



February 10, 2020

President Donald J. Trump
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500

Mr. President:

On behalf of the millions of veterans, service members, their families and survivors that our organizations represent, we call on you to instruct the Secretary of Veterans Affairs to immediately add the four diseases the National Academies of Science, Engineering and Medicine (National Academies) have associated with exposure to Agent Orange to the presumptive disease list: bladder cancer, hypothyroidism, "Parkinson-like symptoms" and hypertension. Recently, in the delayed report to Congress, VA stated they will wait at least until later this year before announcing any decision on adding these presumptive diseases.

Mr. President, Vietnam veterans have long suffered from the ill health effects of Agent Orange exposure. Thousands have died and many have been left to endure these negative health consequences from diseases that have been scientifically linked to Agent Orange. The continued delayed action by VA is causing additional suffering for Vietnam veterans and their families. We urge you to take action and to end the wait, needless suffering and disappointment for an entire generation of veterans.

While the reasons stated by VA are in part to wait for published reports from additional studies, we believe this delay is unnecessary because the scientific community has already provided enough significant data, studies and associations linking these four diseases to Agent Orange exposure. The scientific evidence already meets the established statutory requirements to add bladder cancer, hypothyroidism, "Parkinson-like symptoms" and hypertension as presumptive diseases for Agent Orange exposure.

The National Academies' update on "Veterans and Agent Orange," published in 2016, had an independent committee comprised of fourteen subject matter experts, researchers and medical clinicians. In reference to bladder cancer, the committee analyzed twenty-nine different individual epidemiologic studies, some with multiple cohorts. The committee concluded that evidence is suggestive of an association between herbicides and bladder cancer, as they noted, "after careful consideration and discussion, the VAO committee determined that the available data and scientific literature, taken as a whole, are sufficiently consistent to conclude that there is limited or suggestive evidence for an association of bladder cancer with exposure to" Agent Orange.

In the same report, the committee reviewed the results of fifteen different epidemiologic studies, some with multiple cohorts, for hypothyroidism. Due to the consistent observations of exposures

to Agent Orange being related to perturbations of thyroid function, and to clinical hypothyroidism in particular, the committee considered the body of epidemiologic data, in combination with strong biologic plausibility, to represent suggestive evidence of an association between Agent Orange and hypothyroidism.

Further, the committee clarified that “there is no rational basis for exclusion of individuals with Parkinson-like symptoms from the service-related category denoted as Parkinson’s disease. To exclude a claim for a condition with Parkinson-like symptoms, the onus should be on VA on a case-by-case basis to definitively establish the role of a recognized etiologic factor other than the herbicides sprayed in Vietnam.” Therefore, “Parkinson-like symptoms” should be considered part of the presumptive for Parkinson’s disease.

The National Academies’ Agent Orange update in 2018, comprised by a new committee of twelve subject matter experts, researchers and medical clinicians, noted that three new epidemiologic studies reviewed by the committee in combination with the prior reviewed literature continue to support the conclusion of suggestive evidence for an association of bladder cancer with exposure to Agent Orange.

The 2018 committee noted that new data continue to support previous findings that the chemicals found in Agent Orange can alter thyroid homeostasis. On the basis of the new evidence and that reviewed in previous reports, the committee concluded that there is suggestive evidence of an association between Agent Orange exposure and hypothyroidism.

In reference to hypertension, the 2016 committee noted, “although VA has not found hypertension to be presumptively related to service in Vietnam, the committee reaffirmed the conclusions of previous studies that hypertension should be placed in the category of limited or suggestive evidence of association.”

A VA study, “Herbicide Exposure, Vietnam Service, and Hypertension Risk in Army Chemical Corps Veterans” found that exposure to herbicides is “significantly associated” with the risk of hypertension, or high blood pressure, in members of the Army Chemical Corps. Findings from the study, published November 2016 in the *Journal of Occupational and Environmental Medicine*, point to a higher prevalence of hypertension in veterans of the Corps who were exposed to herbicides during the war, compared with those who were not.

The 2018 National Academies’ report went even further, concluding that there was now sufficient evidence of a relationship between hypertension and Agent Orange. The statistical analyses conducted were robust, used state-of-the-art methods, and adjusted for relevant confounders. The committee concluded, “earlier studies reviewed in previous updates consistently reported increased hypertension with increasing levels of serum dioxin in Vietnam veterans as well as increased prevalence in veterans with higher presumed exposure to Agent Orange. When considered in light of other new research and earlier studies that demonstrated a consistency in the direction and magnitude of this effect, the committee found that this body of literature constitutes sufficient evidence of an association.”

Although the Secretary stated he was waiting on two additional VA studies before making a decision on the four presumptive diseases, based on the epidemiologic studies analyzed by the National Academies, their independent Agent Orange reports, and VA studies showing these same associations, it is apparent these two studies will not change the previous scientific evidence. The two studies in question, the Vietnam Era Health Retrospective Observational Study (VE-HEROeS) and the Vietnam Era Mortality Study, were not designed to specifically address the four presumptive diseases; therefore, their outcomes will not be able to refute all of the assembled studies, science and conclusions.

Mr. President, we are concerned by the November 2019 release of internal documents that indicate some Administration officials challenged the previous Secretary's authority to add these four diseases and may have even impeded such action. Even more alarming is the possibility that the Administration is outweighing the cost of adding these diseases over those veterans in need of VA benefits and health care. When taking all of this into consideration, it appears VA is not waiting on additional science, but continuing to stonewall and delay adding these four diseases based in part on monetary concerns. This is troubling.

Even more troubling are several misleading comments and in some instances, limited or incorrect factual premises that VA made in its report to Congress, dated January 27, 2020, apparently intended to undercut all of the scientific data and epidemiologic studies already accepted in the scientific community that clearly establish an association of the diseases with exposure to Agent Orange. In order to set the record straight, below are our responses to several of the most misleading VA comments challenging the sufficiency of evidence to support new presumption rulemaking:

1. "In general, there was no definitive causal link between Chemicals of Interest (COIs) and the conditions identified in the Veterans and Agent Orange (VAO) report."

While the above statement is correct, it is extremely misleading, as there has never been any statutory or legal requirement of a causal link between the chemicals in Agent Orange and any disease or condition. For that reason, the National Academies have never been tasked with providing information regarding a causal link. The statutory requirement is positive association based on significant statistical association between Agent Orange exposure and the conditions.

The Agent Orange Act of 1991, Public Law 102-4, codified at 38 U.S.C. § 1116, at paragraph (1)(B) states, "each additional disease (if any) that (i) the Secretary determines in regulations prescribed under this section warrants a **presumption of service-connection by reason of having positive association with exposure to an herbicide agent**, and (ii) becomes manifest within the period (if any) prescribed in such regulations in a veteran who, during active military, naval, or air service, served in the Republic of Vietnam during the period beginning on January 9, 1962, and ending on May 7, 1975, and while so serving was exposed to that herbicide agent, shall be considered to have been incurred in or aggravated by such service, notwithstanding that there is no record of

evidence of such disease during the period of such service.” As noted, the statute does not require causation, only association.

The U.S. District Court for the Northern District of California addressed this exact situation in their decision in *Nehmer v. US Veterans’ Admin.*, 712 F. Supp. 1404 (N.D. Cal. 1989). The Court determined that the legislative history, and prior VA and congressional practice, found that Congress intended that the VA predicate service connection upon a finding of a significant statistical association between dioxin exposure and various diseases. The Court held that VA erred by requiring proof of a causal relationship and invalidated VA’s regulation and thus voided all benefit denials made. The Court further held that in combination with VA’s refusal to apply the benefit of the doubt, VA sharply tipped the scales against veterans.

In the National Academies’ VAO report of 2016, the committee recognized that the original VAO committee addressed the statutory mandate to evaluate the association between herbicide exposure and individual health conditions by assigning each of the health outcomes under study to one of four categories on the basis of the epidemiologic evidence reviewed. The committee noted that they believe that the categorization of strength of evidence based on association is consistent with the Court’s holdings in *Nehmer*. The report stated, “in accordance with the court ruling, the committee was not seeking proof of a causal relationship, but any information that supports a causal relationship, such as a plausible biologic mechanism...would also lend credence to the reliability of an observed association.”

VA’s statement that there was “no definitive causal link” between Agent Orange and the diseases, while correct on its face, is highly misleading in the context of determining whether to establish a new presumption. We are greatly concerned about this apparent attempt to establish by implication, new and higher bar that must be crossed before veterans exposed to Agent Orange receive the benefits and health care they deserve.

- 2. “One of the conditions identified by NASEM, hypertension (HTN), has many alternative risk factors (including diet, tobacco use, genetics, race) and commonly occurs at a high rate among elderly populations, so most Vietnam Veterans would probably already have HTN from another cause or at least a combination of causes.”***

This statement from the VA report is not based on any scientific evidence or analysis presented in the report, but appears to be conjecture introduced solely to undercut the scientific conclusions of the National Academies’ report.

The National Academies’ VAO report of 2018 stated that hypertension affects approximately 75 million Americans, or one in every three adults, noting, “owing to its frequency, assessing whether there is increased risk with exposure to the COIs has been challenging. However, the committee for the current update believes that there are enough new data to move the category of association to sufficient evidence.” VA has presented no data or evidence that “most Vietnam Veterans would probably already have

HTN [hypertension] from another cause.” Such an assertion is mere conjecture and ignores the scientifically significant statistical association already established between Agent Orange and hypertension, which resulted in veterans who would not have suffered from hypertension but for their exposure in Vietnam. As Congress intended with the Agent Orange Act of 1991, science should be the driving force to determine if a disease is associated with Agent Orange, not cost or political considerations.

- 3. “The most rigorous study cited by NASEM was conducted on members of the Army Chemical Corps, those with known high occupational exposure, but the exposure experience of this group does not necessarily reflect the experience of the general population of Veterans deployed to Vietnam.”***

This is another example of VA making a statement that is correct on its face, but fails to put it into the proper context. From a scientific analysis point of view, the Army Chemical Corps is exactly the type of group of veterans for such a study, based on their high levels of known exposure. The U.S. sprayed more than 20 million gallons of various herbicides over Vietnam from 1961 to 1971. Due to the massive volume of Agent Orange used and the unknown locations of service members when exposed and sprayed, all Vietnam veterans with recognized service already have their exposure conceded. This was clearly the congressional intent as evidenced by the statutory language in 38 U.S.C. § 1116.

Since the VAO update of 2006, the National Academies have determined that epidemiologic evidence suggests an association between exposure to herbicides and hypertension. In the VAO report of 2018, they have determined there is sufficient evidence of an association.

As we noted previously, the study in question was conducted by the VA and establishes that exposure to herbicides is “significantly associated” with the risk of hypertension, or high blood pressure, in members of the Army Chemical Corps. However, this is not the only study used and cited by the committee. The 2018 VAO report also evaluated six new studies as well as all of the previous studies and literature reviewed by all of the previous eleven VAO reports.

This misleading comment in the VA report does not detract from all of the existing scientific data showing a significant association between hypertension and Agent Orange. Furthermore, the VA report fails to acknowledge all Vietnam veterans with eligible service are already considered to have been exposed to Agent Orange, the critical question is association, not exposure.

- 4. Many of the studies for another condition identified by NASEM, bladder cancer, are not conclusive because of the small numbers of exposed cases, low exposure specificity, and a lack of ability to control for a major confounding factor. For example, cigarette smoking is a major risk factor for bladder cancer but was not controlled in any of the studies reviewed by NASEM. According to cancer research experts, “the most common***

risk factor for bladder cancer is cigarette smoking, although smoking cigars and pipes can also raise the risk of developing bladder cancer. Smokers are 4 to 7 times more likely to develop bladder cancer than nonsmokers.

VA once again seems to imply a new and higher standard should be applied – “conclusive evidence,” and fails to note that the lack of smoking incidents was already addressed by the National Academies in their 2016 VAO report. That report stated that:

*“Because of the large sample size of the Korean Vietnam Veterans Health Study and a correspondingly ample number of incident cases, the observed absence of an association between herbicide exposure and incident bladder cancer cannot be considered a meaningful finding. In contrast, there was a statistically significant two-fold increase in mortality from bladder cancer among veterans in the high exposure-opportunity group relative to those in the low-exposure group. Because information on smoking was not available in the cancer incidence and mortality publications (Yi and Ohrr, 2014; Yi et al., 2014b), it might be hypothesized that the results for bladder cancer mortality could be explained in part by uncontrolled confounding. However, self-reported information on smoking among surviving Korean veterans (Yi et al., 2013b) revealed that the distribution of smoking habits was similar, regardless of exposure opportunity score, indicating that **the results for bladder cancer mortality are unlikely to have been majorly confounded by smoking.**” [emphasis added]*

The National Academies also stated that the toxicologic information on cacodylic acid, a known chemical in Agent Orange, is consistent with findings of an increase in bladder cancer among Vietnam veterans exposed to herbicides.

The VAO reports do indicate that some of the studies lacked information on confounding factors such as smoking; however, as indicated above, this potential confounding factor was addressed by the National Academies, but the 2016 and 2018 VAO reports still concluded that there is a scientifically significant statistical association between Agent Orange and bladder cancer.

The scientific data and epidemiologic studies accepted by the scientific community establish a positive association between all four of these diseases and exposure to Agent Orange. The misleading statements made by VA in its recent report to Congress cannot overcome the strength of the assembled scientific data and the statutory framework for adding presumptive diseases associated with Agent Orange exposure.

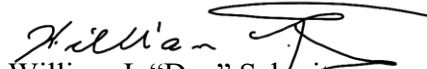
Mr. President, the men and women who served in Vietnam were exposed to Agent Orange and far too many have suffered harmful effects scientifically linked to that exposure. Many of these veterans and their families have been waiting for over three years to receive a positive decision, one that could finally get them the justice and benefits they deserve. We call on you to intervene and end their wait by adding bladder cancer, hypothyroidism, “Parkinson-like symptoms” and

hypertension to the list of Agent Orange presumptive conditions for disability benefits immediately. Thank you for consideration of this request.

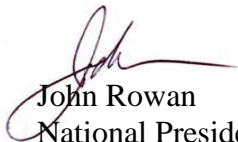
Respectfully,



Stephen Whitehead
National Commander
DAV (Disabled American Veterans)



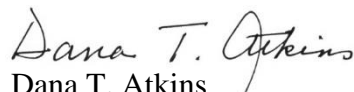
William J. "Doc" Schmitz
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c: Secretary of Veterans Affairs Wilkie