Chairwoman Luria, Ranking Member Bost, and Members of the Subcommittee, thank you for your leadership in introducing the Presumptive Benefits for War Fighters Exposed to Burn Pits and Other Toxins Act of 2020. We are grateful to the bill’s authors for including presumptions for service-connection for any cancer and a list of specified respiratory conditions. We are also grateful that the definition of who is covered by these presumptions includes: post-9/11 veterans exposed to open air burn pits and airborne hazards; veterans with Persian Gulf service since August 2, 1990 (including veterans awarded the Southwest Asia Service Medal for their Persian Gulf War service); and veterans with special operations and other contingency service in a long list of countries since that date.

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 report¹ 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.² 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…”³

The major problem with this recent NAM report on veterans’ respiratory health issues, and with the related 2011 IOM burn pits report,⁴ and with the entire compendium of 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]. 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 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.”

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.” 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.

Recommendations

1. **Amend the legislation to ensure the inclusion of animal studies.** 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 do conduct research – they merely review already-conducted research. Specifically, we recommend the inclusion of “or animals” in each of the six places solely “human” currently appears (additions are underscored; deletions are struck through), as follows:
   a. Amend Section 2(b), “Process to Add Diseases Through Written Petition,” as follows: (b)(1)(A) – “the exposure of humans or animals to one or more covered toxins; and”; and, (b)(1)(B) – “the occurrence of the disease in humans or animals.”
   b. Amend Section 2(c), “Determinations by National Academies,” as follows: (c)(2)(A)(i) – “the exposure of humans or animals to one or 11 more covered toxins; and”
   c. Amend Section 3, title, as follows: “SEC. 3. AGREEMENT WITH THE NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE CONCERNING THE EXPOSURE OF HUMANS TO BURN PITS AND OTHER TOXINS.”
   d. Amend Section 3 as follows: (b)(1) – “Under an agreement between the Secretary and the National Academies, the National Academies shall review and summarize the scientific evidence, and assess the strength thereof, concerning the association between the exposure of humans or animals to covered toxins and each disease suspected to be associated with such exposure.”
   e. Amend Section 3 as follows: (c)(1) – “For each disease reviewed under subsection (b), the National Academies shall determine (to the extent that available scientific data permit meaningful determinations) whether there is a positive association between the exposure of humans or animals to one or more covered toxins and the occurrence of the disease in humans or animals, taking into account the strength of the scientific evidence and the appropriateness of the statistical and epidemiological methods used to detect the association.

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. These contracts 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.

We deeply appreciate your consideration and your interest in this critical matter. For at least 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.

This is a rare opportunity to give affected veterans the justice they deserve and to ensure that the results of this intentional misuse and manipulation of science are not inflicted on future generations of American veterans. We would be pleased to provide further detail on these topics and to meet with you virtually.

Respectfully,

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Anthony Hardie
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Paul Sullivan
Gulf War Veteran, U.S. Army; Former Deputy Secretary, California Department of Veterans Affairs; Director of Veteran Outreach, Bergmann & Moore, LLC; National Vice Chair, Veterans for Common Sense; former Project Manager, U.S. Department of Veterans Affairs; past Executive Director, National Gulf War Resource Center; Advocate for both 1994 and 1998 Persian Gulf War Veteran research and benefits laws that created the RAC-GWVI and the mandated NAM reviews."
END NOTES


5 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
