## Chairman Daniel K. Akaka

## **OPENING STATEMENT**

Oversight on VA Disability Compensation: Presumptive Disability Decision-Making September 22, 2010

Welcome to today's hearing on the VA Presumptive Disability Decision-Making Process. The purpose of this hearing is to discuss whether the current process for developing presumptions is working. Today much of our focus will be on Vietnam veterans and Agent Orange. However, it is important to note that the same process is already in place with respect to presumptions related to the first Gulf War. And, as many know, we are just beginning to hear about the consequences of exposures to potential toxins in connection with the wars in Iraq and Afghanistan and exposures at military installations – such as Camp Lejeune and the Atsugi Naval Air Facility. We must ensure that the method through which presumptions are created is appropriate and transparent – for past and future wars.

Today we take a careful look at the decision-making process for presumptive disabilities, especially in its most recent application, the process that established three new disabilities related to Agent Orange, including ischemic heart disease. Is that process working? How can it be improved?

We will examine the functionality of the overall process, the roles of the various participants in the process, lessons learned from past presumptions created through this process, and how we might apply these lessons to address the challenges facing the process today. Most importantly, throughout this discussion, we must not lose focus on the purpose of the presumptions: to fulfill our promise to care for and compensate veterans for service-connected injuries.

Caring for the wounds of war is a cost of war. When it comes to compensating and treating veterans for service-connected disabilities, the question is never whether to do it; rather it is how to do it. Issues concerning veterans' benefits have largely survived in this partisan era with bipartisan support, mainly because most members of Congress agree that these benefits are tied to the sacrifices made by those who wear the Nation's uniforms and are deserved.

Maintaining that high level of public and political support depends on a clear and sound decision-making process for any expansion of veterans' benefits. If resources are expended in the name of expanding presumptions for service-connected disabilities, when in fact the disabilities are not due to service, the larger effort to provide care and benefits that veterans and their families urgently need and deserve will suffer.

Congress must fulfill its oversight responsibility when there is a plan to significantly increase benefits. The nature of presumptions – granting service-connection for entire classes of veterans rather than looking at them case-by-case – justifies a close and focused review of the decision-making process behind each expansion of presumptions.

As we undertake this review, there are questions relating to the science in connection with the most recent presumptions and Agent Orange exposure – what can science tell us about Vietnam veterans' actual exposure to Agent Orange and about the likely consequences of that exposure?

On the issue of actual exposure, I will seek the views of today's witnesses on the feasibility and desirability of finding a better way to understand which veterans who served in Vietnam were exposed to what levels of Agent Orange. A better understanding of exposure levels would open the way for conducting research on the consequences of Agent Orange exposure. If it is not possible to know with any greater certainty which Vietnam veterans were actually exposed to significant levels of Agent Orange, it may be appropriate to consider research on Vietnam veterans in the aggregate so as to gain a better understanding of the relationship between their current health status and their service in Vietnam.

We will look at questions of process relating to the establishment of presumptions, again both under the Agent Orange Act and generally. What process does the Institute of Medicine follow as it reviews the science and then, once IOM reports to VA, is the process that VA follows appropriate?

Under the Agent Orange Act, the Secretary is called on to determine, on the basis of sound medical and scientific evidence, whether there is a positive association between exposure to an herbicide and the occurrence of a disease. A positive association is defined in the law to exist when the evidence for an association is equal to or greater than evidence against the association. In making the determination, the Secretary is to take into account reports from IOM and all other sound medical and scientific information.

As we look at the recent decision, we must be satisfied that all scientific evidence was made available to the Secretary, and we must understand how this evidence was weighed and considered. For my part, I must be satisfied that the law – enacted almost 20 years ago – is working today, especially in the context of common diseases of aging and of diseases with manifold risk factors.

Senator Rockefeller, Senator Specter and I are the only current members of the Committee who were on the Committee in 1991 when the Agent Orange Act was passed. I recall the difficulties the Congress was facing as we tried to find agreement on how to deal with the consequences of exposure to Agent Orange. The history of the work of the Congress from the late 1970s to the early 1990s is a demonstration of the challenges we were facing. There were many hearings on the subject, various attempts at legislation, much heated debate in Committee and on the floor of both the House and the Senate. There was little agreement on what the available science told us or on how to proceed in light of the available science. In the 101st Congress, the one prior to the Congress in which the Agent Orange Act was enacted, legislation providing an annual cost-of-living adjustment for VA compensation was blocked because we could not reach agreement on Agent Orange issues so no COLA was enacted. There was a strong imperative to find a solution, and from that came the Agent Orange Act. The question before us today is whether the approach set forth in that law is still an appropriate way to proceed.

There are also questions of policy we must address as part of our review – what is the right response when the health issue being debated is a common disease of aging or when there are multiple known risk factors for that disease? We also will examine the respective roles of the Congress and the Executive Branch in resolving such policy matters.

While it is clear that there are real and substantial costs associated with the new presumption, costs which will continue for many years to come, that is not the motivation for this hearing or for our larger work of evaluating the process put in place pursuant to the Agent Orange Act. Keeping our promise to servicemembers and veterans alike requires us to ensure that the presumption process in place today allows us to make informed and accurate decisions regarding service-connected presumption is warranted.

That is exactly the question we must ask with respect to the presumption for heart disease in Vietnam veterans: Is it a consequence of service in Vietnam? In all who were present there, no matter where they served or for how long? We know that heart disease is a common disease of aging in the U.S. population. We know that there are many risk factors associated with having heart disease – Dr. Bild of the National Heart, Lung, Blood Institute of NIH, in response to prehearing questions for today's hearing, stated that between 80 and 90 percent of heart disease can be attributed to life style choices. How can we know whether heart disease diagnosed in a Vietnam veteran now in his late 50s or early, or mid-60s is somehow tied to service in Vietnam 40 years ago? What is the available evidence on that point and how was it evaluated?

Congress enacted the Agent Orange Act of 1991 in an attempt to respond to the concerns of veterans who served in Vietnam by establishing the presumption process to address the uncertain degree of exposure to herbicides among Vietnam veterans. The Act has served as a model for the presumptive process that remains in place today.

As noted above, the Act charges the Secretary of Veterans Affairs with establishing presumptions based on a determination that the credible evidence for an association is equal to or outweighs the credible evidence against an association. This statutory standard was designed to bridge the gap created by uncertainty about levels of exposure and diseases associated with such exposure. The gap stretches between real life and the theoretical basis for presumptions. On the one hand, a veteran who served in Vietnam has a current diagnosis of a disease. On the other, there exists a legal requirement to provide compensation when a linkage can be shown between service and a current health condition.

Service-connected compensation is generally based on three elements – a current disability, proof of an in-service event, and a nexus between the two. With regard to claims based on Agent Orange, the first element is usually easy and straightforward when a Vietnam veteran presents with a health condition. As a result of the presumption that all those who served in Vietnam were exposed to Agent Orange, the second element -- the in-service event -- is provided by that presumption of exposure to dioxin in Agent Orange. Finally, under the Agent Orange Act, the third element, the nexus, is provided by a second presumption – which is supposed to be based on an evaluation of relevant science – that there is a finding that the evidence supporting an association between exposure to dioxin and a specific disease is equal to or outweighs the evidence against such an association.

Prior to the enactment of the Agent Orange Act, Vietnam veterans faced two hurdles -- no ability to show they were exposed to Agent Orange and no ability to link their particular disease to exposure. The Agent Orange Act responded to that situation by establishing the presumption of

exposure in law and by setting up the mechanism by which diseases could be presumed to be associated with Agent Orange exposure.

As we carry out our review of the Agent Orange Act, I believe we need to look at both of those presumptions. What is the basis for assuming that most Vietnam veterans were exposed to Agent Orange? As to the mechanism for linking specific diseases to Agent Orange, what is the basis for our reliance on extrapolation from other, often significantly different exposures, as a result of scarce Vietnam veteran specific research?

In earlier years, the diseases associated with Agent Orange exposure were not common in the general population and had no major, recognized prevalent risk factors, so the causation gap between Agent Orange exposure and those diseases was narrow. The burden on science to bridge that narrow gap was minimal, and within the scope of its capability. However, in more recent years, the burden on science has increased dramatically – with the need to bridge a substantially wider causation gap between Agent Orange exposure and diseases that are far more common in the general population. In the presence of other major risk factors, science has been unable to determine, beyond a limited or suggestive degree, the extent to which Agent Orange might increase an individual's risk for developing diseases common to aging or that are clearly known to relate to specific common risk factors.

For example, the Institute of Medicine states that the medical community has concluded that if a man lives long enough, he will develop prostate cancer. Despite this understanding, the current process has yielded a presumption for prostate cancer based on the possibility that a veteran may have been exposed to any amount of Agent Orange, coupled with the possibility that Agent Orange may have contributed to his risk for prostate cancer by even the smallest incremental amount. With respect to type 2 diabetes, IOM states that family history, physical inactivity, and obesity continue to outweigh any suggested increased risk posed by wartime exposure to Agent Orange. Similarly, the risk factors of age, smoking, obesity, high cholesterol, and high blood pressure pose a much higher risk for developing ischemic heart disease than any suggested increased risk posed by wartime exposure to Agent Orange. Focusing only on the risk factor of age, Vietnam veterans are entering the age where the prevalence of ischemic heart disease is already significant and can only be expected to increase over their lifetimes.

The major risk factors for these common diseases confound examination of any association with Agent Orange and stretch the capability of science beyond its charge in the Agent Orange Act of 1991, which implicitly relies on the ability of science to examine the association of Agent Orange exposure independent of other major risk factors. The Institute of Medicine states that an assessment of the risk posed by Agent Orange would require reliable exposure data, which the presumption process ironically was established to serve as a surrogate for. This circular quandary appears to be a strong indicator that the current presumption process may be inadequate.

Today, we will ask our witnesses to reflect on this quandary and help us explore whether additional factors should be considered to complement the available science, when the underlying science appears to fall short of answering the statutory question of whether a presumption is warranted.

This morning, we will focus on how the current process has resulted in the establishment of service connection for relatively common diseases when exposure data are unavailable and evidence of an association is limited due to confounding by other major risk factors.

The lead witness today will be Secretary Eric K. Shinseki, the Secretary of Veterans Affairs. He will describe how he reached his determination to establish a presumption for ischemic heart disease. We will seek his views on his role in the decision-making process, under the approach established by the Agent Orange Act of 1991; especially with respect to IOM findings of a limited, suggestive association. We will ask how VA and Congress can partner their efforts to improve the process to better serve the needs of veterans who may have been exposed to toxins during military service.

Among the witnesses on the second panel is former Secretary of Veterans Affairs, the Honorable Anthony Principi. We will ask him to describe the challenges he faced with the presumption process, and the primary factors that influenced his decision to establish a presumption for type 2 diabetes.

A second witness on that panel will be Dr. Jonathan Samet, Chair of the Institute of Medicine's Committee on Evaluation of the Presumptive Disability Decision-Making Process for Veterans. We will seek his insight on the lessons that his committee learned from evaluating the process that yielded the presumptions for prostate cancer and type 2 diabetes. We will also seek his views on how we might apply those lessons for current decision-making, such as the presumption for ischemic heart disease.

We have two witnesses from NIH -- Dr. Linda Birnbaum, from the National Institute of Environmental Health Sciences and Director of the National Toxicology Program at the Department of Health and Human Services and Dr. Diane Bild, from the National Heart, Lung, and Blood Institute – who will be asked to provide insight on ischemic heart disease and its major risk factors and to address what role science is currently capable of with respect to determining an association between Agent Orange exposure and IHD, as well as other diseases common to aging and other prevalent risk factors.

We made a promise to care for – and compensate – veterans for service-connected injuries. In that light, I have never, nor will I ever, stop fighting for veterans, most particularly when the issue is directly related to the consequences of service. Keeping our promise requires us to reassess the current presumption process to ensure that it equips all participants with the appropriate authority to consider all relevant factors to determine whether a service-connected presumption is warranted.