

Honorable Eric Shinseki, Secretary of Veterans Affairs

STATEMENT OF  
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BEFORE THE  
SENATE COMMITTEE ON VETERANS' AFFAIRS  
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Chairman Akaka, Ranking Member Burr, Distinguished Members of the Committee, I am pleased to be here today to discuss the role of presumptions of service connection in claims for Veterans' benefits and, in particular, to discuss presumptions established pursuant to the Agent Orange Act of 1991.

Presumptions of service connection have been an important part of the Veterans benefits system since Congress established presumptions for tuberculosis and neuropsychiatric diseases following World War I. Over this period, Congress has established many significant presumptions, including those for diseases of former prisoners of war, diseases associated with ionizing radiation, and undiagnosed illnesses and chronic multisymptom illnesses in Gulf War Veterans. The Department of Veterans Affairs (VA) also plays a vital role in this process. VA's statutory authority to issue regulations governing benefit claims includes the ability to establish fact-based presumptions of service connection. VA has exercised this authority judiciously to establish several significant presumptions to complement and supplement those created by Congress, including presumptions relating to mustard gas exposure and the presumption of service connection for amyotrophic lateral sclerosis (ALS) in Veterans of all periods of service.

The Agent Orange Act of 1991 created an innovative process for establishing presumptions of service connection, one that combines the efforts of Congress and VA, while delineating their respective roles in the process. Under this act, VA is responsible for determining which diseases will be accorded a presumption of service connection, but its determination is guided by evidentiary criteria and decisional standards prescribed by Congress. Specifically, VA is charged with evaluating medical and scientific evidence and analyses from the National Academy of Sciences and other sources in order to determine whether such evidence satisfies the "positive association" standard defined in the Agent Orange Act.

VA takes seriously its responsibilities under the Agent Orange Act. I know that concerns have been expressed regarding the potential impact of my determination under this statute to establish presumptions of service connection for ischemic heart disease, Parkinson's disease, and chronic b-cell leukemias. I can assure you that my determination was made upon careful consideration of the scientific and medical evidence and the governing legal standards, was informed by consultation with medical and legal experts in VA, and reflects the best efforts of all within VA to carry out the requirements of the Agent Orange Act. I welcome this opportunity to explain the determinations VA has made in applying the Agent Orange Act and to discuss the important issue

of how best to utilize presumptions to ensure that Veterans are properly compensated for their disabilities related to herbicide exposure or other factors.

Presumptions in the adjudication process eliminate the need to obtain certain evidence and decide complex issues. They permit VA to accept as established certain facts that would otherwise have to be the subject of extensive development and evidentiary analysis. They also assist Veterans in establishing service connection in cases where the slow development of disability makes direct proof of service connection difficult. For example, there is a longstanding statutory presumption that a Veteran who develops multiple sclerosis to a compensable degree within seven years after leaving service will be presumed to have incurred the disease in service. Congress established that presumption based on scientific evidence that it may take up to seven years from the date of onset for multiple sclerosis to progress to the point of a diagnosable disability. Like most presumptions of service connection, this presumption serves a number of important functions. First, it relieves claimants of the burden of submitting medical evidence directly linking the onset of their condition to service, a burden that would be difficult to meet where the condition manifests at a time remote from service and the relevant medical principles may not be widely known. Second, it ensures that similar claims are given similar treatment. Third, it enables VA to process claims more quickly by relying upon medical principles that need not be independently established in each case. Fourth, it helps Veterans, who may not have been otherwise eligible, to obtain prompt medical assistance for their service connected conditions .

Finally, presumptions are used to implement policy when scientific certainty cannot be achieved in a time frame necessary to address Veterans healthcare issues. This is an important aspect of the presumption process in a benefits system designed to meet the needs of our Veterans. .

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. However, they found it difficult to establish service connection, because the evidence at that time did not clearly link Agent Orange to any specific illness other than a skin condition, chloracne. In a 1984 report, Congress noted that, although VA had granted service connection based on herbicide exposure in more than 1400 cases, fewer than one hundred grants were for conditions other than chloracne or similar skin conditions. Consequently, some Veterans grew to feel that VA was not giving serious consideration to their legitimate concerns regarding the harmful exposures incurred in their service.

In 1984, Congress enacted the Dioxin and Radiation Exposure Compensation Standards Act in an effort to improve this process. The statute included findings that there was scientific uncertainty regarding the health effects of dioxin exposure and that claims based on such exposure present uniquely challenging issues of proof. The statute directed VA to establish standards and guidelines for deciding those claims and to identify the diseases that VA would recognize as being associated with herbicide exposure. It also established an advisory committee to review available research and make recommendations to VA. The statute did not prescribe specific criteria to govern VA's decisions, but included a more general statement of the statute's

purpose. As passed by the House, the bill's stated purpose was to provide benefits for diseases that "may be attributable" to Agent Orange exposure "notwithstanding that there is insufficient medical evidence to conclude that such diseases are service connected." As enacted, however, the statute's stated purpose was to provide benefits for diseases "that are connected, based on sound scientific and medical evidence," to Agent Orange exposure. To implement the statute, VA issued a regulation providing that chloracne was the only disease shown by sound scientific and medical evidence to be associated with Agent Orange exposure and was thus the only disease VA would presume to be service connected.

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 incurrance 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.

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.

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 leukemias and of “limited/suggestive” evidence of an association between herbicide exposure and Parkinson’s disease, ischemic heart disease, and hypertension. 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 leukemias, 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.

I would like to address the concerns that have been expressed regarding my determination with respect to ischemic heart disease. These concerns relate to the economic impact of the presumption, due to the high prevalence rate of ischemic heart disease, and the fact that ischemic heart disease is associated with a number of factors other than herbicide exposure, including age, smoking, serum cholesterol, body mass index, and diabetes. In conducting its review under the Agent Orange Act, VA was cognizant of the prevalence of ischemic heart disease and its known risk factors, and we carefully considered whether and to what extent those factors may be considered in applying the statutory standard.

VA's Office of General Counsel has advised that the Agent Orange Act does not permit me to weigh the potential economic impact of my decision to establish a presumption under that statute. The statute requires that I establish 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. VA’s Office of General Counsel advised me that consideration of the prevalence of ischemic heart disease and the potential economic impact of a presumption would violate the clear requirements of the Agent Orange Act. Accordingly, those factors did not enter into my decision under the positive association standard.

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.

After taking these considerations into account, if VA determines that the evidence demonstrates a positive association between herbicide exposure and a specific disease, then VA has no discretion under the Agent Orange Act to decline to establish a presumption solely on the basis that the disease is independently associated with other known risk factors. Rather, the Act requires that VA establish a presumption and provides that the presumption may be rebutted in individual cases if the evidence shows that the Veteran's disease was due to a factor other than herbicide exposure.

For these reasons, my determination that there is a positive association between herbicide exposure and ischemic heart disease was based solely upon evaluation of the scientific and medical evidence and application of the statutory standard prescribed by the Agent Orange Act. The IOM's Update 2008 report identified nine studies that were considered to be highly informative with respect to this disease. Those studies were rigorously conducted and contained reliable measures of exposure that permitted evaluation of dose-response relationships, which are particularly helpful in determining whether an association exists. Of the nine primary studies, six showed strong and statistically significant associations between herbicide exposure and ischemic heart disease. Several of the studies detected a dose-response relationship and the studies with the best dose information all showed increased risk in the highest categories of exposure. IOM noted that most of the studies had controlled for age, which is the primary risk factor for ischemic heart disease. Some of the studies showed the association persisting after adjustment for numerous other potentially confounding factors. IOM further noted that, although some of the studies did not adequately control for certain risk factors, those risk factors were unlikely to explain the significant increased risks detected in the studies. 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 my judgment, 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.

My determinations regarding ischemic heart disease, Parkinson's disease, and b cell leukemias were not made lightly. They were made in accordance with the responsibilities entrusted to me in the Agent Orange Act and my duty as Secretary of Veterans Affairs to faithfully execute the letter and the purpose of that statute.

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. 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.

The presumptions established by Congress and VA have been invaluable in addressing the challenges of claims involving unique circumstances, such as prisoner-of-war captivity and toxic exposures, and claims involving devastating diseases such as amyotrophic lateral sclerosis (ALS). Based on reports from IOM regarding Gulf War Veterans' health, VA recently proposed to establish presumptions for nine infectious diseases endemic to the Gulf War theater, and we are preparing to revise the existing presumption for medically unexplained chronic multisymptom illnesses to clarify that functional gastrointestinal disorders are covered by that presumption. Presumptions will continue to be an important part of the Veterans' benefits system for the foreseeable future. I look forward to working with Congress to ensure that the process for establishing presumptions of service connection is one that properly meets the needs of our Veterans and our Nation.

This concludes my statement, Mr. Chairman. I would be happy to entertain any questions you or the other members of the Committee may have.