



Agent Orange Review

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Information for Veterans Who Served in Vietnam

October 1994

Secretary Brown Approves Service-Connection for Respiratory Cancers and Multiple Myeloma: Regulations Finalized

On September 27, 1993, Secretary of Veterans Affairs Jesse Brown announced that President Clinton had approved a decision awarding Vietnam veterans suffering from respiratory cancers (including cancers of the lungs, larynx, trachea, and bronchus) and multiple myeloma (a cancer involving the bone marrow) disability payments based on presumed exposure to Agent Orange and other herbicides.



Secretary Jesse Brown

Secretary Brown estimated that this decision would cost approximately \$350 million over a five year period (1994-1998).

President Clinton declared, "It is right and proper that the government accept responsibilities resulting from military service. The cost of these benefits must be viewed as a continuation of the cost of war."

Secretary Brown added, "This action will help to answer some of the remaining questions Vietnam veterans and their families have about Agent Orange exposure and bring us all another step closer to resolving an issue that has preyed on the minds of veterans for decades. This decision also serves as a compelling reminder that a grateful nation must honor its commitment to those who answered the call."

The September announcement followed an intensive review of the National Academy of Sciences' (NAS) Agent Orange report by a high level VA task force. On July 27, 1993, concurrent with release of the NAS report, Secretary Brown announced that the Department of Veterans Affairs (VA) would recognize Hodgkin's disease and porphyria cutanea tarda, a liver disorder, 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.

Seven Conditions Recognized

The September decision brings to seven the number of conditions recognized by VA as being associated with herbicide exposure in Vietnam. In addition to the four conditions (cited above) which have been recognized by Secretary Brown, VA provides disability compensation to Vietnam veterans who suffer with soft tissue sarcoma, non-Hodgkin's disease, and chloracne.

Both the July and September decisions were substantially based on the 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 results are described in detail in the September 1993 issue of the "Agent Orange Review.")

The NAS concluded that there is "sufficient evidence of an association" between herbicide exposure and soft tissue sarcoma, non-Hodgkin's lymphoma, Hodgkin's disease, chloracne, and porphyria cutanea tarda. The NAS panel found "limited/suggestive evidence of an association" between exposure to herbicides and the following health outcomes: respiratory cancers, prostate cancer, and multiple myeloma.

VA Task Force

The special VA task force, headed by Susan H. Mather, M.D., M.P.H., Assistant Chief Medical Director for Environmental Medicine and Public Health, concluded that the credible evidence for a positive association between herbicides and both respiratory cancers and multiple myeloma is at least as strong as the evidence against such an association. On the other hand, the task force found the credible evidence for an association between herbicides and prostate cancers does not equal or outweigh the evidence of no association. The task force recommended that the next NAS review pay particular attention to prostate cancer. Secretary Brown agreed with the conclusions and recommendations of the task force.

Regulations Issued

On September 28, 1993, a proposed rule designed to implement Secretary Brown's decision regarding Hodgkin's disease and porphyria cutanea tarda was published in the Federal Register for public comment. No comments were received. The final rule was printed in the Federal Register on February 3, 1994.

Also on February 3, 1994, a proposed rule designed to implement Secretary Brown's decision regarding respiratory cancers and multiple myeloma was published in the Federal Register for public comment. One comment was received, but no change was made in the proposal. It was finalized and published in the Federal Register on June 9, 1994.

On January 4, 1994, VA published a notice in the Federal Register that Secretary Brown has determined that a presumption of service connection based on exposure to herbicides used in

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About the Review...

The "Agent Orange Review" is prepared by VA's Environmental Agents Service (EAS). The "Review" is published periodically to provide information on Agent Orange and related matters to Vietnam veterans, their families, and others with concerns about herbicides used in Vietnam. The initial newsletter was released in November 1982. This is the twenty-third issue.

The "Review" is prepared approximately one to two months prior to the publication date. This issue was written in mid-August 1994 and does not include developments that occurred since that time.

Comments or questions about the content of the "Review" are encouraged. Suggestions and ideas for future issues of the newsletter should be sent to Donald J. Rosenblum, Writer/Editor, Agent Orange Review, Environmental Agents Service (116A), VA Central Office, 810 Vermont Avenue, NW, Washington, DC 20420.

Requests for additional copies of this issue, should also be directed to Mr. Rosenblum. Please specify the number of copies requested. A limited supply of the last

eleven issues (October 1989, May 1990, August 1990, February 1991, April 1991, August 1991, December 1991, April 1992, September 1992, February 1993, and September 1993) is also available. VA facilities should order additional copies from the VA Forms Depot.

VA updates the "Review" mailing address listing annually based on IRS records. "Review" recipients who have not been filing Federal income tax returns annually and have moved to another residence are encouraged to send their old and new addresses and Social Security number to the Department of Veterans Affairs, Automation Center (200/397), 1615 Woodward Street, Austin, Texas 787724001.

Questions about the Agent Orange Registry examination program should be directed to the Environmental Physician or Agent Orange Coordinator at the nearest VA medical center. Questions regarding VA benefit programs, including disability compensation, should be referred to a veterans benefits counselor at the nearest VA facility. The telephone numbers can be found in the telephone directory under the "U.S. Government" listings.

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Vietnam is not warranted for the following conditions: prostate cancer, peripheral neuropathy, hepatobiliary cancers, bone cancers, female reproductive cancers, renal cancers, testicular cancer, leukemia, abnormal sperm parameters and infertility, cognitive and neuropsychiatric disorders, motor/coordination dysfunction, metabolic and digestive disorders, immune system disorders, circulatory disorders, respiratory disorders (other than lung cancer), nasal/nasopharyngeal cancer, skin cancer, gastrointestinal tumors, bladder cancer, brain tumors, and any other condition for which the Secretary has not specifically determined a presumption of service connection is warranted.

File Claim for Benefits

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.

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

NAS Report Available

Hardbound copies of the 832-page National Academy of Sciences' report, entitled *Veterans and Agent Orange - Health Effects of Herbicides Used in Vietnam*, are available from the National Academy Press, 2101 Constitution Avenue, NW, Box 285, Washington, DC 20055.

The National Academy Press is selling this document for \$79.95 (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.

Single copies of this report were distributed to VA medical center libraries in December 1993/January 1994.

New Presumptive Conditions Described

As noted in the lead article, during the first half of 1994, VA published final regulations to establish presumptive service connection for four additional conditions (Hodgkin's disease, porphyria cutanea tarda, respiratory cancers, and multiple myeloma) based on herbicide exposure. These four diseases are discussed below.

Hodgkin's Disease

The National Academy of Sciences (NAS) defined Hodgkin's disease as a malignant lymphoma characterized by progressive enlargement of the lymph nodes, liver, and spleen, and by progressive anemia.

Nearly all of the case-control and agricultural worker studies reviewed by the NAS show increased risk for this disease. Although only a few of these results are statistically significant, those that are show a positive association. Those that are not statistically significant generally indicate increased risk of Hodgkin's disease, and the pattern of the results is notably consistent.

Hodgkin's disease has a number of clinical features that typically differ from other lymphomas. While there were fewer studies for Hodgkin's disease than for non-Hodgkin's lymphoma, the NAS noted that the pattern of results was consistent with the findings for non-Hodgkin's lymphoma and concluded that there was sufficient evidence for a positive association between exposure to the herbicides used in Vietnam and the development of Hodgkin's disease.

After reviewing the NAS report and noting (1) the difficulty in distinguishing between Hodgkin's disease and non-Hodgkin's lymphoma, (2) the occasional development of both diseases in the same patient, and (3) the biologic relationship between the two diseases in terms of origin, Secretary Brown determined that there is an association between exposure

to herbicides used in Vietnam and the subsequent development of Hodgkin's disease.

Porphyria Cutanea Tarda (PCT)

PCT is a liver disorder manifested by thinning and blistering of the skin in sun-exposed areas. The NAS found that case studies and animal studies provide sufficient evidence to conclude that there is a positive association between exposure to herbicides used in Vietnam and the subsequent development of PCT in genetically susceptible individuals.

This finding conflicts with the conclusions of the Veterans' Advisory Committee on Environmental Hazards, a VA-managed panel of independent medical and scientific authorities. The Advisory Committee found in August 1990 that there was no significant statistical association between exposure to a herbicide containing dioxin and the subsequent development of PCT. A majority of Advisory Committee members felt that while scientific literature, particularly that dealing with an industrial accident in Seveso, Italy, left open the possibility of an association, the existing requirement of a "significant statistical association" was not met. Secretary Derwinski concurred. On March 19, 1991, proposed regulations were published in the *Federal Register* to that effect. On October 21, 1991, the "final rule" on PCT was published in the *Federal Register*.

After reviewing the NAS report and reconsidering the Advisory Committee's conclusions, Secretary Brown found that the "credible evidence for an association outweighs the credible evidence against an association." As indicated in the lead article, new regulations were published in the Federal Register, effectively reversing VA policy with regard to PCT. In view of the clinical evidence that PCT onset occurs soon after exposure and consistent with manifestation periods established for many other presumptive conditions, VA established a one-year manifestation period for PCT (that is, the symptoms must have appeared within one year of last day of exposure).

Respiratory Cancers

The NAS found "limited/suggestive evidence"-- a category it defined as meaning that evidence suggests an association between herbicide exposure and a specific disease, but that chance, bias, and confounding factors cannot be ruled out with confidence -- of association between herbicide exposure and the subsequent development of respiratory cancers (including cancers of the lung, larynx, trachea, and bronchus). In reviewing the NAS report, which noted that not all studies had fully controlled for or evaluated smoking as a confounding factor, VA gave weight to the fact that the studies found relatively high risks for respiratory cancers in production workers. VA also noted that despite the failure of some to control for smoking, it is unlikely that there were major differences in smoking patterns between the study and control groups.

Considering all the evidence, Secretary Brown determined that the credible evidence for an association outweighs the credible evidence against an association between exposure to herbicides used in Vietnam and the subsequent development of respiratory cancers. Based on existing scientific evidence, a thirty-year manifestation period was established.

As with PCT, the Veterans' Advisory on Environmental Hazards has been involved in the issue of respiratory cancers, specifically lung cancer. In May 1991, the Advisory Committee considered approximately forty studies dealing with lung cancer. The Committee observed that most of the studies failed to adequately consider exposure documentation and potential confounding factors, particularly smoking. The only study,

considered by the Advisory Committee, to address the factor of smoking was negative with regard to lung cancer.

The Advisory Committee concluded that, on the basis of available epidemiological data, there is no evidence of a significant statistical association between exposure to herbicides containing dioxin and lung cancer.

On June 27, 1991, Secretary Derwinski found that sound medical and scientific evidence does not establish the required association. On January 21, 1992, the Federal Register published a proposed rule that would have added lung cancer to the list of "diseases not associated with exposure to herbicides containing dioxin." (PCT was the only other condition on the list.) The January 21 proposal was never finalized.

Multiple Myeloma

Multiple myeloma is cancer of specific bone marrow cells, the plasma cell, characterized by plasma cell tumors in various bones of the body. The NAS found "limited/suggestive evidence" of an association between herbicide exposure and the subsequent development of multiple myeloma.

VA found the evidence concerning multiple myeloma convincing. Most of the studies reviewed by the NAS showed an increased risk, although in most cases it was not a statistically significant increase. Multiple myeloma is closely related biologically to B-cell non-Hodgkin's lymphoma; consequently, the epidemiological evidence concerning non-Hodgkin's lymphoma gives added weight to the association between herbicide exposure and multiple myeloma.

Based on this clinical consideration and the weight of the epidemiological evidence, Secretary Brown concluded that there is a positive association between herbicide exposure and multiple myeloma.

Agent Orange Registry Continues to Respond to Veterans' Concerns; More than 235,000 Vietnam Veterans Have Received Examination

Every month hundreds of Vietnam veterans travel to the nearest VA medical center for Agent Orange Registry examinations. The establishment of this examination program was one of the first VA actions in response to concerns raised in the late 1970's regarding the possible delayed health consequences of exposure to Agent Orange and other herbicides used in Vietnam.

The examination is offered at all VA medical centers. Only veterans who had active military service in the Republic of Vietnam between 1962 and 1975 are eligible to participate in the Registry program.

Vietnam veterans who participate in this program are asked a series of questions about their possible exposure to herbicides in Vietnam. A medical history is taken, a medical examination is performed, and a series of basic laboratory tests are done. If the examining physician thinks that consultations with specialists are indicated, arrangements are made for additional examinations. The examination provides each veteran with an opportunity to receive a complete health evaluation and answers to questions concerning the current state of knowledge regarding the possible relationship between herbicide exposure and subsequent health problems.

Registry participants are advised of the results of the laboratory tests and the examination during a personal interview. They also are sent a "follow-up" letter summarizing the findings. Occasionally, previously undetected health problems are found during the Registry examinations. With prompt attention, many times these illnesses can be successfully treated.

Registry participants are automatically added to the mailing list for the "Agent Orange Review." The Registry allows VA to initiate contact with veterans when research results indicate that this action is advisable.

According to National Agent Orange Registry Coordinators Helen Malaskiewicz and Michelle B. Williams, more than 235,000 Vietnam veterans have received Registry examinations. Ms. Williams indicated that the most active VA medical centers are located in Minneapolis, Minnesota, and San Juan, Puerto Rico. Both of these stations have provided examinations to more than 6,000 Vietnam veterans. The following VA health care facilities have performed more than 3,000 Registry exams: American Lake (Tacoma), Washington; Dallas, Texas; East Orange, New Jersey; and Wood (Milwaukee), Wisconsin.

Limitations

While the Registry program has significant potential value to its participants, it also has important limitations. No special Agent Orange tests are offered since there is no test to show if a veteran's medical problem was caused by Agent Orange or other herbicides used in Vietnam. There are tests that show the level of dioxin in human fat and blood, but such tests are used for research and are not done by VA because there is serious question about their value to veterans.

It is important to understand that the Agent Orange Registry is not a scientific study. Because of the self-selected (volunteer) nature of the Registry participants (that is, the individuals decide themselves to be part of the Registry rather than being "chosen" in a scientific manner), this group of veterans cannot, with any scientific validity, be viewed as being representative of Vietnam veterans as a whole. Therefore, the health-related information collected cannot be used for scientific research.

The information can, however, be used to detect possible health trends and can provide some useful facts about the group itself. For example, it is possible to show the numbers in each branch of military service, the period(s) of service in Vietnam, kinds of symptoms veterans are experiencing, and some of the

results of the physical examinations. From this type of information, it is possible to develop the relative frequency or internal proportional distribution of certain health problems. That is, Registry analysts could find that health condition "A" is appearing in five times as many Registry participants as problem "B." However, since participation in the Registry program is entirely voluntary, one cannot make statistically valid comparisons directly between this group of veterans and other groups of veterans or non-veterans.

Separate from Claims Program

VA officials advise veterans that participation in the Agent Orange Registry does not constitute a formal claim for disability compensation. Although the results of a Registry examination may be used to support a compensation claim, a veteran must file an application for disability compensation to be considered eligible for this VA benefit program. Veterans benefits counselors, located in VA regional offices and medical centers, assist many Vietnam veterans in filing claims.

How to Get on the Registry

VA encourages all Vietnam veterans who are interested in participating in this voluntary program are encouraged to contact the nearest VA medical center for an appointment. There is no charge to participants.

Class Action Lawsuit Referral Information

The Department of Veterans Affairs (VA) has received many inquiries regarding the status of claims for compensation from the Agent Orange Settlement Fund. This fund was established by a Federal court as a result of the settlement of a class action lawsuit ("Agent Orange" Product Liability Litigation) brought by Vietnam veterans and their families against the manufacturer of Agent Orange. Neither VA nor any other Federal Executive Branch department or agency is directly involved in the distribution of the settlement funds. Information on this matter can be obtained by calling, toll-free 1-800-225-4712, or writing to the Agent Orange Veteran Payment Program, P.O. Box 110, Hartford, Connecticut 06104.

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