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PRESUMPTIONS OF SERVICE CONNECTION

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General Background

In the early 1990's, the Department of Veterans Affairs (VA) prepared an Analysis of Presumptions of Service Connection at the request of the Chairman of the Senate Veterans Affairs Committee. The Analysis exhaustively described the historical development of presumptions of service connection as used in VA's adjudication of compensation claims that occurred prior to completion of the Analysis. The Analysis was forwarded to the Chairman of the Senate Veterans Affairs Committee on December 23, 1993. Except for a brief synopsis and discussions of presumptions established in the early 1990's, for the most part, the information covered in the Analysis will not be repeated here. Accordingly, those interested in detailed information about the early history of the use of presumptions of service connection in the adjudication of VA's compensation claims should review that document directly.

A presumption may be most simply viewed as a conclusion or inference drawn from the existence of some fact or group of facts. In the context of the adjudication of VA compensation claims, a somewhat more precise and legalistic view is that a presumption relieves a VA claimant of the burden of producing evidence that directly establishes one or more facts that would otherwise be necessary to substantiate the claim. For example, in the case of a veteran claiming disability compensation, if the evidence shows manifestation of a disease covered by a presumption of service connection within the specified period, then service connection may be established (so long as the veteran currently suffers from that same disease at the time that the claim is filed). In such a case, service connection is established even though there is no medical evidence of an actual connection between the disease and the veteran's military service. The effect of the presumption is to shift the burden to the Government to prove that there is no connection between the disease and service.

Although this discussion will primarily address presumptions of service connection, there are several other presumptions that are also commonly used in the adjudication of VA benefit claims. Two of the first presumptions adopted were the presumption of death following an unexplained absence of seven or more years and the presumption of sound condition. The former presumption relieves a person attempting to prove death of the need to produce direct evidence that the death occurred. Normally, the fact of death is established by

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production of a body or a death certificate. When such normal evidence is unavailable, however, death can be established by a showing of an unexplained absence of at least seven years. 38 U.S.C. § 108(b).

The presumption of sound condition provides that every person will be considered to have been in good medical condition when entering the military. 38 U.S.C. § 1111. The presumption does not apply to medical problems specifically noted at the time of entry or problems that are clearly and unmistakably shown to preexist entry and not to have been aggravated by service. Id. This presumption was created for the protection of veterans on the theory that the Government, having given the veteran a clean bill of health upon examination for entry into service, should bear the burden of showing the contrary in a claim for veterans benefits.

Another example of a presumption used in the adjudication of VA benefit claims is the presumption of aggravation of a preexisting disease or injury during service. 38 U.S.C. § 1153. Under the provisions of section 1153, any increase in disability during military service from a preexisting injury or disease will be considered to have been aggravated by such service unless there is a specific finding that the increase in disability is due to the natural progress of the disease.

The use of presumptions in the adjudication of VA benefit claims is not limited to claims for compensation. Other presumptions apply in the adjudication of other VA benefit claims, for example, claims for nonservice connected disability pension. One of the core elements necessary to establish eligibility for VA pension is proof of permanent and total disability. 38 U.S.C. § 1521. For many VA pension claimants, this element may be established presumptively. In this regard, veterans may be presumed to be permanently and totally disabled if they are patients in nursing homes for long-term care because of disability, if they have been determined disabled for purposes of Social Security benefits, or if they are determined to be unemployable as a result of disability reasonably certain to continue throughout their life. 38 U.S.C. § 1502. Moreover, veterans age 65 or older who otherwise meet the eligibility requirements are entitled to receive pension without establishing permanent and total disability. 38 U.S.C. § 1513. Although sections 1502 and 1513 do not expressly include the term "presumption," it is clear that Congress viewed their provisions as creating presumptions of permanent and total disability for VA pension purposes. See section 206, "Expansion of Presumptions of Permanent and Total Disability for Veterans Applying for Nonservice-connected Pension," Veterans Education and Benefits Expansion Act of 2001, Pub. L. No. 107-103, and the discussion of section 207, "Eligibility of Veterans 65 years of Age or Older for Veterans' Pension Benefits," of the same Act at 147 Cong. Rec. H9,139-9,140 (daily ed. Dec. 11, 2001).

There are several reasons justifying the widespread use of presumptions in the adjudication of VA benefit claims. Presumptions may simplify and

streamline the adjudication process by eliminating the need to obtain evidence and decide complex issues. Presumptions also promote accuracy and consistency in adjudications by requiring similar treatment in similar cases. Presumptions may relieve claimants and the VA of the necessity of producing direct evidence when it is impractical or unduly burdensome to do so. Finally, presumptions may implement policy judgments that the burdens arising in certain cases be borne by the Government rather than the veteran claimants notwithstanding the uncertainty surrounding the issue of whether the claimants' disabilities were, in fact, incurred or aggravated by service.

As noted, presumptions are used throughout the process of adjudicating claims for various VA benefits. Their use occurs most extensively, however, in meeting a key requirement necessary to substantiate a claim for VA compensation benefits, i.e., establishing service connection, the showing of a connection between military service and incurrence or aggravation of a veteran's disease or injury. In claims for VA compensation benefits, veterans generally bear the burden of proving their disabilities result from diseases or injuries that were incurred in or aggravated by military service. This burden is generally met by producing evidence the disease or injury occurred coincident to the military service. Once the evidence establishes that a presumption of service connection applies, however, the veteran is relieved of the burden of proving service incurrence or aggravation. In such a claim, unless there is affirmative evidence showing that the disease or disability was not incurred in or aggravated by service, VA must grant service connection.

In many, if not most, claims, it is relatively simple for veterans to meet the burden of proving their disabilities are service connected. The veteran's military records may clearly describe and document the circumstances and medical treatment for an injury or an illness suffered while in service as well as any resulting disability. In such a claim, the veteran's burden of proving service connection is easily met.

In other claims, however, where the manifestation of the disability 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 daunting. The difficulties that can arise in proving service connection were recognized very early. In 1921, Congress first enacted a presumption of service connection for specific diseases to assist veterans in meeting the difficult burden they faced when attempting to establish a connection between their military service and the development of disabilities resulting from such diseases. Act of August 9, 1921, ch. 57, § 18, 42 Stat.147. That Act provided that pulmonary tuberculosis or neuropsychiatric disease developing to a degree of 10 percent or more within two years after service would be considered to have been incurred in, or aggravated by, service.

Since the Act of 1921, Congress and the VA have established additional statutory and regulatory presumptions of service connection for several categories of diseases and illnesses. Presumptions of service connection now cover over forty chronic diseases or disease categories, seventeen tropical diseases, and eighteen diseases, conditions, or disease categories of former prisoners of war. In addition, twenty-one diseases associated with exposure to ionizing radiation, eleven diseases or disease categories associated with exposure to herbicide agents, and undiagnosed illnesses and three unexplained chronic multisymptom illnesses associated with Persian Gulf service may also be service connected on a presumptive basis. 38 U.S.C. §§ 1112, 1116, and 1117 and 38 C.F.R. §§ 3.309 and 3.317. By regulation, 38 C.F.R. § 3.316, VA has created presumptions of service connection for fourteen diseases associated with the exposure of certain veterans to mustard gas and Lewisite. Also by regulation, 38 C.F.R. § 3.310(b), VA created a presumption applicable to veterans suffering cardiovascular disease following certain amputations. Most recently, VA added presumptions for atherosclerotic heart disease, hypertensive vascular disease, and stroke in former prisoners of war to the list of presumptive conditions in 38 C.F.R. § 3.309. These three regulatory presumptions were established pursuant to new guidelines VA established in 38 C.F.R. § 1.18, published on October 7, 2004, to govern its determinations as to whether additional diseases should be presumed to be service connected based on prisoner-of war experience.

The most recent major Congressional developments concerning presumptions of service connection stem from the policy determination by Congress to ease the difficulties experienced by veterans of the Persian Gulf War in proving entitlement to compensation benefits due to the scientific uncertainties surrounding the health hazards of such service. Initially, in 1994, Congress enacted 38 U.S.C. § 1117 authorizing VA to compensate Persian Gulf War veterans suffering from chronic disabilities resulting from undiagnosed illnesses or combinations of undiagnosed illnesses. Such illnesses must become manifest either during active duty in the Southwest Asia theater of operations during the Persian Gulf War or to a degree of 10 percent or more within a presumptive period, as determined by VA, following service in the Southwest Asia theater of operations during the Persian Gulf War.

Subsequently, in 1998 Congress enacted 38 U.S.C. § 1118 establishing procedures to govern VA determinations as to which diseases are to be presumptively service connected based on Persian Gulf War service. The Gulf War procedures are substantially similar to those found in 38 U.S.C. § 1116 governing VA's determinations as to which diseases are to be presumptively service connected based on herbicide exposure. VA has not established any presumptions of service connection under the procedures established in section 1118.

Congress amended 38 U.S.C. § 1117 in 2001 to expand the definition of "qualifying chronic disability" to include not only a disability resulting from an undiagnosed illness, but also any diagnosed illness that VA determines in regulations warrants a presumption of service-connection. At the same time, Congress also 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). In an amendment to 38 C.F.R. § 3.317 implementing the 2001 legislation, VA identified only those three illnesses as meeting the statutory definition of a "medically unexplained chronic multisymptom illness."

Presumptions of Service Connection Since 1991

1. Herbicide Exposure During Vietnam Service

The debate over the health effects of exposure during Vietnam service to certain herbicide agents, including Agent Orange, produced intense controversy that lasted years, generated numerous, conflicting scientific and medical studies, and resulted in litigation that continues today. In the midst of this controversy, Congress enacted the Agent Orange Act of 1991, Pub. L. No. 102-4, codified in part at 38 U.S.C. § 1116. In the Act, Congress established presumptions of service connection for three diseases associated with herbicide exposure during the Vietnam conflict. In addition to adopting certain presumptions, Congress also established a procedure to govern future VA determinations as to which diseases, if any, would be presumptively service connected based on herbicide exposure.

Section 3 of the Act calls for VA to contract with the National Academy of Sciences (NAS), or another nongovernmental, not-for-profit, scientific entity with comparable expertise and objectivity, to perform a biennial review and assessment of the scientific evidence concerning the association between exposure to an herbicide used in the Republic of Vietnam during the Vietnam era and each disease suspected to be associated with such exposure. NAS is to determine, to the extent possible, for each disease it reviews: (a) whether a statistical association with herbicide exposure exists, taking into account the strength of the scientific evidence and the appropriateness of the scientific methods used to detect the association; (b) the increased risk of the disease among those exposed to herbicides during Vietnam service; and (c) whether there exists a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the disease.

Following receipt of a report from NAS, VA must determine whether a presumption of service connection is warranted for each disease discussed in the report. 38 U.S.C. § 1116(c)(1)(A). Whenever VA determines, on the basis of

sound medical and scientific evidence, that a positive association exists between exposure to an herbicide agent and the occurrence of a disease in humans, VA is to prescribe regulations providing that a presumption is warranted for that disease. 38 U.S.C. § 1116(b)(1). An association is to be considered positive "if the credible evidence for the association is equal to or outweighs the credible evidence against the association." 38 U.S.C. § 1116(b)(3). When determining whether a positive association exists, VA is to take into account the reports received from NAS and all other sound medical and scientific information and analyses available. 38 U.S.C. § 1116(b)(2). In evaluating any study, VA is to consider whether its results are statistically significant, are capable of replication, and withstand peer review. Id.

If VA determines that a presumption of service connection is not warranted for a disease covered by a NAS report, it is to publish a notice of that determination in the Federal Register. 38 U.S.C. § 1116(c)(1)(B). The notice is to include an explanation of the scientific basis for the determination that a presumption is not warranted. <u>Id.</u>

VA's authority to establish regulatory presumptions of service connection under Public Law 102-4 would have expired on September 30, 2002. However, section 201(d) of the Veterans Education and Benefits Expansion Act of 2001, Public Law 107-103, extended that authority through September 30, 2015.

VA has established regulatory presumptions of service connection for eight diseases following receipt of reports from NAS under the Agent Orange Act. In its reports, NAS assigns each of the diseases considered to one of four evidentiary categories. The distinctions between categories are based on the weight of the "statistical association." The four evidentiary categories are; (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.

VA has apparently accorded great weight to NAS's conclusions. So far, all of the conditions VA has determined to warrant presumptive service connection under section 1116 have been categorized by NAS as having "sufficient evidence of an association" or "limited/suggestive evidence of an association." On the date of the publication of the first NAS report in 1993, VA announced that it would establish presumptions of service connection for Hodgkin's disease and porphyria cutanea tarda, in addition to the presumptions for soft tissue sarcoma, chloracne, and non-Hodgkin's lymphoma already recognized by VA. VA announced two months later that multiple myeloma and respiratory cancers would also be added to the list of conditions presumed to be service connected based on exposure to an herbicide.

After release of the second NAS report in 1996, VA established presumptions of service connection for acute and sub acute transient peripheral

neuropathy and prostate cancer. Shortly after the third NAS report was published in 1998, which resulted in no significant changes, VA requested that NAS review a recent occupational study by the National Institute of Occupational Safety and Health providing some evidence of an association between herbicide exposure and Type 2 diabetes and to consider a then new Air Force Ranch Hand report that included additional findings regarding diabetes. In October 2000, NAS released a special report in which it concluded that there was "limited/suggestive evidence" of an association between herbicide exposure and Type 2 diabetes. VA's regulation establishing presumptive service connection for Type 2 diabetes was published in 2001. In its 2002 report published on January 23, 2003, NAS concluded that there was "sufficient evidence of an association between exposure to at least one of the chemicals in at least one of several herbicides and chronic lymphocytic leukemia. VA amended 38 C.F.R. § 3.309 to establish a presumption of service connection for chronic lymphocytic leukemia on October 16, 2003.

In Section 505 of the Veterans' Benefits Improvements Act of 1994, Pub. L. No.103-446, Congress amended section 1116 to codify VA's regulatory presumptions based on exposure to herbicides for Hodgkin's disease, porphyria cutanea tarda, respiratory cancers and multiple myeloma.

Section 505 of the Veterans' Benefits Improvements Act of 1996, Public Law 104-275, amended 38 U.S.C. § 1116 (a) to expand the period during which veterans must have served in Vietnam to be entitled to the application of the presumptions of service connection for diseases associated with exposure to herbicide agents to the period beginning January 9, 1962, and ending on May 7, 1975.

Although the presumptions of service connection in section 1116 expressly apply only to veterans who served in the Republic of Vietnam during specified dates, VA's regulations at 38 C.F.R. §§ 3.307(a)(6) and 3.309(e) make those presumptions applicable to any veteran who was exposed to an herbicide agent in service. Veterans who served in the Republic of Vietnam between certain dates are presumed to have been exposed to herbicide agents during such service, but for veterans alleging exposure at other times or locations, evidence must establish herbicide exposure.

Notwithstanding what was intended to be a liberal and broadly inclusive presumption of exposure to herbicide agents during Vietnam service, its implementation has not resulted in universal satisfaction and acceptance. For example, controversy has resulted from VA's interpretation of its regulatory definition of "service in the Republic of Vietnam" in 38 C.F.R. § 3.307. Section 3.307(a)(6)(iii) provides, " '[S]ervice in the Republic of Vietnam' includes service in the waters offshore and service in other locations if the conditions of service involved duty or visitation in the Republic of Vietnam. VA's interpretation of this provision requires that an individual actually have been present within the

Republic's boundaries to be considered to have served there, and thus entitled to the presumption of exposure to herbicide agents. VAOPGCPREC 27-97. "Blue Water Veterans" i.e., veterans who served on deep-water naval vessels in waters off the shore of Vietnam, and veterans who served in other countries, such as Thailand in direct support of our country's efforts in Vietnam believe this interpretation unjustly denies them rights due under the provisions of section 1116. Although such veterans may have been awarded the Vietnam Service Medal, they may have never set foot in Vietnam, or, if they did, may not be able to prove their presence in Vietnam. Under these circumstances, VA will not presume they were exposed to herbicide agents

Congress amended section 1116 most recently in the Veterans Education and Benefits Expansion Act of 2001, Pub. L. No. 107-103. In section 201 of the Act, Congress codified VA's regulatory presumption of service connection for Type 2 diabetes based on herbicide exposure and removed the thirty year limitation on the manifestation of respiratory cancers

The approach taken by Congress in the Agent Orange Act of 1991 differed substantially from that taken in earlier legislation creating presumptions of service connection. In the Agent Orange Act, Congress inserted an independent, nongovernmental scientific entity into the process of determining whether a presumption of service connection would be warranted. In view of the widely differing views on the human health effects associated with herbicide exposure during Vietnam service, it is not surprising that Congress concluded that an objective evaluation from a well-respected, nongovernmental scientific organization was necessary. At the same time, however, Congress ensured that a governmental policy maker, VA, continues to make the ultimate policy decision as to whether presumptions are established.

2. Mustard Gas

Early in 1992, VA recognized that some World War II service members were experimentally exposed to mustard gas during full-body, field or chamber tests of protective equipment. VA proposed a regulation, 38 C.F.R. § 3.316, establishing presumptive service connection for several conditions associated with that exposure. 57 Fed. Reg. 1699 (1992). VA justified the presumptions on the basis that the World War II tests were classified, participants were instructed not to discuss their involvement, medical records associated with the tests are generally unavailable, and no long-term follow-up examinations were conducted. For these reasons, VA concluded some participants may not have filed claims with VA for disabilities resulting from mustard gas poisoning, or, if they did file claims, may have experienced difficulty in establishing entitlement to benefits. Id.

VA indicated that these special circumstances surrounding the World War II testing programs may have placed veterans who participated in them at a

disadvantage when attempting to establish entitlement to compensation for disability or death resulting from experimental exposure. The proposed rule provided, if exposure occurred under certain described circumstances, that disabilities or deaths resulting from specified diseases were to be recognized as connected to a veteran's exposure during service. <u>Id.</u>

A review of the available English language literature regarding the effects of exposure to mustard gas by then Veterans Health Administration personnel of the VA indicated that the chronic, long-term effects of acute mustard gas poisoning may include laryngitis, bronchitis, emphysema, asthma, conjunctivitis, keratitis, and corneal opacities. Chronic forms of these conditions which developed subsequent to experimental exposure during World War II were presumed to be service-connected. 57 Fed. Reg. 33,875 (1992).

Responding to comments on its proposed rule, VA noted in the preamble of the final rule that it had contracted with the National Academy of Sciences (NAS) to conduct a review of the world medical and scientific literature to determine the long-term health effects of exposure to mustard gas. VA indicated that after reviewing the NAS findings, it would determine whether any change to the regulation would be warranted and would do so if appropriate. <u>Id.</u>

After reviewing almost 2,000 medical and scientific papers, consulting with outside experts, and conducting public hearings, NAS issued its report, entitled "Veterans at Risk: The Health Effects of Mustard Gas and Lewisite", in January 6, 1993. VA significantly liberalized the criteria in 38 C.F.R. § 3.316 based upon its review of the report. 59 Fed. Reg. 3,532 (1994). The original regulation applied only to those veterans exposed while participating in secret tests of protective equipment during World War II. The regulation was amended to cover any verified full-body exposure during military service including veterans exposed to mustard gas under battlefield conditions in World War I. The amended regulation also added several new conditions identified in the NAS report as being associated with exposure to mustard gas as well as adding conditions associated with exposure to another vesicant agent, Lewisite, not covered in the original regulation.

3. Ionizing Radiation

In 1988, Congress enacted the Radiation-Exposed Veterans
Compensation Act of 1988, Pub. L. No.100-321, amending what is now 38
U.S.C. § 1112 to establish presumptions of service connection for thirteen
specified diseases associated with exposure to ionizing radiation. The specified
diseases had to manifest to a degree of ten percent or more within forty years
(thirty years for leukemia) of a veteran's active duty participation in a radiationrisk activity. Such activity was defined as onsite participation in atmospheric
nuclear testing, occupation of Hiroshima and Nagasaki during the period

August 6, 1945 to July 1, 1946, or internment as a prisoner of war in Japan which resulted in an opportunity for radiation exposure similar to that of the Hiroshima and Nagasaki occupation forces.

Over the years, Congress has amended the provisions of section 1112 that govern presumptions of service connection based on exposure to ionizing radiation several times. The first amendment occurred in the Veterans' Benefits Programs Improvement Act of 1991, Pub. L. 102-86. Section 104 of that act amended section 1112 to extend the thirty year presumptive period for leukemia to forty years. Section 105 extended presumptive service connection not only to individuals who were engaged in a radiation-risk activity during active duty but also to individuals exposed during active duty for training or inactive duty training.

Section 1112 was next amended in section 2 of the Veterans' Radiation Exposure Amendments of 1992, Public Law 102-578. In section 2, Congress repealed the requirement that, to be presumed service connected based on exposure to ionizing radiation, specified diseases had to become manifest to a degree at least ten percent disabling within 40 years after the veterans' last exposure to radiation. Public Law 102-578 also added cancer of the salivary gland and cancer of the urinary tract to the list of conditions for which presumptive service connection is authorized for veterans who participated in a radiation-risk activity.

In Section 501(a) of the Veterans' Benefits Improvements Act of 1994, Pub. L. No.103-446, Congress clarified that it intended to define the term, "radiation-risk activity," as used in section 1112 to include onsite participation in a test involving the atmospheric detonation of a nuclear device "without regard to whether the nation conducting the test was the United States or another nation."

In 1999, Congress added bronchiolo-alveolar carcinoma to the list of diseases presumed to be service connected as a result of exposure to ionizing radiation during military service in section 503 of the Veterans Millennium Health Care and Benefits Act, Pub. L. 106-117.

The most recent action Congress has taken with respect to presumptions of service connection based on radiation exposure was enactment of section 306 of the Veterans Benefits Improvement Act of 2004, Pub. L. No. 108-454. In section 306, Congress merely codified at section 1112, presumptions for bone, lung, brain, colon, and ovarian cancer that VA had already established by regulation the year before and broadened the definition of "radiation-risk activity" in a manner consistent with VA's then-existing regulation.

VA discussed the basis for these presumptions in the rulemaking proceeding that added these five diseases to 38 C.F.R. § 3.309. 66 Fed. Reg. 41,483 (2001). VA noted that originally, in the Radiation Exposure Compensation Act of 1990 (RECA), Pub. L. No. 101-426, (codified as amended

at 42 U.S.C. § 2210 note) Congress had provided compensation to certain residents of Nevada, Utah, and Arizona who lived downwind from the Government's above-ground nuclear tests, for underground uranium miners, and for persons who participated onsite in a test involving the atmospheric detonation of a nuclear device and contracted specified diseases all of which were also covered in 38 U.S.C. § 1112(c). VA also referred to the fact that the RECA Amendments of 2000, Pub. L. No. 106-245, expanded not only the definition of persons eligible to receive compensation, but also expanded the list of specified diseases for which compensation is payable to include lung, colon, brain, and ovarian cancers, which were not included in section 1112.

Finally, VA noted that Title XXXVI of Pub. L. No. 106-398, the Energy Employees Occupational Illness Compensation Act Amendments of 2000, authorized compensation and benefits for certain Department of Energy (DOE) employees and persons employed by DOE contractors, subcontractors, and vendors who were involved in DOE nuclear weapons-related programs. Under the Act, if one of the covered individuals develops a "specified cancer" after beginning employment at a DOE facility for a DOE contractor, or at an atomic weapons facility for an atomic weapons contractor, the cancer is presumed to have been sustained in the performance of duty and is compensable. A "specified cancer" in this Act included any "specified disease" as defined by RECA as well as bone cancer, which was also not included in section 1112.

VA stated that equity and public policy dictated that veterans should not carry a greater burden of proof to establish a connection between their cancers and their military service than persons covered under RECA and the Energy Employees Act. 66 Fed. Reg. 41,484 (2001). Acting under its authority in 38 U.S.C. § 501 to promulgate regulations regarding the nature and extent of proof and evidence in order to establish entitlement to veterans' benefits, VA amended 38 C.F.R. § 3.309(d)(2) to add bone, brain, colon, lung, and ovarian cancers to its regulatory list of diseases for which service connection may be presumed based on exposure to ionizing radiation. 67 Fed. Reg. 3,612 (2002). VA also amended the definition of "radiation-risk activity" in 38 C.F.R. § 3.309(d)(3)(ii) to include activities in service that are comparable to the activities covered for Department of Energy employees under RECA and the Energy Employees Act.

4. Persian Gulf War

Beginning in August 1990 and continuing through 1991, approximately 700,000 members of the Armed Forces participated in the large-scale military deployment against Iraq in the Southwest Asia theater of operations (Persian Gulf War). During the War, service members were given multiple immunizations, exposed to numerous potentially toxic substances including debris from the military operations and oil well fires, paints, pesticides, infectious agents, chemoprophylactic agents, and indigenous diseases. Moreover, the threat of

chemical and biological agent use added to the psychological stress generally associated with military operations. In the years following their deployment, many Persian Gulf War veterans complained of health problems and illnesses which could be neither diagnosed nor defined, but which they believed were related to their service in the Persian Gulf.

In response, the federal government funded a broad range of research studies on the causes, incidences, and effects of these unexplained health problems. The massive research effort was intended to foster a better understanding of the many issues involved and thereby ensure both the provision of appropriate health care and adequate compensation to veterans for health problems which many attributed to their service during the Persian Gulf War.

On November 2, 1994, notwithstanding the scientific and medical uncertainty surrounding the illnesses associated with Persian Gulf service, Congress enacted the Veterans' Benefits Improvement Act, Pub. L. No. 103-446, codified in part at 38 U.S.C. § 1117, and established the first presumption of service connection applicable to such illnesses. Although finding that additional scientific research was necessary to determine the underlying causes of the illnesses suffered by Persian Gulf War veterans, Congress listed the first purpose of Pub. L. No. 103-446 as the need to "provide compensation to Persian Gulf War veterans who suffer disabilities resulting from illnesses that cannot now be diagnosed or defined, and for which other causes cannot be identified." Pub. L. No. 103-446, § 103(1). In this regard, Congress specifically found that pending the outcome of such research, Persian Gulf veterans who are disabled by such illnesses should be given the benefit of the doubt and provided compensation benefits to offset the impairment in earnings capacities they may be experiencing. Pub. L. No. 103-446 §102(7).

Section 106 of the Act authorized VA to pay compensation benefits to any Persian Gulf veteran suffering from a chronic disability resulting from an undiagnosed illness that became manifest to a degree of ten percent or more during active duty in the Persian Gulf War or within a presumptive period to be prescribed by VA regulation. VA was to base the presumptive period on a review of any available credible medical or scientific evidence and the factors considered in establishment of manifestation periods of other diseases. VA was also to take into account other pertinent circumstances regarding the experiences of veterans of the Persian Gulf War. Finally, the regulations were to address: (1) The nature, period, and geographical areas of military service in connection with which compensation may be paid; (2) the illnesses for which compensation may be paid; and (3) any relevant medical characteristics associated with each such illness.

VA implemented the new Persian Gulf presumption by promulgating 38 C.F.R. § 3.317. In the preamble to proposed section 3.317, VA noted that 38 U.S.C. § 1110 authorizes VA to compensate for disabilities arising from personal

disease or injury incurred or aggravated in the line of duty during active military service. Until enactment of 38 U.S.C. § 1117, however, VA had no authority to compensate for many of the symptoms reported by Persian Gulf veterans because they could not be attributed to a known disease or injury. 59 Fed. Reg. 63,283 (1994).

Section 3.317(a)(1) requires that veterans exhibit objective indications of chronic disabilities resulting from undiagnosed illnesses. Paragraph (a)(3) provides that "objective indications" means both "signs," in the medical sense of objective evidence perceptible to an examining physician, and other indicators that are non-medical in nature but capable of independent verification. To meet the requirement that the regulation contain a description of the illnesses for which compensation may be paid, the regulation requires that undiagnosed illnesses be manifested by one or more signs or symptoms, thirteen categories of which are specified in the regulation. Because other signs and symptoms in addition to the listed categories could legitimately qualify for consideration under section 3.317, the regulation provides that the list of thirteen categories is not exclusive. It also requires a disability to exist for six months or more to be considered chronic.

The regulation established a two-year presumptive period following service in the Southwest Asia theater of operations during the Persian Gulf War for undiagnosed illnesses. Subsection 1117(b) specified that VA establish a post-Gulf-service presumptive period after reviewing any credible medical or scientific evidence, the historical treatment afforded other diseases for which service connection is presumed, and other pertinent circumstances regarding the experiences of Persian Gulf veterans. In establishing the two-year period, VA noted that based upon its experience with chronic diseases with signs and symptoms similar to those covered by the new rule, most illnesses related to Persian Gulf service would be expected to become manifest within one year after such service. In addition, VA indicated that it was not aware of any evidence to suggest that any undiagnosed illnesses would take longer than two years to become manifest. 59 Fed Reg. 63,284 (1994).

In further explaining its proposal of a two-year, rather than a one-year presumptive period, VA noted that it did not begin full-scale operation of its Persian Gulf Registry until November 1992. VA explained that many Persian Gulf veterans first presented their health concerns in connection with a Registry examination that would not have been available to them within one year after leaving the Persian Gulf region. Within two years, however, all veterans of the hostilities in the Persian Gulf would have had this opportunity to document their illnesses. Id.

Finally, with respect to the requirement in subsection 1117(d) that the regulation contain a description of the period and geographical area or areas of military service in connection with which compensation for undiagnosed illnesses may be paid, VA extended eligibility to any veteran who served within the

Southwest Asia theater of operations during the Persian Gulf War. Under 38 U.S.C. § 101(33), this period extends from August 2, 1990, through a date yet to be determined by law or Presidential proclamation. Moreover, VA stated it had no information that indicated that those serving in specific areas of the theater of operations had a greater risk of developing undiagnosed illnesses, and, therefore, believed it appropriate that this provision apply to veterans who served anywhere within that area. <u>Id.</u>

In 1997, VA amended 38 C.F.R. § 3.317 to extend the two-year presumptive period for undiagnosed illnesses through the year 2001. VA justified the extension on growing concerns regarding the adequacy of the two-year presumptive period. VA held a series of veterans' forums nationwide and consulted with members of Congress as well as the leadership of the national veterans' service organizations on the issue. VA concluded that the two-year presumptive period was inadequate because: (1) Despite a broad federal research effort, there was still insufficient data about the nature and causes of these illnesses to justify limiting the presumptive period to two years; and (2) it prevented VA from compensating certain veterans with disabilities due to undiagnosed conditions that may have resulted from their service in the Persian Gulf War. Based upon the consensus concerning the inadequacy of the current presumptive period and the continuing medical and scientific uncertainty about the nature and causes of these illnesses, VA determined that the presumptive period should be extended to disabilities due to undiagnosed illnesses that become manifest through the year 2001. By then, VA anticipated that the results of the ongoing research would shed more light on the issues to guide future policies. 62 Fed. Reg. 23,138 (1997).

In 2001, however, VA again extended the presumptive period for undiagnosed illnesses. This time VA extended it for a five-year period until December 31, 2006. VA justified this extension on the continuing scientific and medical inquiry into the nature and cause of undiagnosed illnesses suffered by Persian Gulf War veterans, the continuing military operations in the Gulf region, and the new claims still being received from Persian Gulf War veterans. 66 Fed. Reg. 56,614 (2001).

Dissatisfied with the federal government's response to the unexplained health problems and continuing compensation needs of Persian Gulf veterans seven years after cessation of active hostilities, Congress enacted the Persian Gulf War Veterans Act of 1998, Pub. L. 105-277, title XVI, codified in part at 38 U.S.C. § 1118. Comparing the chronic, debilitating health problems faced by Persian Gulf War veterans to those suffered by Vietnam veterans based on exposure to Agent Orange, Congress expanded VA's authority to create presumptions of service connection for diseases and illnesses based on Gulf War service. In the 1998 Act, Congress established procedures governing creation of presumptions based on Gulf War service that are substantially similar

to those procedures contained in 38 U.S.C. § 1116 governing VA's presumptive determinations based on herbicide exposure in Vietnam.

Under the provisions of subsection 1118(a), VA is authorized to determine that any diagnosed or undiagnosed illness warrants a presumption of service connection by reason of having a "positive association with exposure to biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War." Whenever VA determines, on the basis of sound medical and scientific evidence, that a positive association exists between exposure of humans or animals to such an agent, hazard, or medicine and the occurrence of an illness in humans or animals VA is to prescribe regulations providing that a presumption is warranted for that illness. 38 U.S.C. § 1118(b)(1). An association is to be considered positive "if the credible evidence for the association is equal to or outweighs the credible evidence against the association." 38 U.S.C. § 1118(b)(3). When determining whether a positive association exists, VA is to take into account reports received from NAS and all other sound medical and scientific information and analyses available. 38 U.S.C. § 1118(b)(2). In evaluating any study, VA is to consider whether its results are statistically significant, are capable of replication, and withstand peer review. Id.

The Persian Gulf War Veterans Act calls for VA to contract with NAS, or a similar scientific organization, to identify the agents, hazards, or medicines to which veterans may have been exposed during their Persian Gulf service and any diagnosed or undiagnosed illnesses that are manifest in Persian Gulf veterans. In addition, Congress directed that NAS determine, to the extent feasible, whether a statistical association exists between exposure to identified Persian Gulf hazards and any identified illness, the increased risk of the illness among human or animal populations due to exposure to such hazards, and whether there is a plausible biological mechanism or other evidence of a causal relationship between exposure and the illness. Finally, the Act specified a nonexclusive list of over thirty substances to which Persian Gulf Veterans may have been exposed and which NAS was to address initially in attempting to identify Persian Gulf hazards.

NAS has completed three reports under the Persian Gulf War Veterans Act. The first report, in 2000, assessed the health effects of exposure to depleted uranium, sarin, vaccinations against botulism toxin and anthrax, and pyridostigmine bromide, which was used as a nerve agent prophylaxis during the Persian Gulf War. The second, received in 2003, discussed the health effects associated with exposure to insecticides and solvents. The latest report, completed in 2004, examined the possible health effects of exposure to fuels, propellants, and combustion products. VA has not established any presumptions of service connection based on those reports.

Congress most recently addressed the compensation needs of Persian Gulf veterans in the Veterans Education and Benefits Expansion Act of 2001, Pub. L. No. 107-103. Subsection 202(a) of this Act amended 38 U.S.C. § 1117 to expand its definition of "qualifying chronic disability" to include not only a disability resulting from an undiagnosed illness, but also any diagnosed illness that VA determines by regulation to warrant a presumption of service-connection. Subsection 202(a) also 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." Finally, subsection 202(b) codified in section 1117 the listing of the thirteen signs or symptoms VA included in 38 C.F.R. § 3.317 that may be considered as manifestations of an undiagnosed illness or a chronic multisymptom illness. VA implemented subsection 202(a) of Pub. L. No. 107-103 by amending section 3.317 to add only chronic fatigue syndrome, fibromyalgia, and irritable bowel syndrome as meeting the definition of a "medically unexplained chronic multisymptom illness." 68 Fed. Reg. 34,539 (2003).

5. Prisoners of War

Section 201 of the Veterans Benefits Act of 2003, Pub. L. No. 108-183, amended 38 U.S.C. § 1112(b) to add cirrhosis of the liver to the disabilities presumptively service connected for former prisoners of war. The addition of cirrhosis to subsection 1112(b) merely codified an amendment to 38 C.F.R. § 3.309 VA had promulgated earlier. 68 Fed. Reg. 42,602 (2003). The regulatory provision was based on a study published in October 2000, by the Institute of Medicine (IOM). The study found a significantly higher risk of cirrhosis among former World War II prisoners of war compared with control groups. Cirrhosis mortality was not found to be associated with any differences in levels of alcohol consumption among World War II and Korean prisoners of war and Korean controls, which were similar to those among U.S. males. Accordingly, VA concluded that it appears that alcohol consumption does not provide an explanation for the higher mortality rates identified in prisoners of war. 68 Fed. Reg. 6,679 (2003).

Section 201 of Pub. L. No. 108-183 provided a presumption of service connection without regard to the length of confinement for certain psychiatric disabilities, cold weather injuries, and traumatic arthritis. Under prior law, fifteen disabilities and diseases were presumed service connected as having been caused by the confinement of former prisoners of war, if the confinement was for a period of thirty days or more. Acknowledging that prisoners of war are often treated brutally, the Senate Committee on Veterans' Affairs report on a similar bill noted that even if they are treated humanely, they suffer extreme mental anguish and concluded, "the 30-day minimum interment requirement for purposes of presumptive service connection may be too restrictive for certain conditions." S. Rep. No. 108-169, 108th Cong. 1st Sess. 11 (2003).

The most recent development concerning presumptions of service connection for diseases associated with the detention or internment of prisoners of war is VA's 2004 promulgation of 38 C.F.R. § 1.18 setting up guidelines to govern the establishment of such presumptions. Section 1.18 provides that VA may establish a presumption of service connection for a disease when there is "at least limited/suggestive evidence that an increased risk of such disease is associated with service involving detention or internment as a prisoner of war and an association between such detention or internment and the disease is biologically plausible." The phrase "limited/suggestive evidence" in paragraph 1.18(b)(1) refers to "evidence of a sound scientific or medical nature that is reasonably suggestive of an association between prisoner-of-war experience and the disease, even though the evidence may be limited because matters such as chance, bias, and confounding could not be ruled out with confidence or because the relatively small size of the affected population restricts the data available for study."

Under subsection 1.18(c), VA may specify a minimum period of detention or internment necessary to qualify for any presumption established. The regulation also states that the requirement that a disease be "associated" with prisoner-of-war service experience may be satisfied by evidence demonstrating either a statistical or a causal association. Finally, subsection 1.18 (f) lists the factors VA is to consider in evaluating any scientific study concerning diseases possibly associated with the prisoner-of-war experience as follows: (1) The degree to which the study's findings are statistically significant; (2) the degree to which any conclusions drawn from the study data have withstood peer review; (3) whether the methodology used to obtain the data can be replicated; (4) the degree to which the data may be affected by chance, bias, or confounding factors; and (5) the degree to which the data may be relevant to the experience of prisoners of war in view of similarities or differences in the circumstances of the study population.

In the same rulemaking proceeding in which VA established the above guidelines, VA also used those guidelines to establish presumptions of service connection for atherosclerotic heart disease, hypertensive vascular disease, and stroke in former prisoners of war.