OFFICE OF SPECIAL MASTERS

90-1729 V

(Filed: April 4, 1997)

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JOHN KEVIN O'LEARY,	*	
Petitioner,	*	
	*	
vs.	*	PUBLISHED
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SECRETARY OF THE DEPARTMENT	*	
OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *		

Michael R. Skow, Sacramento, California, for petitioner.

Karen Hewitt, U.S. Department of Justice, Washington, D.C., for respondent.

French, Special Master.

DECISION

This case arises under 42 U.S.C. §300aa-1 et seq., the National Vaccine Injury Compensation Act of 1986. Petitioner filed his claim on September 27, 1990 alleging that as the result of a diphtheria-tetanus (DT) shot administered on June 26, 1983 in San Diego, California, he sustained an adverse neurological reaction resulting in chronic relapsing inflammatory demyelinating polyradiculoneuropathy (hereinafter CIDP or polyneuropathy).

On May 20, 1993, the court issued an order informing petitioner that because the injury alleged is not an injury listed in the Vaccine Injury Table, petitioner is required to establish his claim by the causation in fact method of proof; the statute's presumption of causation is not available to petitioners in off-Table cases. The medical records contain occasional references to the tetanus vaccine, but Mr. O'Leary did not have on file the opinion of a qualified expert that the tetanus vaccine, in fact, caused Mr. O'Leary's polyneuropathy. The court cannot make a finding of entitlement based on petitioner's allegations alone unsubstantiated by medical records or medical opinion. §13(a)(1).

A General Order of the Chief Special Master, issued on November 1, 1991 explains the criteria for a medical expert opinion. That Order specifies that the expert opinion -

should be in affidavit form attesting to a reasonable degree of medical certainty, that a specific Table injury occurred within the time frames of the Table or that the vaccine in-fact caused the injury alleged. The affidavit must clearly address the factual and medical basis for the doctor's opinion. Affidavits that merely draw a conclusion are not sufficient.

This threshold requirement was set forth early in the proceedings of this case so that petitioner understood the steps necessary to avoid dismissal. In an off-Table case of this kind, petitioner has two requirements: 1) He must establish that the tetanus toxoid is capable of causing the type of injury sustained; and 2) He must establish that the vaccine caused the injury in this particular case.

EXPERT OPINION

On October 1, 1993, petitioner filed the opinion statement and "Medical Literature Review" of Dr. Charles K. Jablecki, one of petitioner's treating physicians. Petitioner's Exhibit 8(a). Dr. Jablecki found scattered reports throughout the medical literature of polyneuropathy occurring after DPT inoculations. (1) He found one particular case, reported by Pollard and Selby and reviewed by Arnason and Soliven, to be good evidence to support a causal relationship:

On three separate occasions, following tetanus toxoid booster, the patient developed an acute inflammatory demyelinating polyradiculoneuropathy (AIDP). The case report by Pollard and Selby is different from that of Mr. O'Leary, in that Mr. O'Leary's condition has become chronic and requires persistent treatment, whereas the case of Pollard and Selby was self-limited, with resolution of weakness several months after each injection. It is neither a large step nor an illogical one to propose that a tetanus toxoid booster can precipitate CIDP in susceptible individuals as has been shown to be the case for tetanus toxoid booster and AIDP.

Id. at 2.

Dr. Jablecki reviewed also a case reported in German literature by Groud et al. bearing a striking resemblance to the case history of Mr. O'Leary in which it was presumed that the tetanus toxoid was followed by relapsing CIDP. He found significant the fact that there is at least one published report in a peer-reviewed neurologic journal "which supports the concept that tetanus toxoid injections can cause a chronic, relapsing polyneuritis (CDIP)." Id. He notes one difference, however, between the two cases; in the case of the German patient, the patient received several injections of tetanus toxoid, and Mr. O'Leary received only one.(2) Dr. Jablecki states further: "One might argue that it takes more than one injection of tetanus toxoid to precipitate a CIDP syndrome." Id. at 3. His opinion is, however, that that argument is speculative and not factually based. He accepts the report of Groud et al. as evidence that tetanus toxoid injection can precipitate a chronic, relapsing polyneuropathy (CIDP). Dr. Jablecki states that petitioner's neurological syndrome is clearly a form of CIDP and, in his medical opinion, is a complication of the tetanus toxoid booster received in June, 1992. Id. at 4.

On March 23, 1994, respondent filed the report of W.C. Wiederholt, M.D. challenging Dr. Jablecki's opinion statement.(3) Dr. Wiederholt claims that the report by Pollard and Selby is irrelevant because the patient suffering three relapsing events was diagnosed as suffering Guillain-Barre' syndrome (GBS or AIDP)(4) and Mr. O'Leary has CIDP. Dr. Wiederholt claims that prevailing medical opinion is that these two conditions, AIDP and CIDP, are separate entities. He is of the opinion that to conclude a causal relationship between a vaccine and a neurological illness on the basis of a single published case is

speculative and without merit; one cannot rule out a random temporal association. Respondent's Exhibit A.

DISCUSSION

The experts do not disagree, apparently, that an affirmative case can be made to link tetanus toxoid and AIDP/GBS as a sequela, although it is a rare event. The 1994 Report of the Institute of Medicine (IOM), Adverse Events Associated with Childhood Vaccines: Evidence Bearing on Causality, acknowledges a causal relationship.[(5)] Dr. Wiederholt does not accept the possibility of a causal relationship with the "chronic" form of the disease, as stated earlier, because only one other case has been documented in the medical literature. Although he claims the two (AIDP and CIDP) are separate entities, the court is troubled by that allegation.

CIDP and AIDP are both inflammatory demyelinating polyradiculoneuropathies. According to Doctors Peter James Dyck, John Prineas, and John Pollard, who discuss Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP) in a recent textbook, the two (CIDP and AIDP) are treated separately only because they differ in course, outlook, and treatment. The mechanisms underlying each remain unknown, but it is not clear, they state, "that their separation will prove to have fundamental validity. . . . [I]t is possible that both syndromes are variants of the same disorder, as their shared pathologic features might suggest." They quote an earlier work by Waksman and Adams describing experiments in animal models: "The presence of acute, chronic, and relapsing variants argues for the thesis that AIDP, relapsing AIDP, and CIDP may similarly constitute variants of a single basic process."[(6)]

Peripheral Neuropathy, 3rd, ed., Chapter 81, W.B. Saunders, 1993, Dyck, Thomas, Griffin, Low, and Podulso, Id. at 1499-1500, 1467.

The court is inclined towards Dr. Jablecki's opinion that CIDP can be caused by the same antigen that on occasion causes AIDP. The basis for his opinion is well researched and his conclusions are thoughtful, his reasoning is sound, and his theory is thought provoking. The court does not subscribe to Dr. Wiederholt's reasoning that a single case report in medical literature could not support the possibility of a causal relationship. If sound medical and scientific principles have been applied in that one case, and the matter has been published for peer review, one is justified in assuming that if it happened once, it could happen again.[(7)] Dr. Wiederholt would hold the court to a more stringent standard of scientific certainty than that required by the statute.[(8)] Based on the persuasive written statement presented by Dr. Jablecki and the the court's own review of the medical literature, articles either filed or referenced in this case, the court finds a preponderance of evidence supports a finding that it is entirely likely that tetanus toxoid can cause CIDP.

The inquiry, however, does not end there. Other factors must be considered in an off-Table claim, and Dr. Jablecki himself has identified the evidentiary problems in proving causation in any individual case, including this one. That problem is whether or not there can be a better explanation for this patient's CIDP. Dr. Jablecki writes:

CIDP can follow a flu-like illness, presumably from activation of an immune response or cross reactivity to the infective virus. Mr. O'Leary does not give a history of such flu-like illness in the months prior to his development of the symptoms . . . . Not uncommonly, CIDP develops without a clear history of a previous viral infection, so the absence of the viral infection does not exclude a post infection etiology. Since we do not know all the factors which can precipitate a CIDP syndrome, there may be explanations for the occurrence of the problem other than the tetanus toxoid booster.

Petitioner's Exhibit 8(a) at 3.

Dr. Jablecki correctly assesses the problem in this case. For purposes of clinical diagnosis, care, and treatment, a treating physician is expected to proceed according to his or her assumptions. Such assumptions, however, may not be legally sufficient to prove the accuracy of those assumptions. The court finds his assumptions insufficient in this case. Too many unknowns exist, and as Dr. Jablecki admits, other causes are possible.

As the evidence stands, the court considers it to be in equipoise. Something more is needed in an off-Table case to tip the scales. The court is ill equipped to identify the type of evidence that might establish petitioner's case. But as an example, in Robinson v. Secretary of HHS, No. 911-1V slip op. (Ct.Fed.Cl., Spec. Mstr., No. 27, 1991), the fact that the petitioner suffered an identical neurological reaction (Guillain-Barre Syndrome or AIDP) after each of two injections of the tetanus toxoid vaccine was sufficient to establish the likelihood that her condition was not merely temporally related, but causally related. In Robinson, this court held that epidemiological studies are not necessarily the standard by which this court is required to render its decision in vaccine cases, but petitioner can point to no studies that might suggest statistical probabilities of random occurrence in the general population. In fact, evidence suggests the incidence in the population to be equal to the background rate of CIDP occurrence. According to Drs. Dyck, et al.:

We reported "a not infrequent history of preceding infection, immunization, or receipt of . . . medical injection within a few weeks or months of onset or exacerbation [of CIDP]. On later analysis it was less clear whether any of the occurrences of preceding infection or receipt of biologic material was higher than in the control populations."

Id. Peripheral Neuropathy, Dyck, Thomas et al. at 1501-1502.

Temporal association to the vaccine is not enough to establish causation. The extra factor is missing. No unusual titers were observed that might implicate the tetanus toxoid. The experts enjoy relatively equal status in credentials and expertise. Dr. Jablecki states his opinion to the necessary level of certainty, but he is opposed by an equally qualified doctor. No other physician is willing to support a vaccine-related cause in Mr. O'Leary's case except as a possibility.[(9)] Mere conjecture does not meet the standard required.

The burden of affirmatively establishing a preponderance of evidence must be shouldered by the petitioner; that level of proof is not apparent here.[(10)]

Under these circumstances, a finding for petitioner would be tantamount to establishing a presumption of causation for any case of CIDP that would arise within temporal relationship to a tetanus toxoid, DPT shot, or any other vaccine combination containing tetanus toxoid. The court declines to so extend the law. Petitioner's claim is denied.

Absent a motion for review filed pursuant to RCFC Appendix J, the clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

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E. LaVon French

Special Master

1. Dr. Jablecki is board certified by the American Board of Psychiatry and Neurology, and by the American Board of Electrodiagnostic Medicine. He is a Neurology consultant at several hospitals in San Diego, and Associate Clinical Professor of Neurosciences at the University of California, San Diego.

2. Mr. O'Leary, in fact, did have one earlier tetanus shot apparently without reaction.

3. Dr. Wiederholt is board certified by the American Board of Qualification in Electroencephalography and the American Board of Psychiatry and Neurology. He is Professor of Neurosciences at the University of California, San Diego, and an attending physician at various San Diego hospitals.

4. Guillain-Barre' syndrome is also called "Acute Inflammatory Demyelinating Polyradiculoneuropathy, or "AIDP."

5. National Academy Press, Washington, D.C. 1994, at 16.

6. Authors Waksman and Adams were researching effects on monkeys of experiments that induced inflammatory disease of peripheral nerve allergic neuritis (EAN), the term used by the experimental team at that time [1955] for AIDP and CIDP. Dyck et al. state:

The acute inflammatory polyneuritis, CIDP, and the experimental autoimmune diseases EAN and the chronic EAN, produced by sensitizing animals to peripheral nerve myelin or the P2 basic protein of peripheral nerve myelin, bear a close resemblance to each other clinically and pathologically, suggesting that these are related diseases with a common pathogenesis.

Id. at 1509.

7. The medical literature suggests that studies of AIDP in past years included the chronic form without differentiating it from the acute form. A 1975 article identified in Petitioner's Exhibit 12 at 12, states:

[T]here are numerous cases on record that, having begun as acute inflammatory polyradiculoneuropathy, have passed on after an incomplete remission or one or more acute relapses, into a chronic slowly progressive neuropathy. Thus it is established that acute inflammatory polyradiculoneuropathy can have a chronic form.

Arnason, B.G., Inflammatory demyelinating Polyradiculoneuropathies, (1975), "Peripheral Neuropathy," at 1110.

8. Dr. Wiederholt participated in a comprehensive epidemiological study of adverse reactions to swine flu vaccine. He determined that a statistically significant increase in incidence of neurologic injury following swine flu vaccine was of sufficient magnitude to establish the likelihood of a causal relationship between that specific vaccination and the neurological sequelae. No epidemiological studies

relative to CIDP or tetanus toxoid that might assist petitioner in this case have been performed. This fact does not preclude petitioner from making his claim, however it makes proof of a causal link somewhat more difficult.

9. Dr. Leonard S. Bernstein expressed interest in Dr. Jablecki's theory; See November 10, 1987 Letter of Dr. Leonard S. Bernstein, M.D., to Dr. Charles K. Jablecki, Petitioner's Exhibit 2 at 40 (filing of April 13, 1992; A letter from a consulting neurologist, Dr. Richard A. Smith, dated December 10, 1984 agrees only that a causal link is possible:

In your case it is possible that the diphtheria-tetanus injection was a precipitating factor. Obviously this would be hard to prove unless other cases are reported.

Medical Records at 67, filed with Petition, September 27, 1990.

10. Mr. O'Leary, petitioner in this case, filed his own report. He has become familiar with the medical literature relating to his condition and has cited medical articles that present the possibility of a causal connection between the tetanus toxoid and disorders similar to his own. Petitioner is not a medical doctor and is unqualified to present expert opinion evidence in this field. In some instances, the court has read the same learned treatises that petitioner, himself, cites. The court, however, does not rely upon Mr. O'Leary's arguments.