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Institute of Medicine Report:  
Improving the Presumptive Disability Decision-making Process for Veterans

Statement of

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Good afternoon Senator Akaka and members of the Senate Committee on Veterans' Affairs. I am Scott L. Zeger, Professor of Biostatistics from Johns Hopkins University in Baltimore, Maryland, a member of the Institute of Medicine Committee who recently authored the report, Improving the Presumptive Disability Decision-making Process for Veterans. On behalf of Dr. Jon Samet, our committee chair and the rest of the 16 members who represent a diversity of scientific and medical disciplines, I am pleased to present a summary of our key findings to you today.

Our Institute of Medicine Committee worked for a year to describe the current process for making presumptive decisions for veterans who have health conditions arising from military service and to propose a more sound scientific framework for making such presumptive decisions in the future.

To address its charge, the Committee met with many stakeholders: past and present staffers from

Congress, the Veterans Administration (VA), the Institute of Medicine, veteran's service organizations, and individual veterans. The Department of Defense (DoD) gave the Committee information about how it tracks 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". 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 the process by which information can best be synthesized to determine if a particular exposure causes a risk to health.

Veterans who have been injured by their service, whether their injury appears during service or afterwards, are owed appropriate health care and disability compensation. For some medical conditions that develop after military service, the scientific information needed to determine that the health condition was caused by their service may be incomplete. In such a situation, Congress or the Department of Veterans Affairs (VA) may elect to make a "presumption" of service-connection so that a group of veterans can be appropriately compensated. Presumptions are made in order to reach decisions in the face of unavailable or incomplete information.

Presumptions were first established in 1921. More recently, several presumptions have been made about Agent Orange exposure during service in Vietnam and around the health risks sustained by military personnel in the first Persian Gulf War.

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 Institute of Medicine, to review the scientific evidence for the health effects of Agent Orange. Subsequently, the Institute of Medicine has produced reports on Agent Orange, evaluating whether there is evidence that Agent Orange is associated with various health outcomes. The Institute of Medicine 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 Committee probed this process. The case studies pointed to a number of difficulties that need 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 Agent Orange, 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 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 recommendations to improve the process:

- As the case studies demonstrated, 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, IOM 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 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 an IOM 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 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 (e.g., 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 Committee's recommended approach (see Figure GS-1 attached) has several parts:

- an open process for nominating exposures and health conditions for review; involving all stakeholders in this process is critical;
  - a revised process for evaluating scientific information on whether a given exposure causes a health condition in veterans; this includes a new set of categories to assess the strength of the evidence for causation, 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 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 Committee's recommendations, we suggest the creation of two panels. One is 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, which 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.

This 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 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 Committee 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 Committee suggests that its 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 Committee recognized that action by Congress will be needed to implement its proposed approach. Legislation to create the two panels is needed and Congress should also act to assure that needed resources are available to create and sustain exposure and health tracking for service personnel and veterans. Many of the changes proposed by the Committee could be implemented now, even as steps are taken to move the DoD and VA towards implementing the model recommended. 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 the Subcommittee might have.