OFFICE OF SPECIAL MASTERS
No. 94-1005V
Filed: December 10, 1997

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BEVERLY WILLIAMS and TRACEY	*	
WILLIAMS, Individually and on	*	
behalf of their minor child,	*	
ALYSSA SHERIDAN DALE WILLIAMS,	*	
	*	
Petitioners,	*	
	*	PUBLISHED
v.	*	
	*	
SECRETARY OF THE DEPT. OF	*	
HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *		

Sandra B. Ribes, Baton Rouge, Louisiana, for petitioners.

David L. Terzian, Washington, D.C., for respondent.

DECISION

GOLKIEWICZ, Chief Special Master

Petitioners filed a petition for compensation under the National Vaccine Injury Compensation Program on behalf of their daughter, Alyssa Williams.[(1)]

Petition, filed 11/15/94. Petitioners allege that Alyssa suffered an encephalopathy and a residual seizure disorder, as defined by the Vaccine Injury Table, after receiving a diphtheria-pertussis-tetanus (DPT) vaccination on July 26, 1993. Petition, filed 11/15/94; Amended Petition, filed 5/8/96. Petitioners claim that Alyssa suffered a seizure episode four days after receiving her second DPT vaccination. Id.

Respondent filed a report on February 13, 1995, pursuant to Vaccine Rule 4(b), denying petitioners' eligibility for compensation under the Act, and recommending dismissal of the case. Respondent argued

that the complete lack of documentation of any neurological symptoms occurring within 72 hours of the July 26, 1993, DPT vaccination precluded petitioners from establishing a Table case. Furthermore, respondent argued that there is insufficient evidence to prove that the DPT was the cause-in-fact of Alyssa's seizures and subsequent death.

On July 18, 1997, the court held an entitlement hearing, including medical expert testimony, in Baton Rouge, Louisiana. See Transcript, filed 8/7/97. At that hearing, the court heard the testimony of Beverly and Tracey Williams, Alyssa's parents, and Dr. Kevin Geraghty, a pediatrician, on behalf of petitioners. Dr. Arnold Gale, a pediatric neurologist, testified on behalf of respondent. The record is now complete and ready for decision.

The issues to be decided in this case are as follows: (1) Did Alyssa manifest the first symptom of the onset of a Table injury (residual seizure disorder and encephalopathy) within 72 hours of her July 26, 1993, DPT vaccination? (2) If the first question is answered in the negative, was Alyssa's seizure disorder and encephalopathy caused in fact by the DPT vaccination she received on July 26, 1993? and (3) If the second inquiry is answered in the affirmative, was Alyssa's death the sequela of her alleged vaccine-related injuries? After considering the entire record, and for the reasons discussed below, the court finds that petitioners have not demonstrated that the first symptom or manifestation of the onset of a Table injury occurred within the Table time frame, and petitioners have failed to prove that the DPT vaccination of July 26, 1993, was the cause-in-fact of Alyssa's seizure disorder and subsequent death. For these reasons, the court finds petitioners are not entitled to compensation.

DISCUSSION

I. Facts

Alyssa was born on March 5, 1993. P. Ex. 1. She was born by caesarian section due to intermittent fetal bradycardia with persistent decelerations. P. Ex. 2 at 108. Her delivery was uncomplicated. P. Ex. 2 at 41. Alyssa weighed 7 lbs., 7 oz., and her Apgars scores were 8 and 9 at 1 and 5 minutes respectively. P. Ex. 2 at 41. She was given blow-by oxygen for several minutes due to cyanosis. P. Ex. 2 at 106. The newborn examination was normal and Alyssa and her mother were discharged after four days. P. Ex. 3 at 2, 21.

Alyssa had a normal neonatal course and her pediatrician, Dr. Gregory Gelpi, did not note any problems prior to July 26, 1993. P. Ex. 4. She was given her first DPT vaccination on April 23, 1993. P. Ex. 4 at 1a. No adverse reactions were recorded. On July 26, 1993, Alyssa had a pediatric visit. She was noted to be a well child and was given her second DPT vaccination. P. Ex. 4 at 8. Mrs. Williams testified that Alyssa was listless and cranky after the shot. Tr. at 12. Mrs. Williams testified that on Thursday, July 29th, the family went to an aquarium in New Orleans. Tr. at 13. She recalled that, while at the aquarium, she noticed "some changes in [Alyssa], as far as her movement and her reaction to me, trying to feed her and things." Tr. at 13. No mention of these alleged "changes" was made in petitioners' affidavit of October 10, 1994. P. Ex. 5. The family stayed the night at the grandmother's house. On July 30th, Alyssa's grandmother allegedly noticed that Alyssa's arm was stiff. Tr. at 13. Later that evening Alyssa's hand started to twitch and shake. Tr. at 14. The twitching episode was videotaped.

Alyssa was taken to see Dr. Gelpi on July 31, 1993. The chief complaint was an episode of hand shaking uncontrollably for two minutes, followed by limpness of that hand. P. Ex. 4 at 8. Her pediatric

examination that day was normal and she was referred to Dr. Lily M. Hsu, a pediatric neurologist. Id. A notation in Dr. Gelpi's records indicates that Alyssa had another twitching episode on August 2, 1993. P. Ex. 4 at 9. An EEG exam scheduled for August 3rd was normal. P. Ex. 9 at 4; 4 at 9.

On August 7, 1993, Alyssa had a seizure involving her entire right side. Tr. at 15; P. Ex. 5, 6. She was then taken to the emergency room P. Ex. 9. The discharge summary from that hospitalization, dated August 8, 1993, states the following:

On July 26, the patient received the second shot of DPT. There was no fever, change of mental status, or other side effect afterward.

* * *

During the past ten days, the patient has been active and alert with no developmental regression.

P. Ex. 9 at 5-6. A CT scan was normal and a repeated EEG revealed a "questionable sharp activity arising from the left central area." P. Ex. 9 at 7. Her diagnosis was "partial complex seizure disorder, etiology unknown." Id.

On August 23, 1993, Alyssa was evaluated by Dr. Barbara Golden, a pediatric neurologist. P. Ex. 7 at 16. Alyssa was having daily "hand quakes" at this time. Id. Dr. Golden referred to normal chromosome and MRI tests. Id. In her report, Dr. Golden indicated that Alyssa was

a very alert and responsive baby in no acute distress. Neurologic examination to me is within normal limits.

... Developmentally and neurologically she looks so normal that I doubt we'll find a real good explanation for her seizures at this point.

Id.

Alyssa was hospitalized from August 25 to September 3, 1993, and from September 9 to September 11, 1993, due to her persistent seizure disorder. P. Ex. 9 at 42-43, 115-16. An EEG exam performed on August 26th was abnormal. P. Ex. 9 at 46.

Alyssa was seen numerous times in subsequent months by the Neuromedical Center in Baton Rouge to monitor her seizure disorder. Dr. Charlotte Hollman, a pediatric neurologist, evaluated Alyssa on October 14, 1993. In her report, she noted that "[t]he neurological examination is entirely within normal limits except for her poor weight-bearing." P. Ex. 7 at 22. A repeated EEG exam was abnormal. Id. Her head circumference was 43 centimeters on December 16, 1993, which was in the 25th percentile. P. Ex. 7 at 26. On January 27, 1994, her head circumference remained at 43 centimeters, which was in the 10th percentile for her age. P. Ex. 7 at 29. However, Dr. Hollman's report stated that Alyssa's developmental milestones were within the normal range. Id.

On April 7, 1994, her head circumference was in the 5th percentile. P. Ex. 7 at 34. Dr. Hollman noted that, while the neurological examination was normal, Alyssa did "look a little droopy, and her eyes are somewhat droopy as well." P. Ex. 7 at 34. Dr. Hollman also noted a "gradual decrease in her head circumference measurement." Id. Her head circumference was in the 5th percentile on April 7, 1994. Id. Dr. Hollman saw Alyssa again on May 12, 1994. In her report from that examination she stated the following:

The neurological examination continues to be normal. She pulls to stand well, she cruises around furniture, she crawls, her reflexes are symmetrical, and her tone is symmetrical. Her head circumference measures 44 centimeters, which is right at the 2nd percentile for age.

P. Ex. 7 at 36.

On April 14, 1994, Alyssa was hospitalized. P. Ex. 9 at 263. Alyssa underwent an extensive neurological consultation and her past medical history, in relevant part, was listed as follows:

Her immunizations are not up to date. Four days after her second DPT, OPV and HIV [sic] she had the seizure disorder which began with fever on 07/30/93. Although no one felt that it was related to the DPT everyone has been hesitant apparently to immunize her further until her seizures are better controlled. Growth and development mother says has been O.K. until about two weeks ago. Actually, since the middle of March when she just hasn't been feeling well and has been lying around.

P. Ex. 9 at 268. Her discharge diagnosis listed status epilepticus, seizure disorder, otitis, pneumonia, septic shock, anemia and cortical atrophy. Id. at 273. On June 9, 1994, Dr. Hollman observed that Alyssa "continues to have a slight delay in her motor development." P. Ex. 7 at 38.

On February 26, 1996, a babysitter checked on Alyssa while she was napping, and found her to be unresponsive with vomitus around the mouth, no pulse and no breathing sounds. EMS report filed August 12, 1996. Emergency efforts failed to revive Alyssa, and she died on that date. The death certificate lists anoxic encephalopathy due to seizure disorder as the cause of death. Death certificate, filed May 8, 1996. The final diagnosis of the autopsy was cerebral edema, anoxic encephalopathy, hemorrhagic bronchitis and hemorrhagic gastritis. Autopsy report, filed May 8, 1996.

II. Expert Testimony

Dr. Kevin C. Geraghty

Dr. Geraghty, board certified in pediatrics and in the subspecialty of Allergy and Immunology, testified on behalf of petitioners. Tr. at 47-110. It is his opinion that the July 26, 1993, DPT vaccination caused Alyssa's encephalopathy and seizures. Dr. Geraghty's expert report, filed May 10, 1995 (hereinafter cited as "P's Exp. Rpt.").

Dr. Geraghty testified that Alyssa's seizures first occurred within 72 hours of her second DPT shot and that they first manifested no later than July 29, 1993. Tr. at 59. He based his opinion on a surmised chronology of events that he believed probably occurred. Tr. at 56-59. Dr. Geraghty testified that Mrs. Williams, who was not trained in neurology, would have missed the more subtle manifestations of seizure activity that he stated probably occurred before July 30, 1993. Tr. at 56. He explained that the seizures at first were unnoticed because Alyssa was in a crib, but when there was more interaction upon visiting her grandmother on July 30th, the seizures were then noticed. Tr. at 58. He opined that, because Mrs. Williams was not initially distressed about the seizures, the seizure events probably anteceded July 30th. Tr. at 56-57. In sum, he stated:

So I believe that it is very prudent to assume that there's a very high probability the first seizure may

well have occurred earlier than July 30. I believe indeed it would have occurred at least by [July 29th].

Tr. at 59.

The basis for Dr. Geraghty's opinion that the DPT vaccination was the cause-in-fact of Alyssa's seizures and encephalopathy was detailed in his expert report. At trial, he stated he had "little to add" to his report in terms of his opinion on causation. Tr. at 71-72. In the expert report, Dr. Geraghty listed six possible theories of how the DPT could have, and did, cause Alyssa's seizures. In each of the six theories, he identified the pertussis toxin as the agent of causation. P's Exp. Rpt. at 6.

Dr. Geraghty's first theory is that the DPT could have caused an increase in Alyssa's histamine level. P's Exp. Rpt. at 6. He opined:

In Alyssa's case such a reaction might well have occurred if she released her own natural histamine from her cells due to an unknown stimulus such as an underlying allergic state that was coincidentally triggered. Documentation of such a possibility would have required doing serial histamine levels.

Id. No testing of Alyssa's histamine levels was ever performed. Tr. 76-78.

Dr. Geraghty's second theory is that the DPT could have caused a drop in blood sugar, or hypoglycemia. P's Exp. Rpt. at 6-7. He referred to a study in which two infants, who had encephalopathies post pertussis vaccination, also had hypoglycemia. He stated in his report:

Such a similar drop in blood sugar in Alyssa could clearly lead to encephalopathy but appropriate tests were not performed. Documentation of such a possibility would have required doing serial sugar and insulin levels.

Id. at 7. No serial sugar or insulin tests were performed. Tr. at 76-78.

Dr. Geraghty's third theory was based on an increase of lymphocytes in the blood. P's Exp. Rpt. at 7. In his opinion, the pertussis toxin prevents lymphocytes from leaving the bloodstream thereby causing an elevation in number. Id. He noted that there was a white blood cell count performed on August 7, 1993. The results of that test showed a "marked increase in [Alyssa's] 'lymphs' at 83%." P's Exp. Rpt. at 7; P. Ex. 9 at 14. In his report, Dr. Geraghty opined that "this 'lymphocytosis' represents that molecular action of the pertussis toxin contained in Alyssa's DPT...." P's Exp. Rpt. at 7. When asked how the lymphocytosis was related to a causal connection between the DPT and Alyssa's injuries, he testified that the elevated lymphocyte count was "a manifestation of the action in [Alyssa's] body ... that pertussis toxin was in her body and functional." Tr. at 78-79.

Dr. Geraghty's fourth theory was stated as follows:

Pertussis toxin also has a demonstrated ability in mice (and perhaps in man) once injected to augment the production of antibodies of the class IgE ("Immunoglobulin E"). This antibody class is the scientific basis for true clinical allergy in humans. The significance in Alyssa's case would be if the pertussis toxin had served to induce or increase her IgE levels in such a way as to cause the release of histamine triggering the harmful action of [histamine shock] as discussed [in his first theory]. Documentation would have required drawing of serial IgE assays.

P's Exp. Rpt. at 7. No serial IgE test was performed. Tr. at 76-78.

Dr. Geraghty's fifth theory of causation was derived from his belief that pertussis disease and the vaccine may cause or predispose one to leakage from blood vessels in the brain. However, he conceded in his report that he was "unaware of any known tests that would have the extreme sensitivity to 'see' this leakage from vessels of the brain." Id. He testified at the hearing that present technology is now sensitive enough to detect cerebral vascular leakage, although it was not at the time of Alyssa's seizure disorder. Tr. at 98.

Dr. Geraghty's sixth and final theory espoused as to causation in this matter involved the development of antibodies against foreign injected neuroantigens. While Dr. Geraghty pronounced this property of the pertussis toxin to be "disconcerting," he admitted that he was "unaware of any test to prove or disprove a role for this mechanism in pertussis vaccine encephalopathy." P's Exp. Rpt. at 7-8.

Finally, despite the many theories of causation, Dr. Geraghty conceded that Alyssa's lymphocytosis and the temporal proximity of the DPT vaccination to the first seizure "are the only two factors that would allow one to remove [the diagnosis of DPT caused] from the general category of an unspecified encephalopathy." Tr. at 102.(2)

Dr. Arnold D. Gale

Dr. Gale, who is board certified in pediatrics and board eligible in child neurology, testified on behalf of respondent. In his opinion, there is no evidence to support a finding that Alyssa suffered a seizure prior to July 30, 1993. Tr. at 115. In addition, he stated that there is no evidence which would indicate the existence of a causal relationship between the DPT vaccine of July 26, 1993, and Alyssa's seizure disorder and subsequent death. Id.

Dr. Gale agreed that, on August 7, 1993, Alyssa had an elevated white blood cell count with eighty-three percent lymphocytes, or lymphocytosis. Tr. at 113. However, he opined that this fact is not significant in relation to her seizures and ultimate death. Id. Dr. Gale conceded that the DPT vaccine can cause lymphocytosis, but that this condition could also be caused by viral infections, stress, seizures, and numerous other illnesses that occur in childhood. Tr. at 117. He stated that lymphocytosis is not a serious condition unless it becomes malignant, as in the case of leukemia. Id. Dr. Gale testified that there was no evidence to suggest that the lymphocytosis could have caused Alyssa's seizures. Tr. at 117-18. He stated that without the accompanying symptoms of fever, shaking, chills, a rash on the skin, enlarged lymph nodes, sores in the mouth, a cough, a runny nose or any upper respiratory tract symptoms, he could not identify a clinical or pathological significance to the lymphocytosis. Tr. at 118-19.

Dr. Gale opined that the cause of Alyssa's seizure disorder, encephalopathy and ultimate death was hypoplasia of the corpus callosum. Dr. Gale's expert report, filed November 22, 1996, (hereinafter cited as "R's Exp. Rpt."); Tr. at 119-120. He based this opinion upon his review of the April 1994 MRI report. Id. He explained that "[h]ypoplasia, or thinning of the corpus callosum is a congenital or embryo-genetic defect that occurs well before birth." Tr. at 120. This type of brain abnormality can cause, *inter alia*, developmental delay, motor disabilities, mental retardation and epilepsy. Tr. at 120-21. Dr. Gale stated that hypoplasia of the corpus callosum is not an acquired defect. Tr. at 121. He testified that the hypoplastic corpus callosum could account for every one of Alyssa's neurological symptoms. Tr. at 123. (3)

III. Statutory Scheme

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation, or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act.[4] The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition.[5] The presumption may be overcome by an affirmative showing that the injury was caused by a factor unrelated to the administration of the vaccine.

In order to demonstrate entitlement to compensation in an off-Table case, petitioners must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. §§ 11(c)(1)(C)(ii)(I) and (II); Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992). The Federal Circuit in Grant summarized the legal criteria required to prove causation-in-fact under the Vaccine Act:

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

Id. at 1148 (citations omitted);[6] see also, Strother v. Secretary of HHS, 18 Cl. Ct. 816 (1989), aff'd without opinion, 950 F.2d 731 (Fed. Cir. 1991). Petitioners do not meet this affirmative obligation by merely showing a temporal association with the vaccination, see Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1993), cert. denied, 469 U.S. 817 (1984) (inoculation is not the cause of every event that occurs within a ten day period following it), nor by eliminating other potential causes of the injury. Grant, 956 F.2d at 1149. This case is measured against these standards.

Table Injury

Petitioners have alleged that Alyssa's injuries qualified under the Vaccine Injury Table of section 14(a), and thus they are entitled to compensation via the statutory presumption. To meet the requirements of section 11(c)(1)(D)(i), petitioners must prove, by a preponderance of the evidence, that the "first symptom or manifestation of the onset" of a Table injury occurred within 72 hours of the administration of a DPT vaccination. The medical records in this case overwhelmingly reflect that the first symptom of neurological abnormality experienced by Alyssa occurred on July 30, 1993. That first symptom occurred four days after her July 26, 1993 DPT vaccination. In their own testimony and affidavits, petitioners aver that Alyssa's first seizure occurred four days after her second DPT. In their attempt to establish a Table case, petitioners rely solely on the opinion of Dr. Geraghty. The problem with this reliance is that Dr. Geraghty's opinion, that Alyssa suffered a Table injury, is pure conjecture. In his own report, Dr. Geraghty concedes that the first seizure was witnessed on the fourth day following the DPT. P's Exp. Rpt. at 4. His entire opinion on this issue is based on his speculation that, because petitioners were not trained in pediatric neurology, they **must** have missed the seizures that probably occurred on Table. Such unsupported guess-work is unavailing and fails to meet petitioners' burden of proof. As such, the court finds that petitioners have not proven a Table case.

Causation-in-Fact

Inasmuch as Alyssa's first seizure occurred on the fourth day after vaccination, it falls outside of the Table time period for the injuries residual seizure disorder and encephalopathy. Therefore, petitioners must affirmatively demonstrate by a preponderance of the evidence that the DPT vaccination in question caused-in-fact Alyssa's neurological injuries, which in turn led to her death. §§ 11(c)(1)(C)(ii)(II). The analysis in this case is two-fold: (1) *can* DPT cause a seizure or encephalopathy four days post vaccination? and (2) *did* DPT cause encephalopathy or seizures in this case? See Huston v. Secretary of HHS, No. 90-1080V (Fed. Cl. filed Nov. 25, 1997); see also, Housand v. Secretary of HHS, No. 94-441V, 1996 WL 282288 (Fed. Cl. Spec. Mstr. May 13, 1997)(two-step causation-in-fact analysis used); Coultas v. Secretary of HHS, No. 93-0081V, 1995 WL 605559 (Fed. Cl. Spec. Mstr. Sept. 29, 1995) (two-step causation-in-fact analysis used).

With regard to the first prong of the analysis, it has been held that a DPT vaccination can cause neurological injury up to seven days post vaccination. See Sharpnack v. Secretary HHS, 17 F.3d 1442 (Fed. Cir. 1994); Estep v. Secretary of HHS, 28 Fed. Cl. 664 (1993), appeal dismissed, (Unpub. Fed. Cir. Oct. 29, 1993); Sumrall v. Secretary of HHS, 23 Cl. Ct. 1 (1991); Wolf v. Secretary of HHS, No. 90-3137V, 1994 WL 142295 (Fed. Cl. Spec. Mstr. April 7, 1994). See also National Childhood Encephalopathy Study (NCES) (Miller et al., 1993) (comprehensive epidemiological study finding statistically significant risk for neurological injury for up to seven days following a DPT vaccination), and Institute of Medicine (IOM) report, DPT and Chronic Nervous System Dysfunction, a New Analysis (National Academy Press 1994) (reviewing NCES study and concluding evidence is consistent with causal relationship under the conditions studied by NCES). In fact, Dr. Gale stated that it is "conceivable" that the DPT can cause neurologic injury beyond three days. Tr. at 161, 163. Thus, the court does not see the first prong of proving causation at issue in this matter. However, petitioners must also prove the second prong, that DPT in fact caused Alyssa's current condition. That inquiry first requires the court to determine whether Alyssa actually suffered a seizure or encephalopathy. The court answers this question affirmatively.

There is no substantive dispute as to the facts in this case. Alyssa's medical records consistently indicate, and respondent does not contest, that she was well prior to her second DPT vaccination on July 26, 1993, and that she subsequently had a seizure disorder and developmental delay. P. Ex. 8 at 1; P. Ex. 9 at 6; Tr. at 75. It is clear to the court that Alyssa developed the symptoms of a seizure disorder and encephalopathy after her July 26, 1993, DPT vaccination. The only question remaining, the issue of causation, is one for the medical experts.

Petitioners' case relied heavily upon the report and testimony of Dr. Geraghty. There were no contemporaneous documents to substantiate their theory of causation. In his report, Dr. Geraghty listed six separate theories as to how the DPT vaccination of July 26, 1993, caused Alyssa's neurological problems and subsequent death. However, with three of his theories[(7)], Dr. Geraghty stated that specific tests would have been necessary to produce evidence that the reactions he hypothesized actually occurred. Those tests were not performed, thus there is no evidence to support any of those three theories. With another two of Dr. Geraghty's theories[(8)], he was unaware of any tests that would reveal evidence of his forecasted reactions. Thus, there was no evidence to support those theories either. The one constant with Dr. Geraghty's testimony on these five causation theories was the paramount importance of conjecture and speculation to reach his conclusions. His method was merely to state general theories of causation and surmise that one of them might have been the cause of Alyssa's neurological problems. Concededly, he could offer no proof linking any of the stated five theories to her specific case. Tr. at 102. As to the above-described five theories, the only objective and substantiated evidence Dr. Geraghty could rely upon was the temporal relationship between the vaccination date and

the first seizure. Temporal relationships are probative, but it takes far more to prove a causation-in-fact case.

Only one of Dr. Geraghty's six proffered theories was supported in part by evidence in the record. In his report, he opined that the pertussis toxin could increase the number and percentage of lymphocytes in the blood. Respondent's expert, Dr. Gale, agreed that there was an elevated lymphocyte count in Alyssa's clinical picture. However, Dr. Geraghty was unable to explain how lymphocytosis could theoretically cause a seizure disorder. Nor was he able to demonstrate any ill effects of the elevated lymphocyte count in Alyssa's blood. He could not even prove that the DPT caused her lymphocytosis. Dr. Gale, on the other hand, was persuasive as he testified that Alyssa's lymphocytosis could have been caused by numerous clinical scenarios which were possible in her case. Thus, Dr. Geraghty's lymphocytosis theory suffers the same fate as his other five theories - it becomes an unsupported hypothesis.

In response to questions posed by respondent's counsel, Dr. Geraghty conceded that other than the lymphocytosis there is nothing pathognomonic for DPT.[(9)] Tr. at 101. However, Dr. Geraghty conceded that there are a number of other causes for lymphocytosis. Tr. at 100. Thus, it is clear to the court that the most that can be derived from the lymphocytosis is that the DPT could have caused it but there is no way of knowing if it did in fact cause it. Dr. Gale persuasively made this point in testifying to the many causes of lymphocytosis, including routine infection, stress, trauma and toxins. Tr. at 113. Dr. Gale stated that in medicine, pathognomonic has a narrower meaning, that is "if that sign is present then one and only one diagnostic consideration is possible." Using this definition he concluded that lymphocytosis is not pathognomonic of anything. Id. It is unnecessary for the court to decide which expert's definition of pathognomonic is correct. What is clear is that lymphocytosis has many causes, some of which, such as infections, are quite common. What Dr. Geraghty failed to establish is that the DPT is the predominate or sole cause of lymphocytosis or that there is some way to distinguish a DPT caused lymphocytosis from one of the other causes. Without such a showing, the lymphocytosis has little or no probative value in establishing the DPT's causative role.

Dr. Gale touched on this difficult reality of proving DPT causation when asked whether it is possible for the DPT to cause neurologic damage four days after vaccination. While stating that it is possible, he stated, however, that he would not know when that occurred. Dr. Gale explained:

There is no study that I am aware of that could be performed if I were highly suspicious on the fourth day . . . that would tell me as a clinician, this patient definitely is having a reaction to the immunization.

I can be highly suspicious . . . . I can think so. But I can't know, because there are no biological markers that have ever been described as pathognomonic, characteristic or even typical to pertussis vaccine, if and when it injures.

Tr. at 161. Clearly, the court does not require a "definite" or "absolute" determination of causation. However, just as clearly, the rank speculations Dr. Geraghty provided in this case are logically and legally deficient. In the absence of epidemiological evidence and biologic markers, how does one prove DPT causation? Dr. Gale, in response to the court's questions, provided some help in what a clinical picture of DPT caused injury may look like where a child presents with neurological problems four days after vaccination. Dr. Gale stated that:

[W]ithin the first twelve hours anyway of being immunized, [the child] started to get sick; surely by the end of the first 24.

And had some clinical manifestations during the entire three-day period, and then on that fourth day

something bad happened. And what would bad be? Well, a kid who was punky [sic], and went on within hours to be really out of it . . . can't focus, gets glazed over --

. . .

becomes comatose, begins to convulse, develops paralysis on the fourth day.

Tr. at 164-165. The court does not mean to suggest that Dr. Gale's description is the only scenario for finding causation-in-fact. However, since there are no medical markers for a DPT caused injury, it would appear that a clinical scenario - beginning shortly after vaccination and continuing unabated to the severe neurologic event - might be necessary to establish causation more probably than not. See Schell v. Secretary of HHS, No. 90-3243V, 1994 WL 71254 (1994), appeal dismissed, 57 F.3d 1083 (Unpub. Fed. Cir. July 1, 1995).

In this case, neither biologic markers or clinical signs and symptoms tie the injury on the fourth day to the DPT vaccination.

Finally, the court was simply unimpressed by the overall quality of Dr. Geraghty's testimony. His almost complete reliance on speculation was most unpersuasive. In addition, his emotional statements about the criminal complicity of the Federal Government were highly unprofessional. Dr. Gale, on the other hand, provided persuasive, reliable evidence through logical, well-reasoned testimony. While his opinion as to an alternate cause was not sufficiently developed or supported to be dispositive in this case, he successfully impeached Dr. Geraghty's theories with sound medical analysis, and reliance on the record.

Establishing the second prong of the causation-in-fact analysis, i.e., did the vaccination in question cause the injury in a particular case, almost always proves to be a difficult and formidable task for petitioners in Program cases. Unfortunately for petitioners, this case is not an exception. Petitioners were unable to demonstrate that the DPT vaccine actually caused Alyssa's seizure disorder or encephalopathy. Because petitioners have not shown that Alyssa's condition and subsequent death were caused by the vaccination, the court finds petitioners are not eligible to receive a Program award.

CONCLUSION

Dr. Geraghty's conjecture as to a causative link between Alyssa's seizure disorder and her second DPT vaccination was unpersuasive. The court found no evidence, other than a mere temporal relationship, that the DPT caused Alyssa's seizure disorder. The medical records were clear and consistent, and Dr. Gale was very credible and highly persuasive. The court was not impressed with Dr. Geraghty's highly speculative and unsubstantiated analysis.

Petitioners have not demonstrated by a preponderance of the evidence that the DPT vaccination Alyssa received on July 26, 1993, was the cause-in-fact of her injury and subsequent death. Therefore, petitioners are not entitled to compensation under the Program. The Clerk shall enter judgment accordingly.

Gary J. Golkiewicz

Chief Special Master

1. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C.A. § 300aa-1 et seq. (West 1991 and Supp. 1997). For convenience, individual sections of the Act will be cited without reference to 42 U.S.C.A. § 300aa.

2. Dr. Geraghty repeatedly expressed that the United States Government should be held criminally liable for employee nonfeasance related to investigating DPT injuries. Tr. at 73, 107, 108. The record is devoid of evidence of any improper governmental behavior in this case. Dr. Geraghty's baseless allegations were presumed by the court to be voiced out of some unidentified frustration, yet considering the seriousness of the charges were viewed as highly unprofessional.

3. At the hearing, a considerable amount of time was devoted to petitioners' concern about Dr. Gale's opinion regarding hypoplasia of the corpus callosum. Specifically, counsel raised the point that Dr. Gale was relying upon the treating physicians' interpretations of the MRI films. He did not examine the films himself. In addition, only one of three MRI films supported Dr. Gale's theory, the others were inconclusive. While Dr. Gale's observations and opinions with regard to the hypoplasia of the corpus callosum were interesting and appropriately proffered, the court draws no conclusion as to their validity. His opinion in that regard was not in any way dispositive. There was not enough evidence presented on this theory for the court to find that a congenital abnormality was the true and alternate cause of Alyssa's neurological maladies. See § 13(a)(1)(B).

4. Petitioners must prove their case by a preponderance of the evidence, which requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before [the special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." In re Winship, 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring) quoting F. James, Civil Procedure 250-51 (1965). Mere conjecture or speculation will not establish a probability. Snowbank Enter. v. United States, 6 Cl.Ct. 476, 486 (Cl. Ct. 1984).

5. Section 14(a).

6. A reputable medical or scientific explanation does not simply mean, however, any theory that a medical expert is willing to espouse. In construing the Federal Rules of Evidence, the Supreme Court recently held that it is the trial judge's responsibility to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S.Ct. 2786, 2795 (1993); see also Vaccine Rule 8(b) (The special master is obliged to consider "all relevant, reliable evidence . . . .").

Rule 702 provides that an expert witness may testify to his "scientific, technical, or other specialized knowledge . . . ." The term "knowledge," however, "connotes more than subjective belief or unsupported

speculation." Daubert, 113 S.Ct. at 2795. Thus, the expert's proposition must have been "derived by the scientific method." Id. This requires that the proponent demonstrate that there is "some objective, independent validation of the expert's methodology." Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), on remand from 113 S.Ct. 2786 (1993). Factors relevant to that determination may include, but are not limited to:

whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Id.; see also Daubert, 113 S.Ct. at 2796-97. The overall touchstone is "whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." Daubert, 43 F.3d at 1316.

7. The "histamine shock" theory, hypoglycemia causing encephalopathy, and increased IgE levels. P's Exp. Rpt. at 6-7.

8. The leakage of blood vessels of the brain and the development of antibodies against foreign injected neuroantigens. P's Exp. Rpt. at 7.

9. Dr. Geraghty's defined pathognomonic as a "red flag . . . causing a one-to-one association." Tr. at 99.