OFFICE OF SPECIAL MASTERS

No. 03-1169V

(Filed: August 31, 2004)

* *		
STEPHANIE CHRISTIAN, as the Mother and Natural Guardian of DYLAN CHRISTIAN, an Infant,	*	
Petitioner,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Michael A. London, New York, NY, for petitioner.
David A. Terzian, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION

Petitioner filed a petition on May 9, 2003 under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that her son Dylan Christian (hereinafter, "Dylan") suffered an on-Table encephalopathy and acute complication sequela in the form of an intractable seizure disorder and brain damage, designated as a Table injury. In reality, petitioner's expert Dr. Marcel Kinsbourne never discussed encephalopathy, but restricted his reports to so-called significant aggravation in the form of seizures, but denying that acellular DPT significantly aggravated or had

any effect on his pre-existing leukodystrophy[1] or Krabbe disease.[2] In essence, Dr. Kinsbourne's two reports assert that acellular DPT caused in fact Dylan's seizure disorder.

Because the undersigned considers the evidence petitioner has filed in support of her allegations not credible, the undersigned did not hold a hearing. Holding a hearing is within the undersigned's discretion. 42 U.S.C. § 300aa-12(d)(3)(B)(v).

---

[1] "What is Leukodystrophy? Leukodystrophy refers to progressive degeneration of the white matter of the brain due to imperfect growth or development of the myelin sheath, the fatty covering that acts as an insulator around nerve fiber. Myelin, which lends its color to the white matter of the brain, is a complex substance made up of at least ten different chemicals. The leukodystrophies are a group of disorders that are caused by genetic defects in how myelin produces or metabolizes these chemicals. Each of the leukodystrophies is the result of a defect in the gene that controls one (and only one) of the chemicals. Specific leukodystrophies include metachromatic leukodystrophy, Krabbé disease, adrenoleukodystrophy, Pelizaeus-Merzbacher disease, Canavan disease, Childhood Ataxia with Central Hypomyelination or CACH (also known as Vanishing White Matter Disease), Alexander disease, Refsum disease, and cerebrotendinous xanthomatosis. The most common symptom of a leukodystrophy disease is a gradual decline in an infant or child who previously appeared well. Progressive loss may appear in body tone, movements, gait, speech, ability to eat, vision, hearing, and behavior. There is often a slowdown in mental and physical development. Symptoms vary according to the specific type of leukodystrophy, and may be difficult to recognize in the early stages of the disease." http://www.ninds.nih.gov/health_and_medical/disorders/leukodys_doc.htm#What_is_Leukodystrophy

[2] "What is Krabbe Disease? Krabbe disease is a rare, degenerative disorder of the central and peripheral nervous systems that is characterized by the presence of globoid cells (cells that have more than one nucleus) in demyelinated portions of the brain. It is one of a group of genetic disorders called the leukodystrophies. These diseases cause imperfect growth or development of the myelin sheath, the fatty covering that wraps around and protects nerve fibers in the brain. Myelin, which lends its color to the "white matter" of the brain, is a complex substance made up of at least ten different chemicals. Each of the leukodystrophies affects one (and only one) of these substances. Krabbe disease is caused by a deficiency of galactocerebrosidase - an essential enzyme for myelin metabolism. Infants with Krabbe disease are normal at birth. Symptoms begin between the ages of 3 and 6 months with irritability, inexplicable crying, fevers, limb stiffness, seizures, feeding difficulties, vomiting, and slowing of mental and motor development. There are also juvenile- and adult-onset cases of Krabbe disease, which have similar symptoms but slower progression." http://www.ninds.nih.gov/health_and_medical/disorders/krabbe_doc.htm#What_is_Krabbe_Disease

This case is dismissed for failure to present a credible prima facie case.

FACTS

Dylan was born on April 23, 1994. At the age of six years, on June 26, 2000, he received acellular DPT, MMR, and varicella vaccines. Med. recs. at Ex. 3, p. 1.

On July 21, 2000, on referral from Dr. Kenneth Misch, Dylan saw Dr. Donald W. Johns, a neurologist. Petitioner told Dr. Johns that she noted Dylan having some trouble walking about two months previously (which would be May 2000 or a month before his vaccinations). Dylan was initially unsteady, but then started to stumble. He had always been less active than his siblings. A CT scan of his brain showed dysmyelination involving the posterior and superior corona radiate, splenium of the corpus callosum, and mamillary bodies. His father has a large head. On examination, Dylan was awake, alert, pleasant, cooperative, and in no acute distress. He had marked macrocephaly. His toes were upgoing bilaterally. He had mild ataxia. Dr. Johns' impression was that he had at least two months of progressive ataxia. An MRI of his brain done July 19, 2000 was clearly consistent with a leukodystrophy. Med. recs. at Ex. 4, p. 1.

On August 21, 2000, Dylan saw Dr. Charles Peters, regarding pediatric bone marrow transplantation. Dylan was diagnosed with globoid-cell leukodystrophy (GLD). Dr. Peters recorded that Dylan was a six-year-old boy with late onset globoid-cell leukodystrophy and he had a three-month history (beginning, therefore, in May 2000) of difficulty walking with stumbling and an unsteady gait. During this time, he also had a history of head trauma. He fell from a bicycle and his sister struck him with a lamp, after which he slept for three to four hours. His GLD severity score was 13. The galactocerebroside GALC levels were: 0.12 for Dylan (showing deficiency), and 1.9 for his mother and 1.8 for his father (showing they are in the carrier range). In February 2000,

Dylan was sick with a respiratory illness for one and one-half months. In May 2000, he was tripping a lot. Med. recs. at Ex. 6, pp. 1, 2, and 3.

Dr. Peters wrote that late-onset globoid-cell leukodystrophy is an autosomal recessive disease, characterized by progressive changes in the central nervous system leading to major motor abnormalities as well as progressive neuropsychological decline, leading ultimately to dementia and early death. The only effective treatment is bone marrow transplantation. He had a three-month history (beginning in May 2000) of difficulty walking, with stumbling and an unsteady gait. Dylan's galactocerebroside level of 0.12 nanomoles per milligram of protein per hour is a disease level of enzyme. Dylan's parents are carriers of Krabbe. Dylan's MRI is consistent with globoid-cell leukodystrophy. His GLD MRI severity score was 13 (meaning moderate to severe). Med. recs. at Ex. 6, pp. 20, 21.

On August 22, 2000, Dr. Lawrence Lockman, a pediatric neurologist, wrote to Dr. Peters that he agrees that Dylan has late onset globoid-cell leukodystrophy. He was doing well until six months ago (February 2000) when had an upper respiratory infection. He did not get better until March 2000. In May 2000, he had three episodes of head trauma: (1) a lamp knocked him out; (2) he crashed his bicycle; and (3) he fell from a swing. Since May 2000, he has tired very easily and appeared pale. On June 26, 2000, he received varicella vaccine. Four days later, he could not walk or stand up for two weeks. Then, he gradually started walking again, but has been clumsy and unsteady since then. He also had myoclonic jerks since a month ago (which would put the onset of seizures in late July 2000). Dylan did not have fever, chills, or weight loss. On physical examination, he had slightly decreased tone bilaterally in his upper and lower extremities. He had a wide-based unsteady gait. He had frequent myoclonic jerks. His galactosylceramide beta-

galactosidase was 0.12. Dr. Lockman concluded that Dylan has late onset globoid-cell leukodystrophy. Med. recs. at Ex. 6, pp. 17, 19.

From September 16 - 20, 2000, Dylan was at the Children's Hospital, Los Angeles. Dr. Lan S. Chen took a history of the present illness. Dylan started having episodes of dropping to the ground, consisting of head jerk, and dropping to the ground with arms going backward. The first episode was six weeks previously (putting the onset of seizures at the end of July, beginning of August 2000) while Dylan was playing Nintendo. Dylan's mother reported that the second episode happened about one week later, but these episodes have been increasing in frequency for the past two to three weeks. In the past two weeks, he has had from two to 6 or 7 episodes per day. He did not have loss of consciousness, loss of hearing, or any myoclonic type of jerks occurring associated with these episodes. He recovered immediately and was not confused afterward. His mother reported that Dylan seemed to remember these incidents. He did not have fever, vomiting, diarrhea, dizziness, pallor, sweating, or diaphoresis associated with these episodes. Dylan had increased slurring of his speech for the past two weeks and a loss of milestones in an ability to put his shoes on by himself. Dylan's mother stated he had his vaccinations and varicella vaccine about one week prior to the onset of these episodes (which would put the vaccinations at the end of July instead of when he actually had them on June 26, 2000). Dylan had an upper respiratory infection lasting one and one-half months in February and March 2000. Med. recs. at Ex. 7, p.6.

On September 16, 2000, Dylan had a CT scan of his brain which showed diffuse white matter disease suggesting leukodystrophy. Med. recs. at Ex. 7, p. 17.

On September 19, 2000, Dylan had an MRI of his brain which showed extensive white matter disease, most consistent with a leukodystrophy. Med. recs. at Ex. 7, p. 11.

On September 20, 2000, Nevada Medicaid informed Dr. Chen that Dylan had already been evaluated and found to have Krabbe disease, which Dr. Wenger's lab confirmed. Dr. Chen confronted Dylan's mother who then produced all the records of the laboratories, explaining that she was unable to accept the diagnosis and that she gave a misleading history because she wanted an "uncontaminated" second opinion. Med. recs. at Ex. 7, p. 49.

On October 23, 2000, Dylan saw Dr. Jin-Young Han who diagnosed juvenile onset Krabbe disease. Dr. Han wrote that Dylan's mother was unable to accept the diagnosis, according to Dr. Wendy G. Mitchell, and gave a misleading history because the mother wanted an "uncontaminated" second opinion. Med. recs. at Ex. 7, p. 1.

On November 8, 2000, Dr. Robert D. Steiner, of the Newborn Follow-up Metabolic Clinic, wrote that Dylan had atonic seizures which began around August 2000. Dylan's mother was given a diagnosis of Krabbe disease on August 1, 2000. She "admittedly and obviously has had a lot of difficulty accepting that this diagnosis and its prognosis are correct. She even went so far as to take him to the Children's Hospital of Los Angeles after she knew the diagnosis, and did not tell them of the diagnosis. He was hospitalized there for six days with a diagnosis of viral encephalitis apparently. Because of this, he has had at least two brain MRIs, one around July 2000 and the other in September 2000." Med. recs. at Ex. 8, pp. 23, 24. Dr. Steiner's impression was that Dylan was a six-and-one-half-year-old with juvenile Krabbe disease (galactocerebrosidase deficiency). "I told his mother that this is the correct diagnosis. This is based on two MRIs showing white matter changes and deficiency of galactocerebrosidase in Dr. Wenger's lab. His primary clinical features of Krabbe disease are the seizures and ataxia." Med. recs. at Ex. 8, p. 25. "Mother again was very reluctant to accept this diagnosis." Med. recs. at Ex. 8, p. 26.

On December 4, 2000, Dr. Steiner e-mailed Esther Berenhaut regarding lead testing that Dylan's mother was having done at their house. "I think mom is really grasping at straws here." Med. recs. at Ex. 8, p. 13. Ms Berenhaut replied, "I think she may think Dylan's problem is now lead poisoning instead of Krabbe." Id.

On January 29, 2001, Dr. Stephen Cederbaum wrote, "The mother does not believe he has this disorder, but believes that this is a postencephalitic process." Med. recs. at Ex. 10, p. 1. She steadfastly denied that there was any hint prior to his MMR vaccination of any neurological problems or any neurological deterioration. Dr. Cederbaum concluded Dylan had probable Krabbe disease. Id.

On January 10, 2002, Dr. Joseph G. LaMancusa, a pediatric neurologist, wrote that the MRI looks like a leukodystrophy or an encephalolithic process. Every member in Dylan's family was a carrier for Krabbe disease. Med. recs. at Ex. 15, p. 1.

Being convinced that Dylan could not have the disease with which he was diagnosed, Dylan's mother continued to change the history she gave to doctors. Now, Dylan had no problems whatsoever before the June 26, 2000 vaccinations, and seizures shortly thereafter. With that history, Dr. Morton I. Hyson opined on March 22, 2002 that Dylan had white matter abnormalities, possibly secondary to vaccination. Med. recs. at Ex. 16, p. 2. Dr. Linda M. Brown, a pediatric neurologist, questioned on July 31, 2002 whether he had Krabbe disease or a postvaccination encephalomyelitis. She noted that all Dylan's family were carriers for Krabbe. Med. recs. at Ex. 17, p. 1.

On September 12, 2002, Dr. David K. Bass interpreted Dylan's brain MRI as showing periventricular and subcortical white matter demyelination. Med. recs. at Ex. 23.

Expert Reports

Petitioner filed the medical expert report of Dr. Marcel Kinsbourne, dated April 22, 2004. P. Ex. 24. He states that Dylan maintained good health until he was about six years old. He accepts that Dylan has clinical, radiological, and laboratory evidence of a leukodystrophy, most likely late-onset Krabbe disease. Id. at p. 2. This leukodystrophy pre-existed his vaccinations. Relying on Dylan's mother's affidavit as to a short interval (within three days) between vaccinations and seizures, Dr. Kinsbourne states that the short interval "implicates the pertussis vaccine." Id. Pertussis vaccine, however, does not cause widespread demyelination. Because Dylan's state of health is significantly worse than it was before vaccination, and became so in less than a day, Dr. Kinsbourne opines that he had significant aggravation "of his condition."

However, he also says Dylan's leukodystrophy did not exhibit clinical progression. He knows no other cause for Dylan's seizures than the pertussis vaccine and pertussis vaccine is well-known to be "the occasional cause" of seizures. Id. at 2, 3.

Petitioner filed a supplemental report from Dr. Kinsbourne, dated May 13, 2004. P. Ex. 25. In this report, he states that Dylan's pre-existing condition (Krabbe disease) was significantly aggravated by the new onset of refractory seizures and had indeed progressed within three days of the acellular DPT. Dr. Kinsbourne admitted that "some" children with Krabbe disease do indeed develop myoclonic seizures and this would constitute a clinical progression of Krabbe disease. But Dylan did not develop seizures until after he received acellular DPT and there is no evidence that he would have developed seizures with his Krabbe absent the vaccination. Then, Dr. Kinsbourne states:

> I do not hold the opinion that the seizures have caused further deterioration in Dylan's development, or that they exacerbated the abnormalities to be found on neurological examination. Their presence is in itself the significant aggravation, and they constitute the injury for which Dylan seeks compensation.

Id. at p. 2.

Dr. Kinsbourne states that because Dylan's neurological disabilities preceded the vaccination, the acellular vaccine did not cause them. Id. He says there is "extensive medical literature" attesting to the propensity of pertussis vaccine, including acellular, causing seizures within three days (and he is not impressed with whether they are febrile or afebrile seizures), but he does not cite any medical literature to support his assertion. Id. at 3.

Respondent filed a report from his expert clinical geneticist and pediatric neurologist, Dr. Gerald V. Raymond. He notes that Dylan's mother did not give a history of seizure activity in her visit to Dylan's pediatrician on July 17, 2000. The history she gave to him and to Dr. Johns, the neurologist, was of Dylan's trouble walking which started two months prior. He was diagnosed on August 1, 2000 with Krabbe disease (globoid cell leukodystrophy or GLD). Dylan's mother gave a three-month history of trouble walking with stumbling and unsteadiness. He had two episodes of head trauma, falling off a bicycle and his sister hitting him with a lamp. Dr. Lockman saw him on August 22, 2000. Dylan's mother told him that Dylan had myoclonic jerks starting one month prior (in July 2000). There were frequent myoclonic jerks causing Dylan to fall. By the time Dylan was seen at the Children's Hospital of Los Angeles, Dylan's mother was giving a history of his receiving varicella vaccine in July 2000 with a wide-stanced gait one week later. The first episode of his sudden paroxysms where his head jerked backward, his eyes rolled back, and he sometimes dropped to the ground was 6 weeks prior (in July) while playing Nintendo.

Dr. Raymond states that he specializes in leukodystrophies and cares for patients with globoid cell leukodystrophy. "Globoid cell leukodystrophy (GLD, Krabbe disease) is a serious genetic disorder that results from a defect in the lysosomal enzyme galactocerebrosidase (GALC) and results in destruction of the myelin of the nervous system." Id. at 4. The age of presentation of GLD is variable. Dr. Raymond opines that Dylan has late onset form of globoid cell leukodystrophy and that the vaccines neither caused or aggravated his disease. Id. at 5.

Fact Affidavits

Dylan's mother filed an affidavit dated March 23, 2003, stating that before he received his June 26, 2000 vaccinations, Dylan was "perfectly normal" and healthy. Shortly after receiving the vaccinations, his health and behavior changed considerably. As they left the clinic where he received the vaccinations, Dylan fell to the ground, with his arms extended straight and his body stiff. He was listless on the ground for a few seconds. She asked him if he were all right and, although dazed, he said "Yes, mom." Mrs. Christian now believes this was his first seizure. That evening, he began crying excessively and began running a fever. He was playing Nintendo with his brother and, when he would lose, he would scream uncontrollably. She states that the crying and high-pitched screaming went on through the night.

The next morning, June 27, 2000, Dylan woke crying, his neck and eyes hurt, and he had wet his bed, which had never happened before. Bed-wetting continued over the next few months. During the day, Dylan rubbed his eyes constantly and complained they burned and itched, and his neck hurt badly. His upper body leaned to the left 10 to 15 inches. She regards this as the first sign of ataxia. She says he suffered another seizure that day. Dylan fell off his bike. He lay there with his arms outstretched and stiff. He had wet his pants. His words were slurred. On June 28, 2000,

Dylan had another seizure in a swimming pool. That day, as all the previous days, Dylan was constantly crying. He fell at the store with his grandmother. He had no energy and was crying. He fell a lot in the next few days, at least twice a day. She does not mention that she lied to the doctors at Children's Hospital of Los Angeles. She states she was certain that Dylan was just a carrier of Krabbe, like all the family members, even his half-sibling. To her, all evidence points to encephalitis.[3] She continued, as she put it, to "search for the correct diagnosis." Id. at 5. She refers to a fifth MRI showing no demyelination and Dylan's condition remaining stable. (Mrs. Christian misreads the MRI of September 12, 2002 which notes the continuing presence of periventricular and subcortical white matter demyelinization apparent and concludes it is a stable MRI.) She never obtained the bone marrow transplant which was recommended for Dylan. Although she prefaces her statement with not being a medical professional, Dylan's mother opines that Dylan had encephalitis beginning within 72 hours of his vaccinations. She is "confident and 100% certain." Id. at 7.

Petitioner filed the affidavit of Jesse Christian, dated April 17, 2003. Jesse is Dylan's older brother. He says Dylan was normal and healthy before his vaccinations. Shortly after the vaccinations, Dylan began to trip and fall frequently and cry non-stop. He had four to 10 seizures a day since receiving the vaccinations.

Petitioner filed the affidavit of Antoinette Gevatosky, dated April 17, 2003. She is Dylan's maternal grandmother and lives around the corner from him. Before the vaccinations, he was healthy. On June 26, 2000, Dylan received his vaccinations and he was not his usual self and was cranky. Within the next few days, he tripped and fell several times. She told her daughter that his

[3] One might note that Dr. Kinsbourne does not state that Dylan had encephalitis.

shoes were too big. But he still tripped with other shoes. His condition got worse and he began to have drop attacks (she does not say when).

DISCUSSION

Dr. Kinsbourne's second or supplemental report contradicts his earlier report. In the first report, Dr. Kinsbourne does not support petitioner's allegation of significant aggravation of a pre-existing condition (leukodystrophy or Krabbe disease). Dr. Kinsbourne specifically states on the bottom of the second page of his report, "his leukodystrophy has not exhibited clinical progression." In that report, Dr. Kinsbourne seems to believe that if Dylan was substantially worse after his DTaP, that is significant aggravation under the Vaccine Act. It is not. Some condition that preexists vaccination must be significantly aggravated in order to have significant aggravation.

Congress defined "significant aggravation" as "any change for the worse **in a preexisting condition** which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health [emphasis added]." 42 U.S.C. § 300aa-33(4). In order for this court to hold that DPaT vaccine significantly aggravated Dylan's leukodystrophy or Krabbe disease, petitioner would have to provide evidence through an expert medical witness that it did so, and Dr. Kinsbourne expressly states in his first report that the leukosdystrophy or Krabbe disease did not progress clinically.

Legislative history provides insight into Congress' interpretation of "significant aggravation:"

> The committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis).

H.R. Rep. 98, 99th Cong., 2d Sess. 15-16, reprinted in U.S.C.C.A.N. 6344, 6356-57.

If the undersigned accepted Dr. Kinsbourne's definition in his first report of significant aggravation, i.e., someone is worse after vaccination than before, then every petitioner in this Program has significant aggravation regardless of whether he or she had a preexisting illness or condition. This is untenable in light of the Act's definition of significant aggravation as well as the legislative history.

Moreover, Dr. Kinsbourne opines in his letter that Dylan was in good health before his vaccination when the records reflect that Dylan had been tripping a lot, crashed his bike, fell from a swing, tired easily, and appeared very pale starting a month before the vaccinations at issue. This is hardly descriptive of someone in good health.

In his second report, in response to the undersigned's Order that he explain some of his statements in his first report, Dr. Kinsbourne then states that the acellular vaccine did significantly aggravate Dylan's Krabbe disease. But his assumption is belied by his statement directly contradicting, again, his assertion of significant aggravation: "I do not hold the opinion that the seizures have caused further deterioration in Dylan's development, or that they exacerbated the abnormalities to be found on neurological examination." Dr. Kinsbourne wants it both ways: no significant aggravation and, yes, significant aggravation.

Dr. Kinsbourne states that acellular DPT caused Dylan's seizures. He accepts that Dylan has Krabbe disease (which must surprise Dylan's mother for whom he is providing evidence), but not that seizures are part of Krabbe disease. He justifies that conclusion by stating, since Dylan did not have seizures before vaccination, how do we know he would have had seizures as part of his Krabbe disease. Dr. Kinsbourne portrays his ignorance here. He has no expertise in globoid-cell

leukodystrophy, unlike respondent's expert Dr. Raymond. Dr. Kinsbourne opines that acellular DPT caused Dylan's seizures because unspecified medical literature says it sometimes does and it does not matter if the seizures are febrile or afebrile. His opinion raises two questions: (1) what is the onset of Dylan's seizures, and (2) assuming onset within 72 hours, did the acellular DPT vaccine cause them?

To satisfy her burden of proving causation in fact, petitioner must offer "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 v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must not only show that but for the DPaT vaccine, Dylan would not have had seizures, but also that DPaT was a substantial factor in bringing about his seizures. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

Before Dylan's mother decided to change her history of Dylan's symptoms, she told doctors in July and August 2000 that Dylan's stumbling, awkwardness, fatigue, and pallor began in May 2000, one month before his vaccinations. He also had head trauma and fell off his bicycle before

he was vaccinated. She said that the onset of his seizures occurred in late July or early August 2000 when he was playing Nintendo, one to two months after he was vaccinated.

Subsequently, Dylan's mother, unable to accept that Dylan had Krabbe disease, reinvented his history. She conflated events. Mrs. Christian stated that, before the vaccinations on June 26, 2000, Dylan was perfectly fine. Only after the vaccinations, within either one week (a history she gave at Children's Hospital of Los Angeles), a few days (to her new doctors Hyson, LaMancusa, and Brown), or the same day as they were walking out the clinic (her affidavit in this litigation), Dylan had the onset of his seizures. Dr. Kinsbourne relies on seizures occurring within 72 hours as the basis for his causation-in-fact opinion. The undersigned does not accept this as the date of onset, but relies on Mrs. Christian's original histories that the onset was in late July or early August 2000, at least a month after the vaccinations.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Ware v. Secretary, HHS, 28 Fed. Cl. 716, 719 (1993); Estate of Arrowood v. Secretary, HHS, 28 Fed. Cl. 453 (1993); Murphy v. Secretary, HHS, 23 Cl. Ct. 726, 733 (1991), aff'd, 968 F.2d 1226 (Fed. Cir.), cert. denied sub nom. Murphy v. Sullivan, 113 S. Ct. 263 (1992); Montgomery Coca-Cola Bottling Co. v. United States, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

There was a time when Mrs. Christian insisted that if Dylan's condition was not a postvaccinal reaction, then it was due to lead poisoning. She refuses to accept the diagnosis of Krabbe disease from ten doctors (one of whom is her expert). She insists that Dylan is just a carrier of Krabbe. Her insistence that Dylan does not have Krabbe disease led her to mislead her doctors, to regard truth as a "contaminant," and to lie in her affidavit.

One basis of Dr. Kinsbourne's opinion that acellular DPT caused in fact Dylan's seizures is the closeness in time of the seizure occurrence to the vaccinations. This close onset is not credible and, therefore, Dr. Kinsbourne's opinion is not credible.

Moreover, temporality alone is not affirmative proof of causation as the Federal Circuit requires. The absence of other factors (and one could hardly call leukodystrophy or Krabbe disease the absence of other factors) is not affirmative evidence of causation. See, Grant, supra. Temporal association is not sufficient alone to prove causation. See, Hasler, supra. Without fever or acute encephalopathy, there is no basis upon which to hold that either whole cell or acellular DPT causes afebrile seizures.

The undersigned has held repeatedly in other cases that DPT (much less DPaT) does not cause afebrile seizures, based on the National Childhood Encephalopathy Study,[4] the Institute of Medicine (IOM), and other literature. See Nanez v. Secretary of HHS, No. 02-1261V, 2003 WL 22434113 (Fed. Cl. Spec. Mstr. Sept. 23, 2003); Borin v. Secretary of HHS, No. 99-491V, 2003 WL 21439673, *11 (Fed. Cl. Spec. Mstr. May 29, 2003); Bruesewitz v. Secretary of HHS, No. 95-

[4] *Whooping Cough: Reports from the Committee on Safety of Medicine and the Joint Committee on Vaccination and Immunization*, R. Alderslade, et al. (Department of Health and Social Security, London: Her Majesty's Stationery Office, 1981), pp. 79-183.

0266V, 2002 WL 31965744 (Fed. Cl. Spec. Mstr. Dec. 20, 2002); Clements v. Secretary of HHS, No. 95-484V, 1998 WL 481881 (Fed. Cl. Spec. Mstr. July 30, 1998); O'Connell v. Secretary of HHS, No. 96-63V, 1998 WL 64185 (Fed. Cl. Spec. Mstr. Feb. 2, 1998), aff'd, 40 Fed. Cl. 891 (1998), aff'd by unpub. opinion, No. 98-5134 (Fed. Cir., Nov. 1, 1999); and Haim v. Secretary of HHS, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Aug. 27, 1993).

The IOM also concluded that DPT does not cause afebrile seizures. Adverse Effects of Pertussis and Rubella Vaccines (1991). The IOM did a meta-analysis of febrile and afebrile seizures and concluded that "even pooling available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccination." Id. at 115

A mother who misleads her doctors by omitting a prior diagnosis and changing the histories of her child's symptoms, who avoids a bone marrow transplant because she has decided she knows better than the doctors how to treat her child, is not believable when she now insists, in the context of litigation, that his seizures occurred the same day as his vaccinations and his pre-vaccination history was uneventful. Nor, for that matter, are the affidavits of petitioner's mother and son credible although they are less egregious than Dylan's mother's affidavit.

Dylan is a very unfortunate boy and his disease is certainly not the fault of his parents who did not know they were Krabbe disease carriers (as, apparently, are all their other children). This is a tragedy without a villain. Dr. Kinsbourne's opinion rests totally on the validity of Dylan's seizure onset being in close proximity to his vaccinations. Yet, even he from time to time accepts that the vaccination had nothing to do with the course of Dylan's Krabbe disease which is following its inevitable course.

The undersigned rules that not only would acellular DPT not be the cause of Dylan's afebrile seizures if they had occurred the same day as the vaccination, but also that the credible medical history petitioner herself gave early on in Dylan's medical treatment is that the onset of Dylan's seizures was at least one month post-vaccination. Clearly there is no causal relationship. The most logical sequence of cause and effect is in the opinion of Dr. Robert D. Steiner, a treating doctor, that Dylan's "primary clinical features of Krabbe disease are the seizures and ataxia."

Petitioner has failed to prove a prima facie case of significant aggravation of a Table encephalopathy because her expert never discusses encephalopathy. Moreover, his interpretation of significant aggravation as applied to seizures conflicts with the statutory definition of significant aggravation. Petitioner has failed to prove a prima facie case of causation in fact seizures.

The undersigned expects that those who sign affidavits will adhere to the truth instead of putting events after vaccination that clearly occurred before (Dylan's stumbling, his fatigue, his falling off his bicycle) and truncating the occurrence of other events (seizures that began in late July or early August now begin the day of vaccination).

CONCLUSION

This case is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.[5]

_____ _____

DATE Laura D. Millman
Special Master

[5] Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.