OFFICE OF SPECIAL MASTERS

June 27, 2005

THOMAS BELL, by his Mother and Next Friend, ANNMARIE BELL,	*	
Petitioner,	*	
v.	*	No. 04-1038V
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

ORDER TO SHOW CAUSE[1]

Respondent is ordered to show cause by July 25, 2005 why this case should not be in damages.

Statement of the Case

[1] Because this Order to Show Cause contains a reasoned explanation for the special master's action in this case, the special master intends to post this order on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and move to delete such information prior to the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

Petitioner filed a petition on June 21, 2004, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that an acellular DPT that Thomas Bell (hereinafter, "Thomas") received on Friday, June 22, 2001, caused a fever up to 102°, decreased oral intake, irritability, and a 45-minute seizure on Saturday, June 23, 2001, after which he had numerous intractable seizures, ultimately an abnormal MRI, and subsequent developmental delays.

Although Thomas may not have had a significantly decreased level of consciousness for 24 hours, which is the regulatory definition of an on-Table acute encephalopathy, clearly Thomas' prolonged initial seizure, followed by subclinical seizures (noted when he was undertaking EEGs) and hypoxia, have resulted in neuronal injury as manifested in his April 27, 2002 MRI of his brain, showing volume loss. His treating pediatric neurologist, Dr. Ralph S. Northam, has stated that the vaccination caused Thomas' seizure disorder (status epilepticus), neuronal injury, and chronic encephalopathy.

Thomas was born on December 20, 2000. He received acellular DPT on Friday, June 22, 2001, when he was six months old. He was taken to Maryview Medical Center Emergency Physicians of Tidewater on Saturday, June 23, 2001, where Dr. Heather Wentworth noted that he had his immunizations the day before when he got a DPT, pneumococcal Pneuovax, and polio vaccination. On the day he was brought to the medical center, he had a slight fever. He was actively seizing with eyes deviated to the right with some right-sided jerking movements. His temperature rectally was 100.1°. He was postictal. Dr. Wentworth diagnosed this as atypical for a febrile seizure in that it lasted so long. Med. recs. at Ex. 6, 16.

Thomas was transferred to Children's Hospital of the King's Daughters (CHKD), on Saturday, June 23, 2001, at 11:30 p.m. Med. recs. at respondent's Ex. B, p. 26. The Emergency

Department (ED) triage assessment notes that Thomas had a fever reaching 102° that day. He was noted to stare and twitch and had been immunized the day before. In the ED, his temperature was 98.4°. Med. recs. at respondent's Ex. B, p. 26.

At 12:20 a.m., Sunday, June 24, 2001, Dr. Elliot Tucker at CHKD noted that Thomas was in his usual state of good health until the day before at about 8:45 p.m. when his mother noted the right side of his body twitching. In the car, his twitching became generalized. On arrival to Maryview ED, his temperature was 100.9°. He was transferred to CHKD, and had had shots the day before. He was somewhat irritable, had a low-grade temperature which peaked at 102°, a mild decrease in his oral intake, and was just not feeling well. Dr. Tucker discussed the case with Dr. Charles Pruitt. The diagnosis was atypical febrile seizure (the seizure lasted 45 minutes). Med. recs. at respondent's Ex. B, p. 28; also P's Ex. 10, p. 1.

At 2:30 p.m., Sunday, June 24, 2001, the history and physical examination at CHKD notes that Thomas had his vaccinations on Friday, June 22, 2001, and had been eating well. He had a temperature of around 102 on Saturday at twelve noon. He was put on Tylenol and Motrin. He was cranky and fell asleep from 5:00 to 7:00 p.m. At about 8:45 p.m., his right arm and leg were twitching and his eyes glazed over. He went to Maryview drooling and still seizing there. He was transferred at CHKD to the ED and was very cranky afterward, but consolable after his mother held him. He had slept some since. His seizure lasted about 45 minutes. He did not have color change and maybe a low fever for the first several hours only. He had a low-grade temperature of about 100.9° at Marvyiew. Med. recs. at respondent's Ex. B, p. 10; also, P's Ex. 10, p. 7.

Thomas underwent an EEG on June 24, 2001, which was abnormal showing frequent left posterior spike discharges without clinical accompaniment. Med. recs. at P's Ex. C, p. 32; also Ex. 10, p. 31.

He had an MRI of his brain on June 25, 2001, which was normal. Med. recs. at P's Ex. C, p. 33; also Ex. 10, p. 29.

On September 29, 2001, Thomas returned to the CHKD ED, where Dr. Joe Leanza wrote that Thomas had been on Tegretol since June 24, 2001. One week before, the Tegretol was stopped. This day, Thomas was very fussy with only half his normal oral intake and he had increased sleeping. At 2:00 p.m., he was quite pale and difficult to arouse. He had a sopping diaper in the morning (which had happened only once before with his previous seizure). He did not have any temperature, but was lethargic and fussy on examination, weak but alert, did not fix his gaze very easily, and had decreased tone. Dr. Leanza discuss Thomas with Dr. Poirier and Dr. Toor, who also examined him. Thomas could quite possibly have been in subclinical status epilepticus all day long with subclinical seizures and postictal phases afterward, making him quite tired. Within 15-20 minutes of Thomas's getting into a hospital room, he had a right-sided seizure with twitching of his fingers. The twitching moved up his arm and then into his right leg. It was secondarily generalized to his whole body, being tonic-clonic in nature. The seizures resolved in 9-10 minutes. The diagnosis was epilepsy with recurrence of seizure activity after stopping seizure medications. He was admitted to CHKD under Dr. Toor. Med. recs. at P's Ex. C, pp. 14, 15; also Ex. 10, p. 63.

On April 24, 2002, Thomas went to the CHKD ED. Dr. Julie Ripplinger-Findlay wrote that Thomas had a seizure at 10:35 p.m. with fever and two breakthrough seizures associated with fever over the prior 48 hours. He had right otitis media. Med. recs. at P's Ex. C, p. 16.

On April 27, 2002, Thomas returned to the CHKD ED. At 4:20 p.m., he had an absence seizure. He had a second seizure at 6:30 p.m., and a third seizure at 8:20 p.m. Med. recs. at P's Ex. C, p. 18.

On April 27, 2002, Michael had an EEG, which was abnormal, showing right posterior slowing and sharp and spike wave discharges. Med. recs. at P's Ex. C, p. 35.

On April 29, 2002, Michael had a brain MRI which had abnormal signal on both FLAIR and T2 weighted sequences in the subcortical and deep white matter of the left parietal occipital lobe. The sulci were more prominent. Dr. Christopher E. Dory suspected volume loss in this segment. This abnormality was not evident on the brain MRI one year earlier. Med. recs. at P's Ex. C, p. 37; also Ex. 10, p. 30.

On June 3, 2002, Thomas saw Dr. Ralph S. Northam, a pediatric neurologist. Dr. Northam noted that Thomas' MRI showing some changes in his left parietal occipital lobe could possibly be related to his previous prolonged seizure. Med. recs. at P's Ex. C, p. 81.

On June 10, 2002, Thomas returned to the CHKD ED. His Tegretol was discontinued the prior week and Trileptal increased. He had three seizures the day before, and three seizures earlier that morning, without fever. Fifteen minutes after his physical examination, he had another seizure. Thomas' oxygen level dipped below 50%. He had eye deviation to the left and general apnea lasting about one minute. Med. recs. at P's Ex. C, p. 20.

On June 10, 2002, Dr. Svinder Singh Toor did a consultation at CHKD. Thomas started having seizures at six months. Since then, the seizures had essentially been intractable. The longest interval without seizures had been about three months. The seizures were not responsive to Tegretol or Trileptal. During a seizure, Thomas became cyanotic. He was slightly delayed in language. While undergoing an EEG, Thomas had a seizure lasting 20 minutes, but he was asymptomatic when the seizure began. Dr. Toor diagnosed status epilepticus, complex partial type with the seizures originating from the right occipital area. Med. recs. at P's Ex. C, pp. 82, 83.

That June 10, 2002 EEG which was abnormal, showing one recorded seizure (an alteration of mental status) and intermittent tonic eye deviation to the left is at p. 39 of P's Ex. C.

On December 26, 2002, Dr. Northam noted that Thomas had some delays in cognition, especially in language. Med. recs. at Ex. C, p. 86.

Thomas had an EEG on February 4, 2003 which was abnormal with right central and central-temporal spike discharges enhanced by sleep. This EEG differed from prior EEGs which showed predominantly posterior and occipital seizure fossa. Thomas was on two anti-convulsants. Med. recs. at P's Ex. C, p. 40.

Mrs. Bell submitted an affidavit, dated June 14, 2004, in which she states that during Thomas' first seizure, he was not responsive to his name, turned blue at the hospital, and had trouble breathing. He was lethargic and fussy. Ex. 7, p. 1.

Dr. Ralph S. Northam, in an affidavit dated May 28, 2004, states that he has been Thomas' treating pediatric neurologist since July 5, 2001. Thomas had a fever on June 23, 2001

of 102°, he was irritable, had decreased oral intake, was not feeling well, and had a 45-minute seizure. Dr. Northam states that, since the time of his first seizure, Thomas has had a chronic encephalopathy, difficult-to-control partial complex seizures, abnormal EEGs, abnormal MRI, global developmental delay, and mild mental retardation. Dr. Northam says that neuronal loss follows a prolonged seizure, resulting in Thomas' volume loss depicted on his April 29, 2002 MRI. Ex. 13, p. 1.

In an unsigned letter dated May 2, 2005, Dr. Northam states that Thomas' 45-minute seizure is a symptom of cortical/brain dysfunction. His signs of acute encephalopathy are irritability, decreased oral intake, and 102° temperature. Filing of May 6, 2005.

DISCUSSION

This case concerns fever after acellular DPT followed by a 45-minute seizure, chronic encephalopathy, and developmental delay. The undersigned has ruled before that acellular DPT may cause a fever prompting a seizure followed by a seizure disorder. See Noel v. Secretary of HHS, No. 99-538V, 2004 WL 3049764, *17 (Fed. Cl. Spec. Mstr. Dec. 14, 2004). See generally McMurry v. Secretary of HHS, No. 95-682V, 1997 WL 402407 (Fed. Cl. Spec. Mstr. June 27, 1997) (whole cell DPT caused fever causing seizure and seizure disorder).

Under 42 U.S.C. § 300aa-12(d)(3)(B)(1), a special master "may require such evidence as may be reasonable and necessary." The undersigned files as court exhibits the following:

C. Ex. #1: "Status epilepticus-induced neuronal injury and network reorganization," by R.S. Sloviter, 40 *Epilepsia* Suppl 1:S34-39, S40-41 (1999)(abstract).

C. Ex. #2: "Total Cerebral Volume Is Reduced in Patients With Localization-Related Epilepsy and a History of Complex Febrile Seizures," by W.H. Theodore, et al., 60 *Arch Neur* 2:250-52 (2003) (abstract).

C. Ex. #3: "Neuroimaging evidence of progressive neuronal loss and dysfunction in temporal lobe epilepsy," by E. Tasch, et al., 45 *Ann Neur* 5:568-76 (2001) (abstract).

C. Ex. #4: "Status epilepticus-induced neuronal loss in humans without systemic complications or epilepsy," by D.G. Fujikawa, et al., 41 *Epilepsia* 8:981-91 (2000) (abstract).

C. Ex. #5: "Remodeling of neuronal circuitries in human temporal lobe epilepsy: increased expression of highly polysialylated neural cell adhesion molecule in the hippocampus and the entorhinal cortex," by M. Mikkonen, et al., 44 *Ann Neur* 6:923-34 (1998) (abstract).

Respondent is ORDERED TO SHOW CAUSE by July 25, 2005 why this case should not be in damages.

IT IS SO ORDERED.

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DATE Laura D. Millman
Special Master