



NVLSP
NATIONAL VETERANS LEGAL SERVICES PROGRAM



FIVE DECADES OF VA SERVICE CONNECTION PRESUMPTIONS

*Positive Statistical Association Is the
Predominant Historical Standard, But VA
Imposes Higher Standard For Toxic
Chemicals Spewed by Burn Pits*

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Executive Summary

The U.S. Department of Veterans Affairs (VA) pays monthly, tax-free disability compensation to veterans who suffer from disabilities that are connected to an injury, disease or event that occurred during the veteran's military service. In fiscal year 2020, the VA paid service-connected disability compensation benefits to more than 5.5 million of the nation's 22 million veterans.

To obtain these benefits, veterans must apply to the VA and ordinarily must demonstrate that they: (1) suffer from a current disability; (2) experienced an injury, disease, or event during military service; and (3) that the in-service injury, disease or event caused or aggravated the current disability. To satisfy the third requirement, the law generally requires an adequate opinion from a medical expert concluding that it is at least as likely as not that the in-service injury, disease or event caused, resulted in, or aggravated the current disability.

However, some veterans—especially those who were exposed to toxic substances in service—often have difficulties obtaining medical nexus evidence establishing a direct link between their individual condition and their toxic exposure. Their disability may have developed long after their military service, making it difficult to trace how their military service resulted in their current condition. They may not know exactly which toxins they were exposed to or for how long. Or they may not have access to a medical provider with expertise in how toxic exposures cause certain conditions.

Because of these difficulties, Congress and the VA have sometimes established a blanket “presumption of service connection” that a particular disease is connected to a particular type of in-service injury, disease, or event. Veterans covered by the presumption do not need a medical opinion linking the current disability to the veteran's service to establish entitlement to service-connected disability compensation. Instead, the presumption of service connection steps in to presume that a medical nexus exists.¹

How much proof that veterans are becoming sick and disabled because of their service does Congress or the VA need before creating a presumption?

When Congress or the VA creates service-connection presumptions, they must decide which disabilities or conditions should be included in the presumption. Even when policymakers agree veterans have been exposed to toxic substances and disabling events, the debate over whether to create a presumption often boils down to a single question: How much proof that veterans are becoming sick and disabled because of their service does Congress or the VA need before creating a presumption?

This Report analyzes almost fifty years of presumptions created by statute or regulation to determine how Congress and VA have traditionally answered that question. The Report finds that Congress and the VA have historically decided whether to establish new presumptions of service connection through the use of a “statistical association” test, rather than a more demanding causation or etiological standard. That is, when Congress or the VA believe that the credible scientific evidence shows that there is a positive statistical association between (1) an injury, disease, or event experienced by veterans during military service and (2) a particular disease, Congress or the VA will typically establish a presumption of service connection for that disease.

VA, however, has not always embraced the statistical association test. This Report also reveals how VA officials have, at times, tried to block diseases from qualifying for presumptive service connection by demanding proof of a cause-and-effect relationship. Thirty-seven years ago, the VA attempted to limit presumptive service connection due to Agent Orange to only one disease—chloracne, a skin condition—by establishing a rule that presumptive service connection can be

established only if the scientific evidence shows a strict cause and effect relationship exists between exposure and the disease. But a federal court struck down VA's cause-and-effect standard in 1989 because it was inconsistent with Congressional intent.

This Report's historical research provides important context to current debates in Congress and at the VA. At the urging of veterans and their advocates, both entities are currently considering whether to establish a presumption of service connection for certain diseases experienced by veterans who were exposed during service to the toxic smoke and fumes spewed by open air burn pits used by the U.S. military in Southwest Asia since 1991 to dispose of ordinance, fuel, batteries, plastics, and other waste. Even though burn pits are widely understood to be toxic, veterans have

significant difficulty in obtaining sufficient medical evidence to prove that their current disease was caused by their exposure to toxins emitted by the burn pits on their base camps. Without a presumption of service connection, the VA denies almost 80% of the claims in which veterans contended that their current respiratory conditions, cancers, and other diseases were caused by the toxins emitted by burn pits.²

During the current debate, certain VA officials argue that a cause-and-effect relationship must exist before creating presumptions for conditions linked to burn pits. This Report demonstrates that those arguments are ahistorical and, if they prevail, would create a higher hurdle to compensation for veterans exposed to burn pits than exists for other types of in-service exposures and events.

I. Background: Service-Connected Disability Compensation and Presumptions of Service Connection

In general, veterans seeking service-connected disability compensation must satisfy three fundamental requirements before the VA will grant compensation benefits. First, there must be evidence of a current disability. Second, there must be evidence of in-service incurrence or aggravation of a disease or injury. Third, there must be evidence of a link or nexus—typically through a medical opinion—between the in-service incurrence or aggravation of a disease or injury and the current disability.³ The VA requires “competent evidence” of *each* of the three required elements in order to qualify for service-connected disability benefits.⁴

The third requirement above is often referred to as the “service connection” or “nexus” requirement. To show service connection, the lay or medical evidence in the record must demonstrate that it is at least as likely as not that the current

disability resulted from the disease, injury, or precipitating event in service.⁵ In other words, the veteran must have at least enough evidence to show a 50 percent chance that the disease, injury, or event in service actually caused the current disability.

Proving a nexus with competent medical evidence can be difficult, particularly for certain types of complex conditions that may arise long after service. Congress therefore has directed that certain conditions be presumed service-connected unless there is affirmative evidence to prove that a particular veteran’s condition is not related to service.⁶ Through the regulatory process, the VA may identify additional diseases that warrant presumptive service connection.⁷

II. Historical Overview of the Standard Used by Congress and the VA to Decide Whether a Disease Should Be Accorded Presumptive Service Connection

Over the last five decades, new presumptions of service connection are overwhelmingly created after Congress or the VA recognizes a statistical association between military service and subsequent development of the disability. As described in more detail below, across a wide array of periods of service, types of in-service events, and diseases, presumptive service connection has historically been based on evidence of a statistically significant association between military service and the disease, rather than the more demanding “cause and effect” association.

That is not to say policy makers are uniform or unflinchingly precise about the standards they use. Sometimes, policy makers muddle the distinction between statistical association and causation. In particular, the VA has occasionally used “cause and effect” language to justify establishing some of its presumptions. But such cases are few, and when the VA uses this language, it is almost always accompanied by other language suggesting the use of a statistical association standard. In other words,

the VA’s use of “cause and effect” language at most makes the standard being used unclear, and rarely does the VA explicitly state that it is looking for a causative link before it establishes a new presumption.

For example, as described below, VA regulations allow the Secretary to establish presumption of service connection for prisoners of war when “there is at least limited/suggestive evidence that an increased risk of such disease is associated with service involving detention or internment as a prisoner of war and an association between such detention or internment and the disease is biologically plausible.”⁸ The regulations then go on to state that this association “may be satisfied by evidence that demonstrates either a statistical association or a causal association.”⁹ The VA has established several presumptions under these regulations, and in doing so, it cites scientific studies demonstrating both a causal relationship and a mere statistical association between POW status and the new presumptive disabilities, without

specifying whether the presumption is being established under the cause-and-effect standard or the statistical association standard.¹⁰

Below, this Report describes service connection presumptions established, whether by Congress or VA, in the last half century.¹¹

A. Presumptive Service Connection of Cardiovascular Diseases for Veterans With Service-Connected Limb Amputations

One of the early examples of granting a disease presumptive service connection status occurred over 40 years ago, in 1979. In the 1970s, Congress required the VA to assess whether there was an association between veterans who suffered a service-related limb amputation and the later development of heart disease.¹² The VA therefore commissioned the National Academy of Sciences (NAS) to conduct a scientific study on this matter. NAS conducted an epidemiological study which led NAS to conclude that such amputations “result in a significant increase in the incidence of cardiovascular disease.”¹³ The NAS report specifically stated that this study did not address whether a cause-and-effect relationship existed, and, further, that the reason for the statistically significant association between these two conditions was not obvious.¹⁴

Shortly thereafter, the VA promulgated a regulation granting presumptive service connection to heart disease when experienced by a veteran with a service-connected limb amputation. Specifically, the regulation provides that service connection is available on a presumptive basis to any veteran who develops “ischemic heart disease or other cardiovascular disease . . . [and] who has a service-connected amputation of one lower extremity at or above the knee or service-connected amputations of both lower extremities at or above the ankles.”¹⁵ The VA established this presumption based solely on the NAS report, and in doing so, VA recognized that the NAS report “did not demonstrate a causal relationship between amputation and heart disease.”¹⁶

B. Presumptive Service Connection of Various Diseases for Veterans Interned as a Prisoner of War

Congress long ago provided a presumption of service connection to a long list of diseases when developed by former prisoners of war, based on the association between internment in war-like conditions and these diseases.¹⁷ Those interned in war-like conditions often experienced malnutrition and severe physical and psychological trauma.¹⁸ 38 U.S.C. § 1112(b) currently provides presumptive service connection to 6 categories of diseases when experienced by a former prisoner-of-war, and to 13 categories of diseases when experienced by a former prisoner-of-war who was interned for at least 30 days.

When Congress granted presumptive service connection status to these diseases, “it based its findings in part on a VA study . . . [that] merely showed ‘a higher incidence’ of physical and psychological disorders that are ‘related’ to the conditions of their imprisonment.”¹⁹ “The [VA] study did not try to establish a causal relationship.”²⁰ Despite the fact that the evidence showed only a significant statistical association between these conditions and status as a former POW, Congress chose to grant these presumptions.²¹

C. Presumptive Service Connection for Diseases For Veterans Exposed to Agent Orange During Vietnam War Era: VA’s Initial Use of a Causation Standard Contrary to Congressional Intent

During the 1960s, the U.S. military sprayed millions of gallons of Agent Orange and other herbicides in Vietnam and other parts of Southeast Asia where members of the U.S. Armed Forces served.²² These herbicides contained the highly toxic chemical contaminant known as dioxin, and they were used to clear dense jungle land where the enemy hid. Many veterans believed that their exposure to the chemical dioxin contained in Agent Orange resulted in their contracting several debilitating diseases, including soft tissue sarcoma (“STS”) (malignant tumors that form in muscle, fat, or fibrous connective tissue) and porphyria cutanea tarda (“PCT”) (deficiencies in liver enzymes). In the

late 1970s, veterans filed a class action lawsuit against the chemical company manufacturers of Agent Orange to obtain compensation for their alleged injuries. In 1984, the manufacturers settled the lawsuit by establishing a \$180 million settlement fund to compensate class members.²³

At the same time, Vietnam veterans pursued disability compensation from the VA, claiming that the diseases they incurred were caused by exposure to Agent Orange during military service in Vietnam. However, the VA consistently took the position that only one disease—chloracne, a skin condition—arose from exposure to Agent Orange.²⁴ Accordingly, the VA routinely denied compensation to veteran-claimants who alleged that exposure to Agent Orange caused diseases other than chloracne.

In 1984, Congress enacted the Veterans' Dioxin and Radiation Exposure Compensation Standards Act (Dioxin Act) amidst veterans' "concern[s] about possible long-term health effects of exposure to herbicides containing dioxin" as well as "scientific and medical uncertainty" regarding the long-term health effects of Agent Orange exposure.²⁵ The Dioxin Act dramatically altered the process governing Agent Orange disability claims. Rather than determining through the exclusive use of individual VA adjudicatory proceedings whether a particular veteran's Agent Orange exposure resulted in his or her claimed disease, the Dioxin Act required the VA to conduct rulemaking to determine which diseases should be accorded presumptive service-connected status due to exposure to herbicides containing dioxin, such as Agent Orange.²⁶ To achieve that purpose, the Dioxin Act required the VA to appoint an advisory committee composed of experts in dioxin, experts in epidemiology, and interested members of the public to review the pertinent scientific literature on dioxin and submit periodic recommendations and evaluations to the VA.²⁷ The Dioxin Act also compelled the VA to adopt regulations governing the evaluation of the scientific evidence.²⁸ Finally, after receiving the recommendations of the Advisory Committee and other members of the public, the Act required the Administrator to promulgate a regulation identifying which diseases should be accorded presumptive service-connected status based on "sound scientific and medical evidence."²⁹

But the result of the VA's rulemaking process was the same as before; the presumptive service connection was limited to chloracne, primarily because the VA insisted on a showing of a "cause and effect" relationship between exposure and disease, in order for a disease to warrant presumptive service-connected status.

Specifically, the VA announced that it would not establish presumptive service connection for any disease based on exposure to herbicides containing dioxin unless the scientific evidence showed that a cause-and-effect relationship exists between dioxin exposure and the disease. The VA published a proposed rule, which set forth five factors to govern evaluation of the scientific evidence.³⁰ The rule also proposed presumptive service connection for only one disease: chloracne. Finally, the proposed rule flatly stated that "[s]ound scientific and medical evidence does not support a *causal association* between dioxin exposure" and any other diseases.³¹

After the proposed rule was issued, the VA informed the Advisory Committee at the outset that it should not recommend that VA accord presumptive service-connected status to any disease unless the evidence showed a cause-and-effect relationship exists between dioxin exposure and the disease in question. The Committee reviewed a number of studies on dioxin's effects on human populations and received written comments on the proposed regulation.³² The Committee ultimately recommended that presumptive service connection should be established for chloracne, but no other disease.

On August 26, 1985, the VA published a final regulation identical to the proposed rule, which stated that "sound scientific and medical evidence does not establish a cause and effect relationship between dioxin exposure" and any other disease but chloracne.³³ The regulation did not preclude a veteran from proving in an individual case that a claimed disease was caused by Agent Orange exposure, but as of December 1987, the VA had denied disability compensation to over 31,000 veterans under this regulation.³⁴

In 1986, NVLSP attorneys filed a class action lawsuit in U.S. district court challenging the VA's 1985 Agent Orange compensation rules. The lawsuit

charged that the VA had violated the Dioxin Act by stacking the deck for what the scientific evidence needed to show for a disease to attain presumptive service-connected status based on dioxin exposure.

The case was assigned to U.S. District Judge Thelton E. Henderson, who certified the case as a class action on behalf of Vietnam veterans exposed to dioxin during military service in Vietnam and the survivors of these veterans. The parties then submitted to the Court sworn affidavits from scientific experts that explained the difference between a significant statistical association and a cause and effect association as follows:

A statistical association “means that the observed coincidence in variations between exposure to the toxic substance and the adverse health effects is unlikely to be a chance occurrence or happenstance.”³⁵ On the other hand, a cause and effect relationship “describes a much stronger relationship between exposure to a particular toxic substance and the development of a particular disease than ‘statistically significant association’ does.”³⁶ To find a causal relationship, a scientist would require a strong and consistent level of association and a plausible explanation of the biological mechanism at work. As one scientific expert on VA’s Advisory Committee testified, “finding a higher than expected incidence of a disease among a particular population alone does not demonstrate a causal relationship”³⁷ To find a causal relationship, “[i]t is necessary to look for many [other] factors,” such as “a linear progression between the greater appearance of symptoms and the increase in dose levels of exposure.”³⁸

The Court ruled that the VA erred by requiring proof of a strict “cause and effect” relationship between dioxin exposure and various diseases because Congress intended only that there be a significant “statistical association” between dioxin and a particular disease in order for that disease to qualify for presumptive service-connected status.

After considering this evidence, Judge Henderson issued an opinion in May 1989 invalidating the VA’s Agent Orange compensation rule on the ground that the VA had imposed a legally invalid and unnecessarily demanding evidentiary standard that violated the 1984 Dioxin Act. The Court ruled that the VA erred by requiring proof of a strict “cause and effect” relationship between dioxin exposure and various diseases because Congress intended only that there be a significant “statistical association” between dioxin and a particular disease in order for that disease to qualify for presumptive service-connected status. Judge Henderson ruled that the cause-and-effect test used by the VA was inconsistent with the Dioxin Act and prior VA and congressional practice.³⁹ He explained:

We hold that the Administrator misinterpreted two important provisions of the Act. The Administrator both imposed an impermissibly demanding test for granting service connection for various diseases and refused to give veterans the benefit of the doubt in meeting that demanding standard. These errors compounded one another, as they increased both the type and the level of proof needed for veterans to prevail during the rulemaking proceedings. We find that these errors, especially compounded with one another, sharply tipped the scales against veteran claimants. As the Act was passed amidst “substantial uncertainty” over the health effects of Agent Orange, we do not find that these errors were harmless; there is a substantial possibility that the errors shaped the conclusions reached by the Advisory Committee and the Administrator. Accordingly, we hereby invalidate the portion of the Dioxin regulation which denies service connection for all other diseases but chloracne.⁴⁰

Three days after Judge Henderson issued his opinion, Secretary of Veterans Affairs Edward Derwinski announced that VA would not appeal the decision and would instead comply with the Court’s order that VA conduct new rulemaking proceedings to replace the VA rulemaking that Judge Henderson had invalidated.

D. Presumptive Service Connection of Various Cancers in Radiation-Exposed Veterans

In 1988, Congress passed the Radiation-Exposed Veterans Compensation Act.⁴¹ The Act granted presumptive service connection for 13 different cancers to veterans who participated in “radiation-risk activities” in service, including onsite participation in a test involving detonation of a nuclear device and the occupation of Hiroshima or Nagasaki during the period immediately following the atomic bombing of those cities.⁴²

The legislative history of the Act makes clear that members of Congress felt no need to establish a cause-and-effect relationship between the levels of radiation to which these veterans had been exposed and their subsequent development of various cancers before they passed these new presumptions into law. Representative Applegate, for instance, one of the sponsors of the bill, acknowledged the “tremendous degree of uncertainty existing within the scientific and medical communities as to the long-term health effects of exposure to low levels of radiation,” but reminded his colleagues “that the principle of ‘service connection’ is one that is based on a point-in-time relationship, not a cause and effect relationship.”⁴³ Thus, presumptions, he stated, “are based upon the theory that, if the disease becomes manifest to a certain degree within a specified period of time after an individual’s discharge from service, principles of sound medical judgment will justify recognizing the inception of the disease as having occurred during a particular point in time coincident with the individual’s service on active duty.”⁴⁴

During the debates on this bill, several other members of Congress in both the House and the Senate either affirmed that proof of a cause and effect relationship was not necessary to establish these new presumptions, or indicated that they felt proving a statistical association was sufficient to do so.⁴⁵ The bill ultimately passed by a vote of 48-30 in the Senate⁴⁶ and 326-2 in the House.⁴⁷ In subsequent years, Congress and the VA expanded the list of radiogenic diseases entitled to presumptive service connection several times.⁴⁸ Neither appeared to require proof of a cause-and-effect relationship

when it added these new presumptions, and instead cited extensively to evidence of statistical associations between the new diseases and exposure to low-level radiation.⁴⁹

E. Presumptive Service Connection of Non-Hodgkin’s Lymphoma for Veterans Who Served in Vietnam During the Vietnam War

In 1990, the VA amended its regulations to grant presumptive service connection to non-Hodgkin’s lymphoma (NHL) for veterans who served in Vietnam during the Vietnam War.⁵⁰ The amendments were “based on the results of a study of the association of selected cancers with service in the U.S. military in Vietnam by the Centers for Disease Control (CDC).”⁵¹ That study, titled “The Association of Selected Cancers with Service in the U.S. Military in Vietnam,” found “that Vietnam veterans have a roughly 50 percent increased risk of developing NHL after service in Vietnam,” and that this “increased risk was not shown in veterans who served in other locations during the Vietnam Era.”⁵² Based on these results, the VA Secretary “determined that there is a relationship between Vietnam service and NHL.”⁵³

The Selected Cancers study on which the VA based its new regulations concluded only that there was an *association* between service in Vietnam and subsequent development of non-Hodgkin’s lymphoma. The study *did not* show any exposures in service *caused* this cancer. In fact, the authors specifically stated that the data does not show that the increased risk might be related to exposure to Agent Orange, and furthermore, “none of the known or suspected risk factors for NHL that [they] controlled for explained the increased risk for Vietnam veterans.”⁵⁴ In short, the authors found only an association, not a causal relationship, and they were unsure of what the cause of this increased risk might be. Nonetheless, the VA Secretary found that a significant statistical association provided a sufficient basis to amend VA regulations to grant service connection to non-Hodgkin’s lymphoma on a presumptive basis.

F. Presumptive Service Connection of Soft Tissue Sarcomas for Veterans Exposed to Herbicides Containing Dioxin

In 1991, the VA finalized a new rule granting service connection on a presumptive basis to any veteran who was exposed to herbicides containing dioxin and who subsequently developed one of several soft-tissue sarcomas (STS).⁵⁵ The VA's proposed rule stated that granting presumptive service connection to STS was "necessary to implement [its] determination that it is at least as likely as not that there is a statistical association between exposure to herbicides containing dioxin and soft-tissue sarcoma," a determination VA had made through a review of "more than 80 scientific and medical documents relating to the connection."⁵⁶ The VA specifically acknowledged that *Nehmer* had "invalidated [its] requirement of proof of a causal connection in determining service connection for diseases associated with dioxin exposure."⁵⁷ Thus, the VA promulgated this rule based solely on a statistical association between exposure to dioxins and development of soft tissue sarcomas, rather than proof of a cause and effect relationship between the two.

G. Presumptive Service Connection of Diseases Related to Dioxin Exposure: Congress Enacts the Agent Orange Act of 1991, Requiring VA to Use a Positive Statistical Association to Create New Presumptions

While VA was in the midst of the rulemaking process for replacing the Agent Orange regulations invalidated by the Court in *Nehmer*, Congress intervened by enacting the Agent Orange Act of 1991 (AOA) at 38 U.S.C. § 1116.

The AOA codified by statute the presumptions that the VA had already established by regulation in the months leading up to the Act's passage—namely, those relating to non-Hodgkin's lymphoma (NHL) and soft tissue sarcomas (STS).⁵⁸ The legislative history shows that both houses of Congress recognized what VA had recognized—that the available scientific evidence did not show a causal relationship existed between exposure to Agent Orange and NHL or STS.⁵⁹ In fact, the legislative history shows that, at the time of passage

of the AOA, "scientific investigative efforts, including [an] exhaustive study conducted by the Centers for Disease Control [CDC] in Atlanta, [had] not established a causal link between exposure to [A]gent [O]range in Vietnam and any disease in humans other than chloracne, a skin condition."⁶⁰ Nonetheless, Congress codified a presumption between Agent Orange exposure and the subsequent development of NHL and STS based on studies showing a significant statistical association between exposure and the two diseases.⁶¹

The AOA also modified the rulemaking process VA was required to use to determine whether additional diseases should be granted presumptive service-connected status. For one thing, the AOA eliminated the need for a VA Advisory Committee in favor of a requirement that VA contract with an independent entity—the National Academy of Sciences (NAS)—to review on a biennial basis the scientific evidence concerning the adverse health effects of dioxin and report its findings to the VA Secretary. After each biennial report, the AOA required the Secretary to determine whether to add diseases to the list of diseases accorded presumptive service connection based on whether the scientific evidence shows a positive statistical association between exposure and disease—essentially the same standard mandated by the Court in *Nehmer*.⁶²

H. Presumptive Service Connection of 16 Additional Diseases For Veterans Exposed to Dioxins

After passage of the AOA, the National Academy of Sciences delivered over a dozen periodic reports to the VA summarizing its findings concerning the association between exposure to herbicides containing dioxin and various diseases. In categorizing the strength of the association between dioxin exposure and various diseases, the NAS made clear that it was using the AOA standard of a positive statistical association as a yardstick. For example, in its 2014 report, the NAS stated that it was tasked by VA and Congress with studying statistical associations between Agent Orange and various conditions, not strict causality, and found that such an association existed for bladder cancer, Parkinsonism disease, and hypothyroidism, among other conditions). See National Academy of

Sciences, *Veterans and Agent Orange: Update 2014* 3, 8 (2014). In its 2018 report, the NAS similarly stated that “the distinctions among categories [of the strength of the available scientific evidence] are based on statistical association and not strict causality.” National Academy of Sciences, *Veterans and Agent Orange: Update 11 11* (2018).

From 1993 on, the VA issued rules providing presumptive service connection for the following diseases based on the NAS reports showing a positive statistical association between exposure to dioxin and the disease:

- Chloracne (VA published rule for disease in 1993)
- Porphyria cutanea tarda (1994)
- Hodgkin’s disease (1994)
- Cancer of the lung (1994)
- Cancer of the larynx (1994)
- Cancer of the bronchus (1994)
- Cancer of the trachea (1994)
- Multiple myeloma (1994)
- Prostate cancer (1996)
- Type 2 diabetes (2001)
- Chronic lymphocytic leukemia (2003)
- Primary AL amyloidosis (2009)
- Ischemic heart disease (2010)
- Chronic B-cell leukemias (other than chronic lymphocytic leukemia) (2010)
- Parkinson’s disease (2010)
- Early onset peripheral neuropathy (2013)

In establishing presumptive service connection for a disease, VA used the positive statistical association standard adopted by Congress in the AOA. For example, when issuing a rule in 2010 providing presumptive service connection for Parkinson’s disease (PD) due to exposure to herbicides containing dioxin, the VA explained:

- “[S]everal studies published since [NAS’] Update 2006 now suggest a specific relationship between exposure to the herbicides of interest and PD. Three of the four studies published since Update 2006 showed a statistically significant odds ratio for development of PD and exposure to herbicides, most notably to 2, 4-D and 2, 4, 5-T and other chlorophenoxy herbicides.

Accordingly, the recent studies are consistent with the body of epidemiologic and toxicologic data suggesting a relationship between exposure to pesticides and PD, but provide more specific evidence of an association between PD and the herbicides used in the Republic of Vietnam. Based upon the available scientific and medical evidence, the Committee placed PD in the category of ‘limited or suggestive evidence of an association.’”⁶³

- “The Secretary has determined that the available scientific and medical evidence presented in Update 2008 and other information available to the Secretary are sufficient to establish a new presumption of service connection for PD in veterans exposed to herbicides, as the credible evidence for an association between exposure to an herbicide agent and the occurrence of PD in humans outweighs the credible evidence against such an association.”⁶⁴

Similarly, the VA rulemaking that led to the 2001 VA rule providing presumptive service connection for Type 2 Diabetes due to exposure to herbicides containing dioxin shows that VA used the positive statistical association standard adopted by Congress in the AOA:

- Following a 1999 National Institute of Occupational Safety and Health report detected a weak association between Type 2 diabetes and dioxin exposure (Calvert GM, Sweeney MH, Deddens J, Wall DK. 1999. Evaluation of Type 2 diabetes, Serum Glucose and Thyroid Function Among U.S. Workers Exposed to 2,3,7,8 tetrachlorodibenzo-p-dioxin. *Occupational and Environmental Medicine* 56:270-276), the VA Secretary requested a special report on the topic from the National Academy of the Sciences (NAS).⁶⁵
- “NAS concluded that ‘there is limited/suggestive evidence of an association between exposure to the herbicides used in Vietnam or the contaminant dioxin and Type 2 diabetes.’

(‘Type 2 diabetes’ is also referred to as ‘Type II diabetes mellitus’ or ‘adult-onset diabetes.’) The term ‘limited/suggestive evidence’ means ‘evidence is suggestive of an association between herbicides and the outcome, but limited because chance, bias, and confounding could not be ruled out with confidence.’ NAS based its conclusion on the totality of the scientific evidence on this issue, not one particular study.”⁶⁶

- NAS observed that “[a]lthough some of the risk estimates in the studies examined by the committee are not statistically significant and, individually, studies can be faulted for various methodological reasons, the accumulation of positive evidence is suggestive.”⁶⁷
- This sufficed for the Secretary to find a positive association warranting a presumption of service connection.⁶⁸

I. Presumptive Service Connection of Three Diseases Based on NAS Reports After Sunset Date of Agent Orange Act

The Agent Orange Act of 1991 required that the VA Secretary enter into an agreement with the National Academy of Sciences (NAS) for the Academy to “review and summarize the evidence, and assess the strength thereof, concerning the association between exposure to an herbicide used in . . . [the Vietnam War] and each disease suspected to be associated with such exposure.”⁶⁹ The Act required NAS to deliver to the VA Secretary periodic written reports detailing its findings and recommendations,⁷⁰ and for the VA Secretary to “determine whether a presumption of service connection is warranted for each disease covered by the report” within 60 days of receiving it.⁷¹ Within 60 days of that determination, the Secretary was then required either to (1) issue a proposed rule, if presumptive service connection was warranted, or (2) publish notice in the Federal Register of the scientific basis for his or her determination, if presumptive service connection was not warranted.⁷²

The provisions of the Act requiring that the Secretary make these determinations and publish his or her findings in the form of a rule or notice had a sunset date of September 30, 2015.⁷³ Despite this, NAS continued to issue its regular reports, finding in 2014 and 2018 that there was a statistical association between exposure to Agent Orange and subsequent development of hypothyroidism, bladder cancer, and Parkinsonism, among other diseases.⁷⁴ The VA took no action on this report, as it was no longer required by law to do so. However, Congress, fortunately, *did* take notice of the findings in the report. In the face of the VA’s inaction, Congress in 2021 established presumptive service connection for these three diseases itself, creating by statute what the VA had failed to do by regulation.⁷⁵

J. Presumptive Service Connection of Amyotrophic Lateral Sclerosis (“Lou Gehrig’s Disease”) for All Veterans With 90 Days Continuous Active Service Due to ALS’s Association with Military Service

Service connection by presumption is available for any veteran that develops Amyotrophic Lateral Sclerosis (ALS), or “Lou Gehrig’s Disease,” at any time after discharge or release from active service under a VA regulation found at 38 C.F.R. § 3.318. The Secretary of Veterans Affairs decided to establish the ALS presumption based on a November 2006 report by the National Academy of Sciences Institute of Medicine that found a statistical association between active service and ALS.⁷⁶ ALS is a rare disease in any population, but studies have shown that veterans are “at a statistically significant greater risk of developing ALS compared to civilians.”⁷⁷ The reason for this higher risk is unknown, but nonetheless, the Secretary felt the statistical association was adequate evidence to establish the presumption.⁷⁸

A veteran must have had at least 90 days of continuous active service to qualify for the presumption. Service connection will not be granted “[i]f there is affirmative evidence that [ALS] was not incurred during or aggravated by active military, naval or air service” or “[i]f there is affirmative evidence” that ALS “is due to the veteran’s own willful misconduct.”

K. Presumptive Service Connection of Illnesses for Veterans Who Served in Southwest Asia Between 1990 and the Present

In the 1990s, Congress granted veterans of the Persian Gulf War presumptions of service connection for many disabilities and illnesses experienced by veterans who served in Southwest Asia at any time between August 2, 1990 and the present.⁷⁹ Specifically, these veterans are entitled to presumptive service connection for a “chronic disability” resulting from an “undiagnosed illness” or a “medically unexplained chronic multisymptom illness (such as chronic fatigue syndrome, fibromyalgia, and irritable bowel syndrome) that is defined by a cluster of signs or symptoms.”⁸⁰

In addition to the abovementioned conditions that were accorded presumptive service connection by Congress, Congress provided VA with authority to grant presumptive service connection based on service in the Southwest theater of operations for additional diseases.⁸¹ In doing so, Congress required the VA to evaluate the scientific evidence using the same positive statistical association standard that it required the VA to use in the Agent Orange Act of 1991.⁸²

L. VA Begins to Establish Service Connection Presumptions for Veterans with Conditions Related to Burn Pit Exposure

Most recently, VA has begun creating service connection presumptions related to burn pit exposure for veterans who served in southwest Asia. In its regulations thus far, however, VA has not clarified what standard of proof it needed to establish a presumption. It appears that VA is moving towards a cause-and-effect standard, even as it disclaims “causation” as a requirement and as it partially relies on evidence of statistical association.

In August 2021, the VA established presumptions of service connection for asthma, rhinitis, and sinusitis, and it used both statistical association and cause and effect evidence to do so.⁸³

The VA looked at (1) epidemiological studies; (2) the 2020 NASEM report, which found “limited or suggestive evidence of an association” between service in Southwest Asia and symptoms of these conditions; and (3) claims data, specifically which conditions were most commonly claimed and granted by the VA and differences in the claims rates between deployed and non-deployed cohorts.⁸⁴ But it also reviewed studies like the EPA’s 2019 Integrated Science Assessment for Particulate Matter, which showed a “likely . . . causal relationship” between exposure to fine particulate matter and respiratory health effects, and ultimately granted a presumption only for conditions that met the “likely causal” standard.⁸⁵

Then, in April 2022, the VA established presumptions of service connection for nine rare respiratory cancers for veterans who served in Southwest Asia, Afghanistan, Syria, Djibouti, or Uzbekistan in recent decades because of veterans’ exposure to burn pits there.⁸⁶ Even though the agency claimed that prevalence rates for these rare conditions “are so low that it is unlikely that any epidemiologic or other study will elucidate a cause,”⁸⁷ the VA again appears to have used a cause-and-effect standard to establish this presumption. The VA states that it “utilized the Bradford Hill criteria to conclude that there were possible relationships” between development of these cancers and exposure to particulate matter in service, and it acknowledges that “[t]he Bradford Hill criteria are used widely in public health research to establish epidemiologic evidence of a causal relationship between a presumed cause and an observed effect.”⁸⁸ Furthermore, in establishing these new presumptions, it cites the EPA’s 2019 Integrated Science Assessment (ISA) for Particulate Matter, which determined that “there is ‘likely to be causal’ relationship between long-term [particulate matter] exposure and cancer.”⁸⁹ Although the VA never explicitly states whether it is using a cause-and-effect standard or a statistical association standard, the evidence cited seems to suggest the former.

III. VA's Duty to Use a Statistical Association Standard to Establish New Presumptives Related to Exposure to Burn Pits

The history above demonstrates the consistent use in the past of a statistical association standard by the VA and Congress to establish new presumptions. Yet, despite this prior practice, in the recent debate over whether presumptions of service connection should be created for veterans who were exposed to burn pits, the VA has recently digressed from this historical practice. Through its rulemaking and in its testimony to Congress related to possible statutory presumptions, VA has made concerning statements suggesting that, in fact, it has been using the much higher causation standard to establish new presumptions, including in cases in which the authorizing statute explicitly commands otherwise.

For example, at a March 2020 hearing before the House Subcommittee on Military Construction, Veterans Affairs, and Related Agencies, within the House Appropriations Committee, former Executive in Charge for the Veterans Health Administration, Dr. Richard A. Stone, admitted that the VA had been looking for causation rather than statistical association in determining whether or not to establish new presumptions for veterans exposed to Agent Orange.⁹⁰ The admission came in response to questioning from Chairwoman Debbie Wasserman Schultz, who asked Dr. Stone why the VA had failed to establish presumptions for bladder cancer and other diseases despite recent scientific evidence showing an association between these conditions and service in Southeast Asia during the Vietnam War.⁹¹

Dr. Stone responded that the VA was undertaking a more comprehensive study which examined documents like veterans' death certificates to determine whether such presumptions were justified.⁹² Chairwoman Wasserman Schultz then asked Dr. Stone to clarify whether this meant the VA was using a causation standard rather than the statistical association standard established by statute for such presumptions:

WASSERMAN SCHULTZ. That sounds more like you're looking for causation,

not association. Are you looking for causation?

STONE. Yes.

WASSERMAN SCHULTZ. Okay. That's not how the presumptive disease law works. You can't—you can't require that causation be proven. Presumptive disease is specifically associated as a result of exposure due to being exposed during your military service. You aren't allowed to decide that now you're going to up the standard and say there has to be direct causation. All the other diseases under this—under this requirement are through association.⁹³

The VA has also made similar statements to veterans and their advocates. In December 2021, veterans service organizations, including NVLSP, expressed concern to the VA about its apparent use of the higher causation standard to establish new presumptions. The VSOs sent a request for information to the VA concerning the decision-making model that was being used to establish new presumptions.

In its response, the VA assured VSOs that the causation language that was part of its original decision-making model has been switched back to association, and in any case, the VA had really been using a public health model to establish presumptions the entire time. The public health model, it said, looks for "(1) an external agent or possible exposure, (2) an individual with an illness or condition, (3) an environment wherein the individual and agent could have interacted, and the environment supports possible exposure, and (4) consideration of Bradford-Hill criteria."⁹⁴

CHAIRWOMAN WASSERMAN SCHULTZ:

That's not how the presumptive disease law works. You can't—you can't require that causation be proven. . . . You aren't allowed to decide that now you're going to up the standard and say there has to be direct causation. All the other diseases under this—under this requirement are through association.

Although VA disavowed the use of causation, the Bradford-Hill criteria are specifically designed to establish a causal relationship between an exposure and a condition. Indeed, in its response, the VA cited to a study which explains the Bradford-Hill model, and that very study calls the model “the most frequently cited framework for causal inference in epidemiologic studies.”⁹⁵ These criteria were *specifically developed* “to help determine if observed epidemiologic associations are causal.”⁹⁶ They include considerations such as the strength a dose-response relationship, a plausible biological mechanism, and experimental evidence, all of which are hallmarks of a causation analysis.⁹⁷

Although VA has not finalized its process or its standard for creating new presumptions, VA’s use of causation models is concerning veterans who wish to see new presumptions granted for conditions related to burn pits and other environmental exposures in the future.

IV. Conclusion

When Congress or the VA have established a new presumption of service connection over the last five decades, they have consistently evaluated the scientific evidence using the more lenient positive “statistical association” standard, rather than a more onerous causal relationship. This deeply embedded tradition reflects the high esteem and debt we owe to veterans who often risked their lives in service to our country.

Given the history of VA and congressional establishment of presumptions under a statistical

association standard, both VA and Congress should use this standard when it adds long-overdue presumptions in the future for veterans exposed to toxic chemicals spewed by open-air burn pits and other environmental hazards overseas. To raise the necessary standard to proof of causation would be to treat veterans exposed to burn pits more harshly than prior generations of veterans. If VA continues its practice to impose a causation standard before creating a presumption of service connection, it will place an extraordinary and onerous burden on veterans with diseases related to burn pits.

ABOUT NVLSP

The National Veterans Legal Services Program (NVLSP) is an independent, nonprofit veterans service organization that has served active-duty military personnel and veterans since 1981. NVLSP strives to ensure that our nation honors its commitment to its 22 million veterans and active-duty personnel by ensuring they have the benefits they have earned through their service to our country. NVLSP has represented veterans in lawsuits that compelled enforcement of the law where the VA or other military services denied benefits to veterans in violation of the law. NVLSP's success in these lawsuits has resulted in more than \$5.2 billion dollars being awarded in disability, death and medical benefits to hundreds of thousands of veterans and their survivors. NVLSP offers training for attorneys and other advocates; connects veterans and active-duty personnel with pro bono legal help when seeking disability benefits; publishes the nation's definitive guide on veteran benefits; and represents and litigates for veterans and their families before the VA, military discharge review agencies and federal courts. For more information go to www.nvlsp.org.

In October 2021, NVLSP launched the Burn Pits Claims Assistance Program (Burn Pits CAP). This Program marks a major expansion of the free legal representation that NVLSP has provided to veterans and their survivors over the last 40 years. The Burn Pits CAP assists veterans exposed to toxic emissions from burn pits while serving overseas by representing them on claims for disability benefits before the U.S. Department of Veterans Affairs (VA).

ABOUT BURN PITS 360

Burn Pits 360 is a 501(c)(3) non-profit veterans organization located in Robstown, Texas. Our mission is to advocate for veterans, active duty service members, and families affected by deployment-related toxic exposures through research, education, outreach and advocacy.

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Endnotes

¹ Congress and VA can also create presumptions of an in-service event so that a veteran does not require individual or direct evidence that an in-service injury or event occurred. For example, VA presumes that veterans who served in the Republic of Vietnam between January 9, 1962, and May 7, 1975, were exposed to certain herbicide agents like Agent Orange. 38 C.F.R. § 3.307(a)(6)(iii); 38 U.S.C. § 1116(a)(3). This report discusses only presumptions related to medical nexus, not presumptions related to the occurrence of an in-service event.

² Steven Beynon, *VA Has Denied About 78% of Disability Claims from Burn Pits*, STARS AND STRIPES (Sep. 23, 2020), <https://www.stripes.com/veterans/va-has-denied-about-78-of-disability-claims-from-burn-pits-1.646181>.

³ See *Palczewski v. Nicholson*, 21 Vet. App. 174, 183 (2007); *Caluza v. Brown*, 7 Vet. App. 498, 506 (1995), aff'd, 78 F.3d 604, 604 (Fed. Cir. 1996) (table). Although the Veterans Claims Assistance Act of 2000 (VCAA), Pub. L. No. 106-475, 114 Stat. 2096 (2000) eliminated the well-grounded claim requirement discussed in *Caluza*, competent evidence for each of the three elements is still required for a grant of service-connected disability compensation. See also 38 U.S.C. §§ 101(2), 1110, 1131; 38 C.F.R. §§ 3.12, 3.4(b)(1), 3.301.

⁴ See *Caluza*, 7 Vet. App. at 506 (rejecting a categorical statement that a medical opinion was required to prove nexus); *Jandreau v. Nicholson*, 492 F.3d 1372, 1377 (Fed. Cir. 2007) (holding that “[l]ay evidence can be competent and sufficient to establish a diagnosis of a condition when (1) a layperson is competent to identify the medical condition, (2) the layperson is reporting a contemporaneous medical diagnosis, or (3) lay testimony describing symptoms at the time supports a later diagnosis by a medical professional.”).

⁵ See 38 U.S.C.S. § 5107(b); 38 C.F.R. § 3.102.

⁶ See 38 U.S.C.S. §§ 1112, 1113, 1116, 1117.

⁷ See 38 C.F.R. §§ 3.307, 3.309, 3.311, 3.313(b), 3.317.

⁸ 38 C.F.R. § 1.18(b). Biological plausibility is typically something scientists look at when they are doing a causation analysis rather than a statistical association analysis. See *Nehmer*, 712 F. Supp. 1404, 1416. But the VA has said it does not think the requirement of a biologically plausible mechanism here means a causal relationship needs to be established, especially given that 38 C.F.R. § 1.18(d) allows presumptions to POWs to be established with either statistical association or cause/effect evidence. See 69 Fed. Reg. 60083, 60085 (Oct. 7, 2004).

⁹ *Id.* § 1.18(d).

¹⁰ See 69 Fed. Reg. 60083 (Oct. 7, 2004).

¹¹ Not included in the list below are a number of infectious diseases which are presumed service connected. Many of the infectious diseases with presumptive service connection are prevalent in certain theaters of service but not the United States, and some of the presumptions for infectious diseases were based simply on the fact that the pathogens which cause the disease were prevalent in a given theater of service and had a high incidence in deployed U.S. troops. See 75 Fed. Reg. 13051, 13054 (Mar. 18, 2010) (establishing presumptions for diseases including brucellosis, shigella, West Nile virus for certain Persian Gulf and Afghanistan veterans). Because the nature of infectious disease is different from the nature of the chronic diseases analyzed in the remainder of this paper, these presumptions are not included below.

¹² When a veteran has a service-connected disability that results in the veteran developing a different disability, VA will grant what is known as “secondary service connection” and pay service-connected disability compensation for both disabilities.

¹³ 44 Fed. Reg. 50339, 50340 (Aug. 28, 1979).

¹⁴ *Id.*

¹⁵ 38 C.F.R. § 3.310(c).

¹⁶ *Nehmer*, 712 F. Supp. at 1419.

¹⁷ Barton F. Stichman, et al., *Veterans Benefits Manual* § 3.4.6.4 (2021–22 ed.).

¹⁸ *Id.*

¹⁹ *Nehmer*, 712 F. Supp. at 1419.

²⁰ *Id.*

²¹ *Id.*

²² Barton F. Stichman, et al., *Veterans Benefits Manual* § 3.8 (2021–22 ed.).

²³ *In Re Agent Orange Product Liability Litigation*, 597 F. Supp. 740 (E.D.N.Y.1984), aff'd, 818 F.2d 145 (2d Cir.1987).

²⁴ *Nehmer v. U.S. Veterans' Admin.*, 712 F. Supp. 1404, 1407 (N.D. Cal. 1989).

²⁵ 38 U.S.C. § 354, Pub.L. 98-542, Statement of Purpose, § 2(1) & (2).

²⁶ See *Nehmer*, 712 F. Supp. at 1407-08.

²⁷ *Id.*; Dioxin Act § 6.

²⁸ Dioxin Act § 5.

²⁹ *Id.*

³⁰ 50 F.R. 15848 (April 22, 1985) (proposed rule).

³¹ *Id.* at 15849–15850 (emphasis added).

³² See *Nehmer*, 712 F. Supp. at 1408.

³³ 38 C.F.R. 3.311a(d).

³⁴ *Nehmer v. U.S. Veterans' Admin.*, 118 F.R.D. 113, 120 (N.D.Cal.1987) (order granting class certification).

³⁵ *Nehmer v. U.S. Veterans' Admin.*, 712 F. Supp. 1404, 1416 (N.D. Cal. 1989) (citing declarations by both party

experts, who agreed on the relevant definitions for both standards).

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.* at 1418-1419 (the court then went on to describe previous examples of VA and congressional practice, including the VA granting service connection for cardiovascular diseases incurred by veterans who suffered amputations of legs or feet (38 C.F.R. § 3.310(b)), and service-connected status for diseases suffered by former prisoners of war (38 U.S.C. § 312(b)), where the VA based service connection status on a study that demonstrated a statistically significant relationship, not a cause and effect relationship).

⁴⁰ *Id.* at 1423.

⁴¹ Radiation-Exposed Veterans Compensation Act of 1988, Pub. L. No. 100-321, 102 Stat. 485 (1988).

⁴² *Id.* §§ 2(c)(2)-(4).

⁴³ 133 Cong. Rec. 21305 (1987).

⁴⁴ *Id.* at 21305-06.

⁴⁵ Rep. Gilman, speaking in support of the bill, stated that “[w]hile there is still no conclusive evidence of the effects of low doses of ionizing radiation on humans, there is a higher incidence of certain illnesses among these atomic veterans.” *Id.* at 21309. Rep. McCloskey supported the bill based on the fact that “[t]his group has been shown to have disproportionate percentages of radiation related diseases.” *Id.* Sen. Daschle stated, “While we will never have absolute scientific proof of the causal relationship between veterans’ disabilities and the exposure to ionizing radiation, we, as policymakers, must come to a policy decision.” 134 Cong. Rec. 8589 (1988).

⁴⁶ 134 Cong. Rec. 8600 (1988).

⁴⁷ *Id.* at 9632.

⁴⁸ See, e.g., Veterans’ Radiation Exposure Amendments of 1992, Pub. L. No. 102-578, 106 Stat. 4774 (1992) (adding cancer of the salivary gland and cancer of the urinary tract to the list of presumptives); Veterans Millennium Health Care and Benefits Act, Pub. L. No. 106-117, 113 Stat. 1545 (1999) (adding bronchiolo-alveolar carcinoma to the list of presumptives); 67 Fed. Reg. 3612 (Jan. 25, 2002) (adding bone, brain, colon, lung, and ovarian cancer to the list of presumptives); Veterans Benefits Improvement Act of 2004, Pub. L. No. 108-454, 118 Stat. 3598 (2004) (codifying the VA’s addition of bone, brain, colon, lung, and ovarian cancer to the list of presumptives).

⁴⁹ See, e.g., 137 Cong. Rec. 33164 (1991) (statement of Sen. Cranston supporting the bill adding salivary gland and urinary tract cancers to the list of presumptives because of evidence of a statistical association between these cancers and exposure to low-level radiation); 66 Fed. Reg. 41483, 41484 (Aug. 8, 2001) (adding bone, brain, colon, lung, and ovarian cancer to the list of

presumptives based primarily on Congress’s recognition that the scientific evidence reviewed for purposes of the RECA Amendments of 2000, which was mostly statistical association evidence, see H.R. Rep. No. 106-697 (2000), “provide[s] medical validation for the extension of compensable radiogenic pathologies”).

⁵⁰ 55 Fed. Reg. 43123, 43123 (Oct. 26, 1990).

⁵¹ *Id.*

⁵² 55 Fed. Reg. 25339, 25339 (June 21, 1990); *The Selected Cancers Cooperative Study Group, The Association of Selected Cancers with Service in the US Military in Vietnam*, ARCHIVES OF INTERNAL MEDICINE 40 (1990),

<https://www.cdc.gov/nceh/veterans/default1d.htm> [hereinafter “Selected Cancer Study”].

⁵³ 55 Fed. Reg. 25339, 25339.

⁵⁴ Selected Cancer Study 83, 88.

⁵⁵ 56 Fed. Reg. 51561 (Oct. 15, 1991).

⁵⁶ 56 Fed. Reg. 7632 (Feb. 25, 1991).

⁵⁷ *Id.* at 7633.

⁵⁸ 38 U.S.C. § 1116(a)(2)(A)-(B).

⁵⁹ 137 Cong. Rec. H719 (1991).

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² Specifically, 38 U.S.C. § 1116(b) of the AOA provides:

- (1) Whenever the Secretary determines, on the basis of sound medical and scientific evidence, *that a positive association exists between (A) the exposure of humans to an herbicide agent, and (B) the occurrence of a disease in humans, the Secretary shall prescribe regulations providing that a presumption of service connection is warranted for that disease* for the purposes of this section.
- (2) In making determinations for the purpose of this subsection, the Secretary shall take into account (A) reports received by the Secretary from the National Academy of Sciences under section 3 of the Agent Orange Act of 1991, and (B) all other sound medical and scientific information and analyses available to the Secretary. In evaluating any study for the purpose 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 a disease in humans and exposure to an herbicide agent shall be considered to be positive for the purposes of this section if the credible evidence for the association is equal to or outweighs the credible evidence against the association.

[Emphasis added].

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ See 66 Fed. Reg. 2376, 2378 (Jan. 11, 2001) (proposed rule).

⁶⁶ *Id.*

⁶⁷ *Id.* at 2379.

⁶⁸ *Id.*

⁶⁹ Agent Orange Act of 1991, Pub. L. No. 102-4, § 3(b)-(c), 105 Stat. 11, 13 (1991)

⁷⁰ *Id.* § 3(g).

⁷¹ 38 U.S.C. § 1116(c)(1)(A).

⁷² *Id.* § 1116(c)(1)(A)-(B).

⁷³ *Id.* § 1116(e)

⁷⁴ National Academy of Sciences, *Veterans and Agent Orange: Update 2014* 3, 8 (2014); National Academy of Sciences, *Veterans and Agent Orange: Update 11* 7 (2018).

⁷⁵ William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Pub. L. No. 116-283, § 9109, 134 Stat. 3388, 4785 (2021).

⁷⁶ 73 Fed. Reg. 54691, 54691 (Sep. 23, 2008).

⁷⁷ *Id.*

⁷⁸ *Id.* at 54692.

⁷⁹ 38 U.S.C. §§ 1117 and 1118.

⁸⁰ 38 U.S.C. § 1117(a)(2). Congress further provided that the “signs or symptoms that may be a manifestation of an undiagnosed illness or a chronic multisymptom illness include” fatigue, unexplained rashes, headache, muscle pain, joint pain, neurological signs or symptoms, sleep disturbances, and gastrointestinal and cardiovascular signs or symptoms. 38 U.S.C. § 1117(g).

⁸¹ 38 U.S.C. § 1118.

⁸² Specifically, Congress provided:

(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**

38 U.S.C. § 1118(b) (emphasis added). It does not appear that the VA has ever added presumptions of service connection beyond those originally specified in 38 U.S.C. §§ 1117 and 1118.

⁸³ Presumptive Service Connection for Respiratory Conditions Due to Exposure to Particulate Matter, 86 Fed. Reg. 42,724 (Aug. 5, 2021).

⁸⁴ 86 Fed. Reg. at 42,726-27.

⁸⁵ 86 Fed. Reg. at 42,727.

⁸⁶ 87 Fed. Reg. 24,421 (Apr. 26, 2022).

⁸⁷ *Id.* at 24,422.

⁸⁸ *Id.* at 24,425.

⁸⁹ *Id.* at 24,424.

⁹⁰ *Department of Veterans Affairs Budget Request for FY2021 Before the Subcomm. on Military Construction,*

Veterans Affairs, and Related Agencies of the H. Appropriations Comm., 116 Cong. (2020).

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ Dep't of Veterans Affairs, Request for Information on Presumptive Conditions Decision Making Model (Dec. 2021) (on file with author).

⁹⁵ Kristen M. Fedak et al., *Applying the Bradford Hill Criteria in the 21st Century: How Data Integration Has Changed Causal Inference in Molecular Epidemiology*, 12 EMERGING THEMES IN EPIDEMIOLOGY 1 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4589117/>.

⁹⁶ *Id.*

⁹⁷ *Id.*