In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 04-1038V
May 20, 2008
Not to be Published

THOMAS BELL, by his Mother and Next Friend, ANNMARIE BELL, Petitioner, v. SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	*	Entitlement; ruling on record; DTaP followed by febrile seizure and seizure disorder

Steven C. Swain, Virginia Beach, VA, for petitioner.
Glenn A. MacLeod, Washington, DC, for respondent.

MILLMAN, Special Master

RULING ON ENTITLEMENT[1]

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 vaccine that Thomas Bell

[1] 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.

(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 undergoing 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.

FACTS

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 Pneumovax, 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 had maybe a low fever for the first several hours only. He had a low-grade temperature of about 100.9° at Maryiew. 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 previously, 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 discussed 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 the results of Thomas' MRI, which showed 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. [The June 10, 2002 abnormal EEG showing one recorded seizure (an alteration of mental status) and intermittent tonic eye deviation to the left is located 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.

Other Submitted Material

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 P. Ex. D, a 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. Dr. Northam states that prolonged or recurrent seizure activity through activity-dependent mechanisms can later the way the immature brain develops and forms synapses. P. Ex. D, last page. Dr. Northam concludes that the acellular DPT was the precipitating factor for Thomas's acute encephalopathy and accompanying prolonged seizure. *Id.*

Attached to Dr. Northam's letter of May 2, 2005 are a series of articles beginning at P. Ex. H which is "Long-term alterations in glutamate receptor and transporter expression following early-life seizures are associated with increased seizure susceptibility" by G. Zhang, et al., 88 *J Neurochem* 91-101 (2004). The authors state that prolonged seizures or status epilepticus in childhood are associated with an increased risk of epilepsy later in life. *Id.* at 91.

Petitioner's Ex. J is an article entitled "The Neurobiology and Consequences of Epilepsy in the Developing Brain" by G.L. Holmes and Y. Ben-Ari, 49 *Ped Research*3:320-25 (2001). The authors state that seizures in the developing brain can result in irreversible alterations in neuronal connectivity. *Id.* at 320. They also state, "It has long been known that severe seizures are associated with brain damage and cell loss in children." *Id.* at 321.

Petitioner's Exs. L-N are articles describing permanent brain damage in animals and humans from recurrent seizures.

Respondent filed two reports from experts. Respondent's Ex. C is an expert report dated October 7, 2004 from Dr. Yuval Shafrir describes Thomas as having a mild form of migratory partial epilepsy of infancy. *Id.* at 10-11. Dr. Shafrir admits that high fever or acute illness will trigger seizure in a patient with a static lesion. *Id.* at 11. He also admits that DPT vaccine is associated with febrile seizures, but the risk of febrile seizures is much lower in DPaT vaccine. *Id.* at 12. Dr. Shafrir did not think there was any evidence to prove that DPaT caused Thomas's epilepsy. *Id.* at 14.

Respondent's Ex. D is a supplemental report dated June 8, 2005 from Dr. Shafrir. He agrees that a focal febrile seizure lasting up to 45 minutes can be considered a form of acute encephalopathy. *Id.* at 1. But this would not satisfy the requirements in the regulations to be a Table encephalopathy. *Id.*

Respondent's Ex. E is an expert report dated May 17, 2005 from a radiologist Dr. Gilbert Vezina who looked at Thomas's CT scan and MRI reports. He states that there is a persistent, non-progressive asymmetry in the size of Thomas's lateral ventricles with a prominent right

atrium. *Id.* at 2. The MRIs show delayed myelination, and the more recent MRI shows an abnormality in the occipital poles with apparent hypermyelination/dysgenesis on the right and less likely hypomyelination on the left. *Id.* He does not think either condition would be caused by vaccination. *Id.*

State of Proceedings

This case was transferred to the undersigned on December 22, 2004.

On June 27, 2005, the undersigned issued an Order to Show Cause requiring respondent to show cause why this case should not be in damages.

On August 5, 2005, at the first status conference the undersigned held with the parties, respondent admitted that petitioner had a strong case but requested the filing of original MRI films, the medical literature Dr. Northam described, and any new medical records.

On September 29, 2005, the parties and the undersigned held a status conference. Respondent requested the undersigned issue an Order describing the strengths of petitioner's case, which the undesigned did in an Order dated September 30, 2005:

1. Thomas Bell had a 102 degree fever after receiving acellular DPT. As the special master has held before, most recently in Noel v. Sec'y of HHS, 2004 WL 3049764 (Fed. Cl. Spec. Mstr. Dec. 14, 2004), acellular DPT may cause a fever leading to a seizure and seizure disorder. Thomas Bell's fever occurred within 24 hours of his vaccination, and was noted in contemporaneous medical records (R.'s Ex. B, p. 10, as well as P.'s Ex. 10, p. 7).

2. Thomas Bell's seizure lasted approximately 45 minutes, which means it was not a benign febrile seizure. It was the beginning of his status epilepticus. See the exhibits listed in number 1 above.

3. His initial seizure was followed by subclinical seizures. See P.'s Ex. C, p. 14, as well as Ex. 10, p. 63, and the recently filed P.'s Ex. G, p. 12. A long-lasting seizure as well as numerous subclinical seizures damage a child's brain. They also indicate an underlying encephalopathy.

4. Thomas Bell's treating pediatric neurologist, Dr. Ralph Northam, is his expert witness, a rare and significant event in vaccine litigation in which the undersigned usually hears from a stable of expert witnesses.

5. Dr. Northam's medical articles in support of his opinion (P.'s Exs. H, I, J, L, L, M, N) confirm his statement that protracted seizures as well as numerous seizures damage the brain.

On October 25, 2005, the parties and the undersigned held a status conference during which respondent's counsel stated he gave the undersigned's Order to Show Cause and Order dated September 30, 2005 listing the strengths of the case to the Division of Vaccine Injury Compensation. Both counsel had talked to life care planners.

A further status conference was held on November 29, 2005 during which petitioner's counsel stated he wanted to know if respondent was going to settle.

On January 10, 2006, a status conference was held during which respondent's counsel stated that respondent would attempt a litigative risk settlement.

Subsequent status conferences were held on March 28, 2006, May 19, 2006. July 11, 2006, August 11, 2006, September 28, 2006, November 30, 2006, January 22, 2007, March 6, 2007, April 10, 2007, May 18, 2007, June 15, 2007, August 20, 2007, October 2, 2007, January 15, 2008, April 2, 2008, and May 16, 2008.

During the May 16, 2008 status conference, respondent's counsel asked for the undersigned to rule on the record before he made a proffer to petitioner on damages.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must prove by preponderant evidence "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Secretary of HHS, 418 F. 3d 1274, 1278 (Fed. Cir. 2005). In Althen, the Federal Circuit quoted its opinion in Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992):

> A persuasive medical theory is demonstrated by "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" the logical sequence being supported by "reputable medical or scientific explanation[,]" *i.e.*, "evidence in the form of scientific studies or expert medical testimony[.]"

In Capizzano v. Secretary of HHS, 440 F.3d 1317, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen . . . ."

Close calls are to be resolved in favor of petitioners. Capizzano, 1440 F.3d at 1327; Althen, 418 F.3d at 1280. *See generally*, Knudsen v. Secretary of HHS, 35 F.3d 543, 551 (Fed. Cir. 1994).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, 956 F.2d at 1149. Mere temporal

association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioner must show not only that but for the vaccine, Thomas would not have a febrile seizure and seizure disorder, but also that the vaccine was a substantial factor in bringing about Thomas's injury. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

The Federal Circuit in Capizzano emphasized the opinions of petitioner's four treating doctors in that case that hepatitis B vaccine caused petitioner's rheumatoid arthritis therein. 440 F.3d at 1326.

This case concerns Thomas's having fever after acellular DPT followed by a 45-minute seizure, repetitive seizures, 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).

Although Thomas's condition does not meet the regulatory requirements for a Table encephalopathy, clearly the facts of the case support the opinion of his treating pediatric neurologist Dr. Northam that the vaccination caused a fever triggering his unusually long seizure leading to subsequent status epilepticus. Respondent's experts Dr. Shafrir and Dr. Vezina focus upon abnormality in Thomas's brain which they say preceded his vaccine reaction. They ignore that if Thomas had a prevaccination abnormality, it would have made him more susceptible to a

prolonged seizure triggered by fever due to the vaccine. As Dr. Northam opined in his reports and as supported in the medical literature, prolonged seizures and repetitive seizures damage irreversibly the infant brain.

Petitioner has proved a prima facie case of causation in fact and is entitled to damages.

CONCLUSION

Petitioner is entitled to damages. The undersigned expects that respondent will make a proffer to petitioner as soon as possible.

IT IS SO ORDERED.

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DATE Laura D. Millman
Special Master