In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 07-0464V

Filed: 31 March 2010

KATHLEEN COBLE and JACQUE COBLE,	*	
Petitioners,	*	
v.	*	**UNPUBLISHED DECISION**[1]
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Michael Andrew London, Esq., Douglas & London, New York City, New York, for Petitioner; *Melonie J. McCall, Esq.*, United States Department of Justice, Washington, District of Columbia, for Respondent.

DECISION ON ENTITLEMENT BASED UPON THE WRITTEN RECORD

ABELL, Special Master:

On 28 June 2007, the Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"),[2] alleging that the Petitioner,[3]

---

[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.

[3] Jacque Coble was improperly joined as a Petitioner.

Kathleen McCool suffered "fibromyalgia and associated neurological disorders," and that such was related to two administrations of the trivalent influenza vaccine, the first on 28 November 2000, and the second on 14 November 2001. Petition at 1. As an alleged vaccine-related injury, Petitioner demanded compensation. Pet. at 2. 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. After sincere attempts throughout calendar years 2008 and 2009 to engage a thoroughgoing, explanatory medical expert to opine in support of the Petition, Petitioner moved on 5 May 2008 for a ruling on the written record, and the Court hereby grants that motion. Respondent filed its Report, pursuant to Rule 4(c), on 20 August 2009, denying compensation, and the Court rules below on the issue of entitlement to compensation.

II. FACTUAL RECORD

Petitioner was born in 1961, and her medical history is remarkable for complications from Crohn's disease, other gastrointestinal concerns, some reactive airway disease, neck pain, stiffness, and weakness, and some other, more common ailments. Pet. Ex. 2 at 297-315, 352-405. She received the first of the two flu vaccines in question on 28 November 2000. Order, dated 9 October 2008. No complaints were mentioned that were neurological in nature, or that were associated with the flu vaccine, at a doctor's visit on 15 December 2000. Pet. Ex. 2 at 90. However, the very next day, 16 December 2000, Petitioner returned, complaining of "acute onset of stiffness and sharp sensation in her neck, followed by a hot feeling with persistent stiffness, arms becoming cold and tingling," and "her hands curling up involuntarily." Pet. Ex. 2 at 1. She told the doctor that these symptoms were reminiscent of symptoms she had experienced roughly a week prior, when "she turned her head wrong and felt a snap in her neck." *Id*. Petitioner returned two days later, on 18 December 2000, at which time her pain symptoms persisted, and mild right arm weakness was observed, leaving an impression of cervical strain. *Id*.

Petitioner's symptoms improved, such that by 11 January 2001, her symptoms were only limited range of motion in her neck and mild and intermittent tenderness in her right upper extremity. Pet. Ex. 2 at 9. However, on 23 January 2001, she returned to the doctor for severe neck and shoulder pain, weakness, and paresthesia. *Id*. at 8. Petitioner was tested to determine the aetiology of her symptoms, but nothing was conclusive, and her symptoms extended beyond what could be identified from physical examination. Pet. Ex. 2 at 12-13, 16-18, 21, 26.

Additional neurological symptoms (unrelated to her shoulder area) led to a neurology referral, which raised concern about a latent demyelinating process. Pet. Ex. 2 at 31-31, 38. As her symptoms waxed and waned, Petitioner's primary care physician was increasingly persuaded that Petitioner suffered from fibromyalgia. Pet. Ex. 2 at 66, 93.

Petitioner received the second of the two flu vaccinations at issue on 14 November 2001. Order, dated 9 October 2008. On 27 December 2001, Petitioner presented to her primary care physician again complaining of her ongoing shoulder pain, as well as pain in her hip, thigh, back, and arm, all of which was attributed to fibromyalgia. Pet. Ex. 2 at 116.

Since that time, Petitioner has been treated for her condition(s), believed to be chronic, by several doctors. The first association of her symptoms with vaccination appears to have been in a history taken at a neurology consultation on 5 November 2005, when she stated onset of her symptoms occurred in December 2000, "shortly after she had gotten a flu shot." Pet. Ex. 2 at 165. This does not appear to jibe with the medical records filed in this matter.

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 trivalent influenza vaccine, listed under category XIII on the Vaccine Table. Trivalent Influenza vaccine is associated on the Vaccine Table with no specific injuries or time periods, and thus Petitioner bears the burden of proving actual causation of any injury claimed to be related to that vaccine. 42 C.F.R. § 100.3(a).

In this case, the medical records mention, but do not in any way support a causative connection between the Trivalent Influenza vaccination claimed to have been 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 has articulated in a three-part test its actual causation 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.[4] Petitioner has not presented a sufficient amount of 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.**

s/ Richard B. Abell
Richard B. Abell
Special Master

[4] *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.").