In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 06-0713V

Filed: 29 April 2009

* * * * * * * * * * * * * * * * * * *		
PAIGE INGLE-PANG,	*	
	*	
Petitioner,	*	
	*	
v.	*	**UNPUBLISHED DECISION**[1]
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
* * * * * * * * * * * * * * * * * * *		

Milton Clay Ragsdale IV, Esq., Ragsdale LLC, Birmingham, Alabama, for Petitioner;
Lisa Ann Watts, Esq., United States Department of Justice, Washington, D.C., for Respondent.

DECISION ON ENTITLEMENT
BASED UPON THE WRITTEN RECORD

ABELL, Special Master:

On 16 October 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 paresthesias and fasciculations, and that such was related to the administration of a trivalent influenza vaccination on 15 October 2004. Petition (Pet.) at 1. This Court is jurisdictionally invested with the task of determining whether Petitioner is entitled to compensation. Due to the lack

[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.

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.") 1-14. After attempts throughout calendar year 2007 (and into 2008) to engage a thoroughgoing, explanatory medical expert to opine in support of the Petition, Petitioner was unable to secure an expert opinion in support of her claim. Therefore, during a status conference convened on 25 October 2007, Petitioner declared that she would move for a ruling on the record, once she had filed a supplemental fact witness affidavit and an amended Petition. Petitioner was granted until 23 November 2007 to do so, but failed to file anything further, until the Court filed an Order to Show Cause on 5 May 2008. Wherefore, Petitioner elected to file nothing further, save a motion for the Court to rule on the record as it stood. The Court, however, granted Respondent opportunity to file a Report, pursuant to Vaccine Rule 4(c), which Respondent filed on 17 July 2008. As the parties have filed all they believe is necessary for the Court to rule, the Court proceeds now to do so.

II. FACTUAL RECORD

Petitioner pre-vaccinal medical history included mitral regurgitation, thoracic back pain, ostopenia of the lumbar spine, neck, and hip, and chronic leg pain. Pet. Ex. 1 at 31-32; Pet. Ex. 2 at 11; Pet. Ex. 3 at 5-7; Pet. Ex. 8 at 1; Pet. Ex. 13 at 1-3. Without documentary evidence other than her VAERS report as proof, Petitioner asseverated that she received some influenza vaccine (which the Court presumes was a "Fluzone" trivalent influenza vaccine for the sake of this Decision on the basis of the VAERS report) on 15 October 2004, administered by her employer, a health facility. Declaration of Petitioner, filed without exhibit number on 24 April 2007.

Petitioner did not file an actual vaccination record or any medical records for the six weeks subsequent to the alleged vaccination. Respondent's Report at 2. However, Petitioner declared that within hours of the alleged vaccine administration, she began to experience tingling, vibrations, and muscle twitching in her extremities, focused in her legs. Declaration of Petitioner.

The first medical record following the alleged vaccination was on 8 December 2004. The history given noted that Petitioner had experienced joint pains in her knees and ankles following a newly-begun exercise regimen, but did not mention the alleged vaccination or any symptoms following it. Pet. Ex. 13 at 4-6. Petitioner also mentioned having been diagnosed previously with fibromyalgia. *Id*. The doctor thought certain medication unnecessary, and recommended only healthy activities and diet with some over the counter vitamin supplement. *Id*.

It was only when Petitioner switched primary care physicians that mention was made in the medical records of a vaccination and ensuing reaction. On 15 February 2005, four months after the alleged date of vaccine administration, Petitioner reported that she had received the vaccination in October 2004 and that she experienced widespread fasciculations (muscle twitching) thereafter. Pet. Ex. 3 at 4-7.

Petitioner underwent a neurologic consultation on 19 May 2005, where she gave a history of "severe" numbness, twitching, and tingling in her extremities after the alleged flu shot, which improved slowly, but were replaced by fasciculations across various general regions of her body. Petition at 3. However, the consulting neurologist reported normal results to lab testing, nerve conduction and EMG studies, evidencing none of the conditions Petitioner complained of. *Id*.

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 sufficiently 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 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 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.**

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.").