Executive Summary:

Science has firmly established that Gulf War Illness is a serious physical condition caused by toxic exposures during the 1990-91 war. Based on this knowledge, research is finally making significant progress toward understanding the mechanisms underlying the illness and identifying treatments. This research is vital to the health of 175,000 ill Gulf War veterans and to future American forces at risk of similar exposures. Unless legislative action is taken to reassert Congressional authority, however, future research will be misled, and this progress will end.

While proclaiming its interest in Gulf War veterans’ health, VA staff is attempting to reassert discredited 1990’s government positions that Gulf War veterans have no special health problem -- just “what happens after every war,” reflecting psychiatric factors. Since no scientific support for these positions exists, government staff has resorted to manipulating research studies to provide apparent support, including reports of the Institute of Medicine ordered by Congress. The entire scientific community relies on these studies to guide future research. These staff actions thus threaten to terminate the progress being made, and mislead science down blind alleys, as has happened for most of the past twenty-three years.

The Congressionally-mandated Research Advisory Committee on Gulf War Veterans Illnesses has reported on these developments to the Secretary of Veterans Affairs and to Congress. VA’s response has been to terminate the independence of the committee, removing its authority to assess the effectiveness of federal research programs, changing its membership, and prohibiting it from releasing reports without written VA approval.

The proposed bill would re-establish appropriate Congressional authority over Gulf War Illness research and enable scientific progress to continue.

- It provides that the Research Advisory Committee on Gulf War Veterans Illnesses will operate independently of VA authority, with nine members appointed by the chairs and ranking members of the House and Senate Veterans Affairs Committees and three members by the Secretary of Veterans Affairs. This model is based on a similar non-partisan advisory committee at the Department of Education, which has operated successfully for over twenty-five years.

- It requires VA to follow previously enacted legislation requiring the Institute of Medicine to consider animal as well as human studies in assessing the health effects of toxic exposures. Most scientific research on toxic substances is necessarily done in animals. This standard relates to the health of veterans of recent wars in Iraq and Afghanistan, as well as Gulf War veterans.

- It declares it to be the sense of Congress that VA conduct other studies that Congress has ordered in accordance with the law, which VA has either materially changed or failed to conduct at all.

The bill is revenue neutral, as the Research Advisory Committee’s functions and costs will not change, and the research studies mentioned in the bill are not mandatory and, in any case, relate primarily to studies already ordered by Congress. It has not yet been formally scored.

Why Legislation Is Needed:
The Research Advisory Committee on Gulf War Veterans Illnesses (the “Committee”) was created by Public Law 105-368, following a 1997 Congressional report entitled “Gulf War Veterans Illnesses: VA, DOD Continue To Resist Strong Evidence Linking Toxic Causes To Chronic Health Effects.” The report concluded: “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.”

The statute provided that the Committee 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 … Persian Gulf War.”

The Committee was first appointed in 2002 by Secretary of Veterans Affairs Anthony Principi, who established a charter that provided for the Committee to have its own staff and the authority to assess the effectiveness of government research, reflecting the independent role that Congress intended. Virtually identical provisions were included in subsequent charters signed by Secretary Principi in 2004, Secretary James Nicholson in 2006, Secretary James Peake in 2008, and Secretary Eric Shinseki in 2010. All recognized that an inherent part of advising on future research plans and strategies is to assess the effectiveness of the research plans and strategies currently being implemented.

To date, the Committee has performed its intended role, providing independent advice to the Secretary of Veterans Affairs and to Congress. Members of the Committee have testified before Congress ten times. The Committee’s reports and recommendations have gradually led the scientific community to recognize the true scope and nature of Gulf War illness and to direct federal research to the right areas and the goal of identifying treatments. In 2008, the Committee issued a comprehensive report that reviewed the scientific literature and concluded that Gulf War illness is real, affects at least one-fourth of those who served in the war, is not associated with psychiatric illness, and was caused by toxic exposures including pesticides, pyridostigmine bromide pills, and possibly oil well fires, multiple vaccinations, and low-level nerve gas released by the destruction of Iraqi facilities. The Committee is currently preparing an update of that report, to be released in April 2014, which will show that scientific studies since 2008 support and further confirm the conclusions of the 2008 report.

In 2010, building on the work of the Committee, an Institute of Medicine report concluded that the multisymptom illness suffered by Gulf War veterans is a “diagnostic entity,” associated with Gulf War service, affecting an estimated 250,000 veterans, which “cannot be reliably ascribed to any known psychiatric disorder,” and that “it is likely that Gulf War illness results from an interplay of genetic and environmental factors.” The report called for a “renewed research effort with substantial commitment” to identify treatments. The chair of the IOM panel emphasized that “[v]eterans 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… and we believe that … answers can likely be found.”

The Research Advisory Committee welcomed the IOM report and the progress being made at the DoD Congressionally Directed Medical Research Program (CDMRP) and at VA. In its 2011 annual report, the Committee 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.”

However, beginning in 2012, career VA and DoD staff pushed back, attempting to re-establish discredited 1990’s positions minimizing the health problems of Gulf War veterans – the same positions that had led Congress to establish the Committee. Since no scientific support for these positions exists,
staff has resorted to manipulating research studies and reports to provide apparent support, including new reports of the Institute of Medicine. These studies and reports address topics fundamental to understanding Gulf War illness, including the number of ill veterans, whether the illness is psychiatric, and whether it is “just what happens after every war.” Unless halted, these actions will mislead the future course of Gulf War illness research, terminating progress just as science has finally turned the corner, not only at VA but also at the effective Gulf War Illness research program Congress has established at CDMRP.

VA’s standard talking point is that it “does not support the notion that some have put forward that these health symptoms arise as a result of PTSD or other mental health issues.” But the “some” who are putting forward this “notion” are VA staff.

In a recent survey of Gulf War veterans, the VA Office of Public Health included the questions to identify PTSD but not Gulf War Illness. In the medical journal Military Medicine, the heads of the three VA War-Related Illness and Injury Study Centers wrote that “chronic multisymptom illness has been documented in armed conflicts since the Civil War” and that a “biopsychosocial approach to the illness . . . will most benefit the patient.” In a briefing to an Institute of Medicine committee studying treatments for chronic multisymptom illness in Gulf War veterans, the director of the VA Post-Deployment Integrated Care Initiative stated that it is unknown whether the illness is physical or psychiatric. The list goes on.

The Committee documented such actions in forty-six pages of findings and recommendations issued in June 2012. Two Committee members testified about them at a March 2013 Congressional hearing. Rather than fix the problems, VA responded in May 2013 by eliminating the independence of the Committee:

- changing the charter of the Committee to remove its charge to assess the effectiveness of VA Gulf War health research;
- eliminating charter terms providing for the Committee to have its own staff (rather than be staffed by the same personnel whose work it formerly assessed); and
- announcing that the Committee membership would be replaced within one year.

VA has falsely characterized these changes as routine. While fresh blood is certainly desirable, two of the three scientists subsequently proposed for membership by VA were stress advocates. One has edited a textbook on stress and belongs to the American Psychosomatic Society. The other published in 2013 that “[p]resupposing a primary, supplementary, or synergistic role for stress in the Gulf War syndrome . . . provides a framework for valid scientific analysis.” VA has sought to backtrack, pulling these names and appointing others. But they have shown where they intend to go, once they are no longer under scrutiny. It is apparent that VA intends to use the Committee itself to resurrect these discredited themes.

VA has attempted to explain the charter changes as necessary to comply with the Federal Advisory Committee Act, or that the Committee’s work constitutes improper oversight. As noted above, however, virtually identical language has been part of five charters signed by four VA Secretaries, including Secretary Shinseki in 2010. All have recognized that an inherent part of advising on future research is to assess the effectiveness of the research already being done.

The clear purpose of the charter change was to stop the Committee from reporting further on VA staff’s efforts to mislead research. And that is exactly the effect it is having. The draft section on VA’s research program (which had appeared in earlier committee reports) had to be removed from the report that the committee will release next month. In the future, VA Secretaries and Congressional committees will not have the benefit of this information.
In addition, VA has recently stated that committee members may not release reports and recommendations without written VA approval. Not even the pretense that the committee is independent remains.

This bill would give back to the Committee the responsibilities and independence that Congress intended and that it exercised prior to May 2013. It also reasserts other appropriate Congressional authority. VA has routinely disregarded laws passed by Congress related to Gulf War research. In some cases, studies ordered by Congress have not been done at all, while others have been changed to produce results VA desired.

Provisions of the Bill:

1. The bill would amend the statute that created the Committee to return to the Committee the functions that it historically performed prior to May 2013, including those that VA has taken away. These provisions come largely from prior charters.

   a. The Committee shall provide advice to the Secretary of Veterans Affairs and to the House and Senate Veterans Affairs Committees on proposed research studies, research plans, or research strategies related to the health consequences of military service during the Gulf War.
   b. The Committee does not conduct research or review individual research proposals prior to funding.
   c. The guiding principle for the Committee is the premise that the fundamental goal of Gulf War health-related research is to ultimately improve the health of ill Gulf War veterans, and the choice and success of research efforts shall be judged accordingly.
   d. The Committee shall assess the effectiveness of federal research to answer central questions on the nature, causes, and treatments for the health consequences of Gulf War service.
   e. The Committee has its own staff, up to four people, rather than relying for staff support on the VA personnel whose work it is responsible to assess. This staff support may be contracted out to a university.

2. The bill provides that the Committee shall continue to function under the Federal Advisory Committee Act within the Department of Veterans Affairs, but independent of Department of Veterans Affairs control. Nine of its members shall be appointed by the chairs and ranking members of the Senate and House Veterans Affairs Committees, and three members by the Secretary of Veterans Affairs. Its budget will be set by Congress within the VA budget, at the same level as the current historical level, it is anticipated. These provisions follow the model of the non-partisan Advisory Committee on Student Financial Assistance, which has operated successfully for over twenty years within, but independent of, the Department of Education.

   a. The Committee will have independent control over its budget, personnel decisions, and other management functions. These provisions are drawn from the Advisory Committee on Student Financial Assistance authorizing statute.
   b. Committee reports shall be submitted to the House and Senate Veterans Affairs committees, the Secretary of Veterans Affairs, and the head of any other federal department conducting Gulf War health research.
   c. Reports shall be approved by the Committee meeting in public session prior to submission.
   d. Reports shall not be subject to review or approval by the Secretary of Veterans Affairs, but proposed recommendations may be submitted to the Secretary for thirty days for comment.
   e. Members will include scientists, doctors, and veterans, as at present.
f. Members will be appointed, in rotation, by the chairs and ranking members of the House and Senate Veterans Affairs Committees and the Secretary of Veterans Affairs.

g. The chairman is appointed jointly by the chairs of the House and Senate Veterans Affairs Committees.

h. The initial membership will include ten members who currently serve on the Committee and two new members chosen through the initial rotation selections. Members will serve three-year terms, except that the initial group will be given one, two, or three-year terms, so that the terms will be staggered. Members will be eligible to be reappointed for one additional term (other than current members who have already served more than three years).

3. The Committee will sunset two years after submitting a report signed by nine of its members that the Department of Veterans Affairs and the Department of Defense are each carrying out an effective research program related to the health consequences of 1990-91 Gulf War service, provided that no report to the contrary has been issued in the interim.

4. The bill would also require VA to follow certain standards regarding Gulf War research.

a. Any research conducted or funded by VA shall refer to the multisymptom illness that afflicts an estimated one-fourth of Gulf War veterans as “Gulf War Illness.” VA’s unwillingness even to put a name on Gulf War Illness undermines any serious research effort to solve it. While the scientific community and CDMRP consistently use the term “Gulf War illness,” VA refuses to adopt this term. Instead, VA continues to use terms such as “medically unexplained illnesses” or “undiagnosed illnesses” that suggest the condition has not been validated or that Gulf War veterans’ complex of symptoms does not constitute a common disease. The VA Gulf War website is entitled “Gulf War Veterans Medically Unexplained Illnesses,” explaining: “We prefer not to use the term ‘Gulf War Syndrome’ [or Gulf War illness] when referring to medically unexplained symptoms reported by Gulf War Veterans. Why? Because symptoms vary widely.” In fact, the IOM has concluded that the illness is a “diagnostic entity.” In March 2014, the IOM recommended that VA use the term “Gulf War Illness.”

Terms like “chronic multisymptom illness” are also unsatisfactory, because, while the term was originated by a CDC researcher to refer to Gulf War illness, it has morphed into an umbrella phrase covering a wide range of illnesses such as chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, etc. While there is some similarity between Gulf War Illness and these illnesses, research has also shown substantial differences. Effective research requires segregating one illness from another.

b. Any Gulf War illness research conducted or funded by VA shall use the case definition recommended by the Committee.

c. Any study ordered from the Institute of Medicine related to the health of Gulf War and other veterans to determine if a potentially toxic exposure is associated with adverse health effects shall use a standard that considers animal studies to the same extent as human studies, as previously ordered by Congress. (See below.)

4. The bill would not require, but would declare it to be the sense of Congress that VA should contract with the Institute of Medicine to conduct several Gulf War studies and reports previously ordered by Congress, which either have not been conducted or were not conducted in accordance with Congress’s direction. VA’s refusal to follow these laws is part of VA staff’s efforts to mischaracterize the health problems of Gulf War veterans.
a. Public Law 111-275, Section 805, required VA to contract with the IOM for a “comprehensive review of the best treatments for chronic multisymptom illness in Gulf War veterans.” VA converted this review into a restatement of discredited fictions that the illness is psychiatric.

The statute directed that the contract provide that the IOM “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 exposures that may have occurred during such service.”

Congress knew that there was virtually no published literature regarding treatments for Gulf War illness, but reasonably thought that doctors with experience in treating these veterans would have practical experience in using different therapies and would know what has been helpful to their patients, although it might not have been formally studied.

VA ignored this express direction and instead contracted with the IOM for a literature review by a committee with no experience in treating Gulf War veterans. The committee was heavily weighted with specialists in somatic medicine and stress, although the comprehensive IOM review eighteen months before had concluded that “the excess of unexplained medical symptoms reported by deployed Gulf War veterans cannot be ascribed to any known psychiatric disorder.” Two VA staff members and four others (reportedly suggested by VA and DoD staff) briefed the committee that the illness is, or may be, psychiatric. VA instructed the IOM committee to review published literature “concerning treatment of populations with a similar constellation of symptoms.”

Following this guidance, the committee found only three Gulf War treatment studies. It reviewed treatment literature for twelve other illnesses, six of them psychiatric. Its report devotes sixteen pages to discussing these psychiatric illnesses and forty-eight pages to psychotherapies. Rather than the valuable treatment experience of Gulf War veterans’ doctors, as Congress intended, the resulting report is a restatement of government positions from the 1990’s that have since been discredited by science: that this “unexplained” illness is psychosomatic, that the same thing happens after every war, that ill Gulf War veterans do not have common symptom clusters, and that “clinicians should approach [the illness] with ‘a person-centered model of care … that helps patients understand that the word psychosomatic is not pejorative.’”

The bill would also declare it the sense of Congress that this report not be used for research or other purposes by VA.

b. Public Law 110-389, Section 804, required that VA contract with the IOM “to conduct a comprehensive epidemiological study … [to] 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 1991 Gulf War veterans, in Post 9/11 Global Operations veterans, and in non-deployed comparison groups. VA has never contracted for this study.

At the Research Advisory Committee on Gulf War Veterans Illnesses meeting on January 7, 2014, the head of the VA Office of Public Health, Dr. Victoria Davies, acknowledged that VA has not ordered the study. She stated that the IOM has told VA that conducting the study is not feasible.
None of Committee scientists agreed with this statement. It could possibly be argued that it would be difficult to study the prevalence of “central nervous system abnormalities that are difficult to diagnose,” but determining the prevalence of multiple sclerosis, Parkinson’s disease, and brain cancer is straightforward epidemiology.

Dr. Davies also stated that VA had covered the same ground elsewhere, referring to a multiple sclerosis study by Dr. Michael Wallin. However, while the study is entitled “The Gulf War era multiple sclerosis cohort,” it actually covers veterans from 1990 to 2007, and provides data only on the incidence of MS by race, sex, and service for that entire period -- nothing on the prevalence among those who served in the Gulf War or among those who served in Post 9/11 operations compared to their non-deployed counterparts. Dr. Davies confirmed that VA has done no studies of the prevalence of Parkinson’s disease or brain cancer in Gulf War or Post 9/11 operations veterans.

c. Public Law 105-277 and Public Law 105-368 require that VA contract with the Institute of Medicine for reports reviewing the scientific literature concerning thirty-three “toxic agents, environmental or wartime hazards, or preventative medicines or vaccines associated with Gulf War service . . . [to] determine . . . “whether a statistical association exists between exposure to the agent . . . and the illness . . . [and] the increased risk of the illness among human or animal populations exposed to the agent . . . ”

The purpose of these reports is to provide the basis for a determination by the Secretary of Veterans Affairs as to whether exposure to an agent warrants a presumption of service connection, which would entitle a veteran with the illness to receive health care and other benefits. The statutes further require that the Secretary of Veterans Affairs consider “the exposure in humans or animals” to an agent and “the occurrence of a diagnosed or undiagnosed illness in humans or animals.”

Congress thus repeatedly provided that the scientific information to be considered included studies of both humans and animals. Most studies of toxic substances are necessarily done in animals, as it would be unethical to test them in humans.

However, VA did not require the IOM to consider animal studies in these determinations, and the IOM has not considered them. Indeed, the IOM deliberately has gone out of its way not to consider them. The first IOM Gulf War report stated that it was applying the same standard that was used in the Agent Orange report that had found an association between Agent Orange and the illnesses of Vietnam veterans, because that standard had “gained wide acceptance for more than a decade by Congress, government agencies, researchers, and veteran groups.”

The standard used in the Agent Orange report was: “a positive association has been observed between [the agent] and a health outcome in studies in which chance, bias, and confounding could be ruled out . . . ” In the first Gulf War report, however, the standard was quietly changed to “. . . a health outcome in human studies in which chance, bias, and confounding could be ruled out.” [emphasis added] This corrupted standard has been applied in all subsequent IOM Gulf War reports.

With relatively few human studies to consider, IOM Gulf War committees have consistently found insufficient evidence of an association between each of the thirty-three toxic agents and illness, and the Secretary has never made a determination of service connection. VA has never directed the IOM to consider animal studies as required by Congress.

IOM representatives have responded that IOM Gulf War reports mention animal studies, and that their standard provides for animal studies to be taken into account in determining whether an association is
biologically plausible. However, under the IOM formula, biological plausibility only comes into play if an association has already been found, and the corrupted standard requires that an association first be found based only on human studies.

This corrupted standard is now being used in IOM reports on the health effects of exposures to veterans of the recent wars in Iraq and Afghanistan. Following reports of illnesses among troops stationed downwind from burn pits where toxic waste was incinerated, VA ordered an IOM report on the long-term health consequences of exposure to burn pits. Stating that it was "[f]ollowing the methods and criteria used by other IOM committees that have prepared reports for the Gulf War and Health Series and the Veterans and Agent Orange Series," the IOM committee in 2011 applied the standard limiting consideration to human studies, and found limited or insufficient evidence of an association between the exposures and illness.

The corrupted standard, using only human studies, was also used in the IOM report on the Long-Term Effect of Blast Exposures released on February 13, 2014.

VA and IOM’s failure to follow Public Laws 105-277 and 105-368 thus continues to impact veterans of recent conflicts as well as Gulf War veterans.

5. The bill would also declare it to be the sense of Congress that IOM Gulf War committees should include at least three members of the Research Advisory Committee (in view of the inappropriate memberships of recent IOM Gulf War committees), that VA notify Congress if any federal employee or contractor seeks to influence an IOM Gulf War report other than toward a scientifically objective outcome, and that VA consult with the Research Advisory Committee regarding the scope of work and charge for any future Institute of Medicine contract related to the health of Gulf War veterans.

6. The bill would also declare it to be the sense of Congress that VA should conduct an additional followup to its recent survey of Gulf War era veterans to ask the questions about their symptoms necessary to determine if they have Gulf War illness according to leading current case definitions.

The survey sent out in April 2012 asked 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 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.”

The former principal investigator of the survey, then a senior epidemiologist in the VA Office of Public Health, testified to a Congressional committee that his superiors lied to the VA Chief of Staff to get him to approve sending the survey out without the symptom questions.

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\(^{ii}\) http://www1.va.gov/RAC-GWVI/Committee_Documents.asp
\(^{iii}\) IOM, Gulf War and Health, Vol. 8 (2010), pp. x, 109, 204, 210, 260-262.
Appendix C