

**STATEMENT FOR THE RECORD
OF
ANTHONY HARDIE, NATIONAL CHAIR & DIRECTOR, VETERANS FOR COMMON SENSE
FOR A DECEMBER 9, 2020 HEARING
OF THE
HOUSE COMMITTEE ON VETERANS' AFFAIRS,
SUBCOMMITTEE ON DISABILITY ASSISTANCE AND MEMORIAL AFFAIRS:
"THE TOXIC WORLD OF PRESUMPTIVE SERVICE CONNECTION DETERMINATIONS:
WHY SHOULD OUR VETERANS WAIT?"**

Chairwoman Luria, Ranking Member Bost, and Members of the Subcommittee, Veterans for Common Sense (VCS) thanks you for holding this critically important hearing on presumptive service connection determinations relative to toxic exposures. In this statement, we will keep our comments focused primarily on the Gulf War cohort.

VCS is a non-profit national advocacy organization deeply involved in this issue for nearly two decades, and all of our leaders are veterans who deployed to Southwest Asia during the first year of the Persian Gulf War (see 38 USC 101(33) and 38 CFR 3.317).

Learning Past Lessons

We recognize and respect that the intent of this hearing is to focus on understanding and providing desperately needed Congressional oversight into the process whereby VA makes its determinations for new presumptive conditions for VA service connection. However, before addressing that core focus, we believe it is of direct relevance to share a brief discussion on two sets of presumptive conditions related to toxic exposures, and how those have played out in actuality following their creation. The point we would like to make is that addressing the process of creating new presumptive conditions is critical, and it is at least equally important to address significant, decades-old VA failures to favorably adjudicate certain toxic exposure-related presumptive conditions for which VA already has clear authority to grant.

VA must first fix the current process. Otherwise, VA will repeat its mistakes made for the Gulf War cohort and the presumptive legislation enacted in 1994, 1998, and 2001.

VCS has provided testimony to this Subcommittee on a number of occasions over the years describing VA's badly broken claims approval process for Gulf War veterans. One of those occasions was July 13, 2017, when this Subcommittee held a hearing entitled, "Examining VA's Processing of Gulf War Illness Claims." The hearing coincided with a July 2017 release of a fact-finding Government Accountability Office (GAO) report initiated at our request, entitled, "Gulf War Illness: Improvements Needed for VA to Better Understand, Process, and Communicate Decisions on Claims".

VCS provided invited-witness testimony during that hearing, along with a longer statement for the record. Our testimony and statement discussed numerous deeply concerning and seemingly intractable issues relative to Gulf War Illness (GWI) claims. As defined in that GAO report, “GWI claims” are a combination of Gulf War-related undiagnosed illness (UDX) and chronic multi-symptom illness (CMI) presumptive toxic claims. That GAO report added emphasis and gravitas to what VCS and predecessor organizations had long been exclaiming: VA continues to improperly deny the vast majority of Gulf War veterans’ GWI claims, despite repeated legislative, regulatory, policy, and training corrective efforts.

Among the serious issues we discussed in that testimony:

- VA’s denial of all GWI claims at a rate greater than 80 percent.
- VA’s denial of UDX claims at a 90 percent rate.
- VA’s denial rates worsening over time.
- These Gulf War claims taking 50% longer than other claims, meaning veterans who are the worst off suffer the longest.

While Congress and GAO have provided needed oversight, VCS is truly disheartened that we have seen no evidence of improvement in these rates and trends.

VCS also emphasized during that hearing that “undiagnosed illness” (UDX) as a presumptive mechanism for granting symptom-based claims for ill Gulf War veterans had clearly failed, notwithstanding the good intentions when the UDX presumptive was created by Congress in 1994. VCS called on Congress to, “work in a bipartisan manner with the President to enact legislation to *once and for all* fix Gulf War Illness claims and the many other Gulf War issues we raise in this and previous written testimony.”

Following that hearing, we were pleased to have a highly constructive meeting with then-Secretary David Shulkin, where we were joined by Vietnam Veterans of America in proposing what we believe to be a viable path forward to remedy these longstanding problems. Part of that path included using as a model VA’s “Schedule for Rating Disabilities; Evaluation of Residuals of Traumatic Brain Injury (TBI),” – another symptom-based condition.¹

Regrettably, despite Dr. Shulkin’s highly favorable response and an agreement to move forward together, he was fired before being able to accomplish our shared goals. Our efforts thereafter to continue discussions with VA on these issues were met with only silence.

The Presumptive Adjudication Process

The complex process for considering potential new presumptive conditions for Gulf War veterans has been a contorted, painstaking one that has yielded little of benefit to ill and suffering Gulf War veterans.

¹ 38 CFR 4.12a, Diagnostic Code 8045, “Residuals of traumatic brain injury (TBI)”.

Historically, VA has relied on a review of available scientific evidence before making a determination regarding creating new presumptive conditions for Gulf War veterans. The National Academy of Sciences, Engineering, and Medicine (NASEM) has conducted and published numerous VA-contracted literature reviews of Gulf War peer-reviewed published research findings. Most of these reports have been released as part of the “Gulf War & Health” series. Most of these reports include conclusions regarding the strength of association between deployment to the Gulf War or Gulf War exposures and particular health outcomes.

As important background information, the NAS (and the Institute of Medicine before it) has used five strength-of-association categories. They are as follows, drawn directly from the Gulf War & Health series volumes:

- **Sufficient evidence of a causal relationship**, that is, the evidence is sufficient to conclude that between being deployed to the Gulf War causes a health outcome.
- **Sufficient evidence of an association**; that is, a positive association has been observed between deployment to the Gulf War and a health outcome in humans.
- **Limited/suggestive evidence of an association**; that is, some evidence of an association between deployment to the Gulf War and a health outcome in humans exists.
- **Inadequate/insufficient evidence to determine whether an association exists**; that is, available studies are of insufficient quality, validity, consistency or statistical power to permit a conclusion regarding the presence or absence of an association.
- **Limited/suggestive evidence of no association**; that is, several adequate studies are consistent in not showing an association between deployment and a health outcome.

VA created a fatal flaw that prevents a reasonable review of peer-reviewed and published studies. VA mandated that NASEM panels be prevented, through their VA-contracted charter, from including animal studies when making these strength of association conclusions. Excluding animal studies prevented NASEM panels from incorporating and weighing the strength of association of *all* of the relevant scientific information about these toxins. Additionally, many if not most smaller pilot studies have also been similarly excluded. Not surprisingly, therefore, the Gulf War and Health series has not led to new presumptive conditions related to Gulf War Illness* for the purpose of VA service-connected disability claims.

(*Note: In 2010, VA announced — based on the 2006 recommendations in Gulf War and Health, Volume 5 — that nine rare endemic infectious diseases would be presumptive for veterans with qualifying Southwest Asia or Afghanistan service.)

A complete list of all conditions considered by NAS (formerly the Institute of Medicine (IOM)) in the *Gulf War & Health* series, comprising over 400 exposures, has been compiled by Veterans for Common Sense. Along with their NAS categories of association, this spreadsheet analysis is entitled, *Conditions Associated with Gulf War exposures – consolidated NAS-IOM listing*. It is

available on the Veterans for Common Sense webpage² and is provided as an attachment to this statement.

In short, the VA-contracted presumptive determination process with NAS has almost entirely failed Gulf War veterans. Most importantly, beyond the endemic infectious disease presumptive determinations that have been relevant to relatively few veterans, the process has led to *no new presumptive conditions* for Gulf War veterans, including:

- **No Presumptive Cancers**, such as the brain cancers that have taken the lives of so many Gulf War veterans.
- **No Presumptive Neurologic or neurodegenerative conditions** (with the exception of ALS, which was granted as a presumptive to any veterans, not just Gulf War veterans), such as the neuropathies and myriad neurologic and neurodegenerative conditions and symptom-sets reported in the Gulf War veteran communities, and by their survivors.
- **No Presumptive Respiratory conditions**, despite heavy exposures to burning Kuwaiti oil well fires and widely reported and heavily claimed (and denied) pulmonary and sinus conditions.
- **No Presumptive structural gastrointestinal or digestive conditions**, including the widely reported (and usually denied) gastro-esophageal reflux disease (GERD).
- **No Presumptive Sleep disorders**, including widely reported (and usually denied) sleep apnea, insomnia, and other diagnosed sleep disorders.
- **No Presumptive conditions related to other major internal organs: liver, kidneys, bladder, etc.**

Meanwhile, decades of medical research have shown that as many as one-third of the nearly 697,000 veterans of the 1991 Gulf War remain ill and suffering with chronic multi-symptom illness – what we typically call Gulf War Illness. It is therefore unfathomable that there have been no presumptive conditions

Meanwhile, the VA Secretary has broad legislative authority (see 38 U.S.C. 1118) to favorably determine new presumptive conditions for Gulf War veterans' claims. However, to our recollection, no VA Secretary has ever actually made such a determination for Gulf War health conditions beyond the largely inconsequential exceptions mentioned herein and in our prior testimony (rare endemic infectious diseases that have affected few individuals; fine-tuning of certain existing presumptive chronic multi-symptom illness; ALS for all veterans not exclusive to those who served in the Gulf War).

Indeed, a process led by a Gulf War veteran advocate who is now a Toxic Wounds Consultant with Vietnam Veterans of America sought for successive VA Secretaries to use this presumptive determination authority to favorably adjudicate a new presumptive condition for service connection, brain cancer, which has fatally afflicted many Gulf War veterans. These sincere efforts were stonewalled by the Office of Management and Budget (OMB) in two successive Administrations of differing political parties. The end result is that afflicted veterans and their

² LINK: <http://veteransforcommonsense.org/nasem-gulf-war-reports>

survivors remain shut out from needed healthcare and benefits that VA should have provided where and when they are needed.

Furthermore, there has been little consistency in the process whereby VA has initiated NAS/IOM reviews, some of which have been initiated only following public pressure. Meanwhile, after an NAS/IOM committee has concluded its work and publicly released its final report, many months – or even years – go by before VA makes determinations based on the findings.

These proposed determinations have typically been published in the Federal Register. Typically, VA request public comments, which VA has then acknowledged, and then proceeded to reject virtually all recommendations made by veterans service and other organizations, veterans, and other stakeholders.

The looming question is: Why has this VA-NAS/IOM process not led to new presumptive conditions for VA service connection for Gulf War veterans?

Is the failure rooted in VA's population (epidemiological) studies, which, if conducted right, would show statistical data exposing any excess prevalence of various health conditions among the Gulf War cohort or logical subcohorts? Certainly, that is one aspect, as exposed in a March 2013 House Veterans' Affairs Committee hearing at which I also testified. As reported by USA Today ("Researcher says officials covered up vets' health data")³ regarding the hearing:

Department of Veterans Affairs officials purposely manipulate or hide data that would support the claims of veterans from Iraq and Afghanistan to prevent paying costly benefits, a former VA researcher told a House subcommittee Wednesday.

"If the studies produce results that do not support the office of public health's unwritten policy, they do not release them," said Steven Coughlin, a former epidemiologist in the VA's public health department. "This applies to data regarding adverse health consequences of environmental exposures, such as burn pits in Iraq and Afghanistan, and toxic exposures in the Gulf War," Coughlin said. "On the rare occasions when embarrassing study results are released, data are manipulated to make them unintelligible."

Or is it failure inherent in the VA-NAS/IOM process?

Certainly, it is that, also. However, rather than restate, the following section is drawn verbatim from a previously submitted Statement for the Record. The Statement was co-authored by James H. Binns, longtime former Chair of the RAC-GWVI; Dr. Roberta White, past scientific director of the RAC; Paul Sullivan, VCS National Vice Chair who helped author the first RAC charter following

³ LINK: <https://www.usatoday.com/story/news/nation/2013/03/13/whistleblower-alleges-veterans-affairs-cover-up/1979839/>

successful enactment of the 1998 legislation directing its creation; and myself. The select portions from that Statement are as follows:⁴

“Collectively in our individual roles, we led the passage of the 1998 legislation creating the congressionally-mandated Research Advisory Committee on Gulf War Veterans’ Illnesses (RAC-GWVI); authored its charter; served as its chair, scientific director, and advocates for affected veterans; co-authored its groundbreaking reports. From these deeply engaged leadership perspectives, we feel an obligation to point out near-certain outcomes should the bill proceed without ensuring that future reviews directed under the legislation also include both human *and animal studies* of toxic exposures.

This gravely serious problem has been made apparent by the many reports released by the National Academies in these regards, including the recent report⁵ and related news release of a National Academy of Medicine (NAM) committee on respiratory health effects among veterans who served in Southwest Asia. “The current uncertainty should not be interpreted as meaning that there is no association — rather, the issue is that the available data are of insufficient quality to draw definitive conclusions,” said the committee chair in a news release about the report.⁶ Similarly, a 2011 National Academies (Institute of Medicine (IOM)) committee concluded there is, “[i]nsufficient data on service members’ exposures to emissions from open-air burn pits,” and that this, “is one of the reasons why it is not possible to say whether these emissions could cause long-term health effects.” However, “the committee pointed out shortcomings in research and gaps in evidence that prevented them from drawing firm conclusions...”⁷

“The major problem with this recent NAM report on veterans’ respiratory health issues, and with the related 2011 IOM burn pits report,⁸ and with the entire compendium of

⁴ Written submission for the record by James Binns, Roberta White, Anthony Hardie, Paul Sullivan for a hearing entitled: “Toxic Exposures: Examining Airborne Hazards In The Southwest Asia Theater Of Military Operations,” Subcommittee on Disability Assistance and Memorial Affairs, Committee On Veterans’ Affairs, U.S. House of Representatives, Washington, DC (September 23, 2020).

⁵ National Research Council 2020. *Respiratory Health Effects of Airborne Hazards Exposures in the Southwest Asia Theater of Military Operations*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25837>

⁶ National Academy of Medicine. September 11, 2020. *New Approaches Are Needed to Determine Whether Respiratory Health Problems Are Associated With Military Deployment to the Persian Gulf Region*. <https://www.nationalacademies.org/news/2020/09/new-approaches-are-needed-to-determine-whether-respiratory-health-problems-are-associated-with-military-deployment-to-the-persian-gulf-region>

⁷ Institute of Medicine, Board on the Health of Select Population, Committee on the Long-Term Health Consequences of Exposure to Burn Pits in Iraq and Afghanistan. October 31, 2011. *News Release: Evidence Inconclusive About Long-Term Health Effects of Exposure to Military Burn Pits*. <https://www.nationalacademies.org/news/2011/10/evidence-inconclusive-about-long-term-health-effects-of-exposure-to-military-burn-pits>

⁸ IOM 2011. *Long-term health consequences of exposure to burn pits in Iraq and Afghanistan*. Washington, DC: The National Academies Press. <https://www.nap.edu/catalog/13209/long-term-health-consequences-of-exposure-to-burn-pits-in-iraq-and-afghanistan>

NAM/IOM reports related to burn pits exposure and Gulf War exposures and health is *not that there are no good human studies* – though that is indeed a true statement. Instead, the real problem is that VA has failed to follow the law by failing to require that NAS reports consider scientific evidence in humans *and animals*.

“Congress in 1998 established the standard for finding an association between toxic exposures and illness in veterans of the 1991 Gulf War. Congress directed that VA and the National Academy of Sciences consider the exposure *of humans and animals* to specified toxins, the occurrence of illness *in both humans and animals*, and the associations between occurrence of illness *in both humans and animals* [38 U.S.C. 1118].⁹ Congress repetitively specified this explicit directive of both human and animal studies because its Members and staff knew that most studies of toxic substances *are necessarily done in animals*.

“However, VA (and, by consequence, the VA-contracted NAM/IOM) did just the opposite, using a standard that limited consideration of associations between illness and exposure *to solely human studies*. This deeply corrupted standard has been used in all subsequent NAS reports on Gulf War exposures and burn pits, and in effect ensures no association can ever be found.

“If the VA-contracted NAM were to follow the law requiring equal consideration of human *and animal* studies of toxic exposure, they would reach dramatically different conclusions about the serious and lasting effects of these toxins on veterans’ health. The recent NAM respiratory health committee noted that the reason for its negative conclusion is that there are no good human studies: “The current uncertainty

⁹ 38 U.S.C. 1118: “(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.” [emphasis added] <https://www.govinfo.gov/app/details/USCODE-2011-title38/USCODE-2011-title38-partII-chap11-subchapII-sec1118>

should not be interpreted as meaning that there is no association — rather, the issue is that the available data are of insufficient quality to draw definitive conclusions.”¹⁰

“Even more dramatically, the 2011 IOM burn pits report found: “Chemicals in all three major classes of chemicals detected [from burn pits at Joint Base Balad, Iraq] ... 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 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, blood effects, cardiovascular toxicity and morbidity, reproductive and developmental toxicity.”¹¹ However, the report's conclusion considered only the sharply limited human studies, excluding this evidence and finding no association relevant to exposed veterans' health.

“In short, the problem is not the science. The problem is the corruption of science through the application of impossible and unlawful standards. The result is a large stack of expensive NAM and IOM reports that do little to nothing to improve the health and lives of veterans suffering the ill effects of toxic exposures from their exposures to burn pits and during the Gulf War.

“Past performance seems likely to be a predictor of future performance. Unless animal studies of toxic exposure are explicitly directed in all legislation that directs NAM studies related to toxic exposures and veterans' health, it is unclear how future NAM considerations of strength-of-association determinations will result in any outcomes more favorable to veterans than NAM to date. And, unless the use of the corrupted standard described above is changed, future NAM reports will be similarly unhelpful to the veterans suffering these adverse health outcomes resulting from their military toxic exposures.”

Our recommendations included the following:¹²

1. **“Ensure animal studies are included in all toxic exposure legislation inclusion that references research.** It is worth noting that in most cases, the animal studies of relevance have already been conducted, and such inclusion would not explicitly authorize nor require additional studies; indeed, these NAM committee do not actually conduct research – they merely review already-conducted research. Specifically, we recommend the inclusion of ‘or animals’ in legislation relative to the consideration of research with regards to toxic exposures.” For example, it would be highly unethical to seek to conduct medical research on the long-term health effects of low-dose sarin nerve agent or mustard gas on human subjects. Thus, such toxic exposure research

¹⁰ IOM News Release, October 30, 2020.

¹¹ IOM 2011, p. 5: http://books.nap.edu/openbook.php?record_id=13209&page=5

¹² Binns et al.

must, by necessity, be conducted solely on laboratory animals (which have been primarily mice and rats).

2. **“Direct prior NAM/IOM reports be redone to include equal consideration of animal studies.** These should be reconsidered to include animal studies of association between toxic exposures and health outcomes, including each NAM and IOM report on respiratory health, burn pits, and Gulf War veterans as has been broadly defined as beginning August 2, 1990 and to a date to be determined.”
3. **“Transparency in VA contracts with NAM.** Past VA contracts with NAM for statutorily-mandated NAM reports on toxic exposures have been kept secret by VA.” All past, present, and future VA contracts with NAS, “should be made public in a timely fashion, perhaps by an explicit requirement that they be published in the Federal Register prior to their execution and allowing for public comment, including by veterans service organization and advocates.”

Meanwhile, the statutory authority granted to the VA Secretary under 38 U.S.C. 1118 has been poorly used if at all to favorably determine new presumptive conditions for Gulf War veterans.

Conclusions

It is therefore concerning when we see legislative advocacy efforts that would essentially model after this VA-NAS process that has almost entirely failed Gulf War veterans, with more than two decades of VA reliance on it.

The few of us Gulf War veterans who remain active advocates on Gulf War veterans’ issues have seen something extremely troubling in our decades-long experience: successive toxic exposure cohorts are each chemically, biologically, and toxicologically unique with their individual toxins and mixes of toxins. However, the Department of Defense and the Department of Veterans Affairs have used consistent methodologies with each successive toxic exposure cohort, which have served to delay, deny, and wait until the toxin-exposed veterans die.

- Creating registries, which are feel-good legislative and administrative advances, but which have had little apparent impact on veterans registered thereunder.
- DoD and VA can never quite get research right, leading NAS to perpetually conclude, in essence, “more studies are needed” – an endless source of frustration for each successive toxic exposure cohort. The end result is affected veterans and military service members are not provided evidence-based healthcare relevant to the etiology of their toxic exposure-induced health conditions and are mostly denied when they make claims for service-connected disability benefits – the gateway to VA healthcare... or

survivor benefits for the loved ones who have ultimately succumbed to their toxic exposures.

- With no acknowledgment or accountability for toxic exposures, toxic hazards continue: burn pits keep burning; depleted uranium munitions continue to be used; pyridostigmine bromide “nerve agent protective pills” are still readied for use by our troops; and so on in seeming perpetuity without DoD ever acknowledging let alone learning the lessons of the past.
- DoD and VA continue with business as usual, continuing in these regards in these now famous words from one of myriad Gulf War hearings: “mistaking motion for progress.”ⁱ

The Committee’s sincere interest in these very serious issues is deeply appreciated. VA has failed and continues to fail Gulf War veterans. It should therefore not be surprising to anyone that VA similarly continues to fail successive generations of veterans suffering the enduring health effects of toxic exposures.

We deeply appreciate your consideration and your interest in this critical matter. For more than 20 years, VA has willfully subverted the explicit intent of Congress regarding the appropriate standard to be used in establishing associations – key to VA creating presumptions for VA claims determinations and the gateway to VA healthcare – where veterans were subjected to toxic exposures during their service. We remain available to provide further detail on these topics as the Committee may see fit.

Respectfully,

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ⁱ Rep. Chris Shays (R-CT), during a hearing entitled, “DOD Chemical and Biological Defense Program: Management and Oversight,” by the Subcommittee on National Security, Veterans Affairs, and International Relations of the Committee on Government Reform, U.S. House of Representatives, 106th Congress; May 24, 2000. Link: <https://www.govinfo.gov/content/pkg/CHRG-106hrg71624/html/CHRG-106hrg71624.htm>