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FULFILLING OUR PROMISES
TO THE MEN AND WOMEN WHO SERVED

STATEMENT OF
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OF THE DISABLED AMERICAN VETERANS
BEFORE THE
COMMITTEE ON VETERANS' AFFAIRS
UNITED STATES SENATE
SEPTEMBER 25, 2019

Chairman Isakson, Ranking Member Tester, and Members of the Committee:

Thank you for inviting DAV (Disabled American Veterans) to testify at today's hearing on "Toxic Exposures: Examining the Presumptive Disability Decision-Making Process."

DAV is a congressionally chartered national veterans' service organization of more than one million wartime veterans, all of whom were injured or made ill while serving on behalf of this nation. To fulfill our service mission to America's injured and ill veterans and the families who care for them, DAV directly employs a corps of National Service Officers (NSOs), all of whom are themselves wartime service-connected disabled veterans, at VA regional offices (VARO) as well as other VA facilities throughout the nation. Together with our chapter, department, transition and county veteran service officers, DAV has over 4,000 accredited representatives on the front lines providing free claims and appeals services to our nation's veterans, their families and survivors. We represent over one million veterans and survivors, more than any other veterans' service organization (VSO). This provides us with an expert understanding and direct knowledge in navigating the VA claims and appeals process.

Mr. Chairman, the men and women who serve are often placed in situations that have long-term health effects that will impact their individual functioning, provide industrial impairments and require physical rehabilitation and future health care. Combat wounds, illnesses, and invisible wounds will stay with them long after service. Our nation has a sacred obligation to care for those who bore the burden of battle. When these men and women are subjected to toxins and environmental hazards, our sense of duty to them must be heightened as many of the illnesses and diseases due to these toxic exposures may not be identifiable for years, even decades after they have completed their patriotic service.

Although there has been some significant progress achieved over the past two decades for veterans who suffered illness due to toxic and environmental exposures,

there are still too many who have yet to receive the full recognition, health care and benefits our nation owes to them. Notwithstanding numerous laws and regulations governing how VA makes presumptive decisions, there are still gaps and breakdowns that have left some veterans, particularly Vietnam veterans, waiting. Throughout this testimony we will refer to the numerous studies and reports from the National Academy of Sciences, to include the National Academy of Medicine formerly known as the Institute of Medicine. From this point we will refer to them collectively as the National Academies.

While reform of the presumptive decision-making process is critical, it cannot be done overnight. There are, however, two actions that the Administration can take immediately related to Agent Orange (AO) presumptions that would provide greater justice and support to Vietnam veterans.

First, the Secretary can accept the recommendations of the National Academies to add four new conditions to the Agent Orange presumptive list. In 2016, the National Academies recommended that Bladder Cancer, Hypothyroidism and "Parkinson-like symptoms" be included. In December 2018, the National Academies found that there was "sufficient evidence" linking Agent Orange and Hypertension, strengthening their prior recommendation, and again calling for it to be included on the AO presumption list.

As I will explain in greater detail below, although the landmark Agent Orange Act of 1991 required VA to make decisions on National Academies' recommendations within 60 days, that law was allowed to expire in 2015. As a result, despite clear scientific and medical evidence, veterans continue to wait for a decision on these four recommended presumptives.

Second, the President can overrule Secretary Wilkie to end the blanket stay on Blue Water Navy claims, rather than waiting until January to begin processing them.

Mr. Chairman, we do not believe that Congress intended, nor that the law requires, VA to stay every pending Blue Water Navy claim. But that is exactly what VA has done. Despite the U.S. Court of Appeals for the Federal Circuit decision in *Procopio v. Wilkie* in January, and subsequent passage of the Blue Water Navy Vietnam Veterans Act in June, there are thousands of sick and dying veterans, as well as surviving spouses, who must continue to wait and wonder if their claims for health care and benefits will be granted. Two of those people are here with us today.

Bobby and Judy Daniels

Robert "Bobby" Daniels, from Missouri, served in the Navy from 1960 to 1964, including service onboard the USS Lexington, an Aircraft Carrier deployed to Vietnam. It was there, while serving as a Machinist's Mate that he was exposed to Agent Orange in the offshore waters. Bobby says that he has the ship logs to prove it.

In 2011, Bobby was diagnosed with prostate cancer and diabetes, diseases that many of his former shipmates have also suffered from. Unfortunately, since 1997, VA has not provided the Agent Orange presumption of exposure for Blue Water Navy veterans like Bobby who served only in the waters offshore Vietnam without ever setting foot on the land. As he began this new battle, Bobby was blessed to have his wife of more than 50 years, Judy, a former school teacher, by his side. Over the years, Bobby and Judy have struggled through tough times together, including taking out a second mortgage to help pay for his medical expenses. Last year Bobby was told that his prostate cancer had reached a terminal stage with no cure possible. Although he had not previously sought benefits due to his prostate cancer or diabetes, he was now worried about how his wife would get by after he was gone, and filed new claims in January and February of this year so that his wife might be eligible for survivor benefits.

When the *Procopio* decision was rendered in January ruling that the *Agent Orange Act of 1991* was clearly intended to include all those who served in the waters offshore, Bobby had new hope that he might finally get long overdue recognition and support from VA. He had accepted that his journey is almost over; he is now focused on getting survivor benefits for his wife Judy after he is gone.

When Congress passed, and the President signed the *Blue Water Navy Vietnam Veterans Act* on June 26, Bobby and Judy, like so many others, celebrated what they thought would finally bring them some measure of justice and support. But just five days later, the Secretary issued a blanket stay on all Blue Water claims until January 1, 2020. Bobby said this blow felt like getting hit in the mouth with a sledgehammer.

So today, Bobby and Judy continue to wait for VA to review and decide his claims, not knowing if or when they might get a decision. And Bobby, who may not make it to the new year, remains fearful and angry that his wife Judy, may not receive the survivor benefits she would be entitled to as a result of his Agent Orange-related conditions.

Frank and Claudia Holt

Frank Holt served in the Navy from November 1960 to November 1964, including service onboard the USS Prichett during the Vietnam War. While serving off the cost of Vietnam, he claimed he was exposed to Agent Orange and was never the same since. For the past two decades, Frank suffered from numerous illnesses, including lung cancer, a disease presumptively linked to Agent Orange. Frank was lucky to have his wife Claudia, a nurse by profession, at his side throughout his health struggles. But like Bobby Daniels and other Blue Water Navy veterans, Frank's claims for health care and benefits due to prostate cancer were denied.

Sadly, on May 13 of this year, months after the *Procopio* decision was rendered, Frank Holt died. Following his death, Claudia applied for survivor benefits, based on the *Procopio* decision and the new law. But because of the blanket stay issued by the

Secretary on July 1, Claudia must continue to wait until at least January before VA will even look at her claim.

Claudia, who is 78 years old and in mourning, is worried about how she will pay her bills, whether or not she'll lose her home, and how she'll keep food on the table and the lights on overhead. Claudia drove almost three hours to be here so that she could represent for her husband who never got his justice, as well as other Blue Water Navy veterans and their spouses who continue to wait.

My colleagues and I have heard from dozens of others who, like Bobby Daniels, Frank Holt and their spouses Judy and Claudia, continue waiting, wondering if they can hold on until January when VA plans to finally begin looking at their claims. It's time to end their wait.

For this reason, DAV, together with other leading veterans organizations, including the Veterans of Foreign Wars (VFW), Vietnam Veterans of America (VVA), Paralyzed Veterans of America (PVA), AMVETS, Fleet Reserve Association (FRA), Military Officers of America (MOAA) and Blinded Veterans Association (BVA), joined with Senator Tester and House Chairman Takano yesterday, to call on President Trump to end the wait for Blue Water Navy Vietnam veterans by lifting the stay.

That is also why we believe today's hearing on the future of presumptive decision-making is so important, to prevent these types of injustices from happening in the future. Our testimony will address the known toxic exposures with resultant presumptive service-connected process, how the current processes are inconsistent and present our recommendations to improve and reform the future of the presumptive decision-making process.

Known Military Toxic Exposures and Presumptive Service Connection

In discussing the future of the presumptive-decision making process, we must examine the history and impact of chemical and toxic exposures thrust upon our military service members. In all of the instances noted below, the U.S. Government or Department of Defense (DOD), exposed military service members to toxins without being fully aware of the immediate or long-term health effects.

Mustard Gas and Lewisite Exposure

During World War II (WWII), both the Axis and Allies produced millions of tons of chemical weapons and had made massive preparations for their use. The U.S. established secret research programs to develop better chemical and toxic weapons and better methods of protecting against these poisons. At the end of WWII, over 60,000 U.S. service members had been used as human test subjects. At least 4,000 of these active military service members had participated in tests conducted with high concentrations of mustard agents or Lewisite in gas chambers or in field exercises over contaminated ground areas. The U.S. service members were intentionally exposed to

mustard agents or Lewisite, from mild (a drop of agent on the arm in "patch" tests) to quite severe (repeated gas chamber trials, sometimes without protective clothing).

All service members in the chamber and field tests, and some in the patch tests, were told at the time that they should never reveal the nature of the experiments. Attention was drawn to these experiments when some of the veterans began to seek benefits from VA for health problems they believed were caused by their exposures to mustard gas and lewisite. Two factors complicated these cases. First, there were often no records or documentation available of a veteran's individual participation in the testing programs. Second, there was a great deal of uncertainty about which health problems were in fact the result of mustard agent or Lewisite exposure.

Not until 1991, over 70 years from the use in WWI and over 50 years from the secret testing in WWII, did the VA provide guidelines for establishing claims related to these exposures. That same year the VA requested a study from the National Institute of Medicine (IOM), currently the National Academy of Medicine. On July 31, 1992, VA published a final regulation, 38 C.F.R. § 3.316, authorizing service connection in claims from veterans who underwent full-body exposure to mustard gas during field or chamber experiments. The report, "Veterans at Risk: The Health Effects of Mustard Gas and Lewisite" was issued in 1993 and prompted an updates to the regulatory provision in 1993 and 1994. We would like to point out that this presumptive, when established in 1992, excluded WWI veterans exposed to mustard gas.

Radiation Exposure

Some of the first atomic veterans were service members who were sent to Hiroshima and Nagasaki to assist in clean-up. Approximately 255,000 troops were involved in the occupation of Hiroshima and Nagasaki. From 1946 to 1962, the United States conducted about 200 atmospheric nuclear tests. Approximately 400,000 service members were present during these atmospheric tests, whether as witnesses to the tests themselves or as post-test cleanup crews. Sworn to secrecy, many of these service members never told anyone of what they witnessed. If they told anyone that they were involved in these nuclear tests, they could have been fined up to $10,000 and tried for treason.

On October 24, 1984, the Veterans' Dioxin and Radiation Exposure Compensation Standards Act was enacted to ensure compensation to veterans and their survivors for disabilities or deaths related to exposure to ionizing radiation during atmospheric nuclear testing or the occupation of Hiroshima and Nagasaki. The law instructed VA to prescribe regulations setting forth specific guidelines, standards, and criteria for adjudicating compensation claims based on radiation exposure.

On September 25, 1985, VA published 38 C.F.R § 3.311b (now designated § 3.311) to implement the radiation provisions of Pub. L. No. 98-542. This regulation contains standards and criteria under which service connection is to be considered for diseases first appearing after service in radiation-exposed veterans.

Effective May 1, 1988, 38 U.S.C. § 1112(c) provided compensation on a presumptive basis for radiation-exposed veterans who developed one of 13 specified diseases to a degree of 10 percent or more within 40 years following participation in a radiation risk activity. The presumptive period for one of the 13 diseases, leukemia, was set at 30 years.

In 1994, the Advisory Committee on Human Radiation Experiments was created to investigate the US government's role in radiation experiments on US service members and American civilians from 1944 to 1974. The Committee found the U.S. government had conducted human experimentation that included injection of radioisotopes and intentional releases of radioactive gases into the environment. The Committee discovered that the government, scientists, and officials involved did not follow any procedures to obtain consent from the subjects in these experiments.

Agent Orange Presumptive

The U.S. program, code-named Operation Ranch Hand, sprayed more than 20 million gallons of various herbicides over Vietnam, Cambodia and Laos from 1961 to 1971. The purpose was to strip the thick jungle canopy that could conceal opposition forces, to destroy crops that those forces might depend on, and to clear tall grasses and bushes from the perimeters of US base camps and outlying fire-support bases. At the time of the spraying, 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), the most toxic form of dioxin, was an unintended contaminant generated during the production of 2,4,5-T and so was present in Agent Orange as well as some other formulations sprayed in Vietnam.

After their service, many Vietnam veterans were developing multiple illnesses and fatal diseases. It was not until Veterans' Dioxin and Radiation Exposure Compensation Standards Act of 1984 that VA recognized presumptive service connection for an illness related to Agent Orange. As we will outline later in this testimony, it took many years of legislation, regulations and court battles to establish exposure to this deadly toxin. Because 20 million gallons were sprayed, VA has ultimately conceded exposure for those who served in Vietnam and the waters offshore.

Persian Gulf War and Undiagnosed Illnesses

In response to the invasion of Kuwait by Iraq in August 1990, the United States led a coalition of 34 countries in Operation Desert Shield in the Persian Gulf. This was followed by Operation Desert Storm, which began in January 1991 with an air offensive and a 4-day ground war; the war ended with a cease-fire in April 1991. Almost 700,000 U.S. troops were deployed to the Persian Gulf region during the height of the buildup.

The U.S. military engaged in further conflicts in the Middle East following the terrorist attacks of September 11, 2001. Operation Enduring Freedom began in October 2001 with troops stationed in and around Afghanistan. Operation Iraqi Freedom began

in March 2003 with the invasion of Iraq, and it ended on August 31, 2010. Operation New Dawn, whose goal was to reduce the number of U.S. military personnel in Iraq, was initiated in September 2010 and ended in December 2011. However, there is still a U.S. military presence in Iraq.

As noted by the National Academy of Medicine report, "Gulf War and Health: Volume 11: Generational Health Effects of Serving in the Gulf War" (2018), veterans who served in the 1990–1991 Gulf War and Post-9/11 were subjected to a variety of exposures during deployment that have been associated with health effects in veterans and other exposed populations. These exposures include burning oil fields, pesticides, nerve agents, depleted uranium, burn pits, particulate matter, vaccinations and many other environmental hazards.

The Persian Gulf War Veterans Acts of 1998, codified at 38 U.S.C. § 1118, was established to associate the numerous health effects known as Persian Gulf Illnesses. It also established a requirement for continual research and studies form the National Academies.

Airborne Hazards and Open Burn Pits

Veterans who served in Southwest Asia during the first Persian Gulf as well as those serving in those locations, including Afghanistan after 9/11, have been exposed to the large scale use of burn pits.

DOD has acknowledged the vast use of burn pits to dispose of nearly all forms of waste. Several studies have indicated that veterans were exposed to burned waste products including, but not limited to: plastics, metal/aluminum cans, rubber, chemicals (such as paints, solvents), petroleum and lubricant products, munitions and other unexploded ordnance, wood waste, medical and human waste, and incomplete combustion by-products. The pits did not effectively burn the volume of waste generated, and smoke from the burn pit blew over bases and penetrated all living areas/quarters.

DOD has performed air sampling at Joint Base Balad, Iraq and Camp Lemonier, Djibouti. Most of the air samples have not shown individual chemicals that exceed military exposure guidelines. The air sampling performed at Balad and discussed in an unclassified 2008 assessment tested and detected all of the following: (1) Particulate matter; (2) Polycyclic Aromatic Hydrocarbons (PAH); (3) Volatile Organic Compounds; and (4) Toxic Organic Halogenated Dioxins and Furans (dioxins).

The VA launched the Airborne Hazards and Open Burn Pit Registry in June 2014 to allow eligible veterans and service members to document their exposures and report health concerns through an online questionnaire. To date, the VA has not created any presumption associate with exposure to airborne hazards and open burn pits.

Contaminated Water

From the 1950s through the 1980s, people living or working at the U.S. Marine Corps Base Camp Lejeune, North Carolina, were exposed to drinking water contaminated with industrial solvents, benzene, and other chemicals. The Caring for Camp Lejeune Families Act of 2012, recognized exposure and treatment for veterans and families members for 15 specific diseases.

In 2017, by regulation, the Secretary established 8 presumptives diseases for active duty, reservists, and National Guard members who were stationed at Camp Lejeune for 30 aggregate days. However, this does not include any requirements for future studies to consider adding any potential new diseases in the future.

As of August 2017, DOD has identified 401 military sites that could be contaminated with the toxic compounds known as per-and polyfluoroalkyl substances (PFAS). PFAS are found at high levels in a concentrate for a firefighting foam which has leaked into groundwater and contaminated drinking water. Currently, there are no presumptive illnesses, diseases or conditions established. Recently VA contracted with the National Academies to undertake a study on PFAS.

DIFFERNCES IN CURRENT PRESUMPTIVE PROCESSES

To best understand the current presumptive decision-making process, we must look at the overall presumptive processes for toxic exposures. The presumptive processes and the presumptive decision-making process are not consistent among all of the different types of exposures; it varies from exposure to exposure. Which means that not all presumptive processes are the same when it comes to establishing concession of exposure, or in adding new diseases linked to the exposure, or requirements for additional studies, or requirements from the Secretary to act on adding new diseases linked to exposure.

Some of these inconsistencies or differences can be traced back to the ways each of the presumptive processes based on each specific exposure is established. There are two paths to establish new presumptive exposure processes; Congress by statute and the Secretary of Veterans Affairs by regulation via the formal rule-making process.

Differences with Presumptive Exposure by Regulation

The presumptive exposures based on mustard gas and Camp Lejeune contaminated water were established by the Secretary via federal rule-making and not based on congressional action. Neither of these regulatory presumptive processes have requirements for additional studies to address potentially new diseases linked the toxic exposures. There is not a specific process in play, for these exposures, that regulates the addition of new diseases or any requirements on the Secretary to define their responses. However, new diseases for these exposures can be added by statute

or federal rulemaking, but again, there are no specific controls or requirements in doing so.

Differences with Conceding Exposure

The current presumptive process for exposure to radiation was established by Congress and further defined by VA regulation per formal rule-making. There are inconsistencies with the concession of exposure for radiation exposure. The statute clearly states that a radiation-exposed veteran is one who participated in radiation-risk activities. It further provides a list of radiogenic diseases that will be service-connected if they become manifested in a radiation-exposed veteran.

VA regulation 38 C.F.R. § 3.311 states that dose estimates for all radiation-exposed veterans, which is not required by the statute, must be conducted to estimate the dose of radiation. The dose estimates are provided by the Defense Threat Reduction Agency. Once they provide their estimate, it is given to a physician with subject matter expertise for an opinion if the estimated dose amount caused the radiation-exposed veteran's radiogenic diseases. This is the only presumptive process that requires estimation of dose of exposure and then a medical opinion if the known diseases are related to the exposure. This places a higher burden of proof on radiation exposed veterans for a presumptive disease than any other presumptive process within the VA. It is more akin to the direct service connection process than an actual presumptive process.

In 2000, the Government Accountability Office (GAO) released a report on the DOD's dose reconstruction program, which established the estimated amount of radiation a veteran could have been exposed to. The report determined that there should be an independent review board that would examine the program, because many of the atomic veterans questioned the program's validity. As a result, Congress mandated an independent review.

The Defense Threat Reduction Agency tasked the National Research Council to conduct the review. In 2003, The Board on Radiation Effects Research, under the auspices of the National Research Council, released its report. It found that while the estimated average dose was valid, estimated individual exposure was uncertain, because many veterans at the time of exposure were not wearing film badges that would collect radiation data. It was determined that methods to estimate "inhaled radioactive materials involve many assumptions that are subject to error" due to a lack of data.

By contrast, the current Agent Orange presumptive process includes requirements for exposure based on the Agent Orange Act of 1991. The Secretary has conceded exposure to the toxin for those who served in the Air Force and a part of Operation Ranch Hand. This concession of exposure was added via 38 C.F.R. § 3.307. The VA has also conceded exposure to Agent Orange for those who served on eight specific Royal Thai Air Forces Bases during the Vietnam Era. However, this was not

added by statue or formal rule-making; it was added via VA's M21-1 adjudication manual. It restricts exposure to Agent Orange to only those who served on the perimeter of the bases.

Until the recent passage of the Blue Water Navy Vietnam Veterans Act, concession of exposure to Agent Orange for those who served on the Korean Demilitarized Zone was only available by the Secretary previously adding it via federal rule-making. The men and women who served in the waters offshore of Vietnam were conceded as being exposed to Agent Orange in 1991. However in 1997, a VA General Counsel Opinion determined only veterans who physically served in Vietnam were exposed to Agent Orange, excluding Blue Water Navy veterans. The Blue Water Navy Vietnam Veterans Act of 2019 has conceded their exposure.

Differences with Future Studies Required

Not all of the presumptives have requirements for future studies to be conducted for reviewing and potentially adding new diseases to the established presumptive diseases lists. There are no requirements for future studies of mustard gas; Camp Lejeune contaminated water, and radiogenic diseases. However, statutes require continued studies and the National Academies recommendations on diseases related to Agent Orange and exposures to toxins in the Persian Gulf. Both respective laws require studies to be conducted by the National Academies. We are concerned that those presumptive processes without required future studies will not provide current information on the toxic exposures and any advances or changes in science that can relate additional diseases or illness to that exposure. These are further evident of the overall differences in the presumptive decision-making process overall.

Time-Required Actions by the VA Secretary on Recommendations

When the Agent Orange Act of 1991 was passed into law, it contained requirements for action by the Secretary when a report and recommendations from the National Academies was received. It noted the Secretary not later than 60 days after the date on which the Secretary receives a report, shall determine whether a presumption of service connection is warranted for each disease covered by the report. If the Secretary determines that such a presumption is warranted, the Secretary, not later than 60 days after making the determination, shall issue proposed regulations setting forth the Secretary's determination. If the Secretary determined that a presumption of service connection is not warranted, the Secretary, not later than 60 days after making the determination, shall publish in the Federal Register a notice of that determination. The notice shall include an explanation of the scientific basis for that determination. It further added that not later than 90 days after the date on which the Secretary issues any proposed regulations under this subsection, the Secretary shall issue final regulations.

This section of the statute included a date to discontinue this requirement. It was reauthorized several times; however, this part of the Agent Orange Act, 38 U.S.C. §

1116, expired on October 1, 2015. This means, the Secretary no longer has a required time frame for actions on recommended diseases to be added as a presumptive to Agent Orange. The lack of the time-required action is having a negative impact on veterans and their families.

The National Academies "Veterans and Agent Orange" update was published in 2016. The committee concluded that there was compelling evidence for adding bladder cancer and hypothyroid conditions as presumptive diseases. Further, the study clarified that Vietnam veterans with "Parkinson-like symptoms," but without a formal diagnosis of Parkinson's disease, should be considered under the presumption that Parkinson's disease and the veterans' are service connected. On November 1, 2017, the VA issued a press release noting they were exploring these new presumptive conditions related to Agent Orange.

In December 2018, the National Academies issued a report noting there was sufficient evidence of a relationship between hypertension and Agent Orange and recommended for it to be added to the presumptive list. In March 2019, at a congressional hearing, Dr. Stone, Executive in Charge of the Veterans Health Administration (VHA) indicated that an answer on these presumptives could be released within 90 days. To date, there has been no action or responses from the VA in reference to a decision on adding these four presumptive diseases.

The Persian Gulf War Veterans Act of 1998, codified at 38 U.S.C. § 1118, originally had these same types of time-required actions by the Secretary. However, those requirements expired on October 1, 2011, as the date was not reauthorized for the future. All of this means there are no current time requirements on the Secretary to act on recommendations made by the National Academies in reference to additional diseases related to toxic exposures.

Causation vs Association

As noted in the many reports from the National Academies, there is a distinction between causation and association of a disease to the specific exposures. There is debate over which requirement should drive the presumptive decision-making process, or whether both should be included.

Regardless of the outcomes from a report or study indicating causation or association, we would like to note, the ultimate decision for adding the presumptive disease lies with the Secretary, as well as Congress, which also has the authority to add diseases, as was the case with radiation-exposed veterans. As noted below, there are differences in the presumptive statutory language and the recommendations by veterans, the VA, and the National Academies.

The Veterans' Dioxin and Radiation Exposure Compensation Standards Act of 1984 used language of both association and causation in describing the evidence required for presumptions. VA interpreted the law as requiring a certain threshold of

evidence for causation, and as a result denied presumptions between Agent Orange and all diseases except Chloracne. Veterans filed a lawsuit against the VA and as determined by district court in *Nehmer v US Veterans Administration*, 1989, the Act was ambiguous and interpreted congressional intent as establishing a threshold of evidence for an association.

The Agent Orange Act of 1991, 38 U.S.C. § 1116, originally stated that each additional disease that the Secretary determines in regulations warrants a presumption of service connection by reason of having positive association with exposure to a herbicide agent. Unfortunately, this requirement of association was not carried forward and ended on October 1, 2015. However, each subsequent report from the National Academies provides their assessments based on this original requirement of association.

In “Veterans at Risk: The Health Effects of Mustard Gas and Lewisite,” issued in 1993, the study only focused on findings of a causal relationship and did not provide any comments or recommendations on diseases that may have an association vs causation. However, since this presumptive was established by regulation, there is no language or directions in reference to ongoing studies or any requirement of causation vs. association.

The Persian Gulf War Veterans Act of 1998, 38 U.S.C. § 1118, notes that the Secretary determines if illnesses or diseases warrant a presumption of service connection by reason of having a positive association with exposure to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine. The plain text of the law notes association and not causation.

In the National Academies report, “Improving the Presumptive Disability Decision-Making Process,” 2008, it made recommendations of causation over association. However, in the National Academies "Veterans and Agent Orange" update 2016; it discussed this question of whether the committee should be considering statistical association rather than causality. The committee believed that the categorization of strength of evidence on association is consistent with the previous court ruling.

Classification Scheme used by the National Academies

The National Academies "Veterans and Agent Orange" reports originally created and provided the four different classifications for associations of diseases to Agent Orange exposure as follows:

> **Sufficient Evidence of an Association**
> Epidemiologic evidence is sufficient to conclude that there is a positive association. That is, a positive association has been observed between exposure to herbicides and the outcome in studies in which chance, bias, and confounding could be ruled out with reasonable confidence. For example, if several small

studies that are free of bias and confounding show an association that is consistent in magnitude and direction, then there could be sufficient evidence of an association.

Limited or Suggestive Evidence of an Association
Epidemiologic evidence suggests an association between exposure to herbicides and the outcome, but a firm conclusion is limited because chance, bias, and confounding could not be ruled out with confidence. For example, a well-conducted study with strong findings in accordance with less compelling results from studies of populations with similar exposures could constitute such evidence.

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

Limited or Suggestive Evidence of No Association
Several adequate studies, which cover the full range of human exposure, are consistent in not showing a positive association between any magnitude of exposure to a component of the herbicides of interest and the outcome. A conclusion of "no association" is inevitably limited to the conditions, exposures, and length of observation covered by the available studies.

The Gulf War and Health reports issued by the National Academies have used five classifications of association that they noted, "gained wide acceptance by Congress, government agencies (particularly VA), researchers, and veterans groups." They present a common message: the validity of an association is likely to vary to the extent to which common sources of spurious associations can be ruled out as the reason for the observed association. The one additional category provided by these reports is:

Sufficient Evidence of a Causal Relationship
Evidence is sufficient to conclude that a causal relationship exists between being deployed to the Gulf War and a health outcome. The evidence fulfills the criteria for sufficient evidence of a causal association in which chance, bias, and confounding can be ruled out with reasonable confidence. The association is supported by several of the other considerations such as strength of association, dose–response relationship, temporal relationship, and biologic plausibility.

It is important to note, that of all the diseases that have ever been recommended to be added to any of the presumptives lists, no diseases classified as *Inadequate or Insufficient Evidence to Determine an Association* or *Limited or Suggestive Evidence of No Association* have been added as a presumptive disease.

RECOMMENDATIONS FOR MOVING FORWARD

While considering the future of the presumptive-decision making process, we must look at all aspects of the presumptive process as well as other ways for the men and women who served to establish entitlement to their earned benefits. Below are DAV's recommendations moving forward for strengthening and reforming the presumptive-decision making process.

1. Improve DOD Recordkeeping, Data Collection and Information Sharing with VA.

In reference to the lack of information regarding exposures while on active duty, the National Academies noted, "It is too late for Vietnam veterans and other more recently deployed veterans, but DOD should prepare the way for addressing the issue of delayed service related health conditions in a more coherent and better documented fashion for future veterans. The compilation of rosters of individuals sent on various deployments is a rudimentary starting point for any subsequent epidemiologic investigations. Documentation of medical procedures such as vaccinations should also be maintained for such cohorts."

As noted throughout our testimony and the many reports from the National Academies, there is a fundamental lack of exposure data for service members to include troop locations, vaccinations, and other relevant information.

DAV supports S.1680, the "Service Member's Occupational and Environmental Transparency Health Act" or the "OATH Act," as this take steps to avoid the lack of medical data and exposure information for future generations of veterans. We also support the ongoing efforts to improve the data collection for the VA's Airborne Hazards and Burn Pit Registry as noted by S. 191, the Burn Pits Accountability Act, and S. 554, the Burn Pit Registry Enhancement Act, as well as the inclusions in the pending National Defense Authorization Act of 2020.

As we look to create better record keeping and data of exposures for future veterans, we must reconcile the poor record keeping for past generations trying to establish their exposure to toxins. As noted, veterans exposed to mustard gas, radiation-risk veterans, veterans exposed to Agent Orange, Persian Gulf veterans, and those serving today, have difficulty establishing their exposures, due in part to poor DOD record keeping, especially during periods of war.

2. Establish Concession of Exposure.

One of the common denominators for all presumptive processes is the concession of exposure to a specific toxin or environmental hazard. There are requirements that must be met to concede the toxic exposure prior to establishing if the

presumptive process applies and thus the granting of association for diseases, illnesses and conditions.

When veterans have been exposed to toxins and current science and medical evidence fails to provide diseases or illnesses, they cannot use the presumptive process to establish service connection for their illnesses. So prior to the establishment of a presumptive process or disease list, the concession of exposure can provide an avenue to establish service connection for access to VA benefits and VA health care.

For example, *The Independent Budget Veterans Agenda for the 116th Congress* notes that a Concession of Exposure can provide veterans exposed to open air burn pits a means to establish service connection as there is currently not a presumptive process for burn pit exposure. Without a presumptive process, veterans exposed to burn pits with associated diseases and illnesses must establish service connection by the means of direct service connection, which requires three components:

1. A current diagnosis of a disease;
2. Evidence of in-service injury, illness, treatment or exposure; and
3. A medical opinion linking the current diagnosis to that in-service event.

VA has reported that since 2007, 80 percent of claims for illnesses and diseases related to burn pits have been denied, mostly as the veteran does not have a medical opinion linking the illness to the claimed exposure. Again, there are few, if any, records to establish a veteran's exposure to and specific toxin from burn pits.

A Concession of Exposure would still require a veteran to provide a diagnosis of a current condition, however, by conceding veterans who served in areas of active burn pits were exposed to certain chemicals and toxins, including those recognized in VA's M21-1, adjudication manual, the veteran would not have to provide personal evidence of exposure. This will still require veterans to have a medical opinion linking the condition to the exposure. By conceding their exposure to the known toxins, a physician will now have a better ability to provide a medical opinion as the toxins of exposure are known.

A Concession of Exposure can provide benefits to veterans before a presumptive process is established or even if one is not created. For example, in April the National Academies started a 21-month study for VA on the long-term health effects of burn pits. If this report does not identify any diseases associated to burn pits, veterans will still have the ability to establish entitlement to service connection on a direct basis by Concession of Exposure and an independent medical exam.

We are currently working with Senators Sullivan and Manchin to draft legislation that would address the need for a Concession of Exposure for veterans exposed to burn pits. They are both committed to providing an avenue for veterans exposed to burn pits to establish entitlement to benefits and VA health care. We look forward to their introduction of the bill in the near future.

3. **Approve Legislation or Regulations Requiring VA to Apply the Court's Holdings in *Combee* Whenever Applicable.**

Currently when the VA adjudicates a claim that associates a disease to a toxic exposure, but the disease is not one of the recognized presumptive diseases, it is usually denied. One of the most common reasons for this denial is that the disease is not listed as a presumptive. However, there is a means for this type of claim to be established based on direct service connection, as determined by the U.S. Court of Federal Appeals. In their decision of *Combee v. Brown*, 34 F.3d 1039, 1042 (Fed. Cir. 1994); they held that notwithstanding the presumption provisions, a claimant is not precluded from establishing service connection with proof of direct causation.

While this precedent has existed since 1994, most VA regional offices fail to apply this legal standard. When a veteran provides evidence of the disease, has a concession of the exposure, and even with an opinion with scientific and medical rationale linking the disease to the exposure, it is denied. These denials are then appealed to the Board of Veterans' Appeals and in many cases are granted by the Board based on the holdings of *Combee*.

Many claims based on a toxic exposure for a disease not recognized as a presumptive can be resolved quickly based on *Combee* and would not add to the backlog of pending appeals.

4. Statutorily Require Future Studies on Toxic Exposures.

Not all of the presumptives have requirements for future studies to be conducted for reviewing and potentially adding new diseases to the established presumptive diseases lists. Only Persian Gulf War Illnesses and Agent Orange associated diseases have statutorily required continuing studies. As noted in the numerous studies and reports from the National Academies, additional scientific research and new medical processes continue to change. Therefore in order to ensure that diseases are properly associated with toxic exposures, any new presumptive processes should have a requirement for new studies every two years.

5. Time Requirement for Action from the Secretary.

As noted above, the statutory provisions that required the Secretary to respond and take actions on the recommendations from the National Academies have expired. While Congress has the ability to reauthorize the law, or directly add presumptions, no such action has been taken in recent years. This lack of statutory mandate, unfortunately, has resulted in no action by VA on the recommendations on three presumptive diseases from 2016 and one from 2018. Veterans with these diseases,

such as bladder cancer, do not have the time to wait for the Secretary to decide on action. These veterans with terminal illnesses are left with no action from the Secretary. These situations need to be avoided in the future. Regardless of whether the Secretary decides to implement the diseases or not, veterans deserve action. A future presumptive decision-making process must include timely action.

We recommend inclusion of the language previously found in 38 U.S.C. §§ 1116 and 1118. We recommend including, "the Secretary not later than 60 days after the date on which the Secretary receives a report from the National Academies, shall determine whether a presumption of service connection is warranted for each disease covered by the report. If the Secretary determines that such a presumption is warranted, the Secretary, not later than 60 days after making the determination, shall issue proposed regulations setting forth the Secretary's determination. If the Secretary determined that a presumption of service connection is not warranted, the Secretary, not later than 60 days after making the determination, shall publish in the Federal Register a notice of that determination. The notice shall include an explanation of the scientific basis for that determination. It further added that not later than 90 days after the date on which the Secretary issues any proposed regulations under this subsection, the Secretary shall issue final regulations."

6. Association of Diseases to Exposure

As noted in the many reports from the National Academies, there is a distinction between causation and association of a disease to the specific exposures. The debate of which requirement should be included in the presumptive decision-making process is noted throughout.

We recommend that the studies from the National Academies continue the use of statistical association between an exposure and a disease or illness. There is judicial precedent as noted by the Court in *Nehmer v US Veterans Administration*, 1989. The Court held, "the legislative history, and prior VA and congressional practice, support our finding that Congress intended that the Administrator predicate service connection upon a finding of a significant statistical association between dioxin exposure and various diseases. We hold that the VA erred by requiring proof of a causal relationship. [712 F. Supp. 1404, 1989].

The National Academies discussed this question of whether they should be considering statistical association rather than causality as has been debated. It is believed that the categorization of strength of evidence on association is consistent with that court ruling. However, we do realize that due consideration should be given to causation as in certain situations it can provide a path to adding a presumptive disease when the statistical analysis for association is not yet available.

It is important to note that in each National Academies report they make their recommendations on adding diseases to the presumptive lists. This is based on their compiled research, studies, statistical analysis and most importantly, their professional

expertise. Veterans rely on the scientific community to make these recommendations. As they have the expertise, we believe VA and Congress should follow their recommendations based on the merits, medical evaluations, and scientific value.

7. Classifications of Scientific Association.

We have discussed and explained the currently used classifications for scientific association between exposures and the identified diseases. We propose the below classification of associations to be used for future studies:

Sufficient: The scientific analysis and evidence is sufficient to conclude that an association exists between the exposure and the disease.

Equipoise and Above: The scientific analysis and evidence is sufficient to conclude that an association is at least as likely as not. 38 U.S.C. § 5107 notes that if the evidence is in equipoise, the benefit of the doubt is resolved in the veteran's favor, thus the presumptive would be established. This would replace the "limited but suggestive" classification.

Below Equipoise: The scientific analysis and evidence is not sufficient to conclude that an association is at least as likely as not.

Against: The scientific analysis and evidence suggests a lack of an association.

In discussion for future presumptive decision-making, we should consider adding a requirement on the Secretary when it comes to adding a disease to the presumptive list from our recommendations above. As there is no current time requirements on the Secretary to act on recommendations and much debate over these issues, requiring any disease as noted above being classified as sufficient association, would require the Secretary to add to the presumptive list unless there is clear and convincing scientific evidence to the contrary.

In conclusion, we have discussed the known toxic exposures with resultant presumptive service-connected process, how the current processes are inconsistent and our recommendations to improve and influence the future of the presumptive decision-making process. Changes to the presumptive processes will have monumental impacts on the men and women exposed to toxins in their military service. We offer our assistance and want to participate in these ongoing conversations and debates to ensure that veterans and their families are able to access all of their VA benefits and VA health care, now and into the future.

Mr. Chairman, this concludes my testimony on behalf of DAV. I would be happy to answer any questions you or other members of the Committee may have.