

Exhibit 10

IMPROVING THE PRESUMPTIVE DISABILITY DECISION-MAKING PROCESS FOR VETERANS

Committee on Evaluation of the Presumptive Disability
Decision-Making Process for Veterans

Board on Military and Veterans Health

Jonathan M. Samet and Catherine C. Bodurow, *Editors*

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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Preface

This committee, the Committee on Evaluation of the Presumptive Disability Decision-Making Process for Veterans (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. Although an individual veteran can establish a direct service connection for an illness, the needed information on the responsible exposure received during military service may be unavailable or incomplete. Additionally, there may be scientific uncertainty as to whether the exposure is known to cause the health condition. To ensure that veterans are compensated when information for direct service connection is needed but unavailable, Congress or the Secretary of the Department of Veterans Affairs (VA) can decide to service connect entire groups of veterans for specific health conditions due to exposures received during service. This decision to compensate particular groups of veterans is called a presumptive disability service-connection decision or, simply, a presumption. A presumption may address unavailable or incomplete information on exposure or gaps in the evidence as to whether the exposure increases risk for the health condition.

Each veteran identified as eligible for coverage under a presumptive decision will have a separate, individual disability rating conducted by the VA and will be eligible for disability compensation based on the nature and severity of the health condition. That is, the presumptive disability service-connection decision is separate from the rating evaluation and compensation process.

General Summary

The United States has long recognized and honored the service and sacrifices of its military and veterans. 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 connect the health conditions to the circumstances of service may be incomplete. When information is incomplete, Congress or the Department of Veterans Affairs (VA) may need to make a “presumption” of service connection so that a group of veterans can be appropriately compensated. The missing information may be about the specific exposures of the veterans, or there may be incomplete scientific evidence as to whether an exposure during service causes the health condition of concern. For example, when the exposures of military personnel in Vietnam to Agent Orange could not be clearly documented, a presumption was established that all those who set foot on Vietnam soil were exposed to Agent Orange.

The Institute of Medicine (IOM) Committee was charged with reviewing and describing how presumptions have been made in the past and, if needed, to make recommendations for an improved scientific framework that could be used in the future for determining if a presumption should be made. The Committee was asked to consider and describe the processes of all participants in the current presumptive disability decision-making process for veterans. The Committee was not asked to offer an opinion about past presumptive decisions or to suggest specific future presumptions. The Committee heard from a range of groups that figure into this decision-making process, including past and present staffers from Congress,

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Ultimately, the decision regarding which proposed topics for potential presumptions deserve full evaluation resides with VA. In the Committee's proposed process, VA also receives scientific input from the Science Review Board. We recommend that VA establish a uniform and transparent process for making decisions regarding presumptions following receipt of evidence reviews. VA should establish procedures with input from the many stakeholders, and a clear, evidence-based rationale should be offered for all decisions. The Committee's recommendations are aimed at providing a sound scientific framework for the presumptive disability decision-making process. The Committee clearly recognizes that there are social, economic, political, and legal factors beyond the scope of scientific evidence that may influence the presumptive disability decision-making process for veterans and the presumptive decisions that are established by Congress and VA.

Scientific evidence is not static, and it often is less than certain. Given that the scientific basis for presumptive decisions will change over time, the Committee recommends that VA should be able to adjust future decisions when such change is scientifically justified. This does not mean that the Committee recommends that benefits previously granted should be terminated. The Committee is aware that disabled veterans and their families are often dependent on such payments and that it could create a hardship to remove them, a matter that VA disability policy recognizes in other situations.

SPECIFIC RECOMMENDATIONS

Based on its evaluation of the current process for establishing presumptive disability decisions and its consideration of alternatives, the Committee has specific recommendations for an approach that would build stronger scientific evidence into the decision-making process and, at the same time, be even more responsive and open to veterans. We propose a transformation of the current presumptive disability decision-making process. We recognize that considerable time would be needed to implement some of these recommendations as would additional investment to create systems needed to track exposures and health status of currently serving military service personnel and veterans. Progress depends on greater research capacity and improvements in the evaluation and utilization of scientific evidence in making compensation decisions. We find that there are elements of the current process that could be changed quickly and we recommend that VA consider prompt action as it moves toward implementation of a new approach. The recommendations that follow are based around the Committee's proposed framework for making presumptive decisions. We list the recommendations in relation to the appropriate body.

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between exposure and disease risk for carcinogens. For individual Vietnam veterans, exposure to Agent Orange cannot be estimated with any certainty, and VA has made a presumption with regard to exposure of Vietnam veterans to Agent Orange (VA, 2002). VA has also presumptively linked certain outcomes, such as prostate cancer and type 2 diabetes, based on evidence for association to Agent Orange exposure. By contrast, presumptions are not needed for combat-related casualties for which there is no uncertainty as to causation.

The role of presumptions becomes evident when the complete suite of information needed by VA for making compensation decisions for groups and for particular individuals is considered. Figure 6-1 describes information gathering and how information may be used for making general and specific judgments about causation and for making evidence-based decisions with regard to compensation. The schema in the figure assumes that the availability of information for making these determinations, as well as the roles of factors beyond the scientific evidence, such as costs and political considerations, are all figured into the process. Presumptions are made when there are gaps in the information related to exposure and causal classification. Factors other than the evidence relevant to the causal classification may affect the compensation decision.

If complete information were available, the process in the table could flow without presumptions, but the review of presumptions in Chapter 2 shows that this ideal has been infrequent and many presumptions have been made. The military workplace and particularly combat can lead to many exposures that may affect future health status and disease occurrence. Military personnel sustain a variety of exposures, some specific to the military and others not, that may increase risk for disease. If exposures of potential concern were tracked during military service and disease surveillance were in place and maintained, even for those who have left active duty, evidence could be generated directly relevant to the causation of disease in veterans. Disease rates could be compared in exposed and nonexposed veterans, for example. Lacking such evidence, reviewing groups turn to epidemiologic studies of other populations and gauge the relevance of the findings for the exposures of veterans. Such groups also give consideration to toxicological and other research information. For a specific individual, the determination of eligibility for compensation would be based ideally in full knowledge of that individual's risk and an estimation of his or her probability of causation, given exposure history and observational information on the associated risk from similarly exposed people. However, this level of information and scientific understanding has not yet been fully achieved for individual causation for any agent.

standing of mechanism of action may have substantial impact in considering the overall weight of evidence.

Committee Recommended Categories for the Level of Evidence for Causation

In light of the categorizations used by other health organizations and agencies as well as considering the particular challenges of the presumptive disability decision-making process, we propose a four-level categorization of the strength of the *overall evidence* for or against a *causal relationship* from exposure to disease:

1. *Sufficient*: The evidence is sufficient to conclude that a causal relationship exists.
2. *Equipoise 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 Equipoise*: 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.

We use the term “equipoise” to refer to the point at which the evidence is in balance between favoring and not favoring causation. The term “equipoise” is widely used in the biomedical literature, is a concept familiar to those concerned with evidence-based decision making, and is used in VA processes for rating purposes as well as being a familiar term in the veterans’ community.

Below we elaborate on the four-level categorization that the Committee recommends.

Sufficient

If the overall evidence for a causal relationship is categorized as Sufficient, then it should be scientifically compelling. It might include

- replicated and consistent evidence of a causal association: that is, evidence of an association from several high-quality epidemiologic studies that cannot be explained by plausible noncausal alternatives (e.g., chance, bias, or confounding), or
- evidence of causation from animal studies and mechanistic knowledge, or
- compelling evidence from animal studies and strong mechanistic

Equipose and Above

To be categorized as Equipose and Above, the scientific community should categorize the overall evidence as making it more confident in the existence of a causal relationship than in the non-existence of a causal relationship, but not sufficient to conclude causation.

For example, if there are several high-quality epidemiologic studies, the preponderance of which show evidence of an association that cannot readily be explained by plausible noncausal alternatives (e.g., chance, bias, or confounding), and the causal relationship is consistent with the animal evidence and biological knowledge, then the overall evidence might be categorized as Equipose and Above. Alternatively, if there is strong evidence from animal studies or mechanistic evidence, not contradicted by human or other evidence, then the overall evidence might be categorized as Equipose and Above. Equipose is a common term employed by VA and the courts in deciding disability claims (see Appendix D).

Again, using the Bayesian model to illustrate the idea of Equipose and Above, Figure 8-5 shows a posterior probability distribution that is an example of belief compatible with the category Equipose and Above.

In this figure, unlike the one for evidence classified as Sufficient, there is considerable mass over zero, which means that the scientific community has considerable uncertainty as to whether exposure causes disease at all; that is, whether β is greater than zero. At *least* half of the mass is to the right of the zero, however, so the community judges causation to be at least as likely as not, after they have seen and combined all the evidence available.

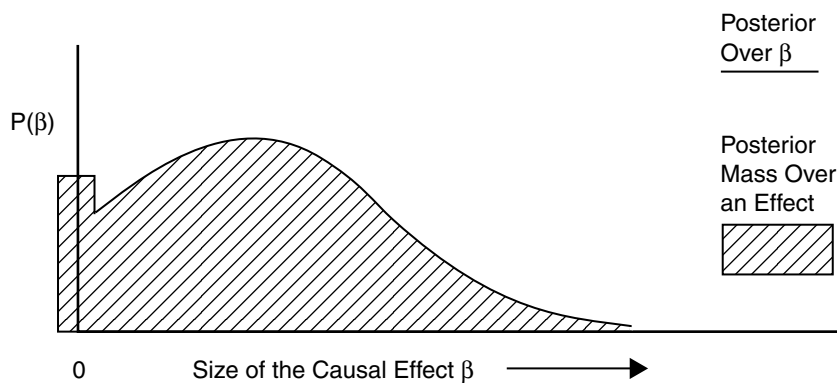


FIGURE 8-5 Example posterior for *Equipose and Above*.

factor may be a more critical issue than employability for amputees given advances in medical technology and emphasis on occupations not requiring physical labor.

(Economic Systems Inc., 2004, p. 2)

The study also suggests that “recruitment and retention” could be included in the range of possible program goals (Economic Systems Inc., 2004, p. 2): The “[l]egislation does not explicitly state that intent of the VA disability program . . . is to provide incentive value for recruitment and retention” (p. 4). However, “during wartime periods, Congress has provided greater benefits or liberalized rules for eligibility, reflecting the intention of attaining sufficient recruitment and retention. Also, Congress has legislated benefits for veterans using phrases similar to ‘in gratitude of service rendered for a grateful Nation,’ indicating that benefits are provided for a variety of different reasons” (Veterans’ Disability Benefits Commission, 2005, pp. 4-5).

Finally, in looking at disability compensation benefits it should also be kept in mind that “compensation for . . . impairment in earnings capacity . . . is not based on the disabled person’s individual capacity loss but only on ‘average’ capacity” (Economic Systems Inc., 2004, p. 2).

Claims may be established by direct evidence that an injury or disease or its aggravation occurred at a point in time coincident to military service. Medical exams, military service records, expert opinions, and credible statements by those with knowledge of the circumstances of the claim are frequently relied upon. Claims may also be established by un rebutted presumptions that have been adopted by VA either as a result of statutory amendment or by administrative regulation.

EQUIPOISE AND BURDEN OF PROOF

38 USC, Section 5107, sets forth standards for “burden of proof” and “benefit of the doubt” with respect to establishing disability benefits entitlement. Subsection 5107(b) further provides, in pertinent part, with respect to such claims that

When, after consideration of all evidence . . . there is an approximate balance of positive and negative evidence regarding the merits of an issue material in the determination of the matter, the benefit of the doubt in resolving each such issue shall be given to the claimant.

(see also 38 CFR § 3.102. Reasonable doubt)

Evidence found to be in such “balance” has often been characterized in Board of Veteran Appeals decisions as being in “equipoise.”

In *Gilbert v. Derwinski*, 1 Vet. App. 49 (1991), an early decision considering the rule, the court employed the following analogy:

The “benefit of the doubt” standard is similar to the rule deeply embedded in sandlot baseball folklore that “the tie goes to the runner.” If the ball clearly beats the runner, he is out and the rule has no application; if the runner clearly beats the ball, he is safe and again the rule has no application; if however the play is close, then the runner is called safe by operation of the rule that “the tie goes to the runner.” . . . Similarly, if a fair preponderance of the evidence is against a veteran’s claim, it will be denied and the “benefit of the doubt” rule has no application; if the veteran “establishes a claim by a fair preponderance of the evidence, the claim will be granted and, again, the rule has no application;