# OFFICE OF SPECIAL MASTERS No. 90-2724V

(Filed: June 23, 1998)

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VAN MULLER, SR, and CAROL MULLER,	*	
as legal representatives of VAN MULLER, JR.,	*	
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	*	
Petitioners,	*	TO BE PUBLISHED
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND	*	
HUMAN SERVICES,	*	
	*	
Respondent.	*	
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* * * * * * * * * * * * * * * * * * * *	*	

T. Carey Wicker, III, New Orleans, LA, for petitioners.

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

## **DECISION AND ORDER**

# MILLMAN, Special Master.

#### **Statement of the Case**

This case was part of the cases pending during the undersigned's Omnibus TS hearing dated October 8-11, 1996 and June 3-4, 1997. Subsequent to my decision in the Omnibus case, dated September 15, 1997, (1) the court determined what course to follow in this individual case. Petitioners have submitted expert reports from Dr. Marcel Kinsbourne, a pediatric neurologist, and Dr. Mark R. Geier, an obstetrician and geneticist. P. Exs. 4 & 24.

Respondent has submitted two affidavits from treating doctors, Dr. Ellen McLean, a pediatrician who has treated Van Muller, Jr. (hereinafter "Van") since birth, and Dr. Jonelle B. McAllister, a pediatric neurologist, who has treated Van since February 9, 1984. R. Exs. DDD & EEE. These affidavits cast doubt on petitioners' allegation that Van's seizure onset began within Table time of his DPT vaccination, thus removing this case from consideration as an on-Table significant aggravation case.

Respondent has also submitted the expert medical report of Dr. Mary Anne Guggenheim, a pediatric neurologist. R. Ex. R.

### **Facts**

Van was born on June 10, 1983. P. Ex. 1, p. 1. He received his first DPT vaccination on August 15, 1983 at the age of two months. Med. recs. at Ex. 6, p. 1. He received his second DPT vaccination on October 17, 1983 at the age of four months. <u>Id</u>. He received his third DPT vaccination on January 13, 1984 at the age of six months. Id.

On February 5, 1984, twenty-three days after his third vaccination, Mrs. Muller informed Dr. McLean that Van was having muscle spasms. Med. recs. at Ex. 6, p.4. Van had three episodes during the past week; however, he was now experiencing these episodes once per day. (2) Id. On February 6, 1984, Dr. McLean noted that Van's history was suggestive of infantile spasms. Id.

On February 9, 1984, Van saw Dr. McAllister, a pediatric neurologist. Med. recs. at Ex. 8, p. 18. Mrs. Muller gave a history that Van began having salaam attacks about two weeks prior to the visit. (3) Id. She noticed these spells usually during drowsy periods, particularly in late afternoon. Id. During these spells, Van raised and outstretched his arms, extended his legs, and grimaced. Id. He did not cry. Id. The episodes occurred in a series, with each seizure usually lasting several seconds. Id. Since Mrs. Muller first noticed these episodes, they occurred every day except for the day prior to his visit with Dr. McAllister. Id. He had no other changes in behavior. Id. He had a mild respiratory infection when the spells began. Id.

A CT scan was conducted which showed leukomalacia. Med. recs. at Ex. 8, p. 17. This was most likely due to strokes in utero. Id.

An MRI performed on January 16, 1995 showed a total of seventeen cortical tubers. R. Ex. P (dated January 30, 1998).

## **Affidavits and Reports**

Petitioners submitted affidavits from Mrs. Carol Muller, Mr. Van Muller, Sr., Emilda Muller, and Dr. Mark Geier. P. Exs. 1, 2, 3, & 4. In addition, depositions were taken of Mr. Muller, Mrs. Muller, Emilda Muller, and Inez Black. R. Filing (dated August 18, 1995).

In her affidavit, Mrs. Muller states that on January 14, 1984, a day after Van's third DPT vaccination, Van had a muscle spasm which lasted for a few seconds. P. Ex. 1, p. 1. During this episode, he became rigid and seemed to go into a daze. (4) Id. She and Mr. Muller witnessed several such episodes over the following weeks. Id.

Mr. Muller states in his affidavit that Van had his first seizure within seventy-two hours of his DPT vaccination. (5) Med. recs. at Ex. 2, p. 1. He further states that Van continued to experience more frequent and severe seizures during which he would lose awareness and his body would become rigid. Id.

Emilda Muller's affidavit states that she was babysitting Van on January 14, 1984 when he became rigid and seemed dazed for a few seconds. Med. recs. at Ex. 3, p. 1. According to her deposition, Emilda Muller did not tell anyone about the incident. Dep. of Emilda Muller, p. 21, lines 21-23 (filed August 18, 1995).

Inez Black, Van's maternal grandmother, stated in her deposition that she took care of Van every day from the time he was three months old. Dep. of Inez Black, p. 11, lines 15-17 (filed August 18, 1995). During this time, she stated that Van cried a lot, screamed, and would not take his bottle. Dep. of Inez Black, p. 12, lines 11-21 (filed August 18, 1995).

Dr. Mark R. Geier states in his affidavit that Van may well have had an in utero insult resulting in minor strokes. P. Ex. 4, p. 5. He also states that the medical records do not establish temporal association between DPT and the onset of seizures. <u>Id</u>. Thus, Dr. Geier relies totally on the affidavits of Mr. and Mrs. Muller and Emilda Muller to establish a temporal association for on-Table significant aggravation.

(6) <u>Id</u>.

In a letter dated June 2, 1998, Dr. Marcel Kinsbourne states that the medical records do not indicate a relationship between Van's seizure disorder and his third DPT. P. Ex. 24, p.1 However, Emilda Muller stated that she observed Van become briefly rigid and dazed within Table time. <u>Id</u>. Based on her testimony, Dr. Kinsbourne opines that DPT significantly aggravated Van's TS. <u>Id</u>. Dr. Kinsbourne agrees with Dr. Guggenheim's opinion that infantile spasms usually occur repetitively rather than singularly. <u>Id</u>. However, he does not regard clustering of seizures to be indispensable to diagnose infantile spasms. <u>Id</u>. Dr. Kinsbourne believes that if Van had a single spasm within Table time, it is likely that he had other unobserved spasms. <u>Id</u>.

Respondent submitted the affidavit of Dr. Ellen McLean. She states that Van received his third DPT in her office on January 13, 1984. R. Ex. DDD, p. 1. Dr. McLean discussed with Mrs. Muller the possibility of fever. <u>Id</u>. She also discussed the more serious neurologic reactions which may occur, warning Mrs. Muller to call if Van had a fever over 101 degrees or unusual crying. <u>Id</u>. Between January 13 and February 5, 1984, no one contacted her about Van. (7) R. Ex. DDD, p. 2.

Dr. McLean stated that she received a phone call from Mrs. Muller on February 5, 1984. <u>Id</u>. Mrs. Muller told her that Van was having muscle spasms. <u>Id</u>. Mrs. Muller stated that Van had six spasms in a twenty-second period. <u>Id</u>. These spasms began during the prior week. <u>Id</u>. Mrs. Muller stated that Van had three episodes in the past week. <u>Id</u>. However, he now had these episodes daily. <u>Id</u>.

Dr. McLean examined Van on February 6, 1984. <u>Id</u>. She did not see any of the activity that Mrs. Muller described; however, she suspected that Van had infantile spasms and referred him for an EEG and neurological examination. <u>Id</u>.

Dr. McLean does not believe that Van had a seizure within three days of his third DPT vaccination. R. Ex. DDD, p. 3. His infantile spasms began some weeks after his vaccination. <u>Id</u>. Van continued to develop even after his seizures began. <u>Id</u>. Dr. McLean did not observe any developmental delay until June 1984. Id.

Dr. Jonelle B. McAllister, Van's treating pediatric neurologist, also submitted an affidavit. Dr. McAllister first saw Van on February 9, 1984. R. Ex. EEE, p. 1. At that time, Mrs. Muller told Dr. McAllister that Van began having salaam-like attacks about two weeks prior. Id. Mrs. Muller also told Dr. McAllister that Van had received his DPT vaccination on January 13, 1984. Id. Dr. McAllister diagnosed infantile spasms. R. Ex. EEE, p. 2. A CT scan revealed prenatal strokes. Id. Dr. McAllister did not diagnose Van's TS until September 1984. Id. In retrospect, Dr. McAllister realizes that the abnormalities on Van's initial CT scan were lesions of TS rather than in utero strokes. Id.

In Dr. McAllister's opinion, Van's initial infantile spasms as well as his current condition are due to his TS and not to his DPT vaccination. R. Ex. EEE, pp. 2-3.

Respondent submitted the medical expert report of Dr. Mary Anne Guggenheim. R. Ex. R. Dr. Guggenheim states that it is unlikely that the single, brief stiffening episode, which Emilda Muller witnessed on January 14, 1984, was a seizure because infantile spasms occur in clusters of repetitive muscle spasms rather than as single episodes. R. Ex. R, p. 1. That Van has seventeen cortical tubers is "predictive" of difficult to control seizures and developmental impairment in a TS patient. R. Ex. R, p. 2. In Dr. Guggenheim's opinion, TS caused Van's neurologic problems which would have occurred even in the absence of his third DPT vaccination. Id.

## **Discussion**

If the onset of Van's infantile spasms occurred within Table time of his third DPT, petitioners benefit from the statutory presumption that DPT caused the seizures. It does not, however, automatically prove that petitioners prevail on a theory of on-Table significant aggravation.

As the court held in its Omnibus TS Decision, if a vaccinee with TS has a seizure as his 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 seizures, and (2) petitioners do not prevail on a theory that DPT significantly aggravated the vaccinee's TS. See Barnes et al., 1997 WL 620115, at \*32-33 (Fed. Cl. Spec. Mstr. Sept. 15, 1997).

The scenario discussed in the holding of the Omnibus TS Decision is illustrated by the instant case. Even if the undersigned believed that the onset of Van's infantile spasms were on-Table, (8) petitioners are still faced with the lack of any post-vaccination symptoms other than Van's seizures. Infantile spasms are the hallmark of the symptomatology exhibited by a TS child, particularly one with numerous tubers. That Van has seventeen cortical tubers is an ample basis upon which to find that his subsequent onset of seizures and developmental delay flow naturally from his congenital disease.

Inez Black testified that Van refused to eat, cried, and screamed when she began babysitting for him at three months of age. These symptoms, however, have no relationship to any of his DPT vaccinations which were administered at two, four, and six months of age.

That infantile spasms begin subtly is well-known. It would take a great leap of imagination to assume that Van had a spasm one day after the third DPT, yet neither of his parents noticed any other spasms for a couple of weeks thereafter. Dr. Kinsbourne is willing to make this leap; the court is not. When Mrs. Muller called Dr. McLean on February 5, 1984, she gave a history of onset of Van's spasms that would put it two weeks after his DPT vaccination. When Van visited Dr. McAllister on February 9, 1984, Mrs. Muller gave a history of onset that would put it one and one-half weeks post vaccination.

Well-established case law holds that information in contemporary medical records is more believable than that produced years later at trial. <u>United States v. United States Gypsum Co.</u>, 333 U.S. 364, 396 (1948); <u>Burns v. Secretary, HHS</u>, 3 F.3d 415 (Fed. Cir. 1993); <u>Ware v. Secretary, HHS</u>, 28 Fed. Cl. 716, 719 (1993); <u>Estate of Arrowood v. Secretary, HHS</u>, 28 Fed. Cl. 453 (1993); <u>Murphy v. Secretary, HHS</u>, 23 Cl. Ct. 726, 733 (1991), <u>aff'd</u>, 968 F.2d 1226 (Fed. Cir.), <u>cert. denied sub nom. Murphy v. Sullivan</u>, 113 S. Ct. 263 (1992); <u>Montgomery Coca-Cola Bottling Co. v. United States</u>, 615 F.2d 1318, 1328 (1980). Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment. <u>Cucuras v. Secretary, HHS</u>, 993 F.2d 1525, 1528 (Fed. Cir. 1993):

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.

Emilda Muller's deposition and affidavit, taken years after the event at issue, are the only evidence that Van's seizures occurred on-Table. Dr. Kinsbourne predicates his opinion of on-Table onset on the assumption that since Emilda Muller saw Van have one seizure, Van had other seizures which went unnoticed. This assumption is pure speculation because it both assumes that lay observers do not notice infantile spasms, and that one lay observer, Emilda Muller, did. Moreover, Dr. Kinsbourne's acceptance that one seizure equals infantile spasms as long as other unseen seizures occur is a weak attempt to fit within Dr. Guggenheim's opinion that infantile spasms occur in clusters, not singly, an opinion with which he agrees.

The court is unpersuaded by the opinions of Drs. Kinsbourne and Geier. They base their opinions solely on the testimony and affidavit of Emilda Muller. The court holds that Van's infantile spasms did not occur on-Table.

Even assuming, <u>arguendo</u>, that Van's onset of seizures occurred on-Table, petitioners would still not prevail on a theory of on-Table significant aggravation. Based on this court's holding in the Omnibus TS Decision, Van clearly falls into the category of a TS vaccinee whose only symptom after vaccination is a seizure. This is insufficient to impeach the evidence that respondent provided to rebut the presumption that DPT caused the seizure. Where there is no fever, excessive screaming, inconsolable crying, anorexia, insomnia, altered affect, or excessive irritability, petitioners have failed to impeach respondent's proof that TS, particularly in a child with numerous tubers, is the cause of the vaccinee's seizures, not the DPT. The vaccination is purely coincidental.

Petitioners have not prevailed in proving that Van's DPT significantly aggravated his TS.

## **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. <u>Barnes et al. v. Secretary</u>, HHS, 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997).
- 2. This history would put onset at sixteen days after vaccination.
- 3. This history would put onset at approximately February 25, 1984, or twelve days after vaccination.
- 4. Mrs. Muller's affidavit is based on Emilda Muller's account of events. During this time, Emilda Muller, Van's paternal grandmother, was babysitting.

- 5. Mr. Muller's statement is also based on Emilda Muller's account of the event.
- 6. Since Mr. and Mrs. Muller rely on Emilda Muller to prove on-Table onset of seizures, in essence, Dr. Geier is relying solely on Emilda Muller's affidavit.
- 7. Dr. McLean stated that she always documents every phone call regarding a patient. R. Ex. DDD, p. 2.
- 8. This assumption seems unlikely, however, in light of the medical records and the affidavits of Drs. McLean and McAllister.