

Exhibit B

The Committee's 2008 report and other Committee findings and recommendations have assessed federal Gulf War research programs pursuant to the Committee's chartered role to "assess the overall effectiveness of government research to answer central questions on the nature, causes, and treatments for health consequences of military service . . . during the 1990-1991 Gulf War." Because of the recent charter change to eliminate this responsibility, this subject will not be addressed in the 2009-2013 update report. The following document was prepared by Committee chairman James Binns as a draft section of the update report for the Committee to consider in the event the charter change was rescinded. Since the charter change was not rescinded, the section was removed from the draft report and from consideration by the Committee. However, it is based on previous findings and recommendations by the Committee.

Federal Research Programs that Address the Health of 1990-1991 Gulf War Veterans

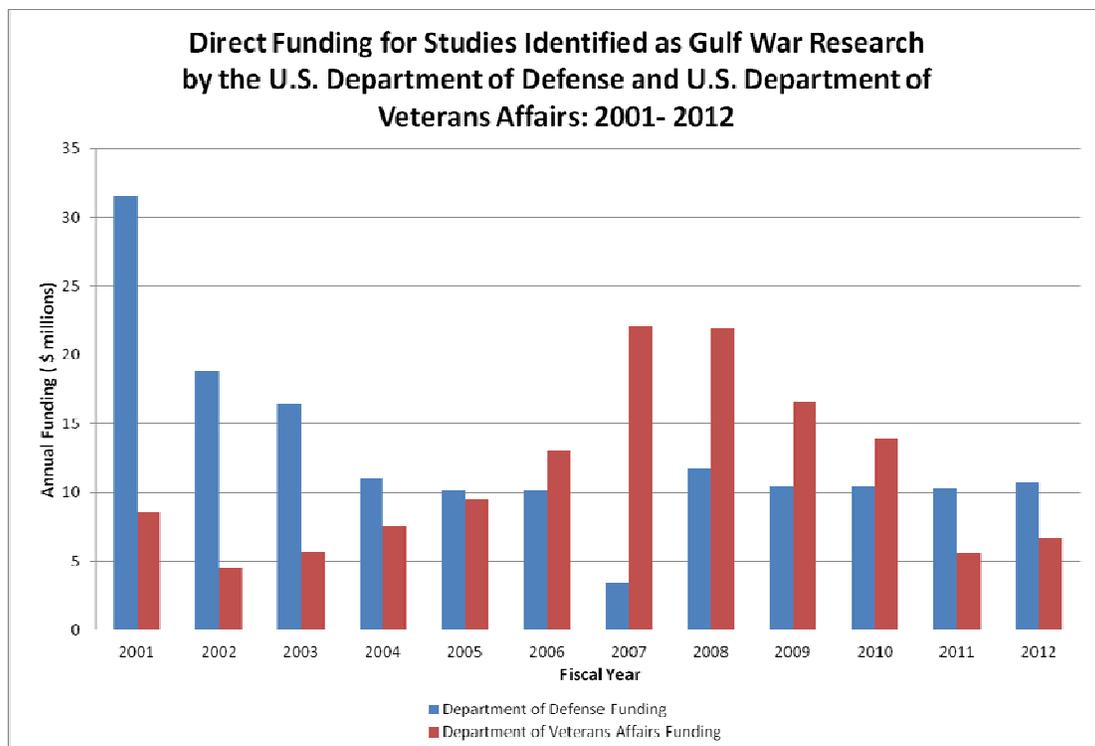
As evidenced throughout this report, important progress has been made in improving the understanding of Gulf War illness. Research is beginning to identify probable underlying mechanisms, promising treatments and biomarkers.

Highly qualified new investigators from prestigious institutions have entered the field, inspired by the 2010 Institute of Medicine committee's belief that "treatments, cures, and, it is hoped, preventions" can "likely" be found with the right research. [IOM 2010] Experienced Gulf War illness investigators "believe, based on recent progress, that these successes are possible, and within sight." [Lea Steele Testimony, 2013]

Regrettably, VA policy has recently reverted to positions similar to those established in the 1990's, when the government asserted that Gulf War veterans had no unusual health problems. Since no scientific support for these positions exists, misleading studies and reports have been generated to justify them. These studies and reports address topics fundamental to understanding Gulf War illness, including the number of ill veterans, whether the illness is psychiatric, whether it is "just what happens after every war," and the case definition of the illness to be used in future research. Unless halted, these actions will mislead the future course of Gulf War illness research, at VA and elsewhere, terminating progress just as science has finally turned the corner.

Federal Gulf War research since 2008 has been conducted by the Department of Veterans Affairs and the Department of Defense.

The following graph shows direct funding for studies identified as Gulf War research by the Department of Defense and the Department of Veterans Affairs from 2001 through 2012.



Gulf War Research at the Department of Defense Congressionally Directed Medical Research Programs

The Department of Defense provided the largest share of Gulf War research funding in the initial decade following the war. However, DoD funding declined from over \$30 million in FY2001 to less than \$4 million in FY2007 as funding of new projects stopped following the onset of new wars in Iraq and Afghanistan. [Deployment Health Working Group Research Subcommittee 2004, Deployment Health Working Group Research Subcommittee 2005, Deployment Health Working Group Research Subcommittee 2006 Deployment Health Working Group Research Subcommittee 2006 Deployment Health Working Group Research Subcommittee 2007, RAC Report 2004]

Recognizing the continued military importance of Gulf War illness research to current and future forces at risk of similar exposures, Congress appropriated \$5 million for new DoD Gulf War illness research in FY2006, which was assigned to the Office of Congressionally Directed Medical Research Programs (CDMRP) of the US Army Medical Research and Materiel Command. Congressional language provided that the funds be used for research that provided insights into the biological mechanisms that underlie Gulf War illness and for studies to evaluate promising treatments and diagnostic biomarkers. [Harris, 1997, Kucinich, 2005]

The CDMRP program began by defining a mission, establishing priorities, and enlisting the input and guidance of experts in the subject and of Gulf War veterans. Ill veterans were placed on the panels that determine the kinds of research proposals the program solicits, and which proposals the program will fund. All proposals are evaluated for scientific merit, but final funding decisions are based on the relevance of the study to program priorities.

CDMRP funding is available on an openly competed, peer-reviewed basis to any investigator, public or private, government or academic. In contrast, VA research programs are only open to VA doctors, which limits the pool of potential researchers and study topics in a new and specialized field like Gulf War illness.

Interest in Gulf War illness in the scientific research community increased following the release of the RAC report in November 2008 and IOM report in April 2010. Congress maintained funding at the \$8-10 million level from FY2009 through FY2012.

In 2011, CDMRP-funded researchers at the University of California, San Diego, reported on the first successful medication study in the history of Gulf War illness research. Preliminary results from a pilot study of the supplement CoQ10, one of the treatment studies funded in the first year of the program, showed significant improvement in one of the most serious Gulf War illness symptoms, fatigue with exertion, and positive improvement in all symptoms.

In 2012 and 2013, positive preliminary results were reported in two additional treatment pilot studies, as other studies funded in the early years of the program began to be completed. Georgetown University scientists reported that Gulf War veterans randomized to receive L-carnosine therapy showed a significant improvement in the digit symbol substitution cognitive task. The L-carnosine group also showed reduced irritable bowel syndrome-associated diarrhea [Baraniuk, 2013]. Researchers from Harvard Medical School and the New England School of Acupuncture found that Gulf War veterans reported a significant improvement in quality of life and pain on self-report measures after acupuncture treatment. A pilot study of the drug mifepristone proved largely unsuccessful.

From its founding in FY2006 through FY2012, the CDMRP program has funded 57 projects, including 18 treatment studies, 11 clinical studies in humans and 7 preclinical studies in animal models. [Lea Steele Testimony, 2013]. The remaining studies were studies of diagnostic biomarkers and studies of mechanisms underlying the illness to identify targets for treatments.

Nine studies have been awarded to investigators from the Department of Veterans Affairs.

The CDMRP program has also funded two multi-site “consortia,” teams of researchers from different institutions who have developed coordinated Gulf War illness research projects, addressing the full spectrum of treatment identification, beginning with animal models. The consortia were also chosen through competitive proposals.

One hundred percent of these CDMRP projects directly relate to Gulf War illness.

In 2012, after the Department of Veterans Affairs reduced its own FY2013 budget for Gulf War research from \$15 to \$5 million, Congress voted to increase CDMRP GWI funding by \$10 million to a total of \$20 million, recognizing the success of the program and the need to maintain overall federal research levels. Due to the sequester process, the actual amount that ultimately reached CDMRP was about \$15.6 million. The program committed the additional FY2013 funds to an innovative multicenter treatment solicitation.

Gulf War research at the Department of Veterans Affairs

From FY2007 through FY2009, Department of Veterans Affairs Gulf War research was largely conducted by the University of Texas Southwestern Medical Center (UTSW) in Dallas. Congressional legislation in 2006 directed VA to establish a Gulf War illness research center at UTSW, funded for five years at a \$15 million annual level [Brown, 2006]. A memorandum of understanding to establish this “Gulf War Illness and Chemical Exposure Research Program” was agreed upon between VA and UTSW. [REFERENCE]

This Committee closely reviewed the UTSW program, holding at least one meeting each year in Dallas during this period. The Committee submitted findings and recommendations [cite to RAC recommendations regarding UTSW] as with other VA research programs, and was critical where appropriate, but appreciated the program leadership’s willingness to engage in open dialogue and to make changes in response to Committee comments and recommendations. The Committee welcomed the program’s unambiguous focus on Gulf War illness.

In recent years, UTSW has published numerous papers reflecting the work of the program. These studies have made significant contributions to the understanding of Gulf War illness, including the extent and type of autonomic nervous system injury [Haley 2013], the extent and site of brain injury and new magnetic resonance spectroscopy techniques to study brain injury, [Gopinath 2012; Li, 2011; Liu, 2011] and research on the prevalence of Gulf War illness [Iannacchione, 2011].

In August 2009, VA cancelled the balance of the UTSW contract, citing a VA inspector general’s report. The report concluded that UTSW had “failed to comply with the terms of the contract related to data ownership and secrecy.” However, the report also concluded that VA’s “use of . . . contracting authority was inappropriate and . . . resulted in multiple problems with contract administration. . . Since VA management chose not to pursue grant authorization, they opted to misuse Federal government regulations and policy.” [Office of the Inspector General, 2009]

The VA press release announcing the termination of the contract stated: "Research into the illnesses suffered by Gulf War Veterans remains a priority for VA. . . The decision not to continue the contract means VA's research program will be able to redirect funds to support additional research into GWVI." [VA Press Release 2009]

The following table shows research officially reported as Gulf War research to Congress by VA from FY2008 through FY2012. During this period, reported VA Gulf War research has declined from \$21.6 million to \$6.7 million.

Table 1. Reported VA Gulf War Illness Research Expenditures from 2008-2012

Focus of VA Gulf War Research Studies†	2008 Funding* (% of 2008 funds)	2009 Funding* (% of 2009 funds)	2010 Funding* (% of 2010 funds)	2011 Funding* (% of 2011 funds)	2012 Funding* (% of 2012 funds)
Gulf War Illness, Effect of Gulf War Exposures	\$17,535,709** (81%)	\$8,687,878** (56%)	\$3,761,795** (27%)	\$1,290,581 (23%)	\$3,874,737 (58%)
Other health problems specific to Gulf War Veterans	\$767,379 (3%)	\$651,989 (4%)	\$353,309 (3%)	\$242,775 (4%)	\$168,600 (2%)
General research on ALS in veterans of all eras	\$2,494,074 (12%)	\$5,664,976 (36%)	\$2,954,873 (22%)	\$1,862,572 (33%)	\$618,840 (9%)
Other general research in veterans of all eras	\$849,885 (4%)	\$653,172 (4%)	\$6,620,240 (48%)	\$2,321,025 (40%)	\$2,060,779 (31%)
Total VA Gulf War Research Funding, by Year	\$21,647,047 (100%)	\$ 15,658,015 (100%)	\$13,690,217 (100%)	\$ 5,716,953 (100%)	\$6,722,956 (100%)
	*Direct costs, as reported in Deployment Health Working Group Annual Report to Congress for each year				
	†Research focus of individual projects categorized by Research Advisory Committee on Gulf War Veterans' Illnesses				
	** Including \$15,000,000 in 2008, \$7,000,000 in 2009, and \$2,300,000 in 2010 spent on the University of Texas Southwestern program				

As the table shows, much of this research was focused on studies involving veterans of all eras rather than the particular health problems of Gulf War veterans, especially Gulf War illness.

Virtually all VA research regarding ALS has been reported as Gulf War research, although it relates to veterans of all eras. The reported "VA Gulf War Biorepository Trust," for example, funded at \$5.7 million in FY2009, was an ALS brain bank with one Gulf War brain out of 61 as of 2010.

Many general VA research projects in veterans of all eras regarding multiple sclerosis, pain, gastrointestinal problems, and medical imaging have similarly been reported as Gulf War research. Examples include a \$5.1 million grant toward the purchase of a 7-tesla MRI scanner for general imaging research, for which there was no pending Gulf War study, and a 2011 study of gastrointestinal pain in women who served in Iraq and Afghanistan during the past decade.

VA Gulf War research includes a mix of investigator-initiated studies, chosen through competitive review, and central office-initiated studies, where central office officials determine in advance the research subject and the individuals chosen to execute it. The central office-initiated studies are often the larger dollar projects, such as the ALS brain bank and MRI scanner noted above.

Achievements of VA Gulf War researchers during this period have included many of the studies cited in this report. A notable example was the 2010 publication by Dr. Han Kang and colleagues of a survey of 30,000 Gulf War era veterans, conducted in 2005, which found that 37% of deployed veterans have multisymptom illness (compared to a rate of 12% in non-deployed veterans of the same era), confirming smaller studies by earlier investigators regarding the excess rate of illness in Gulf War veterans. [J Occup Environ Med. 2009 Apr;51(4):401-10. doi: 10.1097/JOM.0b013e3181a2feeb. Health of US veterans of 1991 Gulf War: a follow-up survey in 10 years. Kang HK, Li B, Mahan CM, Eisen SA, Engel CC.] The 2011 study of Continuous Positive Airway Pressure by Dr. Mohammad Amin, showing statistically significant improvement in some symptoms of Gulf War illness in veterans with GWI and sleep disordered breathing, was one of the first successful Gulf War illness treatment pilot studies. [Amin, 2011]

Additional VA Programs Relevant to Gulf War Research

Prior to the release of the 2008 RAC report, VA programs regarding care, benefits, and public information reflected 1990's government positions that Gulf War veterans had no serious health problem -- just "what happens after every war", due to stress or other psychological factors, affecting relatively few veterans.

As discussed in that report, VA's clinical training program taught doctors that "discussing chronic illness with a Gulf War veteran or a woman with a silicone breast implant is a different matter from discussing it with the average patient." [2008 report, p. 304] There was "no unique Gulf War syndrome." [2008 RAC report, p. 41-42.] "[M]ost have health problems similar to those experienced by veterans of other eras. . . . [M]ost of the symptoms reported by veterans in VA registry examinations were found to be caused by conventional illnesses." [2008 RAC report, p. 304] The approval rate for benefits claims based on "undiagnosed illness" was 26% (compared to 87% for disability claims overall). [2008 RAC report, p. 306]

Following the release of the 2008 report, over the period from 2009-2011, VA significantly improved its programs toward bringing them in line with current research knowledge.

2009-2011

2010 Institute of Medicine report. The 2008 RAC report was released in November 2008. Before the new Administration took office in January, VA staff initiated a new IOM report to compare the findings of the IOM with the findings of the RAC report. The VA charged the IOM to update a 2006 IOM report

regarding scientific literature on the prevalence of cancer, neurodegenerative diseases, birth defects, and psychiatric conditions in Gulf War veterans. [reference VA charge described at <http://www.iom.edu/Activities/Veterans/GulfWarHealth2009.aspx>]

This limited review would have found nothing to substantiate the findings of the RAC report regarding Gulf War illness, since the review would not have addressed undiagnosed illnesses like GWI. The RAC report had described how previous IOM Gulf War reports had been “skewed and limited” by VA’s direction. [2008 RAC report, p. 55] The new report would have been another example of VA shaping the conclusions of IOM reports by limiting the information considered.

However, the Research Advisory Committee alerted the Secretary’s Office, and Secretary Eric Shinseki asked the IOM to invite the Research Advisory Committee to make a presentation to the IOM committee tasked with the report. In April 2009, three RAC committee members briefed the IOM committee on the scientific findings of the RAC report, as well as the history regarding VA’s direction of IOM Gulf War reports. The IOM committee subsequently decided to disregard the limiting instructions of VA staff and conduct a fresh comprehensive review of the literature regarding Gulf War veterans’ health. When its report was completed in April 2010, it largely reached the same conclusions as the 2008 RAC report, as described above.

Gulf War Task Force. VA Chief of Staff John Gingrich, who served as a battalion commander during the Gulf War and had witnessed members of his command become ill, established and chaired an internal VA “Gulf War Task Force” of representatives from all relevant VA offices. The task force prepared a report on needed changes in VA programs based on the findings of the RAC report. [reference: <http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1858>] Secretary Shinseki announced the release of the initial report of the task force in February 2010 as “the first step in a still-unfolding comprehensive plan of how VA will treat and compensate veterans of the Gulf War era.” [cite to <http://www1.va.gov/opa/pressrel/pressrelease.cfm?id=1858>]

VA disability benefits in relation to Gulf War research. A training letter sent by the VA Compensation and Pension Service to all VA regional offices the same month provided new scientifically and legally accurate guidelines to use in determining if a Gulf War veteran who suffers from an “undiagnosed illness” qualifies for health coverage and other benefits. The letter also instructed the offices to re-evaluate past claims to apply the new standard.

The letter acknowledged the connection to environmental hazards in “undiagnosed illness” or “chronic multisymptom illness”: “Because military personnel continue to operate in Southwest Asia and continue to be exposed to potential environmental hazards, including some not experienced during the initial 1990-1991 Gulf War, C&P Service has determined that an adjustment to the regulation is in order.” [cite to <http://www.ngwrc.org/docs/VAtl10-01.pdf>]

Information on Gulf War research provided to VA clinicians. VA revised its training for doctors. The VA online training course, “Caring for Gulf War I Veterans,” released in July 2011, acknowledged that Gulf War illness is not psychological: “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.” [cite to <http://www.publichealth.va.gov/docs/vhi/caring-for-gulf-war-veterans-vhi.pdf> page 40]

Gulf War Research Strategic Plan. In mid-2011, the VA Office of Research and Development agreed to a proposal put forward by Dr. Maximillian Buja, chairman of its Gulf War Steering Committee (GWSC), to prepare a Gulf War strategic research plan using working groups of VA staff and outside advisors. (The GWSC was an entity ORD had established, made up of three RAC members and four

other outside advisors, including Dr. Buja, a former Dean of the University of Texas Health Science Center at Houston.) The RAC had frequently recommended that VA develop a strategic plan to guide its Gulf War research program.

The topics to be considered by the strategic plan were divided among ten working groups. The outside advisors named to the working groups included members of the RAC, members of the VA National Research Advisory Council (NRAC), and others. Ten members of the RAC and its associate scientific director volunteered to serve on the working groups, with five members serving on two working groups.

In addition to ORD personnel serving on the working groups, ORD provided staff support. The working groups met frequently during the fall of 2011 under the leadership of Dr. Buja. Working together, VA staff and RAC members were able to find common ground, and the other outside advisors provided fresh perspectives. The plan acknowledged the reality of Gulf War illness and VA's commitment to implement the 2010 IOM recommendation for "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." ¹A new era of cooperation and productivity appeared to have arrived for VA Gulf War research. The bureaucratic resistance that had held up research progress for twenty years appeared to be removed.

The December 2011 annual report of the RAC stated: "It appears likely that for the first time VA will soon have a comprehensive strategic plan to provide the foundation for an effective Gulf War research program." [cite to <http://www.va.gov/RAC-GWVI/2011annualreport.pdf>]

The draft strategic plan, incorporating the inputs of the working groups, and of a leadership group that coordinated the inputs, was presented to a meeting of the RAC on January 31-February 1, 2012. Several NRAC members who had participated in the working groups were present. The discussion at the meeting was generally constructive and enthusiastic. As noted in the recommendations following the meeting, there was agreement between ORD and the RAC that the plan required the participation of other VA offices involved in research besides ORD, notably the Office of Public Health. [cite to http://www.va.gov/RAC-GWVI/docs/Committee_Documents/strategic_plan_recs.pdf]

2012-2013

This period of progress came to an end in early 2012, as VA policy reverted to positions similar to those established in the 1990's. Since no scientific support for these positions exists, misleading studies and reports have been initiated to justify them. These studies and reports address topics fundamental to understanding Gulf War illness, including the number of ill veterans, whether the illness is psychiatric, whether it is "just what happens after every war," and the case definition of the illness to be used in future research. Unless halted, these actions will mislead the future course of Gulf War illness research, at VA and elsewhere, terminating progress just as science has finally turned the corner.

National Survey of Gulf War Era Veterans. Once a decade, the VA Office of Public Health conducts a survey of 30,000 Gulf War and Gulf War era veterans, which is the basic data source on the health of this group. The survey sent out in April 2012 asks two pages of questions on recent stressful events and worries, nine questions on alcohol use, and the seventeen questions necessary to define PTSD, but not the questions necessary to define Gulf War illness.

The Research Advisory Committee repeatedly asked that the questions necessary to define Gulf War illness be included. Committee members pointed out that "[t]he draft . . . 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. . . [I]t 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.”ⁱⁱ They provided a suggested symptom inventory of less than two pages.

VA staff commented that no symptom inventory was included in the previous (2005) version of the survey, and that sound scientific practice required using the same questions from the 2005 survey so answers could be compared. In fact, however, the original 1995 version of the survey included a symptom inventory, which was dropped in 2005.

Committee members also pointed out that the 1995 survey “identified significantly excess rates of birth defects and adverse pregnancy outcomes in 1991 Gulf War veterans.” However, “these problems were not followed up in the 2005 survey, and are not included in the current survey.”

VA Chief of Staff John Gingrich approved the study after considering these comments and those of OPH staff. The principal investigator of the survey, a senior epidemiologist in the Office of Public Health, subsequently testified to a Congressional committee that his superiors intentionally misled Mr. Gingrich to get him to approve the study without the changes.

“They falsely stated that putting the study on hold long enough to revise the questionnaire would cost the Government \$1,000,000, delay the study for a year or longer, and potentially result in contract default. None of this was true. But as a result, the Chief of Staff ordered the survey to proceed without the changes.”ⁱⁱⁱ

The Office of Public Health has subsequently advised the Committee that it is conducting a sub-study associated with the survey in which the medical records of veterans will be compared to their self-reported medical conditions.^{iv} Since there is no diagnostic code for multisymptom illness, it is virtually certain that the medical records review will show substantially less than the self-reported amount.

Institute of Medicine treatment report launch. In February and April, two VA staff members and four other individuals reportedly suggested by VA staff, briefed a new IOM committee that Gulf War illness is, or may be, a psychiatric problem.

The new IOM committee was commissioned in response to Congressional legislation ordering VA to contract with the IOM for a study of the best treatments for Gulf War chronic multisymptom illness.^v Knowing that there was virtually no scientific literature on treatments (because of the lack of treatment studies prior to the creation of the CDMRP program), Congress specified that the IOM convene a panel of medical practitioners with expertise in treating Gulf War veterans.^{vi} Congress knew these doctors would have practical experience in trying different approaches and know what therapies had been helpful to their patients, although they might not have been formally studied.

VA ignored the law and contracted for a literature review by a committee with no Gulf War health experience.

The speakers who briefed the committee on the nature of chronic multisymptom illness^{vii} were figures associated with government positions in the 1990’s and early 2000’s. Two spoke on “Chronic Stress and Its Role in Emotional, Somatic, and Cognitive Symptoms” and “Vulnerability, Stress Exposure and Depression.” A third featured a slide on the “Overlap Between Chronic Multisymptom Illnesses and Psychiatric Disorders.” The director of the DoD Deployment Health Clinical Center highlighted “stress, PTSD, or somatization” as the likely causes of Gulf War Veterans Illnesses. A staff member from the

VA Center for Implementing Evidence-Based Practice, discussed the “SAD triad: somatization, anxiety, and depression.”^{viii}

The director of the VA Post-Deployment Integrated Care Initiative, speaking on “VA Approaches to the Management of Chronic Multi-Symptom Illness in Gulf War I Veterans,” presented data from an eleven-year-old study showing that VA doctors do not know if Gulf War multisymptom illness is mostly a physical or mostly a mental disorder.^{ix} As noted above, the current VA physician training guidelines state: “What we do know is that chronic multisymptom illness is real and cannot reliably be ascribed to any known psychiatric disorder.”^x The speaker did not mention the current guidelines, although he served on the committee that wrote them.^{xi}

Given that the IOM’s own comprehensive 2010 report had concluded that Gulf War illness “cannot be reliably ascribed to any known psychiatric disorder” (2010 IOM report, p. 109), the selection of these six individuals to provide scientific background for a committee with no experience in Gulf War illness was striking. A former senior VA epidemiologist subsequently testified to Congress that the chief scientist of the VA Office of Public Health identified the first five speakers that the IOM should invite.^{xii} Only one invited speaker provided a view of the illness consistent with current scientific knowledge.

The membership of the treatment committee itself was also striking. The fifteen members included no one with the clinical experience that Congress had specified, four with special interests in somatic and psychosomatic medicine, one specialist in anxiety and traumatic stress, one expert in risk communication, and a professor of psychiatry.^{xiii}

Rather than focus the committee, as Congress desired, on “chronic multisymptom illness or another health condition related to chemical and environmental exposures,”^{xiv} VA instructed the committee to review “all published peer-reviewed literature concerning treatment of populations with a similar constellation of symptoms.”^{xv}

Given this broad assignment, the content of the briefings, and the makeup of the committee, it became clear that its review would focus on psychiatric literature, notwithstanding the unambiguous conclusion of the previous IOM report that the illness was not psychiatric.

Public information. VA public information materials were revised to reflect old positions. The 2012 annual report of the Office of Research and Development characterized VA’s Gulf War research program as “investigating whether service in the Gulf War is linked to illnesses Gulf War veterans have experienced.” Other VA research programs were described in the annual report in terms of solving veterans’ health problems, not whether service-related problems exist.

The scientific literature, the Research Advisory Committee, and the Institute of Medicine had long ago concluded that service in the Gulf War is linked to veterans’ illnesses. As stated by the IOM in 2010, “the committee concludes that there is sufficient evidence of association between deployment to [the] Gulf War and chronic multisymptom illness.”^{xvi}

The VA Office of Public Health website adopted the same inaccurate language to characterize the VA Gulf War research program.

Gulf War Research Strategic Plan. The plan developed over five months by working groups of VA staff and outside advisors was dramatically scaled back to reflect previous practices.

Two weeks following the RAC meeting at which the strategic research plan was reviewed, VA submitted to Congress its proposed budget for FY2013, cutting Gulf War illness research two-thirds compared to the FY2012 budget, from \$15 to \$4.9 million.^{xvii} While actual expenditures in FY2012 were far below \$15 million, as discussed above, VA staff had explained this shortfall as an inability to find good research to fund, and the intention of the strategic plan was to design an effective \$15 million annual program. However, it became apparent that VA did not intend to fund this program.

Four months later VA revealed a revised version of the plan following unilateral changes by VA staff. The changes transformed the plan from a focused strategy to execute the IOM's 2010 call for "a renewed research effort . . . to better identify and treat multisymptom illness in Gulf War veterans" into a bland justification of VA's old policy of reporting research on various problems affecting veterans of all eras as Gulf War research. The changes further eliminated the urgency, commitment, and specificity built into the working group's draft. Except where the plan quoted from outside sources, any mention of "Gulf War illness," or other terminology suggesting an illness related particularly to the Gulf War, was removed.

June 2012 Research Advisory Committee findings and recommendations. At its first meeting following this sea change in VA policy, the Research Advisory Committee prepared a detailed review of the revisions to the strategic plan and the other actions described above. It noted the divergence of these actions from the policy of the Secretary and the intent of Congress. It observed, however, that "[t]hese actions repeat the pattern of the last twenty 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)"

"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 Committee concluded that it had "no confidence in the ability or demonstrated intention of VA staff to formulate and execute an effective VA Gulf War illness research program." It acknowledged "the credible work conducted by many individual researchers, and the positive intentions of some staff members" but recommended that the actions outlined "be thoroughly investigated to identify the individuals responsible and that appropriate action be taken to remove them from positions of authority and influence over Gulf War illness research."^{xviii}

Institute of Medicine treatment report outcome. The IOM Treatment committee presented its report in January 2013. As expected, its literature review found that "[o]nly three [treatment] studies were conducted in military or veteran populations."^{xix} Given its assignment from VA and the background provided by the briefers, it proceeded to consider treatment literature for twelve other diseases, six of them psychiatric, including somatic-symptom disorder, depression, anxiety, PTSD, substance use and addictive disorders, and self-harm.

In its review of drug interventions, for example, the committee considered nine clinical studies. "Only one study involved [a] veteran population," it reported. "[I]t was the only study to use a nonpsychopharmacologic intervention. . . . The other eight studies enrolled people from the general population, most of them female, who had somatoform disorder."^{xx}

Overall, the report devotes forty-eight pages to psychotherapies in its discussion of treatments for chronic multisymptom illness. It counsels doctors treating Gulf war veterans: “[C]linicians should approach CMI with ‘a person-centered model of care . . . that helps patients understand that the word psychosomatic is not pejorative.’”^{xxi}(p. 17)

It claims that the same problems happen after every war: “Throughout modern history, many soldiers returning from combat have experienced postcombat illnesses. . . that cannot now be attributed to any diagnosable pathophysiologic entity or disease.”^{xxii}

It characterizes such illnesses as psychosomatic: “Many soldiers who have postcombat illnesses have long-term unexplained symptoms that cannot now be attributed to any diagnosable pathophysiologic entity or disease; such symptoms are referred to as medically unexplained.”^{xxiii} “Among the many terms used in the literature to label . . . somatic presentations, . . . [current] descriptive terms [include] medically unexplained symptoms. . .”^{xxiv}

This language sharply contrasts with the findings of the 2010 IOM report: “[S]tudies of somatoform disorder in Gulf War veterans . . . do not support the hypothesis that their medically explained symptoms results from this disorder.”^{xxv}

Indeed, wherever the treatment report purports to address actual Gulf War research, it is inaccurate. (The treatment committee did not review all Gulf War health literature as the 2010 IOM committee had done, only the handful of treatment studies.) It states, for example: “Research has identified no symptom clusters, or syndromes.”^{xxvi} In fact, the 2008 RAC Report includes a table of eight such studies covering five symptom clusters, and the text discussed many more.^{xxvii}

Because VA’s instruction to the committee ignored Congress’s focus on “health condition[s] related to chemical and environmental exposures,”^{xxviii} the committee considered no illnesses related to environmental exposures. It never mentions the 2010 IOM report observation that “it is likely that Gulf War illness results from an interplay of genetic and environmental factors.”^{xxix} Rather, it dismisses the idea: “The focus on toxicants may be attributed, at least in part, to ‘a general fear of toxins spread as a result of modern industrial life.’”^{xxx}

In summary, by contracting for a literature review by a committee without Gulf War expertise, misleading the committee to believe that the illness is or may be psychiatric, and directing the committee to consider a broad range of illnesses including psychiatric conditions, VA guided the treatment committee to produce a report that re-asserted all the former positions from the 1990’s. The report bears no resemblance to Congress’s intention in ordering it or to current scientific knowledge.

The statute requires that the findings of the report “be disseminated throughout the Department of Veterans Affairs.”^{xxxi}

Case definition of the illness. An entire section of the Gulf War research strategic plan was devoted to the need and process for developing a case definition for Gulf War multisymptom illness. One working group focused exclusively on this section, illustrating the importance of the subject.

The process customarily used in medical science to define an illness are: 1) the appointment of a consensus panel of experts in that illness and 2) a rigorous analysis to determine which possible definition elements best fit the accumulated research data. This process was accordingly recommended by the working group: “The case definition should be developed by a consensus panel of experts in the field,

utilizing analytic results from a comprehensive evaluation of available data resources.”^{xxxii}

Different case definitions have been used over the years, and the benefits of having a uniform case definition were discussed. However, the wrong case definition would misdirect future Gulf War health research, not only at VA, but throughout the scientific community.

The January 2013 IOM treatment report, for example, developed its own “working case definition”: “the presence of a spectrum of chronic symptoms experienced for 6 months or longer in at least two of six categories – fatigue, mood and cognition, musculoskeletal, gastrointestinal, respiratory, and neurologic – that may overlap with but are not fully captured by known syndromes (such as IBS, CFS, and fibromyalgia) or other diagnoses.” (p. 23)

The definition was not developed using research data and did not involve the consensus, or even the input, of experts in the field. It would expand the scope of the illness to include all populations and any unexplained condition involving two of the common symptom areas listed, divorcing the concept of chronic multisymptom illness from Gulf War service.

Note that this is a radical change. The term “chronic multisymptom illness” was originated by a CDC researcher to describe the disease of Gulf War veterans.^{xxxiii} Note also that the treatment report ignored the definition provided by Congress, which linked the illness to Gulf War service.^{xxxiv}

Absent the connection to Gulf War service, the definition encompasses most unexplained chronic health problems, whether physical or mental. By including all populations and many conditions, the chance of identifying an effective treatment that works on the underlying mechanism of Gulf War multisymptom illness would be reduced dramatically. Gulf War veterans and their doctors would be forever limited to addressing only the most general symptoms and coping skills.

In late 2012, VA assigned the development of a case definition for “chronic multisymptom illness as it pertains to the 1990-1991 Gulf War Veteran population” to the IOM. Contrary to usual good practice, VA’s charge to the IOM called for a literature review, not a comprehensive data analysis. VA staff informed the Committee that the contract was in process in February 2013.^{xxxv}

The Committee recommended that VA instead “sponsor a joint effort with the Gulf War Illness research program at CDMRP to establish an expert consensus and evidence-based case definition for Gulf War illness.” The Committee “emphasize[d] the importance of establishing a case definition specific to the illness resulting from military service in the 1990-1991 Gulf War, in order to provide homogenous groups for research studies. While poorly understood illnesses are known to affect other populations, the environmental conditions and experiences encountered in the 1991 Gulf War theater are distinct from etiologic factors associated with other symptom-defined conditions. Until objective diagnostic tests can be identified for Gulf War illness, it is essential that a symptom-based case definition be established that best characterizes the symptom profile that has been consistently and specifically associated with military service in the 1990-1991 Gulf War.”^{xxxvi}

March 2013 Congressional testimony. Two members of the Research Advisory Committee provided testimony on the recent findings and recommendations of the Committee to a hearing of the House Veterans Affairs Committee Subcommittee on Oversight and Investigations on March 13, 2013. It was the ninth Congressional hearing where Committee members have testified.

VA’s response. VA’s response to the June 2012 and February 2013 recommendations of the Research Advisory Committee has been as follows.

VA did not add the questions necessary to identify Gulf War illness by any existing case definition to the national survey of Gulf War era veterans. The survey results will not be able to determine the prevalence, progression, or correlates of the illness, and are likely to underreport it. Initial results are expected in mid-2014.

VA did not modify the contract for the IOM treatment report to conform to Congress's intent. The report has been completed. Although the IOM committee did not review any Gulf War scientific literature beyond the three treatment studies, the report reasserts government positions from the 1990's that the health problems of Gulf War veterans are no different from what happens after every war, that they are due to psychiatric/psychosomatic factors, and that there is no evidence of a common pattern in their symptoms. The report puts the weight of the IOM behind these findings, although they bear no resemblance to current scientific knowledge. The statute requires that the findings of the report "be disseminated throughout the Department of Veterans Affairs."^{xxxvii}

VA re-set its budgeted Gulf War research spending in FY2014 to \$15 million and has made a number of edits to its website and to the Gulf War strategic plan. However, VA has historically not spent the amount budgeted, and the amount spent has included significant numbers of studies not actually directed at Gulf War veterans.

The VA Gulf War website remains titled "Gulf War Veterans' Medically Unexplained Illnesses"^{xxxviii}. The strategic plan similarly continues to employ terminology that does not acknowledge that Gulf War veterans have any special health problem. The term "chronic multisymptom illness" has been expanded from a term to describe the multisymptom condition of Gulf War veterans to any illness with multiple symptoms, from irritable bowel syndrome to fibromyalgia. While there are similarities among these conditions, research has found important differences, too,^{xxxix} and the key to understanding them lies in segregating them in research studies, while lumping them together eliminates that possibility.

VA proceeded to conclude the contract for the development of a case definition with the IOM through a literature review by a committee with little expertise in the illness, although this is contrary to usual scientific practice. The IOM has never done a case definition of an illness before.^{xl}

Similar to the treatment report, VA's direction to the IOM requires it to consider "published peer-reviewed literature concerning case definitions for other populations with a similar constellation of symptoms."

Also similar to the treatment report, the members appointed to the committee reflect a heavy representation of psychiatric views. The group initially chosen had only three individuals out of fourteen with Gulf War illness research or clinical experience. Two of those three have published papers expressing the view that psychological fear of toxic exposures causes veterans' illnesses. Others include a past president of the Academy of Psychosomatic Medicine, a psychologist who favors a mental health approach to treating multisymptom conditions, and a specialist in the health consequences of psychosocial stress. The members also include three who have previously served on IOM committees that found no connection between toxic exposures and illness, including one member of the 2013 treatment committee.^{xli}

The IOM invited members of the Research Advisory Committee and several Gulf War veterans to address the case definition panel in the open session of the case definition committee's first meeting on June 26, 2013.^{xlii} Several expressed concern that the IOM committee was not qualified to establish a Gulf War illness case definition. The IOM subsequently appointed three new members to the committee. One has experience conducting Gulf War health research, but two of the three are specialists in psychometrics and psychiatry biostatistics, respectively, with no Gulf War health experience.^{xliii}

The working case definition developed by the treatment committee was discussed in a closed session at the first meeting of the case definition committee.^{xliv} A case definition similar to the working definition would determine that future Gulf War illness research would be conducted in a vague, unbounded universe of “chronic multisymptom illness” of whatever origin, losing any chance to identify underlying mechanisms, specific diagnostic tests, and effective treatments. The case definition committee’s report is expected in the Spring of 2014.

Military Medicine editorial. The predictable outcome of the studies and reports described above will be a further shift of VA policy toward 1990’s positions. VA has already begun to signal where it is headed. In July 2013, the chief scientist of the VA Office of Public Health, joined by the heads of the three VA War Related Illness and Injury Study Centers, published an editorial in the journal *Military Medicine* on the “Care of Veterans With Chronic Multisymptom Illness.”^{xlv}

The editorial begins by stating that “CMI has been documented after armed conflicts since the Civil War and unfortunately has surfaced again as Veterans return from the theaters of operation in Afghanistan and Iraq.” The Gulf War is not even mentioned.

The authors assume that the problem is at least partly psychiatric. A “biopsychosocial approach to the illness . . . will most benefit the patient.” An advantage of clinical team care is that “someone will ask a question about the ‘other’ factors affecting the patient.” “Since the psychosocial issues often form barriers to effective management, being aware of them helps the team resolve problems.”

Eliminating oversight. VA’s most significant response to the Research Advisory Committee’s findings and recommendations was to change the charter of the Committee to eliminate its oversight function over VA and other government research.

In May 2013, VA changed the Committee’s charter to eliminate its authority “to assess the overall effectiveness of government research to answer central questions on the nature, causes, and treatments for the health consequences of military service . . . during the 1990-1991 Gulf War.”

The principle “that the fundamental goal of Gulf War health-related government research . . . is to ultimately improve the health of ill Gulf War veterans, and that the choice and success of research efforts shall be judged accordingly” was also eliminated.

VA further eliminated the charter provisions granting the Committee its own staff. While not implemented as yet, this change means that the Committee will in the future be staffed by the same VA personnel whose programs it formerly reviewed.

VA also announced that half the membership of the Committee would be replaced immediately, and the remaining half in one year. VA stated that the changes were being made because the Committee had been operating outside its research oversight role, but the changes made eliminated its research oversight role, and no example of the Committee acting outside that role was provided.^{xlvi}

These provisions have been included in all previous charters of the Committee since its formation in 2002. Indeed, the oversight function was the primary reason why Congress created the Committee. Congress had no confidence in the commitment of the executive branch to address the health problems of Gulf War veterans. The Congressional report which led to the law establishing the Committee, “Gulf War Veterans Illnesses: VA, DOD Continue To Resist Strong Evidence Linking Toxic Causes To Chronic Health Effects,” stated its position clearly:

“After 19 months of investigation, the subcommittee finds the status of efforts on Gulf War issues by the Department of Veterans Affairs, the Department of Defense, the Central Intelligence Agency, and the Food and Drug Administration to be irreparably flawed. . . [W]e find current approaches to research, diagnosis and treatment unlikely to yield answers to veterans’ life-or-death questions in the foreseeable, or even far distant, future.”

For twelve years, this Committee has exercised the responsibilities assigned to it by Congress and by four VA Secretaries. Long restricted by bureaucratic agendas, science is finally making progress. The prospect of finding answers to the diagnosis and treatment of Gulf War illness is now likely, provided good research continues. It is time to applaud and support the scientists working to improve the health of Gulf War veterans and to protect the health of current and future American servicemen and women at risk of similar exposures. It is unconscionable that the greatest obstacle these scientists face is the renewed effort of government staff to shape research to mask the problem rather than to solve it. Until this subject is addressed, once and for all, the need for an independent research advisory committee will continue, and progress will be far slower than it should, and could, be.

Recommendations:

The Committee commends the effective Gulf War illness research program that has been created at the Department of Defense Congressionally Directed Medical Research Program and recommends that Congress authorize and appropriate \$20 million annually for five years to support openly-competed, peer-reviewed studies focused on identifying:

- 1) effective treatments for Gulf War illness,
- 2) objective measures that distinguish ill from healthy veterans, and
- 3) underlying biological mechanisms potentially amenable to treatment.

The Committee reiterates the findings and recommendations previously expressed regarding the Department of Veterans Affairs Gulf War research program in June 2012^{xlvii}, February 2013^{xlviii}, and June 2013^{xlix}.

The Committee recommends that the relationship between the Department of Veterans Affairs and the Institute of Medicine regarding Gulf War health research be investigated and reformed, including:

- 1) Reviewing the informal and formal input of VA and DoD staff into IOM report processes and content;
- 2) Reviewing the process for selecting IOM committee members and background speakers;
- 3) Re-conducting those IOM Gulf War and Health reports not conducted in accordance with the statutes mandating the reports, including:
 - a) The report on the best treatments for chronic multisymptom illness in Gulf War veterans required by Public Law 111-275, Section 805, which was not conducted in accordance with the provision of the statute requiring that the committee preparing the report be comprised of "medical professionals who are experienced in treating [Gulf War veterans] who have been diagnosed with chronic multisymptom illness or another health condition related to

chemical and environmental exposures that may have occurred during such service." (Gulf War and Health, Treatment for Chronic Multisymptom Illness, 2013);

b) The report on the prevalence of "multiple sclerosis, Parkinson's disease, and brain cancers, as well as central nervous system abnormalities that are difficult to precisely diagnose" in Gulf War and recent Iraq/Afghanistan war veterans, required by Public Law 110-389, Section 804, which has never been conducted;¹ and

c) The reports on the health effects of thirty-three "toxic agents, environmental or wartime hazards, or preventive medicines or vaccines associated with Gulf War service" required by Public Law 105-277 and Public Law 105-368, which were not conducted in accordance with the provisions of the statutes requiring that studies in animals, as well as humans, be considered in determining whether a statistical association exists between exposure to a substance and illness (Gulf War and Health Vol. 1 (2000), Vol. 2 (2003), Vol. 3 (2005), Updated Literature Review of Sarin (2004); Updated Literature Review of Depleted Uranium (2008)).ⁱⁱ

ⁱ 2010 IOM report, pp. 260-261

ⁱⁱ See Appendix C.

ⁱⁱⁱ Cite to Coughlin testimony,

^{iv} Presentation of Dr. Victoria Davey, June 18, 2013, http://www.va.gov/RAC-GWVI/June2013MeetingMinutesFinal_NoSig.pdf

^v Veterans Benefits Act of 2010, Sec. 805(a)

http://www7.nationalacademies.org/ocga/laws/PL111_275.asp

^{vi} Veterans Benefits Act of 2010, Sec. 805(b)

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- vii Four other speakers addressed different topics such as complementary/alternative medicine and information technology.
<http://iom.edu/~media/Files/Activity%20Files/Veterans/GulfWarCMITreatment/Meeitng%20%20Agenda/public%20agenda.pdf>
- viii See presentations of Drs. Dusek, Kendler, Clauw, Engel, and Kroenke at
<http://iom.edu/Activities/Veterans/GulfWarMultisymptom/2012-FEB-29.aspx>
- ix See presentation of Dr. Hunt, <http://iom.edu/Activities/Veterans/GulfWarMultisymptom/2012-APR-12.aspx>
- x <http://www.publichealth.va.gov/docs/vhi/caring-for-gulf-war-veterans-vhi.pdf>, p. 40
- xi Ibid, p. iii
- xii <http://veterans.house.gov/witness-testimony/dr-steven-s-coughlin>
- xiii <http://www.scribd.com/doc/150949964/WHITE-PAPER-IOM-CMI-Panel-Membership-Analysis>
- xiv Veterans Benefits Act of 2010, Sec. 805(b)
- xv IOM treatment report p. 14
- xvi 2010 IOM report, p. 210
- xvii [cite to http://www.va.gov/budget/docs/summary/Fy2013_Volume_II-Medical_Programs_Information_Technology.pdf page 3A-5]
- xviii http://www.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf
- xix Treatment report, p.86
- xx Ibid, p. 32
- xxi Treatment report, p. 17
- xxixii Ibid, p. 11
- xxiii Ibid, p. 11
- xxiv Ibid, p. 100
- xxv 2010 IOM report, p. 109
- xxvi Ibid, p. 15
- xxvii 2008 RAC report, p. 28.
- xxviii Veterans Benefits Act of 2010, Section 805(b), see footnote 2.
- xxix 2008 RAC report, p. 261.
- xxx Treatment report, p. 13
- xxxi Veterans Benefits Act of 2010, Sec. 805(a)
- xxxii Gulf War Research Strategic Plan, January 23, 2012 draft, Sec. 5.3.1
- xxxiii IOM treatment report, p. 21
- xxxiv Veterans Benefits Act of 2010, Section 805(e)(1)
- xxxv Minutes, meeting of the Research Advisory Committee, February 4, 2013,
<http://www.va.gov/RAC-GWVI/FebMeetingMinutes.pdf>
- xxxvi Recommendation Regarding Gulf War Illness Case Definition, adopted February 4, 2013,
<http://www.va.gov/RAC-GWVI/CommitteeRecommendation.pdf>
- xxxvii Veterans Benefits Act of 2010, Sec. 805(a)
- xxxviii <http://www.publichealth.va.gov/exposures/gulfwar/medically-unexplained-illness.asp>

^{xxxix} 2008 RAC report, pp. 280-288

^{xl} <http://www.forbes.com/sites/rebeccaruiz/2013/06/28/inside-the-effort-to-define-gulf-war-illness/>

^{xli} <http://www.scribd.com/doc/150949964/WHITE-PAPER-IOM-CMI-Panel-Membership-Analysis>

^{xlii} <http://www8.nationalacademies.org/cp/meetingview.aspx?MeetingID=6711&MeetingNo=1>

^{xliii} Biographies of Drs. Cook and Leoutsakos,

<http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=49546>

^{xliv} <http://www8.nationalacademies.org/cp/meetingview.aspx?MeetingID=6711&MeetingNo=1>

(click on “Closed Session Summary”)

^{xlv} <http://www.warrelatedillness.va.gov/WARRELATEDILLNESS/research/articles/2013-LangeG-wriisc-multidisciplinary-care-of-veterans-with-cmi.pdf>

^{xlvi} Statement of Chief of Staff Jose Riojas, June 17, 2013, http://www.va.gov/RAC-GWVI/June2013MeetingMinutesFinal_NoSig.pdf, p. 10

^{xlvii} http://www.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf

^{xlviii} <http://www.va.gov/RAC-GWVI/CommitteeRecommendation.pdf>

^{xlix} http://www.va.gov/RAC-GWVI/RACrecsJune2013_7_30.pdf

^l [Public Law 110-389, Section 804; www.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf](http://www.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf), Appendix E

^{li} James H. Binns, testimony, U.S. House of Representatives, Committee on Veterans Affairs, Subcommittee on Oversight and Investigations, July 30, 2009, <http://archives.veterans.house.gov/hearings/Testimony.aspx?TID=2125&Newsid=2169&Name=%20James%20H.%20Binns>