October 5, 2012

VIA WEBSITE (WWW.REGULATIONS.GOV) AND CERTIFIED MAIL

Director, Regulations Management (02REG)
Department of Veterans Affairs
810 Vermont Avenue, NW., Room 1068
Washington, DC 20420

Re: Comment submitted in response to: RIN 2900-AO32—Disease Associated With Exposure to Certain Herbicide Agents: Peripheral Neuropathy

To Whom It May Concern:

While the Center for Veterans Advancement (“CVA”) applauds the decision by the Department of Veterans Affairs (“VA”) to delete the inaccurate phrase “acute and subacute,” and any accompanying references suggesting a transient nature, in its definition of service-connected peripheral neuropathy, CVA objects to the repetitive and potentially inaccurate use of the term “early-onset” to describe such a multifaceted condition as peripheral neuropathy.

Introduction

The Agent Orange Act of 1991 directed the VA and the National Academy of Sciences (“NAS”) to conduct periodic comprehensive reviews of all scientific and medical literature regarding the health effects of exposure to herbicides used in the Vietnam War during 1961-1971.\(^1\)

2, 3, 7, 8-tetrachlorodibenzo-\(p\)-dioxin (“TCDD”), the most toxic compound in the dioxins found in Agent Orange and related herbicides, forms as a byproduct during the manufacture of an essential component of Agent Orange, 2, 4, 5-trichlorophenoxyacetic acid (“2, 4, 5-T”). TCDD concentrations varied between batches of Agent Orange, but the most recent research concludes

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that the mean concentration of the toxin in the herbicide was 13 ppm.² A plausible estimate of the total amount of TCDD used in Vietnam in 1961-1971, then, amounts to 366 kilograms.³

Because of the difficulty assessing the variable exposure rate between different units of US military personnel who served in Vietnam, Congress mandates that the VA view service in the Republic of Vietnam as a proxy for herbicide exposure.⁴ It also requires the VA and NAS to conduct their review of Agent Orange scholarship every two years, and issue a report summarizing their evaluation: Veterans and Agent Orange ("VAO").⁵

In the 2010 update, the VAO Committee revised its earlier conclusions regarding the neurological disorder peripheral neuropathy. Peripheral neuropathy is characterized by damage to the nerves that carry information to the brain.⁶ It can be caused by many different factors, including toxicant exposure, and symptoms include numbness, pain, and damage to organs, nerves and muscles.⁷

The VA has allowed the presumption that peripheral neuropathy is due to Agent Orange exposure, and is therefore service-connected, if a Veteran’s symptoms: (1) appear within one year of exposure, at a rate of at least 10% disability; and (2) are temporary. Currently, the VA does not assume a service connection for chronic peripheral neuropathy, defined as peripheral neuropathy that lasts longer than two years.⁸

However, in its “2010 Update,” the VAO finds that: “there is limited or suggestive evidence of an association between exposure to the chemicals of interest and early-onset peripheral neuropathy that may be persistent.”⁹ Thus, the VA’s proposed change to its presumption of service rules, regarding peripheral neuropathy, will now include chronic peripheral neuropathy, in addition to the already-recognized acute/transient peripheral neuropathy. In essence, the change would eliminate the need for condition number 2, above. This change is a boon for Veterans who have suffered from chronic peripheral neuropathy for many years, but have been unable to rely on the presumptive service connection to obtain disability benefits.¹⁰

³ Id.
⁵ Institute of Medicine of the National Academies, Board on the Health of Select Populations. Available online at: http://www.nap.edu/openbook.php?record_id=13166&page=R1 ("VAO Update 2010").
⁷ Id.
⁹ VAO Update 2010 at 634.
¹⁰ These veterans often had to rely on the “direct basis” avenue of recovery established in Combee v. Brown, 34 F.3d 1039 (Fed. Cir. 1994) (holding that the Veteran was not precluded under the Veterans’ Dioxin and Radiation Exposure Compensation Standards Act from establishing service connection with proof of direct actual causation), e.g., Board of Veterans Appeals Citation No. 0802669 (allowing benefits with proof of direct causation rather than presumption of service-connection, since Veteran’s peripheral neuropathy persisted over 20 years).
However, the VA continues to deny benefits to Veterans who may suffer from peripheral neuropathy that appears after one year of exposure, also known as delayed-onset peripheral neuropathy. In other words, the VA will continue to disallow a presumption of service connection to Veterans who cannot meet condition number 1, above.

**Discussion**

The proposed change to the VA’s presumption of benefits rule for Veterans who suffer from peripheral neuropathy expands access to benefits for many Veterans, who not only suffer from a painful disease, but who continue to suffer from the disease for a long period of time. Rather than asserting that the very length of a Veteran’s suffering prevents him or her from receiving necessary benefits, the Veteran will now be able to receive assistance for this condition without having to resort to the lengthy process of proving that his or her condition was a direct result of service.\(^{11}\)

Unfortunately, there remains a group of Veterans who must continue to suffer without the presumption of service connection: those whose peripheral neuropathy manifests 366 days or more after exposure. CVA argues that the VA’s proposed change of the words “acute and subacute” to “early-onset” is not only unnecessarily repetitive, but also that it is substantively inaccurate for the following reasons: (1) The methodological problems of relying on the NAS’s review of the scientific literature, due to the latent nature of the condition; (2) The myriad factors clinically proven to cause peripheral neuropathy, such as alcoholism and diabetes, which intervene in the studies at issue; and (3) The failure of the NAS to fully take into account several studies that unequivocally prove the existence of delayed-onset peripheral neuropathy. CVA addresses each issue in turn.

**Regulatory Construction Problems**

Some of the specific proposed changes to the regulation are unnecessary and confusing. The change to 38 C.F.R. §307(a)(6)(iii), for example, now reads: “...early-onset peripheral neuropathy shall have become manifest to a degree of 10 percent or more within a year after the last date on which the veteran was exposed...” (emphasis added). The repetition of this sentence is entirely unnecessary. Simply stating that peripheral neuropathy must manifest to a degree of 10% within one year without qualifying that the peripheral neuropathy must be “early-onset” is sufficiently clear.

Additionally, the changes to 38 C.F.R. §3.816(b)(2) have no connection whatsoever with the findings of the NAS regarding peripheral neuropathy. Deletion of the list of diseases may make the statute appear more streamlined, though the VA’s presumed concern with repetition here does not parallel its rationale in 38 C.F.R. §307(a)(6)(iii), above. Referring a reader of §816 to §309 appears only to further obfuscate the diseases that receive a presumptive service connection. This may serve to undermine the Agent Orange Act of 1991.\(^{12}\) Congress enacted, and the federal courts have upheld, 38 U.S.C. § 501(a). The intent of Congress is clear in this statute. It is understood that agencies are granted deference in their interpretation of an


\(^{12}\) 38 U.S.C. §316(b).
ambiguous statute. There is no such ambiguity here. Instead, the VA goes beyond its power of agency in deleting language from a regulation without any rationale.

Methodological Problems

Assessment of human exposure to the above-referenced herbicides is by its nature a complex scientific endeavor, best left to experts in the field. The VAO itself highlights the “difficulties of assessing exposure in the complex environment that characterized Vietnam during the period of interest.”

One key difficulty the VAO points out is the potential latent nature of some of the conditions linked to Agent Orange exposure: “many diseases do not appear immediately after exposure.”

The VAO, then, undermines its own recommendation to allow benefits to Veterans who suffer from chronic peripheral neuropathy, but not delayed-onset peripheral neuropathy. The latent nature of this disease, which the Committee itself warns against, may prevent symptoms of peripheral neuropathy from appearing until after one year of exposure. It is illogical to approve benefits for Veterans whose symptoms appear within 365 days of exposure while denying benefits for Veterans whose symptoms for the same condition do not manifest until 366 days after exposure, due to its latency.

In support of the disparity between the law and actual practice, consider the following example taken from the Board of Veterans Appeals (“BVA”). The BVA has considered the latent nature of this condition, and found in favor of disabled Veterans on many occasions. For example, the Phoenix BVA considered service-connection for peripheral neuropathy in one Veteran who did not seek treatment for his condition until 2002. There was classic difficulty with the evaluation of this Veteran’s condition by his doctors: according to the VA examiner, “unfortunately many peripheral neuropathies are of unknown etiology and to arbitrarily assign one to a caustic agent does not seem to be the best medical decision.” However, the Veteran’s private physician offered a different opinion after a comprehensive analysis:

[T]he veteran's claim was denied because he did not complain of symptoms within the very short time period cited by the VA after exposure to herbicides... it is clearly documented in the medical literature that neuropathy can be latent for a period of up to decades, and a denial based on short term exposure and short term initiation of acute complaints seems to be somewhat arbitrary... there is at least a 51 percent probability that the veteran's neuropathy may be directly linked to exposure to dioxin/Agent Orange.

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13 See, Chevron USA v. National Resources Defense Council, 467 U.S. 837, 842–843 (1984) (“If the intent of Congress is clear, that is the end of the matter; for the court as well as the agency must give effect to the unambiguously expressed intent of Congress.”)
14 VAO Update 2010 at 54.
16 BVA, Citation No. 0606156.
17 Id.
18 Id. (emphasis added).
This medical professional, at least, found the VA’s timeline to be “arbitrary,” based on his thorough knowledge of a disease that can be latent “for a period of up to decades.” In that case, as in others, the BVA found a direct link between a Veteran’s peripheral neuropathy and his or her service in Vietnam. Many Veterans, however, do not have the luxury of appealing a VA denial of benefits, which may include spending a significant amount of money and time for the BVA to overturn the decision on a direct-link basis.

**Intervening Factors**

Peripheral neuropathy can arise from many causes. While some of the causes, such as trauma to a nerve due to a combat-related incident, would certainly precipitate the onset of the condition as soon as it occurs, others may take more time to develop in the body, thus leading to delayed-onset peripheral neuropathy.

For example, exposure to toxins can cause the condition. Exposure to some poisons, such as Agent Orange, would lead to early-onset peripheral neuropathy. However, exposure to other poisons, such as the chemicals utilized in chemotherapy treatments to treat Agent Orange-induced cancer, could be the indirect result of a separate condition due to service in the Vietnam era. Veterans exposed to both types of toxins, whether directly or indirectly due to service in Vietnam, should receive the same benefits.

Due to the common intervening factors of peripheral neuropathy and other diseases, particularly alcoholism and diabetes, the VA refuses to rely on recent studies suggesting a relationship between delayed-onset peripheral neuropathy and Agent Orange. It balks at the “confounding nature” of concurrent exposure of these two conditions and peripheral neuropathy. The very fact that these diseases are so intertwined, as expressly stated by the Committee, should be sufficient impetus to include delayed-onset peripheral neuropathy as a presumptive service condition. Veterans should not have to suffer due to the chicken-and-egg nature of alcoholism, diabetes, and peripheral neuropathy.

**Research on Delayed-Onset Peripheral Neuropathy**

As the VAO points out:

Neurological disorders due to toxicant exposure may result in either immediate or delayed dysfunction of any component of the nervous system; immediate effects of toxicants may involve all aspects of the nervous system, whereas delayed effects are likely to produce more focal problems. Diffuse damage to the CNS [central nervous system] may cause alterations in thinking, consciousness, or attention, often in combination with abnormalities in movement. Focal dysfunction can cause myriad syndromes, depending on which area is damaged.

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19 E.g., BVA Citation Numbers 0306225 (Milwaukee, WI), 0606156 (Phoenix, AZ), 0802669 (Atlanta, GA), 0821251 (Tennessee).
21 Id.
22 Id. at 632.
23 VAO Update 2010 at 611(emphasis added).
By this very language, the VAO suggests that Agent Orange can cause delayed-onset peripheral neuropathy. There are additional studies that suggest a link between exposure to the herbicide and delayed-onset peripheral neuropathy, though the VA gives them short shrift, in part because (as discussed above), “…all of the large veteran studies are limited by the confounding nature of concurrent diabetes and alcohol exposure, both of which are also related to neuropathy.”

For example, a study of Czech workers exposed to TCDD while working in a plant between 1965 and 1968 found that seven out of the eleven workers reevaluated suffered from peripheral neuropathy. This is a 64% incidence of the condition after exposure to TCDD. The VA discounts this study, however, not only due to its small sample size, but also because these seven workers also suffered from diabetes.

The VAO discounts another study supporting a link between Agent Orange exposure and delayed-onset peripheral neuropathy. Rosso et al. treated neuronal cell cultures with 2,4-Dichlorophenoxyacetic acid (“2,4-D,” a major ingredient of Agent Orange), and found a decrease in the mechanisms essential to maintaining synaptic connections between nerve cells, and supporting axon regeneration. These mechanisms are essential to recovery from peripheral neuropathy; it is unclear why the VAO discounts this study, despite its “biologic plausibility.”

The VAO also discounts studies on rats, though the scientific community commonly relies upon such testing methods. Two separate studies have reported observations of abnormalities in rats treated with TCDD.

Exposure to a toxicant such as TCDD or other dioxins found in Agent Orange can result in an immediate reaction, resulting in the accepted “early-onset” peripheral neuropathy. However, the VAO itself notes that toxicant exposure can also result in “chronic peripheral neuropathy that occurs years after the external exposure has ended (delayed onset).” The VAO’s summary of

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24 Id. at 632.
26 VAO Update 2010 at 633.
27 Id.
29 VAO Update 2010 at 633.
30 Id.
32 VAO Update 2010 at 630.
the evolving studies of Agent Orange’s effect on peripheral neuropathy in Vietnam Veterans points out that “more recent studies suggest... a relationship [between service and symptoms of neuropathy],” though it attempts to downplay these studies by associating the relationship to a “more sensitive measure of assaying symptom complexes” rather than to a real relationship.\textsuperscript{33} CVA questions the logic behind this conclusion.

**Conclusion**

The Center for Veterans Advancement objects to the proposed rule change regarding peripheral neuropathy for the aforementioned reasons.

To borrow from the Ninth Circuit, “[w]hether the Vietnam War was just or not, whether one favored or opposed it, one thing is clear. Those young Americans who risked their lives in their country’s service and are even today suffering greatly as a result are deserving of better treatment from the Department of Veterans Affairs then they are currently receiving.”\textsuperscript{34}

Thank you for your consideration.

Sincerely,

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\textsuperscript{33} Id. at 632.

\textsuperscript{34} *Nehmer v. United States Department of Veterans Affairs*, F.3d 846, 865 (9th Cir., 2007).