

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

Statement of

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Chairman Isakson, Ranking Member Tester and members of the Committee, thank you for the opportunity to testify today. My name is Dr. David Butler and I serve as a Scholar in the Health and Medicine Division of the National Academies of Sciences, Engineering, and Medicine and as Director of its Office of Military and Veterans Health.

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. We do not advocate for specific policy positions. Rather, we enlist the best available expertise across disciplines to examine the evidence, reach consensus, and identify a path forward. Our 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 Office of Military and Veterans Health that I direct includes the Medical Follow-up Agency, which was established after World War II and which maintains a collection of epidemiologic data on over 100 study populations of former military personnel. I have included a list of recent National Academies reports related to military and veterans health issues in the materials submitted for the committee's attention.

The National Academies have also, when requested, offered perspectives on the decision-making processes used by the Department of Veterans Affairs (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. The study committee formed to research and write that report 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 summary of the report and a list of the people who were involved in its writing is attached to my testimony.

That 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. A presumption might also be made with regard to the link between an exposure and risk for a disease, while the evidence is still uncertain or accumulating as to whether the exposure causes the disease.

Presumptions regarding service connections have long been made; in fact, the first were established in 1921. More recently, a number of 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 its 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) gave the study committee information about its current activities and its plans to track exposures and health conditions of personnel. The 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. The committee 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. It 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 present 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, we have produced 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 National Academies provides its reports to the VA, which then acts through its own internal decision-making process to determine if a presumption is to be made.

The case studies conducted by the 2008 study committee probed deeply into this process. The case studies pointed to a number of difficulties that the 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.

The 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 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. 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 assure that such information is systematically collected in an ongoing fashion.

All of these improvements are feasible over the longer term and, the 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. The study committee's 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 the study committee's recommendations, it 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, and nominate new exposures or health conditions for evaluation as appropriate.

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, the study committee had concern that the approach of relying on association, particularly if based on findings of one study, could lead to "false-positive" presumptions. The committee calls for a broad interpretation of evidence to judge whether a factor causes a disease in order to assure that relevant findings from laboratory studies are adequately considered. The 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.

The 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.

The study committee recognized that action by Congress would be needed to implement its proposed approach. The committee's report notes that legislation to create the two panels would be needed and Congress would also need to act to ensure that needed 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. They 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.

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