OFFICE OF SPECIAL MASTERS

No. 92-0032V

(Filed: May 30, 2000)

DAWN M. BARNES, as Mother and Next Friend of CHRISTOPHER DONALD BARNES, a minor,	*	
Petitioner,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

John M. Shannon, Skaneateles, NY, for petitioner.
Karen P. Hewitt, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

STATEMENT OF THE CASE

On January 6, 1999, the undersigned issued an Order stating that were the tuberous sclerosis (TS) cases not on appeal (at that time, to the Federal Circuit, but ultimately to the U.S. Supreme Court), the undersigned would dismiss this case. On May 30, 2000, the Supreme Court denied certiorari in Hanlon v. Secretary, HHS, No. 99-1223. Since the Federal Circuit has

previously affirmed the undersigned's holdings in the TS cases, this case is dismissed. What follows is the material that the undersigned has previously described in the Order of January 6, 1999.

History

On January 16, 1992, Dawn Barnes, on behalf of her son, Christopher Donald Barnes (herinafter, Christopher"), filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986[1] ("Vaccine Act" or the "Act"). In a decision dated December 29, 1994, the undersigned held that petitioner had satisfied her burden of proving that DPT significantly aggravated Christopher's underlying TS. Subsequently, respondent provided evidence in TS cases to the effect that DPT does not significantly aggravate TS.

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 decision in

[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.

the Omnibus TS case, dated September 15, 1997,[2] the court determined to have an additional hearing in this case. This was held on September 30, 1998 and October 7, 1998. Testifying for petitioner were Dawn Barnes, Gary F. Barnes, and Dr. Gary J. Myers. Testifying for respondent was Dr. Mary Anne Guggenheim.

FACTS

Christopher was born on November 14, 1988, one of twins, the other of whom died in utero. P. Ex. at 9.[3] Prior to his two-month checkup, Christopher was apparently healthy and developing well. P. Ex. at 71. He received his first DPT vaccination on January 18, 1989, at the age of two months. P. Ex. at 67. Petitioner alleges that, within three days, Christopher began screaming, his leg swelled, his eyes rolled back, his face twitched, and his hand and foot shook. P. Ex. at 11-12. Twelve days following the DPT vaccination, Mr. Barnes brought

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[2] Barnes et al. v. Secretary, HHS, 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997). The holding of the Barnes decision is discussed infra. Because Barnes was the first of many cases consolidated for the purpose of taking evidence common to the issue of TS as a factor unrelated, it may be confused with the instant opinion. But the September 15, 1997 decision dealt solely with the persuasiveness of respondent's evidence, not with this particular case.

[3] Citations to P. Ex.__ refer to the exhibits that petitioner attached to the original petition for compensation dated January 16, 1992.

Christopher back to the doctor and described these symptoms to him. P. Ex. at 71. Mr. Barnes stated at that time that the episodes had started since the last visit.[4] Id.

In an effort to evaluate the nature of the symptoms, the doctor ordered an EEG, which was performed on January 31, 1989.[5] P. Ex. at 80. Even though jerking activity occurred during the EEG test, the results indicated no abnormality. P. Ex. at 83. Dr. Robert Kropp, a neurologist at All Children's Hospital, confirmed in his report of March 31, 1989 the events described by the Barneses and the events' timing in relation to the DPT vaccination. Id. His report adds that the episodes occurred primarily as Christopher was awakening or going to sleep. Id. Further, there were no aura, loss of consciousness, precipitating factor or postictal period associated with the jerking episodes, which lasted between ten and sixty seconds. Id. Based on the normal EEG and the relationship between the jerking and sleep, Dr. Kropp concluded that Christopher was experiencing myoclonic

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[4] The timing of the onset of jerking episodes is corroborated by Dr. F. Javier Monreal's examination report of October 2, 1990, and the assessment performed at the E. John Gavras Center on May 10, 1991. P. Ex. at 312, 324.

[5] The history taken at the time of the EEG notes that Christopher, for the past two weeks, had been suffering episodes of eyes deviating from one side or the other and that the instances lasted from a few seconds to a minute. P. Ex. at 80.

jerks as opposed to infantile spasms.[6] P. Ex. at 84. As a precaution, though, he recommended that Christopher no longer receive the pertussis component of the DPT vaccine. P. Ex. at 85.

Apparently, Christopher's symptoms began to resolve. P. Ex. at 87. However, upon Christopher's admission to All Children's Hospital on July 12, 1989, Dr. Kropp noted that, whereas the myoclonic jerks had been absent for several months, over the immediately preceding four to six weeks, Christopher began to experience episodes in which his arms would jerk up in a

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[6] Dr. Gerald M. Fenichel has described infantile spasms as follows:

> The peak age of onset [of infantile spasms] is between 4 and 7 months, and onset always occurs before 1 year of age. . . . Spasms generally occur in clusters, shortly after the infant awakens from sleep, and are not activated by stimulation. . . . There is often considerable delay between spasm onset and diagnosis. . . . Infantile spasms must be differentiated from benign myoclonus of early infancy, benign myoclonic epilepsy of infants, severe myoclonic epilepsy of infancy, and the Lennox-Gastaut syndrome. . . . However, there is some reason to believe that infantile spasms, severe myoclonic encephalopathy, and the Lennox-Gastaut syndrome are a continuum of epileptic encephalopathies. . . . The EEG is the single most important test for diagnosis. However, EEG findings vary with duration of recording, sleep state, and underlying disorder. . . .

Gerald M. Fenichel, Clinical Pediatric Neurology: A Signs and Symptoms Approach 20-21 (2d ed. 1993).

bilateral, symmetrical manner. Id. These occurred both during sleep and while awake, in clusters of four to ten, with one to six clusters a day. Id. The parents observed increased irritability following the incidents. Id. Developmental regression became evident with the onset of the new symptoms, as manifested by a cessation of rolling or grabbing, a decrease in visual fixation, a decrease in putting hands together, and an overall decrease in activity with increasing apathy. P. Ex. at 88. Additionally, an EEG performed on July 12, 1989 revealed generalized background slowing. P. Ex. 93. This time when jerks were witnessed during the test, they were accompanied by generalized bursts of spike and wave abnormalities. Id.

Dr. Kropp evaluated this new activity to be more consistent with infantile spasms than the previous myoclonic jerks. P. Ex. at 101. As distinguishing factors, he listed head dropping, vocalizations, abduction and extension of the arms, and the broken nexus between the episodes and sleep. Id. A CT scan performed on July 12, 1989 revealed the existence of multiple lesions scattered throughout both cerebral hemispheres. P. Ex. at 90. It was felt that such findings were consistent with TS. Id.

Christopher has 22 tubers in his brain. R. Ex. S.

TESTIMONY

Mrs. Dawn Barnes testified first for petitioner. Tr. at 3. Christopher was the survivor of twins, the other having died in utero. Tr. at 5. He had normal development and was just learning to go from back to front. Tr. at 7. She normally slept from 5:00 to 9:00 a.m. Tr. at 9. At the two-month check-up with Dr. Baltrun, her husband took Christopher in for his DPT. Id. Chris cried after his DPT vaccination. Tr. at 11. He was cranky; his leg was swollen, irritated, and red. Tr. at 12. She gave him Tylenol. Id.

Chris drank his formula, but he was whining all night. Tr. at 13-14. On the day after the vaccination, January 19, 1989, he was whining, cranky, and irritable. Tr. at 15. He would not eat. Id. He had a low-grade temperature. Id. The vaccine site was red, swollen, and irritated. Id. He screamed intermittently and would not take the bottle. Tr. at 16. The doctor said to bring him in. Id.

On January 20, 1989, he was up most of the night. Tr. at 19. She came home from work at around midnight. Tr. at 20. She worked six nights a week but not on Sunday. Id. She and her husband thought Chris was having seizures when they saw his face and hands twitching and his eyes rolled back. Tr. at 21. They thought it was a reaction to the DPT vaccination and it would go away. Id. The twitching episodes lasted from 30 to 60 seconds.

Tr. at 22. Christopher would not respond. Tr. at 23. He had a lot of twitching, which increased over the months. Id.

The vaccine site was irritated for four to five days. Tr. at 24. Chris had a low-grade fever for a couple of days. Id. After three or four days, he started to eat again. Id. He never resumed sleeping normally. Tr. at 25. He was groggy after each seizure for 30 minutes. Tr. at 26. His screaming and crying continued. Id.

One week after the DPT vaccination, Christopher's head turned, his eyes deviated, his lip quivered, and his feet and hands twitched. Tr. at 28. This lasted 30 to 60 seconds. Id. The episodes happened more at night than in the day. Tr. at 29.

On January 30, 1989, Chris went to see Dr. Baltrun. Tr. at 30. There was one time that Chris was throwing his arms up. Id. She did not go with Chris to Dr. Baltrun on January 30, 1989 or to have his EEG on January 31, 1989. Id. Chris stopped smiling, playing, or responding within the first week. Tr. at 30-31. He stopped rolling from his back to his stomach. Tr. at 31.

In February 1989, the episodes were stronger, more frequent, and lasted longer. Tr. at 32. They continued through March. Id. On March 31, 1989, Chris saw Dr. Kropp, the neurologist. Id. Chris was nasty, miserable, and cranky. Tr. at 33. The seizures got weaker after that but did not disappear. Id.

Dr. Gary Myers, a pediatric neurologist, testified next for petitioner. Tr. at 74. He is professor of pediatrics and neurology at the University of Rochester. Id. Infantile spasms are one type of myoclonic encephalopathy. Tr. at 78. Chris' January 31, 1989 EEG was normal. Id. At the initial onset of infantile spasms, one may not have a change in the EEG, which will appear later. Tr. at 79. It is difficult to pick up developmental delay in the first year of life. Tr. at 80.

Infantile spasms may fluctuate, although they will not go away. Tr. at 84-84. Repeated seizures can impair a child's intelligence. Tr. at 87. Dr. Myers thinks it is open to question whether or not DPT causes infantile spasms. Tr. at 107. It is possible to aggravate a situation with DPT causing infantile spasms. Tr. at 108. He does not have medical literature to support his opinion. Id. Christopher has seizures because he has tubers. Tr. at 110. In his opinion, TS and prolonged seizures have caused Christopher's current condition. Tr. at 111.

Dr. Myers testified that he cannot tell if Christopher's initial seizures were infantile spasms. Tr. at 113. Chris' onset was at two months. Tr. at 112. Infantile spasms can occur any time after six weeks of age. Tr. at 113. Chris had myoclonic jerks within 72 hours of vaccination. Tr. at 114.

They are generalized seizures including alteration of consciousness and irritability. Tr. at 115. He was afebrile. Tr. at 15.[7] He had numerous cortical tubers. Id. Chris did not have immediate regression or progression of his abilities after the onset of his seizures. Tr. at 16. On January 30, 1989, he was alert and seemed normal. Id. On March 3, 1989, he was neurologically normal. Tr. at 17. His doctor felt he had not developmentally regressed. Id.

Dr. Myers testified that it was a combination of DPT and TS that caused Chris' seizures. Tr. at 19. The temporal association is difficult for him to ignore. Id. However, Chris would have gone on to have seizures later on. Tr. at 20. It was not in his best interest to have an early onset of seizures. Id. There is no medical literature linking DPT and myoclonic seizures. Id.

Dr. Myers said he cannot distinguish between cause and coincidence in whether DPT causes infantile spasms. Tr. at 23. TS causes most cases of infantile spasms. Id. It is not clear if the most common symptom of TS is seizures. Id.

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[7] At the September 30, 1998 hearing, Dr. Meyers' testimony was interrupted due to a scheduling conflict. Later, on October 7, 1998, Dr. Meyers finished his testimony. All subsequent citations to the transcript of Dr. Meyers' testimony refer to the October 7, 1998 transcript. Citations to the transcript for all other witnesses refer to the September 30, 1998 transcript.

Lewis F. Barnes testified last for petitioner. Tr. at 116. He is Mrs. Barnes' ex-husband. Tr. at 117. He was self-employed and home a lot in the winter. Tr. at 118-19. He worked after 3:00 p.m. Tr. at 119. On January 18, 1989, he took Chris to get his DPT. Tr. at 124. He thinks it was in late afternoon. Tr. at 123. Chris cried and napped a little. Tr. at 125. He ate a normal amount of formula. Tr. at 126. He did not sleep much. Id. His leg swelled badly and Mr. Barnes tried to comfort him. Id. Mr. Barnes does not remember if Chris had a fever. Id.

On January 19, 1989, Chris' leg was still swollen. Id. He would wake up and scream. Tr. at 127. The onset of his seizures occurred from two days to a week after the vaccination. Id. His leg was swollen for a couple of days and he continued screaming. Id. Chris never resumed sleeping normally. Tr. at 128. He was jerking, twitching, and quivering. Id. This lasted ten seconds to one minute. Id. Chris was lethargic afterwards. Id. It occurred a few times daily. Id.

Mr. Barnes said he had no idea what was causing the seizures. Tr. at 140. Chris stopped developing after the DPT. Tr. at 141. He did not acquire major milestones after that. Id. He would not try to roll over. Id.

Dr. Mary Anne Guggenheim, a pediatric neurologist, testified for respondent. Tr. at 143. Her opinion is that TS caused Chris' condition. Tr. at 147-48. DPT did not aggravate his TS. Tr. at 148. His seizures, developmental delay, and mental retardation are related to the dysgenesis of his central nervous system that TS caused. Id. Chris did not have an on-Table encephalopathy. Tr. at 159. His brain function was not clearly abnormal. Id. He did not change his feeding patterns and he continued to gain weight. Tr. at 160. On January 18, 1989, Chris weighed eleven pounds two and one-quarter ounces. Tr. at 162. On January 30, 1989, he weighed eleven pounds eleven ounces. Id.

With reference to the meaning of Chris' not being responsive while jerking, Mr. Barnes offered more testimony that Chris kept twitching and would not look at him. Tr. at 164. He held him, rubbed his belly, and raised his voice. Id. The episode lasted ten to sixty seconds. Id. Afterwards, Chris was lethargic and partially unresponsive (not moving, slow to react), and went to sleep. Tr. at 165.

Dr. Guggenheim said the jerks were unusual because they occurred in a series. Tr. at 168-69. Chris did not have a high fever. Tr. at 171. There were no febrile seizures here. Id. DPT did not cause his infantile spasms. Id. Sixty to seventy

percent of TS patients with seizures have infantile spasms. Tr. at 173. Of patients with infantile spasms, twenty to thirty percent have TS. Tr. at 174.

Dr. Guggenheim denied that the earlier the onset of infantile spasms, the more damage. Tr. at 175. Chris had a medium number (22) of tubers. Tr. at 177. No one with more than ten tubers is neurologically intact. Tr. at 177-78. It is very common for TS patients to appear developmentally normal for the first few months. Tr. at 178. Chris is fairly typical for a TS patient, according to Dr. Guggenheim. Id.

On January 30, 1989, when Chris was examined, he was in no acute distress, neurologically within normal, and alert. Tr. at 179. That means he did not have acute encephalopathy because if he had, he would have been unresponsive, not alert, with abnormal eye movements, tone, and strength. Tr. at 181. On March 3, 1989, he was neurologically normal. Id. On March 31, 1989, he had normal reflexes and no acute encephalopathy. Tr. at 183.

Dr. Guggenheim testified that Chris had chronic encephalopathy whose onset was after March 1989 and before July 1989. Tr. at 185. His seizure onset was coincidental to the DPT vaccination. Tr. at 187.

DISCUSSION

The court has previously held that Christopher's seizures began in Table time. This affords petitioner the presumption that DPT vaccine caused these seizures.

What other symptoms did Christopher have on-Table? His leg was swollen, with a red and hard vaccine site. He was fussy and cried. He did not have a fever. His father testified, confirmed by the January 30, 1989 medical record, that Chris was unresponsive when touched during his seizures. If this were a sign of a postictal state, that conflicts with the history that Mr. Barnes gave to Dr. Kropp on March 31, 1989.

As Dr. Robert Kropp, the neurologist, wrote in his March 31, 1989 letter, after the first DPT, Chris did not have any fever, personality change, high-pitched screaming, crying, or tonic-clonic convulsions. He did have leg swelling and, after that, episodes of repetitive movements of the face, arm and leg while waking up or going to sleep. He did not have any aura, loss of consciousness, or crying. He did not have any postictal state. Christopher did not have any medically significant symptoms beyond the infantile spasms. His subsequent medical examinations through March 1989 were normal. Then his symptoms seemed to disappear for several months, only to return in late May or June 1989. Whereas Dr. Kropp thought the initial seizures were myoclonic jerks, but not infantile spasms, the subsequent

seizures were infantile spasms. Whereas his first EEG on January 31, 1989 was normal, his second EEG on July 12, 1989 was abnormal. At that point, he was diagnosed with a minor motor seizure disorder and encephalopathy.

Chris' history of symptoms is somewhat unusual for a TS child in that once his seizures began, they spontaneously stopped. However, that does not negate that initially all he had were slight seizures.

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 et al., supra, at *32-33.

The scenario discussed in the holding of the Omnibus TS Decision seems to be illustrated by the instant case. After DPT, Christopher had a swollen vaccine site. Within three days after the vaccination, he had afebrile myoclonic seizures. However, he did not experience an altered level of consciousness, a diminution of his skills, anorexia, insomnia, inconsolable

screaming, high-pitched crying, or any other symptom such as a high fever that might suggest a cause from the vaccine except his seizures. The parents' testimony that his skills dropped off immediately is not believable in light of the medical records' explicit recitation of his keeping his skills for three months. In light of Dr. Kropp's careful notation on March 31, 1989 of the symptoms Christopher did not have post-vaccination, the parents' recitation of many of these symptoms at trial is suspect as well.

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).

The undersigned holds that DPT vaccination did not significantly aggravate Christopher's TS and petitioner has not prevailed in her proof.

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: _____

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Laura D. Millman
Special Master