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Section 3 still needs working out. done 19 JUL 89  
 add melanoma & basal cell carcinoma  
 remainder subject of future hearings

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9 SEC. 5 PRESUMPTION OF SERVICE CONNECTION FOR DISEASES

10 ASSOCIATED WITH EFFECTS OF EXPOSURE TO CERTAIN  
11 HERBICIDE AGENTS.

12 (a) Findings.--Congress makes the following findings:

13 (1) It is in the public interest to provide for an  
14 independent nonprofit scientific organization which has  
15 appropriate expertise and is not connected to the  
16 Department of Veterans Affairs <sup>or CDC</sup> to review and evaluate the  
17 available scientific evidence regarding associations  
18 between diseases and exposure to dioxin and other  
19 chemical compounds in herbicides and to make judgments on  
20 the degree and probability of such associations, because  
21 there is no uniform body of scientific literature on such  
22 issues.

23 (2) The standard of proof required for a scientific  
24 conclusion of causation is higher than the standard of  
25 proof required for justification of a presumption, for

1 purposes of veterans disability compensation laws, that  
2 an adverse health effect is connected, based on sound  
3 medical and scientific evidence, to active service in the  
4 Armed Forces of the United States.

5 (b) In General.--(1) Subchapter II of chapter 11 of title  
6 38, United States Code, is amended by inserting after section  
7 312 the following new section:

8 "§ 312A. Presumption of service connection for diseases  
9 associated with effects of exposure to certain  
10 herbicide agents

11 "(a) In General.--(1) For the purposes of section 310 of  
12 this title, and subject to section 313 of this title, in the  
13 case of a Vietnam veteran who, during Vietnam service, was  
14 exposed to an herbicide agent containing <sup>dibenzofurans or dioxins</sup> ~~dioxin~~ or 2,4-  
15 dichlorophenoxyacetic acid or to any other herbicide agent, <sup>contaminated with</sup>  
16 each disease (if any) listed in regulations prescribed by the <sup>dioxins or</sup>  
<sup>dibenzofurans</sup>  
17 Secretary in accordance with this section and identified in  
18 such regulations as having positive association with the  
19 biological effects of exposure to such herbicide agent shall  
20 be considered to have been incurred in or aggravated by such  
21 service, notwithstanding that there is no record of evidence  
22 of such disease during the period of such service.

23 "(2) For the purposes of this subsection, a veteran who  
24 performed Vietnam service and has a disease referred to in  
25 paragraph (1) of this subsection shall be presumed to have

1 (A) to determine, in the case of each herbicide  
2 agent--

3 (i) which diseases (if any) have positive  
4 association with the biological effects of exposure  
5 to such agent, including specifically effects  
6 involving <sup>hepatic function, lipid metabolism, heme</sup> porphyrin synthesis, nervous system  
7 function, immune function, reproduction, and birth *heart disease*  
8 defects, and psychological and psychiatric effects;

9 (ii) which diseases (if any) have limited  
10 positive association with such biological effects;

11 (iii) which diseases (if any) have  
12 ~~insubstantial~~ association with such biological  
13 effects; and

14 (iv) to the extent practicable, the biological  
15 basis for the positive, limited positive, and  
16 insubstantial associations of diseases referred to in  
17 subclauses (i), (ii), and (iii) of this clause with  
18 such biological effects; and

19 (B) to estimate the extent of the association  
20 between each such disease and such biological effects  
21 using <sup>all available clinical, epidemiological + experimental and</sup> methods as quantitative and as objective as the <sup>1. statistical</sup>  
22 relevant available data permit.

23 (2) The contract scientific organization shall  
24 specifically determine whether there is positive, limited  
25 positive, or insubstantial association between the biological

1 effects referred to in paragraph (1) of this subsection and  
2 the following diseases:

3 "(A) Non-Hodgkin's lymphoma.

*other lymphomas*

4 "(B) Each soft-tissue sarcoma.

*basal cell carcinoma / melanoma*

5 "(C) Lung cancer.

6 "(D) Each other cancer.

7 "(e) Required Provisions for First Contract.--(1) The  
8 first contract entered into under subsection (c) of this  
9 section shall provide for the contract scientific  
10 organization--

11 "(A) to conduct as comprehensive a survey and  
12 evaluation as is practicable of the completed and ongoing  
13 scientific studies of, and other scientific evidence or  
14 information regarding, the effects that herbicide agents & *contaminants*  
15 have on humans or other animals that have been exposed to  
16 such agents, including an evaluation of the CDC Selected  
17 Cancers Study report; and

18 "(B) make its determinations and estimates on the  
19 basis of the results of such survey and evaluation.

20 "(2) The contract scientific organization shall conduct  
21 the survey and evaluation referred to in paragraph (1)(A) of  
22 this subsection through a panel composed of recognized  
23 experts in toxicology, medicine, epidemiology, statistics,  
24 biochemistry, and related fields. The conduct of such survey  
25 shall be subject to appropriate peer review.

1 subsection when the available data do not permit meaningful  
2 estimates and probabilities.

3 "(4)(A) If a contract scientific organization determines  
4 that a disease has positive association with the biological  
5 effects of exposure to an herbicide agent <sup>or contaminant</sup> used in Vietnam,  
6 such organization shall determine whether there is a  
7 reasonable basis for concluding that a Vietnam veteran with  
8 the highest level of exposure to that herbicide agent <sup>or contaminant</sup> in  
9 Vietnam was exposed to such agent <sup>or contaminant</sup> under the circumstances  
10 necessary for such biological effects.

11 "(B) If a contract scientific organization determines  
12 that there is no such reasonable basis, the organization  
13 shall state that determination in a report under this  
14 subsection and include in such report--

15 "(i) a description of the evidence that supports  
16 such determination;

17 "(ii) a description of the evidence (if any) that  
18 supports alternative conclusions; and

19 "(iii) a full discussion of the organization's  
20 reasons for such determination, including a discussion of  
21 the reasons for the organization's determination that the  
22 evidence referred to in clause (i) of this subparagraph  
23 outweighs the evidence (if any) referred to in clause  
24 (ii) of this subparagraph.

25 "(C) A determination with respect to reasonable basis is

1 fiscal year to such extent or in such amount as is provided  
2 for in an appropriation Act.

3 "(1) Termination of Effectiveness of This Section.--(1)

4 Subsections (b) through (l) and (k) of this section shall  
5 cease to be effective 10 years after the first day of the  
6 fiscal year in which a contract scientific organization  
7 transmits to the Secretary the first report under subsection  
8 (g) of this section.

9 "(2) Paragraph (1) shall not affect the continued  
10 effectiveness of--

11 "(A) subsection (a) of this section and the  
12 regulations referred to in such subsection; and

13 "(B) subsection (j) of this section.

14 "(m) Definitions.--For the purposes of this section--

15 "(1) the term 'Vietnam veteran' means a veteran who  
16 performed Vietnam service;

17 "(2) the term 'Vietnam service' means active  
18 military, naval, or air service in Vietnam during the  
19 Vietnam era;

20 "(3) the term 'herbicide agent' means an agent in an  
21 herbicide used in support of United States and allied  
22 military operations in Vietnam during the Vietnam era;

23 "(4) the term 'biological effect', with respect to  
24 exposure to an herbicide agent, means--

25 "(A) each known biological effect of such



- 1 (2) the Secretary's analysis of such information;
- 2 (3) a discussion of the types and incidences of
- 3 disabilities identified or treated by the Department of
- 4 Veterans Affairs in the case of veterans referred to
- 5 in subsection (a);
- 6 (4) the Secretary's explanation for the incidence
- 7 of such disabilities;
- 8 (5) other explanations for the incidence of such
- 9 disabilities considered reasonable by the Secretary;
- 10 and

11 (6) the evaluation of such report submitted by  
 12 the Director of the <sup>National Institutes of Health (NIH)</sup> ~~Office of Technology Assessment~~  
 13 pursuant to subsection (c)(2). <sub>NIH Research and Grants Division</sub>

Research and  
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14 (c) CONSULTATION WITH ~~OTA~~.—(1) The Secretary of  
 15 Veterans Affairs shall consult with the Director of the  
 16 <sup>NIH Research and Grants Division</sup> ~~Office of Technology Assessment~~ before compiling and  
 17 analyzing any information under this section and shall  
 18 submit each annual report required by subsection (b) to the  
 19 Director before submitting such report to the committees  
 20 referred to in such subsection.

21 (2) The Director of the <sup>NIH Research and Grants Division</sup> ~~Office of Technology Assess-~~  
 22 ~~ment~~ shall review each annual report submitted under  
 23 paragraph (1) and transmit to the Secretary of Veterans  
 24 Affairs the Director's evaluation of the content of the  
 25 report.

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1 ent with the privacy rights and interests of the blood and  
2 tissue donors.

3 (d) LIMITATIONS ON ACCEPTANCE OF SAMPLES.—The  
4 Secretary may prescribe such limitations on the acceptance  
5 and storage of blood and tissue samples as the Secretary  
6 considers appropriate consistent with the purpose specified  
7 in the first sentence of subsection (a).

8 (e) CONSULTATION REQUIREMENTS.—(1) To the extent  
9 provided under any agreement entered into by the Secre-  
10 tary and the National Academy of Sciences, the Secretary  
11 shall consult with the National Academy of Sciences re-  
12 garding the establishment and maintenance of the tissue  
13 archiving system under this section, including any limita-  
14 tion to be prescribed under subsection (d).

15 (2) In the event that the National Academy of Sci-  
16 ences does not enter into an agreement for consultation  
17 under paragraph (1), the Secretary shall consult with the  
18 Director of the <sup>Medical Follow-up Agency</sup> ~~Office of Technology~~ Assessment on the  
19 establishment and maintenance of the tissue archiving  
20 system under this section, including any limitation to be  
21 prescribed under subsection (d).

22 (f) CONTRACT AUTHORITY SUBJECT TO APPROPRIA-  
23 TION.—The contract authority provided in this section shall  
24 be effective for a fiscal year to such extent or in such  
25 amount as is provided for in an appropriation Act.