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PL 102-4 (HR 556)

February 6, 1991

AGENT ORANGE ACT OF 1991

An Act to provide for the Secretary of Veterans Affairs to obtain independent scientific review of the available scientific evidence regarding associations between diseases and exposure to dioxin and other chemical compounds in herbicides, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Agent Orange Act of 1991".

SEC. 2. PRESUMPTION OF SERVICE CONNECTION FOR DISEASES ASSOCIATED WITH EXPOSURE TO CERTAIN HERBICIDE AGENTS.

(a) IN GENERAL.--(1) Chapter 11 of title 38, United States Code, is amended by adding at the end of subchapter II the following new section:

"s 316. Presumptions of service connection for diseases associated with exposure to certain herbicide agents

"(a)(1) For the purposes of section 310 of this title, and subject to section 313 of this title--

"(A) a disease specified in paragraph (2) of this subsection becoming manifest as specified in that paragraph in a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the Vietnam era; and

"(B) each additional disease (if any) that (1) the Secretary determines in regulations prescribed under this section warrants a presumption of service-connection by reason of having positive association with exposure to an herbicide agent, and (2) becomes manifest within the period (if any) prescribed in such regulations in a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the Vietnam era and while so serving was exposed to that herbicide agent, shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of evidence of such disease during the period of such service.

"(2) The diseases referred to in paragraph (1)(A) of this subsection are the following:

"(A) Non-Hodgkin's lymphoma becoming manifest to a degree of disability of 10 percent or more.

"(B) Each soft-tissue sarcoma becoming manifest to a degree of disability of 10 percent or more other than osteosarcoma, chondrosarcoma, Kaposi's sarcoma, or mesothelioma.

"(C) Chloracne or another acneform disease consistent with chloracne becoming manifest to a degree of disability of 10 percent or more within one year after the last date on which the veteran performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

\*12 "(3) For the purposes of this subsection, a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the Vietnam era and has a disease referred to in paragraph (1)(B) of this subsection shall be presumed to have been exposed during such service to an herbicide agent containing dioxin or 2,4-dichlorophenoxyacetic acid, and may be presumed to have been exposed during such service to any other chemical compound in an herbicide agent, unless there is affirmative evidence to establish that the veteran was not exposed to any such agent during that service.

"(4) For purposes of this section, the term 'herbicide agent' means a chemical in an herbicide used in support of the United States and allied military operations in the Republic of Vietnam during the Vietnam era.

"(b)(1) Whenever the Secretary determines, on the basis of sound medical and scientific evidence, that a positive association exists between (A) the exposure of humans to an herbicide agent, and (B) the occurrence of a disease in humans, the Secretary shall prescribe regulations providing that a presumption of service connection is warranted for that disease for the purposes of this section.

"(2) In making determinations for the purpose of this subsection, the Secretary shall take into account (A) reports received by the Secretary from the National Academy of Sciences under section 3 of the Agent Orange Act of 1991, and (B) all other sound medical and scientific information and analyses available to the Secretary. In evaluating any study for the purpose of making such determinations, the Secretary shall take into consideration whether the results are statistically significant, are capable of replication, and withstand peer review.

"(3) An association between the occurrence of a disease in humans and exposure to an herbicide agent shall be considered to be positive for the purposes of this section if the credible evidence for the association is equal to or outweighs the credible evidence against the association.

"(c)(1)(A) Not later than 60 days after the date on which the Secretary receives a report from the National Academy of Sciences under section 3 of the Agent Orange Act of 1991, the Secretary shall determine whether a presumption of service connection is warranted for each disease covered by the report. If the Secretary determines that such a presumption is warranted, the Secretary, not later than 60 days after making the determination, shall issue proposed regulations setting forth the Secretary's determination.

"(B) If the Secretary determines that a presumption of service connection is not warranted, the Secretary, not later than 60 days after making the determination, shall publish in the Federal Register a notice of that determination. The notice shall include an explanation of the scientific basis for that determination. If the disease already is included in regulations providing for a presumption of service connection, the Secretary, not later than 60 days after publication of the notice of a determination that the presumption is not warranted, shall issue proposed regulations removing the presumption for the disease.

"(2) Not later than 90 days after the date on which the Secretary issues any proposed regulations under this subsection, the Secretary shall issue final regulations. Such regulations shall be effective on the date of issuance.

\*13 "(d) Whenever a disease is removed from regulations prescribed under this section--

"(1) a veteran who was awarded compensation for such disease on the basis of the presumption provided in subsection (a) before the effective date of the removal shall continue to be entitled to receive compensation on that basis; and

"(2) a survivor of a veteran who was awarded dependency and indemnity compensation for the death of a veteran resulting from such disease on the basis of such presumption shall continue to be entitled to receive dependency and indemnity compensation on such basis.

"(e) Subsections (b) through (d) shall cease to be effective 10 years after the first day of the fiscal year in which the National Academy of Sciences transmits to the Secretary the first report under section 3 of the Agent Orange Act of 1991."

(2) The table of sections at the beginning of such chapter is amended by inserting after the item relating to section 315 the following new item:

"316. Presumptions of service connection for diseases associated with exposure to certain herbicide agents."

(b) CONFORMING AMENDMENT.--Section 313 of title 38, United States Code, is amended by inserting "or 316" after "section 312" each place it appears.

### SEC. 3. AGREEMENT WITH NATIONAL ACADEMY OF SCIENCES.

(a) PURPOSE.--The purpose of this section is 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.

(b) AGREEMENT.--The Secretary shall seek to enter into an agreement with the National Academy of Sciences for the Academy to perform the services covered by this section. The Secretary shall seek to enter into such agreement not later than two months after the date of the enactment of this Act.

(c) REVIEW OF SCIENTIFIC EVIDENCE.--Under an agreement between the Secretary and the National Academy of Sciences under this section, 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.

(d) **SCIENTIFIC DETERMINATIONS CONCERNING DISEASES.**--(1) For each disease reviewed, the Academy shall determine (to the extent that available scientific data permit meaningful determinations)--

(A) whether a statistical association with herbicide exposure exists, taking into account the strength of the scientific evidence and the appropriateness of the statistical and epidemiological methods used to detect the association;

(B) the increased risk of the disease among those exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and

(C) whether there exists a plausible biological mechanism or other evidence of causal relationship between herbicide exposure and the disease.

(2) The Academy shall include in its reports under subsection (g) a full discussion of the scientific evidence and reasoning that led to its conclusions under this subsection.

(e) **RECOMMENDATIONS FOR ADDITIONAL SCIENTIFIC STUDIES.**--The Academy shall make any recommendations it has for additional scientific studies to resolve areas of continuing scientific uncertainty relating to herbicide exposure. In making recommendations for further study, the Academy shall consider the scientific information that is currently available, the value and relevance of the information that could result from additional studies, and the cost and feasibility of carrying out such additional studies.

(f) **SUBSEQUENT REVIEWS.**--An agreement under subsection (b) shall require the National Academy of Sciences--

(1) to conduct as comprehensive a review as is practicable of the evidence referred to in subsection (c) that became available since the last review of such evidence under this section; and

(2) to make its determinations and estimates on the basis of the results of such review and all other reviews conducted for the purposes of this section.

(g) **REPORTS.**--(1) The agreement between the Secretary and the National Academy of Sciences shall require the Academy to transmit to the Secretary and the Committees on Veterans' Affairs of the Senate and House of Representatives periodic written reports regarding the Academy's activities under the agreement. Such reports shall be submitted at least once every two years (as measured from the date of the first report)

(2) The first report under this subsection shall be transmitted not later than the end of the 18-month period beginning on the date of the enactment of this Act. That report shall include (A) the determinations and discussion referred to in subsection (d), (B) any recommendations of the Academy under subsection (e), and (C) the recommendation of the Academy as to whether the provisions of each of sections 6 through 9 should be implemented by the Secretary. In making its recommendation with respect to each such section, the Academy shall consider the scientific information that is currently available, the value and relevance of the information that could result from implementing that section, and the cost and feasibility of implementing that section. If the Academy recommends that the

provisions of section 6 should be implemented, the Academy shall also recommend the means by which clinical data referred to in that section could be maintained in the most scientifically useful way.

(h) **LIMITATION ON AUTHORITY.**--The authority to enter into agreements under this section shall be effective for a fiscal year to the extent that appropriations are available.

(i) **SUNSET.**--This section shall cease to be effective 10 years after the last day of the fiscal year in which the National Academy of Sciences transmits to the Secretary the first report under subsection (g).

(j) **ALTERNATIVE CONTRACT SCIENTIFIC ORGANIZATION.**--If the Secretary is unable within the time period prescribed in subsection (b) to enter into an agreement with the National Academy of Sciences for the purposes of this section on terms acceptable to the Secretary, the Secretary shall seek to enter into an agreement for the purposes of this section with another appropriate scientific organization that is not part of the Government and operates as a not-for-profit entity and that has expertise and objectivity comparable to that of the \*15 National Academy of Sciences. If the Secretary enters into such an agreement with another organization, then any reference in this section and in section 316 of title 38, United States Code (as added by section 2), to the National Academy of Sciences shall be treated as a reference to the other organization.

#### **SEC. 4. OUTREACH SERVICES.**

Section 1204(a) of the Veterans' Benefits Improvement Act of 1988 (division B of Public Law 100-687; 102 Stat. 4125) is amended--

(1) in clause (1), by striking out ", as such information on health risks becomes known";

(2) by redesignating clauses (1) and (2) as clauses (A) and (B), respectively;

(3) by inserting "(1)" after "PROGRAM.--"; and

(4) by adding at the end the following new paragraph:

"(2) The Secretary of Veterans Affairs shall annually furnish updated information on health risks described in paragraph (1)(A) to veterans referred to in paragraph (1).".

#### **SEC. 5. EXTENSION OF HEALTH-CARE ELIGIBILITY BASED ON EXPOSURE TO AGENT ORANGE OR IONIZING RADIATION.**

Section 610(e)(3) of title 38, United States Code, is amended by striking out "December 31, 1990" and inserting in lieu thereof "December 31, 1993".

#### **SEC. 6. RESULTS OF EXAMINATIONS AND TREATMENT OF VETERANS FOR DISABILITIES RELATED TO EXPOSURE TO CERTAIN HERBICIDES OR TO SERVICE IN VIETNAM.**

(a) **IN GENERAL.**--Subject to subsections (d) and (e), the Secretary of Veterans Affairs shall compile and analyze, on a continuing basis, all clinical data that (1) is obtained by the Department of

Veterans Affairs in connection with examinations and treatment furnished to veterans by the Department after November 3, 1981, by reason of eligibility provided in section 610(e)(1)(A) of title 38, United States Code, and (2) is likely to be scientifically useful in determining the association, if any, between the disabilities of veterans referred to in such section and exposure to dioxin or any other toxic substance referred to in such section or between such disabilities and active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(b) ANNUAL REPORT.--The Secretary shall submit to the Committees on Veterans' Affairs of the Senate and the House of Representatives an annual report containing--

(1) the information compiled in accordance with subsection (a);

(2) the Secretary's analysis of such information;

(3) a discussion of the types and incidences of disabilities identified by the Department of Veterans Affairs in the case of veterans referred to in subsection (a);

(4) the Secretary's explanation for the incidence of such disabilities;

(5) other explanations for the incidence of such disabilities considered reasonable by the Secretary; and

(6) the Secretary's views on the scientific validity of drawing conclusions from the incidence of such disabilities, as evidenced by the data compiled under subsection (a), about any association between such disabilities and exposure to dioxin or any other \*16 toxic substance referred to in section 610(e)(1)(A) of title 38, United States Code, or between such disabilities and active military, naval, or air service, in the Republic of Vietnam during the Vietnam era.

(c) FIRST REPORT.--The first report under subsection (b) shall be submitted not later than one year after the effective date of this section.

(d) FUNDING.--The authority of the Secretary to carry out this section is effective in any fiscal year only to the extent or in the amount specifically provided in statutory language in appropriations Acts.

(e) EFFECTIVE DATE.--(1) This section shall take effect at the end of the 90- day period beginning on the date on which the first report of the National Academy of Sciences under section 3(g) is received by the Secretary, except that this section shall not take effect if the Secretary, after receiving that report and before the end of that 90-day period--

(A) determines that it is not feasible or cost-effective to carry out this section or that carrying out this section would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure; and

(B) notifies the Committees on Veterans' Affairs of the Senate and House of Representatives of the Secretary's determination and the reasons therefor.

(2) In making a determination under this subsection, the Secretary shall give great weight to the views and recommendations of the Academy expressed in that report with respect to the implementation of this section.

## SEC. 7. TISSUE ARCHIVING SYSTEM.

(a) ESTABLISHMENT OF SYSTEM.--Subject to subsections (e) and (f), for the purpose of facilitating future scientific research on the effects of exposure of veterans to dioxin and other toxic agents in herbicides used in support of United States and allied military operations in the Republic of Vietnam during the Vietnam era, the Secretary of Veterans Affairs shall establish and maintain a system for the collection and storage of voluntarily contributed samples of blood and tissue of veterans who performed active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(b) SECURITY OF SPECIMENS.--The Secretary shall ensure that the tissue is collected and stored under physically secure conditions and that the tissue is maintained in a condition that is useful for research referred to in subsection (a).

(c) AUTHORIZED USE OF SPECIMENS.--The Secretary may make blood and tissue available from the system for research referred to in subsection (a). The Secretary shall carry out this section in a manner consistent with the privacy rights and interests of the blood and tissue donors.

(d) LIMITATIONS ON ACCEPTANCE OF SAMPLES.--The Secretary may prescribe such limitations on the acceptance and storage of blood and tissue samples as the Secretary considers appropriate consistent with the purpose specified in subsection (a).

(e) FUNDING.--The authority of the Secretary to carry out this section is effective in any fiscal year only to the extent or in the amount specifically provided in statutory language in appropriations Acts.

\*17 (f) EFFECTIVE DATE.--(1) This section shall take effect at the end of the 90-day period beginning on the date on which the first report of the National Academy of Sciences under section 3(g) is received by the Secretary, except that this section shall not take effect if the Secretary, after receiving that report and before the end of that 90-day period--

(A) determines that it is not feasible or cost-effective to carry out this section or that carrying out this section would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure; and

(B) notifies the Committees on Veterans' Affairs of the Senate and House of Representatives of the Secretary's determination and the reasons therefor.

(2) In making a determination under this subsection, the Secretary shall give great weight to the views and recommendations of the Academy expressed in that report with respect to the implementation of this section.

## SEC. 8. SCIENTIFIC RESEARCH FEASIBILITY STUDIES PROGRAM.

(a) ESTABLISHMENT OF PROGRAM.--Subject to subsections (e) and (f), the Secretary of Veterans Affairs shall establish a program to provide for the conduct of studies of the feasibility of conducting additional scientific research on--

(1) health hazards resulting from exposure to dioxin;

(2) health hazards resulting from exposure to other toxic agents in herbicides used in support of United States and allied military operations in the Republic of Vietnam during the Vietnam era; and

(3) health hazards resulting from active military, naval, or air service in the Republic of Vietnam during the Vietnam era.

(b) PROGRAM REQUIREMENTS.--(1) Under the program established pursuant to subsection (a), the Secretary shall, pursuant to criteria prescribed pursuant to paragraph (2), award contracts or furnish financial assistance to non-Government entities for the conduct of studies referred to in subsection (a).

(2) The Secretary shall prescribe criteria for (A) the selection of entities to be awarded contracts or to receive financial assistance under the program, and (B) the approval of studies to be conducted under such contracts or with such financial assistance.

(c) REPORT.--The Secretary shall promptly report the results of studies conducted under the program to the Committees on Veterans' Affairs of the Senate and the House of Representatives.

(d) CONSULTATION WITH THE NATIONAL ACADEMY OF SCIENCES.--(1) To the extent provided under any agreement entered into by the Secretary and the National Academy of Sciences under this Act--

(A) the Secretary shall consult with the Academy regarding the establishment and administration of the program under subsection (a); and

(B) the Academy shall review the studies conducted under contracts awarded pursuant to the program and the studies conducted with financial assistance furnished pursuant to the program.

(2) The agreement shall require the Academy to submit to the Secretary and the Committees on Veterans' Affairs of the Senate and the House of Representatives any recommendations that the \*18 Academy considers appropriate regarding any studies reviewed under the agreement.

(e) FUNDING.--The authority of the Secretary to carry out this section is effective in any fiscal year only to the extent or in the amount specifically provided in statutory language in appropriations Acts.

(f) EFFECTIVE DATE.--(1) This section shall take effect at the end of the 90- day period beginning on the date on which the first report of the National Academy of Sciences under section 3(g) is received by the Secretary, except that this section shall not take effect if the Secretary, after receiving that report and before the end of that 90-day period--

(A) determines that it is not feasible or cost-effective to carry out this section or that carrying out this section would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure; and

(B) notifies the Committees on Veterans' Affairs of the Senate and House of Representatives of the Secretary's determination and the reasons therefor.

(2) In making a determination under this subsection, the Secretary shall give great weight to the views and recommendations of the Academy expressed in that report with respect to the implementation of this section.

## SEC. 9. BLOOD TESTING OF CERTAIN VIETNAM-ERA VETERANS.

(a) BLOOD TESTING.--Subject to subsections (d) and (e), in the case of a veteran described in section 610(e)(1)(A) of title 38, United States Code, who--

(1) has applied for medical care from the Department of Veterans Affairs; or

(2) has filed a claim for, or is in receipt of disability compensation under chapter 11 of title 38, United States Code, the Secretary of Veterans Affairs shall, upon the veteran's request, obtain a sufficient amount of blood serum from the veteran to enable the Secretary to conduct a test of the serum to ascertain the level of 2,3,7,8- tetrachlorodibenzo-p-dioxin (TCDD) which may be present in the veteran's body.

(b) NOTIFICATION OF TEST RESULTS.--Upon completion of such test, the Secretary shall notify the veteran of the test results and provide the veteran a complete explanation as to what, if anything, the results of the test indicate regarding the likelihood of the veteran's exposure to TCDD while serving in the Republic of Vietnam.

(c) INCORPORATION IN SYSTEM.--The Secretary shall maintain the veteran's blood sample and the results of the test as part of the system required by section 7.

(d) FUNDING.--The authority of the Secretary to carry out this section is effective in any fiscal year only to the extent or in the amount specifically provided in statutory language in appropriations Acts, but such amount shall not exceed \$4,000,000 in any fiscal year.

(e) EFFECTIVE DATE.--(1) This section shall take effect at the end of the 90- day period beginning on the date on which the first report of the National Academy of Sciences under section 3(g) is received by the Secretary, except that this section shall not take effect if the Secretary, after receiving that report and before the end of that 90-day period--

(A) determines that it is not feasible or cost-effective to carry out this section or that carrying out this section would not make a material contribution to the body of scientific knowledge concerning the health effects in humans of herbicide exposure; and

(B) notifies the Committees on Veterans' Affairs of the Senate and House of Representatives of the Secretary's determination and the reasons therefor.

(2) In making a determination under this subsection, the Secretary shall give great weight to the views and recommendations of the Academy expressed in that report with respect to the implementation of this section.

#### SEC. 10. CONFORMING AMENDMENTS TO PUBLIC LAW 98-542.

(a) AMENDMENTS TO SECTION 2.--Section 2 of Public Law 98-542 (38 U.S.C. 354 note) is amended by striking out "that chloracne," in paragraph (5) and all that follows through "herbicides and".

(b) AMENDMENTS TO SECTION 3.--Section 3 of such Public Law is amended by striking out "during service in the Armed Forces in the Republic of Vietnam to a herbicide containing dioxin or".

(c) AMENDMENTS TO SECTION 5.--Section 5 of such Public Law is amended as follows:

(1) Subsection (a)(1) is amended by striking out "during service--" and all that follows through "in connection with" and inserting in lieu thereof "during service in connection with".

(2) Subsection (b) is amended--

(A) by striking out "of exposure to herbicides containing dioxin or" in the first sentence of paragraph (1)(A);

(B) by striking out "evidence indicating--" in paragraph (2)(B) and all that follows through "(ii) a connection to" and inserting in lieu thereof "evidence indicating a connection to";

(C) in paragraph (3)--

(i) by striking out "herbicide or" in subparagraph (A); and

(ii) by striking out "to a herbicide containing dioxin or" in subparagraph (B); and

(D) by striking out "of the appropriate panel" in the first sentence of paragraph (1)(B), in the first sentence of paragraph (2)(A)(i), and in paragraph (2)(B).

(d) AMENDMENTS TO SECTION 6.--Section 6 of such Public Law is amended as follows:

(1) Subsection (a) is amended--

(A) in the matter preceding paragraph (1), by striking out "fifteen members" and inserting in lieu thereof "nine members";

(B) in paragraph (1)--

(i) by striking out "eleven individuals" and inserting in lieu thereof "six individuals";

- (ii) by striking out subparagraph (A);
- (iii) by redesignating subparagraph (B) as subparagraph (A); and
- (iv) by redesignating subparagraph (C) as subparagraph (B) and in that subparagraph--

(I) by striking out "five individuals" and inserting in lieu thereof "three individuals"; and

(II) by striking out "dioxin or"; and  
(C) in paragraph (2)--

(i) by striking out "four individuals" and inserting in lieu thereof "three individuals"; and

(ii) by striking out "dioxin or".

(2) Subsection (d) is amended--

(A) by striking out "eleven" in paragraph (1) and inserting in lieu thereof "six"; and

(B) by striking out "be divided into" in paragraph (2) and all that follows through "(B) an eight-member panel with" and inserting in lieu thereof "have".

(e) EFFECTIVE DATE.--(1) Except as provided in paragraph (2), the amendments made by this section shall take effect at the end of the six-month period beginning on the date of the enactment of this Act.

(2)(A) If the Secretary of Veterans Affairs determines before the end of such six-month period that the Environmental Hazards Advisory Committee established under section 6 of Public Law 98-542 (38 U.S.C. 354 note) has completed its responsibilities under that section and the directives of the Secretary pursuant to the Nehmer case court order, the amendments made by this section shall take effect as of the date of such determination.

(B) For purposes of this paragraph, the term "Nehmer case court order" means the court order dated May 2, 1989, in the case of *Nehmer v. Department of Veterans Affairs*, in the United States district court for the northern district of California (civil action docket number C-86-6160 TEH).

(3) If the Secretary makes a determination under paragraph (2), the Secretary shall promptly publish in the Federal Register a notice that such determination has been made and that such amendments have thereby taken effect as of the date of such determination.

Approved February 6, 1991

PL 102-4, 1991 HR 556