Research Advisory Committee on Gulf War Veterans' Illnesses Comments and Recommendations Regarding New VA Gulf War Illness Research Program

March 1, 2011

Following its review of the Department of Veterans Affairs' (VA) Gulf War Illness research program at its February 28-March 1 meeting, the Research Advisory Committee on Gulf War Veterans' Illnesses (RAC) adopted the following recommendations on March 1, 2011.

In summary, the Committee calls on VA to suspend implementation of three large, resource-intensive Gulf War research projects, which have been advanced without adequate coordination or oversight, pending final approval of a strategic plan for research on Gulf War health issues and appropriate revisions to the three projects. The Committee also calls on VA to move swiftly to facilitate development and final approval of a comprehensive strategic plan for research on the health of Gulf War veterans by the VA Steering Committee on Gulf War Research.

Recommendation 1. The Committee recommends that VA temporarily suspend finalizing and implementing three major Gulf War research projects until a comprehensive Gulf War research plan is approved by the VA Steering Committee on Gulf War Research, and needed revisions are made to the projects. The three projects include: i) Follow-up Study of a National Cohort of Gulf War and Gulf War Era Veterans, ii) Gulf War Era Cohort and Biorepository (CSP #585), and iii) VA Gulf War Veterans' Illnesses Biorepository: Post-Mortem Collection of Tissue from Veterans of the 1990-1991 Gulf War (CSP #501).

The Committee strongly endorses the need for research in the areas addressed by the three projects. However, we are deeply concerned that these major projects, as currently designed, will be ineffective in achieving their fundamental purposes, and incapable of providing the necessary foundation for VA's Gulf War research program. The Follow-up Study of a National Cohort of Gulf War veterans, for example, neglects data collection in the health areas of greatest relevance to 1991 Gulf War veterans (e.g., Gulf War multisymptom illness, neurological diagnoses) while collecting extensive data in areas of lesser significance for this population (e.g., anxiety attacks, psychological stressors). Concerns related to the follow-up survey were previously outlined in the Committee's recommendations of November 2, 2010.

Few details of the other two Cooperative Studies Projects (CSP #585, CSP #501) were provided to the Committee. But the information that was provided raised concerns that the project plans do not reflect adequate expertise in Gulf War health research or appreciation of the urgent need for well-coordinated and focused projects that address priority research questions. For example, the anticipated timelines suggest the projects are unlikely to provide usable data for perhaps another decade. CSP #585, the Cohort and [Blood] Biorepository project, is currently designed to include a two-year pilot, followed by a 5-7 year blood collection period, after which analyses of blood samples can get underway. And, although VA announced plans for a Gulf War brain tissue bank over five years ago, current plans for CSP #501, the post-mortem tissue repository, are limited to a two-year pilot project. Data provided by both projects can potentially provide important insights for advancing diagnostic tests and treatments for ill Gulf War veterans. As designed, however, the two CSP projects fall far short of the coordinated scientific effort required for meaningful progress, and the extended timelines do not reflect the necessary urgency. Further, none of the projects has been reviewed by VA's steering committee for Gulf War research, which the RAC was informed one year ago was being established for this purpose.

<u>Recommendation 2.</u> The Committee recommends that VA act immediately to provide its Steering Committee on Gulf War Research with the information and resources necessary to develop a

comprehensive strategic plan outline for Gulf War research. The plan outline should be carefully developed in conjunction with scientists with expertise in Gulf War research and the specific disciplines to be addressed by the plan. The plan should be finalized by VA and approved by the Steering Committee as quickly as possible, so that the core research projects mentioned above can be appropriately revised and implemented without extended delay, after approval by the Steering Committee.

The need for a well-defined and coordinated research program to successfully address pressing questions related to the health of Gulf War veterans is apparent on its surface, and has been recommended by this Committee for many years. This need was echoed last year by the Institute of Medicine, who called for "detailed planning with access to the very best expertise" as the key to success in the rigorous Gulf War illness research program it recommended.

The lack of a well-managed, strategically-designed program has long undermined the success of VA's Gulf War research effort. Lacking an effective strategy, VA's Gulf War research has provided few results that hold promise for improving the health of Gulf War veterans despite substantial funding ordered by successive Secretaries. In recent years, this failure has been reflected in VA's allocation of major "Gulf War" research expenditures for expensive projects and equipment that, at best, have peripheral relevance to the health of Gulf War veterans. During the same period VA has funded a limited number of smaller projects randomly submitted by VA investigators, which have varying degrees of relevance to priority Gulf War health issues.

On the twentieth anniversary of Desert Storm, the Committee is dismayed that VA has yet to produce an effective Gulf War research program or effectively utilize the input of outside experts in creating one.