In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 05-710V

Filed: 29 April 2008

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GINA LASCUOLA, legal representative of a minor child, FRANCESCA MARIE LASCUOLA	*	
Petitioners,	*	
v.	*	**UNPUBLISHED DECISION**[1]
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* * * * * * * * * * * * * * * * * * * *	*	

James William Fletcher, Esq., Wyrsch, Hobbs & Mirakian, Kansas City, Missouri, for Petitioner; *Lynn Elizabeth Ricciardella, Esq.*, U. S. Department of Justice, Washington, D.C., for Respondent.

RULING ON ENTITLEMENT
BASED UPON THE WRITTEN RECORD

ABELL, Special Master:

On 30 June 2005, the Petitioner filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986 ("Vaccine Act" or "Act"),[2] alleging that her daughter ("Francesca") suffered cardiorespiratory arrest and encephalopathy, and that such was related to the

[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 Petitioners to make such filing has elapsed, the Clerk of this Court shall enter judgment in accord with this decision. Moreover, Petitioners are 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.

administration of Hepatitis B vaccinations on 11 May 2002 and 13 (or 16) June 2002, and/or a DTaP vaccination on 16 August 2002 to Francesca. Petition (Pet.) at 1. As an alleged vaccine-related injury, Petitioner 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.") 1-10. Respondent filed its Report, pursuant to Rule 4(c), on 21 April 2006, denying compensation. After sincere attempts throughout calendar year 2007 to engage a thoroughgoing, explanatory medical expert to opine in support of the Petition, Petitioner moved on 2 January 2008 for a ruling on the written record, and the Court hereby grants that motion.

II. FACTUAL RECORD

Francesca received the Hepatitis B vaccine the day she was born, on 11 May 2002, and she and her mother were discharged from the hospital on 13 May 2002. Pet . Ex. 1 at 1; Pet. Ex. 2 at 1; Pet. Ex. 4 at 15,18. According to Pet. Ex. 5 at 70, Francesca received her second Hepatitis B vaccine a month later at a doctor's office visit for an umbilical cord granuloma and congestion (the Petition alleges that the second Hepatitis B vaccine was administered on 16 June 2002 (Petition at 1)). Petitioner alleges in her affidavit that Francesca began fussing, crying, and experiencing sleep difficulties after that second vaccination. Pet. Ex. 6.

On 30 June 2002, Petitioner found Francesca unresponsive and not breathing; CPR was initiated and emergency help was contacted, and Francesca was brought, pale and cyanotic, to the Emergency Room. Pet. Ex. 8 at 2, 14, 23. Medical attention availed and she began breathing autonomically en route. Pet. Ex. 8 at 2. Clinical history taken from Petitioner at the hospital indicated that Francesca manifested fussiness in the preceding 24 hours, had slept more than usual that day, and had generally been eating well. Pet. Ex. 8 at 14; Pet. Ex. 10 at 634. That clinical history also recounted that Francesca had been irritable in the evenings, which Petitioner had assumed was due to colic. Pet. Ex. 10 at 643. The treating emergency care doctor assessed Francesca's case as "cardiopulmonary arrest; rule out sudden infant death syndrome, infection [and] abuse," and there was no discernable indication of "intracranial trauma or cerebral edema." Pet. Ex. 10 at 635, 645.

Medical examination on 2 July 2002 evidenced the sequela of "hypoxic brain injury," and tests did not indicate sepsis or trauma; however, EEG results did show "stiffening movements" that were suspected to be epileptic in nature. Pet. Ex. 10 at 651-52, 1083. Then, on 3 July 2002, Francesca manifested "a substantial decrease in her neurologic function, with deepening of coma," with CT scan evidence of "severe cerebral edema." *Id*. at 655-56. These negative signs were the

harbinger of a "grim" prognosis that is "associated with a post[-]arrest infant," although that condition fluctuated slightly. *Id*. at 656, 659, 663. A 23 July 2002 CT scan indicated that the "entire supratentorial brain appear[ed] to be undergoing atrophy" and evidence of a "profound anoxic event." *Id*. at 931. Upon discharge on 25 July 2002, Francesca's discharge diagnoses included "anoxic encephalopathy." Pet. Ex. 9 at 1.

Francesca attended a check-up on 16 August 2002, where she was administered the DTaP, haemophilus influenza type b, polio, and Prevnar vaccination. Pet. Ex. 5 at 67. Then, on 26 August 2002, Francesca returned to the emergency room after two apneatic episodes had required resuscitation. Pet. Ex. 10 at 208. EEG results were abnormal and "an active seizure disorder" was indicated. Pet. Ex. 9 at 11. Her discharge diagnoses were anoxic brain injury, seizures, and apnea. Pet. Ex. 5 at 59.

Francesca continues to receive medical attention for similar medical conditions, which have developed into lasting neurologic damage and delay, cerebral palsy, spastic quadriplegia, seizures, and scoliosis. Pet. Ex. 10 at 2030-31.

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 vaccines which Petitioner alleges to have caused Francesca's condition(s) were the DTaP and Hepatitis B vaccines, listed under categories I, II, and VIII on the Vaccine Table. DTaP is associated on the Vaccine Table with encephalopathy (*inter alia*), and Hepatitis B is categorized with no coordinate injury assigned. 42 C.F.R. § 100.3(a). Essentially, this relegates all claims upon Hepatitis B to an "actual causation" theory of relief, under which Petitioner must prove that such vaccine actually caused the injury(ies) alleged.

First, on the claim for the Table presumption of causation, the Petition claims that Francesca suffered from an encephalopathy as a consequence of her DTaP vaccination on 16 August 2002. Petition at 1. The term "Encephalopathy"is a listed Table Injury, corresponding to categories II and III. 42 C.F.R. § 100.3(a). That means that, if the Court were to find that Francesca actually suffered an encephalopathy (as defined in the Table's Qualifications and Aids to Interpretation) within 72 hours of receiving the DTaP vaccine, Petitioner would be entitled to a presumption that the vaccine caused that condition, 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 Francesca's condition fits the Table definition of encephalopathy, 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).

The Vaccine Table's Qualifications and Aids to Interpretation (QAI) posits that an encephalopathy sufficient to be granted the statutory presumption must manifest within 72 hours of vaccination. 42 C.F.R. § 100.3(a)(II)(B). For an encephalopathy to meet the criteria of the Table, it must present acutely and ultimately prove fatal or chronic. § 100.3(b)(2). Further, as to what constitutes an acute encephalopathy in Francesca's situation, "an acute encephalopathy is one that is sufficiently severe so as to require hospitalization ... [and] is indicated by a significantly decreased level of consciousness lasting for at least 24 hours." 42 C.F.R. § 100.3(b)(2)(i). The phrase "significantly decreased level of consciousness" is also a defined term in the QAI. Such state is "indicated by the presence of at least one of the following clinical signs lasting 24 hours or more: (1) Decreased or absent response to environment...(2) Decreased or absent eye contact...or (3) Inconsistent or absent responses to external stimuli. 42 C.F.R. § 100.3(b)(2)(i)(D). The QAI adds, furthermore, that "Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy." 42 C.F.R. § 100.3(b)(2)(i)(E).

Based upon the medical records and other materials filed in this case, it does not appear that Francesca suffered an encephalopathy fitting the Table definition within the 72 hours following her DTaP vaccination on 16 August 2002. Rather, Francesca's level of consciousness was already lowered by that point, and there is nothing in the record to indicate that it decreased further in the 72 hours following the DTaP vaccination or that it remained thus decreased for a period of 24 hours. Moreover, she was not hospitalized again (for apnea, requiring resuscitation) until ten days after the DTaP vaccination. Therefore, there is no evidence in medical records of affidavits that Francesca required hospitalization because of a period of significantly decreased level of consciousness lasting 24 hours or more, occurring within 72 hours of the DTaP vaccination. This description of those crucial 72 hour periods is not contradicted by any other exhibits filed in this case. Given the contents of Francesca's medical records, the Court cannot find by a preponderance that she suffered from an encephalopathy 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 vaccinations 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, 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. 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.").