In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-0591V

Filed: 24 April 2009

LAUREL STIEBLER Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	*	**UNPUBLISHED DECISION**[1]

Ronald Craig Homer, Esq., Conway, Homer & Chin-Caplan, Boston, Massachusetts, for Petitioner; *Glenn Alexander MacLeod, Esq.*, United States Department of Justice, Washington, District of Columbia, for Respondent.

DECISION ON ENTITLEMENT BASED UPON THE WRITTEN RECORD

ABELL, Special Master:

On 16 August 2006, the Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"),[2] alleging that she suffered a neurologic injury, and that such was related to the administration of a tetanus toxoid (Td) vaccination on 23 September 2004. Petition (Pet.) at 1. As an alleged vaccine-related injury, Petitioner

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[1] This opinion constitutes my final "decision" in this case, pursuant to 42 U.S.C. § 300aa-12(d)(3)(A). Therefore, unless a motion for review of this decision is filed within 30 days after the time given herein to Petitioner to make such filing has elapsed, the Clerk of this Court shall enter judgment in accord with this decision. Moreover, Petitioner is reminded that, pursuant to 42 U.S.C. § 300aa-12(d)(4) and Vaccine Rule 18(b), a petitioner has 14 days from the date of decision within which to request redaction "of any information furnished by that party (1) that is trade secret or commercial or financial information and is privileged or confidential, or (2) that are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, "the entire decision" may be made available to the public per the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

[2] The statutory provisions governing the Vaccine Act are found in 42 U.S.C. §§300aa-10 et seq. (West 1991 & Supp. 1997). Hereinafter, reference will be to the relevant subsection of 42 U.S.C.A. §300aa.

demanded compensation for unreimbursable expenses for past or future treatment, pain and suffering, and attorney's fees and costs. This Court is jurisdictionally invested with the task of determining whether Petitioner is entitled to compensation. Due to the lack of substantiating proof of the types statutorily-required and amounting to a preponderance of the evidence, the Court denies compensation.

I. PROCEDURAL HISTORY

Petitioner was represented by able counsel, and filed all of the relevant medical records relating to Petitioner's alleged condition. See Petitioner's Exhibits ("Pet. Ex.") 1-22. Respondent filed its Report, pursuant to Rule 4(c), on 23 March 2007, denying compensation. After sincere attempts throughout calendar year 2007 (and into 2008) to engage a thoroughgoing, explanatory medical expert to opine in support of the Petition, Petitioner moved on 22 May 2008 for a ruling on the written record, and the Court hereby grants that motion.

II. FACTUAL RECORD

Petitioner received the Td vaccine on 23 September 2004, a fifty-one year old woman with a history of chronic pain and nerve irregularity, specifically appurtenant to her neck and shoulders; she had been engaged in physical therapy in the months preceding her vaccination. Pet. Ex. 1 at 183-84, 202, 217. Petitioner's constellation of symptoms led her physicians at one time toward a diagnosis of fibromyalgia. *Id*. at 189. Petitioner's history indicated her symptoms began on the left side in January 2004, and on the right side in June (or August) 2004. *Id*. at 152.

On the day of her vaccination, a ten-year tetanus-diphtheria booster, Petitioner complained to her doctor of some right-sided chest discomfort and tingling, which her doctor ascribed to her diagnosis of fibromyalgia. *Id*. at 179-80. At that time, her right shoulder had a full range of motion. *Id*.

She went to her chiropractor the next day, when her symptoms had improved. Pet. Ex. 2 at 9. One week after vaccination, at a physical therapy session, Petitioner experienced the sensation of a pulled muscle across the right side of her back, extending from the neck to the lower back, causing substantial pain. Pet. Ex. 1 at 177. Her pain improved but persisted. in the following weeks and months. Pet. Ex. 1 at 165, 170.

Later doctoral visits contradicted the fibromyalgia diagnosis somewhat, but no definitive diagnosis or aetiology was stated. Her condition was noted to be weaker, however, particularly in the right side. *Id*. at 161-62. Testing found spinal problems, including C5 radiculopathy, and Petitioner was prescribed steroids, which ameliorated her pain level. *Id*. at 152-53. Later, the C5 radiculopathy was implicated for Petitioner's weakness and nerve problems. *Id*. at 130-31.

It was only in March 2005 that onset was dated to the administration of the Td vaccine, or that her symptoms were tied to that vaccine. Pet. Ex. 1 at 128; Pet. Ex. 7 at 4 (the latter is a chiropractic record). This was later contradicted by another doctor's records, which date onset of right-sided symptoms in August 2004. Pet. Ex. 1 at 104. A physical therapy record from 30 November 2005 notes a history (without explanation) of "brachial neuritis from a tetanus shot." Pet. Ex. 4 at 1-5.

III. DISCUSSION

This Court is given jurisdiction to award compensation for claims where the medical records or medical opinion have demonstrated by preponderant evidence that either a listed Table Injury occurred within the prescribed period or that an injury was actually caused by the vaccination in question. § 13(a)(1). For certain categories of vaccines, the Vaccine Injury Table lists specific injuries and conditions, which, if found to occur within the period prescribed therein, create a rebuttable presumption that the vaccine(s) received caused the injury or condition. §14(a). The vaccine which Petitioner alleges to have caused her condition(s) was the Td vaccine, listed under category I on the Vaccine Table. Td is associated on the Vaccine Table with brachial neuritis (*inter alia*). 42 C.F.R. § 100.3(a).

First, on the claim for the Table presumption of causation, if Petitioner proved to a preponderance that the onset of brachial neuritis occurred between two and twenty-eight days following the vaccination, Petitioner would be entitled to a presumption that the vaccine caused brachial neuritis, requiring Respondent to prove that the condition was caused by a factor unrelated, lest Petitioner prevail on the issue of entitlement. §§11(c)(1)(C)(i) and 13(a)(1)(A)-(B). In finding facts to support or oppose a finding that Petitioner's condition fits these parameters, the Undersigned is directed by the Statute to consider "relevant medical and scientific evidence," to include "any diagnosis, conclusion, [or] medical judgment...contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, [or] condition," as well as "the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." §13(b)(1)(A)-(B). Of course, these sources are not mechanistically determinative, and the Undersigned may consider other portions of the record so as to view the record "as a whole" in arriving at particular factual findings. §13(b)(1)-(2).

Based upon the medical records and other materials filed in this case, it does not appear that Petitioner suffered from brachial neuritis the onset of which occurred between two and twenty-eight days following her Td vaccination on 23 September 2004. Rather, no contemporaneous records even diagnosed Petitioner's condition as brachial neuritis, and those records closest in time to the vaccination attribute the onset of the injury complained of to some number of months before the vaccination was even administered. Most notably, the records from the visit during which Petitioner received the Td vaccination discuss the symptoms as existent at the time of (and before) the vaccination was administered. Given the contents of Petitioner's medical records, the Court cannot

find by a preponderance that she suffered the onset of brachial neuritis within the period prescribed by the Vaccine Table in order to apply the Table presumption of causation.

Secondly, the medical records do not support a causative connection between the Td vaccination administered and the injuries suffered under an actual causation burden of proof. Under the statute, the Court cannot grant a petitioner compensation based solely on the petitioner's asseverations. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). Here, because the medical records do not manifestly support the petitioner's claim of vaccine causation, a medical opinion must be offered in support. No medical expert opinion report was filed by Petitioner to support the claims of causation within the Petition to a preponderance of the evidence, and Petitioner therefore did not surmount the standard set by the settled law on this point. Accordingly, the information on the record extant does not show entitlement to an award under the Program.

A petition may prevail if it can be demonstrated to a preponderant standard of evidence that the vaccination in question, more likely than not, actually caused the injury or condition complained of. *See* § 11(c)(1)(C)(ii)(I) & (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit has indicated that, to prevail, every petitioner must:

> show a medical theory causally connecting the vaccination and the injury. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370.

Furthermore, the Federal Circuit recently articulated an alternative three-part causation-in-fact analysis as follows:

> [A petitioner's] burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Secretary of HHS, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Under this analysis, while Petitioner is not required to propose or prove definitively that a specific biological mechanism can and did cause the injury leading to Petitioner's condition, he must still proffer a plausible medical theory that causally connects the vaccine with the injury alleged. *See Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (1994).

Of importance in this case, it is part of Petitioner's burden in proving actual causation to "prove by preponderant evidence both that [the] vaccinations were a substantial factor in causing the illness, disability, injury or condition and that the harm would not have occurred in the absence of the vaccination." *Pafford v. Secretary of HHS*, 451 F.3d 1352, 1355 (2006) (emphasis added), citing

Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir.1999). This threshold is the litmus test of the cause-in-fact (a.k.a. but-for causation) rule: that the injured party would not have sustained the damages complained of, *but for* the effect of the vaccine. *See generally Shyface, supra*.

Here, Petitioner has not filed medical records or offered medical expert testimony to proffer, let alone explain, a "medical theory causally connecting the vaccination [to] the injury." Certainly absent was a detailed analysis of the Record to indicate a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." As such, Petitioner has not offered a theory of causation as such, but this is certainly not due to lack of opportunity to present a medical expert opinion, *Q.E.F.* There has not been demonstrated to the Court a "a logical sequence of cause and effect showing that the vaccination was the reason for the injury," *Q.E.D.* *See Althen, supra*.

In short, Petitioner has not met the burden of proof set forth in the Act.[3] Petitioner has presented none of the evidence required by the Act in the form of corroborative medical records, and failed to account for the contrary explanations set forth in the medical records that contradicted their contentions.

IV. CONCLUSION

Therefore, in light of the foregoing, no alternative remains for this Court but to **DISMISS** this petition with prejudice. In the absence of the filing of a motion for review, filed pursuant to Vaccine Rule 23 within 30 days of this date, the clerk shall forthwith enter judgment in accordance herewith. **IT IS SO ORDERED.**

Richard B. Abell
Special Master

[3] *See Raley v. Secretary of HHS*, No. 91-0732, 1998 WL 681467 (Fed. Cl. Spec. Mstr. Aug. 31, 1998) (stating "[t]he requirement that [a] petitioner['s] claims must be supported either by medical records or medical expert opinion simply addresses the fact that the special masters are not medical doctors, and, therefore, cannot make medical conclusions or opinions based upon facts alone"); *Bernard v. Secretary of HHS*, No. 91-1301, 1992 WL 101097 (Fed. Cl. Spec. Mstr. Apr. 24, 1992) ("The medical significance of the facts testified to by the lay witnesses must be interpreted by a medical doctor, who, in turn, expresses the opinion either that a compensable Table injury has occurred or that the vaccine in question actually caused the injury complained of. If such an opinion appears in the medical records, then it is unnecessary to call a retained expert witness in order to establish a prima facie case; if, on the other hand, the medical records do not provide such substantiation, then a petitioner must retain a medical doctor who, upon review of the entire record, concludes that it is more likely than not that a compensable injury has occurred.").