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U.S. House of Representatives Committee on Veterans Affairs
Subcommittee on Oversight and Investigations

Persian Gulf War: An Assessment of Health Outcomes on the 25th Anniversary
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With respect to Gulf War veterans' health, VA pays no more attention to Congress than it does to science. As described below, Congress has ordered report after report from the Institute of Medicine (IOM), specifying in law the work to be done. However, VA has consistently failed to contract for what Congress actually ordered. The IOM has been a willing accomplice, changing its own standards of evidence and appointing biased committees to accommodate VA's purposes. As a result, the reports inevitably produce conclusions that deny any connection between toxic exposures and the shattered health of Gulf War veterans, and promote the discredited 1990's VA position that their illness is largely psychiatric.

These same corrupt practices have been employed to deny the effect of toxic exposures from burn pits on the health of recent Iraq and Afghanistan veterans.

1. Public Laws 105-277 and 105-368, enacted in 1998, are the foundation for the IOM Gulf War and Health reports. Congress required VA to contract with the IOM to evaluate the health risks of thirty-three toxic substances and medications to which troops were exposed in the war. The law required consideration of animal studies because most studies of the effects of toxic substances are necessarily done in animals.

But VA did not contract for consideration of animal studies, and the IOM actually changed its standards of evidence to exclude animal studies – the exact opposite of what Congress ordered. As a result, these studies – the basic studies that show these toxic substances are toxic -- have never been considered in any IOM report, and no IOM report has ever found sufficient evidence that any of the thirty-three toxic agents are associated with health problems.

The entire IOM Gulf War series of reports is a house of cards, as detailed in Appendix A.

These same corrupt practices have been employed to deny the effect of toxic exposures from burn pits on the health of recent Iraq and Afghanistan veterans. (below, pp. 12-13)

2. In 2010, in Public Law 111-275, Congress required VA to contract with the IOM for a "comprehensive review of the best treatments for chronic multisymptom illness in Gulf War veterans."

The statute directed that the IOM "shall convene a group 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 . . ."[1]

VA ignored this direction and instead contracted with the IOM for a literature review of largely psychiatric diseases by a committee with no experience in treating Gulf War veterans, heavily weighted with specialists in psychosomatic medicine and stress.[2] Rather than capturing the valuable treatment experience of Gulf War veterans' doctors, as Congress intended, the resulting 2013 IOM treatment report was a restatement of government fictions from the 1990's, foreshadowing the 2016 IOM report and the new VA/DoD Clinical Practice Guideline.

3. In 2008, Congress enacted Public Law 110-389 requiring VA to 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 . . ." in 1991 Gulf War veterans, Post-9/11 Global Operations veterans, and non-deployed comparison groups.[3]

For seven years, VA refused to contract for the study, despite repeated urging by the Research Advisory Committee on Gulf War Veterans Illnesses.[4] In 2015, VA finally contracted with the IOM, but wrote in the contract that the IOM could only use VA data. The IOM committee declined to proceed with the study because the VA data was insufficient for a rigorous study.[5]

In the absence of the study ordered by Congress in 2008, the 2016 report found the evidence insufficient to reach conclusions that these conditions are associated with Gulf War service.[6]

4. The membership of IOM Gulf War report committees has usually been biased toward VA's discredited position, including the 2016 committee.

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[1] Veterans Benefits Act of 2010, Sec. 805, http://library.clerk.house.gov/reference-files/PPL_111_275_VeteransBenefitsAct_2010.pdf

[2] http://www.scribd.com/doc/150949964/WHITE-PAPER-IOM-CMI-Panel-Membership-Analysis

[3] Public Law 110-389, Section 804

[4] http://www.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf (Appendix E)

[5] http://iom.nationalacademies.org/Reports/2015/Considerations-for-Designing-Epidemiologic-Study-for-Multiple-Sclerosis-and-other-Neurological-disorders-Veterans.aspx

[6] 2016 IOM Gulf War and Health report, pp. 102,145,149.

See the November 2014 letter to Dr. Victor Dzau, president of the IOM, attached as Appendix B below (pp. 37-42), objecting to the makeup of the 2016 Gulf War and Health committee. "[T]he membership is grossly imbalanced toward the 1990's government position that Gulf War veterans have no special health problem — just what happens after every war, related to psychiatric issues, and not environmental exposures."

The letter documented that eight the members of the committee were associated with the 1990's government position, including the former 1990's VA Undersecretary for Health, Dr. Kenneth Kizer, who was the chief advocate for the position. Eight members were neutral. Subsequent to the letter, one neutral member resigned and one individual with current Gulf War research experience was added, the only person on the committee with such experience.

The last two pages of the letter analyze the 2016 committee membership. (below, pp. 45-46)

The letter predicted that: "Reviving this discredited fiction will cause veterans' doctors to prescribe inappropriate psychiatric medications, and will misdirect research to find effective treatments down blind alleys — an unconscionable breach of the duty owed to veterans and expected of the Institute of Medicine. "

Appendix A

VA and IOM Collaboration To Exclude Consideration Of Animal Studies Required By Law

Public Laws 105-277 and 105-368 are the foundation for the Institute of Medicine (IOM) Gulf War and Health reports. Congress required VA to contract with the IOM to evaluate the health risks of thirty-three toxic substances and medications to which troops were exposed in the war. The law required consideration of animal studies on a par with human studies because most studies of toxic substances are necessarily done in animals for ethical reasons.

But VA did not contract for consideration of animal studies, and the IOM actually changed its standards of evidence to exclude animal studies – the exact opposite of what Congress ordered. As a result, these studies – the basic studies that show these toxic substances are toxic -- have never been considered in any IOM report, and no IOM report has ever found sufficient evidence that any of the thirty-three listed toxic agents are associated with health problems.

Consider, for example, the twenty-three animal studies on pages 160-161 of the 2008 report of the Research Advisory Committee on Gulf War Veterans Illnesses, showing that low levels of nerve gas, below the level that causes symptoms at the time of exposure, cause long-term adverse health effects, contrary to what was believed at the time of the war. Because of these studies, an update report on the effects of sarin was ordered from the IOM, but as described below, VA and IOM staff conspired to ensure that the report would not consider animal studies in its conclusions, even though new animal studies were the only reason for ordering the report.
http://www.va.gov/RAC-GWVI/docs/Committee_Documents/GWIandHealthofGWVeterans_RAC-GWVIReport_2008.pdf

The entire IOM Gulf War series of reports is a house of cards, as detailed below.

These same corrupt practices have been employed to deny the effect of toxic exposures from burn pits on the health of recent Iraq and Afghanistan veterans. (below, pp. 12-13)

* * *

These 1998 statutes required the IOM to identify illnesses experienced by Armed Forces members who served in the war, "including diagnosed illnesses and undiagnosed illnesses" (the term then used for what is now called "Gulf War Illness"). The statutes then asked, for each of the thirty-three agents and each illness, "whether a statistical association exists between exposure to an agent . . . and an increased risk of illness in human or animal populations."

Congress required consideration of studies in animals because most studies of toxic substances and drugs are necessarily done in animals for ethical reasons. It did not ask for information on how much of an agent Gulf War troops were exposed to. It was well known that no such information exists.

These basic animal studies have never been considered in any IOM report. The 2016 report discusses some animal studies involving exposures to combinations of agents, but it acknowledges that "studies examining single exposures are not considered here" because "[e]arly volumes of the Gulf War and Health series described animal studies . . . on the association between exposure to a single toxicant and the health outcomes that may result. . ."
2016 IOM Gulf War and Health report, Vol. 10, p. 239

But the earlier IOM reports make clear they did not consider these animal studies <u>in their conclusions</u>. The chairman of the 2016 committee, Dr. Deborah Cory-Slechta, was a member of the committee for the 2003 IOM Gulf War report on Insecticides and Solvents, so she is familiar with the procedures used. While the 2003 report "described" numerous animal studies, it admitted that "animal studies had a limited role in the committee's assessment between exposure and a health outcome. Animal data . . . were not used as part of the weight-of-evidence . . ."
2003 IOM Gulf War and Health report, Vol. 2, p. 3

The same admission can be found in every IOM Gulf War report on the health effects of toxic substances. Thus, the 2016 report did not consider these basic animal studies in their conclusions, relying on the earlier reports, but the earlier reports didn't consider them either. As a result, since most studies of toxic exposures are done in animals, no IOM report has ever found sufficient evidence that any of the thirty-three listed toxic exposures and medications are associated with adverse health outcomes.

The whole IOM Gulf War series of reports is a house of cards.

In her preface to the 2016 report, Dr. Cory-Slechta points to the "ever unknowable impact of the various chemical exposures that occurred. . .", because "[o]bjective exposure data gathered during and after the war have been, and are expected to continue to be, unavailable." 2016 IOM Gulf War and Health report, Vol. 10, p. ix

But Congress never asked for consideration of exposure data. It was well known that data did not exist. What it did ask for was consideration of animal data. But it has never gotten it. It has never gotten it because VA did not contract for the reports that Congress ordered.

The IOM has been a willing collaborator in this deceit, changing its own standards of evidence to exclude animal studies – exactly the opposite action from what the law required.

It made this change quietly, and has deceitfully implied that nothing changed. As presented in the 2003 report, "[t]he committee used the [standards of evidence] from

previous IOM studies because they have gained wide acceptance over more than a decade by Congress, government agencies, researchers, and veterans groups." "The [standards of evidence] closely resemble those used by . . . IOM committees that have evaluated . . . herbicides used in Vietnam." 2003 IOM Gulf War and Health report, Vol. 2, p. 3 (See the similar language on p. 3 of the 2016 report.)

In fact, however, the standards were subtly changed from the Agent Orange standards to exclude consideration of animal studies. Animal studies are discussed in the Gulf War reports, but when it comes to arriving at the reports' conclusions, they are not considered, applying the doctored standards of evidence (what the IOM calls the "categories of association").

For sixteen years, VA, DoD, and IOM staff have manipulated IOM Gulf War reports on the health effects of veterans' toxic exposures. As a result, the reports have consistently found "insufficient evidence" that the exposures are associated with illness, leading to VA determinations that the illness does not qualify for benefits as service-connected. Of equal importance, these dishonest reports have also misled researchers seeking to understand the causes of Gulf War illness in order to identify treatments to improve veterans' health and preventive measures to protect future US forces.

In recent years, the same techniques have been applied to IOM reports on the health effects of toxic substances released by burn pits on recent Iraq and Afghanistan veterans.

The balance of this Appendix will review in detail these corrupt practices.

1. The governing statute expressly requires consideration of animal studies.

In PL 105-277 and PL 105-368, Congress in 1998 directed the Department of Veterans Affairs to contract with the National Academy of Sciences (NAS, the parent organization of the Institute of Medicine, IOM), to review the scientific literature regarding substances to which troops were exposed in the 1991 Gulf War to determine if these substances are associated with an increased risk of illness. These reports were to be used by the Secretary of Veterans Affairs in determining whether the illness should be presumed service-connected for the purpose of veterans' benefits.

The law directed the NAS (IOM) to identify the "biological, chemical, or other toxic agents, environmental or wartime hazards, or preventive medicines or vaccines" to which members of the Armed Forces may have been exposed during the war. 38 USC Sec. 1117, note Sec. 1603 (c). [attached to this Appendix below at p. 14] The law listed thirty-three specific "toxic agents, environmental or wartime hazards, or preventive medicines or vaccines associated with Gulf War service" to be considered, including various pesticides; pyridostigmine bromide, a drug used as a nerve agent prophylaxis; low-level nerve agents; other chemicals, metals, sources of radiation; and infectious diseases. 38 USC Sec. 1117, note Sec. 1603 (a), (d). [below, pp. 15-16] The law further required the NAS (IOM) to identify illnesses, "including diagnosed illnesses and undiagnosed illnesses," experienced by Armed Forces members who served in the war. 38 USC Sec. 1117, note Sec. 1603 (c) [below, p. 14]

"For each agent, hazard, or medicine or vaccine and illness identified," the law provided that:
"The National Academy of Sciences shall determine …
(A) whether a statistical association exists between exposure to the agent … and the illness . . .
(B) the increased risk of the illness among human or animal populations exposed to the agent … and
(C) whether a plausible biological mechanism or other evidence of a causal relationship exists …"
38 USC Sec. 1117, note Sec. 1603 (e) [below, p. 16, emphasis added]

The statute went on to provide that the Secretary of Veterans Affairs should consider both human and animal studies in determining whether a presumption of service connection is warranted. He was to consider "the exposure in humans or animals" to an agent and "the occurrence of a diagnosed or undiagnosed illness in humans or animals."
38 USC Sec. 1118 (b)(1)(B) [below, p. 21, emphasis added]

Congress thus expressly required consideration of animal as well as human studies by both the National Academy of Sciences (the Institute of Medicine) and the Secretary of Veterans Affairs. This statutory requirement reflects the fact that most studies on the biological effects of hazardous substances are necessarily done in animals, for ethical reasons. Consider, for example, the twenty-three studies on the long-term effects of low level sarin exposure, or the eighteen studies evaluating the combined effects of pyridostigmine bromide, pesticides and insect repellant listed on pages 160-161 and 170-171 of the 2008 Research Advisory Committee on Gulf War Veterans Illnesses report, all of which were done in animals. http://www.va.gov/RAC-GWVI/docs/Committee_Documents/GWIandHealthofGWVeterans_RAC-GWVIReport_2008.pdf

When the first IOM report was conducted under the law, however, animal studies were omitted from the standard for determining whether an association exists between an exposure and a health effect. The report states:

"For its evaluation and categorization of the degree of association between each exposure and a human health effect, however, the [IOM] committee only used evidence from human studies."
Gulf War and Health, Volume 1, (2000), p. 72 [below, p. 23]

Considering only human studies, and not the much larger relevant literature on animal studies, the IOM committees have never found sufficient evidence of an association for the exposures and illnesses experienced by Gulf War veterans. Following the reports of the IOM, the Secretary of Veterans Affairs has made no determinations of service-connection for these exposures and illnesses for veterans' benefits.
(VA asserts that it covers Gulf War veterans on other grounds for their "undiagnosed illnesses," but VA statistics show that over 80% of such veterans' claims are denied. http://www.scribd.com/doc/241661207/Binns-Parting-Thoughts-093014)

This pattern has been followed in all IOM Gulf War reports to date. More recently, it has been applied to IOM reports on the effects of toxic exposures fromburn pits on the health of recent Iraq and Afghanistan veterans.

2. The exclusion of animal studies was deliberate.

A close examination of what occurred makes clear that the exclusion of animal studies was not an oversight. It was deliberate.

To express conclusions as to whether an association between an exposure and an illness exists, the first IOM Gulf report defined five standards of evidence, which it called the "Categories of Association." Gulf War and Health, Vol. 1, pp. 83-84. [below, pp. 25-26] The same categories have been used in all subsequent IOM Gulf War exposure reports:

- Sufficient Evidence of a Causal Relationship
- Sufficient Evidence of an Association
- Limited/Suggestive Evidence of an Association
- Inadequate/Insufficient Evidence to Determine Whether an Association Does or Does Not Exist
- Limited/Suggestive Evidence of No Association.

Each substance was ranked according to these categories. How a substance is ranked becomes the all-important conclusion of the report as to whether an association exists between an exposure and illness.

Where did these categories come from? The report explained: "The committee used the established categories of association from previous IOM studies, because they have gained wide acceptance for more than a decade by Congress, government agencies, researchers, and veteran groups." "The categories closely resemble those used by several IOM committees that evaluated …. herbicides used in Vietnam …" Gulf War and Health, Volume I, p. 83. [below, p. 25]

IOM Gulf War reports have repeatedly emphasized over the years that their methodology is based on the IOM Agent Orange reports. However, it is revealing to compare a category of association used in the Agent Orange reports with the same category used in the Gulf War reports.

Agent Orange:
"Sufficient Evidence of an Association. Evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between herbicides and the outcome <u>in</u> <u>studies</u> in which chance, bias, and confounding could be ruled out …" Veterans and Agent Orange: 1996 Update, p. 97 [below, p. 27, emphasis added]

Gulf War:
"Sufficient Evidence of an Association. Evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between an

exposure to a specific agent and a health outcome in human studies in which chance, bias, and confounding could be ruled out . . ."
Gulf War and Health: Volume I, p. 83 [below, p. 25, emphasis added]

The Gulf War category does indeed "closely resemble" the Agent Orange category -- with a conspicuous exception. The word "human" has been inserted in the Gulf War category. This addition obviously did not occur by accident. It was deliberate, as was the misleading language that these were the "established categories of association from previous IOM reports."

Thus, not only have the IOM Gulf War studies been conducted in violation of the direction Congress provided in the statute; this violation has been deliberate, with intent to conceal.

As to why it was done, one can speculate based on the knowledge that the Agent Orange language, just a few years earlier, had produced an IOM report that found that Agent Orange exposure was associated with cancer (after two decades of government denial of any health consequence). This finding led to a presumption of service connection for thousands of Vietnam veterans with cancer.

It should be noted that the IOM Gulf War reports state that animal studies were considered for purposes of "biological plausibility": "For its evaluation and categorization of the degree of association between each exposure and a human health effect, … the committee only used evidence from human studies. Nevertheless, the committee did use nonhuman studies as the basis for judgments about biological plausibility, which is one of the criteria for establishing causation." Gulf War and Health, Volume 1, p. 72 [below, p. 25]

The terms of the Gulf War categories of association make clear, however, that biological plausibility and causation only relate to the highest category of evidence, "sufficient evidence of a causal relationship," and are not considered unless there has been a previous finding of "sufficient evidence of association":

"Sufficient Evidence of a Causal Relationship. Evidence is sufficient to conclude that a causal relationship exists between the exposure to a specific agent and a health outcome in humans. The evidence fills the criteria for sufficient evidence of association (below) and satisfies several of the criteria used to assess causality: strength of association, dose-response relationship, consistency of association, temporal relationship, specificity of association, and biological plausibility."

"Sufficient Evidence of an Association. Evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between an exposure to a specific agent and a health outcome in human studies in which chance, bias, and confounding could be ruled out with reasonable confidence." Gulf War and Health, Volume 1, p. 83. [below, p. 25, emphasis added]

Thus, only if there has already been a finding of "sufficient evidence of association" do the issues of causality and biological plausibility arise, and a finding of "sufficient

evidence of association" depends solely on human studies. Unless an association is found based on human studies, biological plausibility -- and animal studies -- are not considered.

It is notable that the statute does not require evidence of a "casual relationship" to trigger a presumption of service connection. It only requires evidence of a "positive association":

"[T]he Secretary shall prescribe regulations providing
that a presumption of service connection is warranted [if the Secretary makes a]
determination based on sound medical and scientific evidence that a
positive association exists between--
(i) the exposure of humans or animals to a biological, chemical,
or other toxic agent, environmental or wartime hazard, or preventive
medicine or vaccine known or presumed to be associated with service
in the Southwest Asia theater of operations during the Persian Gulf
War; and
(ii) the occurrence of a diagnosed or undiagnosed illness in
humans or animals."
38 USC Sec. 1118 (b)(1) [emphasis added, below pp. 20-21]

In short, in direct contravention of the law, the methodology established for the IOM Gulf War reports deliberately excluded animal studies from consideration as to whether an association exists between an exposure and an illness, the only question that matters in the determination of veterans' benefits.

3. VA and IOM staff privately collaborated to produce these results.

As to how this was done, the history of one of the IOM Gulf War reports provides an indication. The 2004 IOM Updated Literature Review of Sarin is the most egregious example of the distortion of science produced by excluding animal studies from the evidence considered in these reports' conclusions. In late 2002, a number of new studies on sarin nerve gas, sponsored by the Department of Defense, revealed that contrary to previous belief, low level exposures (below the level required to produce symptoms at the time of exposure) produced long-term effects on the nervous and immune systems. Naturally, these studies were done in animals, not humans.

A previous IOM report on sarin in 2000 had found insufficient evidence of an association between low-level sarin and long-term health effects based on scientific knowledge as of that date. On January 24, 2003, then-VA Secretary Anthony Principi wrote the president of the Institute of Medicine: "Recently, a number of new studies have been published on the effects of Sarin on laboratory animals." He asked the IOM to report back "on whether this new research affects earlier conclusions of IOM . . . about possible long-term health consequences of exposure to low levels of Sarin." [attached, p. 29]

In 2004, the IOM delivered its report. The Updated Literature Review of Sarin discussed the new animal studies in its text. However, true to form, the report did not consider animal studies in the all-important categories of association, even though the new animal studies were the only reason for doing the report.

"As with previous committees, this committee used animal data for making assessments of biological plausibility … rather than as part of the weight of evidence to determine the likelihood that an exposure to a specific agent might cause a long-term outcome." Updated Literature Review of Sarin (2004), p. 18 [below, p. 30] Accordingly, the report found insufficient evidence of an association.

To understand this bizarre outcome, it is revealing that following Secretary Principi's letter, an IOM proposal was prepared which became the basis for a contract between the IOM and VA.

The proposal for the sarin update was sent to VA on March 11, 2003, with a cover letter from Susanne Stoiber, executive director of the IOM, to Dr. Mark Brown, director of the VA Environmental Agents Service, part of the Office of Public Health. The cover letter stated: "This proposal follows a request from Secretary Anthony J. Principi and discussions with yourself requesting an update of the health effects of the chemical warfare agent sarin." [below, p. 31]

The proposal contained the following "Statement of Task": [below, p. 34]

> "The committee will conduct a review of the peer-reviewed literature published since earlier IOM reports on health effects associated with exposure to sarin and related compounds. Relevant epidemiologic studies will be considered. With regard to the toxicological literature, the committee will generally use review articles to present a broad overview of the toxicology of sarin and to make assessments of biologic plausibility regarding the compound of study and health effects; individual toxicology research papers will be evaluated as warranted.
>
> The committee will make determinations on the strength of the evidence for associations between sarin and human health effects. If published peer-reviewed information is available on the dose of sarin exposure in Gulf War veterans, the committee may address the potential health risks posed to the veterans . . . "

In other words, the Statement of Task established that the update report would use the same "categories of association" as the earlier Gulf War reports. The "determinations on the strength of the evidence" would be made on the basis of the "associations between sarin and <u>human</u> health effects". "With regard to the toxicological literature" (which included the new animal studies), its use would be confined to the assessment of "biological plausibility" to which animal studies had previously been relegated. Thus, the update report would exclude animal studies from its key conclusions, even though animal studies were the only reason for doing the report.

Moreover, the Statement of Task set up another fundamental constraint for the report. The IOM committee would be permitted to address the potential health risks posed to the veterans "[i]f published peer-reviewed information is available on the dose of sarin exposure in Gulf War veterans." As anyone familiar with Gulf War research would know, including Dr. Brown and his IOM counterparts, there is no published peer-reviewed information available on the dose of sarin exposure in Gulf War veterans, for the reason

that no such information was collected during the war. As noted in the previous 2000 IOM report on sarin, "as discussed throughout this report, there is a paucity of data regarding the actual agents and doses to which individual veterans were exposed." Gulf War and Health, Volume 1, p. 84. [below, p. 26] In order for the IOM committee to address the health risks posed to veterans, it had to meet a condition that was impossible to meet.

These constraints in the Statement of Task were not contained in the letter from Secretary Principi requesting the report. (To the contrary, they appear to contradict it.) They must have come from the "conversations with yourself" referred to in Ms. Stoiber's letter to Dr. Brown. Thus, conversations between VA and IOM staff determined the outcome of the report before the IOM committee to prepare the report was ever appointed.

In summary, VA and the IOM have not complied with the law requiring the IOM Gulf War reports, restricting the scientific evidence required to be considered. This action has been deliberate. Conversations between VA and IOM staff have shaped the methodology of the reports so as to predetermine their outcome. Dr. Brown and Ms. Stoiber are long gone, and their successors are more careful regarding what they put in writing, but the corrupted Categories of Asssociation and all the IOM reports based on them still stand.

4. <u>The IOM has recently applied this same corrupt standard to the health of recent Iraq and Afghanistan veterans, denying the adverse effects of toxic substances released by burn pits.</u>

In 2007 on-site military officers with environmental health responsibilities reported dangerous health effects of toxic exposures from burn pits on U.S. bases in Iraq and Afghanistan, particularly Joint Base Balad (JBB). A draft executive summary of a study, dated December 2007, showed dioxin levels at 51 times acceptable levels, particulate exposure at 50 times acceptable levels, volatile compounds at two times acceptable levels, and cancer risk from exposure to dioxins at two times acceptable levels for people at Balad for a year and at eight times acceptable levels for people at the base for more than a year.

DoD Washington said the draft summary contained "incorrect data" due to a "software error" and was "prematurely distributed." Officials in Washington in the DoD Office of Force Health Protection and Readiness denied any lasting health effects: "While exposure to burn pit smoke may cause temporary coughing and redness or stinging of the eyes, extensive environmental monitoring indicates that smoke exposures not interfering with breathing or requiring medical treatment at the time of exposure usually do not cause any lasting health effects or medical follow-up."
http://www.armytimes.com/article/20081027/NEWS/810270315/Burn-pit-at-Balad-raises-health-concerns

An IOM report was ordered by VA to study the subject. "[T]he Institute of Medicine has embarked on a comprehensive study with noted experts in environmental and occupational health to study the issue." "Is Burn Pit Smoke Hazardous To Your Health?", Force Health Protection and Readiness magazine, vol. 5, issue 2, 2010, page 11.

http://home.fhpr.osd.mil/Libraries/FHPR_Online_Magazine/Volume_5_Issue_2.sflb.ashx

Following the pattern established in the IOM Gulf War reports, the IOM burn pit report first pointed out the known health risks of the exposures: "Chemicals in all three major classes of chemicals detected at JBB . . . have been associated with long-term health effects. A wide array of health effects have been observed in humans and animals after exposure to the specific pollutants detected at JBB . . . The health-effects data on the other pollutants detected include: neurological effects, liver toxicity and reduced liver function, cancer, respiratory toxicity and morbidity, kidney toxicity and reduced kidney function, blook effects, cardiovascular toxicity and morbidity, reproductive and developmental toxicity." http://books.nap.edu/openbook.php?record_id=13209&page=5

But then, when it came to arriving at conclusions, the IOM committee applied the Categories of Association that allowed only for consideration of human studies. It stated 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 . . .") http://books.nap.edu/openbook.php?record_id=13209&page=6).

There were no published studies of service members exposed to burn pits, so the committee relied on studies of groups like firefighters and incinerator workers. Accordingly, as reported on VA's website, the committee found only "limited but suggestive evidence of a link between exposure to combustion products and reduced lung function" and "inadequate or insufficient evidence of a relation to combustion products and cancer, respiratory diseases, circulatory diseases, neurological diseases, and adverse reproductive and developmental outcomes." It did not find the “sufficient evidence of an association” required for service connection. http://www.publichealth.va.gov/exposures/burnpits/health-effects-studies.asp

Thus, rigging IOM reports by corrupting the Categories of Association has been extended to a new generation of veterans, as well as continuing for Gulf War veterans.

ATTACHMENTS TO APPENDIX A

TITLE 38--VETERANS' BENEFITS,

PART II--GENERAL BENEFITS

CHAPTER 11--COMPENSATION FOR SERVICE-CONNECTED DISABILITY OR DEATH, SUBCHAPTER II--WARTIME DISABILITY COMPENSATION

Sec. 1117. Compensation for disabilities occurring in Persian Gulf War veterans

* * *

Agreement With National Academy of Sciences Regarding Toxic Drugs and Illnesses Associated With Gulf War

Pub. L. 105-277, div. C, title XVI, Sec. 1603-1605, Oct. 21, 1998, 112 Stat. 2681-745 to 2681-748, as amended by Pub. L. 107-103, title II, Sec. 202(d)(2), Dec. 27, 2001, 115 Stat. 989, provided that:

``SEC. 1603. AGREEMENT WITH NATIONAL ACADEMY OF SCIENCES.

``(a) Purpose.--The purpose of this section is to provide for the National Academy of Sciences, an independent nonprofit scientific organization with appropriate expertise, to review and evaluate the available scientific evidence regarding associations between illnesses and exposure to toxic agents, environmental or wartime hazards, or preventive medicines or vaccines associated with Gulf War service.

``(b) Agreement.--The Secretary of Veterans Affairs shall seek to enter into an agreement with the National Academy of Sciences for the Academy to perform the activities covered by this section. The Secretary shall seek to enter into the agreement not later than two months after the date of enactment of this Act [Oct. 21, 1998].

``(c) Identification of Agents and Illnesses.--(1) Under the agreement under subsection (b), the National Academy of Sciences shall--

``(A) identify the biological, chemical, or other toxic agents, environmental or wartime hazards, or preventive medicines or vaccines to which members of the Armed Forces who served in the Southwest Asia theater of operations during the Persian Gulf War may have been exposed by reason of such service; and

``(B) identify the illnesses (including diagnosed illnesses and undiagnosed illnesses) that are manifest in such members.

``(2) In identifying illnesses under paragraph (1)(B), the Academy shall review and summarize the relevant scientific evidence regarding illnesses among the members described in paragraph (1)(A) and among other appropriate populations of individuals, including mortality, symptoms, and adverse reproductive health outcomes among such members and individuals.

``(d) Initial Consideration of Specific Agents.--(1) In identifying under subsection (c) the agents, hazards, or preventive medicines or vaccines to which members of the Armed Forces may have been exposed for purposes of the first report under subsection (i), the National Academy of Sciences shall consider, within the first six months after the date of enactment of this Act [Oct. 21, 1998], the following:

``(A) The following organophosphorous pesticides:

``(i) Chlorpyrifos.

``(ii) Diazinon.

``(iii) Dichlorvos.

``(iv) Malathion.

``(B) The following carbamate pesticides:

``(i) Proxpur.

``(ii) Carbaryl.

``(iii) Methomyl.

``(C) The carbamate pyridostigmine bromide used as nerve agent prophylaxis.

``(D) The following chlorinated hydrocarbon and other pesticides and repellents:

``(i) Lindane.

``(ii) Pyrethrins.

``(iii) Permethrins.

``(iv) Rodenticides (bait).

``(v) Repellent (DEET).

``(E) The following low-level nerve agents and precursor compounds at exposure levels below those which produce immediately apparent incapacitating symptoms:

``(i) Sarin.

``(ii) Tabun.

``(F) The following synthetic chemical compounds:

``(i) Mustard agents at levels below those which cause immediate blistering.

``(ii) Volatile organic compounds.

``(iii) Hydrazine.

``(iv) Red fuming nitric acid.

``(v) Solvents.

``(vi) Uranium.

``(G) The following ionizing radiation:

``(i) Depleted uranium.

``(ii) Microwave radiation.

``(iii) Radio frequency radiation.

``(H) The following environmental particulates and pollutants:

``(i) Hydrogen sulfide.

``(ii) Oil fire byproducts.

``(iii) Diesel heater fumes.

``(iv) Sand micro-particles.

``(I) Diseases endemic to the region (including the following):

``(i) Leishmaniasis.

``(ii) Sandfly fever.

``(iii) Pathogenic escherechia coli.

``(iv) Shigellosis.

``(J) Time compressed administration of multiple live, `attenuated', and toxoid vaccines.

``(2) The consideration of agents, hazards, and medicines and vaccines under paragraph (1) shall not preclude the Academy from identifying other agents, hazards, or medicines or vaccines to which members of the Armed Forces may have been exposed for purposes of any report under subsection (i).

``(3) Not later than six months after the date of enactment of this Act [Oct. 21, 1998], the Academy shall submit to the designated congressional committees a report specifying the agents, hazards, and medicines and vaccines considered under paragraph (1).

``(e) Determinations of Associations Between Agents and Illnesses.--(1) For each agent, hazard, or medicine or vaccine and illness identified under subsection (c), the National Academy of Sciences shall determine, to the extent that available scientific data permit meaningful determinations--

``(A) whether a statistical association exists between exposure to the agent, hazard, or medicine or vaccine and the illness, taking into account the strength of the scientific evidence and the appropriateness of the scientific methodology used to detect the association;

``(B) the increased risk of the illness among human or animal populations exposed to the agent, hazard, or medicine or vaccine; and

``(C) whether a plausible biological mechanism or other evidence of a causal relationship exists between exposure to the agent, hazard, or medicine or vaccine and the illness.

``(2) The Academy shall include in its reports under subsection (i) a full discussion of the scientific evidence and reasoning that led to its conclusions under this subsection.

``(f) Review of Potential Treatment Models for Certain Illnesses.--Under the agreement under subsection (b), the National Academy of Sciences shall separately review, for each chronic undiagnosed illness identified under subsection (c)(1)(B) and for any other chronic illness that the Academy determines to warrant such review, the available scientific data in order to identify empirically valid models of treatment for such illnesses which employ successful treatment modalities for populations with similar symptoms.

``(g) Recommendations for Additional Scientific Studies.--(1) Under the agreement under subsection (b), the National Academy of Sciences shall make any recommendations that it considers appropriate for additional scientific studies (including studies relating to treatment models) to resolve areas of continuing scientific uncertainty relating to the health consequences of exposure to toxic agents, environmental or wartime hazards, or preventive medicines or vaccines associated with

Gulf War service.

``(2) In making recommendations for additional studies, the Academy shall consider the available scientific data, the value and relevance of the information that could result from such studies, and the cost and feasibility of carrying out such studies.

``(h) Subsequent Reviews.--(1) Under the agreement under subsection (b), the National Academy of Sciences shall conduct on a periodic and ongoing basis additional reviews of the evidence and data relating to its activities under this section.

``(2) As part of each review under this subsection, the Academy shall--

``(A) conduct as comprehensive a review as is practicable of the evidence referred to in subsection (c) and the data referred to in subsections (e), (f), and (g) that became available since the last review of such evidence and data under this section; and

``(B) make determinations under the subsections referred to in subparagraph (A) on the basis of the results of such review and all other reviews previously conducted for purposes of this section.

``(i) Reports.--(1) Under the agreement under subsection (b), the National Academy of Sciences shall submit to the committees and officials referred to in paragraph (5) periodic written reports regarding the Academy's activities under the agreement.

``(2) The first report under paragraph (1) shall be submitted not later than 18 months after the date of enactment of this Act [Oct. 21, 1998]. That report shall include--

``(A) the determinations and discussion referred to in subsection (e);

``(B) the results of the review of models of treatment under subsection (f); and

``(C) any recommendations of the Academy under subsection (g).

``(3) Reports shall be submitted under this subsection at least once every two years, as measured from the date of the report under paragraph (2).

``(4) In any report under this subsection (other than the report under paragraph (2)), the Academy may specify an absence of meaningful developments in the scientific or medical community with respect to the activities of the Academy under this section during the 2-year period ending on the date of such report.

``(5) Reports under this subsection shall be submitted to the following:

``(A) The designated congressional committees.

``(B) The Secretary of Veterans Affairs.

``(C) The Secretary of Defense.

``(j) Sunset.--This section shall cease to be effective on October 1, 2010.

``(k) Alternative Contract Scientific Organization.--(1) If the Secretary is unable within the time period set forth in subsection (b) to enter into an agreement with the National Academy of Sciences for the

purposes of this section on terms acceptable to the Secretary, the Secretary shall seek to enter into an agreement for purposes of this section with another appropriate scientific organization that is not part of the Government, operates as a not-for-profit entity, and has expertise and objectivity comparable to that of the National Academy of Sciences.

``(2) If the Secretary enters into an agreement with another organization under this subsection, any reference in this section and section 1118 of title 38, United States Code (as added by section 1602(a)), to the National Academy of Sciences shall be treated as a reference to such other organization.

``SEC. 1604. REPEAL OF INCONSISTENT PROVISIONS OF LAW.

``In the event of the enactment, before, on, or after the date of the enactment of this Act [Oct. 21, 1998], of section 101 of the Veterans Programs Enhancement Act of 1998 [Pub. L. 105-368, 112 Stat. 3317], or any similar provision of law enacted during the second session of the 105th Congress requiring an agreement with the National Academy of Sciences regarding an evaluation of health consequences of service in Southwest Asia during the Persian Gulf War, such section 101 (or other provision of law) shall be treated as if never enacted, and shall have no force or effect.

``SEC. 1605. DEFINITIONS.

``In this title [enacting section 1118 of this title, amending this section and section 1113 of this title, and enacting this note and provisions set out as a note under section 101 of this title]:

``(1) The term `toxic agent, environmental or wartime hazard, or preventive medicine or vaccine associated with Gulf War service' means a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine that is known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War, whether such association arises as a result of single, repeated, or sustained exposure and whether such association arises through exposure singularly or in combination.

``(2) The term `designated congressional committees' means the following:

``(A) The Committees on Veterans' Affairs and Armed Services of the Senate.

``(B) The Committees on Veterans' Affairs and National Security [now Armed Services] of the House of Representatives.

``(3) The term `Persian Gulf War' has the meaning given that term in section 101(33) of title 38, United States Code."

[Pub. L. 105-368, title I, Sec. 101, Nov. 11, 1998, 112 Stat. 3317, enacted provisions similar to those in sections 1603 and 1605 of Pub. L. 105-277, set out above. See section 1604 of Pub. L. 105-277, set out above.]

TITLE 38--VETERANS' BENEFITS

PART II--GENERAL BENEFITS

CHAPTER 11--COMPENSATION FOR SERVICE-CONNECTED DISABILITY OR DEATH

SUBCHAPTER II--WARTIME DISABILITY COMPENSATION

Sec. 1118. Presumptions of service connection for illnesses associated with service in the Persian Gulf during the Persian Gulf War

(a)(1) For purposes of section 1110 of this title, and subject to section 1113 of this title, each illness, if any, described in paragraph (2) shall be considered to have been incurred in or aggravated by service referred to in that paragraph, notwithstanding that there is no record of evidence of such illness during the period of such service.

(2) An illness referred to in paragraph (1) is any diagnosed or undiagnosed illness that--

(A) the Secretary determines in regulations prescribed under this section to warrant a presumption of service connection by reason of having a positive association with exposure to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War; and

(B) becomes manifest within the period, if any, prescribed in such regulations in a veteran who served on active duty in that theater of operations during that war and by reason of such service was exposed to such agent, hazard, or medicine or vaccine.

(3) For purposes of this subsection, a veteran who served on active duty in the Southwest Asia theater of operations during the Persian Gulf War and has an illness described in paragraph (2) shall be presumed to have been exposed by reason of such service to the agent, hazard, or medicine or vaccine associated with the illness in the regulations prescribed under this section unless there is conclusive evidence to establish that the veteran was not exposed to the agent, hazard, or medicine or vaccine by reason of such service.

(4) For purposes of this section, signs or symptoms that may be a manifestation of an undiagnosed illness include the signs and symptoms listed in section 1117(g) of this title.

(b)(1)(A) Whenever the Secretary makes a determination described in subparagraph (B), the Secretary shall prescribe regulations providing that a presumption of service connection is warranted for the illness

covered by that determination for purposes of this section.

(B) A determination referred to in subparagraph (A) is a determination based on sound medical and scientific evidence that a positive association exists between--

(i) the exposure of humans or animals to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Southwest Asia theater of operations during the Persian Gulf War; and

(ii) the occurrence of a diagnosed or undiagnosed illness in humans or animals.

(2)(A) In making determinations for purposes of paragraph (1), the Secretary shall take into account--

(i) the reports submitted to the Secretary by the National Academy of Sciences under section 1603 of the Persian Gulf War Veterans Act of 1998; and

(ii) all other sound medical and scientific information and analyses available to the Secretary.

(B) In evaluating any report, information, or analysis for purposes of making such determinations, the Secretary shall take into consideration whether the results are statistically significant, are capable of replication, and withstand peer review.

(3) An association between the occurrence of an illness in humans or animals and exposure to an agent, hazard, or medicine or vaccine shall be considered to be positive for purposes of this subsection if the credible evidence for the association is equal to or outweighs the credible evidence against the association.

(c)(1) Not later than 60 days after the date on which the Secretary receives a report from the National Academy of Sciences under section 1603 of the Persian Gulf War Veterans Act of 1998, the Secretary shall determine whether or not a presumption of service connection is warranted for each illness, if any, covered by the report.

(2) If the Secretary determines under this subsection that a presumption of service connection is warranted, the Secretary shall, not later than 60 days after making the determination, issue proposed regulations setting forth the Secretary's determination.

(3)(A) If the Secretary determines under this subsection that a presumption of service connection is not warranted, the Secretary shall, not later than 60 days after making the determination, publish in the Federal Register a notice of the determination. The notice shall include an explanation of the scientific basis for the determination.

(B) If an illness already presumed to be service connected under this section is subject to a determination under subparagraph (A), the Secretary shall, not later than 60 days after publication of the notice under that subparagraph, issue proposed regulations removing the presumption of service connection for the illness.

(4) Not later than 90 days after the date on which the Secretary issues any proposed regulations under this subsection, the Secretary shall issue final regulations. Such regulations shall be effective on the date of issuance.

(d) Whenever the presumption of service connection for an illness under this section is removed under subsection (c)--

(1) a veteran who was awarded compensation for the illness on the basis of the presumption before the effective date of the removal of the presumption shall continue to be entitled to receive compensation on that basis; and

(2) a survivor of a veteran who was awarded dependency and indemnity compensation for the death of a veteran resulting from the illness on the basis of the presumption before that date shall continue to be entitled to receive dependency and indemnity compensation on that basis.

(e) Subsections (b) through (d) shall cease to be effective on September 30, 2011.

(Added Pub. L. 105-277, div. C, title XVI, Sec. 1602(a)(1), Oct. 21, 1998, 112 Stat. 2681-742; amended Pub. L. 107-103, title II, Sec. 202(b)(2), (d)(1), Dec. 27, 2001, 115 Stat. 989.)

References in Text

Section 1603 of the Persian Gulf War Veterans Act of 1998, referred to in subsecs. (b)(2)(A)(i) and (c)(1), is section 1603 of Pub. L. 105-277, which is set out in a note under section 1117 of this title.

Amendments

2001--Subsec. (a)(4). Pub. L. 107-103, Sec. 202(b)(2), added par. (4).

Subsec. (e). Pub. L. 107-103, Sec. 202(d)(1), substituted ``on September 30, 2011'' for ``10 years after the first day of the fiscal year in which the National Academy of Sciences submits to the Secretary the first report under section 1603 of the Persian Gulf War Veterans Act of 1998".

Effective Date of 2001 Amendment

Amendment by section 202(b)(2) of Pub. L. 107-103 effective Mar. 1, 2002, see section 202(c) of Pub. L. 107-103, set out as a note under section 1117 of this title.

studies often focus on one agent at a time, they more easily enable the study of chemical mixtures and their potential interactions.

Research on health effects of toxic substance includes animal studies that characterize absorption, distribution, metabolism, elimination, and excretion. Animal studies may examine acute (short-term) exposures or chronic (long-term) exposures. Animal research may focus on the mechanism of action (i.e., how the toxin exerts its deleterious effects at the cellular and molecular levels). Mechanism-of-action (or mechanistic) studies encompass a range of laboratory approaches with whole animals and in vitro systems using tissues or cells from humans or animals. Also, structure–activity relationships, in which comparisons are made between the molecular structure and chemical and physical properties of a potential toxin versus a known toxin, are an important source of hypotheses about mechanism of action.

In carrying out its charge, the committee used animal and other nonhuman studies in several ways, particularly as a marker for health effects that might be important for humans. If an agent, for example, was absorbed and deposited in specific tissues or organs (e.g., uranium deposition in bone and kidney), the committee looked especially closely for possible abnormalities at these sites in human studies.

One of the problems with animal studies, however, is the difficulty of finding animal models to study symptoms that relate to uniquely human attributes, such as cognition, purposive behavior, and the perception of pain. With the exception of fatigue, many symptoms reported by veterans (e.g., headache, muscle or joint pain) are difficult to study in standard neurotoxicological tests in animals (OTA, 1990).

For its evaluation and categorization of the degree of association between each exposure and a human health effect, however, the committee only used evidence from human studies. Nevertheless, the committee did use nonhuman studies as the basis for judgments about biologic plausibility, which is one of the criteria for establishing causation (see below).

Human Studies

Epidemiologic Studies

Epidemiology concerns itself with the relationship of various factors and conditions that determine the frequency and distribution of an infectious process, a disease, or a physiological state in human populations (Lilienfeld, 1978). Its focus on populations distinguishes it from other medical disciplines. Epidemiologic studies characterize the relationship between the agent, the environment, and the host and are useful for generating and testing hypotheses with respect to the association between exposure to an agent and health or disease. The following section describes the major types of epidemiologic studies considered by the committee.

general use in the United States (PAC, 1996) at that time. However, EPA has since placed restrictions on some of the insecticides used during the Gulf War.

USE OF SOLVENTS IN THE GULF WAR

To determine the specific solvents used in the Gulf War the committee gathered information from several sources, including veterans, OSAGWI (2000), and DOD's Defense Logistics Agency. As a result of its research, the committee ultimately identified 53 solvents for review (Appendix D).

There is little information to characterize the use of solvents in the Gulf War. Wartime uses of solvents (such as vehicle maintenance and repair, cleaning, and degreasing) probably paralleled stateside military or civilian uses of solvents, but operating conditions in the Gulf War (such as ventilation and the use of masks) may have varied widely from stateside working conditions.

The most thoroughly documented solvent exposure involved spray-painting with chemical-agent-resistant coating (CARC) (OSAGWI, 2000). Thousands of military vehicles deployed to the Gulf War were painted with tan CARC to provide camouflage protection for the desert environment and a surface that was easily decontaminated. Not all military personnel involved in CARC painting were trained in spray-painting operations, and some might not have had all the necessary personal protective equipment (OSAGWI, 2000).

Personnel engaged in CARC painting were exposed to solvents in the CARC formulations, paint thinners, and cleaning products. As noted in the OSAGWI report, some of the solvents used to clean painting equipment might have been purchased locally and therefore not identified.

COMPLEXITIES IN ADDRESSING GULF WAR HEALTH ISSUES

Investigations of the health effects of past wars often focused on narrowly defined hazards or health outcomes, such as infectious diseases (for example, typhoid and malaria) during the Civil War, specific chemical hazards (for example, mustard gas and Agent Orange) in World War I and Vietnam, and combat injuries. Discussion of the possible health effects of the Gulf War, however, involves many complex issues, such as exposure to multiple agents, lack of exposure information, nonspecific illnesses that lack defined diagnoses or treatment protocols, and the experience of war itself. The committee was not charged with addressing those issues, but it presents them here to acknowledge the difficulties faced by veterans and their families, researchers, policy-makers, and others in trying to understand Gulf War veterans' health.

Multiple Exposures and Chemical Interactions

Military personnel were potentially exposed to numerous agents during the Gulf War. The number of agents and the combination of agents to which the veterans may have been exposed make it difficult to determine whether any one agent or combination of agents is the cause of the veterans' illnesses. These include preventive measures (such as use of pyridostigmine bromide, vaccines, and insecticides), hazards of the natural environment

Gulf War and Health, Vol. 1, p. 83 [emphasis added]

mittee evaluated the strength of the evidence for or against associations between health effects and exposure to the agents being studied.

Categories of Association

The committee used five previously established categories to classify the evidence for association between exposure to a specific agent and a health outcome. The categories closely resemble those used by several IOM committees that evaluated vaccine safety (IOM, 1991, 1994a), herbicides used in Vietnam (IOM, 1994b, 1996, 1999), and indoor pollutants related to asthma (IOM, 2000). Although the categories imply a statistical association, the committee had sufficient epidemiologic evidence to examine statistical associations for only one of the agents under study (i.e., depleted uranium), there was very limited epidemiologic evidence for the other agents examined (i.e., sarin, pyridostigmine bromide, and anthrax and botulinum toxoid vaccines). Thus, the committee based its conclusions on the strength and coherence of the data in the available studies. In many cases, these data distinguished differences between transient and long-term health outcomes related to the dose of the agent. Based on the literature, it became incumbent on the committee to similarly specify the differences between dose levels and the nature of the health outcomes. This approach led the committee to reach conclusions about long- and short-term health effects, as well as health outcomes related to the dose of the putative agents. The final conclusions expressed in Chapters 4–7 represent the committee's collective judgment. The committee endeavored to express its judgments as clearly and precisely as the available data allowed. The committee used the established categories of association from previous IOM studies, because they have gained wide acceptance for more than a decade by Congress, government agencies, researchers, and veteran groups.

- Sufficient Evidence of a Causal Relationship. Evidence is sufficient to conclude that a causal relationship exists between the exposure to a specific agent and a health outcome in humans. The evidence fulfills the criteria for sufficient evidence of an association (below) and satisfies several of the criteria used to assess causality: strength of association, dose–response relationship, consistency of association, temporal relationship, specificity of association, and biological plausibility.

- Sufficient Evidence of an Association. Evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between an exposure to a specific agent and a health outcome in human studies in which chance, bias, and confounding could be ruled out with reasonable confidence.

- Limited/Suggestive Evidence of an Association. Evidence is suggestive of an association between exposure to a specific agent and a health outcome in humans, but is limited because chance, bias, and confounding could not be ruled out with confidence.

Gulf War and Health, Vol. 1, p. 84 [emphasis added]

- Inadequate/Insufficient Evidence to Determine Whether an Association Does or Does Not Exist. The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association between an exposure to a specific agent and a health outcome in humans.

- Limited/Suggestive Evidence of No Association. There are several adequate studies, covering the full range of levels of exposure that humans are known to encounter, that are mutually consistent in not showing a positive association between exposure to a specific agent and a health outcome at any level of exposure. A conclusion of no association is inevitably limited to the conditions, levels of exposure, and length of observation covered by the available studies. In addition, the possibility of a very small elevation in risk at the levels of exposure studied can never be excluded.

These five categories cover different degrees or levels of association, with the highest level being sufficient evidence of a causal relationship between exposure to a specific agent and a health outcome. The criteria for each category incorporate key points discussed earlier in this chapter. A recurring theme is that an association is more likely to be valid if it is possible to reduce or eliminate common sources of error in making inferences: chance, bias, and confounding. Accordingly, the criteria for each category express varying degrees of confidence based upon the extent to which it has been possible to exclude these sources of error. To infer a causal relationship from a body of evidence, the committee relied on long-standing criteria for assessing causation in epidemiology (Hill, 1971; Evans, 1976).

COMMENTS ON INCREASED RISK OF ADVERSE HEALTH OUTCOMES AMONG GULF WAR VETERANS

As discussed in the beginning of this chapter, the committee reviewed the available scientific evidence in the peer-reviewed literature in order to draw conclusions about associations between the agents of interest and adverse health effects in all populations. The committee placed its conclusions in categories that reflect the strength of the evidence for an association between exposure to the agent and health outcomes. The committee could not measure the likelihood that Gulf War veterans' health problems are associated with or caused by these agents. To address this issue, the committee would need to compare the rates of health effects in Gulf War veterans exposed to the putative agents with the rates of those who were not exposed, which would require information about the agents to which individual veterans were exposed and their doses. However, as discussed throughout this report, there is a paucity of data regarding the actual agents and doses to which individual Gulf War veterans were exposed. Further, to answer questions about increased risk of illnesses in Gulf War veterans, it would also be important to know the degree to which any other differences be-

Veterans and Agent Orange: Update 1996, p. 97 [emphasis added]

Summary Of The Evidence

Categories of Association

The categories of association used by the committee were those used in VAO. Consistent with the charge to the Secretary of Veterans Affairs in P.L. 102-4, the distinctions between the categories are based on "statistical association," not on causality. Thus, standard criteria used in epidemiology for assessing causality (Hill, 1971) do not strictly apply. The distinctions between the categories reflect the committee's judgment that a statistical association would be found in a large, well-designed epidemiologic study of the outcome in question in which exposure to herbicides or dioxin was sufficiently high, well-characterized, and appropriately measured. The categories of association are:

- Sufficient Evidence of an Association Evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between herbicides and the outcome in studies in which chance, bias, and confounding could be ruled out with reasonable confidence. For example, if several small studies that are free from bias and confounding show an association that is consistent in magnitude and direction, there may be sufficient evidence for an association.

- Limited/Suggestive Evidence of an Association Evidence is suggestive of an association between herbicides and the outcome but is limited because chance, bias, and confounding could not be ruled out with confidence. For example, at least one high-quality study shows a positive association but the results of other studies are inconsistent.

- Inadequate/Insufficient Evidence to Determine Whether an Association Exists The available studies are of insufficient quality, consistency, or statistical power to permit a conclusion regarding the presence or absence of an association. For example, studies fail to control for confounding, have inadequate exposure assessment, or fail to address latency.

- Limited/Suggestive Evidence of No Association There are several adequate studies, cover the full range of levels of exposure that human beings are known to encounter, that are mutually consistent in not showing a positive association between exposure to herbicides and the outcome at any level of exposure. A conclusion of "no association" is inevitably limited to the conditions, level of exposure, and length of observation covered by the available studies. In addition, the possibility of a very small elevation in risk at the levels of exposure studied can never be excluded.

studies often focus on one agent at a time, they more easily enable the study of chemical mixtures and their potential interactions.

Research on health effects of toxic substance includes animal studies that characterize absorption, distribution, metabolism, elimination, and excretion. Animal studies may examine acute (short-term) exposures or chronic (long-term) exposures. Animal research may focus on the mechanism of action (i.e., how the toxin exerts its deleterious effects at the cellular and molecular levels). Mechanism-of-action (or mechanistic) studies encompass a range of laboratory approaches with whole animals and in vitro systems using tissues or cells from humans or animals. Also, structure–activity relationships, in which comparisons are made between the molecular structure and chemical and physical properties of a potential toxin versus a known toxin, are an important source of hypotheses about mechanism of action.

In carrying out its charge, the committee used animal and other nonhuman studies in several ways, particularly as a marker for health effects that might be important for humans. If an agent, for example, was absorbed and deposited in specific tissues or organs (e.g., uranium deposition in bone and kidney), the committee looked especially closely for possible abnormalities at these sites in human studies.

One of the problems with animal studies, however, is the difficulty of finding animal models to study symptoms that relate to uniquely human attributes, such as cognition, purposive behavior, and the perception of pain. With the exception of fatigue, many symptoms reported by veterans (e.g., headache, muscle or joint pain) are difficult to study in standard neurotoxicological tests in animals (OTA, 1990).

For its evaluation and categorization of the degree of association between each exposure and a human health effect, however, the committee only used evidence from human studies. Nevertheless, the committee did use nonhuman studies as the basis for judgments about biologic plausibility, which is one of the criteria for establishing causation (see below).

Human Studies

Epidemiologic Studies

Epidemiology concerns itself with the relationship of various factors and conditions that determine the frequency and distribution of an infectious process, a disease, or a physiological state in human populations (Lilienfeld, 1978). Its focus on populations distinguishes it from other medical disciplines. Epidemiologic studies characterize the relationship between the agent, the environment, and the host and are useful for generating and testing hypotheses with respect to the association between exposure to an agent and health or disease. The following section describes the major types of epidemiologic studies considered by the committee.

THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

January 24, 2003

Harvey Fineberg, M.D., Ph.D.
President
Institute of Medicine
The National Academies
500 Fifth Street, NW
Washington, DC 20001

Dear Dr. Fineberg:

The Department of Veterans Affairs appreciates and respects the excellent work contained in the Institute of Medicine (IOM) report on "Gulf War Health." As you know, this report was completed in 2000 in response to a Congressional requirement. The IOM, at that time, reviewed medical and scientific literature on the health effects of certain materials, including Sarin, that Gulf War veterans may have been exposed to during the 1991 Gulf War.

Recently, a number of new studies have been published on the effects of Sarin on laboratory animals. These studies have raised concerns with Gulf War veterans and other Americans regarding the relationship of these studies to possible health consequences of human exposures.

With this in mind, I am requesting IOM examine the medical and scientific literature on health effects of Sarin published since the 2000 Report. I ask that IOM report back to VA, as soon as possible, on whether this new research affects earlier conclusions of IOM. Specifically, in the interest of veterans' health, we would like to know if this new scientific information alters the conclusions about possible long-term health consequences of exposure to low levels of Sarin.

We look forward to meeting with you to discuss additional specifics and timing for this report. If you have any questions about this request, please contact Dr. Susan Mather, Chief Officer, Office of Public Health and Environmental Hazards, at (202) 273-8575.

Sincerely yours,

Anthony J. Principi

Updated Literature Review of Sarin (2004), p. 20 [emphasis added]

OP insecticide data in its conclusion, the committee reviewed the OP epidemiology literature. The committee responsible for GW2 (IOM, 2003a) reviewed the literature on OP compounds. The present committee reviewed relevant epidemiology studies published since the preparation of that report.

Animal studies had a small role in the committee's assessment of association between putative agents and health outcomes. As with previous committees, this committee used animal data for making assessments of biologic plausibility in support of the epidemiologic data rather than as part of the weight of evidence to determine the likelihood that an exposure to a specific agent might cause a long-term outcome.

The committee classified the evidence of an association between exposure to sarin and cyclosarin and a specific health outcome into five categories (Box 1-1). The categories closely resemble those used by previous committees that evaluated the effects of chemicals related to the Gulf War (IOM, 2000a, 2003a) and those used by several IOM committees that have evaluated vaccine safety (IOM, 1991, 1994a), herbicides used in Vietnam (IOM, 1994b, 1996, 1999, 2001, 2003b), and indoor pollutants related to asthma (IOM, 2000b). The committee's conclusions, presented in Chapter 4, represent its collective judgment.

The committee endeavored to express its judgment as clearly and precisely as the available data allowed, and it used the established categories of association from previous IOM studies because they have gained wide acceptance over more

BOX 1-1 Categories of Evidence

Sufficient Evidence of a Causal Relationship

Evidence from available studies is sufficient to conclude that a causal relationship exists between exposure to a specific agent and a specific health outcome in humans, and the evidence is supported by experimental data. The evidence fulfills the guidelines for sufficient evidence of an association (below) and satisfies several of the guidelines used to assess causality: strength of association, dose–response relationship, consistency of association, biologic plausibility, and a temporal relationship.

Sufficient Evidence of an Association

Evidence from available studies is sufficient to conclude that there is a positive association. A consistent positive association has been observed between exposure to a specific agent and a specific health outcome in human studies in which chance1 and bias, including confounding, could be ruled out with reasonable confidence. For example, several high-quality studies report consistent positive associations, and the studies are sufficiently free of bias, including adequate control for confounding.

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Susanne A. Stoiber
Executive Director

March 11, 2003

RE: NAS Proposal No. 03-IOM-051-01

Mark A. Brown, Ph.D.
Director
Environmental Agents Service (131)
Department of Veterans Affairs
810 Vermont Avenue, N.W.
Washington, DC 20420

Dear Dr. Brown:

We are pleased to submit the enclosed proposal, prepared by our Board on Health Promotion and Disease Prevention, in response to the Department of Veterans Affairs' (VA) request for an additional deliverable, Gulf War and Health: Updated Review of the Literature on Sarin, under Task Order #VA-2794-123. The total estimated cost of this project is $100,000.00 for the period from April 1, 2003 to October 31, 2003. As discussed with Institute of Medicine staff, there are sufficient funds remaining in the Gulf War and Health: Volume 2 budget to support this task. A no-cost extension has been requested to allow time to complete this task.

This proposal follows a request from Secretary Anthony J. Principi and discussions with yourself requesting an update of the health effects of the chemical warfare agent sarin; the original review of the health effects of sarin was part of Gulf War and Health: Volume 1. The request comes following the publication of new toxicology studies (three) showing effects in rats following exposure to chronic low doses of sarin and subsequent questions from veterans on whether those results would alter the conclusions of Gulf War and Health: Volume 1.

Commencement of this activity is subject to approval by the Executive Committee of the National Research Council Governing Board at its meeting on March 18, 2003.

THE NATIONAL ACADEMIES
Advisers to the Nation on Science, Engineering, and Medicine

500 Fifth Street, NW
Washington, DC 20001-2721

Phone: 202 334 2177
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The responsible staff officer for this study is Michelle Catlin, Ph.D., Senior Program Officer, 202-334-2777. She may be contacted regarding program matters. Business negotiations are the responsibility of Linda Kilroy, Contract Manager, Office of Contracts and Grants. She may be reached at 202-334-2428.

We shall appreciate your consideration of this matter.

Sincerely,

Susanne A. Stoiber

cc: Secretary Anthony J. Principi

Enclosures

THE NATIONAL ACADEMIES

INSTITUTE OF MEDICINE
Board on Health Promotion and Disease Prevention

SUMMARY

The purpose of this project is to comprehensively review, evaluate, and summarize the available scientific and medical information, published since *Gulf War and Health: Volume 1 Depleted Uranium, Pyridostigmine Bromide, Sarin, Vaccines* (IOM, 2000) and *Gulf War and Health: Volume 2 Insecticides and Solvents* (IOM, 2003), regarding the association between sarin and adverse health effects. If published peer-reviewed information is available in Gulf War veteran population, then the potential health risks posed to Gulf War veterans may be considered. Other relevant issues as indicated by literature, such as health effects associated with combinations of chemicals and genetic susceptibilities may also be reviewed.

BACKGROUND

Almost 700,000 US troops participated in the Gulf War. Most troops returned home and resumed their normal activities. However, within a relatively short time, a number of those who had been deployed to the Persian Gulf began to report health problems they believed to be connected to their deployment. Concern was expressed that their health problems might be related to the biologic and chemical compounds to which the troops may have been exposed.

A number of efforts have attempted to address the many issues surrounding the health consequences of deployment to the Persian Gulf. Most notably, the Presidential Advisory Committee on Gulf War Veterans' Illnesses (PAC) was established by President Clinton in May 1995. The PAC's final report recommended that the Department of Veterans Affairs (VA) enter into an agreement with the National Academy of Sciences to "conduct periodic reviews and analyses of the available scientific evidence to determine statistical associations between Gulf War service and morbidity and mortality. Subsequently, two public laws (P.L. 105-368 and P.L. 105-277) were passed requiring that the VA enter into a contract with the NAS to conduct literature reviews on the putative agents and to determine possible health outcomes related to those agents. There are 34 specific agents that require review as indicated by the two public laws.

In 1998, the VA entered into a contract with the IOM to begin a series of studies related to gulf war and health. In the first study, an IOM committee examined six of the 34 putative agents, including: sarin, cyclosarin, pyridostigmine bromide, depleted uranium, anthrax vaccine, and botulinum toxoid vaccine. A separate IOM committee recently completed the examination of insecticides and solvents. The remaining compounds (as listed in the two public laws) will be reviewed in future studies. In the interim, the VA has recently requested, in response to veterans' concerns, that an updated examination of sarin be conducted. This proposal is for the sarin update only.

PLAN OF ACTION

Statement of Task

The committee will conduct a review of the peer-reviewed literature published since earlier IOM reports on health effects associated with exposure to sarin and related compounds. Relevant epidemiologic studies will be considered. With regard to the toxicologic literature, the committee will generally use review articles to present a broad overview of the toxicology of sarin and to make assessments of biologic plausibility regarding the compound of study and health effects; individual toxicology research papers will be evaluated as warranted.

The committee will make determinations on the strength of the evidence for associations between sarin and human health effects. If published peer-reviewed information is available on the dose of sarin exposure in Gulf War veterans, the committee may address the potential health risks posed to the veterans. The committee may also consider other relevant issues (e.g., exposure to multiple chemical exposure and genetic susceptibilities). The review will include recommendations for additional scientific studies to resolve areas of continued scientific uncertainty when appropriate.

Work Plan

The study will be conducted over a period of 7 months. The committee will conduct its meetings and deliberations via conference calls and email. One short report will be issued.

Expert Committee and Staff

The overall process will be governed by a committee of approximately 6 experts drawn from a broad range of backgrounds, such as toxicology, epidemiology and biostatistics, environmental and occupational health, exposure assessment, and clinical medicine. The committee will have a full staff (study director, senior program officer, research assistant, project assistant). The staff will review the published studies on the compounds of interest and identify key papers for the committee's consideration. The IOM's Board on Health Promotion and Disease Prevention will oversee the project.

Estimated Expenditures

The estimated cost of this project is $100,000 for the period April 1, 2003 to October 31, 2003. There are adequate funds remaining from *Gulf War and Health: Pesticides and Solvents* project to conduct this study; no additional funding from the Department of Veterans Affairs is being requested. A no-cost extension until October 31, 2003 has been requested to allow time for this new study to be completed.

Product and Dissemination Plan

Based upon committee deliberations, a short report will be produced and will be reviewed according to standard National Research Council (NRC) policies and procedures. The report will be distributed to the sponsor and to other interested parties, such as academic researchers, veterans' organizations, and Congress in accordance with the policies of the National Academy of Sciences. Committee members will travel to Washington to conduct briefings as necessary. Copies of the summary will be produced for broader distribution, and made available on the Internet through the National Academy Press (www.nap.edu).

FEDERAL ADVISORY COMMITTEE ACT (FACA)

The Academy has developed interim policies and procedures to implement Section 15 of the Federal Advisory Committee act, 5, U.S.C. App. sec. 15. Section 15 includes certain requirements regarding public access and conflicts of interest that are applicable to agreements under which the Academy, using a committee, provides advice or recommendations to a Federal agency. In accordance with Section 15 of FACA, the Academy shall submit to the government sponsor(s) following delivery of each applicable report a certification that the policies and procedures of the Academy that implement Section 15 of FACA have been substantively complied with in the performance of the contract/grant/cooperative agreement with respect to the applicable report.

PUBLIC INFORMATION ABOUT THE PROJECT

In order to afford the public greater knowledge of Academy activities and an opportunity to provide comments on those activities, the Academy may post on its website (http://www.national-academies.org) the following information as appropriate under its procedures: (1) notices of meetings open to the public; (2) brief descriptions of projects; (3) committee appointments, if any (including biographies of committee members); (4) report information; and (5) any other pertinent information.

UNIQUE QUALIFICATIONS OF THE INSTITUTE OF MEDICINE

The IOM is the health policy arm of the National Academy of Sciences, which was created by a Congressional charter signed by President Abraham Lincoln in 1863 as a private honorary society dedicated to the furtherance of science and its use for the general welfare. The IOM was chartered in 1970 to enlist distinguished members of the appropriate professions in the examination of policy matters pertaining to the health of the public. Under the terms of this charter, the IOM is called upon to act as an official, yet independent, advisor to the federal government in matters of science. The IOM also acts at its own initiative to identify and examine significant issues of health care, research, and education to which to direct its attention.

The IOM, like other Academy units, is uniquely situated to provide assessments in areas of science, health care, and public policy. Studies are undertaken by distinguished individuals selected for their expertise and experience in the topic under study. To a degree unmatched elsewhere, the IOM can secure the participation of virtually any expert whom it invites to serve. At any given time, the IOM has some 80 expert groups with over 1,100 members examining a great range of problems. With rare exceptions, members serve without compensation.
The IOM's Board on Health Promotion and Disease Prevention, which would oversee the proposed study, is broadly concerned with promoting the health of the public, particularly through population-based interventions. The Board examines and develops strategies for disease prevention, taking into account the multiple factors affecting health—genetic endowment, social and environmental conditions, individual behavior (including tobacco use, alcohol consumption, diet, and exercise) and personal preventive services. The Board also addresses both the science base for such interventions and the public health infrastructure, and the education and supply of health professionals necessary for carrying them out.

Throughout all of its work, the Board puts emphasis on population-based interventions as well as clinical preventive services, and on understanding and mitigating risks to the public's health, including environmental, behavioral, and medical. Some of the crosscutting themes that

characterize and guide the Board's work are ethical issues in public health, the application of scientific information in public health policymaking, the evaluation of preventive services and population-based interventions, the efficient allocation of societal resources for prevention, and the development of the science base for health promotion and disease prevention, including behavioral science.

The Board on Health Promotion and Disease Prevention maintains an active research program in veterans' health issues, and in related areas such as environmental and occupational health. Representative studies include the landmark *Veterans and Agent Orange* report, *Update 1996*, *Update 1998*, *Update 2000*, and *Update 2002*, and the health effects of exposure to mustard gas and Lewisite, and several reports regarding the health of Persian Gulf veterans.

Appendix B

Letter to IOM President Regarding Imbalanced Membership of 2016 Report Committee

November 28, 2014

Dr. Victor J. Dzau, M.D.
President
Institute of Medicine
500 Fifth St., NW
Washington, DC 20001

Dear Dr. Dzau,

As former members of the VA Research Advisory Committee on Gulf War Veterans Illnesses, we are gravely concerned by the makeup of the committee that IOM staff has chosen for the upcoming review of Gulf War health literature. The membership is grossly imbalanced toward the 1990's government position that Gulf War veterans have no special health problem — just what happens after every war, related to psychiatric issues, and not environmental exposures.

Reviving this discredited fiction will cause veterans' doctors to prescribe inappropriate psychiatric medications, and will misdirect research to find effective treatments down blind alleys — an unconscionable breach of the duty owed to veterans and expected of the Institute of Medicine.

Science has conclusively demonstrated that this government position has no scientific validity. Just four years ago, an IOM committee chaired by Dr. Stephen Hauser, former president of the American Neurological Association, reviewed the scientific literature and concluded that the chronic multisymptom illness suffered by an estimated 250,000 Gulf War veterans (over one-third of the 697,000 who deployed) is a physical illness associated with Gulf War service, a "diagnostic entity" that "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." http://books.nap.edu/openbook.php?record_id=12835, pages 262, 210, 204, 109, 261

These conclusions reinforced the similar findings and recommendations of our former committee's 452-page 2008 report. Our committee went further to identify the specific environmental exposures responsible, including pesticides, pyridostigmine bromide pills given to troops as a prophylaxis against nerve gas, and possibly low level nerve gas released by the destruction of Iraqi facilities, oil well fires, and multiple vaccinations. In April 2014, our committee published an update report which concluded that "[s]cientific research published since … 2008 …

supports and further substantiates the conclusions of the 2008 report."
http://www.va.gov/RAC-GWVI/RACReport2014Final.pdf, page 5

Yet, as the attached analysis shows, fully half the individuals selected for the new committee are predisposed toward the discredited 1990's government position, either because they promoted it themselves, or because they are professionally oriented to view such problems as psychiatric and/or unrelated to environmental exposures. The rest of the committee are neutral figures with a background in other neurological conditions like Alzheimer's disease and traumatic brain injuries. No member of the committee has been actively engaged in Gulf War health research in the past decade.

Given that the committee is charged with producing a consensus report, it is wholly foreseeable that its conclusions will end up between the group predisposed to 1990's fictions and those who are neutral but unfamiliar with the subject. Compared to the 2010 IOM report, it will be a reversal toward the discredited 1990's position.

For three years, VA has been engaged in a surreptitious campaign to revive the 1990's government position. Since no scientific support for the position exists, VA staff has resorted to manipulating Gulf War research and reports. The Research Advisory Committee has documented this manipulation in forty-six pages of findings and recommendations in June 2012 and in a draft section of its April 2014 report which had to be removed because VA eliminated the committee's oversight authority.
http://www.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf
https://veterans.house.gov/sites/republicans.veterans.house.gov/files/Binns%2C%20ExhibitBtestimony.pdf

In September, VA's Director of Epidemiology, Dr. Robert Bossarte, and his staff presented findings of two new VA studies to the Research Advisory Committee. One showed that diagnoses given to Gulf War veterans in VA hospitals over a ten-year period were no different than those given to veterans of the same era who did not deploy. The other, a large survey, showed that rates of PTSD and depression were dramatically higher than previously reported by Gulf War veterans.

To an inexperienced observer, it might seem that the research on Gulf War veterans' health was changing. However, Research Advisory Committee members quickly pointed out that Dr. Bossarte and his staff were not telling the whole story.
http://www.va.gov/RAC-GWVI/RAC_Recommendation092314.pdf

The diagnoses study presentation failed to mention that VA had no diagnostic code for Gulf War illness or chronic multisymptom illness, that VA doctors at this time were trained to consider the illness as psychosomatic, and that veterans who served during the period of greatest toxic exposures were inexplicably excluded from the study. Similarly, the survey presentation did not disclose that the survey was overweighted with mental health questions to the extent that the Committee had repeatedly recommended against sending it out, http://www.va.gov/RAC-

GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf, Appendix F, and that the survey's principal investigator had testified to Congress that his superiors lied to then-VA Chief of Staff John Gingrich to induce him to release the survey. https://veterans.house.gov/witness-testimony/dr-steven-s-coughlin The presentation did not mention that people suffering from chronic health problems often become depressed after 23 years, but it is not the cause of their illness. Dr. Bossarte and his staff will be presenting to the new IOM committee on December 3. Very likely they will be presenting their new research findings. But no one on the IOM committee will know that they are not being told the whole story, because there are no members with the necessary background. Thus, misleading VA studies will be presented to an imbalanced IOM committee, which will include the findings in its new report, and science will be "revised".

The motivation behind VA's manipulation of science is clear: to hold down benefits costs and claims wait times. In April, Military Times reported that VA Undersecretary for Benefits Allison Hickey was concerned that even using the term "Gulf War illness" "might imply a causal link between service in the Gulf and poor health which could necessitate legislation for disability compensation for veterans who served in the Gulf." http://archive.militarytimes.com/article/20140422/BENEFITS04/304220036/Top-VA-official-questions-use-term-Gulf-War-illness-

She also recently testified to Congress that VA would meet its 2015 claims processing target of 125 days unless she had to add a quarter million new claims to her inventory overnight, as happened in 2010 when Agent Orange coverage was expanded: "That will kill us." http://www.veterans.senate.gov/hearings/va-claims-system-review-of-vas-transformation-progress [1:38:50 mark]

While VA says that it provides care and benefits to veterans suffering from Gulf War illness under the category "undiagnosed illnesses," http://www.publichealth.va.gov/exposures/gulfwar/medically-unexplained-illness.asp, the reality is otherwise. A 2014 VA report to Congress revealed that only 11,216 Gulf War-related claims have been approved, while 80 percent are denied. http://www.scribd.com/doc/241661207/Binns-Parting-Thoughts-093014, page 7. VA's September 2014 press release that "nearly 800,000 Gulf War era Veterans are receiving compensation benefits for service-connected issues" is grossly misleading. http://www.91outcomes.com/2014/09/va-press-release-va-secretary-mcdonald.html VA counts every veteran in the area from 1990 to the present as "Gulf War era," not just those who served in 1990-91.

We are appalled that the government has been able to influence the workings of the Institute of Medicine, the most revered institution in American medical science, to further its shameful campaign to manipulate science to deny veterans care and benefits. Regrettably, however, we are not surprised, as this has been more common than not where Gulf War veterans' health has been concerned. For example:

1. For fourteen years, in response to a law passed by Congress in 1998, VA has ordered and the IOM has prepared reports on the health effects of thirty-three toxic substances to which Gulf War veterans were exposed. The law repeatedly specified that the reports must consider studies in both humans and in animals. For fourteen years, however, these IOM reports have considered only human studies. To do this, VA and the IOM not only have had to disregard the law; they also had to manipulate the standard established in the IOM reports on Agent Orange, inserting the word "human" in the standard. As a result, since most research studies of toxic substances are necessarily done in animals, these IOM Gulf War reports have never found sufficient evidence of an association between these substances and Gulf War veterans' health problems. In turn, VA has never recognized any toxic exposure as a reason for granting these ill veterans care and benefits.
https://veterans.house.gov/witness-testimony/james-h-binns-0

2. The most egregious of these IOM Gulf War reports was the Updated Literature Review of Sarin, in which animal studies were not considered even though new animal studies were the only reason that then-Secretary Principi ordered the report. The outcome of the report was predetermined before the VA-IOM contract was ever signed, by understandings between VA and IOM staff discussed in a cover letter from the then executive director of the IOM to the then head of the VA Environmental Agents Service. https://veterans.house.gov/witness-testimony/james-h-binns-0

3. The Research Advisory Committee recommended in 2008 that these IOM reports be redone in accordance with the law. http://www.va.gov/RAC-GWVI/docs/Committee_Documents/GWIandHealthofGWVeterans_RAC-GWVIReport_2008.pdf, pages 53-55, 57. However, they have not been redone. Worse, the manipulated standard is now being employed in VA-ordered IOM studies of the health of post-9/11 veterans. The 2011 IOM report on the long-term health effects of burn pits used to incinerate waste in Iraq and Afghanistan used the manipulated Gulf War standard (limited to human studies), not the Agent Orange standard. As a consequence, the IOM burn pits committee found "inadequate/insufficient evidence of an association between exposure to combustion products and cancer, respiratory disease, circulatory disease, neurologic disease, and adverse reproductive and developmental outcomes."
http://books.nap.edu/openbook.php?record_id=13209&page=6

4. In 2006, the IOM did a general Gulf War literature review for VA, similar to the current task. Most of the report was a straightforward summary of the research, but IOM's press release and press conference focused on one conclusion that echoed the familiar government theme that there is "no unique Gulf War syndrome." Technically, this only means that others have similar symptoms, but the press release and conference spun the message to imply that Gulf War veterans have no major health problem. http://www.nbcnews.com/id/14801666/ns/health-health_care/t/study-gulf-war-syndrome-doesnt-exist/#.VHLDjUuBNH8

5. The 2013 IOM treatments report was a recent glaring example of VA and IOM collaboration to disregard the law and promote the 1990's government position. A

2010 law required VA to contract with the IOM for a comprehensive review of the best treatments for ill Gulf War veterans by a group of doctors experienced in treating Gulf War veterans "diagnosed with chronic multisymptom illness or another health condition related to chemical and environmental exposures that may have occurred during [their] service."

Instead, VA contracted for a literature review of treatments for all "populations with a similar constellation of symptoms," and the IOM appointed a committee with no experience in treating Gulf War veterans but extensive experience in psychiatric and psychosomatic medicine -- though the 2010 IOM report had just concluded that the illness "cannot be ascribed to any known psychiatric disorder." Analysishttps://veterans.house.gov/sites/republicans.veterans.house.gov/files/Binns%2C%20ExhibitBtestimony.pdf http://www.scribd.com/doc/150949964/WHITE-PAPER-IOM-CMI-Panel-Membership-

The individuals selected to give background briefings to the committee were largely familiar advocates for the 1990's position, who told the committee the problem was psychiatric. http://www.va.gov/RAC-GWVI/docs/Committee_Documents/CommitteeDocJune2012.pdf, pages 24-30. Half the illnesses whose therapies were reviewed were psychiatric. The report revived 1990's themes that that "[t]hroughout modern history, many soldiers returning from combat have experienced postcombat illnesses. . . that cannot now be attributed to any diagnosable pathophysiologic entity or disease," and that "[c]linicians should approach [chronic multisymptom illness] with 'a person-centered model of care . . . that helps patients understand that the word psychosomatic is not pejorative.'" https://veterans.house.gov/sites/republicans.veterans.house.gov/files/Binns%2C%20ExhibitBtestimony.pdf

6. The person who identified the individuals to be invited to brief the treatment committee was the chief scientist of the VA Office of Public Health, according to Congressional testimony by a senior VA epidemiologist who worked for him. https://veterans.house.gov/witness-testimony/dr-steven-s-coughlin

7. One of the psychiatric-oriented briefers was a member of the IOM Board on the Health of Select Populations, the IOM board that oversees veterans' studies. Dr. Kurt Kroenke, an Army doctor and psychiatric-oriented Gulf War researcher in the 1990's, is a leading figure in somatic medicine. He co-chaired the "Conceptual Issues in Somatoform and Similar Disorders" project that laid the groundwork for the controversial expansion of the definition of somatoform disorders in the recently revised Diagnostic and Statistical Manual of Mental Disorders (DSM-5) of the American Psychiatric Association. http://www.ncbi.nlm.nih.gov/pubmed/17600162 http://dxrevisionwatch.com/dsm-5-drafts/dsm-5-ssd-work-group/ He has co-authored publications with two members of the IOM treatment committee and two members of the new IOM committee that begins work December 3.

8. Two other members of the IOM Board of the Health of Select Populations were also leading proponents of the government position on Gulf War health in the 1990's. Dr. Francis Murphy held the position equivalent to chief scientist in VA's Office of Public Health, and Dr. Greg Gray was a Navy doctor who published numerous papers in 1996-2001 that dismissed the idea that Gulf War veterans have any special health problems. Conversely, as of June 2013, no one on the IOM Board of the Health of Select Populations represented current scientific understanding of Gulf War illness. http://www.scribd.com/doc/150949964/WHITE-PAPER-IOM-CMI-Panel-Membership-Analysis. It is currently undisclosed who serves on this board, as its membership has been removed from the IOM website, although the membership of all other IOM boards continues to be listed. http://www.iom.edu/About-IOM/Leadership-Staff/Boards.aspx

In summary, there has been a long-term corrupt relationship between the government and the Institute of Medicine to deny the true state of Gulf War veterans' health, of which the makeup of the new committee is only the latest example.

We are confident that neither you nor VA Secretary McDonald, as newcomers to Washington and to your respective institutions, is aware of this problem. At one point, none of us would have believed it possible either. But it is a cancer that threatens to destroy the integrity and reputations of both organizations. And it makes a mockery of the mission of the IOM "to provide unbiased and authoritative advice to decision makers and the public." http://www.iom.edu/About-IOM.aspx

We urge you to conduct a thorough investigation of this problem and to fix it. The most effective and rapid approach is for the IOM to handle this itself. If it does not, however, we will work with veterans' organizations to show Congress the need to conduct an investigation and enact legislative solutions.

As part of putting IOM on solid ground going forward, we urge you to replace the eight provisional members predisposed to the government's scientifically discredited 1990's position with individuals representing current scientific knowledge of Gulf War research and the health effects of neurotoxic exposures. We also urge you to replace those members of the Board on the Health of Select Populations identified with this position, with individuals representing current scientific knowledge regarding veterans' health and environmental exposures.

Respectfully,

James Binns
Former Chairman, Research Advisory Committee on Gulf War Veterans Illnesses

Beatrice A. Golomb, MD, PhD
Professor of Medicine, University of California San Diego

Current Member, Research Advisory Committee; former Committee Scientific Director

Rev. Joel C. Graves, DMin,
CPT U.S. Army (Ret.)
Former Member, Research Advisory Committee

Marguerite L. Knox, MN, ARNP-FNP/ACNP
COL, South Carolina Army National Guard
Former Member, Research Advisory Committee

William J. Meggs, MD, PhD
Professor and Chief, Division of Toxicology, Brody School of Medicine, East Carolina University
Former Member, Research Advisory Committee

cc: Institute of Medicine Council

Analysis of the Provisional Committee Membership
November, 2014

The provisional committee is grossly imbalanced in favor of the 1990's government position that Gulf War veterans have no special health problem—just what happens after every war, related to psychiatric issues, and not environmental exposures. The following committee members are predisposed toward this position, either because they personally supported it, or because they are professionally oriented to view these kinds of health problems as psychiatric and unrelated to environmental exposures.

Dr. Kenneth Kizer, as VA Undersecretary for Health, 1994-1999, was the chief promulgator of this position, including this 1997 Congressional testimony: "The overall frequency of unexplained symptoms among Gulf War veterans appears to be about the same as in a general medical practice."
http://www.va.gov/OCA/testimony/hvac/sh/hvac61.asp

Dr. Howard Kipen, a member of the VA Persian Gulf Expert Scientific Committee, 1993-1997, has published "Military deployment to the Gulf War as a risk factor for psychiatric illness among U.S. troops" (2005) http://bjp.rcpsych.org/content/188/5/453.long and that "[c]oncerns . . . of a unique Gulf War syndrome, remind us that military personnel returning from wars have regularly described disabling symptoms" (co-authored with Dr. Kroenke). Unexplained Symptoms after Terrorism and War: An Expert Consensus Statement. Journal of Occupational and Environmental Medicine 45(10):1040-8, 2003

Dr. Herman Gibb runs a private consulting firm. The NIH reportedly terminated its contract with his previous firm, while he was president, on grounds that his firm was working for three chemical companies at the same time it was reviewing their chemicals for the government.
http://www.washingtonpost.com/wp-dyn/content/article/2007/04/13/AR2007041301979.html

Dr. Nancy Woods is an expert on midlife and aging women's health; her background relevant to Gulf War illness was as a member of the IOM committee that authored a 1996 report, "The Health Consequences of Service During the Persian Gulf War," which concluded: "Men and women served side by side in conditions that increased the stresses of serving in these grim surroundings . . . Studies of Gulf War veterans suggest that these veterans suffer from a variety of recognized diseases, . . . not the existence of a new disease. "
http://books.nap.edu/openbook.php?record_id=5272&page=R6

Dr. Javier Escobar is a professor of psychiatry at the Robert Wood Johnson Medical School, where his work "focuses on the somatic presentations of psychiatric disorders in primary care . . . as director of the 'Medically Unexplained Physical Symptoms Research Center.'"
http://www.physicianfacultyscholars.org/nac/escobar.html With Dr. Kroenke he was a member of the "Conceptual Issues in Somatoform and Similar Disorders" project that laid the groundwork for the controversial expansion of the definition of somatoform disorders in the recently revised Diagnostic and Statistical Manual of Mental Disorders (DSM-5) of the American Psychiatric Association, and was a

member of the task force that wrote DSM-5.
http://www.ncbi.nlm.nih.gov/pubmed/17600162
http://dxrevisionwatch.com/dsm-5-drafts/dsm-5-ssd-work-group/
http://www.dsm5.org/MeetUs/Pages/TaskForceMembers.aspx He was a member of the 2013 IOM treatment report committee.

Dr. Scott Fishman is board certified in psychiatry and pain medicine. His research includes a focus on "psychiatric issues of chronic illness and pain."
http://www.ucdmc.ucdavis.edu/publish/facultybio/search/faculty/508

Dr. Alberto Caban-Martinez studies musculoskeletal pain in workers related to their occupational risk factors. http://www.cabanmartinezlab.com/#!about/c46c He has studied "The prevalence of Somatic Disfunctions in a Multi-Center Outpatient Osteopathic Medicine Clinic"
http://nhsn.med.miami.edu/documents/cv/a_cabanmartinez_cv_09.pdf and has published that "[c]onstruction workers struggle with a high prevalence of mental distress, and this is associated with their pain and injuries." J Occup Environ Med 2013 Oct;55(10):1197-204

Dr. Deborah Cory-Slecta, the committee chair, has not done Gulf War health research herself but stated in 2013, in connection with service on another IOM Gulf War committee, that she does not believe Gulf War illness research has produced adequate data to show what caused the illness.
http://www.forbes.com/sites/rebeccaruiz/2014/03/12/experts-cant-decide-on-definition-for-gulf-war-illness/ She also served on the 2003 IOM Gulf War committee that concluded there was insufficient evidence to show an association between any illness affecting Gulf War veterans and exposure to pesticides, applying the manipulated standard that excluded animal studies.
http://www.nap.edu/openbook.php?record_id=10628&page=R5

The other half of the committee are neutral, people who have not been engaged in Gulf War health research themselves, but who have a background in studying other neurological conditions and expertise in relevant subjects like neuroimaging, neuropsychology, and neuroepidemiology. They include Dr. Robert Brown, Dr. Ellen Eisen, Dr. Mary Fox, Dr. Clifford Jack, Dr. Joel Kramer, Dr. Francine Laden, Dr. James Noble, and Dr. Anbesaw Selassie.

Conspicuously absent from the committee are any doctors or scientists who have studied Gulf War health in the past decade, who have studied or treated other groups subjected to neurotoxic exposures like farmers or pesticide applicators, or who have studied the effects of Gulf War exposures in animals.