

The Use of Epidemiological Evidence in the Compensation of Veterans

JONATHAN M. SAMET, MD, MS, GUY H. MCMICHAEL III, JD,
AND ALLEN J. WILCOX, MD, PhD, MPH

Men and women serving in the U.S. military are exposed to diverse agents that may affect their health, causing injury and disease while they are in the service or after discharge. This case study addresses the compensation of veterans for injury and illnesses arising from exposures received during military service and focuses on the presumptions that are made around compensation of veterans for conditions arising after their service. Presumptions are made because of evidence gaps related to exposure and causation. The current process for evidence review related to causation involves Institute of Medicine (IOM) committees that evaluate evidence relevant to association. The Veterans Administration uses the IOM reports in making presumptions. A new approach was recommended by an IOM committee: a transparent, evidence-based approach that would lead to decisions by means of an explicit process. The Committee set out six principles as a foundation for its framework: stakeholder inclusiveness, evidence-based decisions, transparent process, flexibility, consistency, and the use of causation, not just association, as the basis for decision making. The committee also called for needed tracking of exposure and associated health outcomes during and after military service. This case study covers “lessons learned” around evidence synthesis, causal inferences, and decision-making. *Ann Epidemiol* 2010;20:421–427. © 2010 Elsevier Inc. All rights reserved.

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INTRODUCTION

This case study addresses the compensation of veterans for injury and illnesses arising from exposures received during military service. It addresses the development of systems for making decisions on causation in the face of uncertainty. The “lessons learned” relate to the classification of strength of evidence, the distinction between association and causation, and the need for comprehensive epidemiological strategies to reduce uncertainty. The case study formed on the basis of an issue that involves millions of veterans and expenditures of billions of dollars. Much of the material reflects the work of a committee of the Institute of Medicine (IOM), the Committee on Evaluation of the Presumptive Disability Decision-Making Process for Veterans (PDDM Committee) (1). The authors of this case study were members of the committee.

CONTEXT: COMPENSATION OF VETERANS

The United States has long recognized and honored military veterans’ service and sacrifices and provided compensation

for injuries and diseases arising from their service. Beyond the possibility of injury and death during combat, men and women serving in the military are exposed to diverse agents that may affect their health, causing injury and disease while they are in the service or after discharge, depending on the length of the period between exposure and the occurrence of the disease. Some of the exposures are well known, if poorly documented, including exposure to Agent Orange, a defoliant during the Vietnam War, and to radiation during the testing of nuclear weapons. Many of the exposures reflect the diverse tasks and functions of military personnel and are comparable with those in parallel civilian occupations. However, some of the exposures are particular to the military and the nature and existence of the exposure may be classified and consequently secret. Specific illness syndromes have also occurred among military personnel that cannot be readily attributed to a single exposure; “Gulf War Syndrome” among participants in the first Gulf War is a recent example.

Veterans injured by their service, becoming ill while in service, or having an illness after discharge that has its origin in their service have long been given health-care coverage and disability compensation. For a veteran to receive compensation, his or her disability must be connected to service. A medical illness or injury that occurred while a member was in military service is considered connected to service, regardless of whether caused by military service or just occurring coincidentally with service. For a medical condition developing after military service, veterans may be compensated if the condition is presumed to be caused by or aggravated by an exposure or an event that occurred during military service (2).

From the Department of Preventive Medicine, Keck School of Medicine and Institute for Global Health, University of Southern California, Los Angeles, CA (J.M.S.); GHM Consulting, Washington, DC (G.H.M.); Epidemiology Branch, National Institute of Environmental Health Sciences, Durham, NC (A.J.W.).

Address correspondence to: Jonathan M. Samet, MD, MS, Professor and Flora L. Thornton Chair, Department of Preventive Medicine, Director, USC Institute for Global Health, University of Southern California, 1441 Eastlake Ave., Rm 4436, Los Angeles, CA 90089. Tel: 323-865-0803; Fax: 323-865-0854. E-mail: jsamet@usc.edu.

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Selected Abbreviations and Acronyms

PDDM = Presumptive Disability Decision-Making Process for Veterans

IOM = Institute of Medicine

VA = Department of Veteran Affairs

This case study focuses on the presumptions that are made around compensation of veterans for conditions arising after their service. Presumptions may be needed regarding whether exposure occurred and whether the exposure contributed to the illness. For example, in the case of Agent Orange, there has been persistent uncertainty as to whether specific military personnel were exposed while in Vietnam and mounting but also-uncertain evidence on the causation of cancer and other diseases by exposure to Agent Orange. A presumption has been made that all personnel with actual service in Vietnam were exposed to Agent Orange; the Department of Veterans Affairs (VA) also makes presumptions around compensation of specific diseases associated with Agent Orange on the basis of reviews of the evidence by IOM and the VA's assessment of the findings of the IOM.

In 1921, the Congress empowered the VA Administrator (now Secretary) to make presumptions, a power also retained and exercised by the Congress. The nearly 150 presumptions that have been made subsequently by Congress or the VA have substantial implications for veterans and for the nation. The VA now provides disability compensation to approximately 3 million veterans and 342 thousand beneficiaries (survivors of those who died as a result of their conditions), expending approximately \$41 billion annually for this purpose (VA 2010 Congressional Submission, Vol. III, 2A-1-3) (3). The costs have increased from \$19 billion in FY 2000 to an estimated \$43 billion in FY2010—as the Vietnam veterans have aged, the list of diseases for which Agent Orange compensation is given has lengthened, and as the Gulf War veterans have become ill over the nearly two decades that have passed since the first conflict.

In the face of uncertainty as to whether particular exposures cause particular illnesses, exposure and causation presumptions have profound consequences, potentially denying compensation to deserving veterans (a “false-negative” outcome) or wrongly awarding compensation (a “false-positive outcome”). Both of these mistaken outcomes have evident ethical and financial implications. False-positives results may be unavoidable if the goal of the compensation system is to assure that all deserving veterans are compensated.

THE CURRENT APPROACH TO MAKING PRESUMPTIONS

The following description of the approach now followed by the VA comes from a review and analysis carried out by

the IOM PDDM Committee. It describes the process, as characterized by the PDDM Committee and offers the Committee's assessment of its limitations. The current presumptive disability decision-making process for veterans involves input from Congress, VA, the IOM, and stakeholders, including veterans service organizations, advisory committees, and the veterans themselves (Fig. 1). Congress has the power to make presumptions and has done so. Court decisions may also affect the process. In the model in Figure 1, Congress or stakeholders acting through Congress may call on VA to assess whether a presumption is needed and the VA may then ask the IOM to review the scientific evidence. The findings of that evaluation are considered by VA in its presumptive disability decision-making process.

The process reflects legislation and the interpretation and application of legislation by the VA and the IOM. Three major legislative actions by Congress have influenced recent presumptions related to exposure and causation: the Radiation Exposed Veterans Compensation Act of 1988 (Public Law 100-321. 100th Cong., 2d Sess.), the Agent Orange Act of 1991 (Public Law 102-4. 102d Cong., 1st Sess.), and the Persian Gulf War Acts of 1995 (Veterans' Benefits Improvement Act of 1994. Public Law 103-446. 103rd Cong., 2d Sess.) and 1998 (Making Omnibus Consolidated and Emergency Appropriations for the Fiscal Year Ending September 30, 1999, and for Other Purposes. Public Law 105-277. 105th Cong., 2d Sess.). The concept of “at least as likely as not” with regard to exposure potential was introduced for radiation exposures and then extended. The Agent Orange Act (Public Law 102-4. 102d Cong., 1st Sess.) passed in 1991 grew out of controversy around the consequences of exposure to this herbicide during the Vietnam War. Congress itself made presumptions for Gulf War illnesses (Veterans Education and Benefits Expansion Act of 2001. Public Law 107-103. 107th Cong., 1st Sess.).

The Agent Orange Act of 1991 (Public Law 102-4. 102d Cong., 1st Sess.) started a process involving the IOM that is still in place. To obtain independent review of the scientific evidence on Agent Orange as called for in the Act, the VA contracted with IOM to conduct systematic reviews. Since its first report in 1994, the IOM has produced biennial reports on Agent Orange that are used by the VA for making presumptive decisions. IOM has also convened committees to prepare multiple volumes related to exposures during the Gulf War. After the VA receives an IOM report, Congress requires VA to respond with a determination as to whether or not the VA will make a service connection for particular health outcomes on a presumptive basis. In general, Congress and the VA act to provide compensation so as to not exclude veterans deserving of compensation while recognizing that some veterans with illnesses not caused by military service will be compensated as a result.

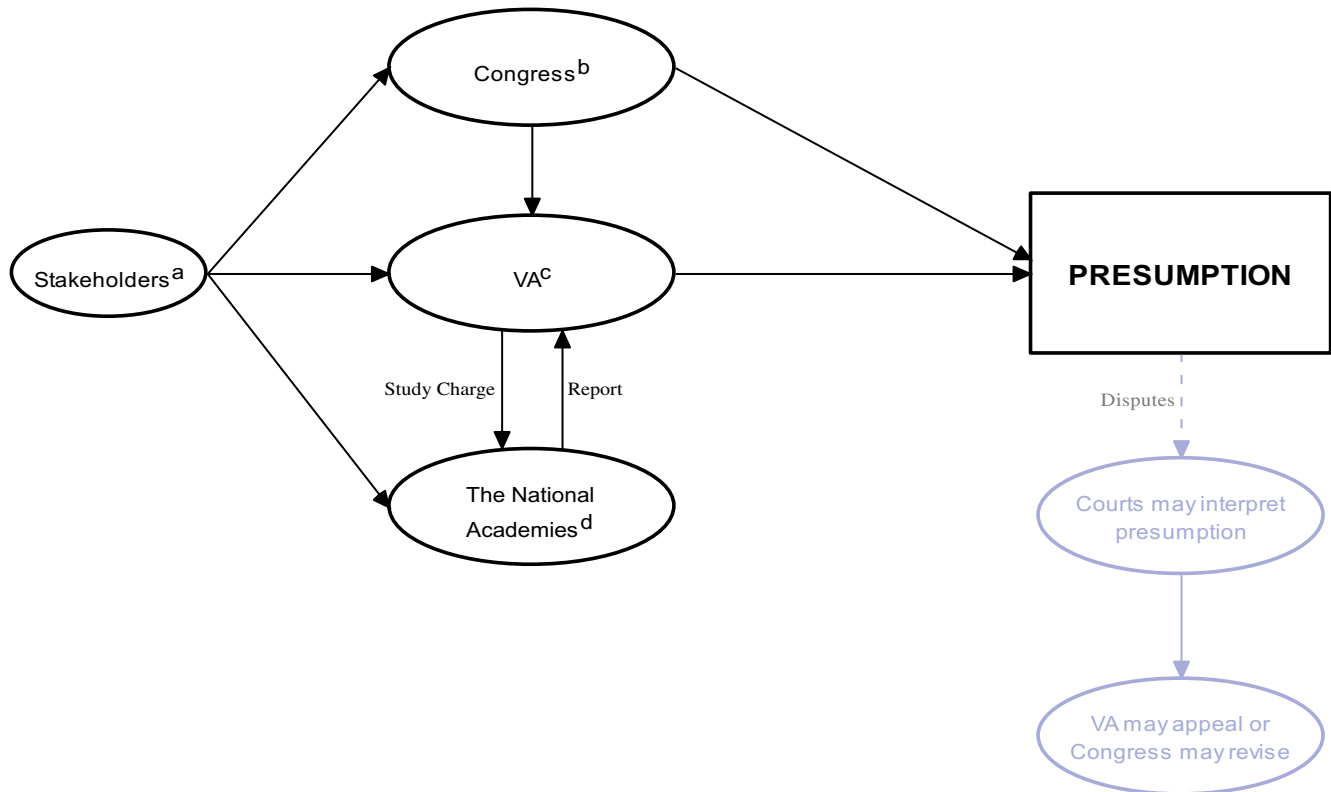


FIGURE 1. Current presumptive disability decision-making process. ^aStakeholders include veterans service organizations, veterans, advisory groups, federal agencies, and the general public who provide input into the presumptive process by communicating with Congress, VA, and independent organizations (e.g., the National Academies). ^bCongress has created many presumptions itself; in 1921, Congress also empowered the VA Secretary to create regulatory presumptions; on several occasions in the past, Congress has directed VA to contract with an independent organization (e.g., the National Academies) to conduct studies. ^cVA can establish regulatory presumptions; VA sometimes contracts with the National Academies to conduct studies and uses the organization's report in its deliberations of granting or not granting regulatory presumptions. ^dThe National Academies (Institute of Medicine and National Research Council) submit reports to VA on the basis of requests and study charges from VA.

With regard to this case study, several features of the process need emphasis:

1. For Agent Orange and Gulf War reports, the IOM carries out systematic reviews. For Agent Orange, the biennial reports focus on available evidence since the last review, whereas the Gulf War reports have focused on particular groups of agents to which military personnel were exposed.
2. For Agent Orange, the strength of evidence in support of *association* is evaluated and classified according to a four-level classification that has been in use since the first report in 1994.
3. The VA uses the IOM reports and classification of evidence in an internal process that involves working groups and recommendations to the VA Secretary. These internal processes are not transparent.
4. In the case of Agent Orange, presumptions providing compensation have been made when the evidence was classified as "limited/suggestive" of an *association*, for instance, prostate cancer and diabetes. For other

conditions, such as hypertension, compensation has not been provided for a similar strength of evidence. In the IOM's classification of strength of evidence for association, "limited/suggestive" is used for an association with Agent Orange when "[e]vidence is suggestive of an association between herbicides and the outcome but is limited because chance, bias, and confounding could not be ruled out with confidence. For example, at least one high-quality study shows a positive association, but the results of other studies are inconsistent" (4). Statistically significant findings in one study have been found as sufficient to meet this criterion.

5. For the illnesses linked to the Gulf War, recent IOM reports have added a category related to causation: "sufficient evidence of a causal relationship."

Uncertainty related to the causation of health conditions in veterans by military service could be reduced by assessing exposures of military personnel and following veterans' cohorts for health outcomes, including mortality. The

complexity of exposures received during service and the conditions of combat complicate any exposure assessment effort. The need for having better exposure data has been recognized repeatedly in numerous external reviews of Department of Defense and VA activities regarding Service member health protection and veteran health care and disability determination (5–13). Better exposure data could facilitate epidemiological research as well as informing decision-making for individual veterans making claims for conditions linked to specific exposures. However, at present, information does not flow from data bases of the Department of Defense to those of the VA, and the VA has limited capacity to carry out large-scale epidemiological research.

Overall, the current process for making presumptions is regarded by some key stakeholders, particularly the veterans service organizations and the veterans themselves, as flawed; its results have not been consistent and the VA makes its decisions without sufficient transparency. The PDDM Committee was troubled by the scientific inconsistencies between the approaches of the Agent Orange and Gulf War and the role of association, rather than causation, in the Agent Orange presumptions. Information is not being gathered to provide a stronger foundation for decision-making; although research of the needed scope would be costly, the economic and other costs of wrongly made presumptions are likely far larger. In terms of finding alternative approaches, this case study is particularly informative in characterizing the body of relevant epidemiological evidence and its role, in identifying the “actors,” and in mapping their relationships (Fig. 1). Alternative approaches can be based around this understanding.

ONE SOLUTION: THE IOM PPDM PROPOSED APPROACH

On the basis of its evaluation of the process in place, input from stakeholders, and review of the intrinsic methodological considerations, the PDDM Committee recommended an approach for making presumptions in the future. A process was proposed that was intended to address the identified problems with the current approach, including problems from the perspective of Veterans. The overall goal of the PDDM Committee was to recommend a transparent, evidence-based approach that would lead to decisions by means of an explicit process that includes synthesis of available evidence. The Committee had six principles as a foundation for its proposed framework: (i) stakeholder inclusiveness, (ii) evidence-based decisions, (iii) transparent process, (iv) flexibility, (v) consistency, and (iv) the use of causation, not just association, as the basis for decision making.

The Committee’s recommended approach (Fig. 2) has multiple elements that are not explicit in the current approach and that are intended to facilitate the translation

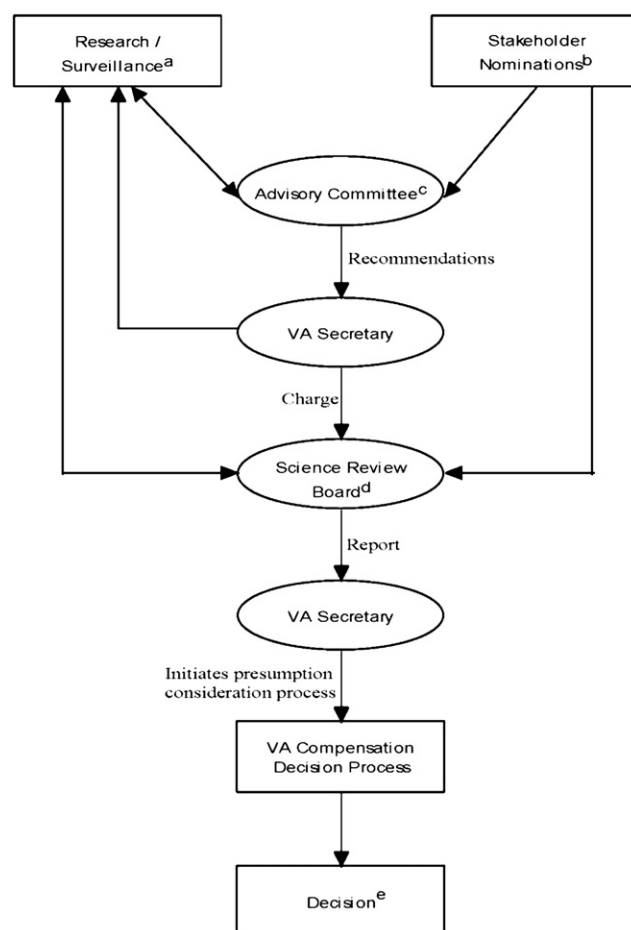


FIGURE 2. Proposed framework for the future presumptive disability decision-making process. ^aIncludes research for classified or secret activities, exposures, etc. ^bIncludes veterans, Veterans Service Organizations, federal agencies, scientists, general public, etc. ^cThis committee screens stakeholders’ proposals and research in support of evaluating evidence for presumptions and makes recommendations to the VA Secretary when full evidence review or additional research is appropriate. ^dThe board conducts a two-step evidence review process (see report text for further detail). ^eFinal presumptive disability compensation decisions are made by the Secretary, Department of Veterans Affairs, unless legislated by Congress.

of scientific evidence into policy. These elements include an open process for proposing exposures and illnesses for review, a systematic evidence review process carried out by an external group, a new evidence classification scheme to define the strength of evidence on causation and to quantify the extent of disease attributable to an exposure, a transparent decision-making process by VA, and an organizational structure to support the process.

To strengthen the base of evidence available on risks to Veterans, the Committee also urged that the VA work with the Department of Defense to comprehensively track exposures of military personnel and to monitor of their

health while in service and thereafter. To implement this approach, new permanent boards would be needed, including an Advisory Committee, serving in an advisory capacity to VA, and a Science Review Board (independent from the VA). The Advisory Committee would consider the exposures and illnesses that might be a basis for presumptions and recommend to the VA Secretary exposures and illnesses needing further consideration. The Science Review Board would evaluate the evidence for causation and classify its strength according to the scheme developed by the PDDM Committee, and estimate the service-attributable fraction of disease in veterans if that information would be needed for policy purposes. The Science Review Board would report to the VA, which would then make a decision in a transparent fashion.

One key proposal by the PDDM Committee, which was intended to facilitate the use of evidence from epidemiological studies and other relevant lines of investigation, was to advance causation, not association, as the appropriate consideration for compensation. The Committee proposed a four-level classification of strength of evidence for causation:

1. *Sufficient*: the evidence is sufficient to conclude that a causal relationship exists.
2. *Equipose and Above*: the evidence is sufficient to conclude that a causal relationship is at least as likely as not, but not sufficient to conclude that a causal relationship exists.
3. *Below Equipose*: the evidence is not sufficient to conclude that a causal relationship is at least as likely as not, or is not sufficient to make a scientifically informed judgment.
4. *Against*: the evidence suggests the lack of a causal relationship.

The point of *equipose*, at which the strength of evidence hangs in balance between certainty and uncertainty, is critical to the Committee's scheme. If the evidence for causation were categorized as *Sufficient* or at *Equipose and Above*, then the Committee would recommend that the VA should consider a presumption for service connection, taking into account the service-attributable fraction if possible. As relevant evidence accumulates, with follow-up of populations and continuation of other lines of research, the balance might move to strengthen or to weaken the case for causality.

LESSONS LEARNED

When We Know Evidence Will Be Needed for Future Policy Decisions, Better Policy Will Result if the Relevant Data Can Actually Be Collected

Presumptions cover gaps in evidence that might be reduced and even avoided with prospective data collection. The long record of presumptions made as the basis for providing compensation speaks strongly to the need for ongoing

tracking of the exposures and associated risks sustained by military personnel. Military service and combat unavoidably involve exposures to complex physical, chemical, biological, and psychological stressors. New exposures have been added over time as the nature of weapons and warfare have changed, for instance, radiation from nuclear weapons and depleted uranium, chemical warfare agents, and vaccines to counter biological agents. Recent wars have been followed by particular problems: the health consequences of Agent Orange after the Vietnam War and Gulf War Syndrome after the first Gulf War.

The need for presumptions will remain if no prospective data are collected on military exposures and veterans' health outcomes. A seamless approach should be the goal, with collection of exposure data while in service and tracking of veteran health outcomes through medical data bases. Feasibility and cost are potential but surmountable barriers. Although the costs of creating the needed evidence base may be considerable, they are likely to be far less than the costs of making false-positive presumptions. Unfortunately, other budget priorities may be a barrier to making the needed investment in data systems, surveillance, and research.

In this example, as in other instances of evidence-based policy decisions, the need for evidence in the decision-making process should be anticipated and prospectively addressed. Epidemiologists can usefully scope the evidence that could be obtained using surveillance and research approaches, and match that potential against the needs of the decision-making process.

Interaction of Policy Experts, Stakeholders, and Scientists Can Help to Prioritize Questions for More Intensive Scientific Evaluation of Existing Evidence

In the example of compensation for veterans, there are various points at which intersections may occur among policy experts, stakeholders, and scientists. However, the existing process does not provide a formal structure for such interactions, which forces veterans and the veterans' service organizations to "lobby" for consideration of particular issues of concern through the Congress and the VA. The political process has been effective at times for the veterans; the Agent Orange Act of 1991 is one example. However, the PDDM Committee observed that the current model fails to provide veterans with reliable pathways for raising their health concerns. The Committee proposed that such pathways be established (Fig. 2).

The Committee encouraged decision-making processes that foster interactions among those who make the decisions, those who are affected by the decisions, and those who produce the evidence that supports the decisions. Without such interactions, various stakeholder groups may lack a shared understanding of the types of evidence that

can be generated and the types of evidence that are most relevant. Scientists may study one aspect of a problem only to learn that they have not addressed a key stakeholder concern. There also needs to be a shared understanding of the potential limitations of available evidence, so that expectations of decision-makers and stakeholders are consistent with scientific findings.

Evaluation of Evidence Needs to Be Done By “Neutral” Scientific Groups With No Reason to Have Bias: The Synthesis Process for Evidence Evaluation Needs to Be Isolated From Stakeholder Influence, and Its Elements Need to Be Clear

In the Agent Orange Act of 1991, the Congress recognized the need for the VA to identify a neutral group to carry out its evidence reviews; the VA responded by contracting with the IOM which establishes expert panels to carry out the reviews. The IOM process is not subject to VA interference and the PDDM Committee proposes a similarly isolated evidence evaluation and synthesis process in its framework. The neutrality and prestige of the IOM are recognized by the various stakeholders. This principle—the neutrality of evidence review panels—needs application in all settings involving review and synthesis of potentially uncertain evidence.

Neutrality can be better documented if the elements of the evidence evaluation process are documented, clear, and adhered to. In the example of the IOM reviews of Agent Orange, a template for the reviews was established with the first report in 1994 and the classification scheme for strength of evidence for association remained in place through subsequent reports. One consequence of a clear and transparent process is that the IOM reviewing panel can act with full knowledge of how differing classifications play into the presumptive decision-making process.

This case study found that although several elements of the IOM review process were pivotal in decision-making, they were put into place without having a full construct of the policy process. The IOM panels carried out their work isolated from the VA, without understanding how to transmit findings to the VA in a way that best served the presumptive decision-making process. The current process has evolved rather than being designed. There has never a clear specification of the level of evidence needed to support decision-making.

One particular problem with the current evaluation approach is the IOM’s classification of the evidence. Evidence is reviewed as to its strength in support of association and not causation. Whether the intent of the Congress was to make a presumption on the basis of association or causation is not clear from careful reading of the Agent Orange Act. Reliance on association, particularly at the level

of “limited/suggestive” has the potential to result in a high level of false-positive decisions. The PDDM Committee framework specifically addresses this issue by calling for causation, and not association, to be the basis for decision-making. This recommendation has been met with resistance from veteran service organizations and some members of Congress, who have the opinion that requiring causation rather than association would make it “too difficult” to establish presumptions that they believe would be warranted.

The PDDM Committee also noted the need for a clear specification as to the level of evidence that would lead to a presumption. Until now, the VA has lacked any prior, explicit principles for decision-making, and has not been consistent in its decision-making. The use of standardized classifications of strength of evidence has shown the seeming inconsistencies in VA decision-making at a given level of evidence for association.

Processes for the Use of Scientific Evidence as the Basis for Policy Formulation Must Be Transparent—This Would Help to Avoid the Appearance of Unfairness and Also Protect Science From Blame for Poor Policy Decisions

The PDDM Committee carefully documented the current process for presumptive disability decision-making up to the “black box” that represents the VA. Like the stakeholders, the PDDM Committee was unable to gain an understanding of how the VA uses the IOM reports and other information to make its recommendations to the VA Secretary. There is similar opacity as to how the VA Secretary responds to these recommendations. The Committee acknowledged that various practical considerations in addition to scientific evidence have influenced decisions in the past, and will inevitably have weight in the future. Still, the lack of open process at the critical step of decision-making is harmful in several respects. Without a transparent process, decisions can seem arbitrary and unfair and can be subject to undue political influence. Furthermore, inconsistent decision-making can reflect poorly on the scientific review process that provides input, making the scientific process itself appear capricious and unreliable. The PDDM Committee recognized this failing of the current process and made certain that all steps of its proposed framework were open and operating with clear principles.

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