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Veterans Affairs: Presumptive Service Connection and Disability Compensation

(name redacted)
Specialist in Veterans Policy

(name redacted)
Legislative Attorney

(name redacted)
Analyst in Disability Policy

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Summary

The United States has provided benefits in varying degrees to those who have worn the uniform and suffered disabilities in service to the nation. In general, a veteran is entitled to compensation for disabilities incurred in or aggravated during active military, naval, or air service. It should be noted that not all persons who served in the military are considered veterans for purposes of veterans benefits. Veterans could meet the burden of proving that their disabilities are service-connected through their military records, which may clearly describe and document the circumstances and medical treatment for an injury or an illness incurred while in service as well as any resulting disability. However, where the manifestation of the disability is remote from the veteran's service and any relationship between the disability and service is not readily apparent, the burden of proving service connection can be a challenge. In such circumstances, Congress and the Department of Veterans Affairs (VA) have relied on presumptions. In the context of VA claims adjudication, a presumption could be seen as a procedure to relieve veterans of the burden to prove that a disability or illness was caused by a specific exposure that occurred during service in the Armed Forces. When a disease is designated as presumptively service-connected, the individual veteran does not need to prove that the disease was incurred during service.

The legislative history of veterans' disease presumptions dates back to 1921 when Congress established a presumption of service connection with an amendment (P.L. 67-47) to the War Risk Insurance Act (P.L. 63-193). It established presumptions of service connection for tuberculosis and neuropsychiatric disease (known today as psychosis) occurring within two years of separation from active duty military service. In the following years, additions to the presumptive list were made by regulation, executive order, and legislation. In the past 22 years, Congress has on three separate occasions created presumptive programs for three distinct groups of veterans: the so-called atomic veterans, who were exposed to radiation from above-ground nuclear tests and the atomic bombs detonated in Japan; Vietnam veterans; and Gulf War veterans. In addition, Congress has added certain disease conditions to the list of presumptions for specific groups of veterans such as former prisoners of war (POWs).

In 1991, the Agent Orange Act (P.L. 102-4) established for Vietnam veterans a presumption of a service connection for diseases associated with exposure to Agent Orange and other herbicides. For the first time, this act required the VA to contract with the Institute of Medicine (IOM) to conduct, every two years, a scientific review of the evidence linking certain medical conditions to herbicide exposure. The VA was instructed to use the IOM's findings, and other evidence, to issue regulations establishing a presumption for any disease for which there is scientific evidence of an association with herbicide exposure.

However, since an increasing proportion of service-connected disability compensation is paid through a presumptive decision-making process, some have raised several policy questions with regard to the current process. This report discusses presumptive service connection, its legislative history, and current challenges in making evidence-based determinations of presumptions. It also discusses the Agent Orange Act (P.L. 102-4) and suggests implications of the process established by the act for future presumptive service-connected determinations.

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Introduction

Beginning with the early colonial settlements of America, the nation has provided benefits in varying degrees to those who have worn the uniform and suffered physical disabilities in service to the nation—sacrifices that are inherent to the profession of arms. In 1718, for instance, the colony of Rhode Island enacted legislation that provided benefits not only to every officer, soldier, or sailor who served in the colony's armed services, but also to the wives, children, parents, and other relations who had been dependent upon a slain servicemember. "The physically disabled were to have their wounds carefully tended and healed at the colony's expense, while at the same time an annual pension was provided to him out of the general treasury sufficient for the maintenance of himself and family, or other dependent relatives."[1] These benefits were continued by the Continental Congress, which passed a resolution on August 26, 1776, providing for disabled veterans to receive half of their monthly pay for life or for as long as their disability existed.[2] From the Revolutionary War to the current conflicts in Afghanistan, Iraq, and elsewhere,[3] as the nature of the nation's wars has evolved, and as the needs of each generation of veterans who fought those wars have changed, Congress has debated, legislated, and revised benefits provided to veterans.

In general, veterans are eligible for disability compensation if it can be demonstrated that the disabling condition or illness is linked to military service. Veterans could meet the burden of proving that their disabilities were service-connected through their military records, which may clearly describe and document the circumstances and medical treatment for an injury or an illness incurred while in service as well as any resulting disability.[4] However, where the manifestation of the disabling disease or condition is remote from the veteran's service and any relation between the disability and service is not readily apparent, the burden of proving service connection can be a challenge. In such circumstances, Congress and the Department of Veterans Affairs (VA) have relied on presumptions to ease the burden placed on the veteran. Since the early 1920s, almost every Congress has examined the issue of whether one may presume that a veteran's disability is service-connected when there is no clear evidence to establish an illness or disability is caused or

[1] U.S. Congress, House Committee on Veterans' Affairs, *The Provision of Federal Benefits for Veterans, An Historical Analysis of Major Veterans Legislation, 1862-1954*, committee print, 84th Cong., 1st sess., December 28, 1955, H.Prt. No. 171, p. 2.

[2] Department of Veterans Affairs, *Veterans Benefits Administration: An Organizational History: 1776-1994*, Washington, DC, November 1995, p. 6. Although the Continental Congress passed resolutions promising benefits, it lacked the authority and resources to implement these benefit laws, and left this task to individual states.

[3] Since the September 11, 2001, terrorist attacks, the Department of Defense (DOD) has been engaged in domestic and overseas military operations. These operations include Operation Noble Eagle, aimed at defending the U.S. homeland against terrorist attacks; Operation Enduring Freedom (OEF), which takes place principally in and around Afghanistan but also covers Guantanamo Bay (Cuba), Djibouti, Eritrea, Ethiopia, Jordan, Kenya, Kyrgyzstan, Pakistan, Philippines, Seychelles, Sudan, Tajikistan, Turkey, Uzbekistan, and Yemen; and Operation Iraqi Freedom (OIF), which focused principally on Iraq between March 19, 2003, and August 31, 2010. Operation New Dawn (OND) coincided with the change of mission for U.S. forces in Iraq and occurred between September 1, 2010, and December 31, 2011. On June 15, 2014, the President authorized U.S. Central Command to work with partner nations to conduct targeted airstrikes of Iraq and Syria as part of the comprehensive strategy to degrade and defeat the Islamic State of Iraq and the Levant, or ISIL. This operation is known as Operation Inherent Resolve (OIR) and includes Bahrain, Cyprus, Egypt, Iraq, Israel, Jordan, Kuwait, Lebanon, Qatar, Saudi Arabia, Syria, Turkey, United Arab Emirates, the Mediterranean Sea east of 25° Longitude, the Persian Gulf, and the Red Sea (sources: http://www.defense.gov/news/casualty.pdf and http://www.defense.gov/home/features/2014/0814_iraq/).

[4] Veterans Benefits Disability Commission, *Honoring the Call to Duty: Veterans' Disability Benefits in the 21st Century*, Washington, DC, October 3, 2007, p. 444.

aggravated by a veteran's military service. More recently, Congress and the VA have relied on scientific evidence to establish presumptions. However, when the scientific evidence is incomplete and there is uncertainty on the question of causation or if other factors such as natural aging could also contribute to disease causation, Congress and the VA are faced with the challenge of instituting a transparent and equitable process to establish presumptions to compensate veterans for service-connected conditions.

In the early 1990's at the request of the then Chairman of the Senate Committee on Veterans' Affairs, the VA prepared an analysis tracing the historical development of presumptions of service connection.[5] More recently, at the request of the Veterans' Disability Benefits Commission,[6] the Institute of Medicine (IOM) of the National Academy of Sciences (NAS) did a comprehensive study evaluating the presumptive disability decision-making process, which was released in 2008.[7] Much of the interest with presumptions has focused on Vietnam veterans' exposure to Agent Orange and its contaminant dioxin.[8] The Veterans' Disability Benefits Commission, in its task assignment to IOM, raised some potential issues with the current process of making presumptions:

> Certain studies (not even necessarily involving veterans), for example, showing that those exposed to [Agent Orange] dioxin have slightly higher rates of diabetes or prostate cancer, have resulted in an inexorable push to compensate all veterans with diabetes/prostate cancer even if it is likely that [Agent Orange] dioxin exposure is a determinative factor in only a small percentage of cases. Since it is impossible to know what role dioxin played in any particular case, all Vietnam veterans with diabetes and prostate cancer have been and are being granted presumptive service connection. Is this presumption fully supported by medical evidence? What amount of increase in occurrence rate is enough to warrant compensation? What approaches could be considered to alleviate this costly result?[9]

Organization of this Report

The purpose of this report is to examine the very complex and sometimes controversial policy issue of establishing presumptive service connection. The material in it is based in large part on

[5] Department of Veterans Affairs (VA), "Analysis of Presumptions of Service Connection," a report to the Senate Committee on Veterans' Affairs, December 23, 1993.

[6] The Veterans' Disability Benefits Commission was established by the National Defense Authorization Act of 2004 (P.L. 108-136), and was charged with providing a "comprehensive evaluation and assessment of the benefits provided under the laws of the United States to compensate veterans and their survivors for disability or death attributable to military service."

[7] National Academy of Sciences, Institute of Medicine, *Improving the Presumptive Disability Decision-Making Process for Veterans*, Washington, DC, 2008, http://www.nap.edu/catalog/11908.html.

[8] The U.S. Air Force, from 1962 to 1971, sprayed nearly 19 million gallons of herbicides in Vietnam, of which at least 11 million gallons were Agent Orange—making it the most widely used herbicide in the war. "Agent Orange (so named because of orange color stripes on the barrels used to store and ship the chemical) was a 50-50 mixture of the herbicides 2,4,5-T and 2,4-D." This mixture was contaminated with varying concentrations of numerous dioxins, including 2,3,7,8-tetrachlorodibenzo-pdioxin (TCDD) during the manufacturing process (National Academy of Sciences, Institute of Medicine, *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam*, Washington, DC, 1994, p. 27; and see, Alvin L. Young, *The History of the US Department of Defense Programs for the Testing, Evaluation, and Storage of Tactical Herbicides*, U.S. Department of Defense, December 2006, p. 8).

[9] National Academy of Sciences, Institute of Medicine, *Improving the Presumptive Disability Decision-Making Process for Veterans*, Washington, DC, 2008, p. 342.

VA's "Analysis of Presumptions of Service Connection," and IOM's "Improving the Presumptive Disability Decision-Making Process for Veterans" reports.

In order to provide some context to the discussion of presumptions, the first part of this report briefly discusses disability compensation and the establishment of service connection for veterans claiming disability compensation. The second part provides an overview of the legislative history of establishing presumptive service connection. Since most of the controversy about establishing presumptions of service connection is related to exposure to Agent Orange, the third part of this report examines the establishment of presumptions for conditions related to Agent Orange. This part also provides a historical overview leading up to the passage of the Agent Orange Act of 1991 (P.L. 102-4). The fourth part of the report discusses the passage of the Agent Orange Act, which set forth the current process for establishing presumptions. Lastly, it briefly discusses some options that may assist policy makers in their deliberations to make the presumptive decision-making process more transparent and equitable.

Disability Compensation for Veterans

The purpose of disability compensation is to assist currently disabled veterans whose injuries are connected to military service[10] Although a veteran may have been ill or sustained an injury while in service, the mere fact that this occurred is not compensable.[11] It should also be noted that not all persons who served in the military are considered veterans for purposes of veterans benefits.

Currently, there are five ways to establish that a disability is service-connected:[12]

1. Through direct service connection—that is, the facts, shown by evidence, establish that a particular injury or disease resulting in a disability was incurred while in service in the Armed Forces;[13]
2. Through aggravation during service—that is, a preexisting injury or disease will be considered to have been aggravated while in service in the Armed Forces;[14]
3. Through proximity—that is, a disability, which is proximately due to, or the result of a service-connected disease or injury which is itself considered to be service-connected.[15] An example would be a veteran developing cardiovascular disease due to a service-connected amputation of a lower limb.
4. Through a finding that the disability was caused by medical care or vocational rehabilitation provided by the Department of Veterans Affairs (VA)—disabilities

[10] 38 U.S.C. §§1110, 1131. These provisions deal with the basic entitlement for disability compensation.

[11] For more information, see CRS Report RL34626, *Veterans' Benefits: Disabled Veterans*, by (name redacted) et al.; and CRS Report R42324, *"Who is a Veteran?"—Basic Eligibility for Veterans' Benefits*, by (name redacted).

[12] The term "service-connected" means, with respect to disability or death, that such disability was incurred or aggravated, or that the death resulted from a disability incurred or aggravated, in line of duty in the active military, naval, or air service (38 U.S.C. §101).

[13] 38 C.F.R. §3.303.

[14] 38 C.F.R. §3.306.

[15] 38 C.F.R. §3.310.

caused by VA provided medical care or vocational rehabilitation are treated as if they are service-connected.[16]

5. Through the application of statutory presumptions—that is, certain diseases as established by law or regulation are considered to have been incurred in or aggravated by service in the Armed Forces even though there is no evidence of such disease during the period of service.[17]

VA has the authority to provide disability compensation to veterans by bypassing the first four criteria.[18] The next section discusses what a presumption is, and provides a brief legislative history of establishing presumptive service connection.

Presumptive Service Connection

What is a Presumption?

In the context of VA claims adjudication, a presumption relieves veterans of the burden to prove that a disability or illness was caused by a specific exposure that occurred during service in the Armed Forces. When a disease is designated as presumptively service-connected, the individual veteran does not need to prove that the disease was incurred during service. In other words, a presumption shifts the burden of proof concerning whether a disease or disability was caused or aggravated due to service from the veteran to the VA. The VA would have to demonstrate that some other intervening event caused the disability in order to rebut the presumption.

Often presumptions are applied to chronic diseases or illnesses that manifest after a period of time (sometimes many years) following service, and that may also occur in individuals who have never served. According to the VA's *Analysis of Presumptions of Service Connection:*

> Generally, a legal presumption is a procedural device that shifts the burden of proof by attaching certain consequences to the establishment of certain basic evidentiary facts. When the party invoking a presumption establishes the basic fact(s) giving rise to the presumption, the burden of proof shifts to the other party to prove nonexistence of the presumed fact. A presumption, as used in the law of evidence, is a direction that if fact A (e.g., manifestation within the specified period of a disease for which a presumption of service connection is available) is established, then fact B (service connection) may be taken as established, even where there is no specific evidence proving fact B (i.e., no medical evidence of a connection between the veteran's disease and the veteran's military service).[19]

[16] 38 U.S.C. §1151.

[17] 38 C.F.R. §3.307.

[18] 38 U.S.C. §501(a)(1).

[19] Department of Veterans Affairs (VA), "Analysis of Presumptions of Service Connection," a report to the Senate Committee on Veterans' Affairs, December 23, 1993, p. i.

Legislative History of Presumptions

The legislative history of veterans' disease presumptions dates back to 1921 when Congress, to ease the decision-making process in VA disability compensation adjudications, used its authority to establish service connection on a presumptive basis. Below is a synopsis of major legislation.

1920s-1940s

The first legislation that specifically established a presumption of service connection was the amendment of August 9, 1921, (P.L. 67-47) to the War Risk Insurance Act (P.L. 63-193). This amendment, among other things, established presumptions of service connection for active pulmonary tuberculosis and neuropsychiatric disease (later known as psychosis) occurring within two years of separation from active duty military service. Prior to the passage of P.L. 67-47, disability compensation for World War I veterans was payable only for a disability directly related to military service. Broadly, the intent of this liberalization legislation was that "as the period beginning with the end of the war lengthened it became increasingly difficult to establish service connection for some ailments, particularly tuberculosis and neuropsychiatric disease."[20] The amendments to the War Risk Insurance Act also gave the then Veterans Bureau authority to establish rules and regulations to carry out provisions in the act. This allowed the agency to promulgate regulations establishing presumption of service connection for certain diseases. As stated in VA's *Analysis of Presumptions of Service Connection:*

> Regulation No. 11 provided that chronic constitutional diseases, other than active pulmonary tuberculosis or neuropsychiatric disease, becoming manifest within one year following the date of separation from active service would be considered as incurred in service or aggravated by service unless there were affirmative evidence to the contrary or evidence establishing that some intercurrent disease or injury which is a recognized cause of the disorder was suffered between the date of separation from service and the onset of the chronic disease. [21]

The next major piece of legislation that established presumptions of service connection was the World War Veterans Act of 1924 (P.L. 68-242) enacted on June 7, 1924. This act made important changes to existing laws on presumptions related to tuberculosis and mental illness. Among other things, this act added the following three diseases to the list of presumptive diseases: dysentery (amebic) (tropical disease added as chronic disease); paralysis agitans (now known as Parkinson's disease); and encephalitis lethargica. Furthermore, this act removed requirements that a veteran must show diagnosis by a medical examination conducted by a medical officer of the then Veterans Bureau or duly qualified physician within the presumptive period. "This provision alone brought within the purview of the legislation thousands of veterans who [until then] had been unable to connect their disabilities with the service so as to be eligible for compensation and [medical care]." [22]

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[20] U.S. Congress, House Committee on Veterans' Affairs, *The Provision of Federal Benefits for Veterans, An Historical Analysis of Major Veterans Legislation, 1862-1954,* committee print, 84th Cong., 1st sess., H. Prt. No. 171, December 28, 1955 (Washington: GPO, 1955), p. 21.

[21] Department of Veterans Affairs (VA), "Analysis of Presumptions of Service Connection," a report to the Senate Committee on Veterans' Affairs, December 23, 1993, p. 10.

[22] U.S. Congress, House Committee on Veterans' Affairs, The Provision of Federal Benefits for Veterans, An Historical Analysis of Major Veterans Legislation, 1862-1954, committee print, 84th Cong., 1st sess., House Committee (continued...)

Between the passage of the World War Veterans Act of 1924 and the act to establish a presumption of service connection for chronic and tropical diseases (P.L. 80-748), several additions were made to the list of presumptive diseases through regulation and executive order. With the enactment of P.L. 80-748 on June 24, 1948, the chronic disease and tropical disease categories were significantly expanded through the codification of presumptive diseases that were previously established by regulation and executive order. Moreover, P.L. 80-748 authorized the VA to add additional chronic diseases to the list. In leading up to the passage of P.L. 80-748, the Administrator of VA asserted that the VA rather than Congress was better suited to decide which disease or disease conditions should be made presumptive:

> It is believed that extreme care should be exercised in augmenting the list of diseases to be afforded the presumption. It is the view of the Veterans' Administration that this can best be accomplished by continuing the existing Veterans Regulation No. 1(a), part I, paragraph I(c), and administrative authority to make the medical and adjudicatory determinations.
>
> Determination governing the selection of diseases to be included under the regulation is essentially one of an involved medical and adjudicatory nature. If a list of diseases is provided by statute it is suggested that the consideration of additions to the present list or subsequent additions to any statutory list would require detailed technical considerations by the Congress which in the opinion of the Veterans' Administration can best be handled administratively. Considering all the facts and circumstances, it is believed that your committee will desire to consider the inadvisability of introducing statutory presumptions of service connection for specific diseases.[23]

1950s-1980s

With the passage of the Veterans Benefits Act of 1957 (P.L. 85-56), Congress codified all laws affecting veterans benefits including the existing list of presumptions and expanded this list by incorporating various presumptions of chronic diseases and disease categories that had been established by regulation and were in effect at that time. At the time P.L. 85-56 was enacted on June 17, 1957, there were 40 chronic diseases or disease categories and 17 tropical diseases that were presumptively service-connected. The 1960s did not see any significant legislative or regulatory changes affecting presumptions of service connection.

The next major legislative change occurred with the enactment of P.L. 91-376 in August 1970. This law established a presumption of service connection for seven categories of diseases and conditions for any veteran held as a prisoner of war (POW) in World War II, the Korean conflict, or the Vietnam War, and who suffered from dietary deficiencies, forced labor, or inhumane treatment in violation of the terms of the Geneva Conventions of July 27, 1929, and August 12, 1949.

It should be noted that up until the late 1970's all the statutory presumptions specified a time period in which a disease or illness needed to have manifested itself. Typically this period was up to one year after separation from active service.

(...continued)

Print No. 171, December 28, 1955 (Washington: GPO, 1955), p. 23.

[23] U.S. Congress, Senate Committee on Finance, *Veterans Chronic and Tropical Diseases–Presumption of Service Connection*, report to accompany H.R. 3889, 80th Cong., June 7, 1948.

In August 1981, Congress passed the Former Prisoner of War Benefits Act of 1981 (P.L. 97-37). This act, among other things, modified the list of statutory presumptions associated with POW status and also changed the presumptive period for eligibility. The Veterans' Compensation and Program Improvements Amendments of 1984 (P.L. 98-223); the Veterans' Benefits Improvements and Health Care Authorization Act of 1986 (P.L. 99-576); and the Veterans' Benefits and Services Act of 1988 (P.L. 100-322) expanded the list of diseases in former POWs for which a presumption of service connection was made. Prior to the passage of the Veterans' Health Care, Training and Small Business Loan Act of 1981 (P.L. 97-72), veterans who complained of Agent Orange-related illnesses were at the lowest priority for treatment at VA medical facilities because these conditions were not considered service-connected. P.L. 97-72 elevated Vietnam veterans' priority status for health care at VA facilities by recognizing a veteran's own report of exposure as sufficient proof to receive medical care unless there was evidence to the contrary.

After taking into consideration the "apprehension and concern among some Vietnam veterans and their families…to the alleged ill-health effects among some Vietnam veterans…to exposure to the dioxin in Agent Orange,"[24] Congress passed the Veterans' Dioxin and Radiation Exposure Compensation Standards Act of 1984 (P.L. 98-542). The act required the VA to develop regulations for disability compensation for Vietnam veterans exposed to Agent Orange. Veterans seeking compensation for a condition they thought to be related to herbicide exposure had to provide proof of a service connection that established the link between the exposure and the disease onset. P.L. 98-542 also authorized disability compensation payments to Vietnam veterans for the skin condition chloracne, which was linked to Agent Orange exposure in numerous epidemiologic studies.[25] This law also established a program to provide disability compensation to radiation-exposed veterans who participated in the U.S. atmospheric atomic tests or in the U.S. occupation of Hiroshima and Nagasaki, Japan. Similar to veterans exposed to Agent Orange, these so-called atomic veterans also had to provide evidence of exposure to receive compensation.

In response to atomic veterans' complaints about the difficulty of getting compensation under P.L. 98-542, Congress in 1988 enacted the Radiation-Exposed Veterans' Compensation Act (P.L. 100-321) which established a presumption of a service connection for 13 specified types of cancer. That list was subsequently expanded, first by legislation, later through the VA administrative action, to 21 cancers.[26]

1990s-2000

In 1991, the Agent Orange Act (P.L. 102-4) established for the first time a presumption of service connection for diseases associated with herbicide exposure (discussed in greater detail below). Under the Agent Orange Act, veterans seeking disability compensation for diseases they thought to be associated with herbicides were no longer required to provide proof of exposure. P.L. 102-4 authorized the VA to contract with the IOM to conduct a scientific review of the evidence linking certain medical conditions to herbicide exposure. According to an article published in 2005 in the

[24] U.S. Congress, House Committee on Veterans' Affairs, *Agent Orange and Atomic Veterans Relief Act,* Report to Accompany H.R. 1961, 98th Congress, 2nd sess., H.Rept. 98-592.

[25] National Academy of Sciences, Institute of Medicine, *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam*, Washington, DC, 1994, p. 678.

[26] For further information, see CRS Report RL33927, *Selected Federal Compensation Programs for Physical Injury or Death*, coordinated by (name redacted) and (name redacted).

Journal of Law and Policy: "The [IOM] process has become an essential step in ensuring that new service connection presumptions command scientific credibility."[27]

The Veterans' Radiation Exposure Amendments of 1992 (P.L. 102-578) amended P.L. 100-321 by adding two more cancers to the presumptive list. This expansion of the list of cancers was based on the "Biological Effects of Ionizing Radiation V" (BEIR V) report by the National Academy of Sciences.[28] The law also repealed the disability compensation requirement that diseases suffered by radiation-exposed veterans must be manifested within 40 years of exposure.

During the mid-1990's, Congress examined disability compensation issues pertaining to Persian Gulf War[29] veterans. In November 1994, Congress enacted the Persian Gulf War Veterans' Benefits Act (P.L. 103-446), allowing the VA to pay compensation benefits to veterans for Gulf War–related disabilities caused by undiagnosed illnesses. This act also codified the VA's regulatory presumptions based on exposure to herbicides for these types of cancer: Hodgkin's disease, multiple myeloma, and respiratory cancers; and porphyria cutanea tarda, a metabolic disease (must occur within one year of exposure).

In 1998, Congress enacted the Persian Gulf War Veterans Act of 1998 (P.L. 105-277), and the Veterans Programs Enhancement Act of 1998 (P.L. 105-368). Similar to the Agent Orange presumptive program, these laws mandated regular and thorough reviews of the scientific and medical literature relevant to the health of Gulf War veterans by the IOM.

The Veterans Education and Benefits Expansion Act of 2001 (P.L. 107-103) expanded the definition of "qualifying chronic disability" to include 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."[30] Furthermore, the Veterans Benefits Act of 2003 (P.L. 108-183) provided a presumption of service connection for cold weather injuries, traumatic arthritis, and certain psychiatric disabilities in former POWs, without regard to length of interment. The Veterans' Housing Opportunity and Benefits Improvement Act of 2006 (P.L. 109-233) added atherosclerotic heart disease or hypertensive vascular disease (including hypertensive heart disease) and their complications (including myocardial infarction, congestive heart failure and arrhythmia) and stroke and its complications to the list of diseases presumed to be service-connected in former POWs.

With passage of the National Defense Authorization Act, FY2008 (P.L. 110-181), Congress established a presumption of service connection for purposes of VA medical care for any veteran of the Persian Gulf War who develops an active mental illness (other than psychosis) if such veteran develops such disability: (1) within two years after discharge or release from the active military, naval, or air service; and (2) before the end of the two-year period beginning on the last day of the Persian Gulf War.

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[27] Mark Brown, "The Role of Science in Department of Veterans Affairs Disability Compensation Policies for Environmental and Occupational Illnesses and Injuries," *Journal of Law and Policy*, vol-13, (2005).

[28] Committee on the Biological Effects of Ionizing Radiation (BEIR), National Research Council, is part of the National Academy of Sciences.

[29] The term "Persian Gulf War" means the period beginning on August 2, 1990, and ending on the date thereafter prescribed by Presidential proclamation or by law (38 U.S.C. §101).

[30] Subsection 202 (a) of the Veterans Education and Benefits Expansion Act of 2001 (P.L. 107-103), December 27, 2001.

On October 10, 2008, the Veterans' Benefits Improvement Act of 2008 (P.L. 110-389) was enacted. Section 106 of this law established a presumption of service connection for osteoporosis for those veterans that the VA determines to have post-traumatic stress disorder (PTSD). It should be noted that presumptive illnesses for POWs fall into two lists.[31] The first list requires no minimum internment period and includes diseases associated with mental trauma and acute physical trauma. Therefore, such diseases are presumptively service-connected for POWs even with a single day of captivity. The second list requires a minimum 30-day internment period, and includes diseases associated with nutritional deficiencies such as osteoporosis. Section 106 of P.L. 110-389 provides a presumptive service connection for osteoporosis for those veterans with PTSD without the 30-day minimum internment requirement.[32]

Establishment of Agent Orange Presumptions

Nearly 40 years after the American military presence in Vietnam[33] ended, the controversy surrounding Agent Orange and its possible association with various illnesses of Vietnam veterans and their offspring continues unabated.[34] In general, no other presumption of service connection has had so many congressional hearings, or has been so extensively studied and debated as has establishment of presumption of service connection for diseases associated with exposure to Agent Orange. Therefore, this section provides a brief legislative history leading up to the passage of the Agent Orange Act in 1991 (P.L. 102-4). It is followed by a discussion of the Agent Orange Act of 1991.

Historical Context: 1977-1991

The dense jungles of South Vietnam allowed Communist troops to engage in guerrilla warfare during the Vietnam War.[35] On December 4, 1961, President Kennedy authorized the Secretary of Defense to test the military effectiveness of defoliation.[36] This defoliation program in Vietnam was called "Operation Ranch Hand." The first major large-scale spraying operation, to clear enemy infiltration routes, began over the mangrove forests in the Ca Mau peninsula in the southernmost region of the Mekong Delta in September 1962.[37] From 1962 to 1971, the U.S. Air Force sprayed nearly 19 million gallons of herbicides in Vietnam, of which at least 11 million gallons were Agent Orange—making it the most widely used herbicide in the war.[38]

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[31] 38 U.S.C. §1112(b); 38 C.F.R. §3.309(c).

[32] Department of Veterans Affairs, "Presumption of Service Connection for Osteoporosis for Former Prisoners of War," 74 *Federal Register* 44288, August 28, 2009.

[33] The term "Vietnam era" means the following: (1) The period beginning on February 28, 1961, and ending on May 7, 1975, in the case of a veteran who served in the Republic of Vietnam during that period; (2) the period beginning on August 5, 1964, and ending on May 7, 1975, in all other cases (38 U.S.C. §101).

[34] Vietnam Veterans of America, *Vietnam Veterans of America Legislative Agenda & Policy Initiatives: 113th Congress*, February 2014, http://vva.org/GovAffairs/VVALegAgenda.pdf.

[35] Wilbur J. Scott, "Competing Paradigms in the Assessment of Latent Disorders: The Case of Agent Orange," *Social Problems*, vol. 35, no. 2 (April 1988), p. 146.

[36] National Academy of Sciences, Institute of Medicine, *Characterizing Exposure of Veterans to Agent Orange and Other Herbicides Used in Vietnam*, Scientific Considerations Regarding a Request for Proposals for Research, Washington, DC, 1997, p. 16.

[37] Ibid.

[38] The different types of herbicide used by U.S. forces in Vietnam were identified by a code name referring to the color (continued...)

In 1977, Congress first became aware of a possible link between disabilities in Vietnam veterans and exposure to Agent Orange when a VA employee charged that Agent Orange had caused a wide variety of disabling conditions and diseases.[39] Since that time Vietnam veterans have attributed various illnesses to Agent Orange exposure, including skin conditions, cancers, chronic diseases, birth defects in children, and numerous other ailments. Since the late 1970s, veterans have urged the VA to provide medical treatment for these disorders and many have filed for disability compensation. Initially, the Department of Defense (DOD) maintained that only a limited number of U.S. military personnel could be positively identified as having been exposed to Agent Orange in South Vietnam (i.e., the crews of aircraft that were used to spray herbicides). However, following the publication of a 1979 General Accounting Office (GAO) report documenting ground troop exposure, DOD acknowledged that ground troops were also exposed to Agent Orange.[40] Likewise, the VA consistently took the position that since the long-term exposure to Agent Orange was unclear, and because of scientific uncertainty of the evidence linking Agent Orange to specific illnesses, it could not compensate veterans who alleged that exposure to Agent Orange had caused their diseases. In testifying before the House Committee on Veterans' Affairs, the then Administrator of Veterans Affairs stated:

> Unless or until some such latent effects of Agent Orange or its derivative components are scientifically documented there are intrinsic limitations to VA's authority to allow these [Agent Orange] claims under current law. Though I cannot emphasize enough our policy to resolve reasonable doubt as to service incurrence of disabilities in favor of claimants, there is currently no medical basis upon which adverse health effects of late-post-exposure onset can be reasonably tied to Agent Orange.[41]

In general, in the early days of the Agent Orange controversy issues fell into three categories:

1. compensation for disabilities possibly related to exposure;
2. answers to questions about the health effects of exposure to Agent Orange; and
3. access to health care for diseases that might be related to the exposure.[42]

From 1979 onward, Congress addressed these issues through various legislative measures. In 1979, in response to concerns expressed regarding possible delayed adverse health effects as a

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(...continued)

of the band around the 55-gallon drum that contained the chemical. These included Agents Orange, White, Blue, Purple, Pink, and Green. From 1962 to 1965, small quantities of Agents Purple, Pink, and Green were used in the defoliation program (National Academy of Sciences, Institute of Medicine, *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam*, Washington, DC, 1994, p. 27).

[39] U.S. Congress, House Committee on Veterans' Affairs, *Agent Orange in Vietnam: Report on Mission to Vietnam*, committee print, prepared by the Honorable Don Edwards, Member, House Veterans' Affairs Committee, to the Committee on Veterans Affairs, on his visit to Vietnam, 98th Cong., 2nd sess., January 31, 1984 (Washington: GPO, 1984), p. 1. Also see, National Academy of Sciences, Institute of Medicine, *Veterans and Agent Orange: Health Effects of Herbicides Used in Vietnam*, Washington, DC, 1994, p. 33.

[40] U.S. General Accounting Office, *U.S. Ground Troops in South Vietnam Were in Areas Sprayed with Herbicide Orange*, FPCD 80-23, 1979, http://archive.gao.gov/f0302/110930.pdf.

[41] Statement of Max Cleland, Administrator of Veterans' Affairs in U.S. Congress, House Committee on Veterans' Affairs, Subcommittee on Medical Facilities and Benefits, *Oversight Hearing to Receive Testimony on Agent Orange*, 96th Cong., 2nd sess., February 25, 1980 (Washington: GPO, 1980), p. 11.

[42] U.S. Congress, Senate Committee on Veterans' Affairs, *Veterans' Agent Orange Exposure and Vietnam Service Benefits Act of 1989*, Report to Accompany S. 1153, 101st Cong., 1st sess., July 24, 1989 (Washington: GPO, 1989), p. 25.

result of exposure to Agent Orange, Congress enacted the Veterans Health Programs Extension and Improvement Act of 1979 (P.L. 96-151). It mandated the VA to conduct an epidemiological study of the possible health effects in veterans who served in Vietnam of exposure to dioxin as found in herbicides including Agent Orange. The scope of that study was expanded by Section 401 of the Veterans' Health Care, Training and Small Business Loan Act of 1981 (P.L. 97-72), which authorized the inclusion of an evaluation of the impact on the health of Vietnam veterans of exposure to other environmental factors which may have occurred in Vietnam. In 1983, the VA transferred to Centers for Disease Control and Prevention (CDC) the responsibility for this entire study.[43] Moreover, P.L. 97-72 authorized the Department to provide certain health-care services to any veteran of the Vietnam era who while serving in Vietnam may have been exposed to dioxin or to a toxic substance in an herbicide or defoliant used for military purposes. P.L. 97-72 allowed veterans to receive health care even if there was insufficient medical evidence to conclude that their medical condition was associated with exposure to Agent Orange. However, the VA did not acknowledge a link between Agent Orange and those diseases, with the exception of chloracne.[44]

According to the *VA's Analysis of Presumptions of Service Connection:*

> Congress' rationale in enacting this legislation, as it related to [Agent Orange] dioxin, was that: [U]ntil the scientific community [is] able to make a determination as to the possible cause and effect relationship of the toxic herbicides utilized as defoliants in the Republic of Vietnam during the Vietnam conflict, the Veterans' Administration should do everything possible to provide the [health] care to such veterans. When a doubt exists, the doubt should be resolved in favor of the veteran.[45]

In addition to the scientific study mandated in P.L. 96-151 and expanded in P.L. 97-72, numerous scientific studies were conducted related to Agent Orange, and the Vietnam experience as a whole, involving the Veterans' Administration, the Environmental Protection Agency (EPA), and the Departments of Health and Human Services, Defense, and Agriculture.

However, the issue of whether to provide disability compensation to veterans exposed to Agent Orange was not taken up by Congress until 1983. In the 98th Congress several measures were introduced[46] that would have created presumptions of service connection for particular diseases and/or directed VA to conduct rulemaking on the subject of presumptions.[47] Several hearings were held in which witnesses testified and provided their views on the proposed measures. One bill, the Vietnam Veterans Agent Orange Relief Act (H.R. 1961) would have allowed for the presumption of service connection for three diseases: chloracne (a severe form of acne), soft tissue sarcomas (cancers), and porphyria cutanea tarda (disorder characterized by thinning and blistering of the skin in sun-exposed areas). The measure would have also permitted the Department to add other

[43] U.S. Congress, Senate Committee on Veterans' Affairs, *Veterans Agent Orange Exposure and Vietnam Service Benefits Act of 1989*, report to accompany S. 1153, 101st Cong., 1st sess., July 24, 1989, S.Rept. 101-82 (Washington: GPO, 1989), p. 27.

[44] Wilbur J. Scott, "Competing Paradigms in the Assessment of Latent Disorders: The Case of Agent Orange," *Social Problems*, vol. 35, no. 2 (April 1988), p. 155.

[45] Department of Veterans Affairs (VA), "Analysis of Presumptions of Service Connection" a report to the Senate Committee on Veterans' Affairs, December 23, 1993, p. 65.

[46] S. 374, 98th Cong., 1st Sess. (1983); S. 786, 98th Cong.,1st Sess. (1983); S. 991, 98th Cong., 1st Sess. (1983); H.R. 1961, 98th Cong., 1st. Sess. (1983); and S. 1651, 98th Cong., 1st Sess. (1983).

[47] Department of Veterans Affairs (VA), "Analysis of Presumptions of Service Connection" a report to the Senate Committee on Veterans' Affairs, December 23, 1993, p.66.

medical conditions through regulations upon determination that Agent Orange may have caused them. H.R. 1961 contained a sunset clause that would have terminated the presumption upon completion of the study mandated by the Veterans Health Programs Extension and Improvement Act of 1979 (P.L. 96-151). Dozens of witnesses testified with widely divergent views on the bill.[48] The then Administrator of the VA opposed the measure stating that

> The compensation program must be attuned to justifiable conclusions about the connection between Agent Orange exposure and disorders possibly arising from that exposure. At the same time we must do our best to avoid taking steps that have the potential for undermining the program's credibility and legitimacy because of inconclusive scientific evidence…. In view of the current state of scientific findings, enactment [of H.R. 1961] would compromise the integrity of the compensation program and engender unfounded fears among Vietnam veterans that lethal illnesses may yet befall them as a result of having answered the duty's call. [49]

On January 30, 1984, the House passed H.R. 1961, as amended, to provide for VA disability compensation, a presumption of service connection for the following three diseases: soft tissue sarcoma, porphyria cutanea tarda, and chloracne. As under the original bi1l, benefits would terminate one year after the CDC epidemiological study, mandated by the Veterans Health Programs Extension and Improvement Act of 1979 (P.L. 96-151), was submitted to Congress. The Senate passed a different version of H.R. 1961 on May 22, 1984. The Senate-passed version did not provide compensation to veterans exposed to Agent Orange. Rather, the Senate bill addressed the process by which the VA handles Agent Orange by establishing rulemaking guidelines to be used by the VA in adjudicating these claims. The Senate bill also provided for judicial review for both the rulemaking process and individual veterans' compensation claims. The final version of H.R. 1961 was enacted into law on October 24, 1984, as the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, (P.L. 98-542).

As stated previously, P.L. 98-542 required the VA to prescribe regulations regarding the determination of service connection of disabilities of veterans who were exposed to herbicides containing dioxin while serving in Vietnam during the Vietnam era. Section 6 of the statute established the Veterans' Advisory Committee on Environmental Hazards and charged the Advisory Committee to provide the VA with evaluations of pertinent scientific studies relating to possible adverse health effects of exposure to dioxin and with recommendations for legislative or administrative action. Section 5(b) of the statute directed VA to issue regulations establishing guidelines ''governing the evaluation of the findings of scientific studies relating to the possible increased risk of adverse health effects of exposure to herbicides containing dioxin or of exposure to ionizing radiation.'' Section 5(b) further provided that the referenced evaluations of scientific studies would be made by the Administrator (now Secretary) of Veterans Affairs after receiving the advice of the Advisory Committee. Finally, Section 5(b) provided that, under the prescribed regulations, VA would make determinations as to whether, and in what circumstances, service connection would be granted for particular diseases based on a finding that a disease is associated with exposure to herbicides containing dioxin.

As this section has illustrated, the attitudes and responses of both Congress and the VA evolved over time as more information regarding Agent Orange, exposure to Agent Orange, and the long

[48] U.S. Congress, House Committee on Veterans' Affairs, *Agent Orange and Atomic Veterans Relief Act*, report to accompany H.R. 1961, 98th Cong., 2nd sess., January 25, 1984, p. 4.

[49] Ibid, p.16 and p. 20.

range health effects became available. Congress initiated hearings to explore the impact of Agent Orange exposure on the Vietnam veterans' population. In the early days of congressional inquiry, the VA was reluctant to recognize a nexus between Agent Orange exposure and certain illnesses in the veteran population. However, this position was modified as more information became available, and as veterans sought compensation for certain illnesses. In attempting to respond to these concerns, Congress directed the VA to conduct a study of possible delayed adverse health effects in 1979 (Veterans Health Programs Extension and Improvement Act of 1979, P.L. 96-151, §307, 93 Stat. 1092, 1097).

In addition to authorizing the VA to conduct a study on the health effects of Agent Orange exposure, Congress in P.L. 97-72 directed the VA to provide priority health care to Vietnam veterans who were suffering from illnesses believed to be caused by exposure to Agent Orange in Vietnam. Congress directed the VA to provide priority healthcare to Agent Orange-exposed Vietnam veterans on an interim basis until the results of the study authorized by P.L. 96-151 became available. In 1984, five years after authorizing the Agent Orange study in P.L. 96-151, Congress enacted legislation requiring the VA to establish guidelines for deciding disability compensation claims brought by Vietnam veterans exposed to Agent Orange. The new law also required the VA to create and consult with a scientific advisory committee on the adverse health effects of dioxin exposure and, for the first time, mandated compensation payments for Vietnam veterans suffering from two diseases, chloracne and porphyria cutanea tarda, for a two-year period.[50]

Agent Orange Act of 1991 (P.L. 102-4)

Agent Orange legislation in the 99th Congress mainly dealt with studies affecting the health of Vietnam veterans rather than compensation issues. The 100th Congress also continued to generally address the same issues raised in previous Congresses, specifically the on-going issue of

[50] Veterans' Dioxin and Radiation Exposure Compensation Standards Act, (P.L. 98-542) As an illustration of the uncertainty surrounding the eventual codification of presumptive Agent Orange disorders, Representative Tom Ridge expressed this concern:

> One of the concerns I have, I guess, is that if we look [for scientific studies] to establish with an absolute degree of medical or scientific certainty the nexus between exposure to Agent Orange and the variety of maladies that may result from that exposure, we may indeed wait 40 or 50 years [to establish presumptive Agent Orange disorders] in spite of the efforts of the VA, in spite of the efforts of other countries, in spite of all the tests we run.

Scientific Research on the Health of Vietnam Veterans Hearing on H.R. 3486 Before the Subcomm. on Hospitals and Health Care of the H. Comm. on Veterans' Affairs, 100th Cong. 16 (1988) (statement of Representative Thomas J. Ridge, Member, House Subcommittee on Hospitals and Health Care). Similarly, Senator John Kerry noted in written testimony before the subcommittee:

> I believe that it is nothing less than wrong on the facts to tell Vietnam veterans that we cannot compensate for diseases which were caused by their exposure to Agent Orange in Vietnam. It is offensive to veterans to tell them that there is not enough "scientific evidence" to justify compensation … Our legislation [S. 1787] would establish a presumption of service connection for two of these diseases, non-Hodgkins lymphoma and lung cancer. In addition [S. 1787] would ask the National Academy of Sciences to review the evidence of the scientific studies and compile a list of other diseases which are linked to suppression of the immune system, which may be linked to dioxin or Agent Orange exposure. If appropriate, these diseases would be added and a presumption of service connection [would be] created.

Ibid. at 67-71 (written testimony of Senator John Kerry before House Subcommittee on Hospitals and Health Care).

determining if health problems among Vietnam veterans exposed to Agent Orange can be attributed to their exposure and how to make that determination.

Despite the passage of the Veterans' Dioxin and Radiation Exposure Compensation Standards Act, (P.L. 98-542), there were concerns among Vietnam veterans about the various scientific studies that were being conducted on the human health effects associated with herbicide exposure during Vietnam service. Furthermore, in 1989, in the case of *Nehmer et al. v. United States Veterans' Administration et a1*.[51] "the court held that VA had erred in two key ways in carrying out the requirement in P.L. 98-542. First, by utilizing too high a standard for determining if there is a linkage between exposure to Agent Orange and a subsequent manifestation of a disease and, second, by failing to give the benefit of the doubt to veterans in prescribing the standards in the regulations for VA to use in deciding whether to provide service connection for any specific disease."[52] In response to these concerns in 1991, after numerous hearings, Congress enacted the Agent Orange Act of 1991 on February 6, 1991(P.L. 102-4). The law codified presumption of service connection for chloracne, non-Hodgkin's lymphoma, and soft tissue sarcoma (other than osteosarcoma, chondrosarcoma, Kaposi's sarcoma, or mesothelioma) associated with Agent Orange. This law also transferred the responsibility of reviewing the scientific literature concerning the association between herbicide exposure during Vietnam service and each health outcome suspected to be associated with such exposure from the VA's Advisory Committee on Environmental Hazards to the National Academy of Sciences.

Moreover, P.L. 102-4 established an entirely new process for evaluating the health effects of exposure to herbicides containing dioxin and for establishing presumptions of service connection for diseases associated with such exposure. The Agent Orange Act requires the Secretary of the VA to conduct new rulemaking proceedings to determine which diseases are sufficiently associated with exposure to Agent Orange so that veterans with approved diseases receive a presumption of service connection. The law states that

> (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.
>
> (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.[53]

[51] Nehmer v. U.S. Veterans Admin., 712 F.Supp. at 1420, 1423 (N.D. Cal. 1989).

[52] U.S. Congress, Senate Committee on Veterans Affairs, *Veterans' Agent Orange Exposure and Vietnam Service Benefits Act of 1989*, report to accompany S. 1153, 101st Cong., 1st sess., July 24, 1989 (Washington: GPO, 1989), p. 35.

[53] 38 U.S.C. §1116 (b).

The Agent Orange Act directed the Secretary to enter into an agreement with the National Academy of Sciences to perform the services as required by the act, and under that agreement, the Academy was to "review and summarize the scientific evidence, and assess the strength concerning the association between exposure to [dioxin] ... and each disease suspected to be associated with such exposure." Moreover, the Academy was to submit its first report no later than 18 months after the enactment of the Agent Orange Act, and, thereafter submit "periodic written reports ... at least once every two years (as measured from the date of the first report)." Furthermore, under the Agent Orange Act, when the Secretary received a report from the Academy, he was required to determine within 60 days "whether a presumption of service connection is warranted for each disease covered by the report," and if he determined that a "presumption is warranted," he was required to issue proposed regulations within 60 days setting forth his determination and to issue final regulations within 90 days after proposing them.[54]

Finally, the Agent Orange Act, as originally enacted, set forth a sunset date for the operation of the provisions that required the Secretary to issue regulations designating service-connected diseases in response to the scientists' reports.[55] The sunset date would be 10 years after the first day of the fiscal year in which the Academy transmitted its first report to the Secretary, and as the first report was transmitted on July 27, 1993, the original effective sunset date was September 30, 2002.

In 2001, 10 years after the passage of the Agent Orange Act, Congress enacted the Veterans Education and Benefits Expansion Act of 2001 (P.L. 107-103). This act amended the sunset date and extended the Secretary's authority to issue regulations designating service connected ailments for another 13 years.[56] Since 1994, as required by law, IOM has issued eight reports concerning associations between health outcomes and exposure to Agent Orange. In addition, IOM has issued three special reports concerning Agent Orange and Type 2 diabetes, Agent Orange and acute myelogenous leukemia in offspring of Vietnam veterans, and the length of presumptive period for association between exposure to Agent Orange and respiratory cancer.

In sum, the Agent Orange Act codified presumptions of service connection for chloracne, non-Hodgkin's lymphoma, and soft tissue sarcoma associated with Agent Orange exposure in Vietnam. With respect to the VA's disability claims process, these presumptions helped to streamline the claims process by allowing Vietnam veterans to establish the second element (in-service occurrence or aggravation of disease) and third element (nexus between in-service occurrence/aggravation of disease and current disease) of the prima facie case for disability compensation, in spite of "[the absence] of evidence of such disease during the period of such service."[57] Additionally, the Agent Orange Act established an entirely new process for evaluating the health effects of exposure to dioxin and other chemical compounds in herbicides and for establishing presumptions of service connection for diseases associated with such exposure. Congress, however, expressly provided that such presumptions created by the VA Secretary pursuant to his authority under the Agent Orange Act may be rebutted by the VA with affirmative

[54] 38 U.S.C. §1116(c)(1)(A), (c)(2).

[55] 38 U.S.C. §316(e), 38 U.S.C.A. §1116(e) (1992).

[56] As a result, the provisions in 38 U.S.C. §1116(b), (c) and (d) have remained in effect since 1991, and will continue to be effective until September 30, 2015, or until such other time as Congress shall establish, should it enact another extension.

[57] 38 U.S.C. §1116(a)(1)(B). *See* Darby v. Brown, 10 Vet.App. 243, 246 (CAVC 1997) (where claimant satisfies requirements of 38 U.S.C. §1116, "the requirements for evidence of both service incurrence and causal nexus are satisfied").

evidence establishing that (1) the veteran was not exposed to Agent Orange during service; (2) the veteran's current disability was triggered by an "intercurrent injury or disease" suffered after separation from service; or (3) the veteran's current disease was caused by his own "willful misconduct."[58] **Appendix A** provides a list of presumptive disease conditions that have been established by the VA and Congress based on exposure to Agent Orange. The next section provides an overview of the current process for establishing presumptions for Agent Orange related conditions as well as for other emerging environmental exposures in veterans.

Current Process for Presumptive Disability Decisions[59]

The current process for establishing presumptive disability decisions involves four major entities: Congress, the VA, the Institute of Medicine (IOM), and other stakeholders, which include—among others—veterans service organizations (VSOs) (See **Figure 1**). As discussed earlier, from time-to-time, Congress has exercised its power to create presumptive disability decisions through legislation but has also delegated authority to the Secretary of the VA to establish presumptions in certain instances.[60] Some presumptive decisions have been challenged in court, leading to a revision of the statutes governing the administration of disability compensation by the VA. For example, in the Veterans' Dioxin and Radiation Exposure Compensation Standards Act of 1984 ("Dioxin Act"), Congress authorized the Secretary of the VA to determine which diseases warranted a presumption of service connection relating to Agent Orange exposure during the Vietnam War.[61] Pursuant to the Dioxin Act, the Secretary promulgated a regulation, which provided (1) a presumption of Agent Orange exposure for any veteran who served in Vietnam and (2) a presumption that a single disorder—chloracne—would be considered service connected and thus, eligible for disability compensation.[62] Because the Secretary determined that there was no "cause and effect" relationship between Agent Orange exposure and two other diseases, the Secretary declined to provide any other disease (besides chloracne) with a presumption of service connection.[63]

As stated previously, in 1989, a federal district court invalidated this regulation because "…although Congress [pursuant to Dioxin Act] intended the VA to predicate service connection upon a finding of a significant statistical association between dioxin exposure and various diseases, the VA had erroneously required proof that a causal relationship existed."[64]

[58] 38 U.S.C. §1113(a). *See* Darby v. Brown, 10 Vet.App. at 246-247 (*rebutting* presumption of service connection provided by 38 U.S.C. §1116 and *denying* disability compensation claim pursuant to 38 U.S.C. §1113(a)).

[59] Major portions of this section were drawn from National Academy of Sciences, Institute of Medicine, *Improving the Presumptive Disability Decision-Making Process for Veterans*, Washington, DC, 2008.

[60] 38 U.S.C. §501(a).

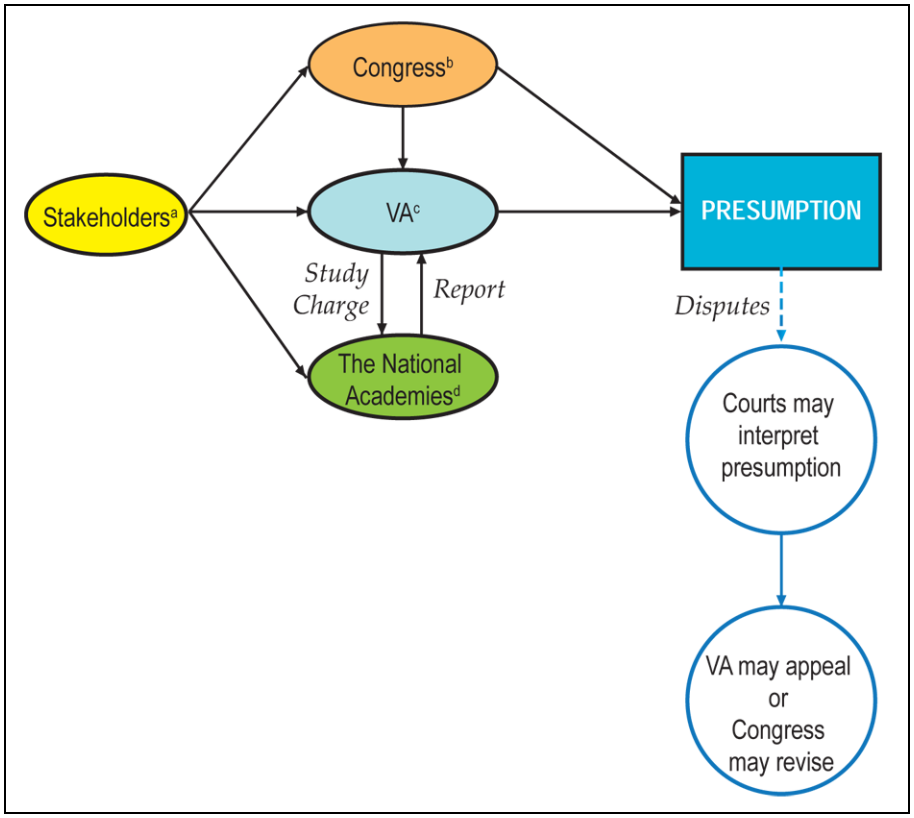
[61] P.L. 98-542, 98 Stat. 2725 (1984).

[62] 38 C.F.R. §§3.311a(b), 3.311a(c) (1988).

[63] 38 C.F.R. §3.311(d) (1988).

[64] Nehmer v. U.S. Dept. of Veterans Affairs, 494 F.3d 846, 850 (9th Cir. 2007) *quoting* Nehmer v. U.S. Veterans Admin., 712 F.Supp. at 1420, 1423 (N.D. Cal. 1989).

Figure 1. Roles of the Participants Involved in the Presumptive Disability Decision-Making Process for Veterans



Source: From 'FIGURE S-1' in National Academy of Sciences, Institute of Medicine, *Improving the Presumptive Disability Decision-Making Process for Veterans*, Washington, DC, 2008, p. 11.

Notes:

a. Stakeholders include (but are not limited to) veterans service organizations (VSOs), veterans, advisory groups, federal agencies, and the general public; these stakeholders provide input into the presumptive process by communicating with Congress, VA, and independent organizations (e.g., the National Academies).

b. Congress has created many presumptions itself; in 1921, Congress also empowered the VA Secretary to create regulatory presumptions; on several occasions in the past, Congress has directed VA to contract with an independent organization (e.g., the National Academies) to conduct studies and then use the organization's report in its deliberations of granting or not granting regulatory presumptions.

c. VA can establish regulatory presumptions; VA sometimes contracts with the National Academies to conduct studies and uses the organization's report in its deliberations of granting or not granting regulatory presumptions.

d. The National Academies (Institute of Medicine and National Research Council) submit reports to VA based on requests and study charges from VA.

VA Presumptive Disability Decisions

A presumption established through legislation usually follows a process through which individual constituents seeking redress from a denial of disability benefits from the VA bring their issues to the attention of Congress. VSOs representing a contingent of veterans or, on rare occasions, executive branch agencies have also lobbied Congress to consider certain presumptions. Through

a 1921 amendment to the War Risk Insurance Act (P.L. 63-193), Congress also granted the Secretary of the VA authority to establish regulatory presumptions (P.L. 67-47).

Role of the Institute of Medicine (IOM)

As previously noted, the Agent Orange Act of 1991 established a new process for evaluating the health effects of exposure to herbicides containing dioxin and for establishing presumptions of service connection for diseases associated with such exposure. P.L. 102-4 directed the Secretary to enter into an agreement with the National Academy of Sciences to review and summarize available scientific evidence regarding an association between diseases and exposure to herbicides used in Vietnam. This agreement, in turn, led to a model by which additional studies could be conducted, a model which is still used today. The Institute of Medicine, established in the 1970s as the health arm of the National Academy of Sciences, provides VA with reports that describe the strength of evidence with respect to linkage of agents and specific health concerns. VA uses this evidence and other information in internal decision making to decide whether a presumption will be made.[65] Congress requires the VA to respond after receiving an IOM report with a determination as to whether VA will make a service connection for particular health outcomes on a presumptive basis.

The National Academies convenes panels of its own members and other experts to conduct studies using a systematic process involving open public meetings, the submission of information by outside parties, reviews of the literature, and investigations of committee members and staff. Committee deliberations are closed to the public as well as to study sponsors. Report drafts are subject to an external peer review process overseen by the National Academies.[66]

With respect to studies pertaining to possible presumptions, a new IOM committee is convened. As of 2009, the IOM had completed eight full, biennial Veterans and Agent Orange Reviews and three focused Agent Orange reviews.

Each review examines and characterizes the strength of evidence, such as epidemiologic and toxicological studies, in terms of its association to health outcomes. The first IOM Veterans and Agent Orange committee characterized the strength of evidence into the following four categories:

1. sufficient evidence of an association;
2. limited/suggestive evidence of an association;
3. inadequate/insufficient evidence to determine whether an association exists; and
4. limited/suggestive evidence of no association.[67]

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[65] National Academy of Sciences, Institute of Medicine, *Improving the Presumptive Disability Decision-Making Process for Veterans*, Washington, DC, 2008, p.2.

[66] For additional information on the National Academies and the committee process see http://nationalacademies.org/.

[67] IOM was additionally contracted to explore possible links between service in the Gulf War I and a host of medical conditions experienced by veterans known collectively as "Gulf War Syndrome." The IOM committees conducting the Gulf War I studies used a similar categorization process that included (1) sufficient evidence of a causal relationship, (2) sufficient evidence of an association, (3) limited/suggestive evidence of an association, (4) inadequate/insufficient evidence to determine whether an association does or does not exist, and (5) limited/suggestive evidence of no association. With minor changes, these categories are still in use today (National Academy of Sciences, Institute of Medicine, *Improving the Presumptive Disability Decision-Making Process for Veterans*, Washington, DC, 2008, pp. (continued...)

VA Presumptive Disability Deliberation Process

The VA has followed a general internal review process for evaluating the study findings from IOM and making recommendations to the Secretary of the VA on whether a specific condition(s) should be granted presumptive status. This process includes an initial review by a working group, a subsequent review by a high-level task force, and a final review by the VA Secretary.

Following the submission of the study findings from IOM, a working group is convened, consisting of representatives from several different parts of the VA. Based on the IOM study findings, review of other relevant academic literature, and possible input from various stakeholders, the working group determines whether there is sufficient scientific evidence to support giving any disease(s) special consideration with respect to disability presumptions. Following deliberations, the working group generates a report, which makes recommendations to an internal VA Task Force based on pre-established legal standards by which the VA Secretary's final decision is bound.

The VA internal review Task Force typically consists of high-level officials who report directly to the Secretary. The Task Force reviews the findings of the Working Group and may provide a separate, but similar, report to the VA Secretary based on the Working Group's recommendations. If the Task Force recommends that a new disability presumption be established, and the Secretary concurs, the Veterans Benefits Administration (VBA) will submit a cost estimate and draft regulations for the presumption(s) to the Office of Management and Budget (OMB) for review. If approved by OMB, the proposed rule is then published in the Federal Register. After the allotted period for public comment, the VBA will then prepare a final rule to be submitted to the Federal Register. A more detailed discussion of VA's review of IOM's findings is provided in **Appendix B**.

(...continued)

64-65).

Representatives at Each Tier of VA's Internal Review of IOM Reports

Tier 1: Working Group Representatives[68]

- Veterans Health Administration (VHA) Office of Public Health and Environmental Hazards (OPHEH)
- Veterans Benefits Administration (VBA)—Compensation and Pension Service (C&P Service)
- Office of the General Counsel (OGC)—Professional Staff Group II
- VHA personnel with specialized medical training or experience
- Outside technical experts such as National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and Environmental Protection Agency (EPA), as needed

Tier 2: Task Force Representatives[69]

- Under Secretary for Health
- Under Secretary for Benefits
- General Counsel
- Assistant Secretary for Policy and Planning
- Other experts (CDC, EPA, as appropriate)

Tier 3: The VA Secretary

Source: Adapted from "Box 3-1" in National Academy of Sciences, Institute of Medicine, *Improving the Presumptive Disability Decision-Making Process for Veterans*, Washington, DC, 2008, p.59.

Presumptive Disability Decisions: Challenges and Concerns

As part of its 2008 study of the current presumptive disability decision making process, IOM conducted several open meetings to solicit input from stakeholders on their experience with the presumption process. A general concern expressed by some stakeholders was that the IOM is not charged with giving guidance on non-military exposures or alternate causes of certain diseases.[70]

Challenges Facing IOM Presumptive Disability Committees

As noted in the 2008 IOM study on the presumptive disability decision making process studying the evidence base relevant to establishing service connection face the following challenges:

- few directly applicable epidemiologic studies;
- no contemporaneous exposure measurements;
- uncertainty about which veterans were exposed to which agents;
- multiple, possibly synergistic exposures;

[68] The members generally are assigned to the working group by supervisory personnel within VHA, VBA, and OGC. The working group may receive input from outside content experts as well as veterans, Veterans Service Organizations (VSOs), and Congress.

[69] Appointed by the VA Secretary.

[70] National Academy of Sciences, Institute of Medicine, *Improving the Presumptive Disability Decision-Making Process for Veterans*, Washington, DC, 2008, p.61.

- possible long latency for health effects from some agents; and
- significant confounders.[71]

The practice of categorizing the strength of evidence is intended to assist the VA in making evidence-based decisions. However, limitations in evidence inhibits the ability of IOM committees to establish causal relationships between military exposures and long-term health effects. IOM therefore has made recommendations to DOD and VA intended to improve the evidence on exposures and health status of veterans.[72]

Concerns Expressed by Presumptive Disability Policy Makers

The narrowed scope of IOM research also presents a dilemma for VA policy makers whose interpretation of study results are used to help determine which condition(s), if any, are given presumptive status in evaluating disability benefits. For example, past IOM committees have not been asked to evaluate the effects that certain exposures–common in nonmilitary settings–may have on the health of veterans. Additionally, potential exposures may vary for individual veterans depending upon where the veteran was deployed in proximity to hazardous conditions. VA does not collect data on the exposure risk of individual veterans; therefore, IOM specifically reports that the VA is "…hindered by not having exposure data for individuals."[73] The combination of these factors makes it difficult to establish a direct cause-and-effect relationship between military exposures and the specific health condition(s). Indeed, based on current statute, the VA is not required to consider evidence on exposure magnitude or duration and all exposures are given equal weight when determining health effects.[74]

Policy Options

This section briefly discusses two major policy options for the current process to establish presumptions related to exposure to Agent Orange: (1) retain the process; or (2) revise the process. Any change to the current process, which is authorized in statute, would require legislation.

Retain the Current Process

If the current process were retained, the likelihood increases that conditions that are associated with age and lifestyle—as opposed to chemical exposure—may become presumptive.

In addition, continuing the current system may also place veterans of more recent conflicts including Gulf War I, Operation Iraqi Freedom (OIF) and Operation Enduring Freedom (OEF) in a less favorable position for presumptive conditions than Vietnam veterans. Unlike the situation with Vietnam veterans, in which the IOM is able to evaluate a substantial body of scientific literature on the possible association between various diseases of interest and specific type of exposure (i.e., herbicides), the plight of veterans who served in the Gulf region is far more

[71] Ibid, pp.64-65.

[72] Ibid, p.24.

[73] Ibid, p.61.

[74] Ibid.

challenging. Not only are there concerns about dozens of different and unrelated environmental hazards (some not under the control of U.S. Armed Forces), but many of the Gulf War era veterans have complex multi-symptomatic conditions that have not been fully diagnosed:

> The VA has had difficulty applying the [IOM] findings to Gulf War veterans because nearly all of the reviewed Gulf War-related hazards represent common, well-characterized occupational exposures that are experienced by virtually all Americans. It may come as a surprise to learn that military environmental exposures generally closely mirror the environmental exposures experienced by all Americans.[75]

Refine the Current Disability Presumption Process

Refinement of the current disability presumptions process would require establishing criteria that convert the current VA process to a more formalized and transparent method of determining what service-connected conditions will be given presumptive status. Specific improvements might include (1) the creation of panels, independent of the VA, to review illnesses to be considered for presumptions and make recommendations the VA Secretary; (2) using *causation*, rather than a positive *association* as the standard for establishing presumptions; and (3) imposing time limits on veterans' presumption claims.

Independent Review of Proposed Presumptions

The use of independent advisory panels prior to conducting IOM-commissioned studies and during deliberations to determine which condition(s) will be recommended for presumption to the VA Secretary has been proposed as one option to increase transparency in the presumptive disability process.

Currently, the VA Secretary initiates deliberations for presumptive disabilities based primarily on issues raised by VSOs, Congress, or other stakeholders representing veterans in the presumption process. To ensure transparency in how the decision to study certain condition(s) is developed, an advisory committee consisting of an independent panel of experts could convene annually to review proposed conditions and nominate condition(s) for further study based on available scientific evidence that illustrates a connection between a certain exposure and a specific health outcome. Public input could also be incorporated into the deliberation process. The advisory committee, rather than the VA, could then charge IOM, or another independent research-based entity, with conducting a study of the condition(s) that have been fully vetted.

Following the conclusion of IOM-commissioned studies, the VA follows a general internal review process that includes an initial review by a working group consisting of VA representatives and needed technical experts. A report from the working group is then forwarded to a high-level task force which makes recommendations directly to the VA Secretary. The duties for reviewing the results of IOM studies and making recommendations to the VA Secretary could also be delegated to an independent panel, with deliberations open to the public.

[75] Mark Brown, "Role of Science in Department of Veterans Affairs Disability Compensation Policies for Environmental and Occupational Illnesses and Injuries, The Science for Judges IV," *Journal of Law and Policy*, vol. 13 (2005), pp. 608-609.

Use Causation as Basis for Presumptions

The Agent Orange Act of 1991 (P.L. 102-4) established the threshold for determining a presumption based only on a positive *association* between herbicide exposure and a health outcome as opposed to using *causation* as the basis. As a result, IOM Agent Orange committees have used a framework based on association (sufficient, limited/suggestive, inadequate/insufficient, and no association) between herbicide exposure and specific health outcomes rather than identifying direct causal mechanisms.

Under current law, a positive association (between dioxin or other compounds in herbicides and a specific condition) exists if the "credible" evidence for an association is equal to or outweighs the "credible" evidence against an association.[76] Also, under law, if a positive association exists, the Secretary is required to issue regulations making the condition presumptive.[77]

As an alternative, following the conclusion of any IOM-commissioned studies and post-study reviews, the VA Secretary could be statutorily restricted to only implementing presumptions for conditions that have a clear and/or direct causal link to military service based on scientific evidence. Conditions where evidence of a service connection does not meet the *causal* threshold, should automatically trigger further research before the Secretary is required to make the condition presumptive. A supplemental study examining the prevalence of the condition among veterans who were deployed to an affected region as compared to an analogous group of veterans who were not deployed could assist in determining whether that condition is more prevalent among the affected veterans than the non-affected veterans. Data and technical experts from other federal agencies such as the National Institutes of Health (NIH), the CDC, and the EPA could assist in conducting this supplemental study. Condition(s) that are determined to have a strong association with certain exposures, coupled with statistical evidence of higher prevalence rates among the affected veterans, could be deemed sufficient for establishing a presumption.

Impose Time Limitations on Presumption Claims

An individual's lifestyle, genetic heritage, and/or the aging process can have an effect on the development of a variety of medical conditions. The influence of these factors is currently not considered in the current presumption process. A health condition related to military service can be expected to manifest within a proximate time period from exposure, and many diseases have multiple risk factors. As time passes, age and lifestyle factors may have a greater influence on the development of a health condition than prior exposure. Using scientific knowledge to impose time limitations on when a condition(s) could be considered "service-connected" may help to reduce the likelihood that extraneous factors—unrelated to military service—influence the determination (or applicability) of presumptions.

[76] 38 U.S.C. §1116(b)(3).

[77] 38 U.S.C. §1116(b)(1).

Appendix A. Disease Conditions Presumptively Service-Connected

Table A-1. Presumptive Service-Connected Diseases Based on Exposure to Agent Orange, 1985-2010

Presumptive Disease	Legislation or Regulation Establishing Presumption	Date Established
Chloracne (a severe form of acne).	Adjudication of Claims Based on Exposure to Dioxin or Ionizing Radiation. Final rules. *Federal Register*, 50(165):34452- 34461.	August 26,1985
Non-Hodgkin's lymphoma (large group of cancers of lymphocytes-white blood cells).	Claims Based on Service in Vietnam. Final regulation. *Federal Register*, 55(208):43123- 43125.	October 26,1990
Soft tissue sarcoma (soft tissue sarcoma is a cancer of soft tissues such as muscles, tendons, and blood vessels). Does not include osteosarcoma, chondrosarcoma, Kaposi's sarcoma, or mesothelioma.	Agent Orange Act of 1991 (P.L. 102-4). Codified Chloracne and Non-Hodgkin's lymphoma previously established by regulation and added Soft tissue sarcoma to the list of presumptive conditions.	February 6, 1991
Soft-tissue sarcoma including the following: Adult fibrosarcoma; Dermatofibrosarcoma protuberans; Malignant fibrous histiocytoma; Liposarcoma; Leiomyosarcoma; Epithelioid leiomyosarcoma (malignant leiomyoblastoma); Rhabdomyosarcoma; Ectomesenchymoma; Angiosarcoma (hemangiosarcoma and lymphangiosarcoma); Proliferating (systemic) angioendotheliomatosis; Malignant glomus tumor; Malignant hemangiopericytoma; Synovial sarcoma (malignant synovioma); Malignant giant cell tumor of tendon sheath; Malignant schwannoma, including malignant schwannoma with rhabdomyoblastic differentiation (malignant Triton tumor); glandular and epithelioid malignant schwannomas; Malignant mesenchymoma; Malignant granular cell tumor; Alveolar soft part sarcoma; Epithelioid sarcoma; and Clear cell sarcoma of tendons and aponeuroses.	Claims Based on Exposure to Herbicides Containing Dioxin (Soft-Tissue Sarcomas) Final regulation. *Federal Register*, 56(199):51651-51653. It should be noted that these regulations were published to implement provisions of P.L. 98-542, which required that determinations as to whether conditions are related to dioxin exposure be made after receiving the advice of the Veterans Advisory Committee on Environmental Hazards (VACEH) based on its reviews of scientific and medical studies.	October 15,1991
Added the following to the list of soft-tissue sarcomas: Extraskeletal Ewing's sarcoma Congenital and infantile fibrosarcoma Malignant ganglioneuroma	Diseases Associated With Service in the Republic of Vietnam. Final rule, *Federal Register*, 58(95):29107-29109	May 19, 1993

Presumptive Disease	Legislation or Regulation Establishing Presumption	Date Established
Hodgkin's disease (is a type of lymphoma. Lymphoma is cancer of lymph tissue found in the lymph nodes, spleen, liver, and bone marrow).	Disease Associated With Exposure to Certain Herbicide Agents. Final rule. *Federal Register*, 59(23):5106-5107.	February 3,1994
Porphyria cutanea tarda (disorder characterized by thinning and blistering of the skin in sun-exposed areas)		
Multiple myeloma (Multiple myeloma is a cancer that begins in plasma cells, a type of white blood cell).	Disease Associated With Exposure to Certain Herbicide Agents (Multiple Myeloma and Respiratory Cancers) Final rule. *Federal Register*, 59(110):29723-29724.	June 9, 1994
Respiratory cancers:		
Bronchus		
Larynx		
Lung		
Trachea		
Hodgkin's disease	Persian Gulf War Veterans' Benefits Act of 1994 (P.L. 103-446). This law codified the diseases that were established by regulation since the enactment of the Agent Orange Act of (P.L. 102-4).	November 2, 1994
Multiple myeloma		
Porphyria cutanea tarda		
Respiratory cancers:		
Bronchus		
Larynx		
Lung		
Trachea		
Prostate cancer	Diseases Associated With Exposure to Certain Herbicide Agents (Prostate Cancer and Acute and Subacute Peripheral Neuropathy). Final rule. *Federal Register*, 61(217):57586-57589.	November 7, 1996
Acute and subacute peripheral neuropathy		
Spina bifida in the children of veterans	The Departments of Veterans Affairs and Housing and Urban Development, and Independent Agencies Appropriations Act, 1997 (P.L. 104-204) provided benefits to certain children of Vietnam veterans who were born with spina bifida.	January 1, 1997.

Presumptive Disease	Legislation or Regulation Establishing Presumption	Date Established
Type 2 Diabetes (Type 2 diabetes“ is also referred to as "Type II diabetes mellitus" or "adult-onset diabetes").	Disease Associated With Exposure to Certain Herbicide Agents: Type 2 Diabetes. Final rule. *Federal Register*, 66(89):23166-23169.	May 8, 2001
Diabetes mellitus (Type 2).	Veterans Education and Benefits Expansion Act of 2001 (P.L. 107-103) codified Type 2 Diabetes that was established by regulation.	December 27, 2001
Chronic lymphocytic leukemia (is cancer of a type of white blood cells called lymphocytes).	Disease Associated With Exposure to Certain Herbicide Agents: Chronic Lymphocytic Leukemia. Final rule. *Federal Register*, 68(200):59540- 59542.	October 16, 2003
Some birth defects in the children of female veterans.[a]	The Veterans Benefits and Health Care Improvement Act of 2000 (P.L. 106-419) required the VA to identify and establish birth defects through regulations.**Error! Reference source not found.** Final rule. *Federal Register* 67 (147) *Federal Register* 49585 -49590, July 31, 2002.	December 1, 2001
AL amyloidosis (Amyloidosis occurs when abnormal proteins build up and form deposits. The deposits can collect in organs such as the kidney and heart).	Presumptive Service Connection for Disease Associated With Exposure to Certain Herbicide Agents: AL Amyloidosis. Final Rule. *Federal Register* 74(87):21258-21260.	May 7, 2009
Hairy cell leukemia and other chronic B-cell leukemias (rare cancer of the blood. It affects B cells, a type of white blood cell (lymphocyte)). Parkinson's disease (Parkinson's disease is a disorder that affects nerve cells, or neurons, in a part of the brain that controls muscle movement). Ischemic heart disease (“an inadequate supply of blood and oxygen to a portion of the myocardium; it typically occurs when there is an imbalance between myocardial oxygen supply and demand").	Diseases Associated With Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and Other Chronic B-Cell Leukemias, Parkinson's Disease and Ischemic Heart Disease). Final rule. *Federal Register* 75(168):53202-53216.	August 31, 2010

Source: Table prepared by the Congressional Research Service based on Appendix F of in National Academy of Sciences, Institute of Medicine, *Improving the Presumptive Disability Decision-Making Process for Veterans*, Washington, DC, 2008, pp. F2-F43 and *Federal Register* notices.

Notes: Definitions and/or description of diseases obtained from MedlinePlus of the National Institutes of Health http://www.nlm.nih.gov/medlineplus/ and from *Federal Register* notices accompanying the establishment of presumptive diseases.

a. Covered birth defects include, but are not limited to, the following: (1) Achondroplasia; (2) Cleft lip and cleft palate; (3) Congenital heart disease; (4) Congenital talipes equinovarus (clubfoot); (5) Esophageal and intestinal atresia; (6) Hallerman-Streiff syndrome; (7) Hip dysplasia; (8) Hirschprung’s disease (congenital megacolon); (9)

Hydrocephalus due to aqueductal stenosis; (10) Hypospadias; (11) Imperforate anus; (12) Neural tube defects (including spina bifida, encephalocele, and anencephaly); (13) Poland syndrome; (14) Pyloric stenosis; (15) Syndactyly (fused digits); (16) Tracheoesophageal fistula; (17) Undescended testicle; and (18) Williams syndrome (38 C.F.R. §3.815

b. Based on a health study completed in October 1998, titled "Women Vietnam Veterans Reproductive Outcomes Health Study" conducted by VA of 8,280 women Vietnam-era veterans. See, Han Kang et al., "Pregnancy outcomes among U.S. women Vietnam veterans," *American Journal of Industrial Medicine*, vol. 38, no. 4 (October 2000), pp. 447-454.

Appendix B. Summary of VA's Review of IOM Reports[78]

The VA has not adopted formal procedures governing its internal review of IOM reports. However, practice has been it involves a three-tiered review. In the first tier, a "Working Group" of VA employees from different operational elements of the VA reviews the IOM report and any other relevant evidence and prepares a summary of its assessment and a statement of recommendations or options. This summary is intended for the benefit of a "Task Force" composed of high-level VA officials. In the second tier, the Task Force, based on the Working Group's input, provides recommendations to the Secretary, usually in the form of a separate written report. In the third tier, the Secretary determines, based on the Task Force's input, whether a presumption of service connection is warranted for any disease.

VA Working Group

The Working Group ordinarily consists of members of the Office of Public Health and Environmental Hazards (OPHEH) of the Veterans Health Administration (VHA), the Compensation and Pension Service (C&P Service) of the Veterans Benefits Administration (VBA), and representatives from the Office of the General Counsel (OGC). Additionally, the Working Group often includes other VHA personnel with specialized medical training or experience concerning a health issue implicated by a particular IOM report. Members are assigned to the Working Group by supervisory personnel within VHA, VBA, and OGC. The Working Group convenes after receiving the briefing from the IOM committee. Prior to the meeting, VHA personnel seek to identify, based on the IOM report and the committee briefing, the diseases that may warrant special consideration because the IOM's findings with respect to those diseases appear to be potentially significant. At the initial Working Group meeting, VHA provides the Working Group members with additional information concerning those diseases, including copies of any significant scientific studies identified in the IOM report and other information concerning matters such as the course of the disease, known causes or risk factors, related conditions or health effects, latency periods (if any), and any other known relevant information. OGC representative briefs the Working Group on the legal standard governing the Secretary's decision. Members of the Working Group discuss whether any of the IOM's findings appear to be potentially significant, in that they might warrant a presumption of service connection for a particular disease or diseases, and the strength of the scientific evidence with respect to such diseases. The Working Group will attempt to reach consensus as to whether the scientific evidence appears to warrant a presumption of service connection for any diseases under the applicable legal standard. If the Working Group reaches agreement that a presumption is or is not warranted on the basis of the scientific evidence and the legal standard, it will agree to put forth a recommendation based on that conclusion. In arriving at such recommendations, the Working Group relies on scientific evidence and the legal standard, and does not consider matters of governmental policy or cost. If the Working Group concludes that the scientific evidence and legal standard do not provide a clear basis for recommending for or against establishing a presumption, but permit a range of options, the Working Group agrees to set forth a range of options for decision by VA policy-making officials. In those circumstances, the Working Group

[78] Adapted from Department of Veterans Affairs, Office of the Secretary, *Final Draft Report of Department of Veterans Affairs Gulf War Illness Task Force to the Secretary of Veterans Affairs*, March 29, 2010, pp. 86-87.

will discuss the factors that preclude a clear recommendation, which may include ambiguity in the governing statutory standard as applied to certain IOM findings, the limited or conditional nature of the IOM's findings with respect to certain diseases, or other factors. The Working Group will discuss the decisional options available to the Secretary and may also discuss the factors that may be relevant to the Secretary's decision among those options. To this extent, the Working Group may discuss the policy considerations that would be relevant to the Secretary's choice among permissible courses of action. Once the Working Group has reached agreement concerning its recommendations or presentation of options, a written report is completed. The Report will contain (1) a summary of the issues to be decided under applicable law and the IOM report, (2) a summary of the findings contained in the IOM report, (3) a summary of the legal standard governing VA's decision, (4) a summary of the Working Group's analysis of the medical evidence in relation to the legal standard, particularly with respect to any potentially significant findings in the IOM report, and (5) a statement of the Working Group's recommendations or of the options identified by the Working Group. The Working Group does not prepare or obtain a cost estimate for the options, although it may provide general information concerning, e.g., the prevalence rates of certain diseases under consideration. If the Working Group report lists a range of options available to the Secretary, it would identify the scientific and legal considerations relevant to the Secretary's choice among those options, and may also identify policy implications associated with various options.

VA Task Force

The Task Force consists of the Under Secretary for Health, the Under Secretary for Benefits, the General Counsel, and the Assistant Secretary for Policy and Planning. There is no established procedure for the Task Force's deliberations. Task Force members receive a copy of the Working Group report and, based on that report, provide advice to the Secretary concerning the Secretary's determination, which may include recommendations based upon the options, if any, outlined by the Working Group. The Task Force often, though not always, provides a separate report to the Secretary.

Secretary

Based on the Task Force's report, the Secretary determines whether or not to establish presumptions for any diseases discussed in the IOM report and directs appropriate action to implement the decision.

Author Contact Information

(name redacted)
Specialist in Veterans Policy
[redacted]@crs.loc.gov, 7-....

(name redacted)
Analyst in Disability Policy
[redacted]@crs.loc.gov, 7-....

(name redacted)
Legislative Attorney
[redacted]@crs.loc.gov, 7-....

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