

On February 21, 1995, this case was assigned to the undersigned special master. On August 31, 1995, respondent filed its report generally denying petitioner's claim on the basis that the evidence did not demonstrate a prima facie case. Respondent argues further that Amy's deficits are due to a factor unrelated to the vaccine, namely, a vascular accident that had its origin on or about May 28, 1986, five weeks after her DPT vaccination.

Petitioner attempted to cure the deficiencies in her factual and medical opinion evidence. Extensions of time were sought and freely allowed for this purpose. Although petitioners expended considerable effort to perfect their case, the court ultimately deemed the evidence insufficient to justify going forward with the case. For these reasons, the court denied petitioners' request for a hearing. [\(1\)](#)

On July 22, 1996, the court informed the parties that unless additional evidence was forthcoming, the court would issue a decision on the merits based on evidence existing in the record as it stands.

On August 14, 1996, the court issued a bench ruling denying petitioners' claim. The bench ruling is found at pages three through twenty-nine of the Transcript of August 14, 1996 proceedings. Both parties appeared by telephone conference call originating in Washington, D.C. Present also by telephone from Anchorage, Alaska were Mrs. Cecilia Bumanglag, Amy's natural mother, and Mrs. Regina Olszewski, Amy's maternal aunt. The court considered carefully the facts claimed and the medical evidence provided on petitioner's behalf and determined that petitioner had failed to establish her claim.

DISCUSSION

The following is a brief summary. Amy was born on November 24, 1984, an apparently normal infant with normal development and no problems of note. On April 21, 1986, she was given an DPT shot. On May 28, 1986, five weeks after her vaccination, Amy was hospitalized because of right hand and arm jerking motions following which she lost the use of that arm. The next day, May 29, 1986, a second incident similar to the first occurred several times in succession involving also the right side of the face. Other neurological signs appeared, and a CT scan showed positive evidence of a diffuse destructive lesion compatible with an infarction. An EEG was abnormal. Doctors identified what appeared to be poor "flow" to that area, and consultants in Seattle, where she was flown, confirmed that Amy had sustained a vascular accident (stroke) resulting in focal seizures, right sided hemiparesis, and a residual seizure disorder from which she has never recovered.

Amy's condition and behavior in the ten-day interval between the vaccination and a visit to the doctor May 1, 1986 are not documented in contemporaneous medical references. Mrs. Bumanglag insists that beginning on the day of her vaccination, Amy exhibited low grade fever, an unusual cry, was extremely fussy, and had to be held constantly. Mother was not unduly alarmed and did not seek medical advice until ten days later, May 1, 1986, at which time she was reassured by Amy's doctor, Dr. Werner.

Evidence to support Mother's claim that her baby was irritable in the interval between vaccination and the first frank seizure for which she was hospitalized on May 28, 1986, can be inferred from medical records:

On May 1, 1986, Dr. Werner documents that the infant had been fussy for "one and one-half weeks." Medical Records (hereinafter MR) filed December 28, 1984 at 60.

On May 28, 1986, Dr. Lillibridge wrote that the baby "was fussy about a month ago, again did not want to be laid down. Otherwise has been well." MR filed January 30, 1991 at 84.

On May 30, 1986, Dr. Wallington wrote that the infant has had "increasing fussiness for the last six weeks . . . crescendoing over the last two weeks. MR filed December 28, 1994 at 90.

A June 13, 1986 medical history, taken at the Neurology clinic in Seattle, notes "fussiness" since about the end of April. MR filed January 30, 1991 at 89-90.

Additionally, in her sworn affidavit, Mrs. Regina Olszewski recalls a phone call on the day after vaccination in which Mother related that she had been up with Amy all night because she was crying and irritable and wanted to be held.

These documents do not necessarily place the onset of irritability within three days; they appear to be the usual approximations one tends to find in these cases, but they arguably place onset of fussiness within the ballpark of time Mother claims it occurred. They do not, however, establish effectively the onset of an encephalopathy. Irritability may be a sign of encephalopathy, but not necessarily so.

MEDICAL EVIDENCE AND STATUTORY REQUIREMENTS

Accepting the foregoing facts as reliable, their significance is to be determined. For this, petitioner must supply, and the court must find persuasive, the testimony of medical experts.

Petitioner may prove her case by either of two methods. The first is by demonstrating that Amy sustained an injury listed in the vaccine injury Table (§ 14) and that onset of its first manifestation occurred within the three-day statutory time frame. This is called the "Table case" method. If respondent fails to prove thereafter that an alternative cause is more likely, petitioner may prevail. If petitioner is unable to establish a Table case, she may present evidence that the vaccine in fact caused the injury. This is popularly called the "causation-in-fact" method, and traditional tort standards of proof apply.

TABLE CASE

Petitioner has been unable to establish onset of the encephalopathy claimed. Irritability or high pitched and unusual or inconsolable crying, in and of themselves, are declared by statute to be insufficient evidence. Section 14(b)(3)(A). Without other neurological signs or symptoms of encephalopathy observable within the three-day time frame, petitioner cannot establish a Table case. Additionally, petitioner must supply persuasive expert opinion to support timely onset. This she has failed to do.

Petitioner speculates that the onset of seizures (a recognizable neurological sign) "probably" occurred within three days but were simply overlooked or unrecognized. Unfortunately, there is not one shred of evidence to support this argument. Petitioner has an affirmative burden to prove that the seizure activity or other sign of neurological injury occurred within Table time. First, Mrs. Bumanglag's memory cannot be relied upon. Her original affidavit, filed in 1990, states that she could not remember whether the first symptoms began within three days. She later recalled that fever and crying did indeed start within three

days, but as stated earlier, that fact does not advance her case. And finally, her supplemental affidavit dated December 21, 1994, states that she believes Amy "had seizures right after the shot" but that she did not recognize them. These speculative statements cannot support a favorable finding.

Pediatrician, Dr. John Tower, one of Amy's pediatricians, wrote as follows in preparation for these proceedings:

There seems to [be] good reason to presume that Amy's first DPT injection . . . has a causal relationship with her subsequent change in personality irritability and finally the seizure and infarction occurring 5-18-86.

Dr. Tower gives no basis for his opinion other than his "long experience as an Alaskan Board Certified pediatrician." He does not explain what he means by a "change" in personality, or how the infarction and seizure five weeks later can be related to the vaccination. Pediatric neurologist, Dr. Shirley Fraser, disagrees with Dr. Tower to a certain extent as will be discussed in the following paragraph.

Dr. Fraser is another of Amy's treating physicians and was called upon to provide an expert opinion in this case. She does not believe that Amy demonstrated encephalopathic symptoms within three days. She concludes that Amy's symptoms occurred within the first ten days but not within the first three. Dr. Fraser's expertise entitles her opinion to be given considerable weight in assessing an encephalopathy, somewhat greater weight than that of Amy's pediatrician whose expertise lies elsewhere. Petitioner, therefore, has failed to present, by a preponderance of evidence, existence of a Table injury in Table time. Petitioner's claim must fail unless evidence of causation in fact is legally sufficient.

CAUSATION IN FACT

The burden of proof in causation in fact cases is more onerous. Both of petitioner's experts, Dr. Tower and Dr. Fraser, believe that Amy's condition is likely to have been causally related to the vaccine. But neither has provided a persuasive basis for his or her position. To establish causation in fact, petitioner is required to prove a causal link between the vaccine and the injury based on a logical sequence of cause and effect supported by scientific or medical theory consistent with sound scientific thought. Such theory must be persuasive and supported in some measure by empirical evidence, studies, or opinions of other experts in the medical community, although that theory need not be accepted by the entire medical community. Without such evidence, a theoretical conclusion or statement in support is simply not sufficient to establish causation in fact. Petitioner's experts in this case have submitted primarily conclusory statements with little or no explanation.

For example, Dr. Fraser seems to imply, although she does not directly so state, that the onset of an encephalopathy began on May first although she does not clarify her reasoning. She believes that Amy suffered an encephalopathy because "we have the definite evidence of a large left hemisphere infarct and right-sided focal seizures [the May 28, 1986 event]." Dr. Fraser concludes that the DPT shot is probably responsible for the infarct and focal seizures because all other possible causes have been "pretty well excluded." Letter of Dr. Shirley H. Fraser, dated March 11, 1996. She states further:

[I]t is my understanding that they [children] can have a reaction to DPT, probably a kind of vasculitis, that results in an event of this sort. . . . [I]t's a matter for an educated guess.

Letter of Dr. Shirley H. Fraser, dated June 24, 1996.

Unfortunately, Dr. Fraser's opinion statement amounts also to speculation. She provided no basis for her opinion that the DPT can be causally linked to events that began, as she supposes, ten days later. She provided no evidence to support the possibility that a vascular accident can be the result of a DPT shot, nor any evidence to support that it did so in this case. Demonstrating the absence of an alternative cause of injury does not fulfill petitioner's affirmative duty to prove causation in fact. Hodges v. Secretary of HHS, 9 F.3d. 958 (Fed. Cir. 1993).

The opinion provided by respondent's expert, Dr. Jerrold M. Milstein, associate professor of Neurology and Pediatrics at the University of Washington, is more persuasive and is based on sounder reasoning. He states that the infarct was the cause of Amy's neurological injuries, not the result:

This is not considered to be an encephalopathy by itself. An infarct can lead to an encephalopathy as a residual, with a wide variety of findings including a hemiparesis.

He explains that the first CT scan after the May 28th seizure demonstrated evidence of the infarct but showed no apparent swelling of the hemisphere. This feature, he argues, is consistent with an acute event, that is, one of very recent occurrence. The second CT scan two days later shows a small amount of swelling of the left hemisphere, which again, in his opinion, is indicative that the infarct occurred at the time of the seizure or shortly before the seizure. He concludes that Amy suffered an acute vascular accident on May 28, 1986 which produced a right sided focal seizure and paresis. The infarction occurred five weeks after vaccination, an interval too distant to suggest a causal relationship between the two.

CONCLUSION

The court concludes that petitioner has provided inadequate evidence of an encephalopathy within Table time frame, and no persuasive evidence that the vascular accident was causally linked to the vaccine. A preponderance of the evidence instead supports a finding that Amy's condition is due to a vascular accident that occurred on May 28, 1986, and is unrelated to the vaccination administered on April 21, 1986, five weeks earlier.

Absent a motion for review filed pursuant to RCFC Appendix J, The clerk is directed to enter judgment accordingly.⁽²⁾

IT IS SO ORDERED.

E. LaVon French

Special Master

1. The special master is not required to conduct hearings upon a finding that such is neither necessary nor reasonable. See § 12(d)(3)(B)(v). That issue has been challenged on several occasions and upheld on review by higher courts. See e.g. Murphy v. Secretary of HHS, No. 90-882V (Order April 19, 1991) [aff'd, 23 Cl. Ct. 726 (Aug.9, 1991); aff'd. per curiam, 968 F.2d. 1226 (Fed. Cir. 1992); reh. denied, cert. denied, 113 S. Ct. 463 (1992)] (hearing denied on the basis that "[t]he record as it now stands is more than sufficient to enable the special master to reach a fair, reasoned, and informed decision on the petition"). See also Hale v. Secretary of HHS, 22 Cl.Ct. 403 (1991) (Decision not to hold hearing was not arbitrary or capricious.); Skinner v Secretary of HHS, 30 Fed. Cl. 402 (1994) (The special master "has an obligation to minimize the cost and complexity of Program proceedings).

2. The court finds that petitioner has filed her case in good faith and that there was a reasonable basis for the claim. Accordingly, the court allows attorney's fees and costs pursuant to a separate decision.