Secretary Brown Announces
VA Will Recognize Additional Conditions

On July 27, 1993, Secretary of Veterans Affairs Jesse Brown announced that the Department of Veterans Affairs (VA) will recognize Hodgkin's disease and porphyria cutanea tarda as service-connected for veterans who were exposed to herbicides during their military service. Since there is no clear record of who was exposed to herbicides in Vietnam, VA presumes all Vietnam veterans to have had such exposure.

The Secretary’s decision was based on the National Academy of Sciences (NAS) review of evidence of the relationship between exposure to Agent Orange and other herbicides used in Vietnam and the subsequent development of medical problems. The NAS review was conducted for VA under the direction of Congress. (The NAS review is described in the adjacent article.)

Secretary Brown indicated that his decision followed consultation with the White House, and reflects the President’s concern and support for those Vietnam veterans whose health may have been affected by military service.

NAS concluded that sufficient evidence exists of an association between herbicide exposure and soft tissue sarcoma, non-Hodgkin’s lymphoma, Hodgkin’s disease, chloracne, and porphyria cutanea tarda. VA already recognized soft tissue sarcoma and chloracne as service-connected for exposure to dioxin-containing herbicides and non-Hodgkin’s lymphoma for service in Vietnam. The Department has been paying compensation to Vietnam veterans for these conditions.

Announcing his decision Secretary Brown said, "This study confirms earlier VA decisions on the health risks of Vietnam service. But it also gives us new information that I believe will help to further resolve the lingering concerns of Vietnam veterans and their families. While VA has been providing health care to Vietnam veterans for conditions they believe may be related to Vietnam service, this decision means that we can now add two conditions to our existing list for compensation purposes."

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NAS Issues Report; Finds Positive Link Between Agent Orange and Five Conditions; Others May Be Associated; Calls for Additional Research

On July 27, 1993, the National Academy of Sciences (NAS) Institute of Medicine's Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides released its initial findings. The Committee found "sufficient evidence" to conclude that there is a positive association between herbicides and (1) soft tissues sarcoma, (2) non-Hodgkin's lymphoma, (3) Hodgkin's disease, (4) chloracne, and (5) porphyria cutanea tarda (in genetically susceptible individuals).

The Committee also found "limited/suggestive evidence" of an association between exposure to herbicides used in Vietnam and three other types of cancer: respiratory cancers (including lung, larynx, and trachea), prostate cancer, and multiple myeloma.

For most conditions reviewed, the Committee concluded that there was "inadequate/insufficient evidence" to determine whether an association exists. The NAS Committee included the following diseases and disorders in this third category: 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 birth-weight, childhood cancer in offspring, abnormal sperm parameters and infertility, 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, and respiratory disorders.

For a small group of cancers, the Committee found "limited/suggested evidence" that there is "no association" with herbicides used in Vietnam. This category included skin cancer, gastrointestinal tumors (stomach cancer, pancreatic cancer, colon cancer, rectal cancer), bladder cancer, and brain tumors. The Committee report noted, however, that even for these conditions "the possibility of a very small elevation in risk at the levels of exposure studied can never be excluded."

Problem: Lack of Exposure Data on Vietnam Veterans

According to Harold Fallon, M.D., who chaired the Committee, the greatest problem encountered in the review 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." Consequently, most studies evaluated by the Committee did not involve Vietnam veterans. Rather, the Committee focused on studies of people who were exposed to herbicides as a result of their jobs or as a result of contact in the environment.

These types of exposures often were at high levels and for long periods of time. Assessing health risks for Vietnam veterans is complicated by the fact that the levels of exposure were extremely wide ranging. While most Vietnam 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.

More Research Needed

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 urged the continuation of the Air Force Health Study of Ranch Hand personnel and the expansion of that investigation to include Army Chemical Corps veterans.

The Committee’s research recommendations emphasize epidemiologic 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 of herbicides and herbicide components is already under way in the United States and abroad. 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 ongoing research will also contribute to the knowledge of potential health effects in this population.

The Committee made the following specific 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.

Recommendation 2. The Department of Defense and the Department of Veterans Affairs should identify Vietnam service in the computerized index of their records.

Recommendation 3. Biomarkers for herbicide exposure should be developed further.

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.

Recommendation 5. The exposure reconstruction models developed according to Recommendation 4 should be evaluated by an independent, nongovernmental scientific panel established for this purpose.

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.

The Committee also recommended that priority be given to additional research on reproductive effects that would help clarify the possible effects of herbicides. In particular, the Committee concluded that extensive reanalysis of the Ranch Hand reproductive data could shed additional light on these questions.

The Committee report noted that although there is sufficient evidence of an association between occupational or environmental exposures to herbicides and several conditions, 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 observed that its 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, White House Agent Orange Working Group, and congressional Office of Technology Assessment conclusions made in 1986 regarding the congressionally mandated Agent Orange Study. The Committee offered four reasons for the different conclusion:

(1) the 1986 conclusions were based in large part on serum TCDD measurements, which the Committee thinks are insufficient for validating exposure to herbicides used in Vietnam;

(2) 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;

(3) 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; and

(4) 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.

Other Recommendations

The law that mandated the NAS review (Public Law 1024, the Agent Orange Act of 1991), required that NAS include in the initial NAS report an evaluation of the feasibility and cost-effectiveness of four specific programs that might be implemented by VA. The NAS conclusions are described below.

Section 6 of that legislation requires VA to compile and analyze, on a continuing basis, all clinical data that (1) are obtained in connection with VA 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. The NAS report indicated that such a system, called the Agent Orange Registry, currently exists.

Section 7 concerned 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 stored biological samples and clinical data for research purposes, the Committee concluded 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 important design, quality control, and ethical issues regarding tissue banks, the Committee did not recommend the establishment at this time of the clinical data (Section 6) and tissue archiving (Section 7) systems described in the law.

Section 8 related to the feasibility of conducting additional scientific research on health hazards resulting from exposure to dioxin and herbicides used in Vietnam. As stated above, the Committee concluded that a series of epidemiologic studies of veterans could yield valuable information if a new, valid exposure reconstruction model can be constructed.

Section 9 would require VA to test for dioxin (TCDD) in any blood sample voluntarily provided by Vietnam veterans who seek VA health care under priority eligibility based on exposure to Agent Orange. The Committee report noted that the purpose of this idea was not stated in the legislation and is unclear. If research purposes are contemplated, the Committee's conclusions about tissue archiving are applicable, and the Committee would not recommend such a program at this time. The Committee realized that such a program might be intended to provide information on individual exposure to dioxins or herbicides to aid in individual compensation decisions. The Committee cannot make recommendations for VA policy but noted that individual TCDD serum levels in Vietnam veterans are usually not meaningful because of common background exposures to TCDD, poorly understood variations in TCDD metabolism, relatively large measurement errors, and exposure to herbicides that did not contain TCDD.

The initial NAS effort cost $995,000. Follow-up reports by the NAS are planned for at least once every two years for the next ten years (to the extent appropriations are available).

The National Academy of Sciences was 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.

The Institute of Medicine was charted 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 Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides' 16 members represented 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.R.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 the review.
Report Availability

Prepublication copies of the 764 page report, entitled Veterans and Agent Orange - Health Effects of Herbicides Used in Vietnam, are now available from the National Academy Press, 2101 Constitution Avenue, NW, Box 285, Washington, DC 20055. The National Academy Press is selling prepublication copies for $85 (plus $4 for shipping and handling for the first copy ordered and 50 cents for each additional book). Purchasers in California, Washington, DC, Maryland, Missouri, Texas, Virginia, or Canada must add appropriate sales tax or GST. To order by telephone using VISA/MasterCard/American Express, call toll-free 1-800-624-6242 or call (202) 334-3313 in the Washington metropolitan area.

The final hardbound edition is expected to be available by November. Although pricing information is not yet available, the Academy has indicated that it will cost less than the prepublication version.

(For additional information about the NAS project, see the April 1992, September 1992, and February 1993 issues of the "Agent Orange Review").

Congressional Hearings Put Spotlight on NAS Findings

On July 27, 1993, immediately following the release of the National Academy of Sciences (NAS) Agent Orange report, the Senate Committee on Veterans' Affairs held a brief hearing on the NAS findings.

Kenneth I. Shine, M.D., President, Institute of Medicine (IOM), and Harold Fallon, M.D., Chairman, IOM's Committee to Review the Health Effects in Vietnam Veterans of Exposure to Herbicides, were the principal NAS representatives. Dr. Shine provided a brief summary of the background for the report and the IOM. Dr. Fallon, Dean of the Medical School at the University of Alabama, Birmingham, presented an overview of the Committee's findings and recommendations.

Jesse Brown, Secretary of Veterans Affairs, provided the initial response of the Department of Veterans Affairs to the NAS report. The full text of his prepared statement is printed in this issue.

The House Committee on Veterans' Affairs held a similar hearing on the NAS report on August 4, 1993.

The Senate Committee on Veterans' Affairs plans to hold a follow-up hearing in September.

Prepared Statement of Secretary Jesse Brown Before Senate Committee on Veterans Affairs on NAS Agent Orange Report

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.

Today's hearing marks 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 that 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 rulemaking 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
we will submit the results to the panel for their review.

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, nongovernmental 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, nongovernmental 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 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 House Committee on Veterans’ Affairs. I am certain that working together we can achieve a just resolution.

**VA Supports Two Year Extension of Agent Orange Special Treatment Authority**

On June 23, 1993, James W. Holsinger, Jr., M.D., Under Secretary for Health at the Department of Veterans Affairs, testified before the Senate Committee on Veterans’ Affairs in support of a two-year extension of the special authority for the treatment of Vietnam veterans for conditions possibly related to Agent Orange exposure.

Health care services under this program are limited to hospital and nursing home care in VA facilities and outpatient care in VA facilities on a pre- or post-hospitalization basis or to prevent a need for hospitalization. Health care services are provided without regard to a veteran’s age, service-connected status or the veteran’s ability to pay for the expenses of such care.

Veterans receiving outpatient care under this program are given priority ahead of nonservice-connected veterans and equal to former prisoners of war who are receiving care for nonservice-connected conditions.

This priority treatment authority was initially established in the Veterans’ Health Care, Training, and Small Business Loan Act of 1981, Public Law 97-72, enacted November 3, 1981. It was extended by the Veterans’ Administration Health-Care Amendments of 1985, Public Law 99-166, enacted December 3, 1985; the Veterans’ Benefits Improvement Act of 1988, Division B of Public Law 100-687, enacted November 18, 1988; and the Agent Orange Act of 1991, Public Law 102-4, enacted February 6, 1991. The authority under the most recent extension expires on December 31, 1993.

On June 10, 1993, Senator Thomas A. Daschle introduced S. 1094 to extend the authority for ten years, through December 31, 2003. Dr. Holsinger testified during the June 23 hearing on this proposal that VA recommends that the authority be extended for two years to allow time to consider whether a long-term extension is warranted in light of the report of the National Academy of Sciences (which had not yet been released). The Under Secretary for Health noted that this would not “preclude further extensions of the Agent Orange eligibility after 1995.”
A combat-disabled Vietnam veteran, Jesse Brown has served as Secretary of Veterans Affairs since January 1993. He directs the second largest department in the federal government. He is the second person to serve in this office since VA became a cabinet department in March 1989. Prior to joining VA, Mr. Brown served more than 25 years with the Disabled American Veterans and had been that organization’s executive director since 1989.

Secretary Brown declared, "I have ordered that we move as quickly as possible to develop and publish regulations on Hodgkin’s disease and porphyria cutanea tarda so that we can begin paying benefits to veterans or their survivors. I have also asked that, as soon as final rules are published, a review be undertaken to identify and re-open claims of Vietnam veterans who may have these two conditions."

He also directed VA staff to review Agent Orange Registry physical examination files to identify Vietnam veterans with a diagnosis of Hodgkin’s disease or porphyria cutanea tarda. If these veterans have not yet filed compensation claims, VA will assist them in doing so once the final rule is published. The Agent Orange Registry program, established by VA in 1978, identifies Vietnam veterans who are concerned about the possible long-term health effects of exposure to Agent Orange.

Because of the NAS findings, VA is reviewing an as-yet-to-be published final regulation that would have allowed compensation for peripheral neuropathy and denied compensation for lung cancer. The lung cancer decision specified that, at the time the regulation was developed, scientific and medical evidence found no significant statistical association between herbicide exposure and lung cancer.

VA also is considering a revision to an existing regulation linking non-Hodgkin’s lymphoma to Vietnam service. The revised rule would link this disease to herbicide exposure, as is currently the case with soft tissue sarcoma and chloracne.

Vietnam veterans who believe they have health problems that may be related to their exposure to Agent Orange while serving in Vietnam who have not filed a claim for disability compensation from VA are encouraged to contact the nearest VA regional office. VA’s nationwide toll-free telephone number is 1-800-827-1000.

Editor Receives VSO Award For Agent Orange Efforts

On July 13, 1993, Mr. Donald J. Rosenblum, editor of the "Agent Orange Review" received an "Award of Excellence" from the national headquarters of VietNow, a Vietnam-era veterans service organization.

The award, presented by Sandra Davis, VietNow National Agent Orange Chairperson, expressed the organization’s appreciation for Mr. Rosenblum’s "professionalism and devotion to the Vietnam veteran community." According to Ms. Davis, Mr. Rosenblum and former Secretary Derwinski are the only VA recipients of the award.