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Statement of

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Presumptive Disability Decision-Making

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Mr. Chairman and members of the committee, my name is Jonathan M. Samet. I am Professor and Chair of the Department of Preventive Medicine, Keck School of Medicine, University of Southern California, and I direct the Institute for Global Health at the University of Southern California.

I have been invited to this hearing today because of my previous role as chairman of an Institute of Medicine (IOM) Committee which examined the presumptive disability decision-making (PDDM) process. By way of introduction, IOM is the health policy arm of the National Academy of Sciences, which was created by a Congressional charter signed by President Abraham Lincoln in 1863 as a private honorary society dedicated to the furtherance of science and its use for the general welfare. The IOM was chartered in 1970 to enlist distinguished members of the

appropriate professions in the examination of policy matters pertaining to the health of the public. Under the terms of this charter, the IOM is called upon to act as an official, yet independent, advisor to the federal government in matters of science.

The IOM, like other Academy units, is uniquely situated to provide assessments in areas of science, health care, and public policy. Studies are undertaken by distinguished panels of individuals selected for their expertise and experience in the topic under study. To a degree unmatched elsewhere, the IOM can secure the participation of virtually any expert whom it invites to serve. Members on IOM study committees serve without compensation.

IOM has a longstanding interest in veterans' health issues and has conducted several studies that touch on ways to improve disability processing performed by the Department of Veterans Affairs.

The study committee that I chaired produced a report titled, "Improving the Presumptive Disability Decision-Making Process for Veterans" (hereafter the PDDM committee). This committee complemented a second IOM study committee which produced a report titled "A 21st Century System for Evaluating Veterans for Disability Benefits". Both of these VA-funded studies were requested by the Veteran Benefits Disability Commission (VBDC), begun in 2006, and completed in 2007.

I am submitting the full summary of the report of the PDDM committee as an attachment to my testimony. Here, I will attempt to provide a brief overview. The VBDC asked the PDDM committee to:

- Describe and evaluate the current model used to recognize diseases that are subject to service connection on a presumptive basis.
- If appropriate, propose a scientific framework that would justify recognizing or not recognizing conditions as presumptive.

In tackling the first task--to review the current presumptive decision-making process--the committee reviewed statutes, received input from the VA, spoke with former congressional staff and reviewed the IOM's methodology in support of this process. I will offer a brief synopsis here.

In 1921, Congress empowered the VA Administrator (now Secretary) to establish presumptions of service connection for veterans. Only Congress and the VA Secretary had the authority to establish presumptions. Over time, presumptions have been made to relieve veterans of the burden to prove that disability or illness was caused by a specific exposure which occurred during military service (e.g., Prisoners of War). Since 1921, nearly 150 health outcomes have been service connected on a presumptive basis.

The current presumptive disability decision-making process for veterans involves several steps and several organizations. The process involves input from many parties—Congress, VA, the National Academies, Veteran Service Organizations, advisory committees, and individual veterans. Congress has on it own authority made presumptions in the past. In the current model, which evolved from the Agent Orange Act, Congress may call on VA to assess whether a presumption is needed. The VA turns to the IOM for completion of a review of the scientific

evidence and a determination as to the strength of evidence linking military service, or some specific element of military service, to risk for some health outcome. Our committee examined several decisions made in the past regarding presumptions, treating them as case studies in order to identify "lessons learned" of potential value for improving the process. In examining these case studies, our committee found variable approaches to synthesizing evidence on the health consequences of military service. The target of scientific evidence reviews had not been consistent and varied between causation (e.g., mustard gas and lewisite, Gulf War) and association alone (e.g., Agent Orange). Starting in 1991 the basis for the scientific review in regard to Agent Orange was specified in the statute (PL 102-4). This statute says, "the Academy shall review and summarize the scientific evidence and assess the strength thereof, concerning the association between exposure to an herbicide …and each disease suspected to be associated with such exposure." Specifically-
(1) whether a statistical association with herbicide exposure exists, taking into account the strength of the scientific evidence and the appropriateness of the statistical and epidemiological methods used to detect the association;
(2) the increased risk of the disease among those exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and
(3) whether there exists a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the disease.
This guidance from the VA has not substantively changed since the beginning of the Agent Orange series of studies, which are now carried out biannually. Each IOM committee in the Veterans Agent and Orange (VAO) Update series is selected as a different and new committee. Each committee has the prerogative to decide how it will review the published literature and to assign categories of strength on assessing association. The several IOM committees since 1991 have been quite consistent in their categorization schemes for strength of evidence, typically assigning four categories:
• Sufficient evidence of an association
• Limited/suggestive evidence of an association
• Inadequate/insufficient evidence to determine whether an association exists
• Limited/suggestive evidence of no association
Once the IOM committee completes its task, it provides its report to the VA. The VA staff described its internal decision-making processes to our committee in a general fashion, and the committee reviewed the VA's Federal Register notices and documents to gain further insights. However, it was unclear to our committee how the VA makes particular determinations once the IOM report is received and how information beyond the IOM's findings figure into decision-making by the VA, such as the size of the affected population of veterans and the potential costs of a presumption. Generally the VA staff makes recommendations to the Secretary and the Secretary decides whether to assign a presumption of service connection to any new condition. That decision is then documented in the Federal Register.

Our committee determined that a more robust and evidence-based process could be envisioned for future cohorts of veterans. We reviewed the current approach to characterizing exposures of veterans to toxins and other stressors that might adversely affect their health. We also considered the scope of epidemiological research undertaken by the DoD and the VA. Our review found gaps in the assessment of exposures of military personnel and in the tracking of their health that could be addressed through a more systematic approach.

We also made recommendations for a future presumptive decision-making process that would build on accumulating evidence on exposure and risk. We recommended that the VA establish an Advisory Committee to provide guidance on disability matters including presumptive disability (if allowed by Congress). That Advisory Committee would serve as a clearing house for new presumptions recommended by veterans, veteran service organizations (VSOs), veterans' families, VA, DoD, other governmental bodies, researchers, or the general public. We also recommended that Congress allow the VA to contract with an independent scientific organization to perform the function of a Science Review Board. This independent scientific entity would consider the relevant evidence and analyze candidate presumptive conditions given to it by the VA through VA's Advisory Committee.

We also recommended the establishment of an independent Science Review Board. This Science Review Board would use a two-step process. In step one, the scientific literature would be reviewed to determine the strength of the evidence to assess whether a given health outcome can be caused by a given exposure. This scientific review process is very much like that currently followed by IOM. The committee recommended that the target of the review should be to determine likelihood of causation and not simply the existence of statistical association. The committee developed a system to grade the strength of the scientific evidence for causation using four levels in ascending order of certainty (highest at top). The upper two levels were set to correspond to 50% or more certainty of causation. If the strength of the scientific evidence reached either of these upper two levels, the process would move on to step two. In step two, the Science Review Board would calculate the service-attributable fraction of disease, if the required data and information were available. This second step assesses how much of the observed disease both in absolute and relative terms can be attributed to the exposure. The calculation is independent of the classification of the strength of evidence for causation, and the magnitude of the service-attributable fraction is not considered in categorizing evidence. Rather, the service-attributable fraction would be of value for decision making, giving an understanding of the scope of the population to be covered by a presumption. In step two, the Science Review Board would consider the extent of exposure among veterans and subgroups of veterans, as well as dose-response relationships. A critical element in the deliberations of the Science Review Board would be evidence available from studies on exposures and health risks to the veterans. When such information is available, the board would estimate the service-attributable fraction and the related uncertainty. The purpose of step two is to convey the impact of the exposure on veterans as a whole for the purpose of decision making and planning, but not to serve, inappropriately, as an estimate of probability of causation for individuals. Some exposures may contribute greatly to the disease burden of veterans, while other exposures (even with a known causal effect) may have a small impact overall. This additional information would be useful to the VA in its decision making as to whether a presumption should be made for the veteran population in general, for subgroups, or not at all. In the absence of service-attributable fraction data, as will likely occur for many exposures over the short-term, we assumed that the VA would consider presumptions on the basis of information considered in step one.

Under this model, the VA Advisory Committee would be more effective, visible, and stakeholder-inclusive in establishing candidate conditions for presumptive determinations. In addition the Science Review Board would permit the VA to receive outside, independent, evidence-based advice that would not be perceived as politically driven or influenced. This

model would also identify important research gaps to which the VA could give special emphasis to reduce uncertainty.

I have been asked to comment on how the PDDM committee would evaluate the three new presumptions, ischemic heart disease (IHD), Parkinson's Disease (PD), and B-cell leukemias in a manner similar to our committee's assessment of previously established Agent Orange presumptions such as prostate cancer and diabetes. Our PDDM committee finished its work and has been inactivated, so my comments are my own and cannot be construed as coming from the PDDM committee or the IOM.

Keep in mind that our PDDM committee performed our case studies well after the presumptions had been established whereas these three new presumptions have not gone into effect, so it is too soon to tell what experiences will result and what lessons will be learned.

Nevertheless I will try to draw from some of the relevant observations we made from our prior case study analysis as they relate to the three new presumptions. I will start with the presumption that is likely to affect the most veterans, that for ischemic heart disease (IHD).

The PDDM committee noted that association and not causation was the target for the IOM reviews on Agent Orange and remarked that causation would be a preferable choice. In addition our committee concluded that it would have been desirable to better integrate information concerning "plausible biologic mechanism or other evidence of a causal relationship" into the interpretation of the evidence. Consideration of mechanistic and other biological evidence is a standard element of causal inference.

Our critique was done with recognition that all of the IOM committees evaluating the effects of Agent Orange were operating under the statutory guidance, incorporating judicial rulings, that were passed from Congress to the VA and then from the VA to IOM. When evaluating any possible medical condition that might be associated with Agent Orange exposure, the VAO update committees were required to perform the three tasks delineated above.

The PDDM report pointed out the imprecise wording included in the explanation of criteria for the "limited/suggestive" category that had been carried along since the first Agent Orange report. Literally interpreted, this implies that a single positive "high-quality" study would permanently keep a health outcome in the "limited/suggestive" category of association no matter how many negative "high-quality" studies were published later. Such a standard did not appear to be reasonable to our committee. It has been brought to my attention that VAO update committees for Update 2006 and Update 2008 have revised this statement to better characterize this particular category of evidence.

Criteria for the strength of evidence can be established, but that evidence exits along a continuum, extending from no evidence at all to full certainty. An element of subjectivity always remains in synthesizing evidence into a particular category of strength of evidence. It requires "expert scientific judgment" to conduct these reviews. IOM has a very systematic process and uses acknowledged experts who have volunteered their time pro bono to arrive at consensus findings and recommendations.

For both prostate cancer and Type II diabetes our PDDM case studies pointed out the difficult challenges of establishing a service connection for a common chronic condition when exposure data are unavailable and evidence of association is limited. There was no additional exposure data available relating to Vietnam veterans when considering an association with IHD.

For prostate cancer and Type II diabetes mellitus, the PDDM committee was unable to judge the rationale for the VA's translation of IOM's VAO update committee's category of "limited/ suggestive" association to a presumptive decision, considering that the congressionally stipulated standard requires evidence to be "equal to or outweighs" lack of such evidence. This basis for this decision on VA's part remains unclear. The designation of the evidence for IHD as limited-suggestive appears reasonable in light of the evidence reviewed. But, the scientific rationale for a presumptive determination is still unclear.

One of the key lessons learned from the PDDM case studies and particularly those related to Agent Orange exposure was a need for high-quality data on cohorts of veterans; ideally such data would include more accurate assessments of exposure during service, evaluation of other risk factors that may have been present during service or have developed after service before the onset of disease, and longitudinal assessments for evaluation of diseases that may have long latency periods. IOM VAO update committees have made this same suggestion since 1994. Such cohort information remains an unquestionably desirable resource for future presumptive decision-making. It is not generally feasible to obtain accurate exposure data many years after the fact.

I will make just a few comments about the other two presumptions, Parkinson's Disease and B-cell malignancies. The VAO committee (Update 2008) observed that data were accumulating with regard to Parkinson's disease. They upgraded the evidence of association to limited/ suggestive based on several recent published studies supporting evidence of an association not just with herbicide exposure, but specifically, exposure to the phenoxyherbicides that were the intended components of Agent Orange.

Regarding B- Cell leukemias, the VAO (Update 2008) determined that B-cell leukemia should be regarded as a form of chronic lymphocytic leukemia (CLL). A previous VAO committee (Update 2002) had already concluded that there was sufficient evidence for CLL being associated with herbicide exposures. Investigation of the biological nature of the cells progressing to B- cell leukemia confirmed that this malignancy is a form of CLL. CLL itself has now been classified as form of non-Hodgkin's lymphoma, which has long been recognized as a presumptive illness. Consequently, the VAO committee (Update 2008) placed this in the "sufficient" association category.

A major theme that emerged from the case reviews was the difficulty of disentangling the potential role of service-related factors in diseases that have multiple causes, particularly as disease rates rise with age through the actions of these causes. Additionally, there is the possibility that the effects of exposures in the military, e.g., Agent Orange, might be synergistically enhanced by other factors. There are multiple causes for all the presumptive conditions mentioned above. Beyond assessing whether these conditions are associated with exposure to Agent Orange and other herbicides, it would be useful to determine to what extent

these exposures are contributing to disease burden among our servicemen and women. In the absence of accurate exposure data this estimation would be difficult for Vietnam veterans, but the PDDM committee concluded that future presumptive decisions would be made more useful if the attributable fraction of the disease burden caused by a military service-related exposure were determined.

I have also been asked to comment on the degree of clarity that the VA has provided to various IOM committees for determining how to weigh conflicting evidence related to possible presumptions. I have not been privy to the contractual discussions that the VA has held with IOM as IOM convened committees to conduct scientific review on potential health effects of military-relevant exposures. Nevertheless, in my opinion, the VA understands the role of IOM as an independent advisory organization and it allows IOM committees to determine how to best search for, weigh, and synthesize the scientific evidence on health effects relating to military-relevant exposures. In recent years congressional legislation has stipulated what should be considered in the scientific reviews conducted for Agent Orange and Gulf War presumptions. The VA has ensured that this congressional guidance is made evident to IOM before IOM conducts its scientific reviews.

Finally, I have been asked to provide my views on the extent to which the PDDM committee's recommendations were followed by the Secretary in his most recent presumptive decisions, especially with respect to ischemic heart disease. The specific basis for this decision is not apparent. As far I am aware, the VA is operating under the established statutory guidelines and procedures used in prior presumptive reviews. The PDDM committee proposed a model that would make the basis for decision making fully transparent so that, for the future, this type of question could be answered.

This concludes my remarks. Thank you for the opportunity to speak with the committee. I will be pleased to address questions from the Senate committee members.