



# Agent Orange Review

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*Information for Veterans Who Served in Vietnam*

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## President Bush Signs Agent Orange Act of 1991



President Bush signs Agent Orange Law as Secretary Derwinski and congressional leaders look on.

On February 6, 1991, President Bush signed into law H.R. 556, the "Agent Orange Act of 1991," a comprehensive compromise agreement designed to respond to the many concerns expressed by Vietnam veterans and families during the past decade.

"I am very proud and pleased to be able to sign this legislation today," declared the President as he asked Veterans Affairs Secretary Edward J. Derwinski and five Members of Congress "instrumental in the passage of this legislation" to join him for bill signing at an 11:15 a.m. ceremony in the Roosevelt Room at the White House. The participating Congressional leaders were G.V. (Sonny) Montgomery, Chairman, House Veterans' Affairs Committee; Bob Stump, Ranking Minority Member, House Veterans' Affairs Committee; Arlen Specter, Ranking Minority Member, Senate Veterans' Affairs Committee; and Frank H. Murkowski and Bob Graham, both members of the Senate Veterans' Affairs Committee.

The legislation is now known as Public Law 102-4. At the same ceremony, the President signed H.R. 3, the "Veterans' Compensation Amendments of 1991," which provides a 5.4 percent increase in compensation for service-disabled veterans and an identical increase for survivors who receive dependency and indemnity compensation benefits.

Among the key features of the Agent Orange legislation is the codification, with minor modifications, of the presumptions of service connection for certain diseases associated with herbicide exposure or Vietnam service that VA has developed in recent years. Specifically, a Vietnam veteran disabled by

non-Hodgkin's lymphoma, soft tissue sarcoma (with some exceptions), or chloracne (within one year of leaving Vietnam) will be presumed to have incurred that disease while on active duty.

The law also establishes a new regulatory mechanism for adding -- or deleting -- presumptions of service connection based on exposure to herbicides in Vietnam. Essentially, VA is required to enter into a contract with the National Academy of Sciences (NAS) under which NAS is to review and summarize the literature related to herbicide exposure and provide advice to VA. Taking into account this advice, VA could amend the list of diseases for which service connection is presumed. The advice will also assist VA in decisions concerning further research efforts.

Public Law 102-4 also extends authority for the VA priority medical treatment for Vietnam veterans with conditions possibly related to exposure to Agent Orange.

Furthermore, the legislation provides for research-related efforts in several areas including tissue archiving, blood sampling and testing, and clinical records review, but does so subject to two important conditions: such activities would not be conducted if VA determines after considering the report of NAS, that they are not feasible or cost effective or would not make a material contribution to the body of scientific knowledge; and such activities would be subject to specific appropriation of funds by Congress.

The law also eliminates the dioxin (Agent Orange) function of the Veterans' Advisory Committee on Environmental Hazards. A more detailed description of the provisions of Public Law 102-4 and an analysis of its effects are contained in the following articles.

VA supported the legislative compromise. In a letter to Congressional leaders, Secretary Derwinski declared "we applaud your efforts and those of your colleagues to work toward a thoughtful and meaningful compromise of this controversial issue. We have testified many times that VA has one overriding goal in this area: providing, as best we can, the truth for our Vietnam veterans about the effects of exposure to Agent Orange. Because, in our opinion, that is the goal of this fine legislation, we are pleased to offer our support."

The legislation passed both the House of Representatives and the Senate without dissenting votes. Asking the House to suspend its rules and pass H.R. 556 (action requiring a two-thirds vote), Chairman Montgomery noted that for "more than ten years, the words 'Agent Orange' have been synonymous with divisiveness and controversy, not only between Vietnam veterans and the Federal Government, but



among the Nation's veterans' service organizations as well."

Chairman Montgomery expressed his hope that the compromise legislation would "salve the bitterness, anxiety, and disappointment which have engulfed both this issue and the earnest attempts to respond to our Vietnam veterans' concerns in a fair and rational manner."

The House vote of 412-0 occurred on January 29, 1991. The following day, the Senate approved the legislation by a vote of 99-0.

Senator Tom Daschle, a longtime critic of VA Agent Orange policies, expressed his appreciation to many of his colleagues and others who had worked to resolve "the very complex and controversial issues surrounding the Agent Orange debate." He praised the work of the Secretary of Veterans Affairs as "especially notable." Senator Daschle commented that Secretary Derwinski has "brought an open mind" to the debate, adding that Derwinski's "willingness to listen to veterans, to reexamine the scientific evidence, and to give veterans the benefit of the doubt has been crucial to the effort to redefine the Federal Government's response to the Agent Orange problem."

## **Section-by-Section Description**

The following article is based on an explanatory statement on the Agent Orange Act of 1991 prepared by House and Senate Committees on Veterans' Affairs.

This legislation was derived, with modifications, from bills considered, but not enacted, during the 101st Congress. These bills include S. 1153, which the Senate passed on August 3, 1989; title VIII of S. 13, which the Senate passed as part of a substitute amendment to H.R. 901 on October 3, 1989; part C of title I of S. 2100, which the Senate Committee on Veterans' Affairs reported on July 19, 1990, but which did not receive Senate consideration prior to the end of the 101st Congress; and H.R. 5326, which the House passed on October 15, 1990.

### **Short Title**

Section 1 provides that the legislation will be cited as the "Agent Orange Act of 1991."

### **Presumptions of Service Connection for Certain Diseases**

Section 2 codifies decisions of Secretary Derwinski announced last year to grant presumptions of service connection for non-Hodgkin's lymphoma and soft tissue sarcoma in Vietnam veterans. It also codifies and expands VA regulations providing a presumption of service connection for chloracne becoming manifest within three months after completion of the veteran's Vietnam service by expanding the manifestation period to one year.

This section creates a procedure requiring the Secretary to establish in regulations a presumption of service connection for other diseases that the Secretary determines to have a positive association with exposure to Agent Orange or other herbicides used in Vietnam. These determinations must be based on sound medical and scientific evidence, taking into account (1) periodic reports by the National Academy of Sciences (NAS) reviewing scientific information regarding possible association between

exposure to herbicides and the occurrence of diseases; and (2) all other scientific information available to the Secretary.

### **Independent Scientific Study of Herbicides**

Section 3 requires VA to seek to enter into a contract with NAS to review scientific and medical information regarding the health effects of exposure to Agent Orange and other herbicides used in Vietnam. If VA is unable to enter into a contract with NAS, VA must seek to enter into a contract with another independent scientific organization having expertise and objectivity comparable to that of NAS.

For each disease suspected of being associated with exposure to an herbicide, NAS will review and summarize the relevant scientific evidence and determine (1) whether there is a statistical association with exposure to the herbicide; (2) the increased risk of disease among those exposed to the herbicides during service in Vietnam; and (3) whether there is a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the disease.

NAS also would include in its reports any recommendations it has for further studies to resolve areas of continuing scientific uncertainty about the health effects of exposure to herbicide agents.

The first report by NAS, due not later than 18 months after enactment of this legislation, will include the Academy's recommendations as to whether the programs under sections 6-9 of this law should be implemented. Follow-up reviews by NAS are required at least once every two years for 10 years after the initial report.

### **Expansion of Outreach Activities**

Section 4 expands the outreach activities required under Public Law 100-687 by requiring VA to provide veterans with annual updates about the health effects of exposure to herbicides.

### **Extension of Special Health-Care Eligibility**

Section 5 extends from December 31, 1990, to December 31, 1993, priority eligibility for VA health care based on possible exposure to Agent Orange or radiation.

### **Compilation and Analysis of Data from VA Examinations and Treatment**

Section 6 requires VA, effective 90 days after receipt of the first NAS report, to compile, analyze, and submit annual reports to Congress about scientifically useful clinical data obtained from VA medical examinations and treatment provided after November 3, 1981, to Vietnam veterans who sought VA health care under section 610(e) of title 38 United States Code based on exposure to Agent Orange or radiation.

The program will be subject to specific appropriations being made to carry it out and will not be implemented if VA determines, giving great weight to the recommendations in the first NAS report, that it is not feasible or cost-effective to carry out the program or that carrying out the program would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure. A decision on the implementation of this effort will be delayed pending receipt of the first NAS report, expected in late 1992.

## **Blood and Tissue Archiving**

Section 7 requires VA, effective 90 days after receipt of the first NAS report, to establish an archiving system for blood and tissue samples contributed voluntarily by Vietnam veterans, for the purpose of facilitating scientific research on the effects of veterans' exposure to dioxin and other agents in herbicides.

This program would be subject to specific appropriations being made to carry it out and would not be implemented if VA determines, giving great weight to the recommendations in the first NAS report, that it is not feasible or cost-effective to carry out the program or that carrying out the program would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure. A decision regarding implementation of this program will be delayed pending receipt of the first NAS report, expected in late 1992.

## **Scientific Research Feasibility Studies**

Section 8 requires VA, effective 90 days after receipt of the first NAS report, to establish in consultation with NAS a program of pilot studies of the feasibility of conducting additional scientific research on health hazards of exposure to herbicide agents or service in Vietnam.

The program would be subject to specific appropriations being made to carry it out and would not be implemented if VA determines, giving great weight to the recommendations in the first NAS report, that it is not feasible or cost-effective to carry out the program or that carrying out the program would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure. A decision concerning implementation of this program will be delayed pending receipt of the first NAS report, expected in late 1992.

## **Blood Testing**

Section 9 requires VA, effective 90 days after receipt of the first NAS report, to test for TCDD in any blood sample voluntarily provided by Vietnam veterans who seek VA health care under priority eligibility based on exposure to Agent Orange. VA is required to provide tested veterans with the results of the test and an explanation of the meaning of the results.

The program would be subject to specific appropriations being made to carry it out, not to exceed \$4 million a year, and would not be implemented if VA determines, giving great weight to the recommendations in the first NAS report, that the program is not feasible or cost-effective to carry out the program or that carrying out the program would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure. A decision regarding implementation of this blood testing program will be delayed pending receipt of the first NAS report, expected in late 1992.

## **Modification of Functions of the Veterans' Advisory Committee on Environmental Hazards**

Section 10 eliminates the Agent Orange functions of the Veterans' Advisory Committee on Environmental Hazards six

months after enactment of the law or upon the VA's determination that the Advisory Committee has completed its responsibilities under the May 2, 1989, court order in *Nehmer et. al. v. U.S. Veterans Administration, et. al.*

## **Public Law 102-4: What Does it Mean**

Many veterans have expressed favorable comments about the enactment of this legislation but are uncertain how the law will affect them and others who served in Vietnam. In fact, the impact of Public Law 102-4 is unclear to most observers. The following section-by-section discussion explains why.

Section 1 merely names the legislation. Section 2 establishes presumptions of service connection for certain diseases in title 38 United States Code. This section has the effect of ratifying and making permanent decisions already made by Secretary Derwinski. Final regulations regarding non-Hodgkin's lymphoma were published in the *Federal Register* in October 1990; proposed rules on soft tissue sarcoma were published in February 1991; and proposed rules on chloracne have been prepared and should be published approximately when the "Review" is released. (See the following article for additional information about the recent publication). The enactment of this legislation makes a reversal of these presumptions, a theoretical but very unlikely possibility, even less likely. With enactment of the law, these presumptions could only be terminated by repeal of this section by Congress.

Section 2 also changes the procedure for establishing future presumptions of service connection for diseases that may be associated with dioxin or Agent Orange. The Secretary will now rely on the National Academy of Sciences (NAS) rather than the Veterans' Advisory Committee on Environmental Hazards, a group of advisors appointed by the Secretary, in establishing these presumptions. Some observers speculate that NAS, completely independent of VA, will be more objective, or at least will be perceived as more objective, than the VA committee. It is unclear whether the NAS conclusions and recommendations will differ from those of the advisory group.

Section 3 requires the independent review of scientific and medical information regarding the health effects of exposure to Agent Orange and other herbicides used in Vietnam. The NAS review will be of critical importance. As noted above, NAS will make reports upon which VA will rely to make determinations regarding presumptions of service connection for diseases not covered by Section 2 of the law. The first of these reports will, no doubt, attract a great deal of attention. The initial report, expected in late 1992, will include recommendations regarding the possible implementation of sections 6-9 of the law.

Section 4, which expands required VA outreach activities on Agent Orange, should not have any significant effect in that ongoing efforts already exceed the new annual requirement. On the other hand, Section 5, which extends priority eligibility for health care based on possible exposure to Agent Orange or radiation, provides a significant benefit to veterans. Authority for this priority program, established by Public Law 97-72 in 1981, expired on December 31, 1990. Thousands of veterans have received medical attention, under this program, at VA

health care facilities throughout the Nation. Without this extension, to December 31, 1993, many Vietnam veterans with disabilities possibly related to Agent Orange would be subject to the means-test and under certain circumstances would be denied needed medical care.

The programs described in Sections 6-9 may be totally implemented, may be partially implemented, or may not be implemented at all. Implementation determinations will be based, to a large extent, on the recommendations in the first NAS report. Obviously, no one knows what these recommendations will be. These programs would also be subject to specific appropriations being made to implement

them. There is always uncertainty when specific appropriations are required. While it is unclear what, if any, long-term impact these provisions may have, there definitely will be no immediate effects since any possible implementation will be delayed until late 1992.

Section 10 eliminates certain functions of the Veterans' Advisory Committee on Environmental Hazards, in six months, in light of the tasks assigned to NAS. This change is necessary to eliminate duplication between these two entities. As explained above, it is not clear what, if any, the impact of this change will be.

## About the "Review"...

This issue of the "Agent Orange Review" was 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 most recent issue of the "Review" was published in February 1991.

The "Review" is prepared approximately two months prior to the publication date. This issue was written in late February/early March and does not include developments that occurred during most of March or April 1991. The "Review" dated February 1991 could not describe Congressional action on the "Agent Orange Act of 1991" that occurred at the end of January.

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 (146A), VA Central Office, 810 Vermont Avenue, NW, Washington, DC 20420. The EAS telephone number is (202) 535-7183.

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

you are requesting. A limited supply of the October 1989, May 1990, August 1990, and February 1991 issues is also available. VA facilities should order additional copies from the VA Supply Depot.

VA updates the "Review" mailing address listing annually. If you have not been filing Federal income tax annually and have moved to another residence, we may not have the best address for you and may not be able to send you future issues of the "Review." Therefore, if this is your situation, please send your old and new addresses and Social Security number to the Department of Veterans Affairs, Data Processing Center (200/397), 1615 East Woodward Street, Austin, Texas 78772.

If you have questions about your Agent Orange Registry examination, contact the Environmental Physician or Agent Orange Coordinator at the VA medical center where you had the examination. Questions about VA benefit programs, including disability compensation, should be directed to a veterans benefits counselor at the VA facility nearest you. The telephone number can be found in your telephone book under "U.S. Government" listings.

## Proposed Soft Tissue Sarcoma Rule Published for Public Comment

On February 25, 1991, VA published in the *Federal Register* a proposed amendment to adjudication regulations which would establish service-connection for soft tissue sarcomas based on exposure to herbicides containing dioxin, Agent Orange is such a herbicide.

The proposed change is necessary to implement Secretary Derwinski's determination that it is at least as likely as not that there is a significant statistical association between exposure to dioxin and soft tissue sarcomas. The Secretary made this determination after receiving advice from the Veterans' Advisory Committee on Environmental Hazards.

At its May 16-17, 1990 public meeting, this committee considered more than 80 scientific and medical documents relating to the connection, if any, between exposure to herbicides containing dioxin and soft tissue sarcomas. The

committee found that the relative weights of valid positive and negative studies permitted the conclusion that it is at least as likely as not that there is a significant statistical association between exposure to herbicides containing dioxin and soft tissue sarcomas. Secretary Derwinski announced his decision to authorize service-connection for these conditions on May 18, 1990.

In making the determination, VA recognized conflicting results among scientific and medical studies. Some studies in Scandinavia reported an association of soft tissue sarcomas with exposure to herbicides. Other studies there, as well as in the United States and New Zealand, found no such association. Valid Vietnam experience studies were both positive and negative. The proposed regulation is not restricted to veterans who served in Vietnam during the Vietnam era. Exposure to herbicides containing dioxin during military service other than in Vietnam would have to be established by appropriate evidence.

Issuance of the proposed regulation was complicated and delayed by significant disagreement among pathologists

regarding what tumors the term "soft tissue sarcoma" includes. With the assistance of the Chief Medical Director, who heads the Department's medical agency, and experts on the Advisory Committee, VA compiled and published in the proposed regulations a list of tumors that will be considered to be soft tissue sarcomas. The regulations make clear that soft tissue sarcomas are defined in terms of the type of tumor rather than tumor location.

For compensation purposes, such tumors must be malignant and arise from tissue of mesenchymal origin, including muscle, fat, blood or lymph vessels, or connective tissue (but not cartilage or bone). Tumors of infancy or childhood and those having a strong known causal association with a specific etiology (such as HIV infection or asbestos exposure) have been excluded because it is unlikely that there is a reasonable probability of a significant statistical association between such tumors and exposure to a herbicide containing dioxin.

The proposed regulation would be effective retroactively to September 25, 1985, the original effective date of VA regulations concerning the adjudication of claims based on exposure to herbicides containing dioxin. Those regulations were invalidated in May 1989 by a decision of the United States District Court for the Northern District of California in *Nehmer, et. al. v. U.S. Veterans Administration, et al.*

The Federal Register notice explained that comments on the proposal must be received on or before March 27, 1991. Comments will be available for public inspection until April 8, 1991. Following careful consideration of all comments received, any necessary revisions will be made, and the final regulations will be published in the Federal Register. Officials in the VA's Compensation and Pension Service anticipate publication by mid-1991,

Question concerning the regulations should be referred to the Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420. The telephone number is (202) 233-3005.

## Negotiations with NAS Underway

VA officials have acted quickly to begin negotiations with the National Academy of Sciences (NAS) for a contract which would require NAS to review scientific and medical information regarding the health effects of exposure to Agent Orange and other herbicides used in Vietnam and to provide advice to VA according to the provisions of Public Law 1024.

"Negotiations are proceeding well," according to Dr. Lawrence B. Hobson, Director, VA's Environmental Agents Service. "We are hopeful that an agreement will be concluded in the near future," added Layne A. Drash, Hobson's deputy, a Marine Corps veteran who served in Vietnam in 1965-66.

Additional information about the contract with NAS will be included in future issues of the "Review."

## CDC Releases Final Report on Selected Cancers Study

The Centers for Disease Control (CDC) recently released the "Final Report" of its Selected Cancers Study. The 244-page report details the background, methodology, and findings of this study, entitled *The Association of Selected Cancers with Service in the U.S. Military in Vietnam*. The publication is dated September 1990.

The study results, initially released in March 1990, prompted Secretary Derwinski to announce that VA would recognize, as service-connected, non-Hodgkin's lymphoma based on service in Vietnam. The Archives of Internal Medicine published three articles about the findings of this research effort in its December 1990 issue. The Selected Cancers Study also has been the subject of several articles in previous issues of the "Review."

The "Final Report" summarized the four findings of this VA-funded investigation as follows:

"1. Vietnam veterans have a roughly 50% increased risk of developing non-Hodgkin's lymphoma 15 to 25 years after military service in Vietnam.

"2. Veterans who served in locations other than Vietnam do not have a similar increased risk of non-Hodgkin's lymphoma.

"3. The increased risk of non-Hodgkin's lymphoma among Vietnam veterans is not explained by exposure to Agent Orange. Because most of the Vietnam veterans in this study were probably not (or only minimally) exposed to Agent Orange, the results do not constitute an adequate test of the hypothesis that exposure to Agent Orange or dioxin is associated with the development of NHL. A sufficient test would require the study of persons with, and others without, known exposure.

"4. Vietnam veterans are not at increased risk for soft tissue or other sarcomas, Hodgkin's disease, nasal cancer, nasopharyngeal cancer, or primary liver cancer." Requests for information regarding this report or the Selected Cancers Study should be directed to the Center for Environmental Health and Injury Control, Centers for Disease Control, Atlanta, Georgia 30333. CDC is part of the U.S. Department of Health and Human Services.

## Adipose Tissue Study Published in March

In March 1991, the *American Journal of Public Health* published the results of the Adipose Tissue Study, formally known as the "Dioxins and Dibenzofurans in Adipose Tissue of U.S. Vietnam Veterans and Controls."

Investigators found that average levels of dioxin in adipose tissue were not significantly different among Vietnam veterans, non-Vietnam veterans, and civilian controls. None of the surrogate measures of Agent Orange such as military branch, service within specific geographic region, military occupation,

and troop location in relation to recorded Agent Orange spray was associated with the dioxin levels in adipose tissue of Vietnam veterans. The results suggest that heavy exposure to Agent Orange or dioxin for most U.S. troops was unlikely,

The *Journal* included an editorial by Michael Gough, Ph.D., currently with the congressional Office of Technology Assessment and chair of the Ranch Hand Advisory Group. Dr. Gough previously chaired the VA Advisory Committee on Health-Related Effects of Herbicides.

For reprints of the study, contact the principal investigator: Han K. Kang, Dr. P.H., Director, Office of Environmental Epidemiology, Department of Veterans Affairs, 1825 K Street, NW, Suite 322, Washington, DC 20006.

(The February 1991 issue of the "Review" indicated that the *Journal* would publish the study in February. Any confusion concerning the change in the date of publication is regretted.)

## New Phone Number for VA Agent Orange HQ Office

The telephone number of the Environmental Agents Service (EAS) recently changed from (202) 233-4117 to (202) 535-7183.

This change occurred in late January 1991 in conjunction with the temporary relocation of EAS, the VA Central Office unit responsible for the management of the Veterans' Health

Services and Research Administration national Agent Orange and low level ionizing radiation programs.

Although EAS has moved out of the VA headquarters' building to facilitate the renovation of that structure, the mailing address has not been affected. Correspondence with EAS should be addressed to Lawrence B. Hobson, M.D., Ph.D., Director, Environmental Agents Service (146A), VA Central Office, 810 Vermont Avenue, NW, Washington, DC 20420.

### 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, established 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 manufacturers 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.

# Agent Orange Review

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Who Served in Vietnam**

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