

THE SECRETARY OF VETERANS AFFAIRS WASHINGTON

January 28, 2003

The Honorable Lane Evans Ranking Democratic Member Committee on Veterans' Affairs U. S. House of Representatives Washington, DC 20515

Dear Congressman Evans:

This is in reply to your December 17, 2002, letter to President George W. Bush regarding your concern that persons who receive a smallpox vaccination during inactive duty training will be denied compensation for disability that may result from such vaccination.

As you may know, on May 14, 2002, the Department of Veterans Affairs' (VA) General Counsel issued a precedent opinion, VAOPGCPREC 4-2002, holding that, if evidence establishes that an individual suffers from a disabling condition as a result of administration of an anthrax vaccination during inactive duty training, the individual may be considered disabled by an "injury" incurred during such training for purposes of 38 U.S.C. §101(24). Section 101(24) defines "active military, naval, or air service" to include any period of inactive duty training during which the individual was disabled or died from an injury incurred in or aggravated by military service in the line of duty. The claim that prompted this General Counsel opinion is currently being re-adjudicated by a VA regional office to determine whether the individual is disabled as a result of the anthrax vaccination administered during inactive duty training.

I want to assure you that we have taken steps to make VA adjudicators aware of the General Counsel opinion. In particular, the opinion was on the agenda of a July 11, 2002, Veterans Benefits Administration conference call to the regional offices and is available to adjudicators on the VA Compensation and Pension intranet site. The opinion was again on the agenda of a conference call to the regional offices on January 9, 2003, specifically with respect to its significance in smallpox vaccination claims.

I, too, hope that neither the President nor any service member suffers an adverse effect as a result of receiving a smallpox vaccination. However, VA adjudicators have been advised that the holding of the 2002 General Counsel opinion "may be used to service connect a disability caused by a smallpox vaccination." Thus, if an individual suffers disability as a result of receiving such a

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vaccination during inactive duty training, VA adjudicators would consider the individual disabled by an "injury" incurred during such training for purposes of establishing entitlement to VA benefits.

I am enclosing a copy of the General Counsel opinion for your information. We appreciate your continued interest in issues related to veterans' benefits.

Sincerely yours,

Anthony J. Princip

Enclosure

Department of Veterans Affairs

Memorandum

Date: May 14, 2002

VAOPGCPREC 4-2002

From: General Counsel (022)

Subj: Meaning of "Injury" for Purposes of Active Service – 38 U.S.C. § 101(24)

To: Director, Compensation and Pension Service (21)

QUESTION PRESENTED:

Whether a former member of the Army Reserve who received two anthrax inoculations during inactive duty training and who alleges suffering from chronic fatigue and chronic Lyme-like disease as a result of these inoculations may be considered to have been disabled by an injury in determining whether the member incurred disability due to active service.

DISCUSSION:

- 1. The claimant had active duty service in the United States Army from May 29, 1995, to June 18, 1999, and was then assigned to the Army Reserve. In preparation for a required two-week tour of duty in Korea, the claimant received three anthrax inoculations, the first two of which were received while on inactive duty training on February 12 and March 11, 2000. The claimant received the third inoculation on March 25, 2000, while in civilian status. The claimant was deployed to Korea from April 10, 2000, to April 24, 2000. The claimant has filed a claim with the Department of Veterans Affairs (VA) seeking service connection for chronic fatigue and chronic Lyme-like illness claimed to have resulted from the anthrax inoculations.
- 2. Pursuant to 38 U.S.C. §§ 1110 and 1131, service-connected disability compensation may be paid for disability resulting from injury suffered or disease contracted in line of duty "in the active military, naval, or air service." Section 101(24) defines the term "active military, naval, or air service" as

¹ The Department of Defense (DoD) mandated anthrax vaccinations for all service members and DoD civilian employees assigned or deployed to high-threat areas. Memorandum of Under Secretary of Defense, Change of Anthrax Vaccine Immunization Program (AVIP) Operational Procedure, March 30, 1999. The Anthrax Vaccine Adsorbed (AVA) involves 6 subcutaneous injections over an 18-month immunization schedule and annual booster doses. Institute of Medicine, *The Anthrax Vaccine: Is It Safe? Does It Work?* at 5 (2002).

including "active duty, any period of active duty for training during which the individual concerned was disabled or died from a disease or injury incurred or aggravated in line of duty, and any period of <u>inactive duty training</u> during which the individual concerned was disabled or died from an <u>injury</u> incurred or aggravated in line of duty." (Emphasis added.) Thus, in the case of inactive duty training, only if the individual suffered an "injury" during such service can disability resulting from such service provide a basis of eligibility for disability compensation.

- 3. The question of what constitutes an "injury" for purposes of section 101(24) must be considered in light of three previous General Counsel opinions in which we analyzed the distinction between "injury" and "disease" under that statute. One such opinion, VAOPGCPREC 86-90 (O.G.C. Prec. 86-90), concerned whether a heart attack sustained following heavy exertion while on inactive duty training was an injury within the meaning of section 101(24). Medical evidence in that case indicated that the heart attack was the result of coronary artery disease, which existed prior to the training period, although the event may have been precipitated by physical exertion. On those facts, we concluded that the claimant's heart attack was not caused by an injury, but rather was attributable to disease.
- 4. In VAOPGCPREC 86-90, we examined the medical cause of the heart attack. We noted the consensus among medical specialists that excessive effort and strain cannot damage a normal heart and concluded that the heart attack was the result of a disease process. We further concluded that Congress intended to exclude "nontraumatic incurrence or aggravation of a disease process, and that manifestations of cardiovascular disease, such as heart attacks of nontraumatic origin, fall within the excluded class of disability, i.e., do not constitute injuries under the statute." In *Brooks v. Brown*, 5 Vet. App. 484, 487 (1993), *aff'd*, 26 F.3d 141 (Fed. Cir. 1994), the United States Court of Veterans Appeals concluded that VAOPGCPREC 86-90 is consistent with the governing statutes and Congress' policy reflected in those statutes. We note that the focus of our holding in VAOPGCPREC 86-90 was clearly on the non-traumatic nature of the cause of the heart attack. We may assume that a heart attack caused by a traumatic external event that is independent of a disease process, *e.g.*, an electric shock, may be considered an injury.
- 5. VAOPGC 6-86 (3-27-86) followed and relied upon what was formerly Op. G.C. 1-81 (subsequently reissued and redesignated as VAOPGCPREC 86-90). ²

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² The VA General Counsel opinion originally designated as Op. G.C. 1-81 was published on May 19, 1981. This opinion was reissued as a precedent opinion on July 18, 1990, and redesignated as VAOPGCPREC 86-90 (O.G.C. Prec. 86-90).

Although VAOPGC 6-86 is not precedential, it illustrates how the opinion now designated VAOPGCPREC 86-90 has been applied. In VAOPGC 6-86, we determined that a claimant who received an influenza vaccination by injection while on inactive duty training and subsequently developed Guillain-Barre syndrome did not incur a disability resulting from an injury for purposes of section 101(24). Referencing what is now VAOPGCPREC 86-90, we reasoned that the term "injury" denotes harm from external trauma, while the term "disease" refers to some type of internal infection or degenerative process. The opinion cited several sources for the proposition that the term "trauma" commonly refers to the application of external force or violence. We further reasoned that, under modern medical practice, the routine insertion of a hypodermic needle into the body is not commonly considered to involve application of external force or violence that is characteristic of injury. However, we recognized that an injection could be considered to have caused a traumatic injury if contact with the needle caused lasting nerve or tissue damage.

- 6. Most recently, in VAOPGCPREC 8-2001, we held that an individual who suffers from post-traumatic stress disorder (PTSD) as a result of a sexual assault that occurred during inactive duty training may be considered disabled by an "injury" for purposes of section 101(2) and (24). This conclusion was based upon the analysis of the preceding General Counsel opinions indicating that "injury" refers to the results of an external trauma rather than a degenerative process and the fact that, according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, of the American Psychiatric Association, at 427 (diagnostic criterion A), a diagnosis of PTSD requires experiencing a traumatic event.
- 7. The concept exemplified by these VA General Counsel opinions is that "injury" refers to the results of an external trauma, rather than a degenerative process. While, as noted in VAOPGC 6-86, "trauma" frequently is defined with reference to external force or violence, the term may commonly be considered to encompass injury to living tissue caused by an extrinsic agent. *Webster's Ninth New Collegiate Dictionary* 1256 (1990). In this regard, we believe that consideration of the nature of vaccines is helpful in resolving the issue of whether introduction of a vaccine into the body may constitute trauma for purposes of determining the nature of harm resulting from the vaccine.
- 8. A vaccine is a suspension of attenuated or killed microorganisms or of antigenic proteins derived from them. Dorland's Illustrated Medical Dictionary 1787 (28th ed. 1994). Vaccines artificially induce the immune system to produce antibodies that will attack invading organisms and prevent disease. National Institute of Allergy and Infectious Diseases, *How Vaccines Work*, *available at* http://www.niaid.nih.gov/daids/vaccine/how.htm. Although vaccines and mass

immunization programs have been extremely successful in protecting the public health against dangerous diseases, "available data indicate that some vaccines are associated with rare but serious adverse effects." *The Anthrax Vaccine: Is It Safe? Does It Work?* at 85. An adverse event following a vaccination may be either local or systemic. *Id.* at 86. The duration of these events may be acute or chronic, and adverse health effects may range from mild to severe. *Id.*

- 9. The foregoing discussion indicates that inoculation with a vaccine involves the introduction of a foreign substance into the body and that, while the substance is intended to and generally does have a beneficial effect, adverse reactions, sometimes of a severe nature, may result. Further, based on the above discussion, we believe that the term "injury" in section 101(24) may be interpreted to include harm not only from a violent encounter but also from exposure to a foreign substance, such as a vaccine. We recognize that in our non-precedential opinion VAOPGC 6-86 we concluded that harm resulting from an influenza vaccination would not be considered to have resulted from an injury. However, VAOPGC 6-86 focused on harm caused by the "routine insertion of a hypodermic needle into the body" and on the absence of external force or violence, rather than on the introduction of an extrinsic agent to body tissue. We believe the common understanding of the concept of "trauma," which is recognized as the cause of "injury," encompasses a broader definition than the one applied in VAOPGC 6-86 and that such broader definition includes serious adverse effects on body tissue or systems resulting from introduction of a foreign substance. Thus, an adverse reaction to a vaccination may be considered an "injury" as that term is used in 38 U.S.C. § 101(24).
- 10. This conclusion is consistent with VAOPGCPREC 86-90, in which the harm suffered (a heart attack) did not result from an external force or substance, but rather from a pre-existing disease. This conclusion is also consistent with VAOPGCPREC 8-2001, in which we recognized that a condition (in that case PTSD) that has characteristics of a disease may be considered to be the result of an injury, where it resulted from an external assault.

HELD:

If evidence establishes that an individual suffers from a disabling condition as a result of administration of an anthrax vaccination during inactive duty training, the individual may be considered disabled by an "injury" incurred during such training as the term is used in 38 U.S.C. § 101 (24), which defines "active military, naval, or air service" to include any period of inactive duty training during which the individual was disabled or died from an injury incurred or aggravated in line of duty.

Consequently, such an individual may be found to have incurred disability in active military, naval, or air service for purposes of disability compensation under 38 U.S.C. § 1110 or 1131.

Tim S. McClain