

OFFICE OF SPECIAL MASTERS

No. 04-1330V

December 16, 2005

Not for Publication

DARRIN and TANYA WOOD, as the Legal *
Representatives of the Estate of their minor son, *
ANDREW BLAKE WOOD, *

Petitioners, *

v. *

SECRETARY OF THE DEPARTMENT OF *
HEALTH AND HUMAN SERVICES, *

Respondent. *

Curtis R. Webb, Twin Falls, ID, for petitioners.
Lynn E. Ricciardella, Washington, DC, for respondent.

MILLMAN, Special Master

DECISION¹

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post this unpublished decision on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub.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.

Petitioners filed a petition on August 16, 2004, under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that vaccinations caused their son Andrew Blake Wood (hereinafter, “Andrew”) a Table encephalopathy.

During a telephonic status conference on December 15, 2005, petitioners’ counsel asked the undersigned to rule on the records filed so far because petitioners were not able to get a supportive opinion from Andrew’s treating pediatric neurologist, Dr. K. Alan Kelts. Petitioners have filed a report from a medical expert, Dr. Marcel Kinsbourne, and a radiologist, Dr. Gary L. Helversen.. Respondent filed a report from a medical expert, Dr. John T. MacDonald.

FACTS

Andrew was born on June 25, 2003, twin B (med. recs. at Ex. 5, p. 6) of twins. His twin is normal. Med. recs. at Ex. 9, p. 1.

A medical record dated June 29, 2003 from Dr. Marcia Beshara at Rapid City Regional Hospital states that Andrew had intrauterine growth retardation, and there was a 20% discordance between him and his twin. Med. recs. at Ex. 4, p. 14. Andrew was discharged home on the ninth day of life. Med. recs. at Ex. 5, p. 6.

He had his first hepatitis B vaccination on July 11, 2003. Med. recs. at Ex. 8, p. 10.

On August 8, 2003, Andrew saw his pediatrician Dr. Benn. Andrew was still fussy and gassy a lot of the time. Med. recs. at Ex. 8, p. 2.

Also, on August 8, 2003, Andrew received acellular DPT, Hib, IPV, and his second hepatitis B vaccination. Med. recs. at Ex. 7, p. 2; Ex. 8, p. 10.

On August 27, 2003, Andrew was in Rapid City Regional Hospital Emergency Department. Dr. Bobbie Ann Schauer wrote that Andrew had been in his usual state of health

until about two weeks ago per the parents. (Two weeks earlier would be approximately August 13, 2003, or five days after Andrew's vaccinations.) That was when he began not eating quite as well and had problems coordinating eating. He could not really suck. He had problems breathing and vomited projectily once after feeding. For the prior two days, he had looked depressed and with depressed affect. On August 27, 2003, he looked limp as well and received CPR for 25 minutes. Med. recs. at Ex. 8B, p. 3.

Andrew was admitted to the pediatric intensive care unit. Med. recs. at Ex. 8C, p. 8. Dr. Steven Benn wrote that Andrew's parents reported that he was doing reasonably well until the morning of admission. *Id.* Dr. Benn saw Andrew on August 8, 2003, at which time Andrew was feeding every 3 to 4 hours during the day and every 5 to 6 hours at night. Mr. and Mrs. Woods said Andrew was doing reasonably well until the morning of admission when they thought he did not look right and appeared pale. They thought he was depressed with an apathetic appearance. He ate well, but had vomiting during the night, some of it projectile. On the day of admission, he ate at 1:00 p.m., vomited, and was more listless but could be aroused. He was sitting in his seat and slumped over. Mr. Woods fed him a bottle, but Andrew was fussy and then gave a gasping-type of respiration, and went limp. He let out a long exhaled breath. *Id.*

On August 28, 2003, Dr. K. Alan Kelts, a pediatric neurologist at Rapid City Regional Hospital, noted that Andrew had had an arrest of unclear etiology, possibly secondary to a possible central nervous system hemorrhage (subdural vs. subarachnoid). Andrew had showed some stiffening and jerking of his left arm and facial quivering the prior night which could be seizures. He had opsthotonic posturing, flushing, eye movements, and fussing associated with painful stimuli or occurring spontaneously. Med. recs. at Ex. 8D, p. 13.

He had a possible encephalopathy subject to his arrest and central nervous system hemorrhage. His previous EEG the night before showed very low amplitude, almost flatline activity. On August 28th, the background activity was higher in amplitude with occasional sharp delta waves occipitally. The CT suggested the possibility of some generalized edema. Andrew had unusual behavior in that he had difficulty coordinating sucking, breathing, gagging, and poor oral intake during the prior couple of weeks. Andrew was the smaller twin and his brother did somewhat better than Andrew in general. Mr. Wood said that things went fairly well for the first month, but a couple of weeks ago, Andrew seemed as if he had to relearn to swallow and suck at the same time. He had difficulty taking a bottle, and continued to have some problems until the present time. “He almost seemed to be ill but, in fact, he had no definite signs of illness when the family brought him in to see Dr. Benn a few days ago.”² Med. recs. at Ex. 8D, p. 14. Dr. Benn used a laryngoscope to look down Andrew’s throat and saw good movement of the vocal cords and no evidence of masses, polyps, or other such problems. *Id.*

An ophthalmologic consultation with Dr. Robert Nixon on August 28, 2003 notes that Mr. and Mrs. Wood gave a history that Andrew had been healthy until “very recently.” Med. recs. at Ex. 8E, p. 17. He had been “a little bit ‘fussy’ over the last 2 weeks but nothing to[o] unusual.” *Id.* However, the prior night, while Mr. Wood was feeding him, Andrew went suddenly limp. *Id.* Brain imaging showed widespread cortical ischemia. *Id.*

² There is no notation in Dr. Benn’s records, filed as P. Ex. 7, of a pediatric visit between August 8, 2003, and Andrew’s hospitalization on August 27, 2003. The parents’ affidavits do not mention this visit either. Dr. Benn’s recitation of the history at P. Ex. 8C, p. 8 on August 27, 2003 also does not reflect a pediatric visit between August 8 and August 27, 2003.

Andrew was discharged from the hospital on September 7, 2003. Med. recs. at Ex. 8C, p. 8.

On September 16, 2003, his pediatrician Dr. Benn noted that Andrew had been discharged from the hospital one week prior following cardiorespiratory arrest at home during which he sustained significant hypoxic ischemic injury leading to a static encephalopathy and significant cortical damage. The etiology was unclear. The consensus was that Andrew had experienced some sort of massive diffuse bilateral stroke. Med. recs. at Ex. 8, p. 4.

On September 18, 2003, his pediatrician Dr. Benn wrote that Andrew's general irritability was improving. Med. recs. at Ex. 8, p. 2.

On October 10, 2003, Andrew received acellular DPT, IPB, Hib, and Prevnar. Med. recs. at Ex. 8, p. 10.

On November 26, 2003, Dr. Kelts noted cardiopulmonary arrest of unclear etiology, but possibly SIDS. Andrew had a central nervous system hemorrhage most likely subcortical associated with hypoxic/ischemic insult to his brain, and encephalopathy. Dr. Kelts noted that Andrew had a difficult perinatal period. Med. recs. at Ex. 9, p. 1.

An MRI taken September 1, 2003 showed subcortical type hemorrhage involving frontal, temporal, parietal, and occipital regions bilaterally in the areas of the infarct. There was also some mild edema in adjacent areas.

A repeat MRI taken on January 4, 2003 showed remarkable diffuse atrophy of cerebral cortex and subcortical white matter involving both cerebral hemispheres approximately equally. It also showed macrocystic encephalomalacia in the right frontal and left temporal parietal lobes,

and very large and symmetrical fluid collections surrounding the brain and between the brain and the skull, probably subdural in location.

A CT scan indicated that the cerebral hemispheres were markedly wasted in a patchy distribution. Med. recs. at Ex. 9, p. 1.

On January 16, 2004, Andrew received acellular DPT, IPV, Hib, Prevnar, and half a flu vaccination. Med. recs. at Ex. 8, p. 10.

Andrew died on April 20, 2005.

Other Submitted Material

Petitioners submitted affidavits dated June 30, 2004 which are P. Exs. 1 and 2. Mr. Wood states that two days after his August 8th vaccinations, Andrew started having difficulty swallowing. He continued to gain weight and have wet diapers. He was fussy. P. Ex. 1, p. 3. He began to cry in mid August 2003 and was very tired. P. Ex. 1, p. 4. He would not eat, but then stopped crying and seemed content again. P. Ex. 1, p. 5. Andrew's parents decided not to take him to see the doctor, thinking he had gas or colic. *Id.* He had another spell of inconsolable crying, but Mr. Wood does not know when or how long it lasted. *Id.* On August 26, 2003, Andrew had an episode of projectile vomiting. *Id.* On August 27, 2003, Andrew looked gray and depressed. *Id.* Mr. Wood picked up Andrew and noted he was floppy. Andrew was holding his breath and then took a large gasp of air. Mr. Wood suctioned his nose, but Andrew did not respond. He gave Andrew a few quick breaths of air, and then called his wife and then 911. P. Ex. 1, p. 6. Drs. Benn and Kelts said that Andrew seems to have had an episode of SIDS followed by a massive stroke. P. Ex. 1, p. 8.

Three days after Andrew's vaccinations on January 16, 2004, Andrew began to have swallowing problems again. P. Ex. 1, p. 11. He was also irritable and his eyes stopped tracking. P. Ex. 1, p. 12.

Mrs. Wood states in her affidavit that, from August 10, 2003 on, Andrew felt floppy, seemed lethargic, and did not eat right. P. Ex. 2, p. 3-4. She felt that Andrew and his twin Alex responded to her differently. P. Ex. 2, p. 4. Andrew was less aware than Alex. *Id.* Mrs. Wood states she does not know why she did not do something in response to this change. She now thinks she and her husband should have brought Andrew in to see Dr. Benn. *Id.*

At a wedding rehearsal on August 14, 2003, Andrew was uncharacteristically fussy and irritable. P. Ex. 2, p. 5. He slept through the entire wedding and was limp. That night, he cried nonstop, then calmed down but would eat very little. *Id.* On August 16, 2003, Andrew cried inconsolably and would not eat. She called Dr. Benn's office and spoke to his nurse and set up an appointment that afternoon. But when she and the family arrived home, Andrew was eating and she cancelled the appointment with Dr. Benn. P. Ex. 2, p. 6. Andrew had another crying incident after August 16 and before August 26, but she does not know when. *Id.*

Even though Andrew was "very very lethargic" and "very limp," and was not eating normally because he had problems swallowing, because he did not have a fever, she and her husband were not overly concerned. P. Ex. 2, pp. 6-7.

She nursed Andrew on August 27, 2003 when he did not look quite right. He seemed to be doing better at sucking, but vomited. P. Ex. 2, p. 7. Dr. Kelts told Mr. and Mrs. Woods that Andrew appeared to have had a massive stroke leaving basically the brainstem and a small portion of his back brain without insult. P. Ex. 2, p. 10.

Within a few days of Andrew's January 16, 2004 vaccinations, he had trouble swallowing and became more irritable. He made something of a comeback in February, but never really swallowed well again. P. Ex. 2, p. 17.

Petitioners filed the expert report of Dr. Marcel Kinsbourne, dated July 1, 2004. P. Ex. 3. His opinion is that Andrew had a Table encephalopathy whose onset was two days after he received acellular DPT. Dr. Kinsbourne stated Andrew had a lowered level of consciousness which persisted 17 days until he had respiratory arrest and massive anoxic damage. He was less interactive, with decreased eye contact, and inconsistent responses to external stimuli. He had widespread hemorrhages in both retinas without retinal detachment secondary to prolonged CPR. An MRI showed a diffuse cortical infarct. A CT scan done on October 14, 2003 showed marked supratentorial brain atrophy with encephalomalacia in the frontal and temporal lobes. An MRI done on November 4, 2003 showed that the entire cortex and subcortical white matter had atrophied to a remarkable degree. *Id.*

On August 30, 2005, petitioners faxed an expert report from Dr. Gary L. Halversen, a radiologist, dated July 6, 2005, which the undersigned filed by her leave on December 16, 2005. P. Ex. 17. Dr. Halversen reviewed radiological records at petitioners' request. A cranial ultrasound of June 27, 2003 was normal. A CT scan done on August 27, 2003 showed diffuse swelling of Andrew's brain with increased density, suggesting subdural hemorrhage at the vertex. *Id.* at p. 1.

An MRI done on August 28, 2003 demonstrated diffuse cortical signal changes and diffusion abnormality consistent with a diffuse acute infarction with changes suggesting blood over the parietal lobes bilaterally. *Id.*

The repeat MRI done on September 1, 2003 showed diffuse areas of hyperintense signal on the T1 weighted images, suggesting hemorrhage.

The follow-up scan of November 4, 2003 showed the areas of previous infarction to have atrophied with a remarkable loss of the cortex of Andrew's brain.

Dr. Halversen stated he was in agreement with the readings of the scans. The findings are consistent with an acute infarction on August 27-28th, 2003. The normal MRA suggests the massive infarction was not secondary to obstruction of the major blood supply to the brain. It could have been secondary to a long anoxic period when Andrew was unconscious, but also could be secondary to infarction from an inflammatory encephalitis which could produce edema and swelling leading to local infarction and then encephalopathy or atrophy. Dr. Helversen stated there was no way of telling whether the vaccinations might have produced an encephalitis which took a number of days to produce the swelling necessary to produce infarction. *Id.*

Over a number of days, the process could have led to edema and infarction or Andrew may have become so ill that he experienced respiratory arrest and then infarcted. (The parents' affidavits state that Andrew's demeanor changed after his vaccinations.) The change in Andrew's demeanor after the vaccination would suggest that a process started at that time which was progressive. *Id.* at 2. The normal angiogram would indicate the infarction was not secondary to vascular insult or obstruction. *Id.*

Respondent filed the medical expert report of Dr. John T. MacDonald, a pediatric neurologist, dated December 27, 2004. R. Ex. A. Dr. MacDonald states that Andrew's episode came on rather abruptly with what appeared to be a cardiopulmonary arrest. *Id.* at p. 1. A CT scan done at 9:33 p.m. on August 27, 2003 showed diffuse decrease in the gray and white matter

with small ventricles and perhaps some small amount of hemorrhage which the doctors felt indicated a diffuse ischemic event. *Id.* at p. 2. Subsequent MRI scan again showed diffuse cortical abnormalities consistent with brain infarction with a small amount of blood over the parietal lobes, probably subarachnoid hemorrhage with edema. *Id.* A subsequent scan showed atrophy of the cortex of the brain. *Id.*

Dr. MacDonald's opinion is that Andrew suffered an acute catastrophic neurological event on August 27, 2003. The brain scan and clinical findings are consistent with bilateral massive infarction of the cortex of the brain in the internal carotid artery distribution. It is difficult frequently to know the etiology of this condition. It can be due to infection, trauma, or an hypoxic-ischemic event of unknown etiology. Dr. MacDonald, in looking at the clinical picture and brain scan findings immediately after admission, thinks this was a very acute event on the day of admission and he would not expect any prodromal-type symptoms to present before this occurred. *Id.*

Such events occur suddenly and there is nothing to suggest some preexisting subtle changes in the brain before this. The parents' description of changes in Andrew over the two weeks following immunization are common and can be seen in otherwise normal babies. They do not signify to Dr. MacDonald any ongoing encephalopathic process that could somehow evolve into the catastrophic neurological injury of August 27, 2003.

Andrew gained weight from August 8, 2003 (4.22 kilograms) to August 27, 2003 (5 kilograms), which confirms that he was doing well. We may never know the cause of his acute episode. *Id.* There is nothing to suggest a relationship to his vaccinations administered August 8, 2003. *Id.*

DISCUSSION

Petitioners allege Andrew had a Table encephalopathy whose onset was two days after his August 8, 2003 vaccinations. There are two reasons why petitioners cannot prevail under a theory of on-Table encephalopathy. The history they gave to four different doctors (Schauer, Benn, Kelts, Nixon) at four different times on August 27 and 28, 2003 indicate that Andrew seemed to have difficulty with swallowing and breathing that began about two weeks prior to admission, which would be approximately August 13, 2003 or five days after vaccination. For an encephalopathy to be on-Table after DPT vaccination, it must occur within three days. 42 C.F.R. § 100.3(a)(II).

Although the parents state in their affidavits that Andrew's symptoms began two days after vaccination, when there is a conflict between what parents state in contemporaneous medical histories and what they say in the context of litigation, numerous case decisions have held that the histories in the contemporaneous medical records are more credible. 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).

Moreover, under the “Qualifications and aids to interpretation” at 42 C.F.R. § 100.3(b)(2)(I), a Table encephalopathy must be an “acute encephalopathy ... that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).” Nothing in the parents’ histories to the four medical doctors or even in their affidavits filed with their petition rises to the level of an acute encephalopathy, which is defined at 42 C.F.R. § 100.3(b)(2)(A): “a significantly decreased level of consciousness lasting for at least 24 hours.” Andrew had some difficulty with swallowing and breathing, but he ate regularly enough to gain weight between August 8 and 27, 2003, and his symptoms were not severe enough to prompt his parents to take him either to see his pediatrician or to go to the emergency room. Andrew’s acute encephalopathy began on August 27, 2003, 19 days after vaccination.

That the symptoms which the parents describe in the medical histories they gave and in their affidavits do not indicate an acute encephalopathy is apparent from a comparison with the regulations:

Section 100.3(b)(2)(i)(D) states:

A “significantly decreased level of consciousness” is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater....:

- (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
- (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or

(3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

Dr. Kinsbourne's expert report is not credible when he opines both onset of a Table encephalopathy two days after DPT and a significantly decreased level of consciousness that persisted for 17 days. It is frankly impossible for Andrew to have had a significantly decreased level of consciousness for 17 days when the medical records histories and the statements of the parents in their affidavits are examined. Even ignoring the medical histories the parents gave which indicated that Andrew was reasonably well, the symptoms described in their affidavits do not lend themselves to an interpretation of an acute encephalopathy extending from August 10, 2003 to August 27, 2003 when Andrew was brought into the emergency department.

Dr. MacDonald's opinion that Andrew had a sudden and catastrophic cardiopulmonary arrest on August 27, 2003 is consistent with the MRIs, CT scans, and clinical findings, as well as the reports of Dr. Kelts and the other petitioners' expert Dr. Helversen who opined that Andrew had an acute infarction. (He opined the possibility of a relationship to the vaccinations if there had been an inflammatory encephalitis following the vaccinations, but there was none.)

This is a tragic case which has caused great suffering for Andrew's family. But as unsatisfactory as it may be to conclude, Dr. MacDonald's opinion that we may never know the cause of Andrew's cardiopulmonary arrest is the only credible opinion.

Petitioners have not made a prima facie case for a Table encephalopathy. They have not attempted to make a case for causation in fact. Petitioners' attorney stated that if he could not obtain Dr. Kelts' support for petitioners' case, he would dismiss. Dr. Kelts did not support

petitioners' case and, in a telephonic status conference held on December 15, 2005, petitioners' counsel asked for a ruling on the record.

CONCLUSION

This petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.³

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master

³ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party's filing a notice renouncing the right to seek review.