

Research Advisory Committee on Gulf War Veterans' Illnesses Findings and Recommendations

June 19, 2012

The Institute of Medicine, the Secretary of Veterans Affairs, and the United States Congress support a robust VA research program to identify treatments for Gulf War illness, the chronic multisymptom condition that destroys the quality of life of at least one in four of 697,000 U.S. 1991 Gulf War veterans.

- The 2010 Institute of Medicine Gulf War and Health Report recommended “a renewed research effort with substantial commitment to well-organized efforts to better identify and treat multisymptom illness in Gulf War veterans.” (pp. 260-261)
“Veterans who continue to suffer from these discouraging symptoms deserve the very best that modern science and medicine can offer . . . to speed the development of effective treatments, cures, and, it is hoped, preventions. . . [W]e believe that, through a concerted national effort and rigorous scientific input, answers can likely be found.” (p. x)
- Secretary of Veterans Affairs Eric Shinseki declared on Feb. 27, 2010, “At VA, we advocate for Veterans – it is our overarching philosophy and, in time, it will become our culture.”
“This new approach is the first step in a still unfolding comprehensive plan of how VA will treat and compensate Veterans of the Gulf War era.”
- In the Veterans Benefits Act of 2010, Congress directed VA to enter into an agreement with the Institute of Medicine “to carry out a comprehensive review of the best treatments for chronic multisymptom illness in Persian Gulf War veterans.”
“[U]nder [this] agreement, the Institute of Medicine shall convene a group of medical professionals who are experienced in treating individuals who served as members of the Armed Forces in the Southwest Asia Theater of Operations of the Persian Gulf War during 1990 or 1991 and who have been diagnosed with chronic multisymptom illness or another health condition related to chemical and environmental exposure that may have occurred during such service.” (Public Law 111-275)

These imperatives reflect the fundamental responsibilities of the federal government to address the medical health consequences of military service. They repeat similar imperatives voiced by Congress, VA Secretaries, and scientific advisory panels over many years. They are vital to the trust that is the foundation of a voluntary force. During those years, scientific evidence has conclusively demonstrated, as stated by IOM, that Gulf War multisymptom illness is a “diagnostic entity” “associat[ed] with deployment to the Gulf War” that “cannot be reliably ascribed to any known psychiatric disorder” and affects “more than 250,000 US Gulf War veterans.” Yet those responsible for VA research fail to mount even a minimally effective program, while promoting the scientifically discredited view that 1991 Gulf War veterans have no special health problem as a result of their service.

- The VA Gulf War research budget has been cut by two-thirds for FY2013, from \$15.0 to \$4.86 million. Of the \$15.0 million budgeted and approved by the Secretary and Congress for FY2012, only \$4.98 million was spent. The two-thirds cut was never discussed with the Research Advisory Committee, established by Congress to provide independent advice to the Secretary on proposed Gulf War health research plans [Appendix A].
- The VA Gulf War Research Strategic Plan has been changed from a focused strategy to execute the IOM's call for "a renewed research effort . . . to better identify and treat multisymptom illness in Gulf War veterans" into an unfocused expenditure of research money across any illness experienced by any Gulf War veteran. Under the changed plan, VA is not obliged to allocate any amount to Gulf War illness research. The VA Office of Research and Development can spend the \$4.86 million budgeted in FY2013 on any illness found in Gulf War veterans, however few, as they have been doing all along. The changes have also eliminated the urgency, focus, follow-up, and teeth built into the original plan by the working groups of VA personnel and expert outside advisors who wrote it. The new draft is not effective or acceptable. The Committee recommends that the working groups be reassembled under Dr. Maximillian Buja to revise the plan at such time as ORD is prepared to respect the IOM's recommendation [Appendix B].
- VA research officials continue to misrepresent to the Secretary of Veterans Affairs and to Congress, in the Annual Report(s) To Congress, the level of research dollars spent addressing the health of Gulf War veterans. The true figures are vastly overstated by the inclusion of funds spent on studies that have little or nothing to do with Gulf War veterans. [Appendix C].
- A new, mission-focused Institute of Medicine treatment study ordered by Congress in 2010 has been blatantly repurposed into an off-point literature review by a committee with no Gulf War illness expertise. The portions of the panel's work accessible to the public indicate that the information provided for review, including information provided by VA staff, is slanted to represent that Gulf War illness may be a psychiatric problem, despite conclusive evidence to the contrary, including the IOM's own 2010 report. Rather than provide insights into treatments for Gulf War illness and exposure-induced health problems, the report is likely to misrepresent current understanding of the problem and to misdirect future treatment and research -- the opposite result from that intended by Congress. [Appendix D]
- VA has never conducted the epidemiologic study ordered by Congress in 2008 to determine if service in the 1991 Gulf War resulted in an excess rate of multiple sclerosis in 1991 Gulf War veterans. [Appendix E].
- VA has recently commissioned a large survey of Gulf War era veterans that omits the questions necessary to identify Gulf War multisymptom illness, the major health problem of this group, while including excessive questions on stress and psychological problems. [Appendix F]

- VA's Gulf War research program is characterized in the VA annual research report ("State of VA Research 2012: Improving Veterans' Lives") as "investigating whether service in the Gulf War is linked to illnesses Gulf War veterans have experienced." The scientific literature, this Committee, and the IOM have long ago concluded that it is. Other VA research programs are characterized in the annual report in terms of solving veterans' health problems, not investigating whether service-related problems exist. This same language is used to characterize the Gulf War research program on the VA Office of Public Health website. These are no mere words of an aberrant copywriter. They are an articulation of the philosophy that is exhibited throughout these examples. [Appendix G]

These actions repeat the pattern of the last twenty-one years, as has been documented in Congressional reports over this period. (See, for example, "Gulf War Veterans Illnesses: VA, DOD Continue To Resist Strong Evidence Linking Toxic Causes To Chronic Health Effects," Nov. 1997) [Appendix H].

Given the current state of scientific knowledge, they are particularly stark today: the refusal to implement the recommendation of the Institute of Medicine, the policy of the Secretary, and the law; the misrepresentation of scientific knowledge regarding Gulf War veterans' health and of the effort being made to address it; the failure to acknowledge that the central health problem of this war even exists.

The Research Advisory Committee has no confidence in the ability or demonstrated intention of VA staff to formulate and execute an effective VA Gulf War illness research program. Staff includes the Office of Research and Development, the Office of Public Health, and personnel from the DoD Office of Force Health Protection and Readiness who interface with them on this subject. The Committee recognizes the credible work conducted by many individual VA researchers, and the positive intentions of some staff members, but they are not the ones calling the shots.

The Committee recommends that the failures and obstructive actions outlined above be thoroughly investigated to identify the individuals responsible and that appropriate actions be taken to remove them from positions of authority and influence over Gulf War illness research. Until this occurs, we see no prospects for meaningful progress in VA Gulf War illness research.

Appendix A: Reduction in VA Gulf War Research Budget

Research and Development Program Funding (dollars in thousands)					
Description	2011 Actual	2012		2013 Request	2012-2013 Inc/Dec
		Budget Estimate	Current Estimate		
OEF/OIF/OND					
Pain.....	\$11,961	\$10,531	\$11,961	\$13,961	\$2,000
Post deployment Mental Health.....	\$41,143	\$39,203	\$41,143	\$46,043	\$4,900
Sensory Loss.....	\$23,731	\$23,076	\$23,731	\$23,166	(\$565)
Spinal Cord Injury.....	\$30,204	\$32,870	\$30,204	\$29,486	(\$718)
Traumatic Brain Injury and Other Neurotrauma.....	\$21,464	\$18,528	\$24,464	\$28,564	\$4,100
Prosthetics.....	\$17,393	\$11,674	\$17,393	\$17,393	\$0
Women's Health.....	\$10,654	\$11,935	\$11,935	\$11,935	\$0
Gulf War Veterans Illness.....	\$4,980	\$15,013	\$4,980	\$4,862	(\$118)

Million Veteran Program (MVP) Budget (dollars in thousands)				
2010 Actual	2011 Actual	2012 Current Estimate	2013 Budget Estimate	
MVP enrollment, sample collection and research.....	\$645	\$12,286	\$19,889	\$27,110

http://www.va.gov/budget/docs/summary/Fy2013_Volume_II-Medical_Programs_Information_Technology.pdf (p. 3A-5)

The official VA budget for FY2013 cuts Gulf War illnesses research two-thirds from \$15 million in the FY12 budget to \$4.86 million for FY13. VA's budget presentation (above) attempts to minimize this cut by comparing the FY13 budget to the amount actually spent in FY12, \$4.98 million. Far from excusing the cut, this means that staff also cut Gulf War illness research spending in FY12 by two-thirds compared to what Congress and the Secretary approved. The Million Veteran Program has been increased approximately by the amount cut from GWI.

The FY13 budget cut was never revealed to the Research Advisory Committee on Gulf War Veterans' Illnesses prior to being implemented, contrary to the statute that created the Committee, which states that the purpose of the Committee is "to provide advice to the [Secretary of Veterans Affairs] on proposed research studies, research plans, or research strategies relating to the health consequences of military service in the Southwest Asia theater of operations during the Persian Gulf War." Public Law 105-368.

VA Office of Research and Development (ORD) staff attempts to explain the cut on the grounds that VA researchers are not interested in Gulf War illness research. To the contrary, VA researchers account for approximately one-half of the projects funded by the DoD CDMRP Gulf War illness research program, often the same projects rejected by VA. The reality is that ORD has chosen to fund only four new investigator-initiated Gulf War illness research proposals in the three years of the current administration (two others are scheduled to be announced shortly).

ORD has done little to attract VA researchers to this topic. Gulf War Illness research is not among the eighteen topics currently mentioned on VA's research website [see: http://www.research.va.gov/outreach/research_topics/default.cfm] ORD and OPH characterize the VA Gulf War research program as investigating "whether" the health problems of Gulf War veterans are related to their service (see Appendix G).

Even more significantly, ORD frequently provides funding for top-down research projects on subjects of interest to them. The vast majority of the research expenses listed in the VA Gulf War research portfolio are for these kinds of projects, such as the \$5.7 million, \$586,000, and \$938,000 spent in FY09, FY10, and FY11 on the "Gulf War Biorepository Trust" (as named by VA staff, although it is really an ALS brain bank for veterans of all eras and includes only a handful of Gulf War veteran samples) and the \$5.5 million spent toward the purchase of an MRI scanner in FY10 [Appendix C]. The strategic plan contains multiple legitimate GWI research topics that urgently require scientific study and could be addressed through such ORD-initiated projects.

Appendix B: Changes That Undermine the Gulf War Research Strategic Plan

The Gulf War Research Strategic Plan was prepared over a five month period in 2011 and early 2012 by ten working groups of 5-8 individuals made up of VA staff members and scientific experts from the Research Advisory Committee on Gulf War Veterans' Illnesses (RAC), VA's Gulf War Steering Committee (GWSC), and VA's National Research Advisory Council (NRAC). The strategic plan was designed to implement the 2010 Institute of Medicine Gulf War and Health report, which called for a renewed research effort to identify and treat multisymptom illness in Gulf War veterans. Over the past four months, VA staff has unilaterally changed this plan to reverse its intent.

Itemized below are some of the specific changes made to the Gulf War Research Strategic Plan developed at considerable effort by the working groups. Taken together, these changes fundamentally undermine the plan's utility to establish a program capable of achieving tangible results.

1. Focus on Treatments for Gulf War Illness and Potential for Success. The 2010 IOM Gulf War and Health report specifically recommended a two-branch research program. The first branch was continued surveillance of Gulf War veterans. The second was "a renewed research effort with substantial commitment to well-organized efforts to better identify and treat multisymptom illness in Gulf War veterans . . . to alleviate their suffering as rapidly and completely as possible." [41] The purpose of the strategic plan was to implement this recommendation.

This language and goal from the IOM report has been eliminated from the strategic plan in both the Executive Summary (1.0) and in the Introduction/ Background section (2.1). The following text was also deleted from both sections:

"In the preface to the report, the chairman of the IOM committee, Dr. Stephen Hauser, a former president of the American Neurological Association, emphasized the need 'to speed the development of effective treatments, cures, and, it is hoped, preventions.' He stressed that the committee regarded this goal as achievable: 'We believe that, through a concerted national effort and rigorous scientific input, answers can likely be found.' "

In addition to eliminating the very purpose of the plan, deleting these passages, which conveyed the importance and hope given to this research by the Institute of Medicine and the highly respected Dr. Hauser, is manifestly inconsistent with attracting new researchers to this field of work.

In place of the IOM's inspiring call for a "renewed," "substantial," "well-organized," and "rigorous" research program to identify treatments for multisymptom illness, staff has substituted in the Executive Summary a bland statement that:

"VA is committed to studying and treating chronic multisymptom illness and any other conditions affecting Gulf War Veterans. No Veteran should feel that his/her particular ailment is less important to VA than any other."

The hard message underlying this statement is that even the \$4.86 million remaining in the Gulf War illness research budget will not be spent on Gulf War multisymptom illness. It can be spent wherever ORD chooses, as ORD has been doing all along (see Appendix C). There will be no robust new research program targeting treatments for Gulf War illness. And, as a result, answers will not be found.

3. Priorities. In Section 4.0, after the sentence ending “. . . the present *Gulf War Research Strategic Plan 2012-2016* identifies the areas of research that appear most likely to succeed in providing new information that will help Gulf War Veterans,” the following sentence has been deleted:

“Such a careful prioritization, based on the best knowledge available at this time, is essential when research funding has finite limits.”

The original draft, as it came out of the working group process, contained priority rankings (A = find funding to do; B = do if funding available in the GWI research budget; C = do only if funding available outside the GWI research budget). The priorities had already been removed by unilateral ORD action prior to the January 23 draft, so they do not appear in that draft either. Prioritization made the difference between the plan being an action plan and a "laundry list" from which research administrators can choose to do (or not to do) pretty much anything.

4. Treatments for Gulf War Illness. The initial sentence of the Treatments section (5.1) of the plan has been revised so that its overall goal is now to find treatments for “ill Gulf War veterans.” These “include” clinical studies to evaluate treatments in chronic multisymptom illness, but by implication also include treatment studies of ALS, MS, and any other disease found in Gulf War veterans. As in the changes to the Executive Summary section, the strategic plan has been changed from a plan focused on a specific condition (variously referred to as Gulf War illness, Gulf War illnesses, and chronic multisymptom illness) to a license to spend Gulf War funding on other diseases where Gulf War veterans constitute only a tiny fraction of the veteran population, as has been ORD’s practice. ORD’s own reports (see Appendix C) reveal that the majority of the treatment studies listed in the VA Gulf War research portfolio are for treatments of ALS and MS, not Gulf War illness.

Section 5.1.5 in the January plan set a goal of up to twenty pilot studies of treatments for Gulf War illness during the five years of the plan and established a Treatment Research Coordinating Center to identify potential pilot study hypotheses and coordinate several pilot studies per year. It suggested the Salt Lake City VAMC as a logical site because of interest expressed there. The revised plan transforms the Center into a “virtual” Treatment Research Coordinating “Activity,” located nowhere, and eliminates any specific numerical goal, even one expressed as “up to.” It must be noted that in the entire tenure of the current administration, notwithstanding the emphasis placed on Gulf War illness by VA leadership and notwithstanding the universal agreement that the identification of effective treatments should be the highest research priority, ORD has funded only four GWI treatment studies, three of which are studies of general therapies that may benefit any chronic disease (exercise, mindfulness, antidepressants), rather than therapies targeted at specific suspected mechanisms of Gulf War illness (as done by studies funded by the DoD CDMRP Gulf War illness research program). A

new GW research portfolio for FY2012, provided by ORD at this meeting, lists a magnetoencephalography study as a treatment, but it is a diagnostic marker study.

5. Database/Surveillance (Sec 5.2). Changes to the Database/Surveillance section (5.2) take the teeth out of its goals and objectives. For example, instead of the goal to "Form a Gulf War Era Veterans' data repository that links federal datasets" ... it now reads "Investigate the feasibility of developing a data repository..." The overall effect is one of watering down the bulleted directives in the plan, moving them from objectives to be accomplished to ideas to potentially pursue.

In addition, this section previously included directives involving other offices within VA—e.g., OPH and the VA Center for Veterans' Statistics—and identified specific changes/improvements to achieve regarding the surveillance/database efforts conducted by those offices. The revised plan weakens this by, for example, changing the language from "Enhance the statistical reporting capabilities in VA's Pre-9/11 Report" in the January draft to "Work with VA's National Center for Veterans Analysis and Statistics to enhance the statistical reporting capabilities of VA's 9/11 Report." The same types of changes were made regarding the OPH Longitudinal Survey.

These changes emphasize that the strategic plan is only an ORD plan, rather than a VA-wide plan. This problem is reflected throughout the strategic plan. These concerns were discussed in detail with ORD and OPH staff at the Jan. 31-Feb 1, 2012 meeting of the RAC (augmented by both GWSC and NRAC participants). At the suggestion of VA staff, the Research Advisory Committee made recommendations that the plan be approved by other VA offices involved in collecting data related to the health of 1991 Gulf War veterans and in otherwise carrying out the plan. Yet after four and a half months of further revisions by staff, the plan remains only an ORD plan.

6. No mention of Gulf War illness. The term "Gulf War illness" is the most common term used for the multisymptom condition that is the signature health problem of the 1991 Gulf War. It is used for this purpose by the Department of Defense in its Gulf War illness research program, by Congress, by the RAC in its 2008 report, and by nearly all U.S. and international scientists conducting research in this area. In the 2010 IOM report, "Gulf War illness" is used interchangeably with "chronic multisymptom illness" or "multisymptom illness" (e.g., "[I]t is likely that Gulf War illness results from an interplay of genetic and environmental factors." p. 261)

Throughout the revised strategic plan, however, VA staff have deleted any impression that there is such a thing as a "Gulf War illness". They retained this term only in statements directly quoted from CDMRP, IOM, and the RAC. But in the text of the plan itself, there is no mention of any illness special to the Gulf War. Some mentions of Gulf War illness in the prior draft were changed to the plural "Gulf War Veterans Illnesses" but most were changed to the generic "chronic multisymptom illness." This was especially stark (and odd) in the case definition section, which now calls for the development of a case definition for "chronic multisymptom illness."

VA's unwillingness to acknowledge that Gulf War veterans have an illness that resulted from Gulf War service—in the strategic plan and in other prominent research documents -- continues to undermine any credible efforts to address this problem. It makes for some tortured logic when a strategic plan originally intended to address a serious and widespread problem does not ever directly mention it.

7. Gulf War Illness Case Definition. The urgent need for a consensus case definition for Gulf War illness stems from the lack of consistency in how this condition has been characterized in different studies. At least ten different methods have been used, making it difficult to compare results across studies.

The purpose of the original Case Definition section (5.3) was to identify the specific steps required to develop a consensus, evidence-based case definition for Gulf War illness in a timely manner. This task was viewed by the working group as particularly urgent, to ensure that all research conducted under the strategic plan would be comparable and adhere to essential standards. There is no need, however, to establish a case definition for the more generic “chronic multisymptom illness,” as directed by the revisions made to the Strategic Plan. “Chronic multisymptom illness” is a general term that can be used for any health problem defined by its symptoms, as found in any population including, for example, fibromyalgia or chronic fatigue syndrome. As documented by multiple studies, these other symptom-defined conditions are poor descriptors of the Gulf War illness problem, and differ from it in important ways.

In addition to the deletion of the concept of Gulf War illness, other deletions that weaken the earlier draft include: 1) a statement that ORD would fund a comprehensive case definition effort, conducted by the most qualified research team; 2) the objective of a targeted timeline, and a table that provided a timeline for developing a case definition, listing specific objectives and milestones; 3) a paragraph outlining the scientific rationale for using the Kansas definition on an interim basis; 4) a section that summarized the overall goals and objectives for the process, emphasizing that the newly-established criteria be developed expeditiously, be evidence-based, and that the consensus panel should include researchers with expertise in Gulf War research and veterans with GWI, and would include members recommended by the RAC and GWSC.

8. Genetics/Genomics. Section 5.4 addresses the opportunity to understand the underlying mechanisms of Gulf War illness through modern genetic/genomic analysis. The IOM placed a high value on the potential benefit of this work, as indicated in Section 5.4.2. The basis for this analysis is the collection and analysis of large numbers of blood samples. The collection from a cohort of Gulf War veterans is planned to be undertaken by VA project CSP 585. As to analysis, the plan states only that ORD will both conduct ORD-initiated studies and fund investigator-initiated studies (once the collection has taken place).

The section also references the Million Veteran Program as a possible source of replicating findings made in the CSP 585 cohort. It also references as “other cohorts” the ALS brain bank (CSP 501) and the “Gulf War Veterans Illnesses Biorepository” (CSP 501B).

This section illustrates the importance of the prioritizations that were removed from the plan by ORD following the conclusion of the working groups' draft and before the January 23 draft. The genetic/genomic component of the research effort is based on CSP 585. CSP 585 was prioritized as an "A" (find a way to do it) by the working groups. CSP 585 has been funded at a level of \$28,000 in FY10, \$5,000 in FY11, and is projected at \$1.9 million in FY12.

On the other hand, CSP 501, the VA-wide ALS brain bank, which has little to do with genetics/genomics and which has only "four or five" Gulf War veteran brains out of eighty-eight (although it has been entitled the "Gulf War Biorepository Trust" in VA's Gulf War research reports), has been funded at levels of \$5.6 million in FY09, \$586,000 in FY10, \$938,000 in FY11, and a projected \$561,000 in FY12. CSP 501 was prioritized as "C" (do only if funds are available from other budgets) by the working group process. CSP 501 may be a fine project, but it is not "Gulf War."

The Million Veteran Program (CSP G002) was also prioritized as "C" by the Gulf War working group process. That program is projected at \$27.1 million in FY13. While it does not appear in ORD's portfolio report of Gulf War research, its funding in the FY13 VA research budget has been increased by \$7.2 million over FY12 (from \$19.9), while budgeted GWI research has been decreased by \$10.1 million (from \$15.0 to \$4.9).

Without prioritization, Gulf War money can be spent on any project referenced in the plan in whatever amount ORD chooses.

The plan states that the recruitment phase of the blood collection project will not be completed until two years into the five year plan. Thus the actual collection of blood, and the conduct of studies using the blood, lie in the more distant future. The plan states that some "smaller" genetic studies will be completed within the five-year plan.

The Research Advisory Committee has recently learned that 2000 Gulf War veteran blood samples were obtained by VA last year from the University of Texas Southwestern Medical Center. Thus, VA already possesses the blood samples necessary to move from the collection stage to the analytical stage for genomics/genetics studies. Yet VA staff has not even mentioned the availability of these samples in the strategic plan or to the Research Advisory Committee, let alone initiated any research projects, either ORD-initiated or investigator-designed, as envisioned by the plan once blood samples are available.

It is well known that studies of twins represent a singularly efficient and productive opportunity for genetics/genomics research. Because identical twins share virtually all their genetics, genetic differences between sick and well twins are readily identifiable and can be found in relatively small groups, although they might remain obscured in thousands of random subjects. The January strategic plan developed by the working groups included the development of a twin registry of Gulf War era veterans, noting its "transformative impact on our ability to understand the long-term health consequences of having served in the Gulf War." (Section 5.2.6) The twin registry has been deleted from the plan.

9. Biomarkers for Gulf War illness. The revised Biomarkers section (5.5) adds language that “the focus [of the plan] will be to identify biomarkers that are elevated at baseline assessment” (Section 5.5.5) While baseline assessments are important, prior studies have repeatedly shown that abnormal results are often only detected in tests that challenge body systems, not in baseline studies.

The revised plan further adds that the detailed biomarker studies listed in Section 5.5.5 will only be conducted “for areas where initial biomarkers of discovery have shown promise.” Since the baseline assessments will often not “show promise,” actual VA research will never get to the detailed studies identified by the working groups.

These alterations are the latest example of the “don’t look, don’t find” approach that has driven so much Gulf War research for two decades, focusing research on the wrong subjects, and producing limited or misleading findings.

References to past studies showing “measures indicative of vulnerability to neurotoxicants (i.e., genetic risk factors including PON1 status)” have been removed. (See language in Section 5.5.5 in January draft, now in Section 5.5.1.)

10. Research using Animal Models for Gulf War illness. The Animal Studies section (5.6) is illustrative of the removal from the strategic plan of the sense of urgency expressed in the IOM report and the January version of the plan. The IOM report’s call for “a renewed research effort . . . to better identify and treat multisymptom illness in Gulf War veterans” has been edited to delete the words “to alleviate their suffering as rapidly and completely as possible.” (5.6.2) “Urgent” has been removed from the “need to identify therapies,”(5.6.1), and “rapidly” has been removed from the “need to utilize the data obtained . . . to implement off-the-shelf therapies for GWI.” (5.6.5)

11. Research Coordination. The Coordination Section (5.7) has been eliminated in large part. The coordination working group envisioned that, rather than throwing the strategic plan over the wall and hoping for the best, the Gulf War Steering Committee should continue to advise ORD in the ongoing execution of the plan. This model of VA staff working together with outside experts had proved highly productive in the creation of the strategic plan itself. This process had produced a plan that was generally applauded by all concerned, and had proved to be a much more effective use of outside advisors than the usual practice of VA staff acting first and then having to deal with expert advisors’ criticisms.

The concept of utilizing an expanded Gulf War Steering Committee to perform this role, as developed over several pages, has been removed from the plan. In its place is a bland statement that meetings of the GWSC will be conducted “as needed” and members will be added “as appropriate.” It is well remembered by those who serve on the GWSC that it was never called to meet for over a year while ORD put together its Gulf War research effort in 2010 and 2011.

In discussions, VA staff attempted to justify this change on the grounds that advisors cannot be permitted to run VA programs, such as to terminate a research project: these decisions and

actions fall within the purview of VA staff. This is, of course, true. If there was language in the January plan that suggested otherwise, it could have easily been clarified.

12. In summary, the strategic plan has been transformed from an action plan to execute the research program recommended by the IOM to a license to continue the VA research policies of the past. The focus on Gulf War illness treatments research, the commitment to a substantial program, a sense of urgency, specific goals, and follow-on mechanisms to monitor and enhance the effective implementation of the plan have been deleted. What remains contains some good ideas, but there is no commitment on the part of VA staff to carry them out. To the contrary, they have reserved to themselves the selection of which parts of the plan will be executed and which will not, as well as to continue to spend "Gulf War" resources on diseases nowhere addressed in the plan except to note that Gulf War veterans may also have them. Taken as a whole, the changes to the plan, together with the other changes implemented over the past five months by VA staff, indicate a continuation of past practices to underfund and misdirect Gulf War illness research, and to perpetuate the myth that nothing special happened to the health of veterans who served in the 1991 Gulf War.

It is particularly tragic to see these practices continuing in 2012, when other scientific research in this area shows such promise and progress. As summarized by Dr. Stephen Hauser, chairman of the IOM Gulf War and Health committee: "Veterans who continue to suffer from these discouraging symptoms deserve the very best that modern science and medicine can offer . . . to speed the development of effective treatments, cures, and, it is hoped, preventions. The committee suggests a path forward to accomplish these goals and we believe that, through a concerted national effort and rigorous scientific input, answers can likely be found."

Perhaps the most honest edit of the strategic plan by VA central office staff was the deletion of "answers can likely be found" under their plan.

Appendix C: Misrepresentation of Gulf War Research Expenditures

VA staff provided the following spreadsheet reports on VA Gulf War research spending for FY09, FY10, and FY11. These reports form the basis for VA Gulf War research totals reported to the Secretary and to Congress in the Annual Report to Congress on Federally Sponsored Research on Gulf War Veterans Illnesses, which is mandated by statute (Section 707 of Public Law 102-585, as amended by section 104 of Public Law 105-368 and section 502 of Public Law 111-163).

As described in the following analyses by Research Advisory Committee staff, the reports consistently misrepresent as Gulf War research, expenditures that have little or nothing to do with Gulf War veterans. For example, the reports include \$5.6 million in FY09, \$586,000 in FY10, and \$938,000 in FY11 for a project entitled the "VA Gulf War Biorepository Trust." In fact, this project is an ALS brain bank, covering veterans of all eras. At last report, it included only "four or five" Gulf War brain samples out of eighty-eight total. (It is disingenuous to suggest, as VA staff now does after the fact, that this ALS project was necessary to prepare the way for a true Gulf War brain bank, as the organization conducting the project has long possessed the necessary experience.) Another example is the \$5.5 million expenditure listed on the FY10 report, representing part of the purchase of a 7-Tesla MRI scanner, although the recipient of the scanner had no current study protocol or grant submission identifying any Gulf War-related use of this equipment. The Gulf War study listed in the VA report had already been completed using a different piece of equipment.

The reports have further inflated the totals by identifying studies on diseases such as ALS and multiple sclerosis as "Gulf War" research. While ALS is disproportionately found in Gulf War veterans, it is service-connected for veterans of all eras and affects fewer than one hundred Gulf War veterans, who constitute only a tiny fraction of U.S. veterans with ALS. Multiple sclerosis also affects veterans of all eras and has not been determined to disproportionately affect Gulf War veterans (VA refuses to conduct such a study). Attributing 100% of ALS and MS research as Gulf War research grossly misrepresents and overstates the amount of federal expenditures for Gulf War research. The reports also include expenditures in diverse other areas that do not involve Gulf War veterans, such as "Understanding Pain of Gastrointestinal Origin in Women That Serve in OEF/OIF" (the current Iraq War).

Apart from the research program at the University of Texas Southwestern, which was cancelled by VA in 2009, only a small part of the studies reported relate to Gulf War illness, the chronic multisymptom condition that is the signature health problem of this war.

(Updated reports provided by ORD to the Committee at this meeting show total expenditures for FY2011 of \$5,977,000 compared to \$5,727,000 shown below. The updated reports also show projected FY2012 expenditures at \$6.8 million. The discrepancy between these numbers and those in the official FY2013 VA budget --see Appendix A -- is unexplained.)

Analysis of Research Projects Included in VA Gulf War Research Portfolio FY2009-2010

On June 28, 2010 and November 1, 2010, VA's Office of Research and Development (ORD) provided the Research Advisory Committee (RAC) with spreadsheets containing information on all projects included in VA's FY2009 and FY2010 Gulf War research portfolios. The following analysis summarizes this information.

RAC staff reviewed information on studies in the FY2009 Gulf War research portfolio to identify the research questions addressed by each project. Projects were then classified according to the degree the study focused on questions relevant to Gulf War service and the health of Gulf War veterans. Results of these analyses are summarized below.

Funding for Projects Included in the VA FY2009 Gulf War Research Portfolio

Total Funding for Projects Identified as Gulf War Research	\$ 15,658,015	100%
Gulf War-related conditions and effects of Gulf War exposures UTSW program: \$6,972,481 (45%) Other projects: 1, 715,397 (11%)	\$ 8,687,878	56%
Projects with more remote relevance to Gulf War veterans' health	\$ 653,172	4%
ALS, Gulf War-specific	\$ 651,989	4%
ALS, General (brain bank)	\$ 5,664, 976	36%

Approximately \$8.6 million (56%) of ORD's FY2009 Gulf War research portfolio funding was for projects focused on issues specifically relevant to the health of Gulf War veterans. However, \$6.9 million dollars of this amount went to fund the University of Texas Southwestern Gulf War Veterans Research Program contract. In addition, Gulf War relevant funding included \$600 thousand (4%) for projects that study symptoms or processes that may relate more peripherally to Gulf War-related conditions and about \$650 thousand (4%) for ALS studies that include a research question relevant to Gulf War service including gene-environment interactions.

Approximately 36% of the total funding in ORD's FY2009 Gulf War research portfolio represented \$5.6 million for a single project called the "VA Gulf War Biorepository Trust." This project was originally presented by ORD to the committee in 2005 as a Gulf War brain bank, in response to a recommendation to create such a brain bank in the committee's 2004 report. In fact, it has been established as an ALS brain tissue bank that does not specifically focus on Gulf War veterans. Of the 61 brains harvested from this program to date, only 1 donor brain came from a Gulf War veteran.

The inclusion of the VA ALS brain bank in the Gulf War portfolio when brain tissue from only 1 Gulf War veteran with ALS has been obtained to date leads to a misperception that VA is spending more to conduct research on the health of Gulf War veterans than is actually the case, particularly since this funding makes up 65% of the FY2009 Gulf War Research portfolio excluding UTSW.

Funding for Projects Included in the VA FY2010 Gulf War Research Portfolio

Total Funding for Projects Identified as Gulf War Research	\$ 13,688,223	(100%)
Studies of GW veterans health and effects of GW exposures UTSW program: \$2, 288,755 (16%) Multisymptom illness: \$1,473,040 (11%) ALS study involving GW veterans: \$353,309 (2%) MS study involving GW veterans: \$120,888 (1%)	\$4,115,104	30%
Projects with more remote relevance to Gulf War veterans' health (7 Tesla MRI system at SFVA)	\$ 5,135,117	38%
ALS, General CSP #567 computer therapy for ALS: \$2,366,460 (17%) CSP #501 ALS brain bank: \$586,413 (4%)	\$ 2,954,873	22%
Other unrelated studies MS, General: \$918,843 (7%) Pain, General \$566,280 (4%)	\$1,485,123	11%

Approximately \$4.1 million (30%) of ORD's FY2010 Gulf War research portfolio funding was for projects focused on issues specifically relevant to the health of Gulf War veterans. Of this amount, 16% went to fund the final approved projects from the University of Texas Southwestern research contract. Only 14% was for ORD-generated projects.

Approximately, \$5.1 million (38%) of the total FY2010 Gulf War research portfolio represented part of the purchase of a single piece of equipment, a 7-Tesla MRI scanner for the San Francisco VA. Funding for this equipment was considered as having remote relevance to Gulf War veterans' health because to date there is no submitted study protocol or grant submission that would identify what the Gulf War-related use of this new MRI scanner will be, while it is acknowledged that the machine will be also be used for researching a wide range of non-Gulf War conditions. The fact that this funding is attributed to a now completed 4-Tesla MRI study by SFVA researchers appears misleading in that it suggests that more funds are being allocated to Gulf War research than is actually the case.

In addition, approximately 22% of the total funding in ORD's FY2010 Gulf War research portfolio included funding for generic ALS studies that do not specifically relate to Gulf War veterans. This included \$2.4 million for "CSP 567, A Clinical Demonstration of an EEG Brain-computer Interface for ALS Patients" and \$586,000 for the CSP 501A study entitled, 'VA Gulf

War Biorepository Trust.’ Although originally introduced to the RAC committee in 2006 as a ‘Gulf War’ tissue bank and listed as the “Gulf War Brain and DNA Bank” on the spreadsheet, this project is in fact an ALS brain tissue bank. Of the 61 brains harvested from this program to date, only 1 donor brain came from a Gulf War veteran. While ALS research is certainly important, and this condition has been shown to affect Gulf War veterans at twice the rate of nondeployed veterans, only about one hundred Gulf War ALS cases have been identified to date, and the vast majority of cases in the VA system are veterans of other eras. To include all generic ALS research in the Gulf War portfolio leads to a misperception that VA is spending more to conduct research on the health of Gulf War veterans than is actually the case.

In addition, the FY2010 Gulf War Research portfolio includes about \$1.5 million for projects that have little clear relevance to the health of Gulf War veterans. The majority of these projects address basic research questions or treatment trials relating to symptoms or conditions that, like ALS, may be found in Gulf War veterans but are not specific to the Gulf War (e.g. multiple sclerosis, pain conditions). Further, the research questions addressed by these projects appear to be unrelated to the development of these conditions in Gulf War veterans.

In summary, over two-thirds (70%) of the funding for the FY2010 Gulf War Research portfolio continues to be for projects that are either unrelated or not specific to Gulf War service and the health of Gulf War veterans or is related to equipment costs that will not primarily service Gulf War related research. Most prominently, the ALS brain bank, ALS-related CSP treatment trial, and several additional treatment trials (MS, pain conditions) that are not Gulf War specific, are identified as “Gulf War Research.”

Projected FY2009 ORD Support for Ongoing Gulf War Research Projects

FullName	VAMC	Title	Focus	Total FY 2009*	Start Date	End Date
Clinical Trials				\$ 18,196		
Amin, Mohammad M	Northport, NY	Inspiratory flow dynamics during sleep in GWS & the effect of CPAP	Prevalence and treatment of sleep disturbances in GW veterans	\$ 9,819	10/16/05	10/15/08
Tuteja, Ashok K. (M.D., M.P.H.)	Salt Lake City, UT	Diarrhea-Predominant Irritable Bowel Syndrome in Persian Gulf Veterans	Treatment of GW veterans with gastrointestinal symptoms		01/01/06	12/31/09
Lin, Henry C. (M.D.)	Albuquerque, NM	Bacterial Overgrowth Associated with Chronic Multi-Symptom Illness Complex	Treatment of GW veterans with gastrointestinal symptoms	\$ 8,377	10/01/08	09/30/11
Biomarkers				\$ 7,327,628		
Fiora, Louis D. (MD)	Boston, MA	VA Gulf War Biorepository Trust	Gulf War Brain and DNA Bank	\$ 5,664,976	08/01/02	09/30/08
Klimas, Nancy G. (M.D.)	Miami, FL	Immunologic Mechanisms and Biomarkers in Gulf War Illness	Immune dysfunction as a mediator of persistent illness in both CFS and Ill GW veterans	\$ 56,200	01/01/06	12/31/09
Molina-Vicenty, Hector D. (M.D.) Blanchard, Melvin (M.D.) Reda, Domenico J. (Ph.D.)	St. Louis, MO	Evaluation of Stress Response Systems in Gulf War Veterans with CMI	Autonomic system and neurohumoral dysregulation in Gulf War veterans	\$ 93,226	10/01/04	03/31/09
Oddone, Eugene Z. (M.D.)	Durham, NC	Genetic Epidemiology of ALS Veterans	Identify genes that may confer susceptibility to the development of ALS and examine the interplay between environmental exposures and genetic susceptibility to ALS	\$ 377,557	07/01/08	09/30/12
Pasinetti, Giulio M. (M.D., Ph.D.)	Bronx, NY	Biomarkers Discovery in ALS	Identification of biomarkers for ALS in CSF and serum from Gulf War veterans	\$ 274,432	07/01/07	06/30/09
Cook, Dane B. (Ph.D.)	East Orange, NJ	Functional Imaging of Pain in Veterans with Unexplained Muscle Pain	Functional imaging of Gulf War veterans with unexplained musculoskeletal pain	\$ 300,782	10/01/08	09/30/12
Weiner, Michael W. (M.D.)	San Francisco, CA	Effects of Gulf War Illness on Brain Structure, Function and Metabolism: MRI/MRS at 4 Tesla	Magnetic Resonance Imaging (MRI) and Spectroscopy (MRS) of Gulf War veterans	\$ 560,455	01/01/05	12/31/09
Gulf War Veterans Illnesses				\$ 750,294		
Li, Mian (M.D., Ph.D.)	Washington, DC	Autonomic Functions of Gulf War Veterans with Unexplained Illnesses	Autonomic dysfunction as an underlying cause of unexplained symptoms in GW veterans	\$ 25,880	09/30/06	12/31/08
Li, Mian (M.D., Ph.D.)	Washington, DC	Motor Neuron Function of Gulf War Veterans with Excessive Fatigue	Loss or damage of motor nerve cells in GW veterans with muscle and joint pain, muscle spasm, or fatigue	\$ 79,242	09/30/06	12/31/08
Bach, Ronald R. (Ph.D.)	Minneapolis, MN	Tissue Factor and Gulf War-Associated Chronic Coagulopathies Gulf War-Associated Chronic Coagulopathies: Tissue Factor, Coagulation, and Immune System Activation	Impaired blood flow and circulation as a cause of cognitive difficulties, somatic pain, fatigue	\$ 273,861	04/01/06	9/30/209
Diamond, David M. (Ph.D.)	Tampa, FL	Effects of Stress on Memory: Brain Circuits, Mechanisms and Therapeutics	Neurobiological basis of memory and development of new therapies for memory storage and retrieval dysfunction	\$ 241,520	04/01/05	03/31/09
Mitchell T. Wallin (M.D., M.P.H.)	Washington, DC	Multiple Sclerosis in Gulf War Veterans	Evaluation of the risk of developing MS in GW veterans	\$ 137,791	10/01/07	09/30/10

* Includes 12.4% administrative overhead (all projects except IDIQ Contract)

Projected FY2009 ORD Support for Ongoing Gulf War Research Projects

FullName	VAMC	Title	Focus	Total FY 2009*	Start Date	End Date
Animal Models of GW Exposures				\$ 581,415		
Shetty, Ashok (Ph.D.)	Durham, NC	Behavior of Neural Stem Cells in a Rat Model of GWS	Effects of pyridostigmine bromide, DEET, and permethrin	\$ 273,801	04/01/07	03/31/10
Mullan, Michael (M.D., Ph.D.)	Tampa, FL	Proteomic Analysis of Cellular Response to Biological Warfare Agents	Effects of pyridostigmine bromide, DEET, and permethrin	\$ 112,400	04/01/06	03/31/09
Panter, Scott (Ph.D.)	San Francisco, CA	Direct Delivery of Neurotoxins to the Brain by an Intranasal Route	Effects of pyridostigmine bromide, DEET, and permethrin	\$ 195,214	01/01/06	12/31/09
				\$ 8,685,533		
				Total Distributed by ORD in FY 2009		
UTSW Medical center	Dallas, TX	Gulf War Veterans Illnesses' Research IDIQ Contract		\$ 7,108,530		
				\$ 15,794,063		
				Total Distributed (ORD) and Obligated (Contract) in FY 2009		

Projected FY2010 ORD Support for Ongoing Gulf War Research Projects

FullName	VAMC	Title	Focus	Total FY 2010*	Start Date	End Date
Clinical Trials				\$ 291,175		
Tuteja, Ashok K. (M.D., M.P.H.)	Salt Lake City, UT	Diarrhea-Predominant Irritable Bowel Syndrome in Persian Gulf Veterans	Treatment of GW veterans with gastrointestinal symptoms	\$ 104,982	01/01/06	12/31/09
Lin, Henry C. (M.D.)	Albuquerque, NM	Bacterial Overgrowth Associated with Chronic Multi-Symptom Illness Complex	Treatment of GW veterans with gastrointestinal symptoms	\$ 168,600	10/01/08	09/30/11
Sanders, Kathryn (Ph.D.)	West Haven, CT	Testing the Feasibility of MC CBT for Veterans with IBS	Treatment of Irritable Bowel Syndrome (IBS)	\$ 17,593	07/01/10	09/30/11
Biomarkers				\$ 6,389,115		
Fiore, Louis D. (MD)	Boston, MA	CSP #501 - VA Gulf War Biorepository Trust	Gulf War Brain and DNA Bank	\$ 586,413	08/01/02	09/30/08
Klimas, Nancy G. (M.D.)	Miami, FL	Immunologic Mechanisms and Biomarkers in Gulf War Illness	Immune dysfunction as a mediator of persistent illness in both CFS and ill GW veterans	\$ 56,200	04/01/06	03/31/10
Oddone, Eugene Z. (M.D.)	Durham, NC	Genetic Epidemiology of ALS Veterans	Identify genes that may confer susceptibility to the development of ALS and examine the interplay between environmental exposures and genetic susceptibility to ALS	\$ 353,309	07/01/08	09/30/12
Cook, Dane B. (Ph.D.)	East Orange, NJ	Imaging of Pain in Veterans with Unexplained Muscle Pain	Functional imaging of Gulf War veterans with unexplained musculoskeletal pain	\$ 258,076	10/01/08	09/30/12
Weiner, Michael W. (M.D.)	San Francisco, CA	Effects of Gulf War Illness on Brain Structure, Function and Metabolism: MRI/MRS at 4 Tesla	Magnetic Resonance Imaging (MRI) and Spectroscopy (MRS) of Gulf War veterans	\$ 5,135,117	01/01/05	12/31/09
Gulf War Veterans Illnesses				\$ 625,148		
Li, Mian (M.D., Ph.D.)	Washington, DC	Autonomic Functions of Gulf War Veterans with Unexplained Illnesses	Autonomic dysfunction as an underlying cause of unexplained symptoms in GW veterans	\$ 101,863	09/30/06	12/31/08
Li, Mian (M.D., Ph.D.)	Washington, DC	Motor Neuron Function of Gulf War Veterans with Excessive Fatigue	Loss or damage of motor nerve cells in GW veterans with muscle and joint pain, muscle spasm, or fatigue	\$ 103,549	09/30/06	12/31/08
Bach, Ronald R. (Ph.D.)	Minneapolis, MN	Tissue Factor and Gulf War-Associated Chronic Coagulopathies Gulf War-Associated Chronic Coagulopathies: Tissue Factor, Coagulation, and Immune System Activation	Impaired blood flow and circulation as a cause of cognitive difficulties, somatic pain, fatigue	\$ 158,089	04/01/06	09/30/11
Mitchell T. Wallin (M.D., M.P.H.)	Washington, DC	Multiple Sclerosis in Gulf War Veterans	Evaluation of the risk of developing MS in GW veterans	\$ 120,886	10/01/07	09/30/10
Veme, G. Nicholas	Cincinnati, OH	Somatic hypersensitivity in Veterans with IBS	Evaluation of altered central pain processing in IBS	\$ 112,400	04/01/09	03/21/12
Provenza, Dawn	Durham, NC	CSP #585 - Gulf War Era Cohort and Blood Biorepository	Recruit new National Cohort of GW Veterans (VHA and non-VHA users) and collect blood and survey data.	\$ 28,361	04/01/10	09/30/13

* Includes 12.4% administrative overhead

Projected FY2010 ORD Support for Ongoing Gulf War Research Projects

FullName	VAMC	Title	Focus	Total FY 2010*	Start Date	End Date
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Model Systems of GW Exposures/illnesses

\$4,094,030

Greenwood, Beverley (Ph.D., FAGG.)	Oklahoma City, OK	Central Mechanisms Modulating Visceral Sensitivity	Central nervous system control of gastrointestinal pain	\$267,687	10/01/08	09/30/12
Turner, Eric E.	San Diego, CA	Transcription factors regulating sensory gene expression and pain pathways	Regulation of central pain	\$168,600	04/01/09	03/31/13
Shetty, Ashok (Ph.D.)	Durham, NC	Behavior of Neural Stem Cells in a Rat Model of GWS	Effects of pyridostigmine bromide, DEET, and permethrin	\$ 136,900	04/01/07	03/31/10
Panter, Scott (Ph.D.)	San Francisco, CA	Direct Delivery of Neurotoxins to the Brain by an Intranasal Route	Effects of pyridostigmine bromide, DEET, and permethrin	\$ 67,752	01/01/06	12/31/09
Vandenbark, Arthur A.	Portland, OR	Immunoregulation of Myelin Specific T Lymphocytes	New treatment for MS	\$ 361,972	01/01/09	12/31/12
Bedlack, Richard	Durham, NC	CSP #567 A Clinical Demonstration of an EEG Brain-Computer Interface for ALS Patients	New treatment for ALS	\$ 2,368,460	10/01/08	01/01/12
Hinrichs, David	Portland, OR	Multiple Antigenic Peptides to Alter the Course of Autoimmune Disease	New treatment for MS	\$ 332,743	04/01/10	03/31/14
Bourdette, Dennis N.	Portland, OR	Lipoic Acid Therapy for Experimental Autoimmune Encephalomyelitis	New treatment for MS	\$224,126	10/01/09	09/30/13
Elmets, Craig A.	Birmingham, AL	Bacterial Host Defense Mechanisms in Polyaromatic Hydrocarbon Carcinogenesis	Effects of oil well fire smoke on carcinogenesis	\$ 165,790	01/01/06	09/30/10

\$ 11,399,468

Total Anticipated for ORD in FY 2010

UTSW Medical Center	Dallas, TX	Gulf War Veterans Illnesses' Research IDIQ Contract	Close-out costs for previously approved task orders and data transfer (no new task orders)	\$ 2,288,755		
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\$ 13,688,223

Total ORD and Obligated Contract in FY 2010

* Includes 12.4% administrative overhead *

Research Funding Summary FY2011

On June 21, 2011, VA Office of Research and Development (ORD) provided the RAC committee office with spreadsheets listing projects included in VA's projected FY2011 GW research portfolio.

Funding for Projects Included in the VA FY2011 Gulf War Research Portfolio

Total Funding for Projects Identified as Gulf War Research	\$ 5,726,951	100%
Studies of Gulf War veterans' health and effects of Gulf War exposures Multisymptom illness: \$1,290,781 ALS: \$242,775	\$ 1,533,556	27%
Projects with more remote relevance to Gulf War veterans' health	\$584,449	10%
ALS, General Brain bank: \$938,151 (16%) CSP #567 ALS therapy: \$741,771 (13%)	\$ 1,862,572	33%
Other unrelated studies MS, General: \$1,103,462 (19%) Pain, General: \$625,014 (11%)	\$1,728,476	30%

Approximately 27% of ORD's FY2011 Gulf War research portfolio funding was for projects focused on issues specifically relevant to the health of Gulf War veterans. This included \$1.3 million for projects focused on treating Gulf War-related conditions, identifying potential biomarkers of illness (including initial funding for the Gulf War tissue repository/brain bank CSP #501B) or the effects of Gulf War exposures, and \$240,000 for a study of ALS involving Gulf War veterans. Approximately \$600 thousand (10%) was approved for projects with more remote relevance to Gulf War veterans' health, including sleep studies and therapies for respiratory illnesses that are not related to Gulf War veterans specifically.

In addition, \$1.8 million (33%) was spent for research in generic ALS studies. Also included were \$1.7 million (30%) in generic studies (not directed at Gulf War veterans) of conditions such as multiple sclerosis (an illness which has not been associated with Gulf War service, although it is suspected) and pain, including a study of women veterans of the current (OIF/OEF) Iraq war.

The overwhelming majority of veterans with ALS, MS, and pain are veterans of other eras. The current inclusion of generic ALS, MS, and pain research in the "Gulf War research" portfolio dramatically overstates VA's Gulf War research commitment. Furthermore, ALS and MS research does not address the dominant health problem of Gulf War veterans, Gulf War chronic multisymptom illness, which is reason for having a Gulf War research program, as recommended by the Institute of Medicine.

Projected FY2011 ORD Support Ongoing Gulf War Research Projects

FullName	VAMC	Title	Focus	Total FY 2011*	Start Date	End Date
Clinical Trials				\$ 472,817		
Lin, Henry C. (M.D.)	Albuquerque, NM	Bacterial Overgrowth Associated with Chronic Mult-Symptom Illness Complex	Treatment of GW veterans with gastrointestinal symptoms	\$ 168,600	10/01/08	09/30/11
Sanders, Kathryn (Ph.D.)	West Haven, CT	Testing the Feasibility of MC CBT for Veterans with IBS	Treatment of Irritable Bowel Syndrome (IBS)	\$ 93,153	07/01/10	09/30/11
Cook, Dane B. (Ph.D.)	East Orange, NJ	Impact of Exercise Training on pain and Brain Function in Gulf War veterans	Treatment of pain in GW veterans with resistance exercise training	\$ 104,167	10/01/10	09/30/15
Kearney, David J. (M.D.)	Seattle, WA	A randomized controlled trial of a mindfulness based intervention for Gulf War Syndrome	Treatment of attention, concentration, and working memory with mindfulness training	\$ 106,898	10/01/10	09/30/12
Biomarkers				\$ 1,683,571		
Flore, Louis D. (MD)	Boston, MA	CSP #501 - VA Gulf War Biorepository Trust	Gulf War Brain and DNA Bank for ALS	\$ 938,151	08/01/02	09/30/12
Kowall, Neil (M.D.) McKee, Ann (M.D.) Renner, Stephen (M.D.)	Boston, MA	CSP #501B - VA Gulf War Biorepository Trust	Gulf War Tissue Repository and DNA Bank - full autopsy collection of tissues	\$ 237,878	10/01/10	09/30/12
Oddone, Eugene Z. (M.D.)	Durham, NC	Genetic Epidemiology of ALS Veterans	Identify genes that may confer susceptibility to the development of ALS and examine the interplay between environmental exposures and genetic susceptibility to ALS	\$ 242,775	07/01/08	09/30/12
Provenzale, Dawn	Durham, NC	CSP #585 - Gulf War Era Cohort and Blood Biorepository	Recruit new National Cohort of GW Veterans (VHA and non-VHA users) and collect blood and survey data.	\$ 5,110	04/01/10	09/30/13
Cook, Dane B. (Ph.D.)	East Orange, NJ	Imaging of Pain Modulation in Veterans with Unexplained Muscle Pain	Functional imaging of Gulf War veterans with unexplained musculoskeletal pain	\$ 259,657	10/01/08	09/30/12
Gulf War Veterans Illnesses				\$ 372,422		
Li, Mian (M.D., Ph.D.)	Washington, DC	Autonomic Functions of Gulf War Veterans with Unexplained Illnesses	Autonomic dysfunction as an underlying cause of unexplained symptoms in GW veterans	\$ 72,667	09/30/06	06/30/11
Li, Mian (M.D., Ph.D.)	Washington, DC	Motor Neuron Function of Gulf War Veterans with Excessive Fatigue	Loss or damage of motor nerve cells in GW veterans with muscle and joint pain, muscle spasm, or fatigue	\$ 25,712	09/30/06	12/31/10
Bach, Ronald R. (Ph.D.)	Minneapolis, MN	Tissue Factor and Gulf War-Associated Chronic Coagulopathies Gulf War-Associated Chronic Coagulopathies; Tissue Factor, Coagulation, and Immune System Activation	Impaired blood flow and circulation as a cause of cognitive difficulties, somatic pain, fatigue	\$ 181,644	04/01/06	09/30/11
Vérme, G. Nicholas	Cincinnati, OH	Somatic hypersensitivity in Veterans with IBS	Evaluation of altered central pain processing in IBS	\$ 112,400	04/01/09	03/21/12

* Includes 12.4% administrative overhead

Projected FY2011 ORD Support for Ongoing Gulf War Research Projects

FullName	VAMC	Title	Focus	Total FY 2011*	Start Date	End Date
Model Systems of GW Exposures/Ilnesses				\$ 3,198,141		
Greenwood, Beverley (Ph.D., FAGG.)	Oklahoma City, OK	Central Mechanisms Modulating Visceral Sensitivity	Central nervous system control of gastrointestinal pain (IBS)	\$ 269,714	10/01/08	09/30/12
Turner, Eric E.	San Diego, CA	Transcription factors regulating sensory gene expression and pain pathways	Regulation of central pain	\$ 168,600	04/01/09	03/31/13
Vandenbark, Arthur A.	Portland, OR	Immunoregulation of Myelin Specific T Lymphocytes	New treatment for MS	\$ 365,944	01/01/09	12/31/12
Bedlack, Richard	Durham, NC	CSP #567 A Clinical Demonstration of an EEG Brain-Computer Interface for ALS Patients	New treatment for ALS	\$ 741,771	10/01/08	01/01/12
Hinrichs, David	Portland, OR	Multiple Antigenic Peptides to Alter the Course of Autoimmune Disease	New treatment for MS	\$ 388,973	04/01/10	03/31/14
Bourdette, Dennis N.	Portland, OR	Lipoic Acid Therapy for Experimental Autoimmune Encephalomyelitis	New treatment for MS	\$ 188,600	10/01/09	09/30/13
Singh, Inderjit	Charleston, SC	Neuroprotection and Myelin Repair Mechanisms in Multiple Sclerosis	New treatment for MS	\$ 159,945	10/01/10	09/30/14
Shromani, Priyattam J.	Charleston, SC	Sleep Neurobiology and Circuitry	Control of sleep	\$ 378,896	10/01/10	09/30/14
Kowall, Nell W.	Boston, MA	Epigenetic mechanisms relevant to the pathogenesis of ALS	Genetic mechanisms underlying ALS	\$ 182,650	01/01/11	12/31/14
Schlosser, Rodney J.	Charleston, SC	Nanoparticle Coupled Antioxidants for Respiratory Illness in Veterans	Nanoparticle (sand) derived respiratory illness	\$ 140,500	04/01/11	03/31/15
Greenwood, Beverley (Ph.D., FAGG.)	Oklahoma City, OK	Understanding Pain of Gastrointestinal Origin in Women that Serve in OEF/OIF	Central nervous system control of gastrointestinal pain (IBS)	\$ 84,300	04/01/11	03/31/15
Shetty, Ashok (Ph.D.)	Durham, NC	Memory and Mood Enhancing Therapies for Gulf War Illness	Development of new therapy for ill Gulf War Veterans	\$ 148,248	07/01/11	06/30/15

\$ 5,726,951

Total Anticipated
for ORD in FY
2011

Appendix D: Failure to Comply with Statute Directing IOM Treatments Study

In the Veterans Benefits Act of 2010, Congress directed VA to enter into an agreement with the Institute of Medicine “to carry out a comprehensive review of the best treatments for chronic multisymptom illness in Persian Gulf War veterans and an evaluation of how such treatment approaches could best be disseminated throughout the Department of Veterans Affairs to improve the care and benefits provided to veterans.”¹

The law provided that “under [the] agreement, the Institute of Medicine shall convene a group of medical professionals who are experienced in treating individuals who served as members of the Armed Forces in the Southwest Asia Theater of Operations of the Persian Gulf War during 1990 or 1991 and who have been diagnosed with chronic multisymptom illness or another health condition related to chemical and environmental exposure that may have occurred during such service.”

In December 2011, the IOM convened a committee to implement this law.² However, this committee is not made up of medical professionals experienced in treating Gulf War veterans with this condition. Rather, it is made up of individuals with no expertise in treating ill Gulf War veterans.

As Congress is aware, the IOM, when asked to review a subject, will typically appoint a committee of doctors and scientists who are trained in the general area but who have no direct expertise in the specific subject to be reviewed. The purpose is to ensure a fresh, impartial review of the scientific literature.

In this case, however, Congress required a different process. Congress knew that there are no effective treatments for these veterans to be found in the scientific literature. As the 2008 Research Advisory Committee report concluded, “No effective treatments have been identified for Gulf War illness.”³ Thus, in addition to funding new research, Congress sought to do its part by directing the IOM to convene a group of doctors who actually treat patients “diagnosed with chronic multisymptom illness or another health condition related to chemical and environmental exposure,” to see what their experience might show that the medical literature did not. By arranging to appoint a committee with no expertise in this topic instead, VA staff have ignored the direction of Congress and ensured that the review will be fruitless.

Worse, committee members have been informed that Gulf War multisymptom illness is

¹ Veterans’ Benefits Act of 2010, Sec. 805, Public Law 111-275,
http://www7.nationalacademies.org/ocga/laws/PL111_275.asp

² <http://www.iom.edu/Activities/Veterans/GulfWarMultisymptom/2012-FEB-29.aspx>

³ 2008 Report of the Research Advisory Committee on Gulf War Veterans Illnesses, November 2008, p. 1. www.va.gov/RAC-GWVI/docs/Committee_Documents/GWlandHealthofGWVeterans_RAC-GWVIReport_2008.pdf

psychiatric. At the February 29, 2012 meeting of the committee, five of the eight speakers chosen for the agenda delivered that message.⁴ (Illustrative slides from these presentations follow.) All comprehensive reviews of the scientific literature plainly state that exactly the opposite is true, including the IOM's own recent review.

- "The excess of unexplained symptoms reported by deployed Gulf War veterans cannot be reliably ascribed to any known psychiatric disorder." 2010 Institute of Medicine report.⁵
- "Studies indicate that the large majority of Gulf War veterans with chronic multisymptom illness do not have psychiatric disorders." 2008 RAC report⁶
- "A substantial proportion of Gulf War veterans are ill with multisymptom conditions not explained by wartime stress or psychiatric illness." 2004 RAC report⁷

No topic in Gulf War health research has been more thoroughly studied than psychiatric illness. That is how we know with certainty that psychiatric illness is actually much lower in Gulf War veterans than in veterans of other wars (not surprising in view of the short duration of the war) and that it does not explain the widespread chronic multisymptom illness in this population.⁸

It is not logical that IOM committee members or staff would have arranged an agenda of psychiatric-oriented presentations on their own, when the IOM's own recent report concluded that the problem is not psychiatric. Given this well-settled finding, it made no sense to include one psychiatric-oriented speaker, let alone five. However, many government officials have historically sought to characterize the health problems of Gulf War veterans as psychiatric, furthering the impression that there is no special health problem connected with Gulf War service. If the new IOM committee could be induced into reporting that the illness is, or may be, psychiatric, it would revive that discredited theory.

⁴ <http://iom.edu/Activities/Veterans/GulfWarMultisymptom/2012-FEB-29.aspx>

("presentations")

Clauw, slide 7: "Overlap Between Multisymptom Illness and Psychiatric Disorders");

Dusik, title: "Chronic Stress and Its Role in Emotional, Somatic, and Cognitive Symptoms";

Engel, slide 8 titled in red "Gulf War Veterans Illnesses: Proposed Etiologies", concluding in red with "stress, PTSD, or somatization";

Kendler, title "Vulnerability, Stress Exposure and Depression: Mediation and Moderation");

Kroenke, slide 10, continuum from "Medical" symptoms to "Psychiatric"

⁵ 2010 Institute of Medicine Gulf War and Health report, p. 109

⁶ 2008 Research Advisory Committee report, p. 73

⁷ 2004 Research Advisory Committee on Gulf War Veterans Illnesses report, p. 21

<http://www.va.gov/RAC->

[GWVI/docs/Committee_Documents/ReportandRecommendations_ScientificProgressinUnderstandingGWVI_2004.pdf](http://www.va.gov/RAC-GWVI/docs/Committee_Documents/ReportandRecommendations_ScientificProgressinUnderstandingGWVI_2004.pdf)

⁸ 2008 Research Advisory Committee report, pp. 61-74

The government's historical position that the illness was psychiatric has never been constrained by contrary facts. This phenomenon has been well documented in Congressional reports. E.g., "Gulf War Veterans Illnesses: VA, DOD Continue To Resist Strong Evidence Linking Toxic Causes To Chronic Health Effects," Nov., 1997.⁹

It has had dramatic consequences for veterans' health. Tens of millions of dollars were spent on research based on the premise that the illness was psychiatric. In 2003, for example, fifty-seven percent of VA's Gulf War research expenditures were directed at studies of psychological factors and stress.¹⁰ Ill Gulf War veterans were often medicated with psychiatric drugs that did not improve and often exacerbated their condition.

As science has progressed, new VA leadership has sought to change these practices. The Secretary of Veterans Affairs determined in 2004 that VA would no longer fund Gulf War illness research based on the stress hypothesis.¹¹ The current Secretary of Veterans Affairs has made Gulf War health issues a priority and initiated numerous reforms to align VA activities with current science.

However, lesser government officials remain in place as administrations come and go, and some have continued to suggest that the illness is psychiatric long after science has resolved that it is not. Previous efforts to mischaracterize the health problems of Gulf War veterans have extended to government officials influencing and misusing IOM reports.¹² The DoD Office of Force Health Protection and Readiness, which works closely with VA on Gulf War illness, has publicized that the IOM report found that PTSD caused multisymptom illness in Gulf War veterans,¹³ when the report expressly concluded that these symptoms cannot be "reliably ascribed to any known psychiatric disorder."

In response to objections of veterans following the February 29 meeting, another public meeting of the IOM committee was held on April 12 and one speaker was invited who presented evidence that the multisymptom illness suffered by Gulf War veterans is physiological. However, that speaker was followed by a representative of the Department of Veterans Affairs, Dr. Stephen Hunt, Director of the VA Post-Deployment Integrated Care Initiative, the only other speaker of the day. Dr. Hunt spoke on "VA Approaches to the Management of Chronic Multi-Symptom Illness in Gulf War I Veterans" and told the committee that science does not know whether the illness is physiological or psychiatric, citing an eleven-year-old paper by himself and one of the psychiatric-oriented speakers from the previous

⁹ <http://www.gpo.gov/fdsys/pkg/CRPT-105hrpt388/pdf/CRPT-105hrpt388.pdf>

¹⁰ 2008 Research Advisory Committee report, pp. 293-294.

¹¹ <http://www.veteransadvantage.com/cms/content/va-will-no-longer-fund-gulf-war-illness-studies>

¹² 2008 Research Advisory Committee report, pp. 53-55.

¹³ <http://health.mil/mediaroom.aspx?MediaID=612daaeb-5034-4d8c-acfb-a49e2851263b>

meeting, Dr. Charles Engel.¹⁴ The new IOM committee has now been presented with a total of six speakers stating a view that the 2010 IOM report determined to be invalid.

Moreover, Dr. Hunt knows it is invalid. He served on the committee¹⁵ that developed the VA Veterans Health Initiative training course for VA doctors, "Caring for Gulf War I Veterans," released last year, which states: "What we do know is that chronic multisymptom illness is real and cannot be reliably ascribed to any known psychiatric disorder. Specifically it cannot be ascribed to somatiform disorder, PTSD (Post Traumatic Stress Disorder), or depression."¹⁶ He included slides taken from the course in his presentation to the IOM. But not this page.

In addition to Dr. Hunt, one of the other psychiatric-oriented speakers is affiliated with VA, Dr. Kurt Kroenke of the VA HSR&D Center for Implementing Evidence-Based Practice, and one is affiliated with DoD, Dr. Engel, Associate Chair (Research), Dept. of Psychiatry, Uniformed Services University, and Director, DoD Deployment Health Clinical Center at Walter Reed. Dr. Engel and Dr. Daniel Clauw, one of the other psychiatric-oriented speakers, are familiar names from the era when Gulf War research dollars went to support the psychiatric theory.¹⁷ Drs. Clauw, Engel, and Kroenke were co-authors of a 2003 "Expert Consensus Statement" on "Unexplained Symptoms After Terrorism and War" which stated that "concerns . . . of a unique Gulf War syndrome, remind[] us that military personnel returning from wars have regularly described disabling symptoms."¹⁸ In short, nothing special happened over there.

The changes to the new IOM treatment study from what Congress intended are fundamental. Instead of the report of a "group of medical professionals ... experienced in treating individuals who served as members of the Armed Forces in the Southwest Asia Theater of Operations of the Persian Gulf War during 1990 or 1991 and who have been diagnosed with chronic multisymptom illness or another health condition related to chemical and environmental exposure that may have occurred during such service," the study has been converted into a review by scientists unfamiliar with the field who have been presented with false information that the illness is or may be psychiatric.

If the new IOM committee proceeds to review treatments for psychiatric disorders, notwithstanding the fact that Gulf War multisymptom illness is not psychiatric, the review will most certainly not improve Gulf War veterans' care. To the contrary, the eventual report will encourage physicians to treat Gulf War veterans with multisymptom illness as psychiatric patients, re-establishing the erroneous and often harmful practices that prevailed in the past. Research will also again be misdirected toward psychiatric mechanisms. As the agency that contracted for the IOM study and the source of at least two misleading presentations (one

¹⁴ <http://www.iom.edu/Activities/Veterans/GulfWarMultisymptom/2012-APR-12.aspx> ("presentations", slides 6 and 7)

¹⁵ www.publichealth.va.gov/docs/vhi/caring-for-gulf-war-veterans-vhi.pdf, p.iii

¹⁶ www.publichealth.va.gov/docs/vhi/caring-for-gulf-war-veterans-vhi.pdf, p. 40

¹⁷

http://www.gulflink.osd.mil/medsearch/BrainNervous/CognitiveLearningAttenti/VA62_4.shtml

¹⁸ http://simonwessely.com/Downloads/Publications/Other_p/96.pdf

entitled “VA Approaches to the Management of Chronic Multi-Symptom Illness in Gulf War I Veterans” from the Director of the VA Post-Deployment Integrated Care Initiative, who knew he was misleading the committee), VA is responsible.

Overlap Between Chronic Multisymptom Illnesses and Psychiatric Disorders

Fibromyalgia

- 2%-4% of population
- Defined by widespread pain and tenderness

Regional Pain Syndromes

- Irritable bowel [IBS]
- Interstitial cystitis/ Painful bladder syndrome
- TMJD
- Tension HA
- Vulvodynia

Psychiatric Disorders

- Major depression
- OCD
- Bipolar
- PTSD
- GAD
- Panic attack

Somatoform Disorders

- 4% of population
- multiple unexplained symptoms — no "organic" findings

(1) Clauw and Chrousos. Neuroimmunomodulation. 1997;4:134-53. (2) Kato K, et al. Arch Intern Med 2006; 166(15):1649-54. (3) Kato K, et al. Psychol Med 2008;1-9.

Dr. Clauw

PENNY GEORGE INSTITUTE
FOR HEALTH AND HEALING

Chronic Stress and Its Role in Emotional, Somatic, and Cognitive Symptoms

Jeffery Dusek, PhD

Research Director
Abbott Northwestern Hospital

ALLINA
Hospitals & Clinics

Founded by the George Family Foundation and the Ted and Dr. Roberta Mann Foundation

Dr. Dusek

Gulf War Veterans' Illnesses Proposed Etiologies

- allergic reaction
- environmental illness
- chronic infection
- chemical exposures
- neurological damage
- metabolic disorders
- rheumatologic disease
- stress, PTSD, or somatization**

Dr. Engel

Vulnerability, Stress Exposure and Depression: Mediation and Moderation

Kenneth S. Kendler, MD
Virginia Institute of Psychiatric and Behavioral Genetics
Virginia Commonwealth University

IOM Presentation
Feb 29, 2012

Dr. Kendler

"MEDICAL" (Axis III)



Disease-specific somatic symptoms only partly explained by medical disorder

Functional somatic syndrome

— — — Symptom only diagnosis — — —

Comorbid depression or anxiety

Somatoform disorder

"PSYCHIATRIC" (Axis I)

Kroenke, Psych Clin N Am 2008

Dr. Kroenke

Rate the degree to which you believe "Persian Gulf Illness" is:



Richardson RD, Engel CC, McFall, W, McKnight K, Hunt SC. Clinician Attributions for Symptoms and Treatment of Gulf War-Related Health Concerns. Archives of Internal Medicine 2001, 161: 1289-1294.

Dr. Hunt

Appendix E: Failure to Execute Statute Ordering IOM Study of Multiple Sclerosis Risk

The following exchange of emails demonstrates that VA has never executed Congress's 2008 order to contract with the Institute of Medicine to conduct a comprehensive epidemiological study to determine the risk of multiple sclerosis in Gulf War veterans.

The IOM study referred to below was not a study to determine Gulf War veterans' risk of having multiple sclerosis. Rather, it was a literature review, which found nothing in the literature because there has been no epidemiological study as required by Congress. VA has funded another study of MS in veterans, but the study is not to determine risk and does not focus on 1991 Gulf War veterans. Thus, four years after the passage of this legislation, it is still unknown whether Gulf War service is associated with an elevated risk of multiple sclerosis.

On Tue, Mar 27, 2012 at 7:05 AM, MFUA <MFUA@nas.edu> wrote:

Anthony-

In response to your question: VA has not to date entered into a specific contract with NAS/IOM to perform the epidemiologic study described in Section 804 of PL 110-389.

David.

From: ANTHONY HARDIE [mailto:anthony.d.hardie@gmail.com] Sent: Saturday, March 24, 2012 2:50 AM To: MFUA Cc: Jim Binns; Lea Steele; Roberta White; Kimberly A. Sullivan Subject: Re: Status of MS IOM Study

Dr. Butler,

Thank you very much for the information.

Could you further advise whether VA ever entered into a specific contract with NAS/IOM on this issue, as specified in the first lines of Section 804 of PL 110-389?

Thank you again.

Anthony

Anthony Hardie

Madison, Wis.

Email: anthony.d.hardie@gmail.com

On Thu, Mar 22, 2012 at 6:24 AM, MFUA <MFUA@nas.edu> wrote:

Mr. Hardie-

The Institute of Medicine conducted a review of the scientific literature regarding multiple sclerosis and Gulf War-era veterans as part of the effort that resulted in the report Gulf War and

Health Volume 8 – Update of Health Effects of Serving in the Gulf War. This report was published in 2010 and may be read and downloaded without cost from links available at the following website:

http://www.nap.edu/catalog.php?record_id=12835

MS was addressed on pages 124-126.

No additional funding has been provided to the National Academies to perform the epidemiologic study described in Section 804 of PL 110-389.

David A. Butler, PhD
Scholar | Director, Medical Follow-up Agency
National Academy of Sciences, Institute of Medicine

From: ANTHONY HARDIE [mailto:anthony.d.hardie@gmail.com] Sent: Sunday, March 18, 2012 3:58 AM To: Butler, David Cc: Jim Binns; Lea Steele; Roberta White; Kimberly A. Sullivan Subject: Status of MS IOM Study

Dear Mr. Butler,

I understand that you are the IOM staff contact for the following:

Multiple Sclerosis (MS) in Vietnam and Gulf War-era Veterans,
Study Director: David Butler, 334-2524 (Keck 872); Chair:
N/

Could you please tell me whether this review, above, is one and the same as the review mandated by law in PL 110-389 on Oct. 10, 2008 (full text below my signature block), "to conduct a comprehensive epidemiological study for purposes of identifying any increased risk of developing multiple sclerosis as a result of service in the Armed Forces during the Persian Gulf War in the Southwest Asia theater of operations or in the Post 9/11 Global Operations theaters"?

If so, can you please tell me how can I obtain any interim reports, as described in the text of the law, below? And, I note that the final report is due Dec. 31, 2012; when do you expect the final report to be released to the public?

Thank you in advance for any information you may be able to provide.

Anthony

Anthony Hardie
Madison, Wis.
Email: anthony.d.hardie@gmail.com
Cell: [\(608\) 239-4658](tel:6082394658)

PL 110-389, October 10, 2008.

SEC. 804. NATIONAL ACADEMIES STUDY ON RISK OF DEVELOPING MULTIPLE SCLEROSIS AS A RESULT OF CERTAIN SERVICE IN THE PERSIAN GULF WAR AND POST 9/11 GLOBAL OPERATIONS THEATERS.

(a) IN GENERAL.—The Secretary of Veterans Affairs shall enter into a contract with the Institute of Medicine of the National Academies to conduct a comprehensive epidemiological study for purposes of identifying any increased risk of developing multiple sclerosis as a result of service in the Armed Forces during the Persian Gulf War in the Southwest Asia theater of operations or in the Post 9/11 Global Operations theaters.

(b) ELEMENTS.—In conducting the study required under subsection (a), the Institute of Medicine shall do the following:

(1) Determine whether service in the Armed Forces during the Persian Gulf War in the Southwest Asia theater of operations, or in the Post 9/11 Global Operations theaters, increased

the risk of developing multiple sclerosis.

(2) Identify the incidence and prevalence of diagnosed neurological diseases, including multiple sclerosis, Parkinson's disease, and brain cancers, as well as central nervous system abnormalities that are difficult to precisely diagnose, in each group as follows:

(A) Members of the Armed Forces who served during the Persian Gulf War in the Southwest Asia theater of operations.

(B) Members of the Armed Forces who served in the Post 9/11 Global Operations theaters.

(C) A non-deployed comparison group for those who served in the Persian Gulf War in the Southwest Asia theater of operations and the Post 9/11 Global Operations theaters.

(3) Compare the incidence and prevalence of the named diagnosed neurological diseases and undiagnosed central nervous system abnormalities among veterans who served during the Persian Gulf War in the Southwest Asia theater of operations, or in the Post 9/11 Global Operations theaters, in various locations during such periods, as determined by the Institute of Medicine.

(4) Collect information on risk factors, such as pesticide and other toxic exposures, to which veterans were exposed

while serving during the Persian Gulf War in the Southwest Asia theater of operations or the Post 9/11 Global Operations theaters, or thereafter.

(c) REPORTS.—

(1) INTERIM REPORT.—The contract required by subsection (a) shall require the Institute of Medicine to submit to the Secretary, and to appropriate committees of Congress, interim progress reports on the study required under subsection (a). Such reports shall not be required to include a description of interim results on the work under the study.

(2) FINAL REPORT.—The contract shall require the Institute of Medicine to submit to the Secretary, and to appropriate committees of Congress, a final report on the study by not later than December 31, 2012. The final report shall include such recommendations for legislative or administrative action as the Institute considers appropriate in light of the results of the study.

(d) FUNDING.—The Secretary shall provide the Institute of Medicine with such funds as are necessary to ensure the timely completion of the study required under subsection (a).

(e) DEFINITIONS.—In this section:

(1) The term “appropriate committees of Congress” means—

(A) the Committee on Veterans’ Affairs of the Senate;

and

(B) the Committee on Veterans’ Affairs of the House of Representatives.

(2) The term “Persian Gulf War” has the meaning given that term in section 101(33) of title 38, United States Code.

(3) The term “Post 9/11 Global Operations theaters” means Afghanistan, Iraq, or any other theater in which the Global War on Terrorism Expeditionary Medal is awarded for service.

Appendix F: Conducting a National Survey of Gulf War Era Veterans Without the Questions Necessary To Identify Gulf War Illness

Follow-Up Study of a National Cohort of Gulf War and Gulf War Era Veterans Recommendations and Comments on Survey Instrument

**Provided by Lea Steele, Ph.D., and Jim Binns, Chair RAC-GWVI
April 4, 2012**

The current draft instrument includes a limited number of useful changes, but still has fundamental flaws that require attention. Our recommended additions of highest priority are summarized below, followed by other comments regarding the survey. An appendix provides further explanation and details on the recommended priority changes.

1. **Highest Priority Modification: Add a Systematic Inventory of Chronic Symptoms, as Required to Assess Gulf War Multisymptom Illness in 1990-1991 Gulf War Era Veterans**

According to VA and other epidemiologic studies, the hallmark health problem of the 1991 Gulf War is the complex of chronic symptoms commonly known as Gulf War illness. This problem is distinct from well-established diagnosed medical and psychiatric conditions, and is more prevalent in 1991 Gulf War veterans than any other condition. Studies have generally found that at least 25% of veterans of the 1991 war were affected, and that few have recovered over time. Because diagnostic tests are not yet available, Gulf War illness is currently defined solely by its symptoms.

The draft survey instrument, like the 2005 survey, does not provide for assessment of Gulf War illness by any case definition. Using this instrument, the OPH survey cannot determine the prevalence, progression, or correlates of this illness. We have appended a symptom inventory that remedies this most egregious problem, which should be added to the instrument. It is relatively brief, and could actually shorten the survey by replacing many other symptom questions that are less relevant to Gulf War-specific health problems. More than 21 years after Desert Storm, it is unthinkable that the largest national study of Gulf War veterans would not provide the data required to evaluate the signature problem of the 1991 Gulf War.

2. **Additional Priority Changes Recommended to Ascertain Rates of Physician-Diagnosed Conditions**

Although Gulf War illness is the most prevalent problem in 1991 Gulf War veterans, it is not the only condition of concern. We appreciate improvements made in the previous draft instrument by adding several questions related to diagnosed conditions. As detailed in the appendix, several additional questions and clarifications are needed to provide a clearer and more complete assessment of diagnosed conditions. This is particularly important for conditions which earlier studies suggest may be elevated among Gulf War veterans, but for which no national data have ever been available.

3. Additional Recommended Changes to the Follow-Up Survey

Overall, the survey instrument does not address the highest priority health questions for veterans of the 1991 Gulf War, as reflected by the broad literature in this area, and findings of both the IOM and the RAC-GWVI. Although no survey can cover all areas of potential interest, it is important for this national survey, at minimum, to address the most prominent health issues and unanswered questions concerning the health of 1991 Gulf War veterans.

The survey is problematic both in what it includes, and in what it does not include. It includes lengthy questions in areas of limited relevance for 1991 Gulf War veterans (e.g., more than 2 pages of questions on recent stressful events and worries, 2 pages devoted to gastrointestinal symptoms, 17 questions to assess PTSD, 9 questions on alcohol use, 15 questions on use of alternative medicine). It collects data on nearly 100 symptoms, all told, few of which can be used to assess Gulf War illness case status. In order to shorten the survey and sharpen its focus on health issues most relevant to Gulf War service, several areas of questioning can be dropped (e.g., recent life events and stressors, details of alcohol use and behavior) or substantially reduced (e.g. existing lists of psychological and physical symptoms). We would be pleased to work with OPH to identify, in detail, questions that could be eliminated in order to make the survey most relevant for Gulf War era veterans.

At the same time, the survey neglects other priority issues, including problems suggested by earlier studies and others for which no national data have ever been reported. For example, VA's 1995 national survey identified significantly excess rates of birth defects and adverse pregnancy outcomes in 1991 Gulf War veterans. These problems were not followed up in the 2005 survey, and are not included in the current survey. Other examples include the lack of questions concerning veterans' use of conventional medical treatments, and the degree to which veterans with symptomatic illness believe they have improved or worsened over time.

The Review Process To Date

The RAC obtained a copy of the OPH survey instrument in 2010 for review, when the time window had nearly expired during OMB's public comment process. We saw numerous serious problems with the proposed instrument, and recommended that it be revised extensively, in conjunction with researchers with expertise specifically in health issues associated with the 1991 Gulf War. Committee recommendations, as noted at that time, were primarily summary comments and examples of the most obvious problems with the instrument.

Despite earlier requests, this is the first opportunity committee members have had to review the modifications made in the instrument. We understand that VA Office of Public Health may have consulted with individuals with survey research expertise in making the limited modifications included in the current draft. However, the most serious problems referred to by the RAC would not be apparent to scientists who, although knowledgeable in general survey research methods, were not familiar with health issues specifically associated with military service in the 1991 Gulf War.

Survey Instrument Concerns in Relation to VA's Overall Gulf War Research Program.

The National Follow-Up Survey is one of the most important research efforts undertaken by VA on behalf of 1990-1991 Gulf War veterans. Ideally, it should provide the foundation for other areas and types of Gulf War research at VA and across federal agencies. We are very concerned that this survey does not serve this broader need, and appears to have been developed without the participation of other federal offices doing Gulf War research, even within VA.

This is well-illustrated by a current situation involving VA's Office of Research and Development (ORD), which originally intended to use the OPH survey to provide baseline health data for the large Gulf War national biorepository project now under development. ORD subsequently determined the OPH instrument will not provide fundamental information needed to adequately characterize Gulf War multisymptom illness and is now working with a group of scientists to develop a suitable questionnaire. At this stage, the ORD effort appears likely to result in a symptom assessment more along the lines of what the RAC recommended for the OPH survey. As a result, it appears that the data collected by the OPH survey instrument, as currently designed, will not be compatible with that collected for the ORD project, given key differences between the two symptom assessments. This means that the OPH survey will not only fail to provide a foundation for the ORD project, it will not even yield data on Gulf War illness that can be used to interpret what is learned from the ORD project. It seems grossly inefficient and illogical for VA OPH to mount a large survey research effort of such fundamental importance, if the project does not support other key elements of VA's Gulf War research program.

APPENDIX: Explanation and Details of Recommended Priority Changes

1. Add a Systematic Inventory of Chronic Symptoms, as Required to Assess Gulf War Multisymptom Illness in 1990-1991 Gulf War era veterans

Gulf War illness refers to the complex of multiple symptoms consistently identified at excess rates in 1991 Gulf War veterans. It is the most prevalent health problem affecting 1991 Gulf War veterans, with studies consistently reporting that at least 25% of veterans are affected, and that few have substantially improved over time. Gulf War illness remains the signature health problem of this deployment, and is the subject of active study by multiple scientific researchers. Current information on the prognosis and impact of Gulf War illness is essential, since national data of this type has not been collected since the 1990s.

In order to identify Gulf War illness, a systematic symptom inventory is required. This involves systematic assessment of the symptoms used to define this condition—including the occurrence, severity, and duration of each symptom. Over the years, a variety of different case definitions have been used by different groups. The current survey instrument does not allow identification of Gulf War multisymptom illness by any case definition.

VA ORD is currently finalizing a strategic plan for Gulf War research, which gives high priority to identifying a consensus case definition for Gulf War illness. The draft plan points out that just two of the existing case definitions have been used by multiple research groups—the Fukuda case definition for multisymptom illness, and the Kansas criteria for Gulf War illness. Although the Fukuda case definition was more often used in the first decade after the war, the Kansas case definition has been preferred by more investigators in recent years, owing to its greater specificity. The draft VA strategic plan recommends use of the Kansas criteria until a consensus case definition can be developed.

The 2005 OPH national survey did not include a systematic symptom inventory and so could not identify Gulf War illness cases by any definition. The current instrument queries nearly 100 symptoms, and also cannot identify Gulf War illness cases. Gulf War illness case definitions require veterans to report on particular symptoms, and whether each is mild, moderate, or severe and has persisted over the prior six months. The OPH instrument asks about many other types of symptoms, variously querying if they were present in the previous two weeks or four weeks, with no standard indicator of symptom severity. It asks about only 5 of the 10 chronic symptoms required to identify multisymptom illness by the Fukuda criteria, and only 9 of the 29 chronic symptoms required for the Kansas criteria.

It is essential that this national survey have the capacity to identify veterans with Gulf War multisymptom illness. This necessitates that the required symptoms are assessed in a way that allows identification of Gulf War illness defined by the currently-preferred case definitions. We recommend adding the symptom inventory outlined below, which includes the questions necessary to ascertain both the Kansas and Fukuda case definitions. The specific symptoms in this inventory are also compatible with VA's initial symptom assessment from the 1995 survey, allowing the current follow-up survey to identify changes that have occurred since that time.

**Symptom Inventory Required to Ascertain Case Status for Gulf War Multisymptom Illness,
as Defined by both the Fukuda and Kansas criteria**

Over the past six months, have you had a persistent or recurring problem with ? <i>(Indicate NO or YES for each)</i>	If YES,		
	NO	YES	How would you rate this problem?
			Mild Moderate Severe
Sore throat	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Tender lymph nodes	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Joint pain or aching	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Stiffness in your joints	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Muscle pain or aching	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Muscle cramping	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Body pain, where you hurt all over	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Fatigue	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Excessive fatigue not due to exertion	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Fatigue lasting more than 24 hours after exertion	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Problems getting to sleep or staying asleep	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Awaken feeling tired or worn out after a full night of sleep	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Headaches	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Feeling dizzy, lightheaded, or faint	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Eyes very sensitive to light	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Blurred vision	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Numbness or tingling in your extremities	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Tremors or shaking	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Low tolerance for heat or cold	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Night sweats	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Sensitivity to certain smells or chemicals	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Skin rashes	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Other skin problems	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Diarrhea (loose or watery stools)	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Nausea or upset stomach	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
Stomach or abdominal pain or cramping	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

Over the past six months, have you had a persistent or recurring problem with ? (Indicate NO or YES for each)

	NO	YES	If YES,		
			How would you rate this problem?		
			Mild	Moderate	Severe
Difficulty breathing or shortness of breath	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Problems with coughing	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Wheezing in your chest	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty concentrating	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Difficulty remembering recent information	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Trouble finding words when speaking	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling down or depressed	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling irritable or having angry outbursts	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling moody	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Feeling anxious	<input type="radio"/>	<input type="radio"/> →	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. Additional Priority Questions/Clarifications Recommended to Ascertain Rates/Types of Physician-Diagnosed Conditions

Although Gulf War illness is the most prevalent health problem among 1991 Gulf War veterans, it is also extremely important to determine if veterans of this war have experienced excess rates of *diagnosed* conditions. Minimal or no national data have ever been collected on many conditions of concern, as reflected by the Institute of Medicine’s determinations of “insufficient evidence” in relation to most medical diagnoses. We commend the OPH team for adding important questions on medical diagnoses, particularly the expanded questions related to neurological conditions.

We recommend several additional questions and clarifications to provide a clearer, more comprehensive assessment of diagnosed conditions. Most relate to conditions for which earlier studies indicate a possible problem among 1991 Gulf War veterans. In some instances, the recommended change merely involves obtaining information on a specific diagnosis, when several types are possible under the existing question. We note this type of change had already been made in some categories in the current draft, and recommend it be done in several more. Specific recommendations are provided below.

Note re: additional questions related to women: The current survey instrument includes a full page of questions for women only, including detailed questions on their menstrual periods and use of hormones (although there have not been prior indications of problems in these areas). Previous studies have suggested that the “women only” conditions listed below may affect women Gulf War veterans at excess rates, although national data have never been collected to provide more definitive information.

<u>Current item</u>	<u>Suggested Addition or Revision</u>
Gastritis	Add: Ulcers (Specify type____) Any other gastrointestinal or digestive disorder (Specify ____)
Other endocrine disorder (including thyroid problem)	Change to: Any thyroid problem (Specify____) Any other endocrine disorder (Specify ____)
Other auto-immune condition (Specify ____)	Change to: Lupus Any other autoimmune condition (Specify____)
Coronary heart disease	Add: Any heart problem (Specify ____) High cholesterol Any other circulatory condition (Specify ____)
None	Add psychiatric disorders to the list of provider-diagnosed conditions: Posttraumatic stress disorder Bipolar disorder or manic depression Schizophrenia Alcohol or drug dependence
FOR WOMEN ONLY:	Add medical history questions, using previous format for physician-dx conditions: Fertility problems or difficulty conceiving Lump or cyst in breast Abnormal PAP smear Frequent yeast infections Any other reproductive or gynecological problem (Specify____)

Appendix G: Officially Characterizing VA's Gulf War Research Effort as "Investigating Whether" Service-Related Health Problems Even Exist

VA's Gulf War research program is characterized in ORD's annual VA research report ("State of VA Research 2012: Improving Veterans' Lives") as "investigating whether service in the Gulf War is linked to illnesses Gulf War veterans have experienced." The scientific literature, this Committee, and the IOM have long ago concluded that it is. Other VA research programs are characterized in the annual report in terms of solving veterans' health problems, not investigating whether service-related problems exist.

This same language is used to characterize the VA Gulf War research program on the Public Health Gulf War illness website.

<http://www.publichealth.va.gov/exposures/gulfwar/medically-unexplained-illness.asp>

DISCOVERY ★ INNOVATION ★ ADVANCEMENT



STATE OF **VA RESEARCH 2012**

Improving Veterans' Lives



PRIORITY RESEARCH AREAS

08 ACCESS AND DISPARITIES

Addressing the challenges posed by minority health care needs and disparities in health care delivery, access, and c

10 AFGHANISTAN AND IRAQ VETERANS

Focusing on the deployment-related health issues of the newest generation of Veterans.

13 AGENT ORANGE

Concerns about health effects from Agent Orange and related chemicals continue.

15 AGING/OLDER VETERANS

Improving the care of older Veterans through integrat research, education and clinical innovation.

18 CAREGIVERS

Studies that examine the health, work, and home life of caregivers for Veterans.

20 CHRONIC DISEASES

Optimizing clinical, psychosocial, and functional outcomes for Veterans with chronic disease.

PROGRAM HIGHLIGHTS

54 VA RESEARCHERS IN THE NEWS

58 AWARDS AND HONORS

64 HISTORICAL ACCOMPLISHMENTS

Cod liver oil capsules
PHOTO: GETTY IMAGES

26 GULF WAR VETERANS' ILLNESSES

Investigating whether service in the Gulf War is linked to illnesses Gulf War Veterans have experienced.

28 INFECTIOUS DISEASES

Advancing the understanding, prevention, and treatment of numerous infectious diseases—from the common cold to AIDS.

32 MENTAL HEALTH

Improving care for Veterans with mental health conditions by implementing evidence-based practices.

34 PERSONALIZED MEDICINE/GENOMICS

The Million Veteran Program will consolidate genetic, military exposure, health, and lifestyle information in a single database.

36 PROSTHETICS AND RELATED TECHNOLOGY

Developing everything that's necessary to help Veterans regain their mobility and independence.

38 POSTTRAUMATIC STRESS DISORDER

Learning more about the causes of PTSD, and developing better ways to treat and prevent the disorder.

70 PROGRAM OVERVIEW

74 IMPLEMENTATION RESEARCH

76 TECHNOLOGY TRANSFER

40 RURAL HEALTH

Expanding and ensuring access to high-quality health care for Veterans living in rural areas.

43 SENSORY LOSS

Developing devices and equipment to help individuals with sensory loss live independently and productively.

44 SPINAL CORD INJURY

Promoting health, functioning, and quality of life for SCI patients through evidence-based methods.

46 TRAUMATIC BRAIN INJURY

Dealing with one of the signature injuries of modern combat.

48 VA HEALTH CARE SYSTEM

Looking at the organization, delivery, and financing of health care to improve the quality and economy of VA care.

52 WOMEN VETERANS

Focusing on biomedical, clinical, rehabilitation, and health services research, VA has become a national leader in women's health research.

77 RESOURCES

78 NATIONAL VA RESEARCH WEEK 2011

Appendix H

Gulf War Veterans Illnesses: VA, DOD Continue To Resist Strong Evidence Linking Toxic Causes To Chronic Health Effects," U.S. House of Representatives, Committee on Government Reform and Oversight, Nov., 1997.

<http://www.gpo.gov/fdsys/pkg/CRPT-105hrpt388/pdf/CRPT-105hrpt388.pdf>