DEPARTMENT OF VETERANS AFFAIRS

Determinations Concerning Illnesses Discussed In National Academy of Sciences Reports on Gulf War and Health, Volumes 4 and 8

AGENCY: Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: As required by law, the Department of Veterans Affairs (VA) hereby gives notice that the Secretary of Veterans Affairs, under the authority granted by the Persian Gulf War Veterans Act of 1998, has determined that there is no basis to establish any new presumptions of service connection at this time for any of the diseases, illnesses, or health effects discussed in the September 12, 2006, and April 9, 2010, reports of the Institute of Medicine of the National Academy of Sciences (NAS), respectively titled Gulf War and Health, Volume 4: Health Effects of Serving in the Gulf War (Volume 4) and Gulf War and Health, Volume 8: Update of Health Effects of Serving in the Gulf War (Volume 8).

FOR FURTHER INFORMATION CONTACT: Gerald Johnson, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, N.W., Washington, DC 20420, telephone (202) 461–9727. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION:

I. Statutory Requirements

The Persian Gulf War Veterans Act of 1998, Public Law 105–277, title XVI, 112 Stat. 2681–742 through 2681–749 (set out as a note under 38 U.S.C. 1117 and codified in part at 38 U.S.C. 1118), and the Veterans Programs Enhancement Act of 1998, Public Law 105–368, 112 Stat. 3315, directed the Secretary to seek to enter into an agreement with the NAS to review and evaluate the available scientific evidence regarding associations between illnesses and exposure to toxic agents, environmental or wartime hazards, or preventive medicines or vaccines to which service members may have been exposed during service in the Southwest Asia theater of operations during the Persian Gulf War. Under this agreement, Congress directed NAS to identify agents, hazards, medicines, and vaccines to which service members may have been exposed during the Persian Gulf War. Congress required NAS, to the extent that available scientific data permits meaningful determinations, to determine for each substance or hazard identified: (1) Whether a statistical association exists between exposure to the substance or hazard and the occurrence of illnesses, (2) whether there is an increased risk of the illness among exposed human or animal populations, and (3) whether a plausible biological mechanism or other evidence of a causal relationship exists. Public Law 105–277, 112 Stat. 2681–747.

In addition, Congress authorized VA to compensate Gulf War Veterans for diagnosed or undiagnosed illnesses that are determined by VA to warrant a presumption of service connection based upon a positive association with exposure, as a result of Gulf War service, to a toxic agent, an environmental or wartime hazard, or a preventive medication or vaccine known or presumed to be associated with Gulf War service. 38 U.S.C. 1118. Thus, upon receipt of each NAS report, VA must determine whether a presumption of service connection is warranted for any disease or illness discussed in the report. A presumption of service connection is warranted if VA determines, based on sound medical and scientific evidence, that there is a positive association between the exposure of humans and animals to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Southwest Asia theater of operations during the Gulf War and the occurrence of a diagnosed or undiagnosed disease or illness in humans and animals. 38 U.S.C. 1118(b). If the Secretary determines that a presumption of service connection is not warranted, the Secretary shall publish in the Federal Register a notice of the determination. 38 U.S.C. 1118(c)(3)(A). Accordingly, this notice announces VA’s determination that no new presumptions of service connection are warranted for any disease or illness discussed in Volume 4 and Volume 8.

II. NAS Reports: Gulf War and Health Series

The NAS has issued eight numbered reports and two unnumbered “updates” in the Gulf War and Health series, which examine the health effects of exposure to specific chemical agents, environmental and wartime hazards, and preventive medicines and vaccines. Federal Register notices have been published on four of the eight numbered reports and two unnumbered updates announcing the Secretary’s determination that the available evidence does not warrant a presumption of service connection for any of the diseases discussed in the four reports: Gulf War and Health, Volume 1: Depleted Uranium, Sarin, Pyridostigmine Bromide, and Vaccines (66 FR 35702 (2001)); Gulf War and Health, Volume 2: Insecticides and Solvents (72 FR 48734 (2007)); Gulf War and Health: Updated Literature Review of Sarin (73 FR 42411 (2008)); Gulf War and Health, Volume 3: Fuels, Combustion Products, and Propellants (73 FR 50856 (2008)); Gulf War and Health, Volume 5: Infectious Diseases (74 FR 15063 (2009)); Gulf War and Health: Updated Literature Review of Depleted Uranium (75 FR 10867 (2010)); and Gulf War and Health, Volume 6: Physiologic, Psychologic, and Psychosocial Effects of Deployment-Related Stress (76 FR 2447 (2011)).

The Volume 4 report is covered in this notice. The findings for Gulf War and Health, Volume 7: Long-Term Consequences of Traumatic Brain Injury are currently under review. The latest report, Volume 8, will also be covered in this notice. Based on Volume 4 and Volume 8, VA published a proposed rule on November 17, 2010 to clarify that FGIDs fall within the scope of the existing presumption of service connection for medically unexplained chronic multisymptom illnesses. 75 FR 70162. Aside from that clarification, VA has determined that no other changes to the existing presumptions relating to multisymptom illness, nor any new presumptions, are warranted at this time.
The NAS issued its Volume 4 report on September 12, 2006. This study differs from previous NAS work in that it compiles, evaluates, and summarizes in one location peer-reviewed scientific and medical literature on the current status of health effects in Veterans deployed to the Persian Gulf irrespective of exposure information, i.e., health responses associated with deployment in the Gulf War Theatre alone. The purpose of the study was to inform VA of illnesses among Gulf War Veterans that might not be immediately evident. Based on this NAS report, the Secretary has determined that the scientific evidence presented in this report and other information available to the committee indicates that no new presumption of service connection is warranted at this time for any of the illnesses described in Volume 4.

The NAS committee conducted extensive searches of epidemiologic literature published since 2005, employing the same search strategies as used for Volume 4, and retrieved over 1,000 potentially relevant references. The titles and the abstracts of the studies were assessed and then narrowed down to focus on 400 potentially relevant epidemiological studies for the review. Similar to the policy utilized in the Volume 4 review, the NAS update committee used only peer-reviewed published literature as the basis for its conclusions, with the exception of some governmental reports.

The NAS update committee reviewed the studies that had been included in Volume 4 as either primary or secondary studies. In Volume 4, the NAS committee did not make determinations as to the strength of the association between deployment to the Gulf War and the specific health effects. Therefore, the NAS update committee was asked to make such determinations during its review. To make these determinations, the NAS update committee reviewed the studies included in Volume 4 to ensure that they would still be classified as either primary or secondary studies.

V. Report Summaries for Volume 4 and Volume 8

The different approaches used by the NAS committee in evaluating Volume 4 and the NAS update committee in evaluating Volume 8 are reflected in the separate conclusions reached by each committee. The task of the NAS committee was to catalog the health outcomes that appeared to have greater prevalence in Veterans who had been deployed to the Gulf War in comparison with Veterans in the military at that time who were not deployed to the Gulf War. In Volume 4, the NAS committee did not specifically evaluate the strength of the association between Gulf War deployment and the specific health outcomes. The Volume 4 studies generally did not associate any observed health effects with exposure to specific hazards of Gulf War service, and therefore provide no basis for establishing new presumptions under 38 U.S.C. 1118 based on exposure to specific agents, hazards, or medicines associated with Gulf War service.

The NAS update committee reviewed epidemiologic studies of health outcomes published after the literature search conducted for the Volume 4 report as well as the studies included in Volume 4. The purpose of this report was to determine the strength of associations between being deployed to the Gulf War and specific health effects. The NAS update committee reviewed only studies that compared the health status of Gulf War Veterans with those of non-deployed Veterans and Veterans deployed to other locations, and then characterized the strength of the evidence for an association between Gulf War deployment and the specific health outcome. Based on the NAS update committee’s findings, VA determined that Volume 8 did not present a basis for establishing new presumptions under 38 U.S.C. 1118 based on exposure to specific agents, hazards, or medicines associated with Gulf War service. Specific findings of Volume 4 and Volume 8 are discussed below.

Multisymptom Illness

The NAS committee for Volume 4 found that Veterans of the Gulf War report higher rates of symptoms or sets of symptoms than their non-deployed counterparts. The committee found that 29 percent of Gulf War Veterans meet a case definition of “multisymptom illness,” compared to 16 percent of non-deployed Veterans. Among the symptoms most often reported by Gulf War Veterans are fatigue, memory loss, confusion, inability to concentrate, mood swings, somnolence, gastrointestinal symptoms, muscle and joint pains, and skin conditions. Gulf War Veterans also reported more instances of chronic multisymptom illness, including chronic fatigue syndrome, fibromyalgia, and multiple chemical sensitivity.

Under current law at 38 U.S.C. 1117 and 38 CFR 3.317, Gulf War Veterans are entitled to compensation for chronic disabilities associated with signs or symptoms of disabilities such as those described above or associated with chronic multisymptom illness. The findings in Volume 4 support the policies of the current presumptions and warrant no change to the existing regulatory presumptions of service connection in 38 CFR 3.317.

In a November 2008 report, the RAC, a Federal advisory committee established to provide research recommendations to VA, indicated that current medical and scientific evidence provides support for the theory that the increased symptomatology reported by Gulf War Veterans may be attributable to exposure to pyridostigmine bromide (PB) in pills given to U.S. troops as a protection against nerve gas and pesticides. The RAC found that several studies provide evidence of an association, including a dose-response relationship, between PB and multisymptom illnesses consistent with “Gulf War Illness,” and between pesticide exposure and such multisymptom illness. The RAC noted also that animal studies had identified significant effects of exposure to combinations of PB, pesticides, sarin, and stress, at dosage levels similar to those experienced by Veterans in the Gulf War, although there is relatively little information from human studies concerning the effects of such combined exposures.

The NAS update committee for Volume 8 reviewed the literature cited in the RAC report, but disagreed with the RAC’s conclusion that chronic multisymptom illness is caused by exposure to PB and pesticides. The NAS update committee concluded that current available evidence was not sufficient to establish a causative relationship between multisymptom illness and any specific drug, toxin, plague or other agent, either alone or in combination. The NAS update committee noted that some studies had found associations between self-reported exposures to PB, pesticides, nerve gas, and mixtures thereof, but that several well-designed studies have concluded that no associations exist for such exposures. The update committee also stated that, although some studies have found that central nervous system (CNS) disorders may persist following acute pesticide exposure, there is no evidence that Gulf War Veterans experienced such acute exposures and no significant evidence of chronic CNS effects from low-level exposures. Based on its review of the available evidence from both human and animal studies, the NAS update committee found insufficient support for the conclusion that pesticides, PB, insect repellants, or combinations thereof are responsible for multisymptom illnesses in Gulf War Veterans.

Based on review of the information in the reports of the NAS and the RAC, VA has determined that the evidence for an association between multisymptom illnesses and specific exposures, such as PB, pesticides, and combinations thereof, is not equal to or greater than the evidence against such an association. VA emphasizes, however, that this conclusion has no effect on VA’s ability under existing law to provide compensation for multisymptom illnesses. Under 38 U.S.C. 1117 and 38 CFR 3.317, VA pays compensation for such illness without regard to its cause. VA will continue to evaluate developments regarding the possible causes of Gulf War Veterans’ chronic multisymptom illnesses, which may affect the understanding and treatment of these illnesses.

The NAS update committee accepted multisymptom illness as a diagnostic entity and assessed the association between symptom reporting indicative of multisymptom illness and deployment to the Gulf War, instead of attempting to determine whether there appears to be a unique illness that could be defined by the symptoms. Most studies indicate an increased reporting of multisymptom illness among deployed Gulf War Veterans, which occurred in multiple studies from several countries, but were subjective with inconsistent findings on physical examinations and laboratory testing requiring further analysis. The NAS update committee determined that there is sufficient evidence of an association
between deployment to the Gulf War and chronic multisymptom illness, but noted that the basis for the relationship is unclear, and recommended further research. These findings support the policy in existing law to provide compensation for Gulf War Veterans’ chronic multisymptom illnesses.

**Psychiatric Symptoms**

The NAS committee concluded that deployment places Veterans at increased risk for symptoms that meet the diagnostic criteria for certain psychiatric illnesses, including post-traumatic stress disorder (PTSD), anxiety, depression, and substance abuse. In Volume 6, the NAS committee explained that the increased risk of psychiatric symptoms has been associated with deployment during any period of war and is thus not limited to Gulf War deployments.

The NAS update committee determined that there is sufficient evidence to establish a presumptive relationship between deployment to the Gulf War and several other psychiatric disorders, including generalized anxiety disorders, depression, and substance abuse. The results of long-term follow-up studies indicate that psychiatric disorders were still evident 10 years after deployment and were shown to be more than two times higher in deployed Veterans compared to non-deployed Veterans.

The NAS update committee further noted that an inference can be made that the high prevalence of medically unexplained disability reported by Gulf War Veterans cannot be reliably attributed to any known psychiatric disorder. Lastly, the NAS update committee determined that traumatic war exposure experienced during deployment in the Gulf War is causally related to PTSD. The NAS update committee explained that though the evidence available from the Gulf War is somewhat limited, it is sufficient to support the conclusion of a causal relationship between combat exposure and the development of PTSD. The NAS committee further noted that similar evidence obtained from other wars is also supportive of their conclusion that combat exposure and PTSD in the Gulf War are causally related.

VA regulations at 38 CFR 4.125(a) require that mental disorders, including PTSD, be diagnosed in accordance with the Diagnostic and Statistical Manual: Fourth Edition (DSM–IV). Under the DSM–IV, the diagnosis of PTSD requires evidence of a pre-morbid traumatic exposure. In order for PTSD to be service connected, the traumatic exposure must have occurred during a period of military service. The NAS update committee did not find a causal relationship between mere deployment to the Gulf War theater and PTSD, nor did it find PTSD to be associated with exposure to a particular toxic agent, hazard, medicine, or vaccine. Rather, it found a causal relationship between PTSD and the traumatic war exposures experienced during deployment to this war zone. Further, these types of exposures are not unique to the Gulf War, but are common to all episodes of combat. Consequently, we do not believe there is a sound basis for establishing a presumption of service connection for PTSD that is limited to Veterans of Gulf War combat service. Such a presumption would treat Gulf War combat Veterans differently than combat Veterans of other wars, without a rational basis for such disparate treatment.

Although the NAS committee found PTSD to be associated with “traumatic war exposure,” and the NAS update committee found a causal relationship between “traumatic war exposures” and PTSD, PTSD deployment and PTSD, PTSD could not be associated with the types of exposure outlined in 38 U.S.C. 1118, involving exposure to hazardous substances known or suspected to be associated with Gulf War service. VA interprets the use of the phrase “traumatic war exposures” used in the reports as being a general reference to the exposures to the dangers of service in a combat area, including risk of death or injury due to enemy attacks. Accordingly, VA does not believe that the reference to “traumatic war exposures” identifies an association between PTSD and a specific “exposure” within the meaning of section 1118.

VA also concludes that it is unnecessary to create a presumption for PTSD for all combat Veterans based on VA’s general rulemaking authority. VA’s current regulations afford combat Veterans essentially the same liberalized standard of proof that a presumption would provide. When a Veteran has been validly diagnosed with PTSD, service connection will be granted if the PTSD is associated with an in-service “stressor.” As noted above, the Veteran must identify a stressor before a valid diagnosis of PTSD can be made. Under VA regulations at 38 CFR 3.304(f), if a Veteran engaged in combat and the claimed stressor relates to combat, VA will accept the Veteran’s lay statement as sufficient evidence of the stressor. Further, under a recent amendment to that regulation, even if the Veteran did not engage in combat, the Veteran’s own statements alone may establish the occurrence of the claimed in-service stressor if the claimed stressor is related to the Veteran’s fear of hostile military or terrorist activity and is confirmed as adequate to support a diagnosis of PTSD, the Veteran’s symptoms are related to the claimed stressor, and the claimed stressor is consistent with the places, types, and circumstances of the Veteran’s service. 75 FR 39843 (July 13, 2010). Accordingly, a Veteran whose claimed stressor relates to the perils of deployment to a war zone generally need not submit any evidence of a stressor beyond the statements made for purposes of the diagnosis of PTSD. A presumption of service connection for PTSD based on traumatic war exposures in the Gulf War theater would neither increase the likelihood of a legitimate claim being accepted, nor speed the adjudication process by which claims are adjudicated.

For similar reasons, VA has determined that the finding of increased prevalence of other psychiatric disorders in Gulf War Veterans does not warrant a presumption of service connection under section 1118. In Volume 4 and Volume 8, NAS found that psychiatric disorders are associated with deployment to the Gulf War, but did not find such disorders to be associated with any particular type of exposure during the Gulf War. In its Volume 6 report, NAS found that an increased risk of psychiatric disorders is associated with deployment to any war zone, and that the prevalence and severity of those disorders were associated with the level of combat experienced. This suggests that the increased prevalence of psychiatric disorders is more likely associated with the inherent perils of combat in any war than with exposure to specific agents, hazards, medicines, or vaccines associated with the Gulf War.

Section 1118(a)(2)(A) and (b)(1)(B) require VA to determine whether a presumption of service connection is warranted by reason of a disease having a positive association with exposure to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine “known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War.” We conclude that the statutory phrase “associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War” is most reasonably construed to refer to a relationship between the substance or hazard and the specific circumstance of service in the Southwest Asia theater of operations during the Persian Gulf War, as distinguished from features of
military service that are not unique to service in the Gulf War. Section 1118 reflects the Government’s commitment to addressing the unique health issues presented by Gulf War Veterans, by establishing a process for identifying diseases and illnesses that may be associated with Gulf War service. The requirement that the substances or hazards at issue be “associated with” Gulf War service makes clear that VA’s task is to examine the unique exposure environment in the Persian Gulf during the Persian Gulf War. Establishing presumptions of service connection under section 1118 applicable only to Gulf War Veterans based on the general circumstance of deployment which is shared by significant other groups of Veterans would not significantly further the statute’s purpose, but would create significant inequities in the Veterans’ benefits system that Congress could not have intended.

VA has also decided not to establish a presumption of service connection for psychiatric disorders in Veterans of any period of deployment to a combat zone under VA’s general rulemaking authority. The category of psychiatric disorders encompasses a diverse array of diagnoses. Further, psychiatric disorders are widespread and may be triggered by many life events, including those occurring before and after service. Although the NAS reports indicate that psychiatric disorders are associated with combat deployment, they provide no basis for evaluating whether Veterans’ psychiatric disorders are more likely caused by wartime deployment than by any of the many other risk factors that are also associated with such disorders or for evaluating possible differences in the degree to which the numerous specific types of psychiatric disorders may be associated with wartime deployment. Accordingly, a general presumption of service connection for psychiatric disorders would be overly broad.

VA believes that VA psychiatric examinations are a more effective way of evaluating whether psychiatric disorders are due to military service than applying a broad presumption that would apply to all Veterans deployed to the Gulf War. VA routinely provides psychiatric examinations to Veterans claiming service connection for psychological disorders and believes that this process is effective.

Cardiovascular Disease, Diabetes, Arthralgia, or Hospitalization

The NAS committee concluded that the evidence did not show that Gulf War Veterans have an increased risk of cardiovascular disease, diabetes, arthralgia, or hospitalization in comparison to non-deployed Veterans. The NAS update committee found that there is limited or suggestive evidence of no association between Gulf War deployment and mortality from cardiovascular disease in the first 10 years after war. The NAS update committee further found that there is insufficient or inadequate evidence to determine whether an association exists between Gulf War deployment and endocrine, nutritional, and metabolic diseases, including diabetes, and Gulf War deployment and musculoskeletal system diseases, including arthralgia. The NAS update committee did not review hospitalization as a separate category as reviewed in Volume 4; rather, the committee included hospitalization as a factor in each specific health outcome reviewed.

In order for a presumption to be warranted the Secretary must establish that there is a “positive association” between “the exposure of humans or animals to a biological, chemical or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War; and [...] the occurrence of a diagnosed or undiagnosed illness in humans or animals.” 38 U.S.C. 1118[b][1][B]. An association is considered “positive” if the credible evidence for an association is equal to or outweighs the credible evidence against the association. 38 U.S.C. 1118[b][3]. For the conditions listed above, the NAS committee concluded that there was not an increased risk, and the update committee found that there was inadequate or insufficient evidence to determine whether an association exists or limited or suggestive evidence of no association with deployment to the Gulf War. Therefore, VA concludes that the evidence of an association for these conditions does not equal or outweigh the credible evidence against an association. Based on this analysis, VA has determined that there was insufficient or inadequate evidence of an association for these conditions as reviewed in Volume 4 and Volume 8, the committee concluded that no new presumptions relating to cancer are warranted at this time.

Mortality From External Causes

The NAS committee noted that studies provided evidence that Gulf War Veterans had an increased risk of transportation-related injury and mortality in the first several years after such service when compared to non-deployed service members. The NAS committee found no evidence that this result was related to a specific exposure in Gulf War service or that it was related to a specific disease or illness.

The NAS update committee identified four new studies of external cause mortality and determined that the evidence indicates a modestly higher mortality from transportation-related causes among Gulf War deployed Veterans than other Veterans. The increase was due to motor-vehicle accidents which diminished or disappeared over time. The NAS update committee concluded that there is limited or suggestive evidence of an association between deployment to the Gulf War and increase in mortality from external causes primarily motor vehicle accidents, in the early years after deployment.

VA notes that VA and other researchers have documented this transitory post-combat deployment health effect among Veterans of other combat deployments, including Vietnam. Further, the findings of Volume 4 and Volume 8 do not identify an “illness” or a specific identified risk factor (e.g., a particular exposure) to concerns about the exposure modeling and the fact that the study period was not within what is believed to be the usual latency period for brain cancer. Further, Volume 4 reported mixed results as to whether an association exists between testicular cancer and deployment to the Gulf War.

The NAS update committee determined that there was insufficient or inadequate evidence of an association between Gulf War exposures and brain cancer. The NAS update committee did not identify any new studies relating to testicular cancer. The NAS update committee noted that many Veterans of the Gulf War are still too young for cancer diagnoses and that the follow-up period following the Gulf War has probably been too short to expect significant results. Thus, the NAS update committee recommends further follow-up in order to make a conclusion about whether there is an association between deployment during the Gulf War and cancer outcomes. Based on the information provided in Volume 4 and Volume 8, the committee determined that no new presumptions relating to cancer are warranted at this time.

Cancer

The NAS committee concluded that the evidence did not show that Gulf War Veterans have an increased overall risk of cancer. However, in one study in Volume 4 an association of brain-cancer mortality with possible nerve-agent exposure was observed. The NAS committee noted that this finding should be interpreted with caution due to concerns about the exposure modeling and the fact that the study period was not within what is believed to be the usual latency period for brain cancer. Further, Volume 4 reported mixed results as to whether an association exists between testicular cancer and deployment to the Gulf War.

The NAS update committee determined that there was insufficient or inadequate evidence of an association between Gulf War exposures and brain cancer. The NAS update committee did not identify any new studies relating to testicular cancer. The NAS update committee noted that many Veterans of the Gulf War are still too young for cancer diagnoses and that the follow-up period following the Gulf War has probably been too short to expect significant results. Thus, the NAS update committee recommends further follow-up in order to make a conclusion about whether there is an association between deployment during the Gulf War and cancer outcomes. Based on the information provided in Volume 4 and Volume 8, the committee determined that no new presumptions relating to cancer are warranted at this time.

Mortality From External Causes

The NAS committee noted that studies provided evidence that Gulf War Veterans had an increased risk of transportation-related injury and mortality in the first several years after such service when compared to non-deployed service members. The NAS committee found no evidence that this result was related to a specific exposure in Gulf War service or that it was related to a specific disease or illness.

The NAS update committee identified four new studies of external cause mortality and determined that the evidence indicates a modestly higher mortality from transportation-related causes among Gulf War deployed Veterans than other Veterans. The increase was due to motor-vehicle accidents which diminished or disappeared over time. The NAS update committee concluded that there is limited or suggestive evidence of an association between deployment to the Gulf War and increase in mortality from external causes primarily motor vehicle accidents, in the early years after deployment.

VA notes that VA and other researchers have documented this transitory post-combat deployment health effect among Veterans of other combat deployments, including Vietnam. Further, the findings of Volume 4 and Volume 8 do not identify an “illness” or a specific identified risk factor (e.g., a particular exposure)
known or suspected to be associated with Gulf War service. Without these conditions, 38 U.S.C. 1118 does not authorize VA to establish a presumption for the increased risk of transportation-related injury or death. Because this phenomenon has not been connected to a disease or injury incurred or aggravated in service, VA has no statutory authority to compensate Veterans or their survivors through a new presumption, absent new legislative authority. See 38 U.S.C. 501 and 1110. Thus, after careful review of the findings of mortality from external causes, primarily motor vehicle accidents, in the early years after deployment, the Secretary has determined that the scientific evidence presented in Volume 4 and Volume 8 indicates that no presumption of service connection is warranted at this time.

**Skin Conditions**

The NAS committee found that some studies provided evidence that Gulf War Veterans have a higher incidence of certain skin conditions (atopic dermatitis and warts) than non-deployed Veterans, but that the findings were not consistent among the relevant studies. The NAS committee identified no evidence linking those conditions to any particular exposure in Gulf War Service. The NAS update committee determined that there was insufficient or inadequate evidence of an association between deployment to the Gulf War and skin disorders and noted that the inconsistency in the studies suggests that the findings may be due to chance. Based on the inconsistent evidence of an association between deployment to the Gulf War and skin disorders and because these skin conditions have not been attributed to any particular exposure in the Gulf War, VA has determined that no new presumption of service connection is warranted for dermatological conditions.

**Amyotrophic Lateral Sclerosis**

The NAS committee and the NAS update committee found that some studies indicate that Gulf War Veterans may have an increased risk of amyotrophic lateral sclerosis (ALS). In another report issued in November 2006, titled *Amyotrophic Lateral Sclerosis in Veterans: Review of the Scientific Literature*, a separate NAS committee concluded that there is evidence of an increased risk of ALS in Veterans of all periods of service. In September 2006, VA issued regulations establishing a presumption of service connection for ALS following any period of qualifying service. 73 FR 54691 (Sept. 23, 2008). Because this presumption applies to all Gulf War Veterans, there is no need for a separate presumption that is applicable only to Gulf War Veterans.

**Other Diseases of the Nervous System**

The NAS committee found that available studies generally did not provide evidence of an increased prevalence among Gulf War Veterans of peripheral neuropathy. The NAS update committee found that available studies generally did not provide evidence of an increased prevalence among Gulf War Veterans of peripheral neuropathy, multiple sclerosis, other neurological diseases such as Alzheimer’s disease, dementia and Parkinson’s disease, or other neurological outcomes. The NAS update committee therefore concluded that there was inadequate or insufficient evidence to determine whether an association exists between deployment to the Gulf War and multiple sclerosis, other neurological diseases, or other neurological outcomes. The NAS update committee noted that in one study, the few positive findings may be limited or suggestive evidence of an association between such deployment and peripheral neuropathy. Based on the committees’ findings, the Secretary has determined that no new presumptions are warranted for these conditions.

**Neurocognitive and Neurobehavioral Performance**

The NAS committee defined primary studies as “high quality studies that used neurobehavioral tests that had previously been used to detect adverse effects in population-based research on occupational groups.” The findings compared neurobehavioral performance in deployed Veterans and non-deployed Veterans. The NAS committee concluded that the primary studies of Veterans deployed to the Gulf War compared to Veterans not deployed to the Gulf War do not demonstrate differences in cognitive and motor measures as determined through neurobehavioral testing. However, the NAS committee did conclude that Gulf War Veterans who had at least one symptom commonly reported by Gulf War Veterans (such as fatigue, memory loss, confusion, inability to concentrate, mood swings, somnolence, gastrointestinal distress, muscle or joint pain, or skin or mucous membrane complaints) had poorer performance on cognitive tests than returning Veterans who did not report any such symptoms. The NAS update committee reviewed two additional studies that were classified as secondary. Primary studies of deployed Gulf War Veterans versus non-deployed Veterans did not demonstrate differences in cognitive and motor measures to determine the neurobehavioral testing. The NAS update committee concluded that there is inadequate or insufficient evidence to determine if an association exists between deployment to the Gulf War and neurocognitive and neurobehavioral performance.

Decreased neurocognitive or neurobehavioral performance is not in itself a disease or illness for which service connection may be established. Further, Volume 4 and Volume 8 did not find evidence of an association between such decreased performance and any Gulf War exposure. Accordingly, VA has determined that no presumption relating to neurocognitive and neurobehavioral performance is warranted at this time.

**Sexual Dysfunction**

The NAS committee reviewed one primary study on self-reported sexual dysfunction in Volume 4. In this study the self-reported sexual problems were verified through physician interviews. The NAS committee found that Gulf War Veterans consistently report an increased prevalence of sexual problems when compared to nondeployed Veterans. The NAS update committee did not consider any new primary studies, but considered seven additional secondary studies in Volume 8. The NAS update committee noted that in one study, assessing exposures specific to Gulf War service, there was no association between nerve agent exposure and reported sexual problems among Veterans deployed to the Gulf War. The NAS update committee further noted that all of the studies relied exclusively on survey responses except for the primary study reviewed in Volume 4. The NAS update committee acknowledged that studies assessing the prevalence of sexual problems are generally limited to self-reported symptoms, but warned that these studies should be interpreted with caution given concerns about their susceptibility to selection and reporting biases. The NAS update committee concluded that there was limited or suggestive evidence of an increased prevalence of self-reported sexual difficulties among Gulf War Veterans. Although the NAS update committee found limited or suggestive evidence of an increase in self-reported sexual dysfunction, it did not find an increase in any specific or verified disease, nor did it find evidence associating any such condition with Gulf War exposure. Accordingly, VA has determined that a presumption of
service connection for sexual dysfunction is not warranted at this time.

Other Genitourinary Outcomes

The NAS committee did not discuss other genitourinary conditions in Volume 4. In Volume 8, the NAS update committee found that studies showed an increased incidence of self-reported genitourinary symptoms or diseases among Veterans of Gulf War deployments. It found that such studies were limited by self-reported outcomes, lack of clinical confirmation, potential recall bias, and generally poor response rates. The NAS update committee identified no reports based on confirmed diagnoses showing increased incidence of genitourinary conditions among Veterans of Gulf War deployments. The NAS update committee also found that hospitalization studies provide evidence that hospitalizations for genitourinary conditions were not increased in that population. Accordingly, the NAS update committee concluded that there was inadequate or insufficient evidence to determine whether an association exists between Gulf War deployment and specific conditions of the genitourinary system, and that there is limited or suggestive evidence of no association between Gulf War deployment and hospitalization for genitourinary diseases. Accordingly, VA has determined that a presumption of service connection for genitourinary conditions is not warranted at this time.

Fertility Problems

In Volume 4 and Volume 8, the NAS committee and the NAS update committee assessed fertility problems such as semen parameters, hospitalization for infertility or genitourinary system diseases, self-reported difficulties in achieving a pregnancy, and serum concentrations of reproductive hormones in males. The NAS committee reviewed two primary studies in Volume 4. The NAS committee found that, although it appears that there is no difference in the prevalence of male fertility problems or infertility between Veterans deployed to the Gulf War and nondeployed Veterans, it is difficult to draw any conclusions due to the small number of available studies.

The NAS update committee additionally reviewed one primary study and four secondary studies in Volume 8. The NAS update committee found that there was no evidence of significant differences in concentrations of male reproductive hormones between Gulf War Veterans and nondeployed Veterans, but noted that this question was only addressed by one study. The NAS update committee further noted that, although it appears that infertility problems are reported more frequently among Gulf War Veterans compared to their nondeployed counterparts, these findings should be interpreted with caution because of the small number of available studies and their susceptibility to reporting bias and selective participation. The NAS update committee concluded that there was inadequate or insufficient evidence to determine whether an association exists between deployment to the Gulf War and fertility problems. Based on the NAS committee and the NAS update committee’s findings, VA has determined that no presumption of service connection for fertility problems is warranted at this time.

Adverse Pregnancy Outcomes

The NAS committee and the NAS update committee reviewed studies concerning adverse pregnancy outcomes, such as the prevalence of spontaneous abortions, stillbirths, ectopic pregnancies, preterm births, low birth weight, and macrosomia, in the pregnancies of Gulf War deployed and nondeployed men and women. In Volume 4, the NAS committee reviewed one primary study and two secondary studies. The primary study was the only study of adverse pregnancy outcomes that used hospital discharge records rather than relying exclusively on self-reported outcomes.

In Volume 8, the NAS update committee reviewed five additional secondary studies evaluating the effect of deployment on adverse pregnancy outcomes. The NAS update committee found that one of the primary studies reviewed in Volume 4 noted an increased risk of spontaneous abortion and ectopic pregnancy among active-duty personnel admitted to military hospitals for pregnancy-related diagnoses, but that these results may not be generalized to Veterans who have left service or to pregnancy-related admissions to nonmilitary hospitals. The NAS update committee observed that such findings for spontaneous abortion were not replicated in the four secondary studies of female Veterans reviewed in Volume 8. The NAS update committee further observed that, in Volume 8, the one secondary study that addressed ectopic pregnancies did not indicate any increased incidence among either male or female Veterans of Gulf War deployments. The NAS update committee noted that among males reporting on their female partners, there was no consistent association for abortions, spontaneous abortion, preterm birth or low birth weight, but three studies showed a modest increase in self reported miscarriages among deployed males reporting on their female partners. The NAS update committee concluded that there was inadequate or insufficient evidence to determine whether an association exists between deployment to the Gulf War and adverse pregnancy outcomes. Based on the NAS committee and the NAS update committee findings, VA has determined that a presumption of service connection for adverse pregnancy outcomes is not warranted at this time.

Birth Defects

In Volume 4, a study identified birth defects among infants of military personnel born from January 1, 1989, to December 31, 1993, from population-based birth defect registries in six States: Arizona, Hawaii, Iowa, Arkansas, California, and Georgia. The study compared 48 selected congenital anomalies diagnosed from birth to the age of 1 year between Gulf War Veterans’ and non-deployed Veterans’ infants conceived before, during or after the war; and between infants conceived by Gulf War Veterans before and after the war. The study found three cardiac defects and one kidney defect among infants conceived after the war to Gulf War Veteran fathers. The study also found a higher prevalence of hypospadias, a genitourinary defect among sons conceived post-war to Gulf War Veteran mothers compared to their non-deployed counterparts. Aortic valve stenosis, coarctation of aorta, and renal agenesis and hypoplasia were also elevated among infants conceived by Gulf War Veteran fathers prior to the war.

The NAS update committee reviewed the studies identified in the Volume 4 report and considered a study by Doyle et al. (2004) as a primary study due to medical confirmation of self-reported outcomes. The Doyle study was considered a secondary study in the Volume 4 report. The study evaluated the prevalence of self-reported birth defects among the offspring of Veterans deployed to the Gulf and among the offspring of non-deployed Veterans who responded to a postal questionnaire. No significant associations with birth defects were found for infants of mothers deployed to the Gulf, although the analyses were limited.

Based on the primary studies of both reports and the availability of medical confirmation in those studies, there is some suggestion of increased risk of
birth defects among the offspring of Gulf War Veterans. However, there is no consistent pattern of higher prevalence of birth defects among offspring of male or female Gulf War Veterans, and no single defect, except urinary tract abnormalities, has been found in more than one well-designed study. The NAS update committee concluded there is inadequate or insufficient evidence to determine whether an association exists between deployment to the Gulf War and specific birth defects. Accordingly, VA has determined that there is no basis for a presumption relating to birth defects of the offspring of Veterans deployed to the Gulf War. VA notes further that it has no authority under 38 U.S.C. 1118 or other statutes to pay benefits for disability in the children of Gulf War Veterans.

Respiratory Symptoms

The NAS committee found that the reporting of respiratory symptoms, but not specific respiratory illnesses, is more prevalent in deployed Gulf War Veterans than in their non-deployed counterparts. The NAS committee identified five primary studies that examined the association between pulmonary conditions and deployment to the Gulf War. The committee found that respiratory symptoms, but not specific respiratory illnesses, are more prevalent in deployed Gulf War Veterans than in their non-deployed counterparts. Two of these studies analyzed data of Gulf War Veterans and non-deployed Veterans derived from a cohort of randomly selected participants from a previous 1995 study who had completed the earlier mailed questionnaire on self-reports of health conditions. One study reported on the prevalence of self-reported asthma, bronchitis, and emphysema and found no significant differences between the Gulf War Veterans and non-deployed Veterans after adjusting for smoking and demographic variables. An additional study applied spirometry and symptom interviews to a random selection of Gulf War deployed Veterans compared to non-deployed Veterans. A 2004 study found that only a history of smoking preexisting asthma from new onset asthma.

The NAS committee found that no study using objective estimates of exposure to nerve agents due to the destruction of a munitions site at Khamisiyah, Iraq, in 1991 found any increased risk of respiratory disease or other problems with pulmonary function. Based on the information in Volume 4, VA has determined that a presumption of service connection for respiratory disease with exposures at Khamisiyah is not warranted at this time.

The NAS update committee identified three additional primary studies of respiratory outcomes and the deployment to the Gulf War. The studies found a non-significant increase in respiratory disease hospitalizations for Veterans deployed to Southwest Asia after the Gulf War and no excess deaths due to diseases of the respiratory system among Gulf War Veterans versus non-deployed Veterans. The third study identified no increase in mortality risk due to respiratory diseases among Veterans exposed to the chemical munitions destruction at Khamisiyah compared to the unexposed Veterans. One study found a non-significant increase in respiratory disease hospitalizations for Veterans deployed to Southwest Asia after the Gulf War as compared to Gulf War Veterans. The NAS update committee found that studies based on self-reported symptoms and self-reported diagnoses related to the Gulf War have inconsistently but frequently shown an increase among Gulf War Veterans.

There appears to be no increase in respiratory disease among Gulf War Veterans when examined with objective measures of disease. Pulmonary function studies and mortality studies have shown no significant excess of lung function abnormalities or of death due to respiratory disease among Gulf War Veterans. The NAS update committee concluded that there is inadequate or insufficient evidence to determine whether an association exists between deployments to the Gulf War and respiratory disease. The NAS update committee further concluded that there is limited or suggestive evidence of no association between deployment to the Gulf War and decreased lung function in the first 10 years after the war.

Current VA regulations at 38 CFR 3.317 provide a presumption of service connection for chronic disability due to signs or symptoms affecting the respiratory system. Because chronic respiratory signs and symptoms are already included in § 3.317 and because an association between deployment to the Gulf War and either respiratory disease or decreased lung function could not be established, VA has determined that a presumption of service connection for respiratory disease is not warranted at this time.

Diseases of the Blood and Blood-Forming Organs

The NAS committee in Volume 4 did not specifically address blood diseases. The NAS update committee in Volume 8 found that available studies did not show an increased incidence of diseases of the blood and blood-forming organs in Gulf War Veterans. Accordingly, the NAS update committee concluded that there was inadequate or insufficient evidence to determine whether an association exists between deployment to the Gulf War and such diseases. Based on the NAS update committee’s findings, the Secretary has determined that no new presumption relating to diseases of the blood and blood-forming organs is warranted at this time.

Structural Gastrointestinal Diseases

The NAS committee and the NAS update committee found that studies showed an increased incidence of self-reported gastrointestinal symptoms or disorders among Veterans of Gulf War deployments. As noted above, the NAS update committee found sufficient evidence of an association between deployment to the Gulf War and functional gastrointestinal disorders and has addressed that finding in a separate rulemaking, 75 FR 70162 (proposed Nov. 17, 2010). The NAS
update committee also found that there was inadequate or insufficient evidence to determine whether an association exists between Gulf War deployment and structural gastrointestinal diseases, such as peptic ulcer and inflammatory bowel disease (which includes ulcerative colitis and Crohn’s disease). Although some of the reviewed studies found increased incidence of self-reports of certain structural gastrointestinal diseases, the NAS update committee noted that the lack of diagnostic testing to validate those results was a significant confounding factor, because physicians not infrequently place an organic disease label (such as gastritis or peptic ulcer) on a patient’s symptoms without performing diagnostic studies. The NAS update committee also noted that studies did not find an increased incidence of hospitalization or death due to gastrointestinal disease in Veterans of Gulf War deployments. Based on these findings, the Secretary has determined that no new presumption relating to structural gastrointestinal diseases is warranted at this time.

VI. Conclusion

After careful review of the findings of Volume 4 and Volume 8, the Secretary has determined that the scientific evidence presented in these reports indicates that no new presumption of service connection is warranted at this time for any of the illnesses described in the NAS 2006 and NAS update committee’s 2010 reports. It is important to note that VA’s determination that presumptions of service connection are not warranted at this time for the health effects in question is not intended to suggest that they are irrelevant to further investigations of Gulf War Veterans’ health or that they may not in any circumstances form the basis for presumptions of service connection under Public Law 105–277. In the event future evidence links any illnesses to exposures associated with Gulf War service, VA may establish presumptions of service connection for such illnesses pursuant to Public Law 105–277. It is equally important to note that VA’s determinations not to establish presumptions do not in any way preclude claimants from seeking and establishing service connection for these diseases and illnesses or any other diseases or illnesses that may be shown by evidence in an individual case to be associated with service in the Gulf War.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and

Authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on March 31, 2011, for publication.

Dated: April 8, 2011.

William F. Russo,
Deputy Director, Regulations Policy and Management, Department of Veterans Affairs.

DEPARTMENT OF VETERANS AFFAIRS

Veterans’ Rural Health Advisory Committee; Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92–463 (Federal Advisory Committee Act) that the Veterans’ Rural Health Advisory Committee will conduct a teleconference meeting on Thursday, April 21, 2011, from 2 p.m. to 4 p.m., in Room GL20, 1722 I Street, NW., Washington, DC. The toll-free number for the meeting is 1–800–767–1750, and the access code is 57165#. The meeting is open to the public.

The purpose of the Committee is to advise the Secretary of Veterans Affairs on health care issues affecting enrolled Veterans residing in rural areas. The Committee examines programs and policies that impact the provision of VA health care to enrolled Veterans residing in rural areas and discusses ways to improve and enhance VA services for these Veterans.

The Committee will discuss the Committee’s Annual Report to the VA Secretary, VA Veteran Centers services, rural women Veteran health care, and the meeting agenda and planning for the Committee’s upcoming June 2011 meeting in Helena, Montana. A 15-minute period will be reserved at 3:40 p.m. for public comments. Individuals who wish to address the Committee are invited to submit a 1–2 page summary of their comments for inclusion in the official meeting record. Members of the public may also submit written statements for the Committee’s review to Christina White, Designated Federal Officer, Department of Veterans Affairs (10ASA), 810 Vermont Avenue, NW., Washington, DC 20420 or e-mail at rural.health.inquiry@va.gov. Any member of the public wishing to attend or seek additional information should contact Ms. White at (202) 461–7100.