OFFICE OF SPECIAL MASTERS

No. 95-198V

(Filed: March 29, 1999)

* *		
TODD R. ULICNY and MICHELLE K. ULICNY, Parents and Next Friends of CARRINGTON TODD ULICNY,	*	
Petitioners,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Robert T. Moxley, Cheyenne, WY, for petitioners.

Karen P. Hewitt, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

Statement of the Case

On March 8, 1995, Todd R. Ulicny and Michelle K. Ulicny on behalf of their son, Carrington Todd Ulicny (hereinafter "Carrington"), filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986[(1)] ("Vaccine Act" or the "Act"), alleging that DPT significantly aggravated Carrington's underlying tuberous sclerosis (TS). Subsequently, respondent provided evidence in TS cases in an Omnibus TS hearing to the effect that DPT does not significantly aggravate TS.

Petitioners have satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-11(c) by showing that: (1) they have not previously collected an award or settlement of a civil action for damages arising from the vaccine injury; (2) the DPT vaccination was administered to Carrington in the United States; and (3) they have incurred $1,000.00 in unreimbursable medical expenses prior to filing the petition.

The above-captioned matter was part of the TS cases pending during the undersigned's Omnibus TS hearing dated October 8-11, 1996 and June 3-4, 1997. Subsequent to the court's Omnibus TS Decision, dated September 15, 1997,[(2)] the court determined to take evidence in this case. The court held a hearing on January 14, 1999. Testifying for petitioners were Todd R. Ulicny, Michelle K. Ulicny, and Dr. Marcel Kinsbourne. Testifying for respondent was Dr. Mary Ann Guggenheim. The court heard summations on February 26, 1999.

FACTS

Carrington was born on December 15, 1992. Med. recs. at Ex. 4, p. 1. He was diagnosed in utero as having an intracardiac tumor. Id. An EEG he underwent on December 15, 1992 while hospitalized showed abnormality on the left side of his brain: rhythmic delta in the left occipital area.[(3)] Med. recs. at Ex. 3, p. 44. This can be seen in seizure disorders. Id. He has two paternal uncles and one paternal great uncle with mental retardation. Med. recs. at Ex. 4, p. 2. An MRI done on December 16, 1992 while Carrington was hospitalized showed multiple brain lesions. Med. recs. at Ex. 4, p. 39. A CT scan was also abnormal. Id. He was discharged from Saddleback Memorial Medical Center on December 18, 1992 with a diagnosis of cardiac tumor and TS. Med. recs. at Ex. 4, p. 2.

Carrington saw Dr. L. Brody, a neurologist, on December 22, 1992. Med. recs. at Ex. 6, pp. 1-3. Dr. Brody cautioned the Ulicnys in great detail about the manifestations of infantile spasms in TS patients, although Carrington had not begun having them. Med. recs. at Ex. 6, p. 3.

Carrington received his first DPT vaccination on February 8, 1993, when he was seven weeks old. Med. recs. at Ex. 5, pp. 9-10. None of the medical records gives a precise date for the onset of Carrington's post-vaccinal seizures.[(4)] During that visit, Dr. Kent, the pediatrician, telephoned Dr. Brody and obtained the opinion that it was okay to give DPT to Carrington. Med. recs. at Ex. 5, p. 10. Carrington and the Ulicnys saw Dr. Brody for a regular visit after the appointment with Dr. Kent. Med. recs. at Ex. 6, p. 4.

Ten days after the DPT vaccination, Carrington saw Dr. Brody on February 18, 1993. Med. recs. at Ex. 6, p. 5. The Ulicnys described Carrington's movements to Dr. Brody and he wrote that Carrington had some left handed clonic jerks and occasional myoclonic jerks. Id. His EEG showed right central sharp waves. Id. Dr. Brody diagnosed partial simple seizures and prescribed Phenobarbital. Id. He told the Ulicnys to telephone him if the bilateral jerks increased. Id.

Mrs. Ulicny kept a calendar and recorded Carrington's first post-vaccinal twitching occurring ten times in both arms at 6:30 p.m. on February 12, 1993, four days after vaccination. P. Ex. 16, p. 2. This was followed by twitching five times in both arms at 7:00 a.m. on February 13th. Id. There was no twitching on February 14th, 15th, or 16th. Id. On February 17th, he had several spasms in his left hand and arm. Id. On February 18, 1993, he had an EEG and was put on Phenobarbital. Id. Mrs. Ulicny noticed twitches again on February 27, 1993. P. Ex. 16, p. 3. Carrington's dosage of Phenobarbital was increased on March 1, 1993. Id. Mrs. Carrington telephoned Dr. Brody on March 24, 1993 about Carrington's twitching in his left arm, leg and eye that happened when he woke up from a nap. Id. Dr. Brody raised the dosage of Phenobarbital. Id. Carrington's EEG looked good: no seizure activity on the left side. Id. On March 25th, Carrington had a small fever of 99.7 degrees, but his temperature was normal on March 26th and 27th. Id. On March 29, 1993, Carrington twitched five times in his left arm once. P. Ex. 16, p. 4. On March 31, 1993, he twitched four times at 1:00 p.m. and two times at 9:30 p.m. Id. He was very fussy. Id.

On April 1, 1993, Carrington was still cranky and twitched eight times once in the shoulders. Id. On

April 2, 1993, he twitched four times once in the left arm and hand, but was not cranky. Id. On each day in April, Mrs. Ulicny recorded exactly the number and location of twitches. Id. The same is true for the remaining months. P. Ex. 16, pp. 1-13.

An EEG done on February 18, 1993 showed normal background but frequent focal epileptiform discharges in the right mid-temporal and central areas. Med. recs. at Ex. 7, p. 1. An EEG done one month later, on March 19, 1993, was normal. Med. recs. at Ex. 7, p. 2. An EEG done on April 6, 1993 showed focal seizures emanating from the right central area manifested by left arm twitching. Med. recs. at Ex. 7, p. 3. This suggested a destructive lesion in that area, consistent with Carrington's diagnosis of TS. Id. By contrast, on May 28, 1993, Carrington's EEG showed frequent left hemispheric discharges, consistent with right-sided seizures. Med. recs. at Ex. 7, p. 4.

On July 29, 1993, Mrs. Ulicny told Dr. John Mersh, a pediatrician, that Carrington's first seizure was after his first DPT. Med. recs. at Ex. 11, p. 7. On October 26, 1993, she told Dr. Moyra Smith that Carrington was well until he was two months old when he received DPT and developed seizures shortly thereafter. Med. recs. at Ex. 13, p. 2.

Carrington has 28 cortical tubers. R. Ex. N.

TESTIMONY

Todd R. Ulicny testified first for petitioners. Tr. at 10. He had been a financial analyst and attended law school for two and one-half years but did not finish. Tr. at 11-12. He also worked for six months at the National Tuberous Sclerosis Association. Tr. at 13. He is thirty-two years old. Tr. at 11. Carrington is his and his wife's only child. Tr. at 14. He knew from Carrington's birth that Carrington had TS. Tr. at 19-20. Two of his uncles are mentally retarded, but they do not have TS. Tr. at 25-26. Dr. Brody became their neurologist and Dr. Kent became their pediatrician. Tr. at 28. Dr. Kent was wonderful and very knowledgeable. Tr. at 31.

Because Mr. Ulicny did not feel informed enough about TS after his and his wife's meeting with Dr. Brody on December 22, 1992 (one week after Carrington's birth), he did research on Lexis-Nexis and Medicine Westlaw,[(5)] to which he had access as a law student, and found other TS cases which this court decided, as well as other material. Tr. at 30-31. That material caused him to be anxious about Carrington's receiving DPT vaccine. Id.

Mr. Ulicny printed out all he could find on the computer databases to bring to Dr. Kent on February 8, 1993 because he wanted to talk to him about whether or not he should be concerned about giving Carrington DPT. Tr. at 32. His wife thought as well that DPT might not be a good idea because of the debate going on concerning administering DPT to children with TS. Id. By the time they got to Dr. Kent's office, they had made up their minds not to give DPT to Carrington. Id. They discussed Carrington's bladder infection weeks before and then Dr. Kent mentioned the DPT. Tr. at 33. At that point, Mr. Ulicny pulled out the articles, told Dr. Kent he was a law student, and asked his opinion on DPT being administered to TS children. Id. Dr. Kent thought that lawyers exaggerate the risks in order to earn money and that there was not anything to worry about. Tr. at 33-34. The material Mr. Ulicny showed Dr. Kent included court cases on DPT and TS, including references to Dr. Manuel Gomez and an article he wrote. Tr. at 34. Petitioners' counsel's partner Richard Gage was the named counsel for those TS cases. Tr. at 34.

Mr. Ulicny pressed Dr. Kent on whether giving DPT to Carrington was really a good idea in light of the controversy. Tr. at 35. Dr. Kent replied that whooping cough was a horrible disease and the vaccine was

preferable to risking their child's contracting whooping cough. Id. Mr. Ulicny also mentioned acellular pertussis vaccine, but Dr. Kent did not have any on hand. Tr. at 35-36. Dr. Kent asked the Ulicnys if they would like him to call Dr. Brody. Tr. at 36. When they said yes, he did and told Dr. Brody that the Ulicnys had showed him articles about vaccine dangers. Id. Dr. Brody felt it was safe to give Carrington the vaccine. Id. The Ulicnys agreed, but Mrs. Ulicny said to Mr. Ulicny, "Are we really going to do this then?" Id. They decided to rely on the doctors' expertise. Tr. at 36-37. They saw Dr. Brody immediately afterward for a previously-scheduled appointment, not only for Carrington, but also for Mr. Ulicny to see if he had TS. Tr. at 37. Carrington looked neurologically good to Dr. Brody. Tr. at 38.

Mr. Ulicny was under the impression that when Carrington saw Dr. Kent and Dr. Brody on February 8, 1993, it was a Tuesday.(6) Tr. at 38. Carrington got progressively agitated that day and cried. Id. Mr. Ulicny does not know when Carrington's irritability started. Id. Carrington had discomfort. Id. The vaccine site was red and raised. Id. Carrington cried out but not with a normal cry, more like a wail. Tr. at 38-39. He did not eat properly. Tr. at 38. They did not touch the vaccine site. Tr. at 39.

Mr. Ulicny testified that Carrington's first seizure occurred on Wednesday, February 9, 1993(7) which was the day after the DPT vaccination. Id. He gazed off into the distance and had a cramping motion on his left side. Id. He cocked his head, had a fixated look, and his left arm tensed up. Tr. at 39-40. They gave him Tylenol drops for fever. Tr. at 41. He had a fever of 102 degrees.(8) Id.

He does not know how long the vaccine site was sore. Tr. at 50. Carrington would not eat for a few days. Id. His sleep was broken by his cries. Tr. at 51. He seemed to be in pain. Id. On Wednesday, February 10, 1993, Mrs. Ulicny saw the seizure, too.(9) Tr. at 53.

Neither of the affidavits of Mr. and Mrs. Ulicny reflects that Carrington did anything but seize after his vaccination, although, during one seizure, he stopped eating. Tr. at 83. They do not mention wailing, escalation of irritation, a raised vaccine site, or failure to eat. Id. Mr. Ulicny explained the discrepancy between their affidavits and his testimony by saying that no one asked him about these symptoms as if they were important. Id. When he and Mrs. Ulicny tape recorded their conversation with Dr. Kent on March 30, 1993, they did not tell him about any symptom after vaccination except the seizures. Tr. at 84-85.

When asked about his affidavit which says the onset of Carrington's seizures was two days after vaccination, or February 10, 1993, whereas he just testified that it was one day, or February 9, 1993, Mr. Ulicny said the onset was two days. Tr. at 75. He acknowledged that he had been in discussion with his counsel's partner Richard Gage before he tape recorded Dr. Kent on March 30, 1993 and wrote three drafts of a letter to Dr. Kent in early April 1993. Tr. at 82. He stated that Mr. Gage may have said to him that the onset of symptoms within three days of vaccination was important in pursuing a claim for compensation prior to the time he tape recorded Dr. Kent and wrote the three drafts of the letter to Dr. Kent. Tr. at 83.

Mr. Ulicny acknowledged that Dr. Brody on December 22, 1992 (one and one-half months before the vaccination) had cautioned him and Mrs. Ulicny about infantile spasms. Tr. at 75. He was also aware at that meeting that seizures are the most common manifestation of TS. Tr. at 76.

Mr. Ulicny admitted that in the transcript of his and his wife's conversation with Dr. Kent on March 30, 1993, he did not mention symptoms after the vaccination such as irritability or a raised vaccine site. Tr. at 85. He said he did not think they were significant. Id.

The twitch that Mrs. Ulicny recorded in her calendar for Friday, February 12, 1993, was a raised arm

movement that lasted 8 to 30 seconds. Tr. at 86-87. Mr. Ulicny stated he saw two events on Wednesday, February 10, 1993, that lasted 8 to 15 seconds each. Tr. at 90. He was on the couch holding Carrington. Tr. at 91. On Thursday, February 11, 1993, he and his wife saw hand twitching. Id.

They called Dr. Brody on Monday, February 15, 1993, and he recommended videotaping the seizures. Tr. at 92. Mr. Ulicny does not know where the videotape is. Id. On March 30, 1993, at Carrington's four-month visit, Dr. Kent found him to be normal on physical examination. Tr. at 102. So did Dr. Brody, who saw him subsequently. Tr. at 103.

Mrs. Michelle Ulicny testified next for petitioners. Tr. at 111. She has TS but no cortical tubers. Tr. at 114. When Carrington received his DPT vaccination on February 8, 1993 from 9:00 to 10:00 a.m., he was fussy, cried in pain, and ate less. Tr. at 121-22. His vaccine site was raised and red. Tr. at 122. He had a low fever, about 99 degrees, and was fussy at night. Id. He had a high-pitched cry and she could not comfort him. Id. On Tuesday, February 9, 1993, by afternoon, he was back to normal. Tr. at 123. His fever and crying were over and his eating and sleeping returned to normal. Id. She admitted that her affidavit does not include any symptoms besides seizures. Tr. at 145.

Wednesday, February 10, 1993, was a normal day. Tr. at 124. On Thursday, February 11, 1993, at 7:00 a.m., Carrington woke and she changed him. Tr. at 125. She turned on the light and noticed him twitching five times. Id. He had a funny look which lasted five seconds. Id. In the evening, she told Mr. Ulicny. Tr. at 125-26. On Friday, February 12, 1993, Carrington twitched ten times at 6:30 p.m., which she noted in her calendar. Tr. at 126-27. Mrs. Ulicny said that she most likely made this entry in her calendar on the evening of February 12th. Tr. at 135-36. On February 13th, she recorded more twitches. Tr. at 135.

When asked why she did not record any twitches for February 14th, 15th, and 16th, she replied that Carrington did not have twitches on those days. Id.

She thinks Carrington was developmentally delayed by the age of four months. Tr. at 146. He did not roll over until seven months and did not walk until 17 months. Id. He had left-sided weakness within one month of his DPT inoculation. Tr. at 146-47. He would not hold a rattle in his left hand. Tr. at 147. He had left-sided seizures. Id.

Dr. Marcel Kinsbourne testified next for petitioners. Tr. at 150. Carrington's first EEG at birth on December 15, 1992 showed rhythmic delta waves with a frequency of one and three per second, revealing the possibility of an unstable part of his brain. Tr. at 151. Dr. Kinsbourne stated that the areas of firing and stopping were not seizures, but occur in those with seizure disorders. Tr. at 153. One does not diagnose a seizure on an EEG. Tr. at 155. It is a behavioral and subjective event and happens paroxysmally. Id. Carrington's first EEG's bursts of spikes (pointy waves) are consistent with a seizure disorder. Tr. at 157. Instability itself is not epileptiform, but delta activity could lead to a seizure disorder. Tr. at 157-58.

Carrington's second EEG, dated February 18, 1993, showed isolated spike or sharp waves, which are epileptic discharges. Tr. at 159. It showed two subclinical seizures but no clinical abnormality. Id. Carrington has 28 cortical tubers and focal dysfunction in the areas of the tubers. Tr. at 154-55. In Carrington's second EEG, his delta activity was normal. Tr. at 158-59. This was not the salient part of his seizure activity. Tr. at 159. The focal part is in his right central and temporal areas. Tr. at 159. Carrington had a seizure disorder in February 1993. Tr. at 160. TS children's brains are unstable electrically and at risk for seizure disorders. Id. It has never been shown that TS by itself leads to seizures in all cases. Tr. at 161-62. Dr. Kinsbourne stated that eighty percent of TS patients will have

seizure disorders at some point in their lives. Tr. at 162.

If Carrington's seizures began two days after his DPT, Dr. Kinsbourne's opinion is that DPT was the precipitating factor in their onset. Tr. at 161. If his seizures began after three days, Dr. Kinsbourne could not state what the precipitating factor was. Id. Dr. Kinsbourne stated that the relative risk of having a seizure is seven times higher[(10)] within three days of a DPT based on his interpretation of the National Childhood Encephalopathy Study (NCES).[(11)] Tr. at 165. Carrington did not have infantile spasms, but asymmetrical, focal seizures. Tr. at 166. His EEGs did not show hypsarrhythmia, the hallmark of infantile spasms. Id. Dr. Kinsbourne stated that DPT would more readily cause minor seizures, relying on the Cody article[(12)] in which two children had afebrile seizures and seven children had febrile seizures, for a ratio of 1 in 1700 children having short seizures. Tr. at 168.

The NCES and Cody studies were differently designed and a direct comparison of the two by relative risk is not possible because the Cody study did not deal with relative risk. Tr. at 182. When queried how he could apply the NCES to this case since the NCES authors used children whose seizures lasted more than thirty minutes, Dr. Kinsbourne said he was not applying the NCES to this case, merely mentioning it to explain why he does not go beyond 72 hours in linking DPT to a seizure. Tr. at 167. The children in the Cody study did not have TS. Tr. at 168.

Dr. Kinsbourne stated that Carrington did not have a febrile seizure. Tr. at 169. Since there were only two children with afebrile seizures in the Cody study, and 15,000 records, that would be a risk of one out of 7,000 to have a DPT-induced seizure. Tr. at 173-74. However, Dr. Kinsbourne qualified his answer by saying he was not giving a causation in fact opinion in Carrington's case. Id.

The Cody study was not a case-controlled study and, therefore, relative risk cannot be calculated from it. Tr. at 182. Carrington's post-vaccinal symptoms of fussiness, not eating, fever, crying, and raised vaccine site had dissipated by Tuesday before his father saw the first seizure on Wednesday. Tr. at 184. Dr. Kinsbourne stated that a benign vaccine reaction is irrelevant to a neurologic event. Tr. at 184-85.

Focal seizures are not as bad as infantile spasms. Tr. at 189. Carrington has tubers on the right side of his brain. Id. Dr. Kinsbourne agrees there is a correlation between the location of the tubers and the location of the seizures. Id. The number of tubers is a risk factor for seizures. Tr. at 190. The higher the number, the higher the risk. Id. Carrington's 28 tubers cause considerable cortical disruption. Tr. at 190-91. Others with 28 tubers who did not have DPT would have similar conditions. Tr. at 192.

Carrington would not have been admitted into the NCES study. Id. Cody did not study TS children. Id. There must be some chemical in DPT that causes seizures. Tr. at 196. Fever is not a sufficient explanation for the seizures. Tr. at 195-96.

Dr. Mary Ann Guggenheim testified for respondent. Tr. at 200. Her opinion is that Carrington's TS caused his seizures. Tr. at 203. It is fairly common to have a relatively minor reaction to DPT for the first day and one-half after vaccination. Tr. at 204. Carrington had a minor reaction, not a neurological one, and not encephalopathy after his DPT vaccination. Id. His tubers caused disturbance of the cortical neuronal network on the right side of his brain. Tr. at 206. Hence, his seizures were left-sided. Id. There is no evidence of an acute encephalopathic reaction. Id. He had a high likelihood of developing seizures. Id.

Carrington has extensive tubers. Id. One of the more extensive ones is in the right frontal area and right motor strip (the posterior part of the frontal area). Tr. at 207. Clinically and in medical literature, TS causes seizures without any external event identified. Id. (Dr. Kinsbourne interjected that his extraneous

factor is not necessarily an external event. Tr. at 208-09. He thinks an extraneous factor means more than the number of tubers. Tr. at 209. A tuber is not an active working brain. Tr. at 208-09. Carrington had a lot of tubers. Tr. at 210.)

Dr. Guggenheim stated that there is a maturational effect, i.e., epileptiform activity is more likely to occur as the brain matures. Tr. at 215. Similarly, the neuronal network develops more synaptic connections. Tr. at 215-16. The cortex of a term infant is not very active. Tr. at 216. Its physical activity is primarily the brainstem and deep brainstem. Id. By Carrington's second EEG, his neurons were firing electrically. Tr. at 220. Multiple areas of his cortex were affected. Tr. at 220-21.

Carrington had three manifestations of brain disorder: (1) motor dysfunction of the left side of his body (cerebral palsy); (2) partial complex seizures; and (3) cognitive and behavioral difficulties. Tr. at 224. All three of these are due to his TS, which caused disturbances of his cortical area. Tr. at 225. The majority of TS patients have seizures. Id.

The seizure activity did not cause damage to Carrington. Tr. at 228. They were too brief. Id. They were not infantile spasms or epilepsy and there was no anoxia. Id. Carrington has developmental delay because his cerebral cortex is inadequate. Tr. at 229. It does not function because it is abnormal due to its abnormal neurons. Id. Dr. Guggenheim testified that Carrington's current condition is due to his TS even if the court were to hold that his seizures were due to DPT. Tr. at 230. (Dr. Kinsbourne interjected that Carrington's brief initial seizures caused his mental retardation over time. Tr. at 245. A child with 28 tubers has severe TS. Tr. at 246.)

If Carrington were her patient when he was born, she would have told his parents that he would most probably have seizures and abnormal development. Tr. at 230-31. The more severe the TS, the more likely an early onset of seizures and worse outcome. Tr. at 232. Seizures and outcome are both symptoms of TS. Id. Prolonged status epilepticus and infantile spasms can damage the brain; otherwise, brief, either partial or generalized seizures do not cause damage. Tr. at 232-33. People with 28 tubers are at high risk for infantile spasms. Tr. at 266. Carrington did not have infantile spasms. Id. TS individuals with 28 tubers are likely to have seizure onset within the first year of life. Id. We do not know how TS causes the seizure onset although Dr. Gomez testified at the Omnibus TS Hearing about misfiring of neurons at the periphery of the tubers. Tr. at 267-68. She does not know why the seizure would occur at that particular minute. Tr. at 274. She does not know of anyone with 28 tubers who is normal. Tr. at 272.

Dr. Kinsbourne on rebuttal mentioned the Decker twins[(13)] who had 17 and 23 tubers, but marked difference in their mental delay. Tr. at 275. In addition, he insisted that seizures lead directly to developmental delay. Tr. at 276. However, as the court pointed out to him, and he agreed, the Decker twins had infantile spasms, which Dr. Guggenheim agreed were damaging. Tr. at 276-77. Damien, the more affected twin, had six weeks of uncontrolled infantile spasms before being put on an anticonvulsant (ACTH) which worked. Tr. at 276. Destry, the less damaged twin, had one week of infantile spasms which then disappeared and he was never placed on anticonvulsants. Id.

DISCUSSION

The Vaccine Act affords petitioners two theories of recovery, thereby allowing them to prove causation by showing that either: (1) a Table-injury occurred or (2) the vaccine was the cause-in-fact of the injury. The former theory is governed by Section 14(a) of the Act which contains a Vaccine Injury Table. If the injuries described in this Table occur within the statutorily defined time period, petitioners have proven the existence of a "Table-injury," creating a rebuttable presumption of causation. To rebut this presumption, respondent must provide affirmative evidence demonstrating that a known factor unrelated

was the cause-in-fact of the vaccinee's condition.[(14)]

As the court held in its Omnibus TS Decision, if a vaccinee with TS has a seizure as his or her sole symptom following DPT vaccination, without any indicia of a vaccine reaction, e.g., fever, screaming, inconsolable crying, altered affect, insomnia, anorexia, or excessive irritability, the court will hold that: (1) TS is the factor unrelated to the vaccination that caused his or her seizures, and (2) petitioners do not prevail on a theory that DPT significantly aggravated the vaccinee's TS. See Barnes, supra, at *32-33.

Petitioners herein allege that Carrington experienced fever, inconsolable crying, insomnia, anorexia, and irritability after his first DPT vaccination on February 8, 1993. This tracks almost completely the court's Omnibus TS Decision except for altered affect. However, Mrs. Ulicny testified that Carrington's fever was never high, all these symptoms went away, and he returned to normal by the afternoon of February 9, 1993, before he ever seized.

Based on respondent's proof, both at the Omnibus TS hearing and at the trial of the instant action, the court holds that Carrington's severe TS, manifested by 28 cortical tubers, is the cause in fact of his seizures as well as his current condition. Mr. Ulicny testified that Carrington's first seizures occurred at some time on February 10, 1993. Petitioners' expert, Dr. Kinsbourne, stated that the occurrence of benign symptoms of a vaccine reaction, such as fever, crying, and lack of sleep, are unconnected to the development of a serious neurologic condition after DPT. Based on the court's prior holding in the Omnibus TS Decision as well as Dr. Kinsbourne's testimony herein, the court holds that Carrington's first seizures were unrelated to his DPT reaction of fever, inconsolable screaming, anorexia, irritability, and insomnia if, indeed, these occurred. Petitioners have not impeached respondent's proof of causation in fact.

Petitioners' attempt to impeach respondent's evidence is unavailing. Firstly, Dr. Kinsbourne's testimony equating a seven times relative risk for developing seizures after DPT based on the NCES is inapposite, as he himself admitted during questioning. The authors of the NCES did not include any TS children and they did not include any children who had seizures of less duration than thirty minutes. Carrington has TS and his seizures lasted seconds.

Secondly, the authors of the NCES could find no relationship between DPT and the onset of infantile spasms because the incidence of infantile spasms occurred just as frequently after DT vaccination as after DPT vaccination.[(15)] Although Carrington did not have infantile spasms, infantile spasms are the seizure that most TS children experience as babies. It would therefore be significant to the court if the NCES had concluded that DPT vaccine causes infantile spasms because it would be relevant to other afebrile seizures. However, the NCES did not make such a conclusion.

Thirdly, Dr. Kinsbourne's thesis that there must be something extraneous to TS itself in order for a TS child to start seizing is based on nothing but conjecture. He did not cite any medical literature, clinical experience, or any other basis for this opinion. The court has recognized in the Omnibus TS Decision that more factors than tuber number play a role in the deterioration of condition of TS children over time, e.g., size and location of the tubers. The court recognizes as well (as do both experts in the case) that medical knowledge has not yet specified the significance of the roles of size and location of the tubers. We know that excision of a large tuber may result in easing of seizures, and that location of lesions on one side of the brain (as the right side of Carrington's brain) results in seizures on the other side of the body (Carrington's left side). However, the relationships are not precise or unchanging.

Dr. Kinsbourne's discussion of extraneous factors is not only speculative but confusing in that he seems to rely not only on factors besides tuber number, such as size and location of tubers, but also on extrinsic

factors, such as DPT. Yet, he denigrates the role of fever as being in any way related to the onset of seizures. The undersigned, however, recognizes that most children with TS seize and become mentally retarded and finds nothing very surprising in Carrington's outcome.

Dr. Kinsbourne's emphasis on Dr. Gomez's statement in the 1995 American Journal of Neuroradiology article[(16)] that all mentally retarded TS patients have a history of seizures and, therefore, seizures themselves might cause brain damage omits a few important details. Firstly, the types of seizures that TS patients generally have as babies is infantile spasms, and infantile spasms are known to cause damage. Dr. Guggenheim emphasized this in her testimony. The only other seizures that cause damage are status epilepticus and anoxic or hypoxic seizures because of the deprivation of oxygen to the brain. Secondly, as Dr. Guggenheim also stated, that TS patients with mental retardation also universally had a history of seizures does not mean that the seizures caused the mental retardation. She said that a severe case of TS (which Carrington has) would cause both seizures and mental retardation, i.e., they are both symptoms of the disease rather than one being causative of the other.

Dr. Kinsbourne's reference to the Decker twins to show that an extrinsic factor such as DPT must exist to trigger seizure onset in a TS child does not prove that an extrinsic factor is indeed necessary (except in legal terms, i.e., to prove petitioners' case). Respondent has amply proved that serious TS, as part of its course, manifests in seizures. In Carrington's case, Dr. Guggenheim testified that Carrington's brief myoclonic seizures did not damage him. Dr. Kinsbourne testified that they led to his current condition, i.e., they are causally linked to his current state. Without some basis to support his opinion, Dr. Kinsbourne is not credible both as to the necessity of a factor extrinsic to TS, i.e., DPT, for onset of seizures and to the effect of Carrington's seizures on his current condition.

The question remains whether or not Carrington had seizures on-Table after his DPT. The court holds that Carrington's seizures were not on-Table and that it is unlikely that he had significant post-vaccinal symptoms of inconsolable crying, fever, anorexia, irritability, and insomnia (even though if he had these symptoms, they would apparently be irrelevant, according to Dr. Kinsbourne). The basis for the court's holding is the total absence of the mention of any of these symptoms to any of the numerous doctors the Ulicnys took Carrington to see.

The Ulicnys are in the unique position of having had a diagnosis of TS for Carrington at his birth, plus an MRI, EEG, and CT scan, all of which alerted them to the necessity of watching their child for seizures. Having to maintain a vigilant watch must have been terrible for them. They saw the pediatric neurologist, Dr. Brody, just one week after Carrington was born, on December 22, 1992. He warned them about infantile spasms in TS children, as recorded in his notes for December 22, 1992:

I spent a great deal of time going over tuberous sclerosis with the parents who understood it quite readily. [He discusses having the parents examined for TS, particularly Mr. Ulicny because he had headaches.]... Parents will endeavor to obtain copies of the brain imaging studies as well as the EEG itself for my review. ... I have cautioned the family in great detail about the manifestations of infantile spasms....

Moreover, Mr. Ulicny was not one to rest on what Dr. Brody told him. Mr. Ulicny, a law student as well as a financial analyst, looked up TS in Lexis-Nexis and Health & Medicine Westlaw, and came up with a great deal of material, including this court's other opinions in TS cases. He became alarmed about DPT and the controversy of injecting it in TS patients, but Dr. Kent and a phone call to Dr. Brody persuaded him and his wife on February 8, 1993 that it was in Carrington's best interest to protect him from pertussis disease.

Knowing, as they did, that there were other TS parents who had brought suit for alleged DPT injuries to their children and that there was an ongoing controversy over whether DPT damaged children with TS, Mr. and Mrs. Ulicny could not possibly have ignored Carrington's symptoms of inconsolable crying, fever, anorexia, irritability and insomnia after DPT vaccination if they had been anything but minor, assuming they happened at all. It is beyond belief that if Carrington indeed had experienced a vaccine reaction such as the parents testified, they would not have brought Carrington immediately back to Dr. Kent or Dr. Brody and would not report these symptoms in subsequent histories to medical personnel.

In fact, the Ulicnys did not see Dr. Brody until ten days after the vaccination, on February 18, 1993, at which time they described to him Carrington's movements and he noted that Carrington had some left handed clonic jerks and occasional myoclonic jerks. Carrington's EEG showed right central sharp waves. Dr. Brody diagnosed partial simple seizures and prescribed Phenobarbital.

The Ulicnys did not return to Dr. Kent until a month after the DPT vaccination, on March 8, 1993.

The closest the Ulicnys came to documenting their allegations was their surreptitious recording of Dr. Kent when they visited him on March 30, 1993 for Carrington's four-month visit. They did not want Carrington to receive the second DPT vaccination. Before this visit, the Ulicnys had retained counsel and were contemplating suit, as expressed in one of their drafts of a letter to Dr. Kent a few days after the tape recording.

In light of Mr. Ulicny's retention of counsel as well as his prior knowledge of TS lawsuits, Mr. Ulicny's denial of any litigative intent when he and his wife visited Dr. Kent is not believable. Interestingly, they wrote to Dr. Kent that, during their visit to him on March 29, 1993,[(17)] Dr. Kent acknowledged to them the correlation between DPT and Carrington's onset of seizures. That is an incorrect statement in light of the transcript of that conversation (which occurred three days before the date of this letter) in which Dr. Kent does not acknowledge a correlation:

That could have been, but what we do know is that (hard to understand) what was going to bring out his seizures but the shots have always been fingered for it, and uh, so it could have been that he fell off the bed, and just that fall (clap), or he could have cried really loud one day, which he was very angry, or he kind of had a cold or the flu...all of these things could have, uh, started the ball rolling.

Mrs. Ulicny kept a detailed journal of Carrington's daily behavior. The first day that she recorded twitching (in both arms with the frequency and the time) was on February 12, 1993, four days after DPT vaccination. She also recorded twitching of both arms on February 13, 1993. However, she did not record twitching on the subsequent three days, February 14th, 15th, and 16th. When asked why she did not record twitching on those three days, she testified that was because Carrington did not twitch then. The inescapable conclusion why she did not record twitching on February 11, 1993, although she testified Carrington twitched then, is that he did not twitch then. There is nothing recorded for February 10th either (even though Mr. Ulicny testified that he discussed the twitching with his wife) leading to the same conclusion that this twitching never occurred.

The court cannot find credible that the Ulicnys, knowing their child has TS whose hallmark is seizing, before Carrington had started twitching, would be vigilant in monitoring his health by pursuing medical and legal research on TS children's experience with DPT, confronting their pediatrician with this material, and needing to be persuaded to give the DPT, but after Carrington experienced twitching would fail to record any twitches or other symptoms in their highly-detailed calendar until 4 days post DPT or take the child immediately to the doctor or even give a history of these events to any medical practitioner at any time if the onset were indeed on-Table. The closest their subsequent histories in the

medical records come to on-Table onset is "shortly thereafter [the DPT],"[(18)] and that is not sufficient to put onset on-Table.

From the date of Carrington's birth, not just after the onset of seizures, Mrs. Ulicny was a zealous observer of his medical condition. On December 16, 1992, the day after he was born, she wrote in her calendar that the doctors found tubers in his brain. On December 17th, she wrote he was diagnosed with TS. On December 18th, she wrote that they had their first night of horror. On December 19th, she wrote they had a good day and a good night. On December 20th, she wrote they had a hard night. On December 21st, she wrote they had a good day. She wrote the doctor's appointment on December 22nd and Carrington had a good night (sleeping five and one-half hours) on December 23rd. On December 24th, she wrote that Carrington liked the swing. On December 29th, she wrote another doctor's appointment and that Carrington tried soy but it did not work, suggesting that he was experiencing digestive problems with milk. On January 4, 1993, she wrote she called to make an appointment with Dr. Kent. On January 6th, she wrote that they saw Dr. Lagrew. On January 8th, she wrote that Carrington had his circumcision. On January 12th, she wrote they saw Dr. Kent. On January 21st, she wrote to call Dr. Kent if he did not call her about appointments. On January 22nd, she wrote that her husband had a final exam. On January 23rd, she wrote that Carrington had 100 degree fever. On January 24th, she wrote that Carrington's fever had risen to 101 degrees. On January 25th, she wrote that Carrington's fever remained the same, he had a bladder infection, and they saw Dr. Lam for Carrington to have urine and blood cultures. On January 26th, she wrote that Dr. Kent drew blood from Carrington and did a chest x-ray of him. Carrington had 99 degrees temperature. He received Bacticillin. On January 27th, she wrote that Carrington's temperature was 97 degrees, as it was on January 28th. On January 29th, she canceled an ultrasound for Carrington and took him to the photographer. On February 1, 1993, she saw the dermatologist, Dr. Alpern. On February 3rd, they returned to Dr. Lagrew. On February 5, 1993, a sonagram was performed. On February 8, 1993, they saw Dr. Kent at 9:00 a.m., Dr. Brody at 10:00 a.m.(Carrington), Dr. Brody at 11:00 a.m. (Mr. Ulicny), and Dr. Alpern at 2:45 p.m.

Then Mrs. Ulicny wrote nothing until February 12th when she wrote that Carrington twitched. To suggest that Carrington had twitched between February 8th and 12th without Mrs. Ulicny noting that in her calendar in light of the detailed notes she had taken since Carrington's birth is not believable. It is also not believable that if Carrington had any symptoms beyond a mild reaction to the DPT, she would have failed to write them down. She certainly had written in the past when Carrington had a fever and when he did not sleep or was behaving poorly (i.e., a night of horror). If this child indeed were crying inconsolably, not eating, irritable, and not sleeping, Mrs. Ulicny would have diligently recorded those symptoms.

She continued noting his twitching on February 13th, but did not record any twitching on February 14th, 15th, or 16th because, as she testified, he did not twitch then. For February 17, 1993, she recorded in her calendar that she noticed a spasm in Carrington's left hand and arm several times. She recorded on February 18, 1993 that Carrington received an EEG and was put on Phenobarbital for seizures. Mrs. Ulicny's diligent note-taking continued through the rest of the evidentiary submission (March 1994). P. Ex. 16.

Weighing, on the one hand, the Ulicnys' failure to tell any medical practitioner the day on which Carrington started seizing and Mrs. Ulicny's careful calendar notation of an onset of four days after vaccination with, on the other hand, their current testimony, buttressed by a taped conversation with and drafts of a letter to Dr. Kent after the Ulicnys obtained legal counsel who had carefully spelled out the importance of on-Table onset, the court must conclude that the information that arose prior to a litigative bias and closer in time to the event is the more accurate and therefore the actual date.

Normally, this court weighs the discrepancy between histories given in contemporaneous medical records with subsequent testimony and opts for the histories in the records. See, e.g., United States v. United States Gypsum Co., 333 U.S. 364, 396 (1948); Burns v. Secretary, HHS, 3 F.3d 415 (Fed. Cir. 1993); Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (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).

By analogy, the court here opts for the only indication of onset which is both contemporaneous with the onset (being on the same day) and before any motive to prevail in a legal action arose. The court holds that onset was as Mrs. Ulicny indicated on her calendar: four days post-vaccination.

The court suspects that what really happened to Carrington after the DPT is that he did not experience any untoward reaction notable enough for Mrs. Ulicny to record in her calendar. Additionally, had Carrington started twitching on Wednesday or even Thursday (two and three days post-vaccination, respectively), Mrs. Ulicny would have noted that on her calendar. His arm and leg began to twitch, however, on Friday four days after the vaccination, and Mrs. Ulicny recorded that in her calendar. Mrs. Ulicny duly noted Carrington's twitching on Saturday, February 13th. The Ulicnys contacted Dr. Brody on Monday, February 15th, at which time he told them to videotape Carrington. Carrington did not twitch again until February 17th. The Ulicnys brought him in to see Dr. Brody on February 18th.

All of this is consistent with a pattern of mild, short twitches subsequently diagnosed as simple partial seizures. It is also consistent with the course of a severe case of TS. It is not consistent with a vaccine reaction.

Petitioners do not prevail not only because they have failed to show on-Table onset,[(19)] but also because it is obvious that this child was already neurologically compromised from birth. This case is unlike other TS cases because Carrington had an EEG at birth, which was abnormal. Although he did not manifest clinical seizures until he was two months of age, Carrington is in the unique position of not only having a disease (TS) which makes him a candidate for seizure disorder and mental retardation, but also of having abnormal firing of his neurons[(20)] right from birth. This is obviously in the absence of any DPT vaccine. No extraneous or extrinsic factor such as DPT, about which Dr. Kinsbourne speculated concerning onset of seizures in a TS individual, was present.

As Dr. Manuel R. Gomez, the world expert on TS, states in Tuberous Sclerosis, 2d ed. (Raven Press, 1988), at 23:

Notably, when the seizures start early in life, they are likely to persist for months or years despite anticonvulsant therapy. ... The seizures of successfully treated patients may recur as infantile spasms or as another type of generalized seizures such as tonic-clonic, tonic, atonic or myoclonic, or as complex partial seizures.

Dr. Gomez also states on the same page that there is a correlation between the number of lesions shown on MRI and the development of seizures in the first year of life: "the majority of our patients with more than five low attenuation lesions in the head CT scan had infantile spasms." Id. Carrington has 28 cortical tubers on MRI.

Even though this court does not accept that there is some magic number, be it Dr. Gomez's 5 tubers as mentioned in his text, or 8 tubers according to respondent's Omnibus TS evidence, or 9.9 tubers,

according to Dr. Gomez's 1995 American Journal of Neuroradiology article, beyond which disaster strikes, at some point, doctors agree that a child with a lot of tubers is not going to be normal. Carrington has a lot of tubers.

Apparently, Mrs. Ulicny has TS although she does not have cortical tubers. It is sad that Carrington was born with this affliction, but that does not make the normal course of his disease, which is all that this court concludes happened in this case, a consequence of DPT.

Petitioners have failed to satisfy their burden of proving that the onset of Carrington's seizures was within Table time of his DPT vaccination. Because petitioners have failed to satisfy their burden, the burden of showing that TS is the known factor unrelated to DPT that caused in fact Carrington's seizures and current condition does not pass to respondent.

Substantial Factor

During closing arguments, petitioner's counsel, who also represents appellants in Hanlon v. Secretary, HHS, 40 Fed. Cl. 625 (March 20, 1998), appeal docketed, No. 98-5120 (Fed. Cir. May 28, 1998), and Plavin v. Secretary, HHS, 40 Fed. Cl. 609 (Mar. 19, 1998), appeal docketed, No. 98-5168 (Fed. Cir. Sept. 14, 1998),[(21)] asserted that this court's Omnibus TS Decision is legally flawed because it did not take into account the principles that the U.S. Court of Appeals for the Federal Circuit enunciated in Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999). Summation transcript (hereinafter, sum. tr.) at 6, 11-13. He stated that DPT is a substantial factor in all TS cases if the statutory presumption applies (i.e., the court finds on-Table onset), and respondent can never satisfy its burden of proving that a known factor unrelated, e.g., TS, is the cause in fact of the vaccinee's seizures and current condition because DPT remains a substantial factor in the onset of the child's seizures. Sum. tr. at 15-18, 26.

Although this court holds that Carrington's seizures occurred off-Table, because petitioner's counsel asked the court to deal with the issue of the Shyface substantial factor holding as applied to the TS cases, sum. tr. at 52, the court will do so although this is dictum.

This court in its Omnibus TS Decision did not use the words "substantial factor," but it certainly recognized that where petitioners prove the vaccinees had on-Table onset of seizures, they are entitled to the presumption of causation from the vaccine. In the language the Federal Circuit used in Shyface, that means the statute legally presumes that DPT caused the child's seizures because the vaccine was a substantial factor. Respondent may always rebut this presumption, as it did in the Omnibus TS hearing. All presumptions are rebuttable.

When respondent proved that TS in children with numerous tubers leads to seizures, particularly infantile spasms, it also proved that a vaccinee who does not have a reaction encompassing fever, anorexia, insomnia, altered level of consciousness, altered affect, inconsolable crying, or high-pitched screaming, in essence, a child like Michael Hanlon or Rachel Plavin (or Carrington in the instant case) is experiencing the normal course of his or her TS.

At that point, petitioners had the opportunity to impeach respondent's evidence, but failed to do so.

In the language of Shyface, when respondent met its burden to show that TS is a known factor unrelated that caused in fact the vaccinee's seizures and current condition, respondent successfully rebutted the statutory presumption that the vaccine was a substantial factor. Respondent met that burden by showing that TS is the predominant factor, which is a higher burden than a substantial factor (which is itself higher than a but-for factor).[(22)] In light of respondent's evidence, the court held that respondent

successfully rebutted the presumption that DPT[(23)] caused the seizures and current condition. In Shyface terminology, this translates into DPT was no longer a substantial factor (much less a but-for factor) in the child's seizure onset and development of his or her current condition.

Petitioners' counsel herein agreed during summations that all predominant factors are substantial factors. Sum. tr. at 15. Thus, even though the wording of the court's Omnibus TS Decision does not use the phrase "substantial factor" in describing TS, the court's finding that TS more likely than not is the cause (i.e., the predominant factor) of the child's seizures and worsened condition is legally sufficient under the Shyface holding since it subsumes substantial factor.

Petitioners' counsel asked the undersigned to consider the holdings in two cases: Gruber v. Secretary, HHS, No. 95-34V, 1998 WL 928423 (Fed. Cl. Spec. Mstr. Dec. 22, 1998) (awarding compensation for significant aggravation of a prior seizure disorder), and Brown v. Secretary, HHS, 34 Fed. Cl. 152 (1995) (affirming the undersigned's decision awarding damages for on-Table encephalopathy and seizures). Sum. tr. at 12, 18.

Petitioner's counsel, referring to the Chief Special Master's decision in Gruber, stated in summation that "it isn't appropriate to focus on the course of an underlying disorder until the course of the underlying disorder is an absolutely known blueprint." Sum. tr. at 12. The undersigned will presently discuss whether Gruber indeed states this, but a standard of an "absolutely known" blueprint for an underlying disorder to satisfy respondent's burden of showing a known factor unrelated is not the legal standard for causation in fact proof. The legal standard remains proof by a preponderance of the evidence. As the Federal Circuit stated in Knudsen, supra, at 548-49, the causation in fact standard is "whether a sequence of cause and effect is 'logical' and legally probable, not medically or scientifically certain" (citations omitted).

Gruber concerned infant Irene who had eye fluttering beginning six or more weeks before her third DPT vaccination, and body jerking the day after her third DPT vaccination. The Chief Special Master held that petitioners prevailed because testimony established that her seizures post-third DPT were the onset of her significant aggravation, and her pre-existing severe myoclonic epilepsy (SME) was an idiopathic factor unrelated.

Unlike Gruber, in the TS cases, after petitioners satisfied their burden of proving a prima facie case when the seizures occurred on-Table, and their experts testified that the on-Table seizures caused the vaccinee's current condition which was significantly worse than his or her prevaccination condition, respondent succeeded in provint that TS is a known (not idiopathic) factor unrelated which caused the vaccinee's current condition as well as the on-Table seizures. Moreover, the genetic cause of TS is known, and testimony and evidence submitted during the Omnibus TS hearing pinpointed the chromosomes upon which the genes are located. Barnes, supra, at *18.

Petitioners' counsel in the instant case asked the court to consider not only Gruber, but also Brown, supra. A consideration of Brown, which was the undersigned's case, need not detain us long. Because of the Federal Circuit's initial holding in Whitecotton, 17 F.3d 374 (Fed. Cir. 1994), and the United States Supreme Court's reversal and remand in Shalala v. Whitecotton, 514 U.S. 268 (1995), the undersigned reconsidered the evidence concerning whether Leslie Brown had a pre- or post-vaccination onset of encephalopathy, concluding that it was post-vaccination. Because the undersigned concluded that onset was post-vaccination, significant aggravation was not relevant to the holding of the case.

Petitioner's point, sum. tr. at 18, for the undersigned's rereading Brown was that Shyface, supra, created "new law." As the undersigned has amply discussed, supra, Shyface does not so much create new law as

analyze more minutely the interplay of factors when a court holds that more than two factors affected a vaccinee's condition. In Shyface, the Federal Circuit held that both DPT and E. coli were factors (in equipoise) in the child's demise, but since DPT was a substantial (although not predominant) factor, petitioners were entitled to compensation. Shyface, supra, at 1353.

In the TS cases, the undersigned has held that respondent satisfied its burden of showing that, except in delineated circumstances, TS is the cause in fact of the vaccinee's current condition. In essence, respondent proved that TS was the predominant (which subsumes substantial) factor. Respondent rebutted the presumption that DPT caused the vaccinee's current condition or even the on-Table seizures. Unlike Shyface, where E. coli remained a factor, DPT dropped out as any factor at all in those cases in which a TS child had no symptoms other than twitching on-Table after the vaccination.

In answer to petitioners' counsel's argument herein, the mere issuance of an appellate court decision does not vitiate all decisions preceding it. The TS Omnibus Decision is not defective legally in light of Shyface.

CONCLUSION

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

IT IS SO ORDERED.

Dated: _____ _____

Laura D. Millman

Special Master

1. The statutory provisions governing the Vaccine Act are found at 42 U.S.C.A. § 300aa-1 *et seq.* (1991 & Supp. 1994). Hereinafter, for ease of citation, all references will be to the relevant subsection of 42 U.S.C.A. § 300aa.

2. Barnes v. Secretary, HHS, 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997). The holding of the Barnes decision is discussed infra.

3. Respondent's expert, Dr. Mary Ann Guggenheim, described this EEG as showing an abnormal electrical pattern of left occipital rhythmic delta (slow waves). R. Ex. X. Petitioners' expert, Dr. Marcel Kinsbourne, agreed with Dr. Guggenheim's analysis during his testimony. Tr. at 151-52.

4. A VAERS (Vaccine Adverse Event Reporting System) report filed by Dr. Kent lists February 8, 1993 as the date of onset for staring episodes with tonic movements lasting a few seconds, notable by both parents on at least three difference occasions. Med. recs. at Ex. 2, p. 2. But since the date of onset conflicts with the parents' allegation of two-day onset and there is no confirmation of this date in any medical record, the court does not give this date any weight. Dr. Kent left empty the space for "Dates of Administration (From/To)." The court assumes that when Dr. Kent wrote in 2/8/93 for "Reaction Onset," he mistakenly thought that that was the space to inscribe the date of vaccination.

5. The category is actually Health & Medicine, under which are available federal cases and medical research. See Westlaw Database Directory.

6. However, February 8, 1993 was a Monday.

7. February 9, 1993 was actually a Tuesday.

8. Mr. Ulicny's testimony was later refreshed by his counsel that Carrington had a fever of 101 degrees when he had a bladder infection two weeks before vaccination. Mr. Ulicny did not remember what degree temperature Carrington had after vaccination. Tr. at 43-44.

9. Their affidavits and trial exhibits state that Mrs. Ulicny saw the seizure on February 11th, not February 10th.

10. The transcript incorrectly notes that Dr. Kinsbourne said "several" instead on "seven."

11. R. Alderslade, et al., "The National Childhood Encephalopathy Study: A report on 1000 cases of serious neurological disorders in infants and young children from the NCES research team," Department of Health and Social Security, Whooping Cough: Reports from the Committee on the Safety of Medicines and the Joint Committee on Vaccination and Immunisation (London: Her Majesty's Stationary Office, 1981). Although the NCES was not filed as an exhibit by either party in this case, it can be found among the exhibits filed during the Omnibus TS proceeding at P. Ex. 80 and 80A. Barnes, supra, 1997 WL 620115, at *15 n.25.

12. C.L. Cody, et al., "Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children," 68 Pediatrics 650-60 (1981). P. Ex. 22. No sequelae were detected following these reactions. All convulsions occurred within 24 hours of immunization with a median time of 14 hours. All but two of the nine had elevated temperature, with two of those with fever having a history of previous febrile convulsions. All of the children returned to normal within 48 hours. Id. at 653. No infant developed infantile spasms, encephalopathy, or permanent brain damage. Id. at 656, 658.

13. Decker v. Secretary, HHS, No. 90-1115V, 1998 WL 408614 (Fed. Cl. Spec. Mstr. June 26, 1998); Decker v. Secretary, HHS, No. 90-1116V, 1998 WL 408776 (Fed. Cl. Spec. Mstr. June 26, 1998).

14. 42 U.S.C § 13(a)(1)(B).

15. Barnes, supra at *15.

16. M.R. Gomez, et al., "MR Findings in Tuberous Sclerosis Complex and Correlation with Seizure Development and Mental Impairment," 16 *Am. J. Neuroradiol*. 149-55 (1995).

17. This should be March 30, 1993.

18. Their history to Dr. Moyra Smith on October 26, 1993, eight and one-half months later.

19. But even if, arguendo, there were on-Table onset, Carrington had no other symptoms that would show a neurological reaction to the vaccine.

20. As Dr. Kinsbourne put it in his testimony, "In other words, neurons are beating together. They are firing and stopping, and firing and stopping, so wave forms appear on the EEG. Those are not seizures, but this kind of activity does occur in some people who at other times have seizures." Tr. at 153. Even though Carrington's first EEG was not epileptiform, its abnormality was consistent with a brain that

could and did manifest a seizure disorder.

21. Respondent is appealing Suel v. Secretary, HHS, No. 90-935V, 1997 WL 617034 (Fed. Cl. Sept. 22, 1997), appeal docketed, No. 98-5153 (Fed. Cir. Aug. 18, 1998). All three cases are consolidated before the U.S. Court of Appeals for the Federal Circuit.

22. The court notes that in Shyface, the Federal Circuit held that the two factors, DPT and E. coli bacteria, were in equipoise, i.e., neither was the predominant factor. However, the Federal Circuit found DPT to be a substantial factor and reversed the dismissal in the lower courts, awarding the statutory death benefit of $250,000.00.

23. Although the Omnibus TS evidence dealt solely with DPT vaccine, the same evidence concerning the consequences of TS would be applicable in cases where other Table vaccines are involved.