

## Presumptions established pursuant to the Agent Orange Act of 1991

Written by By Carolie Watkins Guest Columnist  
Friday, 15 January 2016 10:56

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### ***Part 1 of 2***

In 1991, Congress enacted the Agent Orange Act of 1991, which prescribed a more focused and proactive policy for addressing these Veterans' concerns. The Act directed VA to seek to contract with the National Academy of Sciences, a respected independent expert scientific body, to evaluate the evidence regarding the health effects of exposure to herbicides.

Under that requirement, VA receives reports every two years from the National Academy's Institute of Medicine (IOM). The act further directed VA to establish presumptions of service connection for any disease discussed in the IOM's reports for which the evidence showed a "positive association" between herbicide exposure and the development of the disease in humans.

The statute specifies that a "positive association" exists whenever the Secretary determines that the credible evidence for an association is equal to or outweighs the credible evidence against an association. The language and legislative history of this act made clear that it did not require evidence of a causal association, but only credible evidence that herbicide exposure was statistically associated with increased incurrence of the disease. The Act further specified that, in determining whether a positive association exists, VA must consider the IOM's report and any other sound scientific and medical evidence available to VA.

The Agent Orange Act was a compromise between the desire for scientific certainty and the need to address the legitimate health concerns of Veterans exposed to herbicides in service. By establishing an evidentiary threshold lower than certainty and lower than actual causation, Congress required that presumptions will be established when there is sound scientific evidence, though not conclusive, establishing a positive association between a disease and herbicide exposure.

Based on the numerous reports received from IOM since 1991, VA has established presumptions of service connection for 12 categories of disease associated with herbicide exposure. While there is always room to review decisions with respect to specific diseases, there is no question that the actions of Congress and VA related to the Agent Orange Act demonstrate the Government's commitment to provide Vietnam Veterans with treatment and compensation for the health effects of herbicide exposure.

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It has long been known that dioxin, a contaminant of Agent Orange, is a potent carcinogen. As our troops returned from Vietnam, many expressed concerns that the health problems they were experiencing had been caused by their exposure to Agent Orange.

In view of this history, VA is mindful of its duty to faithfully execute the requirements of the Agent Orange Act and to ensure that its determinations are made in a manner consistent with the standards Congress has established. Each report from the IOM is reviewed by a working group of VA employees with medical, legal, and program expertise, and by a task force of senior VA leaders. I benefit from the advice and analyses of these groups and others in VA; but as Secretary, I am responsible for determining whether the evidence regarding any disease satisfies the statutory standard.

VA identified an additional recent study by Humblet and Birnbaum, 2008, which analyzed numerous prior studies and concluded that the studies with the best exposure data and comparisons were consistent in finding an association between dioxin exposure and increased risk of ischemic heart disease.

In July 2009, VA received the most recent IOM report, known as "Update 2008." The most significant findings in this report are the findings of "sufficient" evidence of a positive association between herbicide exposure and chronic b-cell leukemia's and of "limited/suggestive" evidence of an association between herbicide exposure and Parkinson's disease, ischemic heart disease, and hypertension.

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After reviewing the IOM's analyses and relevant scientific studies, and consulting with medical and legal experts in VA, I determined that the evidence concerning b-cell leukemia's, Parkinson's disease, and ischemic heart disease met the "positive association" standard of the Agent Orange Act. Accordingly, VA proposed regulations to establish presumptions of service connection for those diseases. The evidence regarding hypertension was less compelling and, in my view, did not establish a positive association under the statute.

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The impact of other known causes and risk factors for ischemic heart disease is relevant in interpreting the results of scientific studies concerning that disease. In determining whether a study provides evidence for an association between herbicide exposure and a particular disease, IOM routinely evaluates the extent to which the study controlled for other known risk factors for that disease in order to minimize or rule out the possibility that an increased prevalence in the study population may be due to factors other than herbicide exposure.

By considering this factor, IOM is able to draw conclusions regarding how strongly the evidence shows that an association between herbicide exposure and a disease exists, independent of other known risk factors. In reviewing the IOM reports, VA also takes this factor into account in determining whether, and to what extent, a study provides evidence for an association between herbicide exposure and the disease independent of other risk factors. Studies that do not adequately control for other risk factors are generally less reliable than those that do.

Taking into account the number of statistically significant findings, the strong evidence of dose-response relationship, and the extent to which the studies controlled for risk factors including age, the evidence for an association between herbicide exposure and ischemic heart disease satisfies the “positive association” standard of the Agent Orange Act. The statute therefore directed that I establish a presumption of service connection, without regard to other independent risk factors.

VA’s Office of General Counsel advised that the Agent Orange Act does not permit weight of the potential economic impact of my decision to establish a presumption under that statute. The statute requires establishment of a presumption if the “positive association” standard is met, and it provides that the standard will be met if the credible scientific and medical evidence for an association is equal to or outweighs the credible scientific evidence against an association.

Additionally, the statute does not permit VA to exclude a disease from consideration on the basis that it is a common disease. Rather, it directs VA to determine whether a positive association exists for each disease discussed in the IOM reports it receives.

A significant portion of the costs associated with the new presumptions is the result of a series of Federal court decisions in the Nehmer class-action litigation. In that case, the United States Court of Appeals for the Ninth Circuit has held that, each time VA establishes a new presumption under the Agent Orange Act, it must make retroactive payments based on claims filed as early as 1985.

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This ruling overrides statutes expressly prohibiting retroactive payments based on such new presumptions, and it thus substantially increases the costs associated with presumptions under the Agent Orange Act. Under the Nehmer decisions, this requirement for retroactive payment will continue to apply to any future presumptions established before the Agent Orange Act's 2015 sunset date or any later date that may be established by future extensions of the act.