

**THE NATIONAL ACADEMIES RESEARCH ON
VA'S PRESUMPTIVE DISABILITY DECISION-MAKING PROCESS**

Statement of
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Chairwoman Luria, Ranking Member Bost and members of the subcommittee, thank you for the opportunity to testify today. My name is Dr. Sverre Vedal and I am Professor Emeritus in the Department of Environmental and Occupational Health Sciences at the University of Washington School of Public Health. I'm speaking to you today in my capacity as a member of a committee formed by the National Academies of Sciences, Engineering, and Medicine that produced a report to address the U.S. Department of Veterans Affairs' (VA) presumptive disability decision-making process. I also served more recently on the Committee on the Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations.

The National Academy of Sciences was created more than 150 years ago through a congressional charter signed by Abraham Lincoln in order to serve as an independent, authoritative body outside the government that could advise the nation on matters pertaining to science and technology. Every year, approximately 6,000 Academies members and volunteers serve pro bono on our consensus study committees or convening activities. The National Academies do not advocate for specific policy positions. Rather, they enlist the best available expertise across disciplines to examine the evidence, reach consensus, and identify a path forward. National Academies reports, proceedings, and other publications are available via the web in PDF form without charge.

The National Academies have a long history of advising the federal government on the health effects of military service in general and on the effects of in-theater exposures resulting from military activities in particular. The National Academies have also, when requested, offered perspectives on the decision-making processes used by the VA in their determination of whether a particular health problem in a veteran may be associated with their military service. The most

recent report addressing this issue as it relates to toxic exposures—*Improving the Presumptive Disability Decision-making Process for Veterans*—was released in 2008. I served on the study committee formed to research and write that report. It was a multidisciplinary group of 16 people who covered the broad range of expertise needed to take on this important, but very challenging topic. A copy of the report’s summary is included with my testimony.

Our study committee was charged with describing the current process for how presumptive decisions are made for veterans who have health conditions arising from military service and with proposing a scientific framework for making such presumptive decisions in the future. Presumptions are made in order to reach decisions in the face of unavailable or incomplete information. They address the gaps in evidence that introduce uncertainty in decision-making. Presumptions have been made with regard to exposure and the association between exposure and outcome. In trying to assess whether a particular health problem in veterans can be linked to their exposures in the military, a presumption might be needed because of missing information on exposures of the veterans to the agent of concern or because of uncertainty as to whether the exposure increases risk for the health condition.

Presumptions regarding service connections have long been made; in fact, the first were established in 1921. Presumptions have been made with regard to the consequences of herbicide (generically referred to as “Agent Orange”) exposure during service in Vietnam and the health risks resulting from a series of exposures experienced by military personnel involved in the Persian Gulf conflicts.

To address our charge, the 2008 National Academies committee met with the full range of involved stakeholders, including Congress, the VA, Veterans Service Organizations, and individual veterans. The Department of Defense (DoD) provided the study committee with

information about its activities and its plans to track exposures and health conditions of personnel. Our committee attempted to formally capture how the current approach works and completed a series of case studies to identify “lessons learned” that would be useful in proposing a new approach. We also considered how information is obtained on the health of veterans and how exposures during military service can be linked to any health consequences via scientific investigation. We gave substantial attention to how information can best be synthesized to determine if an exposure is associated with a risk to health and whether the association is causal.

The approach to presumptive disability decision-making largely flows from the Agent Orange Act of 1991, which started a model for decision-making that is still in place. In that law, Congress asked the VA to contract with an independent organization—the National Academies—to review the scientific evidence regarding wartime exposure to herbicides in Vietnam. Subsequently, the National Academies have produced public reports evaluating the potential association between wartime exposure and health outcomes in Vietnam veterans (the Veterans and Agent Orange series) and a variety of exposures and health outcomes related to service in the Gulf conflicts (the Gulf War and Health series). The VA then acts through its own internal decision-making process to determine if a presumption is to be made.

The case studies conducted by our 2008 study committee probed deeply into this process. The case studies pointed to a number of difficulties that our committee said needed to be addressed in any future approach:

- Lack of information on exposures received by military personnel and inadequate surveillance of veterans for service-related illnesses.
- Gaps in information because of secrecy.

- Varying approaches to synthesizing evidence on the health consequences of military service.
- In the instance of wartime exposures to herbicides in Vietnam, classification of evidence for association but not for causation.
- A failure to quantify the effect of the exposure during military service, particularly for diseases with other risk factors and causes.
- A general lack of transparency of the presumptive disability decision-making process.

Our study committee discussed in great depth the optimum approach to establishing a scientific foundation for presumptive disability decision-making, including the methods used to determine if exposure to some factor increases risk for disease. This assessment and the findings of the case studies led to a number of observations and recommendations to improve the process:

- Congress could provide a clearer and more consistent charge on how much evidence is needed to make a presumption. There should be clarity as to whether the finding of an association in one or more studies is sufficient or the evidence should support causation.
- Due to lack of clarity and consistency in congressional language and VA's charges to the committees, National Academies committees have taken somewhat varying approaches since 1991 in reviewing the scientific evidence, and in forming their opinions on the possibility that exposures during military service contributed to causing a health condition. Future National Academies committees could improve their review and classification of scientific evidence if they were given clear and consistent charges by the study sponsors and followed uniform evaluation procedures.

- The internal processes by which the VA makes its presumptive decisions following receipt of a National Academies report have been unclear. The VA should adopt transparent and consistent approaches for making these decisions.
- Adequate exposure data and health condition information for military personnel (both individuals and groups) usually have not been available from DoD in the past. Such information is one of the most critical pieces of evidence for improving the determination of links between exposures and health conditions. Approaches are needed to ensure that such information is systematically collected in an ongoing fashion.

All of these improvements are feasible over the longer term and, our committee said, are needed to ensure that the presumptive disability decision-making process for veterans is based on the best possible scientific evidence. Decisions about disability compensation and related benefits such as medical care for veterans should be based on the best possible documentation and evidence of their military exposures as well as on the best possible information. A fresh approach could do much to improve the current process. Our recommended approach had several parts:

- an open process for nominating exposures and health conditions for review, involving all stakeholders in this process;
- a revised process for evaluating scientific information on whether a given exposure causes a health condition in veterans, including a revised set of categories to assess the strength of the evidence for association and an estimate of the numbers of exposed veterans whose health condition can be attributed to their military exposure;
- a consistent and transparent decision-making process by the VA;

- a system for tracking the exposures of military personnel (including chemical, biological, infectious, physical and psychological stressors), and for monitoring the health conditions of all military personnel while in service and after separation; and
- an organizational structure to support this process.

To support our recommendations, we suggested the creation of two panels. One was an Advisory Committee (advisory to VA), that would assemble, consider and give priority to the exposures and health conditions proposed for possible presumptive evaluation. Nominations for presumptions could come from veterans and other stakeholders as well as from health tracking, surveillance and research. The second panel would be a Science Review Board, an independent body that would evaluate the strength of the evidence (based on causation) which links a health condition to a military exposure and then estimates the fraction of exposed veterans whose health condition could be attributed to their military exposure. The Science Review Board's report and recommendations would go to the VA for its consideration. The VA would use explicit criteria to render a decision by the VA Secretary with regard to whether a presumption would be established. In addition, the Science Review Board would monitor information on the health of veterans as it accumulates over time in the DoD and VA tracking systems.

The study committee recommends that the following principles be adopted in establishing this new approach:

1. Stakeholder inclusiveness
2. Evidence-based decisions
3. Transparent process
4. Flexibility
5. Consistency

6. Causation, not just association, as the target for decision-making.

The last principle needs further discussion, as it departs from the current approach. In proposing causation as the target, our study committee had concerns that the approach of relying on association, particularly if based on findings of one study, could lead to “false-positive” presumptions. We called for a broad interpretation of evidence to judge whether a factor causes a disease in order to ensure that relevant findings from laboratory studies are adequately considered. Our report also recommends that benefits be considered when there is at least a 50% likelihood of a causal relationship, and does not call for full certainty on the part of the Science Review Board.

Our 2008 report suggested that this framework be considered as the model to guide the evolution of the current approach. While some aspects of the approach may appear challenging or infeasible at present, feasibility would be improved by the provision of appropriate resources to all of the participants in the presumptive disability decision-making process for veterans and future methodological developments. Veterans deserve to have these improvements accomplished as soon as possible.

Our study committee recognized that action by Congress would be needed to implement the proposed approach. Our report notes that legislation to create the two panels would be needed, and Congress would also need to ensure that resources were available to create and sustain exposure and health tracking for service personnel and veterans. Many of the changes proposed by the National Academies could be carried out even as steps were taken to move the DoD and VA towards implementing the full model recommended. We concluded that veterans deserve to have an improved system as soon as possible.

Thank you for the opportunity to testify. I would be happy to address any questions that you might have.