)(1) of Title 28 of the United States Code shall be amended by adding the word "natural" before the word "person."

Section 5 provides that the protection accorded officers of the federal government and persons acting under them, by allowing removal of cases brought against them in state court to a federal court, is limited to natural persons and shall not be extended to include fictitious "persons" such as private corporations. This amendment is required to avoid removal under this provision to the federal courts of civil suits brought against Government contractors who claim to be "acting under" a federal officer. This will restore the original purpose of the statute which was to accord individual federal officers and agents acting under them the protection of a federal forum for presentation of any defense of official immunity from suit for acts taken under color of federal office. The Supreme Court has unanimously interpreted this statute to exclude government agencies, corporations and other entities from this protection. See International Primate Protection League v. Administrators of Tulane Educational Fund. U.S (May

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20, 1991). The Amendment clarifies that such protection, and therefore removal from state court, found unnecessary for private institutions.

Federal Courts have made inconsistent interpretations of this provision, resulting in an unintended, unnecessary and anomalous expansion of the jurisdiction of the federal courts over certain private corporations. The amendment would accordingly restrict federal jurisdiction by adopting the reasoning of such cases as C.H. v. American Red Cross 684, F.. Supp. 1018, 1023 (E.D. Mo. 1987) (rejecting the theory that the persons acting under him" who can also invoke "Section 1442(a)(1) includes entities other than natural persons"). Although "the majority of those courts that addressed the issue explicitly and rendered a reasoned decision of law decided that Section 1442 authorizes only natural persons to remove," Roche v. American Red Cross. 680 F. Supp. 449, 454 (D. Mass. 1988), any remaining ambiguity in the law is now resolved by Congress to avoid further uncertainty and litigation over the issue.

SECTION 6. A new Chapter 160 titled "Class Actions" shall be added to Title 28 of the United States Code.

SECTION 7. A new Section 2371 shall be added to Chapter 160 of Title 28 of the United States Code which shall be as follows:

Dismissal or Compromise of Class Action Suit.

(a) Any compromise or stipulated dismissal of a class action suit shall be by agreement of the parties that is reasonably precise and shall not delegate to the judge who approves the dismissal or compromise any authority to add additional terms to the agreement.

(b) No action to interpret, arbitrate or otherwise enforce such an agreement may be brought before a judge who has approved the dismissal or compromise

(c) No member of a class shall be subsequently bound or held to have had a claim adjudicated by a compromise who has not received actual notice of the precise terms of the compromise, and of the right to reject the compromise, or who timely exercises such right after notice thereof.

COMMENT

(A) A new Chapter 160 is added to regulate the class action litigation practices of certain judges under F.R.Civ.P., Rule 23(e), which are inconsistent with 28 U.S.C. ss 2072. The latter provision, referring to the federal rules, requires that;

Such rules shall not abridge, enlarge or modify any substantive right and shall preserve the right of trial by jury as at common law and as declared by the Seventh Amendment of the Constitution.

(B) Section 7 adds new Section 2371 to Chapter 160 of Title 28 of the United States Code to modify class action settlement practices under F.R.Civ.P., Rule 23(e) by which certain federal judges have exceeded the authority granted by Congress to the prejudice of the due process rights of litigants.

In the Agent Orange litigation a class was certified that, according to the presiding judge, included both veterans who had claims for injuries allegedly caused by Agent Orange, and other absent persons who had no such injuries, and therefore no claims that could be adjudicated at the tim

of the settlement. These persons, present and absent, were lumped together as "class members" and their existing and non-existing claims were, according to the presiding judge, settled by attorneys representing both groups of veterans, and their families. These attorneys were found by the Court of Appeals to have had fee arrangements that presented a conflict of interest inducing them to settle all claims early and cheaply. It was against the interest of persons who had not manifested injuries to prematurely settle their potential claims, which could become valuable claims as time passed and statistical evidence proving the causation of their injuries became available.

Nothing in current law prevented the presiding judge from first grouping these claims for a settlement by which weak claims worth little or nothing would obtain a small "nuisance value" amount of damages and potentially strong claims would receive nothing, and then imposing this settlement on attorneys appointed by the judge, whose fees were awarded by the same judge. The same judge then approved the settlement as reasonable to the "class" although it was opposed by most veterans with claims who were able to present their views. The views of the persons whose claims were settled before they arose, and who lacked any knowledge of the suit or the settlement, and who were most prejudiced by the settlement could not be heard.

The presiding judge, who was directly engaged in developing the terms of the settlement agreement, was authorized by the settlement to determine who among the plaintiffs would receive any part of the settlement, and also acquired authority to directly supervise a $50 million foundation having broad discretionary goals that was created with a large portion of the settlement funds.

Because the judge set a time for opting out of the class action one week prior to the settlement agreement, no class member had an opportunity to reject the terms of the settlement. If they had, the judge's powers to alter the agreement, and determine who would receive any of the damages, meant that they would have purchased a "pig in the poke."

Subsequently, persons who had received no notice of the earlier case, or of the settlement, and had no opportunity to opt out, claimed that the actual settlement agreement did not by its terms include their claims. Alternatively they argued that if it did purport to settle their claims they were not adequately represented by counsel who approved such an agreement, because such a settlement was clearly against their interest in preserving their right to sue until their claims arose and were provable. However these persons were not permitted to litigate these issues other than before the same presiding judge who imposed the settlement.

This case illustrates the dangers of investing federal judges with powers free of the usual restraints of juries, the adversarial system, and actual consent of litigants. One judge should neither exercise such unstructured powers through the device of class action "settlement," nor monopolize litigation of all issues in a case affecting important interests of thousands of litigants.

Section 7 would prohibit the use of Rule 23 for the settlement of claims without the consent of the party purportedly settling the claim, a practice which violates traditional notions of due process. It would also prevent the abuse of powers exercised by a federal judge over the appointment and compensation of class action attorneys, which are extraordinary in our adversary system of justice, so as to secure from those attorneys a settlement inconsistent with the interests of their purported clients, to obtain a delegation of powers to adjudicate issues without a jury trial, and to grant the judge powers that are not provided by law and would not result from the normal course of litigation.

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Finally this section would prevent insulating such an agreement from the interpretation of courts other than the judge who approved such a settlement. This would prevent alteration of the terms through subsequent interpretation or monopolizing all litigation with respect to the agreement or related claims, Requiring judges other than the one approving the agreement to determine such matters as its validity, application to third parties who are strangers to the agreement, adequacy of representation, interpretation of its terms in subsequent litigation, and other enforcement matters will help limit the potential for abuse of the enormous unstructured power assumed by the federal courts under Rule 23. Otherwise Rule 23 will continue to be used to subvert the Seventh Amendment right to jury trial, as it has been used against Agent Orange veterans.

SECTION 8. Section 1445 of Title 28 of the United States Code shall be amended by adding a new subsection (d), as follows:

(d) A civil action in state court, brought by a member or veteran of the armed forces of the United States, and alleging claims arising under state law shall not be removed to any District Court of the United States, irrespective of whether the same civil action was adjudicated or settled, or is pending, in a federal court.

COMMENT

Section 8 reconfirms the "well pleaded complaint" doctrine in the context of the Agent Orange litigation. In Ivy v. Diamond Shamrock a previous class action settlement in a New York federal court was held to provide a "federal question" for removal of the case from Texas state court, although the plaintiffs' claims arose exclusively under state law and contained no substantial element of federal law. The Ivy plaintiffs alleged that their claims did not exist at the time of the previous settlement and that the New York court lacked jurisdiction over the Ivy plaintiffs.

Section 8 confirms that a res judicata defense is no ground for removing a case from state court, and that a class action settlement may be collaterally attacked in state court by raising questions whether the court which settled the first case had jurisdiction over the plaintiffs and their claims in the previous action. No single judge should have a monopoly over interpretation of the law with respect to the claims of Armed Forces personnel. Limitation of this section to armed forces personnel carries no implication for the propriety of removal of any cases brought by other persons under similar circumstances. It is intended to expressly assure the availability of a non-federal forum for Agent Orange victims to pursue their state claims, and to bar any removal to federal court of any civil action that alleges such claims irrespective of any prior or ongoing litigation in federal court.

Section 8 would provide to members and veterans of the Armed Forces a similar right to choose a convenient forum for their claims as has been extended to seamen under the Jones Act. See Pate v. Standard Dredging Corp., 193 F.2d 498 (5th Cir. 1952).

SECTION 9. Section 1445 of Title 28 of the United States Code shall be amended by adding a new subsection (e) as follows:

(e) No case shall be removed from state court except in accordance with law enacted by Congress and codified in this Chapter. No case may be removed by any decree, writ or other order in equity.

COMMENT

Section 9 adds new subsection (e) to Section 1455 of Chapter 89 of Title 28 of the United States Code to clarify that there are no inherent judicial powers included in the All Writs Act to remove a case from state court. In this sensitive area of relations between state and federal governments all powers of removal are provided by an express enactment of Congress. In Ivy v. Diamond Shamrock, a previous class action settlement in a New York federal court was held to provide grounds, under the All Writs Act, for removal of a Texas class action based exclusively upon state law. This was an unwarranted intrusion on the powers of state courts to adjudicate a state based claims in state courts except where specifically provided otherwise by Congress. This provision makes clear that Congress intends to limit the powers of removal to the express grounds enacted by Congress and that no writ under the All Writs Act can be used to create jurisdiction in a federal court which does not exist under an express grant of power by Congress.

SECTION 10. Section 455(d) of Title 28 of the United States Code is amended to add the following provision:

(3) "interest" includes any interest, whether or not it arises from judicial activity.

Section 10 adds a new provision to subsection (d) of Section 455 of Title 28 of the United States Code to clarify that a conflict of interest is grounds for disqualification irrespective of whether the conflicting interest arose out of judicial activity. In Ivy v. Diamond Shamrock, District Judge Jack B. Weinstein declined to disqualify himself from hearing Ivy after a conflict was revealed between that case and his role as a fiduciary in a foundation set up as a result of a previous class action settlement. In Liljeberg v. Health Services Acquisition Corp., U.S. 108 S. Ct. 2194, 2202 (1988) a similar conflict was described as "obvious" by the Supreme Court, which compelled the district judge's disqualification and also vacated his orders. Judge Weinstein declined to follow the rule in Liljeberg on the grounds that his role as fiduciary for the foundation was a result of judicial action. Under as 455(b) a conflict of interest disqualifies a judge irrespective of whether the conflict actually causes partiality, and irrespective of the circumstances under which the conflict arises. This amendment clarifies this rule.

For further information please contact:
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AGENT ORANGE COORDINATING COUNCIL MEMBER ORGANIZATIONS:

Agent Orange Victims & Widows Support Network
Air Force Sergeants Association
American Ex-Prisoners of War
American Legion
Blinded Veterans Association
BRAVO
Catholic War Veterans, USA
Fleet Reserve Association
Jewish War Veterans of USA
Marine Corps League
Military Order of Purple Heart
National Association of Military Widows
National Vietnam Veterans Coalition
New Jersey Agent Orange Commission
Oklahoma Agent Orange Foundation
Polish Legion of American Veterans, USA
The Retired Officers Association
Veterans of Foreign Wars of US
Veterans of the Vietnam War
Vietnam Veteran Agent Orange Health Study
Vietnam Veterans of America

E. R. ZUMWALT, JR.
ADMIRAL, U S. NAVY (RET)

August 4, 1993

The Honorable G.V. Montgomery
Chairman, Committee on Veterans' Affairs
U.S. House of Representatives
335 Cannon House Office Building
Washington, DC 20515

Dear Mr. Chairman:

In addition to my prepared statement, I submit herewith this letter containing information not available to me at the time of the preparation of my statement.

The Institute of Medicine Report fails to include any conclusions regarding the ability of dioxin to cause or be associated with an overall increase in the cancer rate (see page 8-12). The Environmental Protection Agency (EPA) recently reviewed the same studies on chemical production workers summarized by the IOM and came to a definite conclusion, as part of its ongoing effort to evaluate the risks of dioxin. After undergoing extensive public and expert review, and after open workshop meetings, the EPA's second draft report on human epidemiology (EPA Publication No. EPA/600/AP-92/001g, June, 1993) states:

> *Other TCDD related hormonal effects, including immune suppression, may result in multi-organ sensitivity and may contribute to the overall increased mortality from all malignancies combined seen in all four cohort production worker subcohorts with higher estimated TCDD exposures...These increased relative risks, while not large (10% to 70%) are consistent and are either statistically significant or of borderline significance. While no one tissue site can account for this observed increase, lung cancer is also increased in three of these.*

In view of this fact, I now recommend that the House Veterans' Affairs Committee amend existing legislation to authorize compensation to Vietnam veterans experiencing any form of cancer or to their families in the case of deceased Vietnam veterans.

As a separate matter, the Institute of Medicine did not list peripheral neuropathy as a disease associated with exposure to Agent Orange or other herbicides used in Vietnam.

Since the Committee on Environmental Hazards, before it was disestablished by Congressional statute, recommended to the Secretary of Veterans Affairs the addition of that disease as one for which there should be compensation, and in view of the fact that relatively modest number of veterans who are affected have been expecting that disease to be compensated in the near future, I strongly urge that it not be removed from the diseases for which the Vietnam veterans will be provided compensation.

Sincerely,

E R Zumwalt JR

Admiral E.R. Zumwalt, Jr., USN (Ret.)

c: The Honorable Jesse Brown, Secretary of Veterans Affairs

The Need for Research on the Generational Effects of the Vietnam War

Bryan C. Smith, Ed.D., Project Director
National Information System for Vietnam Veterans
and their Families
Center for Developmental Disabilities
Department of Pediatrics, School of Medicine
The University of South Carolina

I am delighted to share this time with these distinguished scholars and to have this opportunity to express my thoughts with you. I appreciate the invitation. Thank you.

I am on the faculty of the Center for Developmental Disabilities at The University of South Carolina and I am the Director of the National Information System for Vietnam Veterans and their Families (NIS) project. This project is a central Information and Referral System funded by the Agent Orange Class Assistance Program. Our mission is to connect Vietnam veterans who have children with disabilities to services they need to enable them to raise their child or children with disabilities. I am here today, not as a representative of the Agent Orange Class Assistance Program, but in my role as a University of South Carolina faculty member. I am also representing over 14,000 Vietnam veterans, their children, and family members whom we have helped over the last four years. During this time we have amassed a unique set of data on more than 10,000 veterans' children that now enables us to offer testimony to this committee on the effects of the Vietnam war on veterans' children. These data paint a picture of a generation that must now receive our attention. But first, let me briefly describe the NIS so you can understand why I am here.

The main function of the NIS is to provide outreach to, and be a central information and referral service for, Vietnam veterans who have children with disabilities. Our challenge and task is to connect these children and families with community or national resources that can meet their needs. Examples of the services we provide to these veteran families include referring a family to a disability-related support group for more information on cerebral palsy, and working with parents to explain the rights guaranteed by the Individual's with Disabilities Education Act (IDEA) and assisting them in getting the appropriate education their child needs and is entitled to receive. Frequently, our work becomes extremely complex. For example, it may require the coordination of a full range of services for a family who has a six month old little girl who has never left the hospital and now must travel across six states to have a liver transplant in order to survive. In this case, the NIS would work with the family and service providers to coordinate air transportation for the child and family, investigate Medicaid reciprocity between the states, if necessary, work with programs like the Ronald McDonald House to arrange housing, and

perhaps involve other philanthropic organizations to provide financial support for things not covered through insurance, Medicaid or other family resources.

The NIS does this by utilizing a staff of Information Specialists who are trained to understand and wade through the intricacies of the service delivery system. Information Specialists help the families sort out problems, identify the benefits and services available to them, and give them insight into issues related to their children's development. Most importantly, the Information Specialists help them understand how various agencies and processes work and how families can cut through the bureaucracy to access services to which they are entitled.

The Information Specialists use a database of over 114,000 services from programs that include Medicaid, Title V programs, special education programs, early intervention services, and private resources such as parent support groups, disability-related organizations and pharmaceutical foundations.

I am here today to share what we have learned from working with these families and to encourage you to sanction the research that will provide the answer to the question that so many veterans have asked us: "Are my kids' disabilities caused by my exposure to Agent Orange?" Less common, but associated questions, are those that relate to risks in the outcomes of future pregnancies and why genetics counselors and other medical professionals are unable to give them a straight answer related to those risks.

Statement of the Problem

Most of the Vietnam veterans' children helped by the NIS had multiple problems within and between categorical disability groupings. Fifty-five percent of the children with disabilities had multiple disabilities averaging approximately over nine disabilities per child. Thirty percent of the families had more than one child with disabilities.

The most common conditions we have seen in veteran's children are: learning disabilities and attention deficit disorders (36.1% of the children who needed help from the NIS had these conditions), skin abnormalities (24.1%), immune deficiencies (20.3%), birth defects (17.8%), and asthma (10.9%). Many of these conditions can be grouped into the area of immune response disorders. These disorders include persistent skin rashes, respiratory infections, chronic fevers, allergies and asthma. We have observed that these immunological dysfunctions, which may sound minor in relationship to the impact of a birth defect or disability, are very serious and often disabling themselves. They occur in many members of the same family constellation and persist for many years. In fact, many veterans report that their children have never lived a day without these conditions. I have brought a list of the conditions that has a tally showing the number of family members with each diagnosed condition. The total number of conditions

exceeds the number of persons helped by the NIS because of children having multiple diagnoses. This list has more than 900 different diagnostic entities. I will leave this copy for you.

The average age of veteran's children helped by the NIS was 15.1 years, with the actual ages ranging from birth to 28 years. Comparing average ages for each of the five successive years shows an annual increase of only 8 tenths of a year (9 and 1/2 months) in the ages of the children helped. The question this raises is why don't the ages increase one year in one year's experience? The answer lies in the number of new babies coming into the Vietnam veteran population and these children already have problems that caused one of their parents to initiate a search for help. The 0-3 age group is 4% of the children helped by the NIS. Although the Vietnam veterans' average age is around 45, they are still having children and their children are still having disabilities.

Vietnam veteran families, like all families, vary in the ways they meet the challenges of parenting children with disabilities. Some pursue lead after lead to locate community resources to cover their informational, material, and support needs. Others discover inner resources they had not previously tapped. Sometimes members of extended families rally to support them during crises or stressful situations. Many families are very successful in responding to the problems or special concerns they must address; other veteran families are far less efficacious in coping with immediate and long-term needs. Generally, Vietnam veterans are not seeking disability compensation for their children, they are seeking help with their medical expenses and they are seeking services to improve the lives of their children.

Of the families calling the NIS, the average number of services needed per child was 4.8. The average number of referrals made to meet those service needs was 2.4. The most frequently needed service was for different types of support services. There were more referrals for support services than there were clients, which means that almost everyone needed this type of service and that some needed more than one of the 28 different types of support services, including case management/service coordination. The greatest service need was for financial assistance services, primarily to help pay medical bills, both outstanding bills and future ones; next was medical diagnosis and evaluation services; and counseling (including psychiatric).

Vietnam veterans with children face the usual issues that all families face in raising their children. And just like any family with a member who has a disability, they have the additional challenge of dealing with their children's special needs. These may include solving the financial burdens of medical care, finding special equipment, learning about the condition(s) and what the child needs, and identifying the services to meet those needs. Problems for Vietnam veterans become even more complex than those of other parents because of the difficulty the veteran's service system has in addressing the issues of family health problems. For a number of reasons, many veterans have acquired a distrust of the institutional service system created to help

Vietnam veterans or their family members. Of the veterans calling the NIS for help with their own problems, 36.8% of them were seeking help for Post Traumatic Stress Disorder.

We have worked with Vietnam veteran families for over four years, and families having children with disabilities for over thirteen years. From that experience, we have drawn our own subjective conclusions. It is readily observable that many disabilities and severe, chronic health conditions appear to occur more frequently in Vietnam veterans' families than they do in the general population. Autism, as one example, occurs at approximately 1.4% in families served by the NIS, a rate 35 times higher than the .04% prevalence experienced nationally by the general population. This gives rise to the question, "What is it that might be causing this difference?" To answer this, we must first be sure that there is, indeed, a larger occurrence. It is important to realize, however, that the NIS receives calls from veterans and family members seeking services and is not conducting studies using a sample drawn randomly from the total Vietnam veteran population. Any conclusions from the NIS data can only be implied to the larger group being helped by the NIS, not to all Vietnam veterans' children. To determine whether the children helped by the NIS are actually experiencing a rate that is significantly different from the general population would require a scientifically controlled research design.

What has caused us to begin to ask some of these questions is what we have seen in all the groups we have served. We have operated four national information and referral programs. The one most comparable to the NIS for Vietnam Veterans and their Families was the National Information System serving families with children, ages 0-21, with disabilities and special health care needs. While there are many similarities between the families and children in these two groups, several differences and unique characteristics are apparent in Vietnam veteran families and their children with disabilities.

The magnitude of these differences and unique characteristics provides some indicators of a relationship between the Vietnam experience and disabilities and health conditions manifested in the children of those veterans. In our efforts to help Vietnam veterans' families, we observed these unique characteristics:

- 55% of the veterans' children have multiple disabilities with an average of 9.5 conditions per child
- 30% of the families have more than one child with disabilities (It is not uncommon for a veteran to have six or seven children, all having severe disabling conditions)
- Most Vietnam veteran parents also have disabilities
- Occasionally, a veteran will report having one or more children without disabilities born before the War and two or three children with disabilities born after Vietnam.

Recommendations for Action

Given these indicators, what could be done next? The rest of my comments relate to actions that could be taken that might lead to a formal examination of possible causes of these unique characteristics.

The research process usually proceeds along the following sequence:

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observation-->indicators-->literature review-->hypothesis formation-->controlled study-->hypothesis accept or reject

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We are at the beginning of this process, having gone through the observation. **The indicators are there,** or I wouldn't be giving this testimony today. The literature has been impartially reviewed and reported by several credible sources including Admiral Zumwalt, The Scientific Task Force, and the National Academy of Sciences. While the focus of these reviews has been on adults, they have only briefly touched on the generational effects of toxic exposures because there is very little published in this area. I believe a hypothesis can be formed by this committee at the conclusion of our testimony.

The cause and effect questions are questions that should have been answered before herbicides were used in Vietnam and they still need to be answered today. They need an answer to relieve the guilt and to direct the frustration carried by many veteran families. They need an answer so that genetics counselors can do their jobs by giving people an indicator of risk in their prediction on birth outcomes. They need an answer because it's a moral and ethical issue that will not go away and most importantly, because **Vietnam veterans deserve the answers.**

Twenty years ago, family members could predict that cigarette smoking by a family member would cause a premature death. They were so certain of their prognosis that many of them referred to cigarettes as coffin nails and that each one smoked would reduce life expectancy by 14 minutes. When a death of a smoker occurred, the cigarettes were blamed, yet another 15 years would pass before there was enough scientific evidence accumulated that demonstrated that a cause and effect relationship existed. When it was finally concluded, the evidence was so strong that even secondary smoke was implicated.

Vietnam veteran family members believe that something in the Vietnam experience contributed to the next generation's health problems. Unlike smoking, which has a longitudinal exposure, the Vietnam war and Agent Orange exposure was time limited; and hopefully there will never be another large group of people exposed that would provide a comparison group. We cannot wait another 15 years before we formally look at whether a cause and effect relationship exists.

The issue of cause is multidimensional. One dimension is due to multiple factors that can cause the conditions. Another is that the conditions are not unique to this population. When a child has a traumatic event, such as a bicycle accident resulting in a broken arm, we can directly associate the single cause and the outcome, i.e., the broken arm was caused by the fall. But the conditions the Vietnam veterans' children have, such as cancer, learning disabilities or birth defects, do not have a single potential cause. For many of them, the cause is still not known. What makes the interpretation even more difficult is trying to connect the outcome with

something in the parent's lifestyle or something teratogenic that the parent may have been exposed to many years ago. Another complication is that Vietnam veterans were exposed to a variety of hazards ranging from arthropod vectors, anti-malarial drugs, Agent Orange, fungal infections and the stress of combat. Which of these, or their combinations, may have contributed to an increase in the incidence of child health problems in subsequent generations may never be determined. **What can be determined is that the Vietnam experience did or did not result in generational effects.**

As I indicated earlier, we are at the beginning of the research process. The indicators are there, the literature has been impartially reviewed, and we are at the point where a hypothesis can be formed. From a scientific point of view, there are a number of issues that cry out for investigation. May I be so bold as to suggest one hypothesis that I believe would be appropriate: **The Vietnam experience resulted in a wide variety of generational effects that manifest themselves as disabilities and chronic health conditions.**

Once this research is completed, if the findings indicate a relationship, as I suspect they will, this committee will have assisted Vietnam veterans in obtaining access to appropriate and quality health care and a range of supportive services needed by their families.

Thank you for giving me this opportunity to speak today.

National Information System
Listing of Diagnosed Conditions 1989-1993

- Aberfeld Syndrome (chromodrodystrophic Myxedema) 1
- Abused 55
  - Neglect 4
  - Sexual 15
  - Other 36
- Adnexitis 2
- Alpart's Syndrome 1
- Amputation 23
- Angel Syndrome 1
- Aortic Stenosis 3
- Aortic Valve Insufficiency 2
- Appendicitis 3
- Apert's Syndrome (acrocephalosyndactyly) 1
- Apnea 16
- Arthritis 164
  - Juvenile, Rheumatoid 26
  - Other 138
- Asthma 982
- Attention Deficit Disorder 608
  - ADD w/Hyperactivity 342
  - Other Attention Deficit Disorder 266
- Autism 107
  - Bartter's Disease 1
  - Pervasive Developmental Disorder 6
  - Other 100
- Behavior Disorders, Child 498
  - Autistic-like 9
  - Aggression 37
  - Delinquency 21
  - Echolalia 1
  - Fire Starter 2
  - Hyperactivity 191
  - Inappropriate Sexual Behavior 5
  - Lying 2
  - Sadism 1
  - Self-mutilation 7
  - Social Alienation 7
  - Other Behavior Disorders 215
- Birth Defects 1870
  - Agenesis 19
    - Bladder 3
    - Corpus Collosum 3
    - Intestinal 5
    - Liver 1
    - Sacral 1
    - Urethral 2
    - Uterine 1
    - Other 3
  - Atelectasis 1
  - Atresia 59
    - Anus, Imperforate 26
    - Biliary 1
    - Esophageal 15
    - Intestinal 2
    - Pulmonary 4
    - Tracheal 2
    - Urethral 1
    - Vaginal 7
    - Other 1
  - Bone Malformation 39
  - Brain Malformation 8
  - Breast, Malformaton 7
  - Bronchial Cleft 1
  - Chest Malformation 44
    - Pectus Excavatum 27
    - Pectus Carinatum 9
    - Other 8
  - Congential Dislocations 45
    - Hip, Dislocation at Birth 34
    - Other 11
  - Craniofacial Anomalies 399
    - Cranioschisis 6
    - Craniosynostosis 2
    - Ear Deformity 64
      - Blockage 2
      - Canal, None 6
      - Ear Drums, None 8
      - Other 48
    - Eye Deformity 29
      - Cataracts, Congenital 3
      - Eyes Not Open At Birth 2
      - Eyes, Crossed At Birth 2
      - Tear Ducts, None 2
      - Other 20
    - Facial Anomalies 10
      - Treacher-Collins Syndrome 3
      - Other 7
    - Jaw Abnormalities 21
    - Mouth Abnormalities 217
      - Cleft Lip 57
      - Cleft Palate 141
      - Teeth, Two Rows 2
      - Tongue, Attached to Palate 1
      - Tongue, Deformed 2
      - Tongue, Unattached 1
      - Other 13
    - Nasal Passage, Malformed 10
    - Other Craniofacial Anomalies 40
  - Epispadias 2
  - Fistula 6
  - Gastroesophageal Reflux 10
  - Gastroschisis 11
  - Genital Malformation 67
    - Anorchism 7
    - Cryptorchism 12
    - Hypospadias 22
    - Testicle, Supernumerary 1
    - Vagina, Missing 3
    - Uterus, Missing 1
    - Other 21
  - Great Vessels, Transportation 4
  - Heart Defect, Congenital 308
  - Hemiphypertrophy 5
  - Holoprosencephaly 1
  - Hydrocephalus 65
  - Joint Deformity 11

- Kidney Malformation....26
  - Kidney, Two Pair....2
  - Kidney,Missing....5
  - Other....19
- Limb Defect....483
  - Adactyly....18
  - Arm/Hand, Missing....12
  - Clubfoot....140
  - Erb's Palsy....3
  - Finger, Deformed....15
  - Flat Feet....16
  - Knees, Malformed....6
  - Knees, Missing....3
  - Length Inequality....36
  - Limb Reduction....15
  - Nails, Malformed....16
  - Nails, Discolored....1
  - Pigeon-toed....2
  - Polydactyly....18
  - Ptosis....1
  - Syndactyly....22
  - Toes, Deformed....21
  - Other....138
- Lungs, Missing....1
- Lungs, Scarred....2
- Macrocephaly....2
- Micrencephaly....2
- Microcephaly....15
- Muscle, Missing....11
- Neural Tube Defects....4
- Obstruction....10
  - Intestinal....5
  - Ureteral....2
  - Urethral....3
- Organs, Transpositioned....7
- Rectum, Supernumerary....4
- Siamese Twins....1
- Situs Inversus....5
- Spleen, None....1
- Stomach, Malformed (surgically corrected)....4
- Thyroid, none....2
- Ureter, Deformed....3
- Ureter, Supernumerary....1
- Other Birth Defects....174

Beckwith-Wiedemann Syndrome....1

Bladder Disorders....36
- Exstrophy....8
- Neurogenic....2
- Other Bladder Disorders....26

Bleeding Disorder....55
- Epistaxis....37
- Hematuria....10
- Hemmorhage....3
- Hemmorhage, Gastrointestinal....2
- Other Bleeding Disorders....3

Bloch-Swzbenger Syndrome....1

Blood Disorders....171
- Anemia....72
  - Aplastic....6
  - Hemolytic, Autoimmune....15
  - Megaloblastic....
  - Sickle Cell....12
  - Thalassemia....3
  - Other....35
- Coagulation Disorders....9
  - Hemophilia....7
  - Other....2
- Hypercapnia....1
- Lecithin Acyltranferase....1
- Leukocytosis....2
- Leukopenia....1
- Neutropenia....2
- Pelger-Huet Anomaly....1
- Purpura....3
  - Ideopathic Thrombocytopenic....1
  - Thrombotic Thrombocytopenic....1
  - Other....1
- Spherocytosis, Hereditary....1
- Thrombocytopenia....6
- Other Blood Disorders....72

Bone Disease....64
- Developmental....9
- Exostoses, Multiple....1
- Rickets....1
- Other Bone Diseases....53

Bone Marrow Diseases....7

Brain Disorders....107
- Damage Chronic....69
- Disease....15
- Dysfunction (Organic)....22
- Other Brain Disorders....1

Breast Disease....4

Cancer....481
- Bladder....2
- Bone....6
- Bone Marrow....1
- Breast....1
- Carcinoma....16
  - Adenocarcinoma....1
  - Basal Cell....1
  - Bronchogenic....1
  - Squamous Cell....2
  - Tetracarcinoma....1
  - Other....10
- Cervical....5
- Colon....11
- Ears....1
- Esophageal....2
- Genital....2
- Leukemia....45
- Liver....2
- Lymphoma....127
  - Hodgkin's Disease....16
  - Non-Hodgkin's....62
  - Other....49
- Lung....11
- Nasopharyngeal....2
- Ovarian....2
- Pancreatic....2
- Prostate....5

- Rectal....1
- Sarcoma....74
  - Histiocytosis....2
  - Liposarcoma....1
  - Lymphasarcoma....1
  - Retinoblastoma....2
  - Soft Tissue....42
  - Synovioma....3
  - Other....23
- Skin....29
- Stomach....3
- Testicular....3
- Thyroid....2
- Uterine....2
- Vaginal....4
- Wilm's Tumor....7
- Other Cancer....113

Cartilage Disease....2
Cat Eye Syndrome....1
Celiac Disease....4
Central Nervous System Damage....7
Cerebral Palsy....233
Charcot Manic Tooth Disease....2
CHARGE Association....3
Circulation Disorder....14
Colon Disease....17
Coma....2
Cornelia de lange Syndrome....3
Cri-du-chat Syndrome....2
Crohn's Disease....18
Crouzon's Syndrome....6
Cushing's Syndrome....1
Cystic Fibrosis....10
Cysts....124

- Brain....3
- Breast....4
- Esophageal....1
- Kidney, Polycystic....4
- Ovarian....19
- Vaginal....2
- Other Cysts....91

Dandy-Walker Syndrome....2
Deaf/Blind....5
Death....391

- Autism....1
- Birth defects, Multiple....22
  - Anencephaly....1
  - Brain Damage....1
  - Other....20
- Cancer....80
  - Bone....1
  - Colon....6
  - Glioblastoma....1
  - Leukemia....6
  - Lung....2
  - Lymphoma....11
    - Hodgkin's Disease....1
    - Non-Hodgkin's....6
    - Other....4
  - Melanoma....2
  - Meningioma....1
  - Neoplasm, Brain....5
  - Pancreatic....3
  - Sarcoma....6
    - Chondrosarcoma....1
    - Soft Tissue....5
  - Stomach....3
  - Other....33

Heart Failure....6
Hurler's Syndrome....1
Immune Deficiency....1
Infection....1
Neonatal....28
Neuromuscular Disease....2
Osteogenesis Imperfecta....1
Pediatric....71
Pulmonary Disorder....2
Sudden Infant Death Syndrome....3
Suicide....5
Werdnig-Hoffman Disease....2
Other Deaths....165
Dental Disorders....236

- Caries....14
- Dentia Tarda....2
- Disease....76
  - Pulp Disease....1
  - Other....75
- Enamel Hypoplasia....7
- Luxation....1
- Malocclusion....2
- Supernumerary Teeth....15
- Temporomandibular Joint Syndrome....5
- Tooth Abnormalities....26
- Tooth Discoloration....3
- Tooth Erosion....1
- Tooth Exfoliation....1
- Tooth Migration....1
- Tooth, unerupted....1
- Other Dental Disorders....81

Deficiency Disease....7

- Vitamin Deficiency....3
- Other Deficiency Disease....4

Developmental Delay....87
Developmental Disability....30
Diabetes, Insipidous....13
Diabetes Mellitus....144

- Juvenile....48
- Other Diabetes Mellitus....96

Digeorge Syndrome....2
Digestive System Abnormalities....68

- Constipation....8
- Diarrhea....29
- Diseases....8
  - Hischsprung's Disease....4
  - Other....4
- Diverticula....5
  - Colonic....4
  - Esophageal....1
- Other Digestive System Abnormalities....18

Dizziness....25

Donohue Syndrome....1
Down Syndrome (Trisomy 21)....107
Dual Diagnosis....2
Duane's Syndrome....1
Dysautonomia, Familial....1
Ear Disease....26
Eating Disorder....21
  Anorexia Nervousa....4
  Bulimia....8
  Pica....1
  Other Eating Disorders....8
Ectodermal Dysplasia....2
Edema....16
Ehlers-Danlos Syndrome....2
Elephantiasis....1
Encephalocele....2
Endocrine Disorder....3
Esophageal Disease....3
Eye Abnormalities....101
  Blepharitis....5
  Coloboma....4
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  Cholelithiasis....2
  Other Gall Bladder Diseases....12
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  Uterine Disease....2
  Vaginal Diseases....2
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  Other Hearing Disorders....448
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  Enlarged Heart....5
  Heart Diseases....179
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  Mitral Valve Prolapse....13
  Murmur....6
  Myocardial Infarction....10
  Takayasu Syndrome....2
  Tricuspid Valve Insufficiency....1
  Wolff-Parkinson-White Syndrome....1
  Other Heart Disorders....9
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Hormone Imbalance....3
Huntington's Disease....1
Hyaline Membrane Disease....4
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  Cellulitis....3
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  Cystitis....3
  Duodenitis....1
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  Epiglottitis....2
  Fibromyositis....3
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  Ileitis....3
  Iritis....1
  Laryngitis....3
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  Tendonitis....7
  Thyroiditis....2
  Tonsillitis....15
  Tracheitis....1
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    Other....1
  Pyelonephritis....1
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  Renal Acidosis....1
  Uremia....1
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- Tuberous Sclerosis....9
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- Ureteral Disease....1
- Urethral Disease....2
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  - Arteriosclerosis....7
  - Embolism....2
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  - Idiopathic Avascular Necrosis....1
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  - Other Vascular Disorders....12
- Venereal Disease....2
- Ventilator Dependent....12
- Vertigo....5
- Vision Disorders....632
  - Astigmatism....5
  - Blindness....148
  - Blurred Vision....3
  - Cataracts....18
  - Color Blindness....5
  - Glaucoma....21
  - Lens Dislocation Subluxation....1
  - Retinal Degeneration....22
    - Detachment....1
    - Retinitis Pigmentosa....3
    - Other....18
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  - Other Vision Disorders....394
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  - Self-induced....1
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  - Blood Disorder....3
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    - Leukemia....2
    - Lymphoma, Non-Hodgkins....2
    - Other....13
  - Diabetes....1
- Eating Disorder....2
  - Bulimia....1
  - Other....1
- Emotional Disorder....205
  - Hyperactivity....35
  - PTSD....51
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- Fragile X Syndrome....1
- Gastrointestinal Disorder....34
- Glands, Swollen....1
- Growth Disorder....6
- Hearing Disorders....10
- Heart Disorder....1
- Infertility....3
- Kidney Disorder....3
- Learning Disabilities....120
- Leishmaniasis....1
- Liver Disorder....3
- Lupus....5
- Memory Disorder....9
- Mental Retardation....5
- Motor Dysfunction....11
- Muscular Dystrophy....2
- Multiple Sclerosis....1
- Neoplasm....19
  - Melanoma....1
  - Other....18
- Neurologic Disorder....9
- Numbness....27
- Orthopedic Disability....39
  - Arthritis....9
  - Osteogenesis Imperfecta....2
  - Scoliosis....3
  - Other....25
- Peripheral Neuropathy....24
- Respiratory Disorders....33
- Sex Drive, Diminished....3
- Seizure Disorder....3
- Sleep Disorder....10
- Speech Disorder....2
- Thyroid Disorder....3
- Tourette's Syndrome....5
- Weight Loss....18
- William Syndrome....2
- Other Undiagnosed....231

- Homelessness....16
- Incarcerated....27
- Unemployed....13

- Total....24857

WRITTEN STATEMENT FOR THE COMMITTEE ON VETERANS' AFFAIRS

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The National Vietnam Veterans Birth Defects/Learning Disabilities Registry

PROJECT DESCRIPTION

The National Vietnam Veterans' Birth Defects/Learning Disabilities Registry is a cooperative project between the Association of Birth Defect Children (ABDC) and the New Jersey Agent Orange Commission (NJAOC). This registry is a part of ABDC's larger project, the National Environmental Birth Defects Registry (NEBDR).

The NEBDR was created to fill an important area of data deficiency in the reporting of birth defects and developmental disabilities in the United States. According to an October 1991 General Accounting Office report, estimates of the rate of birth defects in the United States range widely. Very poor data are at the center of the uncertainty. For example, one study found that approximately 2 to 3 percent of a group of children were diagnosed with a detectable physical or functional disorder at birth, but follow-up of the same children found the actual rate of disorders reached 16 percent (Chung, et al 1975). The dearth of nationwide information further limits our knowledge about reproductive and developmental disease (GAO, 1991)

According to the GAO report, the cause of 60% of reproductive and developmental disease is unknown, but 74% of a group of experts surveyed by the National Research Council predicted that up to 25% or more of these reproductive problems will be found to have been environmentally induced.

Several states and the Center for Disease Control currently use hospital discharge data to evaluate the incidence and types of reproductive problems occurring in the nation. This type of monitoring may fail to record from one-half up to two-thirds of birth defects and developmental disabilities (Chung, et al 1975). Hospital discharge data does not record developmental delay, learning and attention problems, immunological problems, autism, and other functional problems that may cause a greater proportion of childhood disabilities than structural birth defects.

The NEBDR was developed to gather more comprehensive data on structural birth defects and functional disabilities by collecting information directly from the parents of infants and older children with birth defects. The reporting parent(s) is also asked about the prenatal environmental exposures of the mother and preconceptual exposures of the father. One of the early challenges of this project was the design of the data collection instrument. A standardized testing format with bubble-in categories was adopted because everyone who has gone through the public school system is familiar with filling out this type of questionnaire. All data are entered by hand in a customized computer format that models the questionnaire. Information entered into the program automatically goes into more than twenty separate tables that can be connected in multiple ways for data analysis.

The development of the questionnaire took more than a year and went through several revisions after review by outside experts. Five-thousand questionnaires have been distributed to date and 1200 have been returned and entered into the data base. This pilot testing of the project has revealed the need for only minor changes in the questionnaire. The questionnaire has performed remarkably well with a large group of individuals of varied educational backgrounds. The project has also been well-received by the academic and professional communities.

The first distribution of NEBDR questionnaires has been to the entire ABDC mailing list of 5,000. This population represents families of children with birth defects and developmental disabilities all over the nation; professionals working with these

populations; birth defect support groups; hospitals, colleges, universities, public and private libraries and state or federal agencies working with developmental disabilities. In addition, ABDC has approximately 1000 families of Vietnam veterans on its mailing list.

Since 1988, ABDC and the NJAOC have been discussing the feasibility of using the NEBDR to collect data on the incidence of various birth defects and disabilities reported in the children of Vietnam veterans. In April of 1991, the state of New Jersey approved a contract with ABDC to collect data on the Vietnam veterans' children through the NEBDR. The NJAOC developed an additional page of questions to add to the NEBDR questionnaire and a new cover letter describing the cooperative project. These new components were added to a second printing of questionnaires.

The new questionnaires have been distributed by both the NJAOC and ABDC. At the time of this report, a total of 1200 questionnaires have been entered into the NEBDR. Eight-hundred of these questionnaires were returned by Vietnam veterans and 400 from other families on ABDC's mailing list..

PRELIMINARY DATA ANALYSIS

ABDC and NJACO have undertaken an early analysis of the data on disabilities in Vietnam veterans' children as compared to non-veterans' children in the registry to facilitate the National Academy of Sciences' review of the possible effects of herbicides/dioxin on reproductive outcome. Although 800 questionnaires have been returned by Vietnam veterans, over 65,000 cases of adverse reproductive outcomes were reported to the court during the Agent Orange litigation, so these initial findings may be modified as more data are collected.

Current data comparisons have revealed no increases in any major category of structural birth defects, but a pattern of functional problems in Vietnam veterans' children is emerging. This pattern includes statistically significant increases in the following conditions: all areas of learning and attention problems; chronic skin disorders (eczema, psoriasis, acne-like rash, skin fungus and other skin problems); benign tumors; cysts; allergic disorders (hives, asthma, hayfever, food intolerance and other allergies); growth hormone deficiency; immune problems (frequent upper respiratory and urinary tract infections); emotional/behavioral problems (depression, mood swings, obsessive/compulsive, anger, breaks laws, borderline personality and schizophrenia); prolasped heart valves and a range of miscellaneous categories including: tinnitus, frequent headaches, heat/cold sensitivity, fatigue, muscle pain/weakness, joint pain, unexplained fevers, hair loss, tooth problems and chronic stomach problems.

This pattern of disability is very similar to symptoms reported in children with Chronic Fatigue Immune Dysfunction Syndrome (CFIDS Chronicle, 1991). Discrete immunological defects have been noted in several studies of patients with CFIDS and most recently in research at the National Institutes of Health. (CFIDS Chronicle, 1993) Although most veteran families do not have the financial resources to have a comprehensive immunological evaluation of their children, some of the most seriously affected children have been tested and have markers similar to those found in CFIDS patients. In a study of teenagers with CFIDS, over half had reported a pattern of recurrent infections, allergic disorders, colic, spitting up and stomach cramps during the first 5 years of life. This symptom complex was twice what was expected in a normal healthy population and parallels our findings in Vietnam veterans' children. Some of the major difficulties reported in older children and teenagers with CFIDS are neurocognitive deficits which also seem to mirror the learning, attention and emotional problems reported in Vietnam veterans' children.

CAN PRENATAL DAMAGE TO THE IMMUNE SYSTEM CAUSE A SYNDROME OF IMMUNE DYSFUNCTION?

The development of the human immune system begins late in the fetal period, is functioning at birth and reaches maximum capacity around the time of puberty (Paul, 1984; Claman, 1987). The immune system is susceptible to chemical injury from a variety of agents. The developing fetus is unable to recognize and react to a wide range of foreign substances, and it is more susceptible to long-term immunotoxic effects than is the adult (Lewis et al., 1978; Bick, 1985; Hausman and Weksler, 1985). Exposure in utero, when the

immune system is developing, could have long-term effects on the ability of an individual to generate an immune response (Osburn and Schultz, 1973). The effects of TCDD on the thymus and on immune-system responses are more severe and long-lasting if TCDD is administered both before and after birth rather than only at birth (Vos and Moore, 1974; Faith and Moore, 1977; Luster et al., 1979). Thymic atrophy and cell-mediated immunosuppression also are extensive after perinatal exposure, at which time the immune system is being developed in utero (Thomas and Hinsdill, 1979; Fine et al. 1989) Upon perinatal exposure to TCDD, there is a significant reduction in early lymphopoiesis. These studies show that the developing fetal or neonate immune system could be at greater risk of suppression if it is exposed to environmental toxicants (NRC, 1992).

Because the cellular events responsible for immune processes also are involved in embryogenesis, many immunosuppressive xenobiotics would be expected to be developmental toxicants (NRC, 1992). A review of the literature has revealed that most teratogens are also immunotoxicants (Mekdeci, 1991). Although no pattern of major structural anomalies has been identified in Vietnam veterans' children reporting to the registry, there is new research suggesting that learning disabilities and attention deficit disorders may be related to differences in the size and symmetry of certain areas of the brain (Hynd et al., 1990). These studies suggest that something interferes with the normal growth patterns in the brain's cortex during fetal development.

MALE-MEDIATED BIRTH DEFECTS

Dr. Donald Mattison, from the School of Public Health at the University of Pittsburgh, has reported that animal studies have identified more than 100 chemicals that can produce spontaneous abortions or birth defects in offspring fathered by exposed males. Some of these chemicals include alcohol, anesthetic gases, lead, solvents, pesticides and a variety of industrial chemicals (Harris, 1991). Paternal use of noxious agents may exert deleterious effects directly by genetically altering the sperm, or indirectly by exerting modifying effects on the environmental surrounding the mating germ cells (Pollard & Smallshaw, 1988). Dr. Robert Dixon, former chief of the Laboratory of Reproductive and Development Toxicology at the National Institute of Environmental Health Sciences contends that semen, like breast milk, may be a collecting point for some toxic agents (Emmett, 1980). The human sperm cell has a moderate fat content and a high nucleic acid content, both of which are quite efficient in binding chemicals such as chlorinated or brominated chemicals (Jansson, 1980). A study of men working with lead has found twice the concentration of lead in their semen as in their blood. Dr. Ralph Dougherty reported high levels of four toxic chemicals in a study of seminal fluid of 132 male students at Florida State University. Dr. Dougherty developed a monoclonal antibody assay for dioxin that could be used to measure TCDD levels in seminal fluid (Dougherty, 1990).

NURTURE VERSUS EXPOSURE

Some disciplines would attribute a pattern of disability that includes learning, attention, behavioral, allergic, infectious and skin problems in addition to symptoms typical of CFIDS to the nurturing environment. This explanation is an especially attractive alternative in the Vietnam veterans who are suffering from PTSD and a variety of health problems that some professionals have related to the stresses of war and failure to reintegrate within society. ABDC analyzed disabilities in the non-veteran population to address this possible etiological explanation. The same pattern of learning, behavioral, allergic, immunological and attention problems occurred together although the percentage of children with this syndrome was much smaller than in the Vietnam veteran cases. This finding would tend to argue against nurture since the non-veteran families did not suffer the same war-related stresses experienced by Vietnam veterans.

THE VIRAL HYPOTHESIS

Research on CFIDS has focused on identifying a viral cause for this pattern of disability because antibodies to a variety of latent viruses are often elevated in the syndrome. Immunosuppressive treatments, such as irradiation, neonatal thymectomy, or the use of immunosuppressive drugs, can result in an increased incidence of parasitic, viral, fungal or bacterial infections (NRC, 1992). When the developing immune system has been damaged before birth, there will also be an increased incidence of infections and viral reactivation syndromes. If the pattern of disability found in Vietnam veterans could be attributed to a new virus, there should be an equal prevalence of this pattern of disabilities in both veteran and non-veteran children since any new virus that may have been brought back from Vietnam would certainly have spread to the general population in the last twenty-five years.

A number of viruses have immunosuppressive effects when they are in an active state and a syndrome involving immune incompetence could result in periodic or chronic reactivation of these viruses. One herpes virus of particular concern is Human Herpes Virus 6 which has been found in both HIV positive patients and CFIDS patients. During active stages, HHV 6 attacks both T and B cells thus contributing to the destruction of the immune system. Although some studies have shown widespread exposure to HHV-6 in the general population, this virus could contribute to chronic health problems in children whose immune systems were damaged prenatally.

CHALLENGES TO THE REGISTRY 'S DESIGN

There are several challenges that could be made to both the design of the NEBDR and the data interpretation. The NEBDR depends on self-reported data which is subject to memory-recall bias. However, both the Vietnam veterans and the non-veterans filling out the questionnaires are equal in this respect since all respondents have children with defects and/or disabilities. Since some of these children were born a number of years ago, memory loss about the events and possible exposures during pregnancy could also be a factor. To assess this problem, ABDC stratified the data in veteran and non-veteran groups to compare children of the same age group. The results of the analysis were essentially the same and the pattern of disability found in Vietnam veterans' children remained statistically significant when compared to non-veterans' children.

The registry could also be challenged by the claim that parents have been sensitized to report certain types of defects associated with certain exposures. This does not seem to be happening in this data collection. Neural tube defects and oral clefts have been associated with Agent Orange exposure in the media yet neither category has been more reported more frequently to the registry by Vietnam veterans than by non-veterans.

CONFIRMING THE HYPOTHESIS

In summary, the current analysis of data on Vietnam veterans' children compared to the children of non-veterans in the NEBDR has identified a pattern of disabilities that could be related to prenatal damage to the immune system. Investigation of this hypothesis could be facilitated through continued data collection from larger numbers of both Vietnam veterans and non-veterans which would help to balance out any artifacts inherent in early data collection. Focused case control studies could be designed to look at subsets of the Vietnam veterans' children with the typical pattern of disability identified by the registry. Comprehensive immunological and neurocognitive testing of these subsets could be used to identify markers similar to those being found in CFIDS patients. Magnetic resonance scans could confirm whether there are any anatomical differences in the size or symmetry of critical areas of the brain and look for evidence of UBO's (unidentified bright objects) like those found in the MRI's of CFIDS patients. (Some researchers have suggested that the UBO's in the brain scans of CFIDS patients represent areas of demyelination.) The registry could also be used to compare the Vietnam veteran cases with cases gathered at environmental sites where exposures to dioxin, herbicides and similar chemicals have been reported.

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ASSOCIATION OF BIRTH DEFECT CHILDREN, INC.

The National Environmental Birth Defect Registry

a project of

the Association of Birth Defect Children
5400 Diplomat Circle, Suite 270
Orlando, Florida 32810
(407) 629-1466

Dear Parent,

The National Environmental Birth Defect Registry has been created to collect information about birth defects, learning disabilities, childhood cancers and other childhood disabilities that may be related to environmental (drugs, chemicals, radiation, pesticides) exposures of the mother and/or the father during or before the pregnancy. You should fill out a separate questionnaire for each of your children with one or more of these disabilities. (Extra questionnaires can be obtained by writing or calling ABDC. Copies of this form cannot be used.) Please complete the questionnaire with a number two pencil or black pen. PRINT clearly and/or fill in the circles where indicated. Return the completed form to the Association of Birth Defect Children in the enclosed envelope.

Be sure to indicate whether you would like to participate in ABDC's parent matching project. If you check YES on the parent matching question, we will match you with other families who have children with disabilities similar to those of your child. All individual personal information obtained through this questionnaire is confidential except for names and addresses exchanged for parent matching.

If you have any questions about filling out this questionnaire, please call ABDC at (407) 629-1466 9 a.m. to 4 p.m.

Thank you for helping with this important project,

Betty Mekdeci,
Executive Director

The National Environmental Birth Defect Registry has been supported in part by a grant from:

National Coalition Against the Misuse of Pesticides
Washington, D.C.

DO NOT WRITE IN THIS SHADED AREA 5279

PLEASE DO NOT FOLD OR STAPLE

ASSOCIATION OF BIRTH DEFECT CHILDREN, INC.

REGISTRY QUESTIONNAIRE

(Please print in ink or #2 pencil.)

ID No.:_____ **(leave blank)** **Date:** ____/____/____ (Mo / Day / Yr)

Reporting parent's name: _____

Street/POB: _____ **Apt. no.:** _____

City: _____ **State:** _____ **Zip:** _____

Phone: ( ) _____

I would like to be matched with other families of children with similar disabilities. ○ yes ○ no

CHILD DISABILITIES INFORMATION

Child's name: _____

Sex: M ○ F ○ **Blood type:** O ○ A ○ B ○ AB ○ **Race:** White ○ Black ○ Hispanic ○ Asian ○

Date of birth: ____/____/____ (Mo / Day / Yr) **Nationality:** _____

Place of birth - City: _____ **State:** _____

Has child been hospitalized because of birth defects? ○ Yes ○ No

Hospitalization date(s): _____ **Cause:** _____

_____ **Cause:** _____

_____ **Cause:** _____

Name of child's main physician: _____ **Telephone number:** ( ) _____

If child has died, list date and cause of death.

Cause of death: _____ **Date:** ____/____/____ (Mo / Day / Yr)

CHILDHOOD DISABILITIES CODES

Please fill in the bubble by each condition your child has. If a condition your child has is not listed, please write the name of the condition in the Other space in the appropriate column.

Central Nervous System (CNS)

- ○ A001 anencephaly
- ○ A002 microcephaly
- ○ A003 hydrocephaly
- ○ A004 porencephaly
- ○ A005 craniosynostosis
- ○ A006 bony defect of skull
- ○ A007 encephalocele
- ○ A008 absence corpus callosum
- ○ A009 spina bifida
- ○ A010 spina bifida/meningomyelocele/meningocele
- ○ A011 holoprosencephaly
- ○ A012 cerebral palsy
- ○ A013 other CNS: _____

If you were exposed to Agent Orange, please answer these additional questions.

1. Branch of Service:

- ○ Army
- ○ Marines
- ○ Navy
- ○ Coast Guard
- ○ Air Force
- ○ Other

2. Dates of Service in Vietnam:

First Tour:
From _____ To _____

Second Tour:
From _____ To _____

Third Tour:
From _____ To _____

3. Rank:

First Tour: _____

Second Tour: _____

Third Tour: _____

4. Corps areas served in:

- ○ I Corps
- ○ II Corps
- ○ III Corps
- ○ IV Corps

5. MOS:

Number _____

Name _____

6. Secondary MOS:

Number _____

Name _____

7. Year(s) in Vietnam:

- ○ Pre 1965
- ○ 1965
- ○ 1966
- ○ 1967
- ○ 1968
- ○ 1969
- ○ 1970
- ○ 1971
- ○ 1972
- ○ 1973
- ○ Post 1973

8. Were you hospitalized while in Vietnam?

- ○ Yes
- ○ No

8a. If yes, explain: _____

_____

_____

_____

9. Note the area you were in or near during your tour(s) in Vietnam:

I Corps
- ○ Danang
- ○ Chu-Lai
- ○ Phu Bai
- ○ Hue
- ○ Quang Tri
- ○ Dong Ha
- ○ Con Thien
- ○ Khe Sahn
- ○ Ashau Valley
- ○ Other

II Corps
- ○ Pleiku
- ○ Dak To
- ○ Kontum
- ○ Phu Cat
- ○ Qui Nhon
- ○ Tuy Hoa
- ○ Cam Ranh
- ○ Nha Trang
- ○ Quang Nhai
- ○ Other

_____ _____

III Corps
- ○ Saigon
- ○ Bien Hoa
- ○ Long Binh
- ○ Tam Ky
- ○ Cu-Chi
- ○ Phuoc Vinh
- ○ Bear Cat
- ○ Lai-Khe
- ○ Vung Tau
- ○ Other

IV Corps
- ○ My Tho
- ○ Can Tho
- ○ Ben Tre
- ○ Rung Sat
- ○ Dong Tam
- ○ Ben Tuy
- ○ Ca Mau
- ○ Rach Gia
- ○ Chau Doc
- ○ Other

_____ _____

10. Do you have any other biological children who do not have birth defects or learning disabilities?

- ○ Yes
- ○ No

10a. If yes, please list year of birth and sex of child:

_____ _____
Year Sex

_____ _____
Year Sex

11. Have you had any miscarriages?

- ○ Yes
- ○ No

11a. If yes, please list number and years:

_____ _____

_____ _____

12. Did you have any foreign travel (outside continental U.S.) during the five years prior to your child's birth?

Father: ○ Yes ○ No Where? _____

Mother: ○ Yes ○ No Where? _____

CHILDHOOD DISABILITIES CODES (Continued)

Limb Defects

- ○ B016 reduction deformity upper limb (missing or small fingers, hands or arms)
- ○ B017 reduction deformity lower limb (missing or small toes, feet or legs)
- ○ B018 arthrogryposis
- ○ B019 twisted upper limb
- ○ B020 twisted lower limb
- ○ B021 dislocated hip
- ○ B022 contractures of elbows/knees or other joints
- ○ B023 clubfoot
- ○ B024 clubfoot with bone deformity
- ○ B025 other limb _____

Muscle

- ○ C031 pectoralis (large chest) muscle - (absent or underdeveloped)
- ○ C032 muscular dystrophy
- ○ C033 diaphragmatic hernia
- ○ C034 hiatal hernia
- ○ C035 other muscle _____

Chest

- ○ D039 lung - (absent or underdeveloped)
- ○ D040 pectus excavatum (caved in chest)
- ○ D041 pigeon chest (chest bowed out)
- ○ D042 other chest _____

Spine

- ○ E046 scoliosis
- ○ E047 malformations of vertebrae
- ○ E048 other spine _____

Eye

- ○ F051 cataract
- ○ F052 anophthalmia (missing eye)
- ○ F053 micropthalmia (small eye)
- ○ F054 coloboma
- ○ F055 aniridia
- ○ F056 nystagmus
- ○ F057 defect in vision
- ○ F058 strabismus
- ○ F059 other eye defect _____

Ear

- ○ G061 external ear - (absent or malformed)
- ○ G062 deaf
- ○ G063 hearing loss
- ○ G064 other ear _____

Mouth/Jaw/Face

- ○ H067 cleft lip
- ○ H068 cleft palate
- ○ H069 micrognathia (small jaw)
- ○ H070 facial bone deformity
- ○ H071 macroglossia (large tongue)
- ○ H072 other _____

Cardiovascular

- ○ I076 common truncus
- ○ I077 transposition great arteries
- ○ I078 tetralogy of fallot
- ○ I079 ventricular septal defect
- ○ I080 atrial septal defect
- ○ I081 endocardial cushion defect
- ○ I082 pulmonary valve stenosis/atresia
- ○ I083 tricuspid valve stenosis/atresia
- ○ I084 aortic valve stenosis/atresia
- ○ I085 hypoplasia left heart syndrome
- ○ I086 patent ductus arteriosis
- ○ I087 coarctation of aorta
- ○ I088 pulmonary artery anomaly
- ○ I089 pulmonary atresia or hypoplasia
- ○ I090 prolasped valve
- ○ I091 heart murmur
- ○ I092 other heart _____

Gastrointestinal (GI)

- ○ J096 pyloric stenosis
- ○ J097 tracheo-esophageal anomaly
- ○ J098 rectal and/or intestinal atresia
- ○ J099 imperforate anus
- ○ J100 Hirschsprung disease
- ○ J101 inguinal hernia
- ○ J102 omphalocele
- ○ J103 other GI _____

Liver/Bile Duct/Spleen

- ○ K106 absent gall bladder
- ○ K107 biliary atresia
- ○ K108 absent spleen
- ○ K109 other _____

CHILDHOOD DISABILITIES CODES (Continued)

Genitourinary (GU)

- ○ L111 hypospadius
- ○ L112 undescended testicles
- ○ L113 absent kidney
- ○ L114 malformed kidney
- ○ L115 bladder exstrophy
- ○ L116 polycystic kidney
- ○ L117 absent bladder
- ○ L118 malformed ureter
- ○ L119 hermaphrodite
- ○ L120 malformed sex organs
- ○ L121 hydrocele
- ○ L122 other GU _____

Skin

- ○ M126 port wine stain
- ○ M127 cafe au lait birth mark
- ○ M128 strawberry birth mark
- ○ M129 other birth mark
- ○ M130 eczema
- ○ M131 psoriasis
- ○ M132 acne-like rash
- ○ M133 skin fungus
- ○ M134 other skin problem _____

Tumors - Benign

- ○ N138 lipoma
- ○ N139 hemangioma
- ○ N140 cavernous hemangioma
- ○ N141 other benign tumor _____

Syndromes

- ○ O145 Downs
- ○ O146 Pierre Robin
- ○ O147 Marfan
- ○ O148 Apert
- ○ O149 Trisomy
- ○ O150 Cornelia de Lange
- ○ O151 Goldenhar
- ○ O152 Klippel-fiel
- ○ O153 Dandy Walker
- ○ O154 Turner's
- ○ O155 Treacher Collins
- ○ O156 Nail-Patella
- ○ O157 other syndromes _____

Cancer

- ○ P166 neuroblastoma
- ○ P167 leukemia
- ○ P168 lymphoma
- ○ P169 Wilms tumor
- ○ P170 colon cancer
- ○ P171 Hodgkins disease
- ○ P172 Non-Hodgkins lymphoma
- ○ P173 other cancer _____

Cysts

- ○ Q179 brain
- ○ Q180 ovarian
- ○ Q181 other cysts _____

Growth Retardation (GR)

- ○ R186 growth hormone deficiency
- ○ R187 dwarf
- ○ R188 midget
- ○ R189 constitutional short stature
- ○ R190 other GR _____

Learning Disabilities (LD)

- ○ S196 dyslexia/reading
- ○ S197 math
- ○ S198 speech
- ○ S199 language processing
- ○ S200 spelling/writing
- ○ S201 other LD _____

Attention Deficit Disorders

- ○ T205 Attention Deficit Without Hyperactivity
- ○ T206 Attention Deficit With Hyperactivity _____

Developmental Delay (DD)

- ○ U207 retardation
- ○ U208 motor skills delay
- ○ U209 other DD _____

Emotional/Behavioral (E/B)

- ○ V213 depression
- ○ V214 obsessive/compulsive
- ○ V215 mood swings
- ○ V216 anger
- ○ V217 breaks law/rules of society
- ○ V218 borderline personality
- ○ V219 schizophrenia
- ○ V220 other E/B _____

CHILDHOOD DISABILITIES CODES (Continued)

Allergies
- ○ W224 hives
- ○ W225 asthma
- ○ W226 hayfever
- ○ W227 food intolerance
- ○ W228 drug reaction
- ○ W229 other allergy _____

Immune Defect
- ○ X231 primary immune defect
- ○ X232 frequent pneumonia
- ○ X233 frequent urinary tract infections
- ○ X234 frequent upper respiratory infections
- ○ X235 frequent ear infections
- ○ X236 hypogammaglobulinemia
- ○ X237 other immune defect _____

Endocrine
- ○ Y241 early puberty
- ○ Y242 pituitary defect
- ○ Y243 thyroid defect
- ○ Y244 diabetes
- ○ Y245 other endocrine _____

Miscellaneous
- ○ Z251 ear noises (tinnitus)
- ○ Z252 seizures
- ○ Z253 frequent headaches
- ○ Z254 heat/cold sensitivity
- ○ Z255 sensitivity to light
- ○ Z256 fatigue
- ○ Z257 muscle pain/weakness
- ○ Z258 joint pain
- ○ Z259 unexplained fevers
- ○ Z260 hair loss
- ○ Z261 blood disease
- ○ Z262 tooth problems (missing, fused, no enamel, etc.)
- ○ Z263 stomach problems (ulcer, diarrhea, gastritus)
- ○ Z264 jaundice at birth
- ○ Z265 other problems not listed _____

MOTHER DATA

Mother's name: _____ **Marital status:** ○ Married ○ Single ○ Widow ○ Divorced

Date of birth: ___/___/___ (Mo Day Yr) **Race:** ○ White ○ Black ○ Hispanic ○ Asian **Blood type:** ○ O ○ A ○ B ○ AB

Age during this pregnancy: _____ **Nationality:** _____

Where did you live during pregnancy? City: _____ **State:** _____

Occupation before pregnancy: _____ **Place of employment:** _____

Occupation during pregnancy: _____ **Place of employment:** _____

A. When did mother first realize she was pregnant?
- ○ 1 week
- ○ 2 weeks
- ○ 3 weeks
- ○ 4 weeks
- ○ 5-8 weeks
- ○ 9-12 weeks
- ○ 13-20 weeks

B. When did mother first receive prenatal care?
- ○ 1 week
- ○ 2 weeks
- ○ 3 weeks
- ○ 4 weeks
- ○ 5-8 weeks
- ○ 9-12 weeks
- ○ 13-20 weeks
- ○ 21-32 weeks

C. Was the care regular?
- ○ Yes
- ○ No

D. Did mother receive genetic counseling or screening during this pregnancy?
- ○ Yes
- ○ No

E. Do any members of mother's family have problems similar to those of your child?
- ○ Yes
- ○ No

If yes, please explain:
_____
_____

F. Did mother have amniocentesis during this pregnancy?
- ○ Yes
- ○ No

Did any abnormalities show up?
- ○ Yes
- ○ No

G. Did mother have an ultrasound examination during this pregnancy?
- ○ Yes
- ○ No

If yes, please list number and dates:
_____

Did any abnormalities show up?
- ○ Yes
- ○ No

MOTHER DATA (Continued)

H. List any illnesses mother had during this pregnancy and month(s) of illness.

1. _____ Month(s): _____
2. _____ Month(s): _____
3. _____ Month(s): _____

I. Was mother tested for rubella during pregnancy?
○ Yes ○ No
If yes, what were the results?
○ Positive ○ Negative

J. Did mother have any sexually transmitted disease (STD) during this pregnancy?
○ Yes ○ No
If yes, please list name of the STD:
_____

K. Did mother eat raw or undercooked meat during this pregnancy?
○ Yes ○ No

L. Did mother empty the cat's litter box during this pregnancy?
○ Yes ○ No

M. Was mother tested for toxoplasmosis?
○ Yes ○ No
If yes, please list results:
_____

N. How long did mother work during pregnancy?
○ 1 month ○ 6 months
○ 2 months ○ 7 months
○ 3 months ○ 8 months
○ 4 months ○ 9 months
○ 5 months

O. Was mother exposed to any chemicals in her workplace?
○ Yes ○ No
If yes, please list name or type of chemical(s) if known:
_____
_____
_____

P. Month(s) of exposure
○ 1 month ○ 6 months
○ 2 months ○ 7 months
○ 3 months ○ 8 months
○ 4 months ○ 9 months
○ 5 months

Q. Did mother work at a video display terminal during this pregnancy?
○ Yes ○ No
If yes, for how many hours a day?
○ Less than 1 hour ○ 5-6 hours
○ 1-2 hours ○ 7-8 hours
○ 3-4 hours ○ More than 8 hours
If yes, for how many months during pregnancy?
○ 1 month ○ 6 months
○ 2 months ○ 7 months
○ 3 months ○ 8 months
○ 4 months ○ 9 months
○ 5 months

R. Did mother live in an agricultural area during this pregnancy?
○ Yes ○ No

S. Did mother have home and/or yard pest control service during this pregnancy?
○ Yes ○ No
If yes, number of times exposed:
⑨①②③④⑤⑥⑦⑧⑨⑩

T. Did mother have a contaminated water supply during this pregnancy?
○ Yes ○ No
If yes, what was the water contaminated with?
_____

U. What type of water did mother drink during this pregnancy?
○ City tap ○ Well ○ Bottled

V. Did mother live near a hazardous waste site during this pregnancy?
○ Yes ○ No
Name of site: _____

W. Was mother exposed to fresh paint fumes during this pregnancy?
○ Yes ○ No
If yes, during what month of pregnancy:
○ 1 ○ 6
○ 2 ○ 7
○ 3 ○ 8
○ 4 ○ 9
○ 5

X. Did mother have any hobbies which exposed her to chemicals during this pregnancy (Ex. photography developing chemicals, paint, glue, solvents, wood stripper)?
○ Yes ○ No
If yes, please list and give month of exposure:
1. _____ Month(s): _____
2. _____ Month(s): _____
3. _____ Month(s): _____

ENVIRONMENTAL EXPOSURES DURING PREGNANCY

(If you were exposed to any of the following substances during pregnancy, please fill in the bubble in the space under the month(s) of exposure. Also, please list the name of the substance and amount of exposure, if known.)

	Month of Exposure		
	1-3 months	4-6 months	7-9 months
Anti-nauseants/motion sickness medications	○	○	○
Pain killers (Ibuprofen, aspirin, Tylenol, Motrin, etc.)	○	○	○
Tranquilizers	○	○	○
Antihistamines (allergy medications)	○	○	○
Muscle relaxers	○	○	○
Sedatives	○	○	○
Appetite suppressants (diet pills)	○	○	○
Cold/cough medication	○	○	○
Nose sprays	○	○	○
Asthma medications	○	○	○
Allergy shots	○	○	○
Decongestants	○	○	○
Hormones	○	○	○
Antibiotics	○	○	○

ENVIRONMENTAL EXPOSURES DURING PREGNANCY

(If you were exposed to any of the following substances during pregnancy, please fill in the bubble in the space under the month(s) of exposure. Also, please list the name of the substance and amount of exposure, if known.)

	Month of Exposure		
	1-3 months	4-6 months	7-9 months
Anti-spasmodics (for stomach cramps)	○	○	○
Arthritis medication	○	○	○
Diuretics	○	○	○
Diabetes medications	○	○	○
Thyroid medications	○	○	○
Fungicides (to treat fungal infections)	○	○	○
Vaginal medications	○	○	○
Anti-psychotics	○	○	○
Alcohol - number of glasses during pregnancy	○	○	○
Smoking - number of cigarettes per day	○	○	○
Aspartame (NutraSweet)	○	○	○
Illegal drugs	○	○	○
Vitamins (especially megadoses)	○	○	○
Diagnostic X-rays	○	○	○

ENVIRONMENTAL EXPOSURES DURING PREGNANCY

(If you were exposed to any of the following substances during pregnancy, please fill in the bubble in the space under the month(s) of exposure. Also, please list the name of the substance and amount of exposure, if known.)

	Month of Exposure		
	1-3 months	4-6 months	7-9 months
Anti-inflammatories	○	○	○
_____			
Blood thinners	○	○	○
Flu shots	○	○	○
_____			
Anti-convulsants	○	○	○
Anesthetics	○	○	○
_____			
Heart medications	○	○	○
_____			
Blood pressure medications	○	○	○
_____			
Anti-depressants	○	○	○
_____			
Fertility drugs	○	○	○
_____			
Stimulants	○	○	○
_____			
Accutane (acne medication)	○	○	○
_____			
Steroids	○	○	○
_____			
Antacids	○	○	○
_____			
Laxatives	○	○	○
_____			

ENVIRONMENTAL EXPOSURES DURING PREGNANCY

(If you were exposed to any of the following substances during pregnancy, please fill in the bubble in the space under the month(s) of exposure. Also, please list the name of the substance and amount of exposure, if known.)

	Month of Exposure		
	1-3 months	4-6 months	7-9 months
Ultra sound examination	○	○	○
_____			
Pesticides (insecticides, fungicides, herbicides)	○	○	○
_____			
Chemical exposure(s) in workplace	○	○	○
_____			
Other exposures not listed	○	○	○
_____			

FATHER DATA

Father's name: _____ **Nationality:** _____

Date of birth: ___/___/___ (Mo Day Yr) **Race:** White ○ Black ○ Hispanic ○ Asian ○ **Blood type:** O ○ A ○ B ○ AB ○

If father has died, please list cause and date of death: _____ **Date:** ___/___/___ (Mo Day Yr)

Occupation prior to child's birth: _____ **Place of employment:** _____

Exposed to Agent Orange: ○ Yes ○ No

If yes, place and date of AO exposure: _____ **Date:** ___/___/___ (Mo Day Yr)

OTHER ENVIRONMENTAL EXPOSURES PRIOR TO CHILD'S BIRTH:

A. Chemical exposure in workplace:
○ Yes ○ No
If yes, please list name of substance if known:
_____
Number of years exposed: _____

B. Doctor prescribed medications or over-the-counter drugs used regularly prior to child's birth. Please list:
_____

C. Recreational drugs used regularly prior to child's birth. Please list:
_____

D. Did father drink alcoholic beverages prior to child's birth?
○ Yes ○ No
If yes, amount consumed on a daily basis:
○ 1 drink ○ 4 drinks
○ 2 drinks ○ 5 drinks
○ 3 drinks ○ 6 or more drinks

E. Did father smoke prior to child's birth?
○ Yes ○ No
If yes, how many packs per day:
○ Less than 1 pack ○ 2 packs
○ 1 pack ○ More than 2 packs

F. Did father have hobbies that involve chemical exposure (ex. photography developing, wood working, furniture refinishing.)
○ Yes ○ No
If yes, list hobby and/or chemical exposure, if known
_____

G. How many hours per day did father spend with this hobby?
○ Less than 1 hour ○ 3 hours
○ 1 hour ○ 4 hours
○ 2 hours ○ 5 or more hours

FATHER DATA (Continued)

H. Was father exposed to radiation prior to this child's birth?
○ Yes ○ No

How exposed? _____

I. Was father exposed to pesticides through farming, gardening or spraying home/and or yard?
○ Yes ○ No

If yes, please list brand names, if known:

_____

J. How frequently was father exposed to these pesticides?
○ Daily ○ Several times a week ○ Several times a year
○ Less than once a week ○ Monthly

Number of years exposed: _____

K. Do any members of father's family have problems similar to those of your child?
○ Yes ○ No

If yes, please explain:

_____

_____

L. Has father had any of the following symptoms and/or illnesses:

Sensitivity to light
○ Yes ○ No

Impaired sight or hearing
○ Yes ○ No

Chronic skin rashes
○ Yes ○ No

Mood swings
○ Yes ○ No

Sleep disorders
○ Yes ○ No

Depression
○ Yes ○ No

Outbursts of rage
○ Yes ○ No

Cardiovascular disorders
○ Yes ○ No

Abnormal hairiness
○ Yes ○ No

Respiratory problems
○ Yes ○ No

Liver disorders
○ Yes ○ No

Stomach problems
○ Yes ○ No

Fat or carbohydrate metabolism disorders
○ Yes ○ No

Urinary tract disorders
○ Yes ○ No

Reduced sex drive, impotence
○ Yes ○ No

Weakness of lower extremities
○ Yes ○ No

Cancer
○ Yes ○ No

Fatigue
○ Yes ○ No

Nervousness
○ Yes ○ No

Numbness in fingers and/or toes
○ Yes ○ No

Alcohol intolerance
○ Yes ○ No

Thyroid disorder
○ Yes ○ No

Benign tumors (not cancerous)
○ Yes ○ No

New Jersey
Agent Orange Commission

Association of
Birth Defect Children

Vietnam Veterans National Birth Defects/Learning Disabilities Registry

a project of

New Jersey Agent Orange Commission
P.O. Box 1717
Trenton, NJ 08607-1717
(609) 530-8162

Association of Birth Defect Children
5400 Diplomat Circle - Suite 270
Orlando, FL 32810
(407) 629-1466

Dear Veteran:

This questionnaire represents the combined efforts of the New Jersey Agent Orange Commission and the Association of Birth Defect Children (ABDC) to establish a National Birth Defect/Learning Disabilities Registry and Data Base for the children of Vietnam veterans.

Information collected from questionnaires will be combined with data in the ABDC National Environmental Birth Defect Registry to compare the children of Vietnam veterans to the children of non-veterans.

You should fill out a separate questionnaire for each of your children with one or more of these disabilities. (Extra questionnaires can be obtained by calling our offices or writing to us.) Please complete the questionnaire in number two (#2) pencil only. Copies of this questionnaire cannot be used. Print clearly and/or fill in the circles where indicated.

Be sure to indicate whether you would like to participate in ABDC's parent matching project. If you mark yes on the parent matching question, we will match you with other families who have children with disabilities similar to those of your child. All individual personal information obtained through this questionnaire is confidential except for names and addresses exchanged for parent matching.

If, for any reason you elect not to participate, please return the questionnaire to us so it can be used by another veteran.

William W. Lewis
Executive Director
NJAOC

Betty Mekdeci
Executive Director
ABDC

The National Environmental Birth Defect Registry has been supported in part by a grant from:

National Coalition Against the Misuse of Pesticides
Washington, D.C.

DO NOT WRITE IN THIS SHADED AREA 15541

PLEASE DO NOT FOLD OR STAPLE

ASSOCIATION OF BIRTH DEFECT CHILDREN, INC.

REGISTRY QUESTIONNAIRE

(Please print in ink or #2 pencil.)

ID No.: _____ **(leave blank)** **Date:** ____/____/____ (Mo / Day / Yr)

Reporting parent's name: _____

Street/POB: _____ **Apt. no.:** _____

City: _____ **State:** _____ **Zip:** _____

Phone: ( ) _____

I would like to be matched with other families of children with similar disabilities. ○ yes ○ no

CHILD DISABILITIES INFORMATION

Child's name: _____

Sex: M ○ F ○ **Blood type:** O ○ A ○ B ○ AB ○ **Race:** White ○ Black ○ Hispanic ○ Asian ○

Date of birth: ____/____/____ (Mo / Day / Yr) **Nationality:** _____

Place of birth - City: _____ **State:** _____

Has child been hospitalized because of birth defects? ○ Yes ○ No

Hospitalization date(s): _____ **Cause:** _____

_____ **Cause:** _____

_____ **Cause:** _____

Name of child's main physician: _____ **Telephone number:** ( ) _____

If child has died, list date and cause of death.

Cause of death: _____ **Date:** ____/____/____ (Mo / Day / Yr)

CHILDHOOD DISABILITIES CODES

Please fill in the bubble by each condition your child has. If a condition your child has is not listed, please write the name of the condition in the Other space in the appropriate column.

Central Nervous System (CNS)

- ○ A001 anencephaly
- ○ A002 microcephaly
- ○ A003 hydrocephaly
- ○ A004 porencephaly
- ○ A005 craniosynostosis
- ○ A006 bony defect of skull
- ○ A007 encephalocele
- ○ A008 absence corpus callosum
- ○ A009 spina bifida
- ○ A010 spina bifida/meningomyelocele/meningocele
- ○ A011 holoprosencephaly
- ○ A012 cerebral palsy
- ○ A013 other CNS: _____

CHILDHOOD DISABILITIES CODES (Continued)

Limb Defects

- ○ B016 reduction deformity upper limb (missing or small fingers, hands or arms)
- ○ B017 reduction deformity lower limb (missing or small toes, feet or legs)
- ○ B018 arthrogryposis
- ○ B019 twisted upper limb
- ○ B020 twisted lower limb
- ○ B021 dislocated hip
- ○ B022 contractures of elbows/knees or other joints
- ○ B023 clubfoot
- ○ B024 clubfoot with bone deformity
- ○ B025 other limb _____

Muscle

- ○ C031 pectoralis (large chest) muscle - (absent or underdeveloped)
- ○ C032 muscular dystrophy
- ○ C033 diaphragmatic hernia
- ○ C034 hiatal hernia
- ○ C035 other muscle _____

Chest

- ○ D039 lung - (absent or underdeveloped)
- ○ D040 pectus excavatum (caved in chest)
- ○ D041 pigeon chest (chest bowed out)
- ○ D042 other chest _____

Spine

- ○ E046 scoliosis
- ○ E047 malformations of vertebrae
- ○ E048 other spine _____

Eye

- ○ F051 cataract
- ○ F052 anophthalmia (missing eye)
- ○ F053 micropthalmia (small eye)
- ○ F054 coloboma
- ○ F055 aniridia
- ○ F056 nystagmus
- ○ F057 defect in vision
- ○ F058 strabismus
- ○ F059 other eye defect _____

Ear

- ○ G061 external ear - (absent or malformed)
- ○ G062 deaf
- ○ G063 hearing loss
- ○ G064 other ear _____

Mouth/Jaw/Face

- ○ H067 cleft lip
- ○ H068 cleft palate
- ○ H069 micrognathia (small jaw)
- ○ H070 facial bone deformity
- ○ H071 macroglossia (large tongue)
- ○ H072 other _____

Cardiovascular

- ○ I076 common truncus
- ○ I077 transposition great arteries
- ○ I078 tetralogy of fallot
- ○ I079 ventricular septal defect
- ○ I080 atrial septal defect
- ○ I081 endocardial cushion defect
- ○ I082 pulmonary valve stenosis/atresia
- ○ I083 tricuspid valve stenosis/atresia
- ○ I084 aortic valve stenosis/atresia
- ○ I085 hypoplasia left heart syndrome
- ○ I086 patent ductus arteriosis
- ○ I087 coarctation of aorta
- ○ I088 pulmonary artery anomaly
- ○ I089 pulmonary atresia or hypoplasia
- ○ I090 prolasped valve
- ○ I091 heart murmur
- ○ I092 other heart _____

Gastrointestinal (GI)

- ○ J096 pyloric stenosis
- ○ J097 tracheo-esophageal anomaly
- ○ J098 rectal and/or intestinal atresia
- ○ J099 imperforate anus
- ○ J100 Hirschsprung disease
- ○ J101 inguinal hernia
- ○ J102 omphalocele
- ○ J103 other GI _____

Liver/Bile Duct/Spleen

- ○ K106 absent gall bladder
- ○ K107 biliary atresia
- ○ K108 absent spleen
- ○ K109 other _____

CHILDHOOD DISABILITIES CODES (Continued)

Genitourinary (GU)
- ○ L111 hypospadius
- ○ L112 undescended testicles
- ○ L113 absent kidney
- ○ L114 malformed kidney
- ○ L115 bladder exstrophy
- ○ L116 polycystic kidney
- ○ L117 absent bladder
- ○ L118 malformed ureter
- ○ L119 hermaphrodite
- ○ L120 malformed sex organs
- ○ L121 hydrocele
- ○ L122 other GU _____

Skin
- ○ M126 port wine stain
- ○ M127 cafe au lait birth mark
- ○ M128 strawberry birth mark
- ○ M129 other birth mark
- ○ M130 eczema
- ○ M131 psoriasis
- ○ M132 acne-like rash
- ○ M133 skin fungus
- ○ M134 other skin problem _____

Tumors - Benign
- ○ N138 lipoma
- ○ N139 hemangioma
- ○ N140 cavernous hemangioma
- ○ N141 other benign tumor _____

Syndromes
- ○ O145 Downs
- ○ O146 Pierre Robin
- ○ O147 Marfan
- ○ O148 Apert
- ○ O149 Trisomy
- ○ O150 Cornelia de Lange
- ○ O151 Goldenhar
- ○ O152 Klippel-fiel
- ○ O153 Dandy Walker
- ○ O154 Turner's
- ○ O155 Treacher Collins
- ○ O156 Nail-Patella
- ○ O157 other syndromes _____

Cancer
- ○ P166 neuroblastoma
- ○ P167 leukemia
- ○ P168 lymphoma
- ○ P169 Wilms tumor
- ○ P170 colon cancer
- ○ P171 Hodgkins disease
- ○ P172 Non-Hodgkins lymphoma
- ○ P173 other cancer _____

Cysts
- ○ Q179 brain
- ○ Q180 ovarian
- ○ Q181 other cysts _____

Growth Retardation (GR)
- ○ R186 growth hormone deficiency
- ○ R187 dwarf
- ○ R188 midget
- ○ R189 constitutional short stature
- ○ R190 other GR _____

Learning Disabilities (LD)
- ○ S196 dyslexia/reading
- ○ S197 math
- ○ S198 speech
- ○ S199 language processing
- ○ S200 spelling/writing
- ○ S201 other LD _____

Attention Deficit Disorders
- ○ T205 Attention Deficit Without Hyperactivity
- ○ T206 Attention Deficit With Hyperactivity _____

Developmental Delay (DD)
- ○ U207 retardation
- ○ U208 motor skills delay
- ○ U209 other DD _____

Emotional/Behaviorial (E/B)
- ○ V213 depression
- ○ V214 obsessive/compulsive
- ○ V215 mood swings
- ○ V216 anger
- ○ V217 breaks law/rules of society
- ○ V218 borderline personality
- ○ V219 schizophrenia
- ○ V220 other E/B _____

CHILDHOOD DISABILITIES CODES (Continued)

Allergies

- ○ W224 hives
- ○ W225 asthma
- ○ W226 hayfever
- ○ W227 food intolerance
- ○ W228 drug reaction
- ○ W229 other allergy _____

Immune Defect

- ○ X231 primary immune defect
- ○ X232 frequent pneumonia
- ○ X233 frequent urinary tract infections
- ○ X234 frequent upper respiratory infections
- ○ X235 frequent ear infections
- ○ X236 hypogammaglobulinemia
- ○ X237 other immune defect _____

Endocrine

- ○ Y241 early puberty
- ○ Y242 pituitary defect
- ○ Y243 thyroid defect
- ○ Y244 diabetes
- ○ Y245 other endocrine _____

Miscellaneous

- ○ Z251 ear noises (tinnitus)
- ○ Z252 seizures
- ○ Z253 frequent headaches
- ○ Z254 heat/cold sensitivity
- ○ Z255 sensitivity to light
- ○ Z256 fatigue
- ○ Z257 muscle pain/weakness
- ○ Z258 joint pain
- ○ Z259 unexplained fevers
- ○ Z260 hair loss
- ○ Z261 blood disease
- ○ Z262 tooth problems (missing, fused, no enamel, etc.)
- ○ Z263 stomach problems (ulcer, diarrhea, gastritus)
- ○ Z264 jaundice at birth
- ○ Z265 other problems not listed _____

MOTHER DATA

Mother's name: _____ **Marital status:** ○ Married ○ Single ○ Widow ○ Divorced

Date of birth: ___/___/___ (Mo Day Yr) **Race:** ○ White ○ Black ○ Hispanic ○ Asian **Blood type:** ○ O ○ A ○ B ○ AB

Age during this pregnancy: _____ **Nationality:** _____

Where did you live during pregnancy? City: _____ **State:** _____

Occupation before pregnancy: _____ **Place of employment:** _____

Occupation during pregnancy: _____ **Place of employment:** _____

A. When did mother first realize she was pregnant?

- ○ 1 week
- ○ 2 weeks
- ○ 3 weeks
- ○ 4 weeks
- ○ 5-8 weeks
- ○ 9-12 weeks
- ○ 13-20 weeks

B. When did mother first receive prenatal care?

- ○ 1 week
- ○ 2 weeks
- ○ 3 weeks
- ○ 4 weeks
- ○ 5-8 weeks
- ○ 9-12 weeks
- ○ 13-20 weeks
- ○ 21-32 weeks

C. Was the care regular?

- ○ Yes
- ○ No

D. Did mother receive genetic counseling or screening during this pregnancy?

- ○ Yes
- ○ No

E. Do any members of mother's family have problems similar to those of your child?

- ○ Yes
- ○ No

If yes, please explain:

_____

_____

F. Did mother have amniocentesis during this pregnancy?

- ○ Yes
- ○ No

Did any abnormalities show up?

- ○ Yes
- ○ No

G. Did mother have an ultrasound examination during this pregnancy?

- ○ Yes
- ○ No

If yes, please list number and dates:

_____

Did any abnormalities show up?

- ○ Yes
- ○ No

MOTHER DATA (Continued)

H. List any illnesses mother had during this pregnancy and month(s) of illness.

1. _____ **Month(s):** _____
2. _____ **Month(s):** _____
3. _____ **Month(s):** _____

I. Was mother tested for rubella during pregnancy?
○ Yes ○ No
If yes, what were the results?
○ Positive ○ Negative

J. Did mother have any sexually transmitted disease (STD) during this pregnancy?
○ Yes ○ No
If yes, please list name of the STD:
_____

K. Did mother eat raw or undercooked meat during this pregnancy?
○ Yes ○ No

L. Did mother empty the cat's litter box during this pregnancy?
○ Yes ○ No

M. Was mother tested for toxoplasmosis?
○ Yes ○ No
If yes, please list results:
_____

N. How long did mother work during pregnancy?
○ 1 month ○ 6 months
○ 2 months ○ 7 months
○ 3 months ○ 8 months
○ 4 months ○ 9 months
○ 5 months

O. Was mother exposed to any chemicals in her workplace?
○ Yes ○ No
If yes, please list name or type of chemical(s) if known:
_____
_____
_____

P. Month(s) of exposure
○ 1 month ○ 6 months
○ 2 months ○ 7 months
○ 3 months ○ 8 months
○ 4 months ○ 9 months
○ 5 months

Q. Did mother work at a video display terminal during this pregnancy?
○ Yes ○ No
If yes, for how many hours a day?
○ Less than 1 hour ○ 5-6 hours
○ 1-2 hours ○ 7-8 hours
○ 3-4 hours ○ More than 8 hours
If yes, for how many months during pregnancy?
○ 1 month ○ 6 months
○ 2 months ○ 7 months
○ 3 months ○ 8 months
○ 4 months ○ 9 months
○ 5 months

R. Did mother live in an agricultural area during this pregnancy?
○ Yes ○ No

S. Did mother have home and/or yard pest control service during this pregnancy?
○ Yes ○ No
If yes, number of times exposed:
⓪①②③④⑤⑥⑦⑧⑨⑩

T. Did mother have a contaminated water supply during this pregnancy?
○ Yes ○ No
If yes, what was the water contaminated with?
_____

U. What type of water did mother drink during this pregnancy?
○ City tap ○ Well ○ Bottled

V. Did mother live near a hazardous waste site during this pregnancy?
○ Yes ○ No
Name of site: _____

W. Was mother exposed to fresh paint fumes during this pregnancy?
○ Yes ○ No
If yes, during what month of pregnancy:
○ 1 ○ 6
○ 2 ○ 7
○ 3 ○ 8
○ 4 ○ 9
○ 5

X. Did mother have any hobbies which exposed her to chemicals during this pregnancy (Ex. photography developing chemicals, paint, glue, solvents, wood stripper)?
○ Yes ○ No
If yes, please list and give month of exposure:
1. _____ **Month(s):** _____
2. _____ **Month(s):** _____
3. _____ **Month(s):** _____

ENVIRONMENTAL EXPOSURES DURING PREGNANCY

Please fill in the bubble under the trimester of pregnancy you were exposed. For example, if exposed during the first trimester, fill in the bubble (1-3 months). If exposed throughout your pregnancy, fill in all three bubbles. List name and amount of substance, if known.

	Trimester of Exposure		
	1-3 months	4-6 months	7-9 months
Anti-nauseants/motion sickness medications	○	○	○
_____			
Pain killers (Ibuprofin, aspirin, Tylenol, Motrin, etc)	○	○	○
_____			
Tranquilizers	○	○	○
_____			
Antihistamines (allergy medications)	○	○	○
_____			
Muscle relaxers	○	○	○
_____			
Sedatives	○	○	○
_____			
Appetite suppressants (diet pills)	○	○	○
_____			
Cold/cough medication	○	○	○
_____			
Nose sprays	○	○	○
_____			
Asthma medications	○	○	○
_____			
Allergy shots	○	○	○
_____			
Decongestants	○	○	○
_____			
Hormones	○	○	○
_____			
Antibiotics	○	○	○
_____			

ENVIRONMENTAL EXPOSURES DURING PREGNANCY

Please fill in the bubble under the trimester of pregnancy you were exposed. For example, if exposed during the first trimester, fill in the bubble (1-3 months). If exposed throughout your pregnancy, fill in all three bubbles. List name and amount of substance, if known.

	Trimester of Exposure		
	1-3 months	4-6 months	7-9 months
Anti-spasmodics (for stomach cramps)	○	○	○
_____			
Arthritis medication	○	○	○
_____			
Diuretics	○	○	○
_____			
Diabetes medications	○	○	○
_____			
Thyroid medications	○	○	○
_____			
Fungicides (to treat fungal infections)	○	○	○
_____			
Vaginal medications	○	○	○
_____			
Anti-psychotics	○	○	○
_____			
Alcohol - number of glasses during pregnancy	○	○	○
_____			
Smoking - number of cigarettes per day	○	○	○
_____			
Aspartame (NutraSweet)	○	○	○
_____			
Illegal drugs	○	○	○
_____			
Vitamins (especially megadoses)	○	○	○
_____			
Diagnostic X-rays	○	○	○
_____			

ENVIRONMENTAL EXPOSURES DURING PREGNANCY

Please fill in the bubble under the trimester of pregnancy you were exposed. For example, if exposed during the first trimester, fill in the bubble (1-3 months). If exposed throughout your pregnancy, fill in all three bubbles. List name and amount of substance, if known.

	Trimester of Exposure		
	1-3 months	4-6 months	7-9 months
Anti-inflammatories	○	○	○
_____			
Blood thinners	○	○	○
_____			
Flu shots	○	○	○
_____			
Anti-convulsants	○	○	○
_____			
Anesthetics	○	○	○
_____			
Heart medications	○	○	○
_____			
Blood pressure medications	○	○	○
_____			
Anti-depressants	○	○	○
_____			
Fertility drugs	○	○	○
_____			
Stimulants	○	○	○
_____			
Accutane (acne medication)	○	○	○
_____			
Steroids	○	○	○
_____			
Antacids	○	○	○
_____			
Laxatives	○	○	○
_____			

ENVIRONMENTAL EXPOSURES DURING PREGNANCY

Please fill in the bubble under the trimester of pregnancy you were exposed. For example, if exposed during the first trimester, fill in the bubble (1-3 months). If exposed throughout your pregnancy, fill in all three bubbles. List name and amount of substance, if known.

	Trimester of Exposure		
	1-3 months	4-6 months	7-9 months
Ultra sound examination	○	○	○
_____			
Pesticides (insecticides, fungicides, herbicides like Agent Orange*)	○	○	○
_____			
*Fill out page 11 if exposed to Agent Orange			
Chemical exposure(s) in workplace	○	○	○
_____			
Other exposures not listed	○	○	○
_____			

FATHER DATA

Father's name: _____ **Nationality:** _____

Date of birth: ___/___/___ (Mo Day Yr) **Race:** ○ White ○ Black ○ Hispanic ○ Asian **Blood type:** ○ O ○ A ○ B ○ AB

If father has died, please list cause and date of death: _____ **Date:** ___/___/___ (Mo Day Yr)

Occupation prior to child's birth: _____ **Place of employment:** _____

Exposed to Agent Orange: ○ Yes ○ No

If yes, place and date of AO exposure: _____ **Date:** ___/___/___ (Mo Day Yr)

OTHER ENVIRONMENTAL EXPOSURES PRIOR TO CHILD'S BIRTH:

A. Chemical exposure in workplace:
○ Yes ○ No
If yes, please list name of substance if known:
_____
Number of years exposed: _____

B. Doctor prescribed medications or over-the-counter drugs used regularly prior to child's birth. Please list:
_____

C. Recreational drugs used regularly prior to child's birth. Please list:
_____

D. Did father drink alcoholic beverages prior to child's birth?
○ Yes ○ No
If yes, amount consumed on a daily basis:
○ 1 drink ○ 4 drinks
○ 2 drinks ○ 5 drinks
○ 3 drinks ○ 6 or more drinks

E. Did father smoke prior to child's birth?
○ Yes ○ No
If yes, how many packs per day:
○ Less than 1 pack ○ 2 packs
○ 1 pack ○ More than 2 packs

F. Did father have hobbies that involve chemical exposure (ex. photography developing, wood working, furniture refinishing.)
○ Yes ○ No
If yes, list hobby and/or chemical exposure, if known:
_____

G. How many hours per day did father spend with this hobby?
○ Less than 1 hour ○ 3 hours
○ 1 hour ○ 4 hours
○ 2 hours ○ 5 or more hours

FATHER DATA (Continued)

H. Was father exposed to radiation prior to this child's birth?
○ Yes ○ No

How exposed? _____

I. Was father exposed to pesticides through farming, gardening or spraying home/and or yard?
○ Yes ○ No

If yes, please list brand names, if known:

_____

J. How frequently was father exposed to these pesticides?
○ Daily ○ Several times a week ○ Several times a year
○ Less than once a week ○ Monthly

Number of years exposed: _____

K. Do any members of father's family have problems similar to those of your child?
○ Yes ○ No

If yes, please explain:

_____

_____

L. Has father had any of the following symptoms and/or illnesses:

Sensitivity to light		**Fat or carbohydrate metabolism disorders**	
○ Yes	○ No	○ Yes	○ No
Impaired sight or hearing		**Urinary tract disorders**	
○ Yes	○ No	○ Yes	○ No
Chronic skin rashes		**Reduced sex drive, impotence**	
○ Yes	○ No	○ Yes	○ No
Mood swings		**Weakness of lower extremities**	
○ Yes	○ No	○ Yes	○ No
Sleep disorders		**Cancer**	
○ Yes	○ No	○ Yes	○ No
Depression		**Fatigue**	
○ Yes	○ No	○ Yes	○ No
Outbursts of rage		**Nervousness**	
○ Yes	○ No	○ Yes	○ No
Cardiovascular disorders		**Numbness in fingers and/or toes**	
○ Yes	○ No	○ Yes	○ No
Abnormal hairiness		**Alcohol intolerance**	
○ Yes	○ No	○ Yes	○ No
Respiratory problems		**Thyroid disorder**	
○ Yes	○ No	○ Yes	○ No
Liver disorders		**Benign tumors (not cancerous)**	
○ Yes	○ No	○ Yes	○ No
Stomach problems			
○ Yes	○ No		

If you were exposed to Agent Orange, please answer these additional questions.

1. Branch of Service:

- ○ Army
- ○ Marines
- ○ Navy
- ○ Coast Guard
- ○ Air Force
- ○ Other

2. Dates of Service in Vietnam:

First Tour:

From _____ To _____

Second Tour:

From _____ To _____

Third Tour:

From _____ To _____

3. Rank:

First Tour: _____

Second Tour: _____

Third Tour: _____

4. Corps areas served in:

- ○ I Corps
- ○ II Corps
- ○ III Corps
- ○ IV Corps

5. MOS:

Number _____

Name _____

6. Secondary MOS:

Number _____

Name _____

7. Year(s) in Vietnam:

- ○ Pre 1965
- ○ 1965
- ○ 1966
- ○ 1967
- ○ 1968
- ○ 1969
- ○ 1970
- ○ 1971
- ○ 1972
- ○ 1973
- ○ Post 1973

8. Were you hospitalized while in Vietnam?

- ○ Yes
- ○ No

8a. If yes, explain: _____

_____

_____

_____

9. Note the area you were in or near during your tour(s) in Vietnam:

I Corps	II Corps
○ Danang	○ Pleiku
○ Chu-Lai	○ Dak To
○ Phu Bai	○ Kontum
○ Hue	○ Phu Cat
○ Quang Tri	○ Qui Nhon
○ Dong Ha	○ Tuy Hoa
○ Con Thien	○ Cam Ranh
○ Khe Sahn	○ Nha Trang
○ Ashau Valley	○ Quang Nhai
○ Other	○ Other
_____	_____

III Corps	IV Corps
○ Saigon	○ My Tho
○ Bien Hoa	○ Can Tho
○ Long Binh	○ Ben Tre
○ Tam Ky	○ Rung Sat
○ Cu-Chi	○ Dong Tam
○ Phuoc Vinh	○ Ben Tuy
○ Bear Cat	○ Ca Mau
○ Lai-Khe	○ Rach Gia
○ Vung Tau	○ Chau Doc
○ Other	○ Other
_____	_____

10. Do you have any other biological children who do not have birth defects or learning disabilities?

- ○ Yes
- ○ No

10a. If yes, please list year of birth and sex of child:

Year	Sex
_____	_____
_____	_____

11. Have you had any miscarriages?

- ○ Yes
- ○ No

11a. If yes, please list number and years:

_____ _____

_____ _____

12. Did you have any foreign travel (outside continental U.S.) during the five years prior to your child's birth?

Father: ○ Yes ○ No Where? _____

Mother: ○ Yes ○ No Where? _____

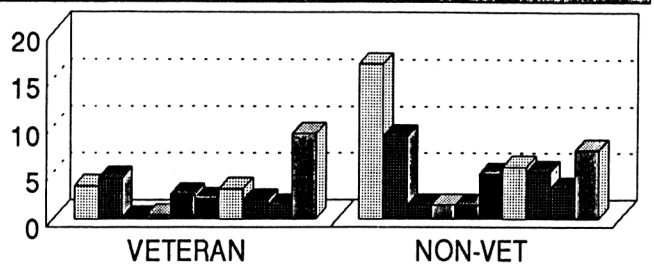
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT
LIMB DEFECTS					
B016-REDUCTION DEFORMITY UPPER LIMB	26	3.85	65	16.58	91
B017-REDUCTION DEFORMITY LOWER LIMB	30	4.44	35	8.93	65
B018-ARTHOGRYPOSIS	1	0.15	6	1.53	7
B019-TWISTED UPPER LIMB	3	0.44	6	1.53	9
B020-TWISTED LOWER LIMB	18	2.67	6	1.53	24
B021-DISLOCATED HIP	15	2.22	19	4.85	34
B022-CONTRACTURES OF ELBOWS/KNEES	22	3.26	22	5.61	44
B023-CLUBFOOT	14	2.07	20	5.10	34
B024-CLUBFOOT W/BONE DEFORMITY	10	1.48	13	3.32	23
B025-OTHER LIMB	62	9.19	29	7.40	91

N=1067 VETERAN: 675 NON-VET: 392 FILE: BD-LS-2
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY: LIMB DEFECTS



B016-REDUCTION UPPER	3.58	16.58
B017-REDUCTION-LOWER	4.44	8.93
B018-ARTHOGRYPOSIS	0.15	1.53
B019-TWIST UPPER LIMB	0.44	1.53
B020-TWIST LOWER LIMB	2.67	1.53
B021-DISLOCATED HIP	2.22	4.85
B022-JOINT CONTRACTURS	3.26	5.61
B023-CLUBFOOT	2.07	5.1
BO24-CLUBFOOT W/DEFORM	1.48	3.32
B025-OTHER LIMB	9.19	7.4

N=1067 FILE:BD-2:LIMB DEFECTS:PER 100 CASES. VETERANS 675, NON-VET 392
JUNE, 1993

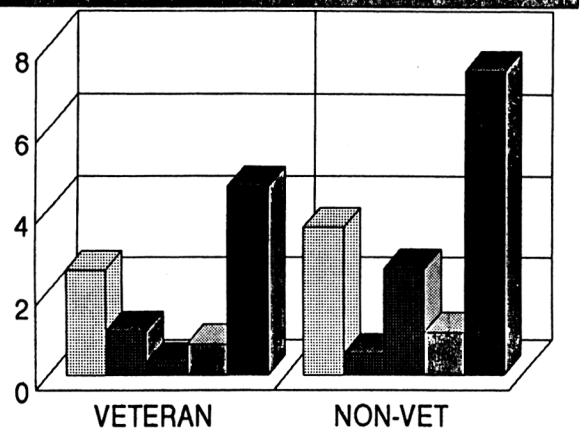
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT
MUSCLE					
C031-PECTORALIS	17	2.52	14	3.57	31
C032-MUSCULAR DYSTROPHY	7	1.04	2	0.51	9
C033-DIAPHRAMGMATIC HERNIA	2	0.30	10	2.55	12
C034-HIATAL HERNIA	5	0.74	4	1.02	9
C035-OTHER MUSCLE	31	4.59	29	7.40	60

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS-3
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY: MUSCLE



C031-PECTORALIS	2.52	3.57
CO32-MUSCULAR DYSTROPH	1.04	0.51
CO33-HERNIA-DIAPHRAM	0.3	2.55
C034-HIATAL HERNIA	0.74	1.02
C035-OTHER MUSCLE	4.59	7.4

N=1067 FILE:BD-3:MUSCLE: PER 100 CASES. VETERANS:675, NON-VET:392
JUNE, 1993

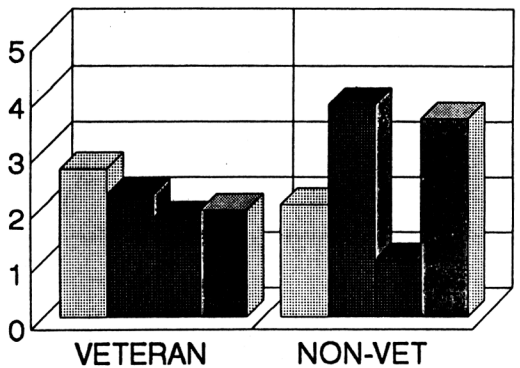
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT
CHEST					
D039-LUNG	18	2.67	8	2.04	26
D040-PECTUS EXCAVATUM	15	2.22	15	3.83	30
D041-PIGEON CHEST	12	1.78	4	1.02	16
D042-OTHER CHEST	13	1.93	14	3.57	27

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS-4
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT LEARNING DISABILITIES REGISTRY: CHEST



	VETERAN	NON-VET
D039-LUNG	2.67	2.04
D040-PECTUS EXCAVATUM	2.22	3.83
DO41-PIGEON CHEST	1.78	1.02
DO42-OTHER CHEST	1.93	3.57

N=1067 FILE:BD-4:CHEST:PER 100 CASES. VETERANS 675 NON-VET:392
JUNE, 1993

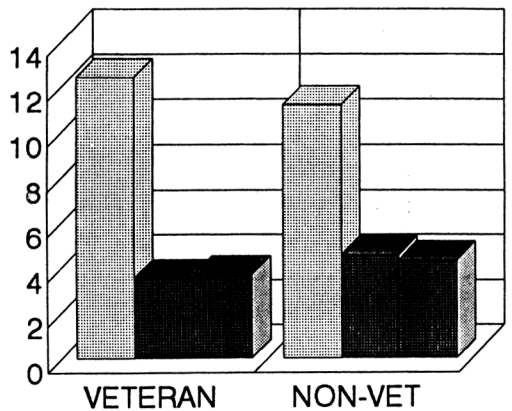
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT
SPINE					
E046-SCOLIOSIS	84	12.44	44	11.22	128
E047-MALFORMED VERTEBRAE	24	3.56	18	4.59	42
E048-OTHER SPINE	25	3.70	17	4.34	42

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS-5
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:SPINE



E046-SCOLIOSIS	12.44	11.22
E047-VERTEBRAE/MALFORM	3.56	4.59
E048-OTHER SPINE	3.7	4.34

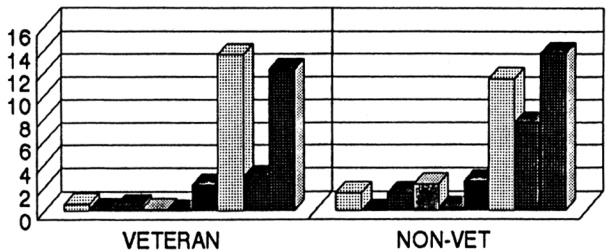
N=1067 FILE: BD-5:SPINE: PER 100 CASES. VETERANS 675, NON-VET 392
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT
EYE					
F051-CATARACT	4	0.59	6	1.53	10
F052-ANOPHTHALMIA	1	0.15	0	0	1
F053-MICROPTHALMIA	3	0.44	6	1.53	9
F054-COLOBOMA	1	0.15	9	2.30	10
F055-ANIRIDIA	0	0	1	0.26	1
F056-NYSTAGMUS	15	2.22	10	2.55	25
F057-DEFECT IN VISION	92	13.63	45	11.50	137
F058-STRABISMUS	20	2.96	30	7.65	50
F059-OTHER EYE DEFECT	83	12.30	54	13.78	137

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS-6
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:EYE



F051-CATARACT	0.59	1.53
F052-ANOPHTHALMIA	0.15	0
F053-MICROPTHALMIA	0.44	1.53
F054-COLOBOMA	0.15	2.3
FO55-ANIRIDIA	0	0.26
FO56-NYSTAGMUS	2.22	2.55
F057-VISON DEFECT	13.63	11.5
F058-STRABISMUS	2.96	7.65
F059-OTHER EYE DEFECT	12.3	13.78

N=1067 FILE:BD-6:EYE: PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT
EAR					
G061-EXTERNAL EAR	20	2.96	22	5.61	42
G062-DEAF	15	2.22	11	2.81	26
G063-HEARING LOSS	69	10.22	42	10.71	111
G064-OTHER EAR	50	7.41	30	7.65	80

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS-7
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

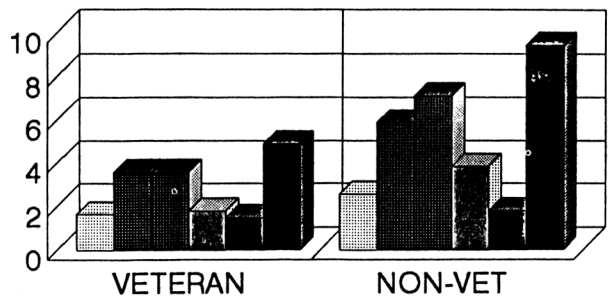
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
MOUTH/JAW/FACE						
H067-CLEFT LIP	11	1.63	10	2.55	21	
H068-CLEFT PALATE	24	3.56	23	5.87	47	
H069-MICROGNATHIA	24	3.56	28	7.14	52	
H070-FACIAL BONE DEFORM	12	1.78	15	3.83	27	
H071-MACROGLOSSIA	10	1.48	7	1.79	17	
H072-OTHER	33	4.89	37	9.44	70	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS-8
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY: MOUTH/JAW/FACE



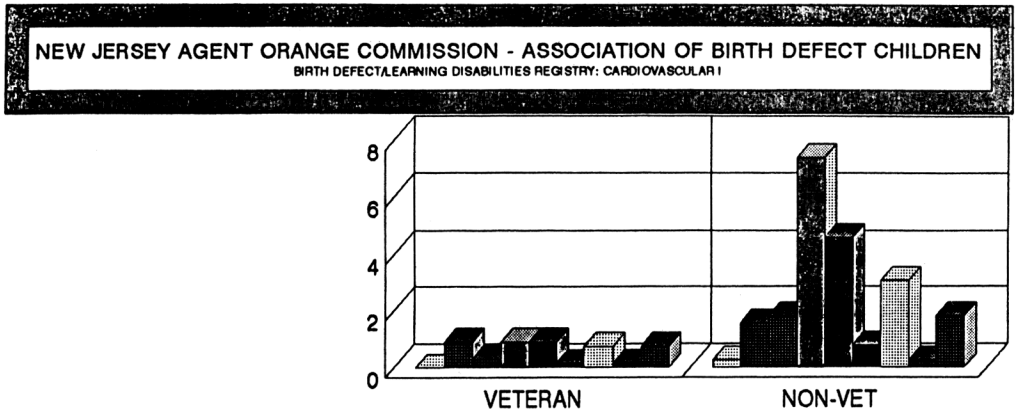
H067-CLEFT LIP	1.63	2.55
HO68-CLEFT-PALATE	3.56	5.87
HO69-MICROGNATHIA	3.56	7.14
H070- FACIAL BONE	1.78	3.83
H071-MACROGLOSSIA	1.48	1.79
H072-OTHER	4.89	9.44

N=1067 FILE:BD-8 : MOUTH/JAW/FACE PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
CARDIOVASCULAR						
1076-COMMON TRUNCUS	0	0	1	0.26	1	
1077-TRANSPOSITION GREAT ARTERIES	6	0.89	6	1.53	12	
1078-TETRALOGY OF FALLOT	2	0.30	7	1.79	9	
1079-VENTRICAL SEPTAL DEFECT	6	0.89	29	7.40	35	
1080-ATRIAL SEPTAL DEFECT	6	0.89	18	4.59	24	
1081-ENDOCARDIAL CUSHION DEFECT	1	0.15	3	0.77	4	
1082-PULMONARY VALVE STENOSIS/ATRESIA	5	0.74	12	3.06	17	
1083-TRICUSPID VALVE STENOSIS/ATRESIA	2	0.15	1	0.26	3	
1084-ACRTIC VALVE STENOSIS/ATRESIA	5	0.74	7	1.79	12	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS-9
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993



I076-COMMON TRUNCUS	0	0.26
I077-GREAT ARTERIES	0.89	1.53
I078-FALLOT TETRALOGY	0.3	1.79
I079-VENTRICAL SEPTAL	0.89	7.4
I080-ATRIAL SEPTAL	0.89	4.59
I081-ENDOCARDIAL CUSHN	0.15	0.77
I1082-PULMONARY VALVE	0.74	3.06
I083-TRICUSPID VALVE	0.15	0.26
I084-AORTIC VALVE	0.74	1.79

N=1067 FILE:BD-9 :CARDIOVASCULAR I PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

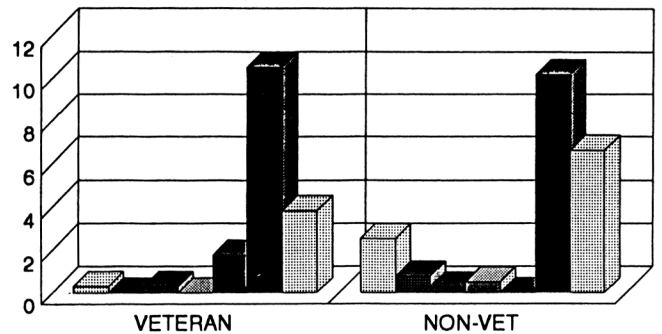
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
CARDIOVASCULAR						
1085-HYPOPLASIA LEFT HEART SYNDROME	1	0.15	2	0.51	3	
1086-PATENT DUCTUS ARTERIOSIS	2	0.30	10	2.55	12	
1087-COARCTATION OF AORTA	0	0	3	0.77	3	
1088-PULMONARY ARTERY ANOMALY	2	0.30	1	0.26	3	
1089-PULMONARY ATRESIA OR HYPOPLASIA	0	0	2	0.51	2	
1090-PROLAPSED VALVE	12	1.78	0	0	12	
1091-HEART MURMUR	71	10.52	40	10.20	111	
1092-OTHER HEART	26	3.85	26	6.63	52	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS10
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY: CARDIOVASCULAR II



I086-PATENT DUCTUS	0.3	2.55
1087-AORTA COARCTATION	0	0.77
I088-PULMONARY ARTERY	0.3	0.26
I089-PULMONARY ATRESIA	0	0.51
I090-PROLAPSED VALVE	1.78	0
I091-HEART MURMUR	10.52	10.2
I092-OTHER	3.85	6.63

N=1067 FILE:BD-10 : CARDIOVASCULAR II PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

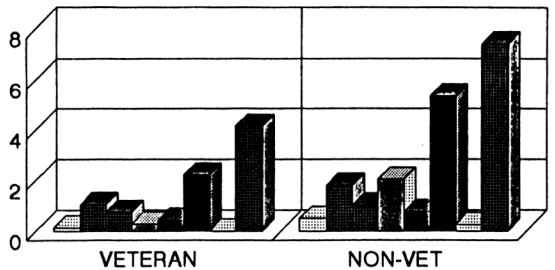
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
GASTROINTESTINAL (GI)						
J096-PYLORIC STENOSIS	1	0.15	2	0.51	3	
J097-TRACHEO-ESOPHAGEAL ANOMALY	7	1.04	7	1.79	14	
J098-RECTAL AND/OR INTESTINAL ATRESIA	5	0.74	4	1.02	9	
J099-IMPORFORATE ANUS	2	0.30	6	2.04	10	
J100-HIRSCHSPRUNG DISEASE	3	0.44	3	0.77	6	
J101-UNGUINAL HERNIA	15	2.22	21	5.36	36	
J102-OMPHALOCELE	0	0	1	0.26	1	
J103-OTHER GI	28	4.15	29	7.40	57	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS-11
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:GASTROINTESTINAL



JO96-PYLORIC STENOSIS	0.15	0.51
JO97-TRACHEO-ESOPHAGEL	1.04	1.79
J098-RECTAL/INTESTINAL	0.74	1.02
J099-IMPERFORATE ANUS	0.3	2.04
J100-HIRSCHSPRUNG	0.44	0.77
J101-INGUINAL HERNIA	2.22	5.36
J102-OMPHALOCELE	0	0.26
J103-OTHER GI	4.15	7.4

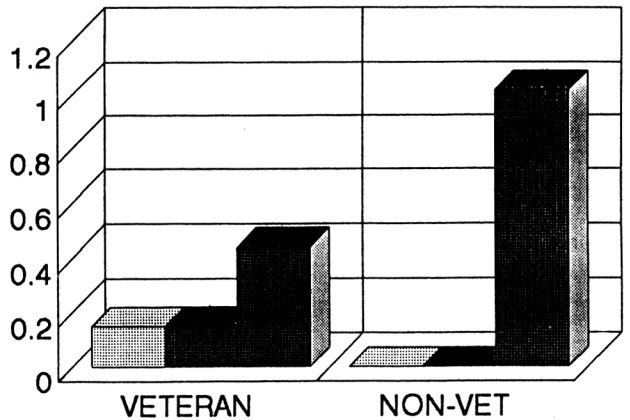
N=1067 FILE:BD-11 : GASTROINTESTINAL (GI) PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
LIVER/BILE DUCT/SPLEEN						
K107-BILIARY ATRESIA	1	0.15	0	0	1	
K108-ABSENT SPLEEN	1	0.15	0	0	1	
K109-OTHER	3	0.44	4	1.02	7	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS11A
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:EAR



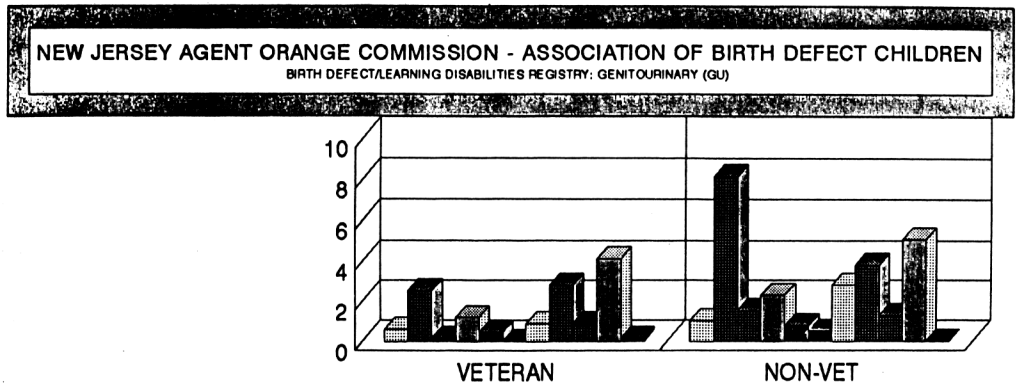
K107-BILIARY ATRESIA	0.15	0
K108-ABSENT SPLEEN	0.15	0
K109-OTHER	0.44	1.02

N=1067 FILE:BD-11A :LIVER/BILE DUCT/SPLEEN PER 100 CASES. VETERAN 675, NON VET 392
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
GENITOURINARY (GU)						
L111-HYPOSPADIUS	4	0.59	4	1.02	8	
L112-UNDESCENDED TESTICLES	17	2.52	32	8.16	49	
L113-ABSENT KIDNEY	1	0.15	6	1.53	7	
L114-MALFORMED KIDNEY	8	1.19	9	2.30	17	
L115-BLADDER EXSTROPHY	3	0.44	3	0.77	6	
L116-POLYCYSTIC KIDNEY	0	0	2	0.51	2	
L118-MALFORMED URETER	6	0.89	11	2.81	17	
L120-MALFORMED SEX ORGANS	19	2.82	15	3.83	34	
L121-HYDROCELE	6	0.89	5	1.28	11	
L122-OTHER GU	28	4.15	20	5.10	48	
L117-ABSENT BLADDER	1	0.15	0	0	1	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS12
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993



L111-HYPOSPADIUS	0.59	1.02
L112-TESTICLES,UNDES	2.52	8.16
L113-ABSENT KIDNEY	0.15	1.53
L114-MALFORMED KIDNEY	1.19	2.3
L115-BLADDER EXSTROPHY	0.44	0.77
L116-POLYCYSTIC KIDNEY	0	0.51
L118-MALFORMED URETER	0.89	2.81
L120-MALFORMED SEX ORG	2.82	3.83
L121-HYDROCELE	0.89	1.28
L122-OTHER GU	4.15	5.1
L117-ABSENT BLADDER	0.15	0

N=1067 FILE:BD-12 : GENITOURINARY (GU) PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

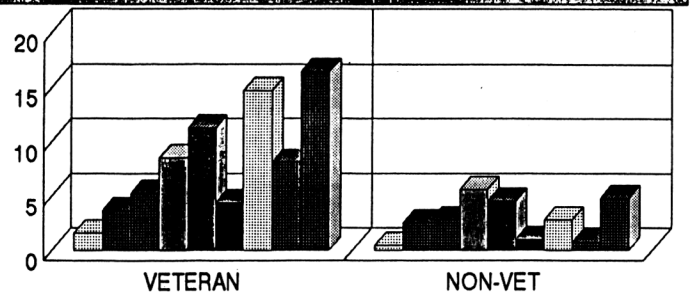
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
SKIN						
M126-PORT WINE STAIN	11	1.63	2	0.51	13	
M127-CAFE AU LAIT BIRTH MARK	25	3.70	10	2.55	35	
M128-STRAWBERRY BIRTH MARK	36	5.33	11	2.81	47	
M129-OTHER BIRTH MARK	58	8.59	22	5.61	80	
M130-ECZEMA	76	11.26	18	4.59	94	
M131-PSORIASIS	30	4.44	4	1.02	34	
M132-ACNE-LIKE RASH	99	14.67	11	2.81	110	
M133-SKIN FUNGUS	55	8.15	3	0.77	58	
M134-OTHER SKIN PROBLEM	111	16.44	19	4.85	130	

N=1067 VETERAN:675 NON-VET:393 FILE: BD-LS13
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT LEARNING DISABILITIES REGISTRY: SKIN



	VETERAN	NON-VET
M126-PORT WINE STAIN	1.63	0.51
M127-CAFE AU LAIT	3.7	2.55
M128-STRAWBERRY	5.33	2.81
M129-OTHER BIRTH MARK	8.59	5.61
M130-ECZEMA	11.26	4.59
M131-PSORIASIS	4.44	1.02
M132-ACNE-LIKE RASH	14.67	2.81
M133-SKIN FUNGUS	8.15	0.77
M134-OTHER SKIN	16.44	4.85

N=1067 FILE:BD-13 : SKIN PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

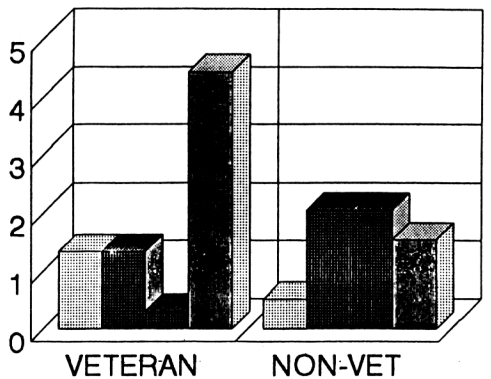
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
TUMORS-BENIGN						
N138-LIPOMA	9	1.33	2	0.51	11	
N139-HEMANGIOMA	9	1.33	8	2.04	17	
N140-CAVERNOUS HEMANGIOMA	2	0.30	8	2.04	10	
N141-OTHER BENIGN TUMOR	30	4.44	6	1.53	36	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS14
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY: TUMORS BENIGN



	VETERAN	NON-VET
N138-LIPOMA	1.33	0.51
N139-HEMANGIOMA	1.33	2.04
N140-CAVERNOUS HEMANGI	0.3	2.04
N141-OTHER BENIGN	4.44	1.53

N=1067 FILE:BD-14 : TUMORS-BENIGN PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

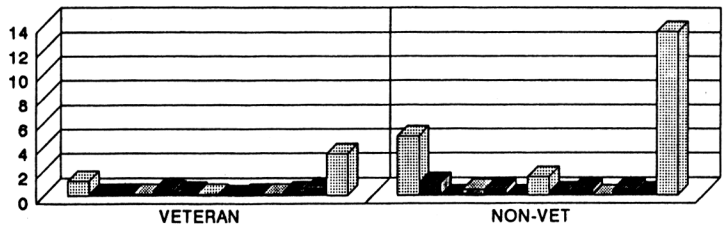
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
SYNDROMES						
0145-DOWNS	8	1.19	19	4.85	27	
0146-PERRE ROBIN	1	0.15	4	1.02	5	
0147-MARFAN	1	0.15	0	0	1	
0148-APERT	1	0.15	2	0.51	3	
0149-TRISOMY	3	0.44	2	0.51	5	
0150-CORNELIA DE LANGE	2	0.30	0	0	2	
0151-GOLDENHAR	1	0.15	6	1.53	7	
0152-KLIPPEL-FIEL	0	0	1	0.26	1	
0153-DANDY WALKER	1	0.15	2	0.51	3	
0154-TURNER'S	1	0.15	0	0	1	
0155-TREACHER COLLINS	2	0.30	2	0.51	4	
0156-NAIL-PATELLA	4	0.59	1	0.26	5	
0157-OTHER SYNDROMES	23	3.41	53	13.52	76	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS15
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT LEARNING DISABILITIES REGISTRY: SYNDROMES



O145-DOWNS	1.19	4.85
O146-PIERRE ROBIN	0.15	1.02
O147-MARFAN	0.15	0
O148-APERT	0.15	0.51
O149-TRISOMY	0.44	0.51
O150-CORNELIA DE LANGE	0.3	0
O151-GOLDENHAR	0.15	1.53
O152-KLIPPEL-FIEL	0	0.26
O153-DANDY WALKER	0.15	0.51
O154-TURNER'S	0.15	0
O155-TREACHER COLLINS	0.3	0.51
O156-NAIL-PATELLA	0.59	0.26
O157-OTHER SYNDROMES	3.41	13.52

N=1067 FILE:BD-15:SYNDROMES PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

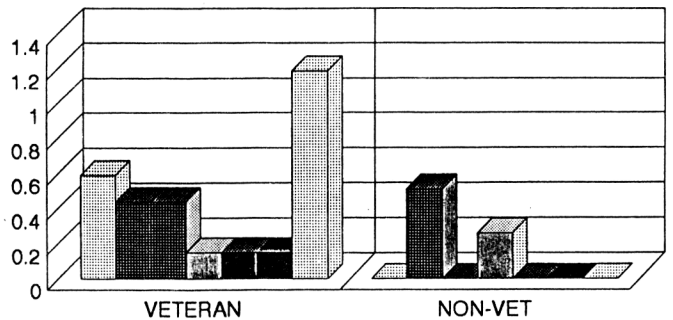
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
CANCER						
P166-NEUROBLASTOMA	4	0.59	0	0	4	
P167-LEUKEMIA	3	0.44	2	0.51	5	
P168-LYMPHOMA	3	0.44	0	0	3	
P169-WILMS TUMOR	1	0.15	1	0.26	2	
P171-HODGKINS DISEASE	1	0.15	0	0	1	
P172-NON-HODGKINS LYMPHOMA	1	0.15	0	0	1	
P173-OTHER CANCER	8	1.19	0	0	8	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS16
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:CANCER



P166-NEUROBLASTOMA	0.59	0
P167-LEUKEMIA	0.44	0.51
P168-LYMPHOMA	0.44	0
P169-WILMS TUMOR	0.15	0.26
P171-HODGKINS DISEASE	0.15	0
P172-NON-HODGKINS LYMP	0.15	0
P173-OTHER CANCER	1.19	0

N=1067 FILE:BD-16:CANCER PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

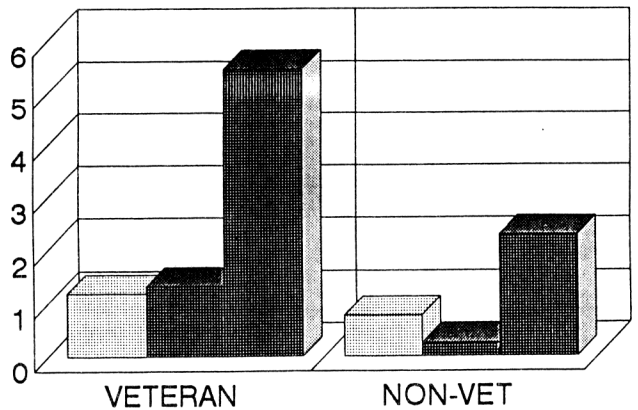
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
CYSTS						
Q179-BRAIN	8	1.19	3	0.77	11	
Q180-OVARIAN	9	1.33	1	0.26	10	
Q181-OTHER CYSTS	37	5.48	9	2.30	46	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS17
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY: CYSTS



Q179-BRAIN	1.19	0.77
Q180-OVARIAN	1.33	0.26
Q181-OTHER CYSTS	5.48	2.3

N=1067 FILE:BD-17:CYSTS PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

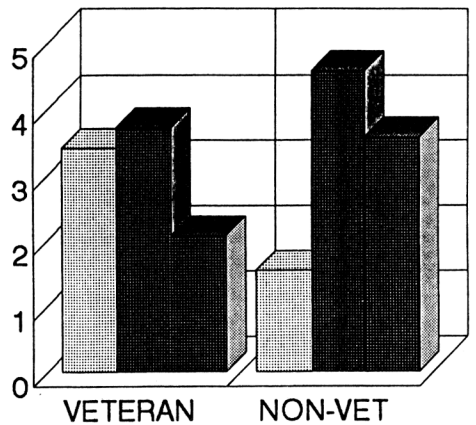
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
GROWTH RETARDATION (GR)						
R186-GROWTH HORMONE DEFICIENCY	23	3.41	6	1.53	29	
R189-CONSTITUTIONAL SHORT STATURE	25	3.71	18	4.59	43	
R190-OTHER GR	14	2.07	14	3.57	28	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS18
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1992

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:GROWTH RETARDATION (GR)



R186-GROWTH HORMONE DF	3.41	1.53
R189-CONST SHORT STAT	3.71	4.59
R190-OTHER GR	2.07	3.57

N=1067 FILE:BD-18 :GROWTH RETARDATION (GR) PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

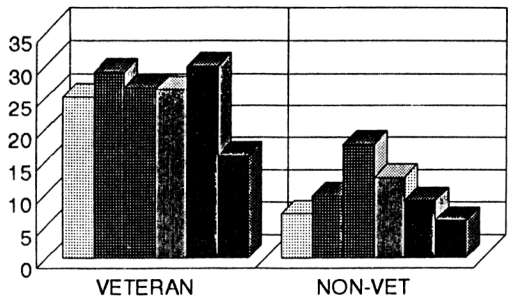
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
LEARNING DISABILITIES (LD)						
S196-DYSLEXIA/READING	169	25.04	27	6.89	196	
S197-MATH	195	28.89	38	9.69	233	
S198-SPEECH	179	26.52	69	17.60	248	
S199-LANGUAGE PROCESSING	177	26.22	49	12.5	226	
S200-SPELLING/WRITING	201	29.78	35	8.93	236	
S201-OTHER LD	107	15.85	23	5.87	130	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS19
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:LEARNING DISABILITIES



	VETERAN	NON-VET
S196-DYSLEXIA/READING	25.04	6.89
S197-MATH	28.89	9.69
S198-SPEECH	26.52	17.6
S199-LANGUAGE PROCESS	26.22	12.5
S200-SPELLING/WRITING	29.78	8.93
S201-OTHER LD	15.85	5.87

N=1067 FILE:BD-19:LEARNING DISABILITIES PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

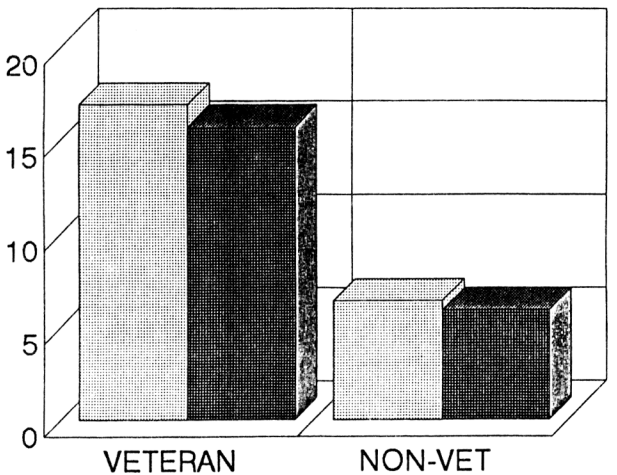
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
ATTENTION DEFICIT DISORDER						
T205-WITHOUT HYPERACTIVITY	114	16.89	25	6.38	139	
T206-WITH HYPERACTIVITY	106	15.70	23	5.87	129	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS20
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY: ATTENTION DEFICIT DISORDERS



	VETERAN	NON-VET
T205-WITHOUT HYPER	16.89	6.38
T206-WITH HYPER	15.7	5.87

N=1067 FILE:BD-20:ATTENTION DEFICIT DISORDERS PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

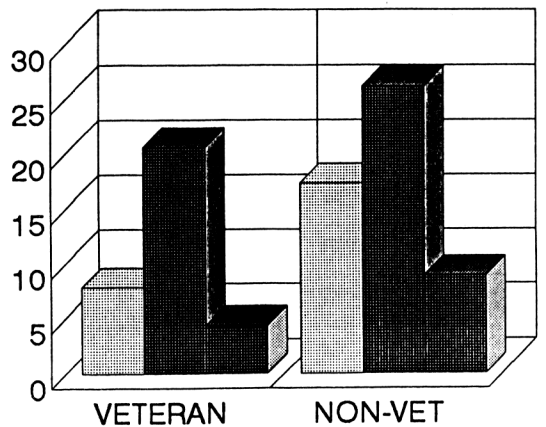
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
DEVELOPMENTAL DELAY (DD)						
U207-RETARDATION	53	7.85	68	17.35	121	
U208-MOTOR SKILLS DELAY	139	20.59	103	26.28	242	
U209-OTHER DD	29	4.30	35	8.93	64	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS21
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY: DEVELOPMENTAL DELAY (DD)



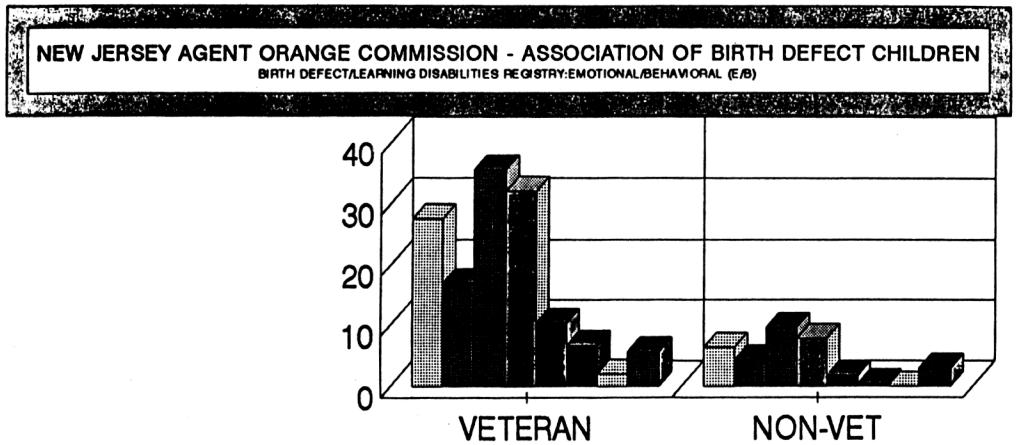
	VETERAN	NON-VET
U207-RETARDATION	7.85	17.35
U208-MOTOR SKILLS DELY	20.59	26.28
U209-OTHER DD	4.3	8.93

N=1067 FILE BD-21:DEVELOPMENTAL DELAY (DD) PER 100 CASES. VETERAN 675 NON-VET 392
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
EMOTIONAL BEHAVIOR (E/B)						
V213-DEPRESSION	186	27.56	25	6.38	211	
V214-OBSESSIVE/COMPULSIVE	115	17.04	17	4.34	132	
V215-MOOD SWINGS	240	35.56	38	9.69	278	
V216-ANGER	216	32.00	31	7.91	247	
V217-BREAKS LAWS/RULES OF SOCIETY	70	10.37	7	1.79	77	
V218-BORDERLINE PERSONALITY	46	6.82	2	0.51	48	
V219-SCHIZOPHRENIA	14	2.07	0	0	14	
V220-OTHER E/B	38	5.63	12	3.06	50	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS22
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993



V213-DEPRESSION	27.56	6.38
V214-OBSESSIVE/COMPUL	17.04	4.34
V215-MOOD SWINGS	35.56	9.69
V216-ANGER	32	7.91
V217-BREAKS LAW/RULES	10.37	1.79
V218-BORDER PERSONALIT	6.82	0.51
V219-SCHIZOPHRENIA	2.07	0
V220-OTHER E/B	5.63	3.06

N=1067 FILE:BD-22: EMOTIONAL/BEHAVIORAL (E/B) PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

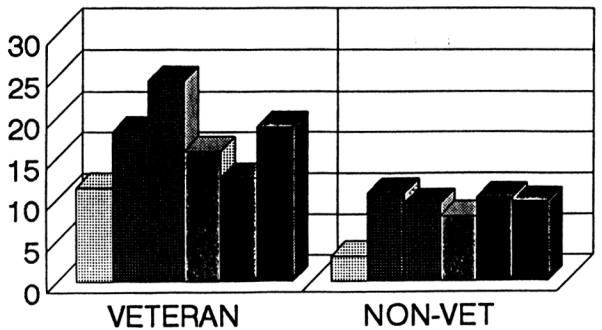
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
ALLERGIES						
W224-HIVES	77	11.41	12	3.06	89	
W225-ASTHMA	123	18.22	42	10.71	165	
W226-HAYFEVER	165	24.44	37	9.44	202	
W227-FOOD INTOLERANCE	107	15.85	31	7.91	138	
W228-DRUG REACTION	85	12.59	40	10.20	125	
W229-OTHER ALLERGY	127	18.82	38	9.69	165	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS23
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

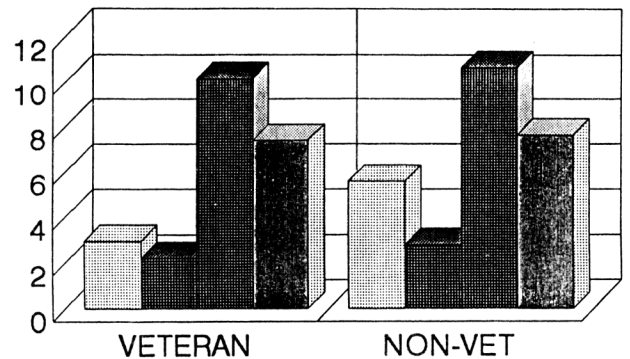
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY: ALLERGIES



	VETERAN	NON-VET
W224-HIVES	11.41	3.06
W225-ASTHMA	18.22	10.71
W226-HAYFEVER	24.44	9.44
W227-FOOD INTOLERANCE	15.85	7.91
W228-DRUG REACTION	12.59	10.2
W229-OTHER ALLERGY	18.82	9.69

N=1067 FILE:BD-23:ALLERGIES: PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:EAR



G061-EXTERNAL EAR	2.96	5.61
G062-DEAF	2.22	2.81
GO63-HEARING LOSS	10.22	10.71
G064-OTHER EAR	7.41	7.65

N=1067 FILE:BD-7 :EAR PER 100 CASES. VETERAN 675, NON VET 392
JUNE, 1993

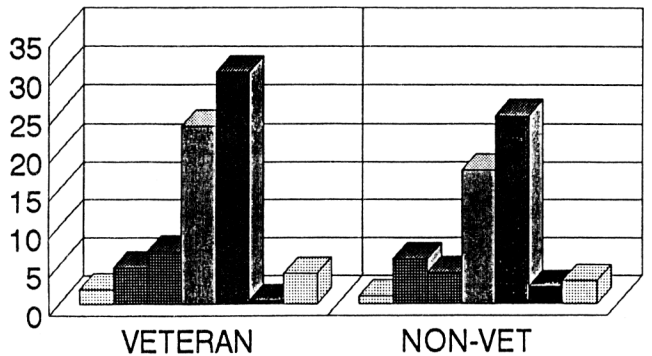
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
IMMUNE DEFECT						
X231-PRIMARY IMMUNE DEFECT	13	1.93	4	1.02	17	
X232-FREQUENT PNEUMONIA	32	4.74	23	5.87	55	
X233-FREQUENT URINARY TRACT INFECTIONS	46	6.82	16	4.08	62	
X234-FREQUENT UPPER RESPIRATORY INFECTIONS	158	23.41	69	17.60	227	
X235-FREQUENT EAR INFECTIONS	195	28.89	92	23.47	287	
X236-HYPOGAMMAGLOBULINEMIA	3	0.44	9	2.30	12	
X237-OTHER IMMUNE DEFECT	27	4.00	12	3.06	39	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS24
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:IMMUNE DEFECT



	VETERAN	NON-VET
X231-PRIMARY IMMUNE	1.93	1.02
X232-PNEUMONIA	4.74	5.87
X233-URINARY INFECTION	6.82	4.08
X234-UPPER RESPIRATORY	23.41	17.6
X235-EAR INFECTIONS	30.37	24.77
X236-HYPOGAMMAGLOBULIE	0.44	2.3
X237-OTHER IMMUNE	4	3.06

N=1067 FILE:BD-24:IMMUNE DEFECT: PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

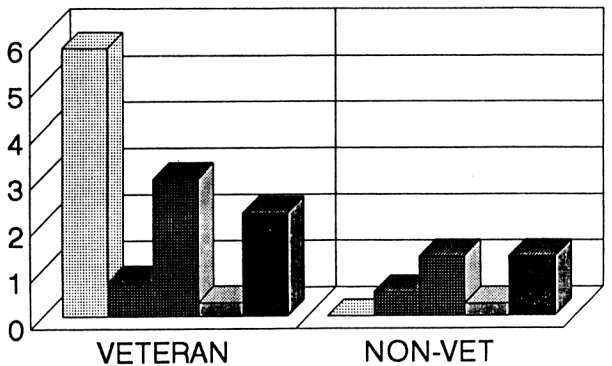
NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
ENDOCRINE						
Y241-EARLY PUBERTY	39	5.78	0	0	39	
Y242-PITUITARY DEFECT	5	0.74	2	0.51	7	
Y243-THYROID DEFECT	20	2.96	5	1.28	25	
Y244-DIABETES	2	0.30	1	0.26	3	
Y245-OTHER ENDOCRINE	15	2.22	5	1.28	20	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS25
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL.
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN

BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:ENDOCRINE



Y241-EARLY PUBERTY	5.78	0
Y242-PITUITARY DEFECT	0.74	0.51
Y243-THYROID DEFECT	2.96	1.28
Y244-DIABETES	0.3	0.26
Y245-OTHER ENDOCRINE	2.22	1.28

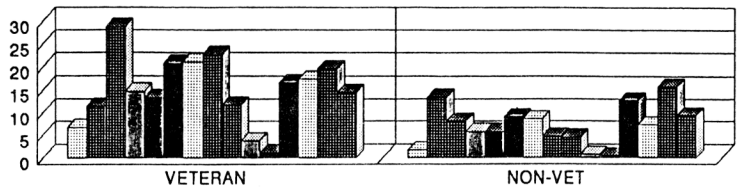
N=1067 FILE:BD-25 ENDOCRINE: PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY

CATEGORY	VETERAN COUNT	PER 100 CASES	NON VET COUNT	PER 100 CASES	TOTAL COUNT	CHI-SQUARE 2X2
MISCELLANEOUS						
Z251-EAR NOISES (TINNITUS)	46	6.81	7	1.79	53	
Z252-SEIZURES	78	11.56	53	13.52	131	
Z253-FREQUENT HEADACHES	195	28.89	32	8.16	227	
Z254-HEAT/COLD SENSITIVITY	100	14.81	23	5.87	123	
Z255-SENSITIVITY TO LIGHT	91	13.48	23	5.87	114	
Z256-FATIGUE	141	20.89	36	9.18	177	
Z257-MUSCLE PAIN/WEAKNESS	143	21.19	34	8.67	177	
Z258-JOINT PAIN	154	22.81	19	4.85	173	
Z259-UNEXPLAINED FEVERS	80	11.85	18	4.59	98	
Z260-HAIR LOSS	26	3.85	3	0.77	29	
Z261-BLOOD DISEASE	8	1.19	2	0.51	10	
Z262-TOOTH PROBLEMS	112	16.59	50	12.76	162	
Z263-STOMACH PROBLEMS	116	17.48	29	7.40	147	
Z264-JAUNDICE AT BIRTH	133	19.70	62	15.82	195	
Z265-OTHER PROBLEMS NOT LISTED	100	14.82	37	9.44	137	

N=1067 VETERAN:675 NON-VET:392 FILE: BD-LS26
NOTE: * IS SIGNIFICANCE AT 95% CL, ** IS SIGNIFICANCE AT 97.5% CL, *** IS SIGNIFICANCE AT 99% CL. .,
JUNE, 1993

NEW JERSEY AGENT ORANGE COMMISSION - ASSOCIATION OF BIRTH DEFECT CHILDREN
BIRTH DEFECT/LEARNING DISABILITIES REGISTRY:MISCELLANEOUS



Z251-EAR NOISES	6.81	1.79
Z252-SEIZURES	11.56	13.52
Z253-FREQUENT HEADACHE	28.86	8.16
Z254-HEAT/COLD SENSITV	14.81	5.87
Z255-LIGHT SENSITIVE	13.48	5.87
Z256-FATIGUE	20.89	9.18
Z257-MUSCLE-PAIN-WEAK	21.19	8.67
Z258-JOINT PAIN	22.81	4.85
Z259-UNEXPLAINED FEVER	11.85	4.59
Z260-HAIR LOSS	3.85	0.77
Z261-BLOOD DISEASE	1.19	0.51
Z262-TOOTH PROBLEMS	16.59	12.76
Z263-STOMACH PROBLEMS	17.48	7.4
Z264-BIRTH JAUNDICE	19.7	15.82
Z265-OTHER	14.51	9.44

N=1067 FILE:BD-26 MISCELLANEOUS: PER 100 CASES. VETERAN 675, NON-VET 392
JUNE, 1993

STATEMENT OF JOHN HANSON, DIRECTOR
NATIONAL VETERANS AFFAIRS AND REHABILITATION COMMISSION
THE AMERICAN LEGION
BEFORE THE COMMITTEE ON VETERANS AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
AUGUST 4, 1993

Mr. Chairman and Members of the Committee:

The American Legion commends you on the speed with which you scheduled a hearing on the Institute of Medicine's report on the effects of herbicides on Vietnam veterans.

For far too many years, The American Legion has been asking questions about a number of health problems faced by these veterans, and demanding action with few tangible results.

Many of the other witnesses today will detail their particular struggles with VA, the Centers for Disease Control, the Department of Defense and the chemical industry. Our own battles with those groups - and others - are well documented and the memory of those fights still leaves a bitter taste.

You know that we funded and conducted our own study of the health of Vietnam veterans when the government refused to act. The Legion and the Vietnam Veterans of America joined in a law suit against the federal government on this issue; the only lawsuit the Legion has ever filed against the government in its 75 year history.

The position of The American Legion on Agent Orange today is no different than it was throughout the 1970s and 1980s.

We sincerely believe that - for some reason - this government has consistently ignored legitimate medical complaints of Vietnam veterans and their families for so long that even modestly good news, such as we heard last week, provides little comfort.

While we have speculated about the reasons for the delays and false starts, we know that what is important now is not why there were no studies done earlier; but rather there must be additional studies conducted. We sincerely hope that the lessons learned from Agent Orange will be applied to research conducted for Desert Storm veterans.

We, of course, were relieved to see a panel of experts say that it is indeed possible for at least five medical conditions to be associated with exposure to chemicals used in Vietnam. And, we recognize that Secretary Brown could have delayed the granting of service connection - just as his predecessor did. We commend the Secretary for his swift action on that matter. But, we also know that this group of scientists was not charged with the job of finding cause and effect; but rather with a review of the literature on herbicide and dioxin exposure. As Dr. Fallon and Dr. Shine said last week, much work is yet to be done, and The American Legion is reinforcing its appeal for this government to get on with the work.

We cannot lose sight of the fact that many veterans have died without the benefit of VA survivors' benefits for their families. Others have become so debilitated by their medical conditions that they can no longer contribute to the economy of the country they served. We cannot lose sight of the fact that every year a good, solid, independent and scientifically valid epidemiological study is delayed, more veterans and their families are affected by the impact of their exposure to defoliating agents in Vietnam.

Mr. Chairman, how long must we wait for such a study? How long must the victims and survivors who are following this proceeding wait to know just how far this committee is willing to go on the veterans' behalf? The Institute of Medicine study offers important new evidence which supports action that will lead to an independent epidemiological study of the people who served in Vietnam. We do not ask this committee or this government to recommend action that

cannot be justified; and we know that many questions are still unanswered. We are simply asking for the delays and bureaucratic stonewalling to cease so we can, once and for all, put the remaining issues of Vietnam behind us.

Vietnam was never just a military conflict. Practically everything about its conduct was subject to review and reconsideration. Added to the confusion since we left Vietnam has been the legacy of our actions there. As The American Legion worked on the issue of the effects of herbicide spraying, we knew that we were walking into a complicated area. But, the more we interviewed concerned veterans with rare diseases, we knew we had to act. Optimistically, we felt certain that this government would agree.

We were not prepared for the denial, the lies and the name calling that resulted from our inquiries and others. We could not understand the absolute reluctance of a government to face its responsibilities and try to find some answers. We faced interference from at least one administration, and saw scientific studies become so truncated that they were useless.

The effects of dioxin exposure have always been in dispute, and the particular effects of exposure to the herbicidal agents in Vietnam were also controversial. In our opinion -- and in the opinion of a number of scientists we worked with over the years -- the best way to find an answer was to ask a question. But, for many reasons, it seems, those questions were disturbing to the government.

The American Legion is tired of the gamesmanship. Tired of the lies and double talk. If Vietnam veterans were not bitter for other reasons, they surely must be disgusted when they see how their government has behaved on this issue.

It is important to remember, no study has yet to declare that the exposure to Agent Orange was harmless.

4

Rather, we have seen that the so-called evidence does not indicate harmful effects.

So, Congress and VA are starting a new chapter - and we hope the beginning of the epilogue. Let's move forward and finally agree that an independent, scientifically powerful study should be done so we can put the doubts to rest.

Thank you.

STATEMENT OF
DAVID W. GORMAN
ASSISTANT NATIONAL LEGISLATIVE DIRECTOR
FOR MEDICAL AFFAIRS
OF THE
DISABLED AMERICAN VETERANS
BEFORE THE
COMMITTEE ON VETERANS AFFAIRS
U.S. HOUSE OF REPRESENTATIVES
AUGUST 4, 1993

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

On behalf of the more than 1.4 million members of the Disabled American Veterans (DAV) and its Women's Auxiliary, may I say how much we welcome the opportunity to appear before the Committee this morning to present our views on the National Academy of Sciences (NAS), Institute of Medicine (IOM) report: "Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam."

Mr. Chairman, this is a landmark day. For it can now be said that Vietnam veterans and those caring individuals involved in and dedicated to ensuring Vietnam veterans and their families receive what they believe they are entitled to from the Department of Veterans Affairs (VA) finally have received answers to questions that have long eluded reasonable and acceptable resolution.

Also present, in our view, is an atmosphere of optimism that we are close to finding additional answers to additional questions.

Mr. Chairman, our optimism today is derived basically from three sources: 1) the persistence of Congress in pursuing meaningful legislation, oversight and action regarding Agent Orange; 2) the independence, credibility, devotion and commitment of the IOM in pursuing this study in a timely fashion; and, 3) the commitment of Secretary Jesse Brown, to do what is right and in the best interest of veterans.

As you well know, Mr. Chairman, the issue of Agent Orange and its potential adverse health effects to those exposed has been present since 1978. For the past 15 years, Vietnam veterans and their loved ones have been patiently waiting for answers from the scientific and medical communities, as well as responses to their concerns from the Congress and VA. All too often those answers were not forthcoming. Perhaps definitive answers from the scientific and medical communities may never be known.

This seems to be the single most frustrating aspect of the Agent Orange debate -- that of medicine to provide satisfactory answers, acceptable to a majority about the effects of Agent Orange exposure to ones' overall health and well-being. Seemingly, for each study done concluding one point, another study would surface discounting the findings of the other. Thus, the debate raged.

On February 6, 1991, Public Law 102-4 was signed. In part, P.L. 102-4 required VA to enter into an agreement with the National Academy of Sciences. The stated purpose was "...to provide for the National Academy of Sciences, an independent nonprofit scientific organization with appropriate expertise which is not part of the Federal Government, to review and evaluate the available scientific evidence regarding associations between diseases and exposure to dioxin and other chemical compounds in herbicides."

Further, the Act provided "...the Academy shall review and summarize the scientific evidence, and assess the strength thereof, concerning the association between exposure to an herbicide used in support of the United States and allied

military operations in the Republic of Vietnam during the Vietnam Era and each disease suspected to be associated with such exposure."

Additionally, the Act provided "The Academy shall make any recommendations it has for additional scientific studies to resolve areas of continuing scientific uncertainty relating to herbicide exposure." The Act also made provisions for the NAS to undertake subsequent reviews of the scientific literature that may become available and report their findings and recommendations from such reviews to the Secretary.

It bears stating that the entity asked by Congress to undertake the mandated study -- NAS -- is, as described by the President of the IOM:

> " a nongovernmental organization created by an act of Congress and signed into law in 1863 by President Lincoln. The NAS is dedicated to the furtherance of science and technology and to their use for the promotion of general public welfare. A private, nonprofit society of distinguished scholars engaged in scientific and engineering research, the NAS has a mandate to advise the federal government on scientific and technical issues of pressing importance. Its members, drawn from universities and the private sector, are elected by their peers on the basis of exemplary professional achievement. Members, along with other leading experts, voluntarily participate in National Research Council and IOM studies and serve without compensation.
>
> The IOM was chartered by the NAS in 1970 to serve as an advisor to the federal government on issues that affect the public's health, as well as to act independently in identifying important issues of medical care, research, and education. The IOM brings to this mission more than two decades of experience in conducting independent analyses of pressing health problems that involve federal policy decisions."

With that background, Mr. Chairman, the DAV feels confident in the findings of the report and comfortable with the recommendations made therein. We are confident and encouraged that the process employed to address this difficult issue is in fact working. We do recognize, however, that the release of this report is only the first step in many yet to be taken to finally address and resolve the many complex issues surrounding exposure to dioxin.

As we understand the report and its recommendations, the DAV is supportive of Secretary Brown's immediate decisions.

We support the decision to have the Veterans Benefits Administration begin the rule making process to recognize Hodgkins disease and porphyria cutanea tarda (PCT) as being associated with exposure to herbicides. VA already has authority to grant service-connection for other diseases identified by IOM as having a statistical association to exposure, soft tissue sarcomas, non-Hodgkins lymphoma and chloracne.

The IOM report also noted limited or suggestive evidence of an association between exposure and three other types of cancer: respiratory cancer, prostrate cancer and multiple myeloma. In regard to those conditions, we understand Secretary Brown has established a panel to review and solicit comments on the report from other medical and scientific authorities, and interested parties, to include the Veterans' Service Organizations. It is expected the process of further analyzing the report and soliciting comments will be completed in a timely fashion -- within 60 days -- to enable the Secretary to make additional decisions as required by P.L. 102-4.

According to the report, for most other cancers, diseases and disorders reviewed, insufficient data was available to determine an association between exposure and the subsequent development of such conditions. These diseases included, but were not limited to, bone cancer, leukemia and disorders ranging from nervous system disorders to birth defects. Additionally, it was concluded that gastrointestinal cancers and brain tumors had no association with exposure.

Mr. Chairman, it is important to note here that with respect to the recognition of additional diseases being related to service in Vietnam, the VA will be contacting those veterans listed on the Agent Orange Registry urging them to apply for benefits.

The report also recommended certain actions be undertaken regarding future research activities One recommendation dealt with establishing an exposure index not by measurement of dioxin in the blood but, based on historical reconstruction of records. Those reconstructions would take into account factors such as troop movements, ground and perimeter spraying, herbicide shipments to various military bases, the type of terrain and foliage typical of the locations sprayed and the various military missions of the troops located there. It was recommended that a nongovernmental organization be commissioned to develop and test models of herbicide exposure relating to Vietnam veterans.

It was felt by the Committee that if a better model of exposure were developed then the possibility to undertake a number of important epidemiological studies would be enhanced. We agree with that recommendation. It was also recommended that a continuation and expansion of the Ranch Hand Study be authorized, and that the Army Chemical Corps and an appropriate comparison group be studied.

Mr. Chairman, we are heartened by Secretary Brown's actions to direct the Under Secretary for Health to prepare an action plan that will implement the research recommendations made by the Committee and agreed to by the Secretary. We urge this plan be prepared in the most timely manner possible and it be shared with the Veterans Affairs Committees, Veterans' Service Organizations and other appropriate parties with an interst in this issue.

Mr. Chairman, the DAV is in agreement with Secretary Brown's decisions up to this point in time based on the IOM's recommendations. Also, our belief is that we are now beginning to see a resolution to the major questions involved in the Agent Orange debate. We would, however, urge, in the strongest possible terms, that the VA continue to pursue, as expeditiously as possible, all available avenues attendant to this issue. Only by doing so will the VA have met its commitment to Vietnam veterans and their families.

Mr. Chairman, this concludes my testimony and I want to extend DAV's appreciation to you and the Committee for the timely conduct of this hearing and allowing us to present our views.

STATEMENT OF

DENNIS M. CULLINAN, DEPUTY DIRECTOR
NATIONAL LEGISLATIVE SERVICE
VETERANS OF FOREIGN WARS OF THE UNITED STATES

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES HOUSE OF REPRESENTATIVES

WITH RESPECT TO

HEALTH EFFECTS OF HERBICIDES USED IN VIETNAM

WASHINGTON, D.C. AUGUST 4, 1993

MR. CHAIRMAN AND MEMBERS OF THE COMMITTEE:

Speaking on behalf of the 2.2 million members of the Veterans of Foreign Wars of the United States, I wish to express our deep gratification at having been provided this opportunity to comment on the report prepared by the Institute of Medicine of the National Academy of Sciences concerning the health effects of Agent Orange and other herbicides on Vietnam veterans. The VFW is proud to include among its membership approximately 600,000 Vietnam veterans, many of whom where exposed to dioxin and other chemical toxins which were present in Agent Orange as well as other herbicides used in Vietnam. Additionally, the VFW has long championed the cause of providing VA health care on a service-connected basis to Vietnam veterans suffering from Agent Orange related disabilities as well as the provision of VA compensation to such veterans when there is any evidence of a causal relationship between a given disability and toxic herbicidal agents. Thus it's truly a privilege for me to be here today.

The NAS Institute of Medicine Study under discussion today represents the most thorough and all inclusive review of herbicide research ever conducted by the Federal government. The VFW notes that in addition to the three diseases already linked to Agent Orange for which compensation is already awarded by VA: soft tissue sarcoma, Non-Hodgkin's lymphoma and Chloracne, the

study has determined that Porphyria Cutanea Tarda, a metabolic liver disorder effecting skin and hair, and Hodgkin's disease, a lymphoma cancer with a number of manifestations, have been established as being attributable to herbicide exposure.

The VFW will now take this opportunity to thank and congratulate the Secretary of Veterans Affairs, Jesse Brown, for showing himself to be a true and committed Secretary for Veterans Affairs by establishing these two additional diseases to be compensable service-connected disabilities. This was done immediately upon release of the study and goes a long way toward demonstrating that the time of hesitancy and vacillation on this most important veterans issue is finally over. It presents a victory of compassion and common sense over bureaucratic inertia and intractable skepticism.

The VFW also notes that the report establishes "limited/suggestive evidence" that respiratory cancers, prostate cancer, and a bone disorder called Multiple Myeloma may also be linked to exposure to the toxic agents found in herbicides. In this regard, the VFW again offers its support of Secretary Brown who has indicated that he intends to make a determination on these additional disabilities within 60 days. Vietnam veterans have already had to wait far too long for the answers to their often terrifying questions regarding their herbicide-related disabilities, and the VFW strongly believes that prompt action is more than warranted in this case. We would only ask that the determination as to whether these three additional disabilities are service-connected be made with the utmost compassion and with all reasonable doubt resolved in this nation's veterans' favor.

It is known that from 1962 to 1971 U.S. military forces sprayed nearly 19 million gallons of herbicides over approximately 3.6 million acres in Vietnam. It is further known that Agent Orange, the herbicide containing the specific, deadly chemical agent, dioxin, informally known as TCDD, comprised 11.2 million gallons of the total amount sprayed. Thus, while the VFW ac-

knowledges the growing body of evidence that, as a group, Vietnam veterans did not suffer substantially high exposure to herbicides, it is also clear to us that certain Vietnam veterans, such as those who participated in Operation Ranch Hand and those who served in the most heavily sprayed areas, suffered extremely high exposure levels. Since the deadly nature of dioxin as well as certain other toxic agents found in herbicides is now a well documented scientific fact, the VFW holds that any veteran who demonstrably suffered significant exposure to toxic agents incidental to military service be awarded service-connected compensation and care for his or her disabilities on the most liberal basis. The Institute of Medicine's report under discussion today clearly states that the "existing epidemiologic data basis is severely lacking in quantitative measures of individual exposure to herbicides and dioxin." The report goes on to state that the "intensity and duration of individual exposures is a key component" in ascertaining whether specific disabilities are attributable to exposure to dioxin or other toxins found in the herbicides used in Vietnam. It is clear from the report that the available data is clearly lacking in this regard. The VFW further notes that while even very sound epidemiological studies are quite effective at establishing a connection between exposure to a certain agent and a particular health outcome affecting a large number of people, they are totally inappropriate and inadequate for discerning health effects for only a small number of people. The available Agent Orange data, therefore, would totally overlook the ill-health effects of certain highly susceptible veterans for whom are only relatively minimal herbicide exposure resulted in a disease or disability. We believe this lends force to our view that whenever exposure is established, the concerned veteran should be granted service-connected for any disability which is not clearly the result of some other factor.

The VFW also places special emphasis on the finding that additional research is highly warranted in order to resolve areas

of continuing scientific uncertainty concerning the health effects of the herbicides used in Vietnam. Based on the paucity of reliable data with respect to the ill-health effects of herbicide exposure, especially in the Vietnam veterans, the panel concludes that "a series of epidemiologic studies of veterans could yield valuable information if a new, valid exposure reconstruction model could be developed." Further, this scientific panel goes on to recognize the value in continuing the existing Ranch Hand study and expanding it to include Army Chemical Corps veterans. The VFW urges that this recommendation be heeded and that such ongoing research be authorized and funded by the Congress. Such additional studies coupled with the information being provided by other toxicology and epidemiology studies of herbicide exposure on non-veterans already being carried in the United States and abroad could finally bring an end to the nagging health questions facing America's Vietnam veterans and provide them with the compassion and care they deserve.

Mr. Chairman, the VFW is highly supportive of the panel's recommendation urging the furtherance of the scientific investigation and understanding of bio-markers as they pertain to the establishment of individual herbicide exposure. Once recognized, such biological sign posts will allow it to be established with a high degree of certainty whether a veteran suffered herbicide exposure or not. We are also supportive of the development of a valid herbicide exposure reconstruction model based on historical evidence. This would allow, at the very least, the determination of which groups of Vietnam veterans were likely exposed to Agent Orange as well as other herbicides. Finally, I would emphasize our support of the panel recommendation that the Department of Defense and the Department of Veterans Affairs identify Vietnam service in the computerized index of their records. As is indicated in the report, Vietnam service is not a flagged item in the military's computerized index at this time. This complicates epidemiologic studies of veterans and effectively prohibits

searches or selection of records of individuals who have served in Vietnam. The VFW notes the committee finding that "adding this indicator to the computerized data base would facilitate future mortality studies based on computerized records thereby increasing accuracy and decreasing costs...." The VFW believes such indexing should be carried out immediately.

Mr. Chairman, this concludes my statement. Once again I wish to express to you and the other members of this Committee the thanks of the Veterans of Foreign Wars for all you have done in working toward the resolution of the Agent Orange issue. A germane VFW Resolution is appended to this statement, and I would be happy to respond to any questions you may have.

STATEMENT OF

VIETNAM VETERANS OF AMERICA

Presented by

Paul S. Egan
Executive Director

Before the
House Veterans Affairs Committee

on the
Report and Recommendations
of the
National Academy of Sciences
on
Agent Orange and Vietnam Veterans

August 4, 1993

DISCUSSION

Mr. Chairman and members of the Committee, Vietnam Veterans of America (VVA) appreciates the opportunity to present its views on the report and recommendations of the National Academy of Sciences on Agent Orange and Vietnam veterans.

A preliminary examination of this major scientific review indicates proof, for the first time, of what Vietnam veterans have charged for two decades: the Agent Orange that was sprayed across South Vietnam from 1961 through 1971 caused a broad array of deadly cancers and other health hazards for Americans who served there.

Finally an unbiased scientific panel has looked at the evidence with open eyes and has seen the obvious connections that no U.S. government-based study has been willing to see. This honest report, slated to be the first of several over the next few years, is going to make a serious difference to thousands of Vietnam veterans and their families.

The report by the National Academy of Science's Institute of Medicine, titled "Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam," indicates that the 16-member panel found strong evidence associating several cancers and other conditions with exposure to Agent Orange. The Department of Veterans Affairs (VA) has recognized only three of these -- soft-tissue sarcoma, non-Hodgkin's lymphoma and chlorachne -- for treatment and compensation.

Based on these findings, Secretary of Veterans Affairs Jesse Brown has moved quickly to expand the list of compensable diseases by adding Hodgkin's disease and porphyria cutanea tarda (PCT), which the study found to have, in its guarded scientific wording, "sufficient evidence of an association" between exposure in Vietnam and affliction with the illnesses.

Vietnam Veterans of America is often critical of the VA, but we want to state clearly that the initial steps Secretary Brown has taken were both appropriate and compassionate. Although the law under which the study was initiated gives him 60 days to make determinations, he has not only immediately added the most obvious of the ailments to the list of compensable conditions, he has also ordered the rapid notification of veterans know to have been denied aid for these illnesses of their eligibility for help. This step was a logical necessity, and we appreciate the speed and the initiative with which he has taken it.

These first steps have been entirely laudable. What happens in the 60-day response period is of perhaps greater importance. We are encouraged both by the Secretary's commitment to evaluate the report very carefully before responding, and by the willingness the Secretary's office has shown to solicit the input of the veterans service organizations, which have vast and diverse experience with veterans suffering from the diseases that fell lower on the list in the NAS report.

The Next Steps at VA

The NAS report lists respiratory cancers, prostate cancer and multiple myeloma in the category of having limited or suggestive evidence of an association between Vietnam service and disease. This odd-sounding characterization stems from the scrupulousness of the scientists on the panel, who refused to use the usual two-step evaluation that lists diseases as clearly caused by Agent Orange or not caused by Agent Orange. Far too many studies have treated a failure to find a compelling connection as proof that no connection exists. That is bad science.

Diseases in the category of having "limited or suggestive evidence of an association" have evidence to support their association with Agent Orange, the panel says, but the studies do not bear it out as clearly as in the first category. One good study may make the connection, the report points out, but other studies fail to. The report uses the word "association" rather than "causality" because what it is identifying is a heightened risk. An individual can be sprayed

repeatedly with Agent orange and never contract any of these diseases, and a person with no exposure whatsoever can still come down with any of them. A disease with a heightened risk -- an "association" -- is one that a veteran probably would not have contracted without exposure to dioxin while on active duty, which is why the presumption of service-connection is made.

The standard in any claim for veterans benefits or treatment is reasonableness. Congress has enacted presumptions of service connection where it is more reasonable to presume the connection than to require individual veterans to prove it. The blanket presumptions that are reasonable for soft-tissue sarcoma, non-Hodgkin's lymphoma, chlorachne, Hodgkin's disease and porphyria cutanea tarda (PCT) may make less sense for diseases farther down the list, but it is important to construct sensible rules for them so that what connection does exist is not simply swept away.

How can we do that? Take a disease such as lung cancer, which is ranked in the limited/suggestive evidence category. There is solid evidence in at least one good study which controlled for smoking that Agent Orange can cause lung cancer, but we recognize that not every veteran with lung cancer was exposed to Agent Orange. Still, every veteran with lung cancer who was exposed to Agent Orange and is not a serious smoker ought to be covered by presumption, and every veteran with lung cancer who was exposed to Agent Orange and is a heavy smoker ought to fall under the test of reason. Was the exposure to dioxin high? How much does he or she smoke? And what portion of the disability rating ought to be allotted to the effects of Agent Orange? The VA has enough experience with conditions which are aggravated by a service connection to rule sensibly in these cases if given sensible guidelines rather than defensive positions.

The Report's Call for More Research

Why would Vietnam veterans find a report encouraging that says the dioxin in Agent Orange caused a great deal more cases of deadly illnesses than any government study has claimed? The question is not whether Vietnam veterans are at greater risk. Agent Orange-exposed Vietnam veterans are already sick, and they know why. What is encouraging is that they can finally pin responsibility for it on their patriotic service and receive the help they have been denied for so long. That is what makes the report's call for further study so important.

A legislative proposal before Congress now, offered by Senator Tom Daschle (D-SD), himself a Vietnam veteran, calls for government-funded research in Vietnam into the effects of dioxin exposure. Such research is of major importance to Vietnam veterans and their families, and indeed, to an America increasingly plagued by environmental hazards.

VVA supports such research because Vietnam provides, unfortunately, the best laboratory for dioxin exposure and health effects studies. Agent Orange was sprayed across the south and not at all in the north, so northerners provide a scientific control group without the background contamination from dioxin that most of the industrial world has. Thus there is a larger population for detailed studies, with both lower and higher exposures -- and longer ones -- than most American soldiers, which was the same reason the NAS cited industrial studies.

Research in Vietnam can perfect what we know about where Agent Orange was used and what its effects are. What we need to know about birth defects is waiting to be found there, as well as specific effects on women, which our women veterans need to know. This research needs to be undertaken soon, because the specific marker -- elevated blood dioxin levels -- needed for such study is gradually decreasing in people's bodies.

VVA recommends that President Clinton set up an Office of Agent Orange Studies under White House supervision, similar to those for AIDS and drug abuse. For $2,000,000 per year, we can get critical information that the NAS report was unable to find, because NAS reviewed studies that others have done and not enough has been done in Vietnam. It is most efficacious, we believe, for results of high quality in a reasonable time, that such studies be conducted under

sole source contracts, with the following criteria:

1. The studies must be independent of government agencies. They can be performed by scientists at medical schools, universities and research institutes.
2. They must make use of scientists who have already worked in Vietnam, because work there demands skills and knowledge that take time to develop.
3. They must include experts in both dioxins and herbicides, with professional background in both exposure assessment and health effects.
4. They must include MDs and PhDs in occupational medicine, exposure assessment and the epidemiology of dioxin and related chemicals.
5. Such research should include exposure assessment, cancer studies, reproductive studies, neurological and neurobehavioral studies, immune system studies and studies in biomarkers of exposure and sensitivity.

All further studies, VVA contends, must be funded by the U.S. government, but conducted independently. What the NAS report shows is that we were right all along in pointing to the unwillingness of every federal agency that has studied Agent Orange to admit the damage that our government has done to its own soldiers -- damage it has repeatedly shirked any responsibility for. Congress understood that when it funded this report, and we expect Congress to stand with us in making the VA responsive to its findings.

The NAS report's criticism of the study conducted by the Centers for Disease Control supports our own complaints, and demonstrates the need for an independently-contracted exposure study, with protocols and design methodology to be reviewed by NAS or some other non-government organization of equal stature. We urge Congress to take responsibility for this as soon as possible.

The Agent Orange Class Action Suit

In addition, the report's findings demonstrate with incredible clarity that the 1984 preemptive settlement of the Agent Orange Class Action suit was both premature and far too narrow. The settlement's unique bar against further individual or group lawsuits, even by veterans who took no part in the original suit, has provided a ring of barren earth across which no veteran can go in search of legal redress.

The irony behind the Agent Orange Class Assistance Program's meager compensation is that a veteran who has suffered an industrial exposure to dioxin may sue and collect damages as a worker, but has no rights as a veteran for the same maladies caused by the same chemicals. The judicial review that Congress has granted has, in Agent Orange cases, been defoliated by federal court action. VVA wants to state for the record its hope, shared by other veterans as well, that the Supreme Court in its upcoming session will grant certiorari in the Ivy v. Diamond Shamrock case, and will take a closer look at not only the injustice wrought by the far-reaching ruling in the Agent Orange Class Action suit, but at the growing tendency of courts to arrange preemptive settlements of class action tort suits, barring non-participants from pursuing individual justice.

Conclusion

In conclusion, Vietnam Veterans of America comes before you this morning with a grim satisfaction, vindicated in speaking so long for veterans whose illnesses were caused and neglected by the government that sent them to war, and which they served so willingly. A panel of courageous and honest scientists has clung carefully to the language of science, avoiding the language of policy. That language is yours to use, Mr. Chairman and members of the Committee. We ask that you read this study with policy in mind, and that the policies you write

in response to this landmark report -- and those you urge the Secretary of Veterans Affairs to write -- rely upon reason and science, and give the veteran the benefit of the doubt.

Mr. Chairman, this concludes our testimony.

WRITTEN COMMITTEE QUESTIONS AND THEIR RESPONSES

HONORABLE CHRISTOPHER SMITH
QUESTIONS SUBMITTED FOR THE RECORD
DR. SHINE AND DR. TOLLERUD
INSTITUTE OF MEDICINE
FULL COMMITTEE
AUGUST 4, 1993

1) AS YOUR REPORT HAS WISELY NOTED, EXPOSURE RECONSTRUCTION MODELS ARE CLEARLY NEEDED TO FURTHER STUDY THE EFFECTS OF AGENT ORANGE. WHAT KIND OF TIME FRAME DO YOU THINK WOULD BE NEEDED TO DESIGN AND TEST EXPOSURE MODELS?

It is not possible to say how much time would be required to design and test exposure models. In addition to the fact that the mechanism for conducting the design and testing has not yet been indicated, the actual process will depend on the methods chosen by the researchers, the extent to which additional data sources need to be accessed, and so on.

2) THERE WAS "INADEQUATE/INSUFFICIENT" EVIDENCE FOUND IN YOUR STUDY REGARDING THE RELATION OF DIOXIN TO BIRTH DEFECTS. SHOULD THE HOUSE VETERANS' AFFAIRS COMMITTEE CALL FOR A SPECIFIC STUDY OF THE AGENT ORANGE IMPACT ON THE CHILDREN OF VIETNAM VETERANS?

A specific study of children of Vietnam veterans has been undertaken in the Ranch Hand cohort. Also, the committee included in its recommendations for further research that reproductive outcomes receive priority attention. As indicated in the report: "Future analysis of the Ranch Hand data may contribute important evidence regarding an increased risk of birth defects among offspring of exposed Vietnam veterans." As this would constitute a reanalysis of existing data, the committee believes that some additional results on reproductive outcome could be available fairly quickly. Methodologic concerns regarding the analysis of the Ranch Hand data are described in Appendix C of the report, and should be taken into account in any new analysis of the data.

HONORABLE BOB STUMP
QUESTIONS SUBMITTED FOR THE RECORD
DR. TOLLERUD
INSTITUTE OF MEDICINE
FULL COMMITTEE
AUGUST 4, 1993

1) OF THE FOUR CATEGORIES WHICH WERE USED TO SIGNIFY THE FINDINGS OF THE NAS/IOM REPORT, ONE OF THEM WAS, "LIMITED/ SUGGESTIVE EVIDENCE FOR AN ASSOCIATION." PLEASE EXPLAIN WHAT IS MEANT BY THAT TERM AND WHAT DIRECTION SHOULD POLICY MAKERS TAKE FROM THE CATEGORIZATION WHEN DELIBERATING WHETHER OR NOT CONDITIONS IN THIS CATEGORY SHOULD BE ADDED TO THOSE PRESUMED TO BE SERVICE CONNECTED?

"Limited/suggestive" evidence was defined by the committee as: "Evidence is suggestive of an association between herbicides and the outcome, but is limited because chance, bias and confounding could not be ruled out with confidence. For example, at least one high quality study shows a positive association, but the results of other studies are inconsistent." All conditions in this category "reflect the committee's judgement that a statistical association would be found in a large, well-designed epidemiologic study of the outcome in question in which exposure to herbicides or dioxin was sufficiently high, well-characterized, and appropriately measured on an individual basis."

Compensation policy was not part of the committee's mandate so the committee cannot say whether conditions should be added to service connected conditions.

2) BASED ON YOUR REPORT, IN LAYMAN'S TERMS, WHAT DO YOU THINK THE VETERANS SERVICE ORGANIZATIONS SHOULD TELL VIETNAM VETERANS SUFFERING FROM ONE OF THE CONDITIONS IN THE "INADEQUATE/ INSUFFICIENT EVIDENCE TO DETERMINE WHETHER AN ASSOCIATION EXISTS" CATEGORY ABOUT THE RELATIONSHIP BETWEEN HIS MEDICAL CONDITION AND SERVICE IN VIETNAM?

WHAT ELSE WOULD HAVE TO BE LEARNED ABOUT THOSE CONDITIONS BEFORE THEY COULD BE CONSIDERED UNDER THE CATEGORY OF "SUFFICIENT EVIDENCE OF AN ASSOCIATION?"

Inadequate/insufficient evidence of an association is as defined in the report as: "The available studies are of insufficient quality, consistency or statistical power to permit a conclusion regarding the presence or absence of an association. For example, studies fail to control for confounding, have inadequate exposure assessment, or fail to address latency." Beyond this, the committee cannot make policy recommendations to Veterans Service Organizations or others.

The specifics vary by outcome, but to be considered sufficient evidence: "A positive association has been observed between herbicides and the outcome in studies in which chance, bias and confounding could be ruled out with reasonable confidence. For example, if several small studies that are free from bias and confounding show an association that is consistent in magnitude and direction, there may be sufficient evidence for an association."

3) REGARDING THE MOST CURRENT STUDY OF THE 337 RANCH HAND VETERANS AND THEIR SERUM SAMPLES, CAN YOU GIVE US SOME IDEA AS TO WHEN WE MIGHT EXPECT THE RESULTS OF THESE ANALYSES AND A NEW ESTIMATE ON HOW LONG IT TAKES THE BODY TO PROCESS TCDD AND ELIMINATE IT?

The committee does not know when. The Ranch Hand researchers would have to indicate when results might be available.

4) PLEASE GIVE US SOME IDEA OF WHAT THE BACKGROUND LEVEL IS FOR TCDD AS COMPARED TO WHAT IT MIGHT BE FOR ONE WHO SERVED IN AN AREA IN VIETNAM THAT WAS SPRAYED WITH AGENT ORANGE.

Background levels of TCDD are not well defined, and there is no agreement concerning exactly what those levels might be. Because individual exposure data are lacking, as explained in chapter 6 of the report, the committee cannot say what the TCDD levels would be for a veteran who served in an Agent Orange sprayed area of Vietnam.

5) WHAT OTHER CHARACTERISTICS WOULD EFFECT THE SERUM TCDD LEVELS IN THE 640 VIETNAM VETERANS? WOULD DISEASE BE A FACTOR?

In the study of 640 Vietnam veterans, "researchers found that serum TCDD levels varied with several personal characteristics, including age, race, body mass, and region of residence. It has also been suggested that disease may affect serum TCDD levels. . . . . Reverse causality, in which health outcomes affect the measured serum TCDD level years after exposure, can better explain some relationships between serum TCDD and health outcomes in the Ranch Hand study than a direct model in which TCDD causes the outcome."

6) HOW DOES AGE AND DIETARY CHANGES IN THE BODIES OF THE RANCH HAND VETERANS AFFECT THE REDUCTION FOR TCDD SERUM LEVELS?

It is not known specifically how age and dietary changes in the bodies of the Ranch Hand veterans affect reduction of serum levels.

7) CAN YOU EXPLAIN WHAT IS MEANT BY THE STATEMENT AS CONTAINED IN THE COMMITTEE'S REPORT THAT IN THE SEVESO, ITALY ACCIDENT IN 1976, THE RESULTS OF THAT STUDY SUGGESTED THAT THE EXPOSURE OF IMPORTANCE WAS FALLOUT ON THE DAY OF THE ACCIDENT.

The results of a study in Seveso on blood samples taken from residents of the area closest to the Seveso accident (Zone A) indicated that the predominant route of exposure was direct exposure to the TCDD-containing fallout from the cloud released after the factory explosion. The serum TCDD levels did not correlate with soil levels of TCDD, the number of days an individual stayed in Zone A, or whether local food was consumed. "None of these data correlated with serum TCDD levels, strongly suggesting that the exposure of importance was fallout on the day of the accident."

HONORABLE BOB STUMP
QUESTIONS SUBMITTED FOR THE RECORD
INSTITUTE OF MEDICINE
FULL COMMITTEE
AUGUST 4, 1993

1) DOES YOUR REPORT SHOW THAT THE WORK OF THE RANCH HAND STUDY, CENTERS FOR DISEASE CONTROL OR THE OFFICE OF TECHNOLOGY ASSESSMENT WAS FLAWED OR LACKING IN INTEGRITY?

The committee report was not intended to show whether or not any work was flawed. Controversy has surrounded the study of Agent Orange since the first questions of herbicide-related health effects in Vietnam veterans were raised more than 20 years ago. In the course of its work, the committee heard allegations of scientific misconduct and claims of a government conspiracy to suppress information on health effects, as well as serious disagreements among scientists about the interpretation of laboratory and clinical data. Congress called upon the National Academy of Sciences to review the scientific evidence on the possible health effects of exposure to herbicides. The committee was not charged with investigating or resolving these controversies, and it did not attempt to do so. The committee took these issues into consideration only to the extent that they had a direct bearing on the scientific results that are the subject of this review.

2) THE INSTITUTE'S RESEARCH RECOMMENDATIONS INCLUDE ONE FOR DEVELOPMENT OF EXPOSURE RECONSTRUCTION MODELS FOR VIETNAM VETERANS. PLEASE TELL THE COMMITTEE MORE ABOUT THESE RECOMMENDATIONS.

From the committee's report:

"Exposure assessment has been a weak aspect of most epidemiologic studies of Vietnam veterans. The military reports and personal testimony reviewed by the committee suggest that a sufficient range of exposure to herbicides may exist among Vietnam veterans for valid epidemiologic studies of certain health outcomes, and the committee believes that it is possible to develop valid exposure reconstruction models for epidemiologic studies using methods of historical exposure reconstruction. Such models would estimate the likelihood that each individual veteran was exposed to herbicides in Vietnam and possibly quantify their degree of exposure. These models (described in more detail in the report) would incorporate information from existing military records about troop movements and herbicide spraying (including, but not limited to, the HERBS and Services HERBS tapes). The models must also include

less formal sources of historical information about ground and perimeter spraying, such as records of herbicide shipments of individual bases from the major shipping depots, and consideration of the types of terrain, typical foliage, and military mission of the bases or troops located there. Supplemental information gathered from surveys of military officers with first-hand knowledge of herbicide operations in Vietnam, such as the 1971 survey conducted by the Army could also be incorporated into the exposure model."

"Historical exposure reconstruction is a well-developed specialty in occupational health research that requires substantial professional judgment. The committee recommends that the DVA arrange for a nongovernmental organization with appropriate experience in historical exposure reconstruction to develop and test potential models of herbicide exposure for use in studies of Vietnam veterans. This group will need access to DOD and DVA records to carry out this work."

"Herbicide exposure reconstruction models for Vietnam veterans must be evaluated thoroughly before epidemiologic studies based on these models proceed. The committee has identified three possible approaches to such an evaluation, which are discussed in more detail in Chapter 6: (1) internal consistency checks, (2) comparisons of model exposure measures with serum TCDD measurements, and (3) assessment of the association between exposure reconstruction measures and health outcomes shown in occupational or environmental studies to be associated with herbicides. Scientific judgment is required in interpreting the results of such an evaluation, so the committee cannot specify explicit criteria for acceptance or rejection of the new exposure reconstruction models in advance of their development and testing."

"The committee recommends that an independent, nongovernmental scientific panel be established to review the results of the proposed evaluation studies and judge the validity and feasibility of the exposure reconstruction models. This panel should have expertise in historical exposure reconstruction and epidemiology. To maintain the public and scientific credibility of the study, the panel members should be nongovernmental and independent of the organization that develops the exposure reconstruction models."

"A number of possible epidemiologic studies could provide additional information on the health effects of exposure to herbicides in Vietnam beyond what is already known. Highest research priority should be given to those health effects for which additional study is likely to change the balance

of the evidence for or against an association. This includes

a. health outcomes for which current evidence is limited/suggestive of an association (lung and respiratory cancers, prostate cancer, and multiple myeloma);
b. health outcomes for which current evidence is insufficient or inadequate to determine whether an association exists, but which, in the committee's judgment, are plausible based on animal toxicologic data (such as nasal/nasopharyngeal cancer) or for which there are known associations with related chemical compounds in humans (such as liver cancer and polychlorinated biphenyls; Nicholson, 1987);
c. health outcomes for which the typical age at onset has not yet been reached by members of the Vietnam veteran cohort (such as prostate cancer)."

"The committee also recommends that priority be given to additional research on reproductive outcomes that would help clarify the possible effects of herbicides. Since Vietnam veterans are expected to have relatively few additional children because of their age, reanalyses of existing reproductive data, especially those based on registries, with the new exposure reconstruction measures proposed in this chapter, would be especially relevant. In particular, the committee believes that extensive reanalysis of the Ranch Hand reproductive data could shed additional light on these questions (see Chapter 9 and Appendix C)."

"Although there is sufficient evidence of an association between occupational or environmental exposure to herbicides and non-Hodgkin's lymphoma, Hodgkin's disease, and soft tissue sarcomas, the existing information on dose-response relationships is incomplete, especially with regard to Vietnam veterans. If a valid exposure reconstruction method can be developed, it might be applied to the exposure data available from existing case-control studies to provide additional dose-response evaluations. Further refinement of the clinical and pathological definitions of soft tissue sarcomas in epidemiologic studies would also help to determine which of the specific cancers in this class are associated with herbicides and/or TCDD."

"The exposure reconstruction models to be developed could be used in either case-control or cohort studies. The type of study design will depend on the health outcome being investigated. Rare health effects, for instance, will likely require case-control studies, as described in Chapter 5."

"The cost of these epidemiologic studies will depend on the study design. A design based on an exposure reconstruction model applied to computerized troop location records using existing mortality data or health outcome data could be relatively inexpensive. Adding detailed record review by experts or analysis of clinical or morbidity data would substantially increase costs. A study design involving serum TCDD measurements would also increase cost, if current costs for the biochemical assays are not reduced."

"Although the number of women Vietnam veterans may be too small to provide adequate statistical power in a study by themselves, the committee believes that women Vietnam veterans should be included in Vietnam veteran studies whenever appropriate."

"The committee recognizes that the recommendations for development of a historical exposure reconstruction model and its use in epidemiologic studies might seem at variance with the Centers for Disease Control (CDC) (Pirkle, 1993), White House Agent Orange Working Group (AOWG) (Young et al., 1986), and Office of Technology Assessment (OTA) (Gibbons, 1987) conclusions with regard to the congressionally mandated Agent Orange Study. The committee has come to a different conclusion for four reasons: First, the CDC-AOWG-OTA conclusions were based in large part on serum TCDD measurements, which the committee feels are insufficient for validating exposure to herbicides used in Vietnam, as explained in Chapter 6. Second, the arguments underlying the earlier conclusion that individuals in combat units were widely dispersed and that troop movement data are incomplete imply that exposure measurements may be imprecise, not that they are invalid. However, these arguments do suggest that historical reconstruction of exposure will have some degree of nondifferential misclassification bias, and the effect of this bias on risk estimates would likely be to underestimate true effects if they existed, possibly to the point that they would not be detected. Third, the committee is proposing the use of more, but less formal, information on exposure than was considered in 1986. This includes the development and use of informal information on perimeter spraying, which might account for more meaningful herbicide exposure than the aerial spraying documented on the HERBS tapes. Finally, the committee does not know whether the approach it proposes will prove valid or whether new methods will identify a sufficient number of highly exposed Vietnam veterans for an epidemiologic study. In the committee's judgment, however, the likelihood that this approach will be successful is sufficient for it to be recommended."

3) IS IT POSSIBLE THAT, AFTER FURTHER EVALUATION BY A SCIENTIFIC PANEL, NO EXPOSURE RECONSTRUCTION MODEL WOULD BE FOUND TO BE FEASIBLE?

It is possible that no model is feasible.

4) IF NO EXPOSURE RECONSTRUCTION MODEL WAS FOUND TO BE FEASIBLE, COULD THERE BE SOME OTHER BASIS FOR FURTHER EPIDEMIOLOGIC STUDY FOR VIETNAM VETERAN EXPOSURE TO AGENT ORANGE?

Exposure measurements/estimates are essential to epidemiologic studies of associations with disease outcomes. If no exposure data are available, no studies can be done.

5) PLEASE ELABORATE ON THE REASONS WHY CLINICAL DATA AND TISSUE ARCHIVING SYSTEMS ARE NOT RECOMMENDED, IN THE ABSENCE OF A CLEAR STUDY DESIGN TO GUIDE THEM? ISN'T IT A GOOD IDEA TO ARCHIVE BASIC DATA AND TISSUE SAMPLES SO THAT THEY ARE AVAILABLE FOR FUTURE RESEARCH EFFORTS, SHOULD THEY BE NEEDED?

"To be scientifically valid . . . a study based on stored biological samples or clinical data must be designed with a sampling plan appropriate for hypotheses to be tested. . . . Storage of biological samples or medical records from self-selected individuals or from those who feel that they are suffering from disabilities due to herbicide exposure is unlikely to yield scientifically valid information on the health effects of herbicides; any epidemiologic study based on these data would suffer from misclassification bias. . . . Results obtained to date indicated that human tissue monitoring may become increasingly informative, provided that difficult issues of system design, quality control, and ethics are resolved."

"Balancing the strengths and weaknesses of stored biological samples and clinical data for research purposes, the committee feels that systems of this sort have scientific value, but only to the extent that they are components of specific, well-designed studies. In the absence of a clear study design to guide such activities -- and without resolution of the design, quality control and ethical issues -- the committee does not recommend the establishment of the clinical data and tissue archiving systems described in sections 6 and 7 of the law at this time."

6) THE MANDATE OF THE INSTITUTE OF MEDICINE WAS TO EVALUATE THE AVAILABLE SCIENTIFIC EVIDENCE REGARDING THE "ASSOCIATION" BETWEEN EXPOSURE TO DIOXIN OR OTHER CHEMICAL COMPOUNDS IN HERBICIDES USED IN VIETNAM AND A WIDE RANGE OF HEALTH EFFECTS. IN LIGHT OF YOUR EVALUATION, WHERE DO WE STAND WITH REGARD TO DETERMINATIONS OF "CAUSALITY" IN INDIVIDUAL CASES?

Consistent with its congressional mandate, the committee did not make determinations of causality in individual cases. Association is a statistical concept that cannot be translated directly into individual causality. Public Law 102-4 states that the DVA contract with the NAS to review and evaluate the available scientific evidence regarding "associations" between diseases and exposure to dioxin and other chemical compounds in herbicides used in Vietnam during the Vietnam era. This is what the committee accomplished in its report.

7) AT PAGE 18 OF THE EXECUTIVE SUMMARY, YOU STATE THAT THE LIKELIHOOD THAT THIS APPROACH (DEVELOPMENT OF AN EXPOSURE RECONSTRUCTION MODEL AND ADDITIONAL EPIDEMIOLOGIC STUDIES) WILL BE SUCCESSFUL IS SUFFICIENT FOR IT TO BE RECOMMENDED.

CAN YOU ESTIMATE HOW LIKELY SUCCESS IS -- EVEN CHANCE, VERY LIKELY OR HOWEVER YOU WOULD CARE TO CHARACTERIZE IT?

We can say nothing further than what has been stated earlier.

8) YOUR TESTIMONY STATES ON THE ONE HAND THAT "INFORMATION ON THE EXTENT OF HERBICIDE EXPOSURE AMONG VETERANS IS PRACTICALLY NONEXISTENT." HOWEVER, YOU SEEM TO HOLD OUT GREAT HOPE FOR THE ABILITY OF HISTORICAL RECONSTRUCTIONS TO GAUGE EXPOSURE.

CAN YOU EXPLAIN HOW HISTORICAL RECONSTRUCTIONS WOULD IMPROVE THE ANALYSIS ON ASSOCIATED HEALTH EFFECTS AND COMMENT MORE ON THE FEASIBILITY FOR HISTORICAL RECONSTRUCTION?

Exposure of <u>individual</u> veterans, in a documented fashion is virtually non-existent. However, if information on potential exposure could be pulled together, and degrees of different exposure amounts could be determined, useful information on the association with disease could result. If disease occurred more frequently among those with higher potential exposures, this would provide valuable scientific information regarding an association. Exact individual exposure information is not necessary for good epidemiologic research to be conducted.

9) WHILE FURTHER WORK ON EXPOSURE MAY NOT IDENTIFY INDIVIDUAL EXPOSURE LEVELS, COULD IT AT LEAST IDENTIFY GROUPS OF VIETNAM VETERANS EXPOSED TO THE RELATIVELY HIGH LEVELS OF HERBICIDES AS IN THE INDUSTRIAL STUDIES USED TO REACH NAS CONCLUSIONS, ABOUT ASSOCIATION BASED ON SUFFICIENT STATISTICAL EVIDENCE AND LIMITED EVIDENCE OF AN ASSOCIATION?

Possibly yes; groups exposed to relatively high levels of herbicides might be identified.

10) HOW MUCH MORE WEIGHT SHOULD BE GIVEN TO STUDIES OF COHORT GROUPS SUCH AS THE RANCH HAND COHORT, AS OPPOSED TO HISTORICAL RECONSTRUCTION, IF FEASIBLE?

It is not an "either/or" matter as to whether one type of study design should be used over the other. Both have a role, in that all information available should be evaluated together when results are replicated in other populations, as support is then generated for associations under investigation. The two study designs are also not comparable to each other in terms of the types of research questions addressed. Although a cohort design is an attempt to move forward through time and identify disease, with exposure categories defined in an unbiased fashion before disease develops, the sample size of the Ranch Hand cohort is not sufficient in most instances to statistically identify excess occurrence of disease. However, historic reconstruction of exposure will allow for a larger sample to be studied, and identification of potentially associated health outcomes will be more likely, although the amounts of exposure will potentially be less than that found among the Ranch Hand cohort.

11) HAVE ANY OF THE DISEASES WHICH THE NAS REPORT CONCLUDED HAD SUFFICIENT EVIDENCE TO DETERMINE A POSITIVE ASSOCIATION OR A LIMITED/SUGGESTIVE ASSOCIATION APPEARED IN THE RANCH HAND COHORT GROUP TO ANY STATISTICALLY SIGNIFICANT DEGREE?

One case of STS was detected, and none was expected, which might be translated into a "statistically significant" difference. This is discussed on page 8-60 of the prepublication report. The Ranch Hand cohort is relatively small, particularly when attempting to detect excesses of many of these rare health outcomes. Given the small sample size, and rare outcome, excesses would not necessarily be expected. The absence of detecting such outcomes in the Ranch Hand cohort does not necessarily indicate that these are not real. The recommended addition of the Chemical Corps to the Ranch Hand cohort was an attempt to increase the sample of those heavily exposed, so that rare outcomes

would be more likely to be detected, if in fact an association existed.

12) YOUR REPORT SEEMS TO VERIFY THE FINDINGS OF THE CDC STUDY. WHAT, IF ANY, ARE THE MAJOR SHORTCOMINGS OF THE CDC STUDY. IS A COHORT STUDY OF VIETNAM VETERANS SUCH AS RANCH HAND THE BEST REMAINING AVENUE TO PURSUE?

There were three major epidemiologic CDC studies involving Vietnam veterans - the Selected Cancers Study, the Vietnam Experience Study and the Birth Defects Study. As there were several studies, the committee is not sure which study is referred to in the question concerning verification and shortcomings. The methods used in these studies are summarized in Chapter 7 of the report.

Again, it is not an "either/or" matter as to whether one type of study design should be used over the other. Both have a role, in that all information available should be evaluated together when results are replicated in other populations, as support is then generated for associations under investigation.

13) GIVEN YOUR TESTIMONY REGARDING THE IMPORTANCE OF QUESTIONS REGARDING WHAT YOU CALL ATTRIBUTABLE RISK, WOULD A POLICY DECISION TO COMPENSATE ALL VIETNAM VETERANS WHO DEVELOP PROSTATE CANCER OR ANY OTHER CONDITION IN THE CATEGORY OF "LIMITED/SUGGESTIVE EVIDENCE OF AN ASSOCIATION" BE SCIENTIFICALLY FOUNDED IF FUTURE RESEARCH DETERMINES THAT THERE IS A SLIGHTLY HIGHER CHANCE OF GETTING PROSTATE CANCER THAN THE GENERAL POPULATION? SHOULD WE COMPENSATE ALL VIETNAM VETERANS? PLEASE EXPAND ON THE APPLICABILITIES OF ATTRIBUTABLE RISK TO YOUR FINDINGS.

The committee cannot comment on policy decisions regarding compensation of prostate cancer, or on whether all Vietnam veterans should be compensated. The proportion of the risk for disease that can be attributed to, or is determined by, a particular exposure, is often referred to as the attributable risk for that exposure in the development of disease. The amount of risk attributed to Agent Orange or herbicides for any health outcome evaluated was not determined because given the large uncertainties that remain about the magnitude of potential risk from exposure to herbicides in the occupational, environmental, and veterans studies that the committee reviewed, inadequate control for important confounders in these studies, and the lack of information needed to extrapolate from the level of exposure in the studies reviewed to that of individual Vietnam veterans, it was not possible for the committee to quantify

the degree of risk likely to have been experienced by Vietnam veterans because of their exposure to herbicides in Vietnam.

14) IN THE STELLMAN STUDY TO WHICH YOU REFER IN VARIOUS PORTIONS OF YOUR REPORT YOU INDICATE THAT (AND I QUOTE) 1) "... THE USE OF A SELF-ADMINISTERED QUESTIONNAIRE DOES NOT YIELD THE BEST RESPONSE RATE AND QUALITY OF INFORMATION." 2) "... NO ATTEMPT WAS MADE TO VALIDATE THESE CONDITIONS (RELATIONSHIP BETWEEN AGENT ORANGE EXPOSURE, AND 'ADULT ACNE') BY MEDICAL OR PHYSICAL EXAMINATION." 3) "... THIS STUDY, INDIRECTLY MEASURED HERBICIDE EXPOSURE AND DID NOT SPECIFICALLY MEASURE IMMUNE RESPONSIVENESS." 4) "IN ADDITION, SELF-REPORTED DISEASE DATA ARE SUBJECT TO RECALL BIAS THAT MAY CONFOUND THESE RESULTS." AND, 5) "CONCLUSIONS TO BE DRAWN ARE LIMITED BY THE POTENTIAL FOR MISCLASSIFICATION OF EXPOSURE AND THE LACK OF VALIDATION OF SELF REPORTED DIAGNOSES. IT IS UNCLEAR IF ADEQUATE ADJUSTMENTS WERE MADE FOR MODIFIERS SUCH AS CIGARETTE SMOKING AND OBESITY." BASED ON THE ABOVE QUOTES CONTAINED IN YOUR REPORT, WHY WAS THIS STUDY USED AS PART OF YOUR REVIEW?

All studies that came to the committee's attention were reviewed and the scientific methods of each were considered. The contributions of each individual study to the committee's conclusions varied by the quality and relevance of the studies.

15) THE EXECUTIVE SUMMARY AT P. 19 STATES THAT INDIVIDUAL TCDD (DIOXIN) SERUM LEVELS IN VIETNAM VETERANS ARE USUALLY NOT MEANINGFUL. WILL IT BE POSSIBLE TO MAKE MEANINGFUL DETERMINATIONS ABOUT INDIVIDUAL EXPOSURES SO THAT VIETNAM VETERANS CAN KNOW WHETHER THEY ARE AT SIGNIFICANT RISK FOR SPECIFIC HEALTH PROBLEMS?

The committee cannot say whether meaningful determinations of an individual Vietnam veteran's exposure can be made in order to know whether they are at significant risk for specific health outcomes.

16) DOES YOUR REVIEW ATTEMPT TO RATE IN SOME SYSTEMATIC COMPARATIVE WAY THE STUDIES REVIEWED?

The committee judged the quality and relevance of all studies, but did not assign specific numeric ranks to rate them.

HONORABLE CHRISTOPHER SMITH
QUESTIONS SUBMITTED FOR THE RECORD
SECRETARY JESSE BROWN
DEPARTMENT OF VETERANS AFFAIRS
AUGUST 4, 1993

1) I understand the VA will begin contacting veterans on the Agent Orange Registry who already have the diseases which you administratively added to the compensation list. Will those Vietnam Veterans who were previously denied compensation be contacted as well?

A-1) Yes. We are reviewing four major data information resources to identify potential claimants. Briefly, these potential claimants include:

a) veterans whose VA records indicate denial of a claim for a disability which is now recognized

b) veterans included in our Agent Orange Registry

c) veterans who have requested VA medical care for a condition now recognized

d) deceased veterans whose VA records indicate denial of a claim for a condition now recognized and who may have survivors eligible for service-connected death benefits.

2) VA has agreed to explore the Academy recommendation to include a Vietnam service marker in the personnel record of veterans. Would it also be appropriate given the concerns about environmental hazards to include a marker in the personnel files of Gulf War veterans?

A-2) As noted, VA is currently reviewing the feasibility of providing a computerized indicator to assist in the identification of veterans with Vietnam service as recommended by the Academy.

The development of a similar marker for Persian Gulf veterans will not pose a significant problem because the Department of Defense (DoD) has provided VA, at its request, with a computerized listing of all personnel who served in the Persian Gulf theater of operations. (No such roster exists for Vietnam veterans). This computerized database, which is periodically updated by the DoD, currently includes the names, social security numbers, troop locations and other information on approximately 657,000 service personnel. This listing can be readily accessed by VA to assist in verifying Persian Gulf service and for research and health surveillance purposes. We believe that the availability of this computerized database will achieve the same goals in addressing the health concerns of Persian Gulf veterans as would a special marker in personal medical files.

HONORABLE BOB STUMP
QUESTIONS SUBMITTED FOR THE RECORD
SECRETARY JESSE BROWN
DEPARTMENT OF VETERANS AFFAIRS
AUGUST 4, 1993

1) Mr. Secretary, in establishing the panel to review and identify those veterans whose cases may be reopened, who have you designated to sit on the panel?

A-1) A team of program experts from VBA's Compensation and Pension Services and VHA's Environmental Epidemiology Service has been assembled to develop lists of veterans who may be eligible for VA benefits for disabilities recognized to be the result of exposure to herbicides used in Vietnam. Soon, we will begin to contact veterans for whom addresses are available. For others, and for survivors of veterans whose deaths may have been due to a disability resulting from exposure to herbicides, claims folder review will be done at the regional office level.