

OFFICE OF SPECIAL MASTERS
Not for Publication
No. [redacted]
Originally issued [redacted] 2005

* * * * *
[Redacted], by his Mother and Next *
Friend, [Redacted], *
 *
 Petitioner, *
 *
 v. *
 *
 SECRETARY OF THE DEPARTMENT OF *
 HEALTH AND HUMAN SERVICES, *
 *
 Respondent. *

* * * * *
Clifford J. Shoemaker, Vienna, VA, for petitioner.
Alexis B. Babcock, 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¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master must post this unpublished decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub.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. On May 18, 2005, petitioner filed a Motion to Redact Special Master's Decision. Petitioner requested redaction of his medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy. Of the 27-page decision, petitioner moved to redact every single page, including

Petitioner filed a petition on [redacted], under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that MMR and acellular DPT vaccinations administered on [redacted] caused [redacted] twitching, light sensitivity, and emotional fragility. Petition, at ¶ 4. This case was transferred to the undersigned on March 4, 2005.

The undersigned did not hold a hearing in this case, which is within her discretion. Section 300aa-12(d)(3)(B)(I). Petitioner submitted expert medical affidavits from Dr. Carlo Tornatore, an adult neurologist, Dr. Joseph A. Bellanti, an immunologist, and Dr. John Barthelow Classen, an emergency care physician.² Respondent filed an expert medical report from Dr. Russell D. Snyder, a pediatric neurologist.

FACTS

[Redacted] was born on [redacted].

On [redacted], he was brought to his doctor with a complaint that he was fussy and sleeping less but some. Med. recs. at Ex. 3, p. 2.

On [redacted], Dr. [redacted], a neurosurgeon, saw [redacted] to determine if he had craniosynostosis. [Redacted] spent several months of his life in a baby seat and had developed a flat occiput. X-rays suggested lamboid synostosis. On examination, [redacted's] head was

descriptions of the experts' testimony, documents submitted, and the holding of the undersigned in this and other cases. Respondent objected that redaction was appropriate only for the vaccinee's name, his mother's name, and the names of his treating physicians. The undersigned agrees with respondent. In addition, the undersigned also redacts the names of the city and hospitals where the vaccinee was taken (as well as the case number in the electronically posted version). Without any personal identifying information, no member of the public reading this decision on the court's website will be able to link it to petitioner or petitioner's child. This will protect their privacy.

² By telephone conversation between petitioner's counsel and the undersigned's law clerk, petitioner stated that petitioner is not relying upon Dr. Classen.

brachycephalic with rather prominent parietal bosses. Dr. [redacted] stated this appeared to be positional brachycephaly and not true craniosynostosis. Med. recs. at Ex. 3, p. 13.

On [redacted], [redacted] was taken to the emergency department after having a seizure lasting approximately two minutes at 12:50 p.m. He was alert and responsive. Med. recs. at Ex. 8, p. 1. His temperature was 103.7°. Med. recs. at Ex. 8, p. 2. He had a positive strep A test. Med. recs. at Ex. 8, p. 4. He had gram positive cocci in pairs. Med. recs. at Ex. 8, p. 5. He was diagnosed with streptococcus pneumoniae. Med. recs. at Ex. 8, p. 6. A nurse next door to the [redacted] had given [redacted] mouth to mouth four times. Med. recs. at Ex. 8, p. 9. He had a fever for three hours before he had the seizures. Med. recs. at Ex. 8, p. 17. Initially, he was a little lethargic, but on discharge from [redacted] Hospital, he was active and interested. *Id.* He was diagnosed with febrile seizure and strep throat. *Id.* See also med. recs. at Ex. 3, p. 4.

By [redacted], [redacted] was back to his old self. Med. recs. at Ex. 3, p. 4.

On [redacted], Mrs. [redacted] stated that [redacted] had had a seizure at 5:30 a.m. in the context of a sore throat. He had a five-minute, febrile seizure during which his eyes rolled. It was tonic-clonic and occurred during sleep (he had been sleeping with his mother). He had 103° at the time, although 97.8° in the doctor's office. He was alert within 15-30 minutes after the seizure. *Id.*

On [redacted], the doctor discussed [redacted's] two febrile seizures with Mrs. [redacted]. [Redacted's] cousin had seizures. Mrs. [redacted] told the doctor that [redacted] had some intermittent shaking episodes during his first hour of sleep. Med. recs. at Ex. 3, p. 5.

On [redacted], [redacted] had an EEG which was normal. He had isolated twitching movements in his sleep which Dr. [redacted] stated were variably associated with myogenic (of muscular origin) artifact. There were no epileptiform features. Med. recs. at Ex. 3, p. 11.

On [redacted], Mrs. [redacted] called her pediatrician to say that [redacted] had had stomach cramps for four days. Med. recs. at Ex. 15, p. 6. He saw the doctor that day. He had a history of pain with bowel movements since drinking a “Power Ranger” drink. He seemed to get gastrointestinal upset with milk products, too. Med. recs. at Ex. 15, p. 7. The doctor diagnosed him with gastroenteritis. *Id.*

On [redacted], Mrs. [redacted] brought [redacted] in to [redacted] Medical Associates for a referral because [redacted] snored and had respiratory distress. [Redacted] was diagnosed with sleep apnea.³ Med. recs. at Ex. 13, p. 5. [Redacted] was referred to Dr. [redacted].

On [redacted], Dr. [redacted], an otolaryngologist, described [redacted] as a snorer and mouth-breather for many years. He was reported to stop breathing and gasp for air. He requested from Mrs. [redacted] the opportunity to assess the severity of [redacted’s] apnea. Med. recs. at Ex. 13, p. 6.

On [redacted], Dr. [redacted] noted that, by looking at an x-ray, he saw that [redacted] has prominent adenoid tissue in his nasopharynx, which could be the cause of his snoring. He was a

³ Sleep apnea is “transient attacks of failure of automatic control of respiration, resulting in alveolar hypoventilation, which becomes more pronounced during sleep. It may result in acidosis and in vasoconstriction of pulmonary arterioles, producing pulmonary arterial hypertension.” Dorland’s Illustrated Medical Dictionary, 27th ed. (1988) at 112. “The cumulative effect of recurrent spells of apnea is hypoxemia and shallow, nonrefreshing sleep, which may lead to excessive drowsiness, personality change, impairment of intellectual functioning, and heightened tendency to accidents during waking hours.” Stedman’s Medical Dictionary, 27th ed. (2000) at 111-12.

candidate for an adenoidectomy with possible tonsillectomy. Med. recs. at Ex. 13, p. 7. (There are no medical records filed showing that [redacted] had an adenoidectomy or tonsillectomy.)

On [redacted], [redacted] saw his doctor with a low-grade fever and cough. His vaccinations were deferred. Med. recs. at Ex. 13, p. 8.

On [redacted], when he was [redacted] years old, he received MMR, acellular DPT, and oral polio vaccines. Med. recs. at Ex. 13, pp. 1, 9. Four days later, he saw his pediatrician at [redacted] Care. The history Mrs. [redacted] gave was that, on the prior evening, [redacted], [redacted] announced to his parents a vague sensation. Mrs. [redacted] stated he had “[redacted] in his head” that lasted about 15 seconds and occurred twice, once during dinner and once while playing with his father. He had no other complaints and nothing suggesting a postictal occurrence (i.e., after a seizure). He did not have any more episodes. At the doctor’s office, there was no evidence of any problem. On examination of Michael’s eyes’ fundi (the part of the eye opposite the pupil), the doctor found him normal. His diagnosis was a habit tic. Med. recs. at Ex. 13, p. 10.

Two and one-half weeks later, on [redacted], Mrs. [redacted] telephoned the pediatrician and said that [redacted] had an infection in his right molar and the dentist wanted to x-ray him and possibly give him penicillin. Mrs. [redacted] refused, stating that [redacted] had a [redacted] episode on [redacted] and she was concerned about seizure activity. The nurse replying to Mrs. [redacted’s] call stated it was safe to x-ray [redacted] and also safe for him to take penicillin. The nurse consulted with Dr. [redacted] who stated she had never known an x-ray or penicillin to cause seizure activity. Med. recs. at Ex. 13, p. 11.

Ten days later, on [redacted], [redacted] returned to [redacted] Care, where Mrs. [redacted] told Dr. [redacted] that [redacted] was having episodes of crying very easily and was irritable. This was new behavior for him. She was concerned about his [redacted]. Also, he was sensitive to light. Mrs. [redacted] noted that [redacted] got crying spells whenever he ate [redacted]. He did well if his mother eliminated [redacted] from his diet. Dr. [redacted] diagnosed hypoglycemia.⁴ Med. recs. at Ex. 13, p. 12.

On [redacted], [redacted] had his blood glucose tested. It was 77 mg/dl, which is on the low side of normal. Med. recs. at Ex. 13, p. 4.

Two and one-half months later, on [redacted], [redacted] returned to Dr. [redacted] because Mrs. [redacted] was concerned about his hypoglycemia. She said [redacted] had an episode the prior week where he got the [redacted]. [Redacted] still described [redacted] in his abdomen and head, but Dr. [redacted] noted there was no visible seizure activity. Med. recs. at Ex. 13, p. 14.

On [redacted], [redacted] saw Dr. [redacted], an endocrinologist, who thought his problems were not endocrine in nature and recommended a neurologic evaluation and a psychiatric evaluation. Med. recs. at Ex. 10, p. 1. Mrs. [redacted] told Dr. [redacted] that when she switched [redacted] to a high protein diet in [redacted], he seemed to do a little bit better until [redacted], when he again had some major problems with [redacted]. Mrs. [redacted] described

⁴ Hypoglycemia is “an abnormally diminished concentration of glucose in the blood, which may lead to tremulousness, cold sweat, piloerection [erection of the hair], hypothermia, and headache, accompanied by irritability, confusion, hallucinations, bizarre behavior, and ultimately, convulsions and coma.” Dorland’s, at 804. “Autonomic symptoms include sweating, trembling, feelings of warmth, anxiety, and nausea. Neuroglycopenic symptoms include feelings of dizziness, confusion, tiredness, difficulty speaking, headache and inability to concentrate.” Stedman’s, at 861.

the [redacted] as waking him up and [redacted] inside his head and sometimes inside his stomach for the whole evening. She would give him protein which seemed to help and he would then go back to sleep. Otherwise, he was healthy and very bright. He did well in school. Med. recs. at Ex. 10, p. 19.

On [redacted], [redacted] saw Dr. [redacted], a pediatric endocrinologist, at [redacted] Medical Associates, concerning his hypoglycemia and questioned if he were having seizure activity. Med. recs. at Ex. 13, p. 15.

Two weeks later, on [redacted], [redacted] saw Dr. [redacted], a pediatric neurologist. Mrs. [redacted] told Dr. [redacted] that in mid-[redacted], [redacted] received MMR, DPT, and OPV. Over the next two days, he was tired, listless, and moody with occasional crying. Dr. [redacted] records, "He resolved from those symptoms and was unremarkable until [redacted] about two weeks later when he was noted to have some sensation of '[redacted] in his head and [redacted] in his eyes' and would become [redacted]." Med. recs. at Ex. 14, p. 1. At no time did [redacted's] parents notice that [redacted] had a tremor, but subsequently, on several occasions, [redacted] complained of "[redacted] in his stomach." *Id.* On occasion, [redacted] would develop features of [redacted] and tremor after eating various quantities of [redacted]. [Redacted's] parents could not clearly define the amplitude and nature of his tremor. Since [redacted], [redacted] had had intermittent tremulousness precipitated by a [redacted] load. He would also become tired and sleep more after ingesting large quantities of [redacted]. *Id.*

[Redacted's] mother stated that, occasionally, [redacted's] eyes watered while he complained about shimmering and trembling of his eyes. But neither parent saw any nystagmus (rapid, involuntary, oscillatory motion of the eyeball). [Redacted] stated he could not tolerate

heat or light as he once could. His gait, motor strength, coordination, and cognitive skills remained unchanged. A student in kindergarten, [redacted] was very bright, articulate, and socially interactive. *Id.*

As a very young child, [redacted] had two brief febrile seizures which were not associated with any sequelae. Otherwise, he had been in good health. *Id.* His family history is positive for epilepsy in a cousin. Med. recs. at Ex. 14, p. 2. One of his prior febrile seizures (at 18 months of age) was associated with a significant strep infection. *Id.*

On examination, Dr. [redacted] found [redacted] to be neurologically normal. There was no evidence of any abnormality of movement and response. Dr. [redacted] tested [redacted] for nystagmus with an optokinetic drum and [redacted's] response was normal. With his arms outstretched, [redacted] did not have tremor. [Redacted] touched his nose with his index finger, without any evidence of past pointing or distal tremor. Further testing showed no evidence of abnormality. *Id.*

Dr. [redacted] concluded, "At this time [redacted] has had sensory symptomatology without overt objective visible symptomatology wherein he complains of these sensations of his eyes tremoring, his stomach [redacted] and feeling [redacted] all over. With regard to his changes of behavior and his response to various [redacted] loads clearly I believe continuation of his pediatric endocrine work-up with glucose tolerance test, Insulin levels and other appropriate studies would be recommended." *Id.*

An EEG was done on [redacted], which was normal in the prolonged 24-hour state. There was one report of restless movement, but no significant EEG change. Med. recs. at Ex. 14, p. 7; Ex. 10, p. 42..

A little over a month later, on [redacted], Dr. [redacted] saw Mrs. [redacted] and reviewed [redacted's] findings. [Redacted] had low glucose at 43 mg/dl. Dr. [redacted] stated, "At this time [redacted's] findings still by history are consistent with metabolic basis for his [redacted] based on his handling of glucose. I have asked at this point that the mother seriously pursue the work up with Dr. [redacted] for evaluation of any hyperinsulin-like states or reactive hypoglycemia-like states or other causes of chronic hypoglycemia that may be responsible for his symptoms." Med. recs. at Ex. 14, p. 11. He suggested that [redacted] see a pediatric ophthalmologist about his undue photic sensitivity and increased tearing.

Dr. [redacted] concludes, "At this time I emphatically told Mrs. [redacted] that there is no evidence of primary neurologic disease and that any further evaluation must really be carried from the endocrinologic standpoint." *Id.*

On [redacted], [redacted] saw Dr. [redacted], the endocrinologist, again. He had a blood glucose of 43. His symptoms persisted as before with [redacted] inside and changes in behavior. He was now clingy in attachment to his mother. Once, very early in the morning, he was very weak and limp when he was staying with an uncle and had not eaten much the day before. When his mother appeared, he came around quickly and he was given food. He did not have a cold sweat, visible shakiness, or pallor. At this time, with a blood sugar of 43, Dr. [redacted] recommended a thorough evaluation for hypoglycemia. Med. recs. at Ex. 10, p. 6; Ex. 9, p. 3. [Redacted] used to be cooperative in taking high protein snacks, but was now starting to refuse them and wanted sweet foods. His grandmother was dying and Mrs. [redacted] thought that might be affecting [redacted]. Med. recs. at Ex. 9, p. 3.

On [redacted], Dr. [redacted's] nurse [redacted] taught Mrs. [redacted] how to do home blood glucose monitoring on [redacted]. She pricked him but could not get a full drop of blood and he refused to let her prick him again, although he said he would let her do it that night. Med. recs. at Ex. 9, p. 4.

On [redacted], [redacted] saw Dr. [redacted] again. [Redacted] complained of [redacted] inside his head and would occasionally be limp in the morning if he missed dinner. He did respond to eating protein and even the [redacted] in his head sometimes responded to eating protein. Since he was last seen, [redacted] reported he no longer had the [redacted] in his head. He had one episode of being limp in the morning when he missed his dinner. Med. recs. at Ex. 9, p. 4.

In a letter dated [redacted], Dr. [redacted] states she saw [redacted] again and was still not convinced he had hypoglycemia. When he saw Dr. [redacted], [redacted] had a blood sugar of 41. She asked Mrs. [redacted] to start checking [redacted's] [redacted] at home when he had symptoms, but she did not do that. She did check [redacted] randomly and his [redacted] were always 81-90. She gave the meter back to the pharmacy because Mrs. [redacted] said that checking [redacted's] blood was very traumatic. Dr. [redacted] told her it is very important to check during the time [redacted] was complaining of symptoms so as to determine whether low blood [redacted] played a part in this. Dr. [redacted] thought [redacted] might have some medium chain CoA dehydrogenase deficiency which causes a failure of conversion from sugar metabolism to fat metabolism, which is not uncommon. Dr. [redacted] noted that since she gave him the blood sugar testing equipment, [redacted's] symptoms improved quite a bit although he still occasionally complained of stomach aches. He did not complain of [redacted] in his head

any more. Med. recs. at Ex. 10, p. 7. Dr. [redacted] discussed with Mrs. [redacted] further evaluation for hypoglycemia, including a glucose tolerance test and a 24-hour fast. Dr. [redacted] was going to get Mrs. [redacted] a new meter so she can again test [redacted] at home should the symptoms occur to see if he is hypoglycemic during the symptoms. Med. recs. at Ex. 10, p. 8.

On [redacted], Mrs. [redacted] telephoned her pediatrician. She was very upset because no one called her back. She stated that [redacted] has been having seizures and she wanted to know in what direction to go. Med. recs. at Ex. 13, p. 19. (There is no follow-up appointment filed in the records and no emergency room or hospital admission filed in the records to reflect that [redacted] had seizures in [redacted].)

On [redacted], Dr. [redacted], a pediatric endocrinologist, evaluated [redacted] for possible hypoglycemia. Mrs. [redacted] told Dr. [redacted] that, in [redacted], [redacted] had two seizures at night. [Redacted's] neonatal period was complicated by respiratory difficulty and sleep apnea. He had two febrile seizures, one at 18 months during a bout of strep septicemia, and one at two years of age. In [redacted], he was put on a high protein diet to avoid the presumably hypoglycemic episodes. He currently ate three major meals and multiple snacks during the day. [Redacted's] eyes were sensitive to light and he drinks water excessively. Recently, he had trouble sleeping and twitched his muscles at night. His father has had asthma since early childhood and his mother has chronic fatigue syndrome. Med. recs. at Ex. 10, p. 10. [Redacted's] neurologic examination was nonfocal. Dr. [redacted's] clinical impression was that his symptoms were compatible with either hypoglycemia or seizures. Med. recs. at Ex. 10, p. 11.

On [redacted], [redacted] was taken to [redacted] Hospital emergency department with a seizure consisting of “full body tremors.” Med. recs. at Ex. 8, p. 22. His temperature was 97.8°. His seizure occurred at 1:40 a.m. He had been sleeping when he started to tremble all over for 10 seconds. His mother easily woke him and then his trembling stopped. He feels fine now. Med. recs. at Ex. 8, p. 23.

In [redacted], [redacted] had a 24-hour EEG performed. The history was that [redacted] had a history of [redacted]. Mrs. [redacted] told Dr. [redacted] that [redacted] had one seizure in [redacted] which wakened him from sleep with convulsions and another event one hour later. The EEG recorded frequent muscle movement artifact but no clear cut epileptiform disturbance. A number of jerks were recorded. When [redacted] emerged from sleep, the background recorded activity associated with the emergence of sleep without any paroxysmal epileptiform disturbance. On [redacted], the EEG recorded paroxysmal spikes and slow wave discharges seen maximally frontally and bifrontally. Dr. [redacted’s] impression, signed [redacted], was that [redacted’s] 24-hour ambulatory Digitrace EEG was abnormal due to bifrontal hemispheric electrographic features of paroxysmal abnormality. Med. recs. at Ex. 10, pp. 12-13.

On [redacted], [redacted] saw Dr. [redacted] again. [Redacted] had a 48-hour Digitrace EEG (see Med. recs. at Ex. 14, pp. 19-20) which was normal during the first 24 hours, but in the second 24 hours, showed bifrontal epileptiform discharges without secondary generalization in his sleep recording. There was no correlation between the discharge and the subsequently noted findings (he had episodes during sleep of frequent muscle movement best described as

myoclonic⁵ movements). [Redacted] had had a generalized seizure on [redacted]. Med. recs. at Ex. 14, p. 12.

Dr. [redacted] said that [redacted's] sleep physiology might be due to apnea secondary to upper airway obstruction due to hypertrophied tonsils and adenoids. He recommended pursuing metabolic evaluation with Dr. [redacted] and also beginning Depakote for treatment of his primary EEG abnormality that correlated with his documented seizures. He also recommended a possible ENT evaluation of [redacted's] upper airway obstruction that may be associated with nocturnal apnea, producing decreased oxygen saturation and contributing to a hypoxic factor for a latent seizure disorder. In addition, [redacted] should be evaluated for any "glucose abnormalities that may have also been of concern in the past and have yet [to] be fully elucidated [as] a part of his ongoing investigation by pediatric endocrinology." *Id.*

On [redacted], [redacted] returned to [redacted] Hospital for a sleep disorder study and polysomnogram report. Med. recs. at Ex. 8, p. 24. Mrs. [redacted] described [redacted] as experiencing constant twitching and jerking while asleep, where he moved his arms, hands, and shoulders, especially during the first few hours of sleep. Occasionally, she said he sat straight up in bed with all muscles extremely tight, but he was not awake at the time. [Redacted] was tested overnight. He had mild periodic leg movements that on occasion were associated with an EEG arousal. His heart rate would increase to 120 beats per minute during the arousals. His EEG was unremarkable and revealed no evidence of seizure activity. [Redacted] exhibited rare snoring and occasional mild loud breathing. Dr. [redacted], board-certified in sleep medicine, concluded

⁵ Myoclonus is "shocklike contractions of a portion of a muscle, an entire muscle, or a group of muscles, restricted to one area of the body or appearing synchronously or asynchronously in several areas." Dorland's, at 1090.

there was no significant obstructive sleep apnea or hypopnea detected and no evidence of parasomnia or seizure activity. Med. recs. at Ex. 8, p. 24.

On [redacted], Dr. [redacted] saw [redacted] again after having had a sleep study. Med. recs. at Ex. 14, p. 18. He did not have obstructive apnea or hypoventilation. His EEG was unremarkable. He had mild rare snoring. Med. recs. at Ex. 14, p. 17.

On [redacted], Dr. [redacted] wrote a follow-up note on [redacted]. [Redacted's] fasting blood sugar of 79 mg/dl was normal. His fasting insulin was also normal. There was no evidence of hormonal or metabolic abnormalities. He considered hypoglycemia very unlikely. Med. recs. at Ex. 10, p. 18.

Dr. [redacted] saw [redacted] on January 6, 1999. [Redacted] was on Depakote. He had no focal findings. He had some diffuse joint pains and some neck pain, but no evidence of any other abnormality. His neurologic examination was normal. Mrs. [redacted] was concerned about his multiple rheumatologic complaints. Neurologically, [redacted] was doing quite well. Med. recs. at Ex. 7, p. 8.

On [redacted], Dr. [redacted], a Ph.D. clinical psychologist, interviewed [redacted] followed by testing on [redacted]. [Redacted's] neurologist, Dr. [redacted], referred [redacted] to this psychologist. Throughout the testing, there was no overt indication of seizure-like activity. Med. recs. at Ex. 18, p. 2. There were no overt indications of serious emotional problems. *Id.* He maintained satisfactory attention and was not overly restless. *Id.* [Redacted's] IQ performance placed him in the high average range of intellectual functioning. *Id.* His attention/concentration level was normal. Med. recs. at Ex. 18, pp. 3-4. He performed well on perceptual-motor tests. Med. recs. at Ex. 18, p. 4. His written language score was one year

below his chronological age. He had processing difficulties with phonemes. Med. recs. at Ex. 18, p. 5. His math skills were weak. Med. recs. at Ex. 18, p. 6. [Redacted] had much more difficulty expressing his thoughts in writing than verbally. Med. recs. at Ex. 18, p. 9.

Other Submitted Material

Mrs. [redacted's] affidavit, dated [redacted], states that, within 48 hours of his MMR, DPT, and polio vaccinations, [redacted] experienced [redacted] in his eyes and head, emotional fragility, weepiness, mood swings, photophobia, and restless sleep. Affidavit, at ¶ 5. [Redacted's] symptoms increased with shaking in his [redacted]. Affidavit, at ¶ 7. By [redacted], [redacted's] condition was deteriorating. Affidavit, at ¶ 8. By [redacted], [redacted] was twitching and jerking every night throughout the night, activity which continued. On [redacted], [redacted] had multiple full seizures throughout the night. Affidavit, at ¶ 11.⁶ By [redacted], seizure activity was occurring regularly. Affidavit, at ¶ 13.⁷ P. Ex. 19.

Petitioner filed the expert medical report dated February 16, 2000 of Dr. Joseph A. Bellanti, an immunologist. P. Ex. 20. Dr. Bellanti saw [redacted] on February 4, 2000. He notes [redacted's] early respiratory difficulties due to narrowed nasal passages. He also notes [redacted's] febrile seizure with generalized tonic-clonic convulsions in the context of *S. pneumoniae* at the age of 15 months on [redacted], after having an upper respiratory infection.

⁶ There is no hospital admission or emergency department visit filed in the medical records for [redacted] in [redacted]. Mrs. [redacted] told Dr. [redacted], a pediatric endocrinologist, that [redacted] had had two brief seizures on [redacted]. She told Dr. [redacted] in [redacted] that [redacted] had a seizure in [redacted] which waked him from sleep with convulsions and another event one hour later.

⁷ [Redacted's] movements in his sleep predate his [redacted] vaccinations and were felt to have a muscular, not epileptiform, origin. He was subsequently tested asleep in [redacted] and, although he had twitching leg movements, his EEG did not show seizure activity.

At the age of two years, on [redacted], [redacted] had a second tonic-clonic seizure similar to the first one. The first one lasted two minutes and was a grand mal seizure. [Redacted] had had fever for three hours before seizing. The second seizure occurring at two years occurred at 5:30 a.m., lasted five minutes, and was also associated with fever. *Id.* at 1. Dr. Bellanti states that afterwards, [redacted] has had “many seizures without fever and usually always when he is sleeping.” *Id.* Mrs. [redacted] thinks [redacted] can provoke these seizures.

Dr. Bellanti’s impression is that [redacted] had a post-vaccinal exacerbation of a pre-existing convulsive disorder which he has had since he was [redacted] months old. “There seems to be a temporal relationship between the second MMR which he received on [redacted] to his current clinical status.” *Id.* at 2. Dr. Bellanti’s CV is at P. Ex. 20, p. 3.

Petitioner filed a medical expert report from Dr. John Barthelow Classen, an emergency care physician, dated February 1, 2004. P. Ex. 21. Dr. Classen states that [redacted] has a residual seizure disorder starting soon after he received MMR, acellular DPT, and OPV vaccines. His opinion is that the vaccines caused his disease. Dr. Classen states, at page 2 of his report, that Dr. [redacted], [redacted’s] neurologist, diagnosed [redacted] on [redacted] with possible partial complex seizures. (This is directly contrary to Dr. [redacted’s] report which found [redacted] to have a normal neurologic examination. There was no objective evidence of any abnormality, even though, subjectively, [redacted] complained of tremors. Dr. [redacted] recommended an EEG to rule out the possibility of partial complex seizures. A subsequent EEG was normal. Med. recs. at Ex. 14, pp. 2, 7.) Dr. Classen states that wild pertussis toxin is known to cause nerve damage as does inactivated pertussis toxin found in vaccine. P. Ex. 21, at 3. He

also states that wild tetanus toxin has a tropism for nervous tissue and causes nerve damage as does the deactivated tetanus toxin. *Id.*

Dr. Classen states that, since [redacted] previously had received all the vaccines he received on [redacted], he would have antibodies to those vaccines in his blood by [redacted]. Medical literature establishes that injection of an antigen into an animal that already has antibodies to that antigen can lead to formation of immune complexes and vasculitis, causing nerve damage. *Id.* ([Redacted] was never diagnosed with vasculitis or immune complexes. Dr. Bellanti tested [redacted] for immune disorders and found him normal.)

Dr. Classen then discusses medical literature that shows that DPT vaccine can cause seizures. *Id.* He repeats that [redacted] has recurrent seizures that Dr. [redacted] described as partial complex on [redacted] (again Dr. Classen is in error). P's Ex. 21, at 4. He states that [redacted] had several more seizures and an abnormal EEG on [redacted], one year after the vaccinations at issue. *Id.* Dr. Classen states that Dr. [redacted], [redacted's] pediatrician, misdiagnosed him initially with a habit tic, which should be reserved for chronic movement disorders. Dr. Classen states that intermittent movement disorders are "better classified" as seizures. *Id.*

Dr. Classen thinks five days between vaccination and onset of symptoms is consistent with causality. *Id.* He reviews medical literature of varying time periods between vaccinations and seizures. No other cause than the vaccines was ever proved. P's Ex. 21, at 7. The undersigned filed by her leave Dr. Classen's CV on April 21, 2005. Dr. Classen is not board-certified in any specialty. He makes his living as a physician in an urgent care setting. See CV at

2. The procedures Dr. Classen performs are repair of lacerations, reading of trauma x-rays, splinting of fractures, and general medical/pediatric care. *Id.*

Petitioner filed the expert medical report of Dr. Carlo Tornatore, an adult neurologist, which is undated. (Initially the petitioner's exhibit number was 21, but petitioner corrected the exhibit number to 23.) Dr. Tornatore interprets Dr. [redacted's] Digitrace EEG report, dated [redacted] (med. recs. at Ex. 10, pp. 12-13) as proof that [redacted] had convulsions immediately after MMR, DPT, and polio vaccine in [redacted]. Dr. [redacted] writes:

History: The record consists of several components. The first consists of push button events of which 7 events were noted. The EEG is performed on a patient with a history of [redacted], where the patients [sic] head and eyes are noted to move. He can respond. He is alert and aware during the event. He had one witnessed seizure in April of 1998, that awakened him from sleep with convulsions and another event one hour later. The episodes began immediate [sic] after MMR, DPT and polio vaccine in [redacted]. Also he has complained of stomach [redacted] and hurting.

...The [EEG] record reveals frequent muscle movement artifact. During the push button events, which are recorded, muscle movement artifact is seen, but clear cut epileptiform disturbance is not recorded. A number of typical jerks is recorded.

Dr. [redacted's] letter dated the following day, [redacted], states that [redacted] had episodes during sleep of frequent muscle movement, best described as myoclonic movements, during the 48-hour Digitrace EEG. "He did have a generalized seizure on [redacted]." Med. recs. at Ex. 10, p. 14. He notes that during the second 24 hours of the Digitrace EEG, there was in fact no correlation between the bifrontal epileptiform discharges seen and the noted findings of muscle movements. Dr. [redacted] discussed the possibility of apnea as an explanation for [redacted's] abnormal sleep movements. At no time does Dr. [redacted] attribute these movements to seizures beginning immediately after Michael's [redacted] vaccinations. Dr. [redacted] began [redacted] on Depakote to treat the primary EEG abnormality that did correlate with his

documented seizure. Besides evaluating [redacted's] apnea, Dr. [redacted] suggested further glucose evaluation. *Id.*

Dr. Tornatore assumes from Dr. [redacted's] [redacted] report discussed above that Dr. [redacted] “subsequently recognized as convulsive, i.e., recurrent seizures” [redacted's] episodes occurring [redacted] days after receiving acellular DPT, MMR and oral polio vaccines. Dr. Tornatore's opinion is that these vaccines caused [redacted's] seizure disorder because of the temporal relationship of the seizure disorder and vaccination as well as a plausible biological mechanism. He states that multiple studies show that acellular DPT can result in seizures, although at a lower rate than whole cell pertussis vaccine. P's Ex. 23, at 2.

Dr. Tornatore continues that the theory is that bacterial endotoxin present in the vaccine acts as a neurotoxin after administration. The resulting neurotoxicity can lead to a convulsant event. Subsequently, kindling of the seizure focus, due to repetitive convulsions, leads to chronic intractable epilepsy as in [redacted] case. He had a history of febrile seizures and may have had a propensity for convulsive activity which the vaccines precipitated. In either case, Dr. Tornatore believes that the vaccines caused [redacted's] seizure disorder. P's Ex. 23, at 3.

Dr. Tornatore's CV is P's Ex. 22. He is an Assistant Professor in the Department of Neurology at Georgetown University Medical Center. P's Ex. 22, at 3.

Respondent filed an expert medical report from Dr. Russell D. Snyder, a board-certified pediatric neurologist, dated January 9, 2005. R's Ex. A. Dr. Snyder states that [redacted's] first documented seizures occurred years before the vaccinations at issue. Additional seizures occurred ten months after these vaccination, apparently associated with fever. The kindling which Dr. Tornatore described in his report is a laboratory phenomenon associated with animals,

but not humans. Dr. Snyder found it difficult to associate [redacted's] [redacted] vaccinations with seizures occurring 10 months later in [redacted]. R's Ex. A, at 2.

Dr. Snyder states that an important characteristic of epileptic seizures is their stereotypical nature. They can have bizarre features, but the features are relatively consistent from one seizure to the next, generally involving only a single body system and a single focus in the nervous system. "The unusual constellation of multiple and varied symptoms without objective signs which [redacted] displayed in the days and weeks following the immunizations in question would be unlikely manifestations of a seizure disorder," says Dr. Snyder. *Id.*

Dr. Snyder concludes that the vaccinations of [redacted] did not influence [redacted's] course or outcome. They did not cause a new seizure disorder. They did not significantly aggravate a pre-existing seizure disorder. [Redacted] did not have an acute or chronic encephalopathy. *Id.*

Dr. Snyder's CV is R. Ex. B. Attached to Dr. Snyder's opinion are four articles or excerpts from texts, mostly on the subject of kindling.

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 filed the following as court exhibits in this case:

C. Ex. #1: "Hypoglycemia" from "The Way Up" Newsletter.

C. Ex. #2: "Over Consumption of [Redacted] Causes Fatigue."

C. Ex. #3: "Panic Attacks" from The Analyst.

C. Ex. #4: "Pure, White and Deadly."

C. Ex. #5: “Snoring, Intermittent Hypoxia and Academic Performance in Primary School Children,” by M.S. Urschitz, et al., 168 *Amer J Respiratory & Critical Care Med* 464-68 (2003).

The first four exhibits show that many of the symptoms about which [redacted] complained ([redacted], mood swings, crying spells, blurred vision, sense of internal [redacted], fatigue, depression) occur in the context of excess consumption of [redacted].

The fifth exhibit shows that snoring in young children can lead to deficits in mathematics and spelling.

DISCUSSION

Petitioner does not allege a Table injury. Therefore, she must prove her allegations by causation in fact. To satisfy her burden of proving causation in fact, petitioners must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 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 not only show that but for the vaccine, [redacted] would not have had the injury, but also that the vaccine was a substantial factor in bringing about his injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

The medical records show that [redacted's] first [redacted] episodes occurred before [redacted], when Mrs. [redacted] told a doctor that [redacted] had some intermittent [redacted] episodes during his first hour of sleep. This was over three years before his [redacted] vaccinations.

On [redacted], Michael had an EEG. The history Mrs. [redacted] gave to Dr. [redacted] was that [redacted] had isolated twitching movements in his sleep. Dr. [redacted] wrote that these movements were variably associated with myogenic (of muscular origin) artifact. Dr. [redacted] found no epileptiform features on EEG. Thus, three years before his [redacted] after the vaccinations at issue, [redacted] was evaluated for muscular twitching in his sleep because his mother was concerned that these were seizures. But they were not seizures.

All three of petitioner's medical experts ignore these episodes of [redacted] and twitching that predate [redacted's] [redacted] vaccinations by [redacted] years.

In the evening of the [redacted] day after his [redacted] vaccinations, [redacted] told his parents about a vague sensation. He had [redacted] in his head lasting about 15 seconds, which occurred twice. He did not have any other complaints. He did not have fever. The information given to the pediatrician's office is that [redacted] had no behavior suggesting he had had a seizure, such as a postictal occurrence. His eyes were normal. The pediatrician diagnosed him with a habit tic.

[Redacted] weeks after the vaccinations at issue, Mrs. [redacted] was concerned about [redacted's] getting an x-ray from his dentist who might also possibly prescribe penicillin. At the time of her phone call to her pediatrician's office, she stated that [redacted's] head [redacted] occurred on [redacted], which was [redacted] days before the vaccinations at issue. The

pediatrician's office okayed [redacted's] receiving x-rays and penicillin as not being a seizure threat.

[Redacted] month after the vaccinations at issue, Mrs. [redacted] took [redacted] back to his pediatrician, complaining of [redacted's] emotional lability, photophobia, and irritability. She told Dr. [redacted] that [redacted] had crying spells whenever he ate [redacted]. However, he did well if his mother eliminated sweets from his diet.

Almost [redacted] months after the vaccinations at issue, [redacted] returned to his pediatrician, having had an episode of [redacted] the prior week. He still described [redacted] in his head and abdomen, but Dr. [redacted] noted no visible seizure activity.

Almost [redacted] months after the vaccinations at issue, [redacted] saw the pediatric neurologist, Dr. [redacted], who did a thorough examination, including of [redacted's] eyes, and concluded that although [redacted] had subjective complaints of tremor, objectively he was neurologically normal. Physical examination showed no sign of tremor. A 24-hour EEG done 10 days later was normal with one report of restless movement, but no EEG change.

[Redacted's] glucose at one point descended to 43 mg/dl. Dr. [redacted] advised exploring both [redacted's] endocrine situation (the excess [redacted] prompting his [redacted]) and his history of snoring and apnea (leading to abrupt movements in sleep). Even though Dr. [redacted], the endocrinologist who succeeded Dr. [redacted], at one point opined that [redacted's] symptoms were compatible with either hypoglycemia or seizures, the undersigned does not find the view of an endocrinologist that [redacted] may have had seizures dispositive on this point.

Mrs. [redacted] gave a history to Dr. [redacted] and Dr. [redacted] of [redacted's] having two brief seizures in [redacted], but she did not file with this court any medical records (visits to a doctor and/or emergency room, or any hospital admission) that would verify her assertion.

Mrs. [redacted] took [redacted] to an emergency room on [redacted] and gave a history that he had full body tremors at 1:40 a.m. Interestingly, she told the ER personnel that [redacted's] trembling stopped when his mother woke him.

On [redacted], Dr. [redacted] signed a report describing the first abnormal EEG [redacted] had ever had. But, in addition to the bifrontal hemispheric electrographic features of paroxysmal abnormality (which constituted the neurologic abnormality), [redacted] had frequent muscle movements that were not correlated with EEG findings (and were not indicative of neurologic abnormality). Dr. [redacted] put [redacted] on an anti-convulsive.

The undersigned finds little difference between [redacted's] pre-vaccination condition where he had two brief seizures as a toddler and intermittent leg movements that were not evidence of seizures during sleep, and his post-vaccination condition, where he continued movements in his sleep, and had possible seizures at least 10 months post-vaccination.

But, arguendo, if the undersigned assumes the neurologist Dr. Tornatore's opinion is valid that [redacted's] movements [redacted] days after the vaccinations at issue were seizures, what is the basis for believing that MMR and/or DPT caused them? Dr. Tornatore offers as a basis of causation that there are toxins in pertussis vaccine. This is the same testimony he gave before the undersigned in Brusewitz v. Secretary of HHS, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Spec. Mstr. Dec. 20, 2002), concerning DPT's causing afebrile seizures. The undersigned rejected Dr. Tornatore's testimony in that case. In the absence of fever or an acute

encephalopathy (a significantly decreased level of consciousness) during the time that the vaccinee has a seizure, the undersigned has not heard or read any credible evidence that DPT can cause an afebrile seizure.

The undersigned has never accepted that either whole cell or acellular DPT causes afebrile seizures. See Nanez v. Secretary of HHS, No. 02-1261V, 2003 WL 22434113 (Fed. Cl. Spec. Mstr. Sept. 23, 2003); Borin v. Secretary of HHS, No. 99-491V, 2003 WL 21439673, *11 (Fed. Cl. Spec. Mstr. May 29, 2003); Bruesewitz v. Secretary of HHS, supra; Clements v. Secretary of HHS, No. 95-484V, 1998 WL 481881 (Fed. Cl. Spec. Mstr. July 30, 1998); O’Connell v. Secretary of HHS, No. 96-63V, 1998 WL 64185 (Fed. Cl. Spec. Mstr. Feb. 2, 1998), aff’d, 40 Fed. Cl. 891 (1998), aff’d by unpub. opinion, No. 98-5134 (Fed. Cir., Nov. 1, 1999); and Haim v. Secretary of HHS, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Aug. 27, 1993).

The Institute of Medicine (IOM) also concluded that DPT does not cause afebrile seizures. Adverse Effects of Pertussis and Rubella Vaccines (1991). The IOM did a meta-analysis of febrile and afebrile seizures and concluded that “even pooling available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccination.” Id. at 115.

Dr. Tornatore’s assumption that Dr. [redacted] in his [redacted] Digitrace EEG report accepts that [redacted] had convulsions starting [redacted] days post-vaccination is strained and not merited by the report or Dr. [redacted’s] subsequent reports and letters.

The immunologist Dr. Bellanti’s opinion that the MMR vaccination exacerbated [redacted’s] pre-existing seizure disorder is similarly untenable because the undersigned does not

accept that [redacted's] vaccinations, including MMR, caused his symptoms occurring [redacted] days or weeks later. [Redacted] did not have a measles reaction. He had no fever, rash, or upper respiratory infection within five to 15 days following his MMR vaccination. Temporality alone does not justify a holding of causation in fact. See Hasler, supra.

Although petitioner has expressed no interest in relying upon the report of the emergency care physician Dr. Classen, a brief comment upon his opinion is necessary for the sake of completeness. Dr. Classen distorts Dr. [redacted's] notation in [redacted's] first visit to rule out possible partial complex seizures to mean that Dr. [redacted] diagnosed partial complex seizures, which he did not. Quite the opposite. Dr. [redacted] found that, although [redacted] complained of tremors, he had no tremors objectively. [Redacted] was normal neurologically. That medical literature states that both the pertussis and tetanus toxoid elements of DPT can cause seizures is not at issue. The issue is, in this case, did DPT cause [redacted] to have his symptoms and were those symptoms seizures? Dr. Classen's opinion is not helpful.

Respondent's neurologist Dr. Snyder states that he cannot see the connection between [redacted's] vaccinations on [redacted] and his first reported subsequent seizures [redacted] months later. (He accepts that [redacted] had seizures in [redacted].) He also opines that [redacted's] head [redacted] and tremors are not seizures.

Granted that petitioner may never know if [redacted] truly had episodic hypoglycemia because she refused to take his blood when he complained of [redacted], and [redacted] outgrew his enlarged adenoids that were causing his snoring and possibly his non-neurologic muscle twitching and shaking (which medical literature states can result in deficits in mathematics and

spelling), the undersigned holds that Michael's symptoms [redacted] days after his MMR, acellular DPT, and OPV vaccinations on [redacted] were unrelated to his vaccinations.

If, arguendo, [redacted's] symptoms [redacted] days after the vaccinations at issue were seizures, contrary to the opinions of [redacted's] pediatrician and pediatric neurologist, and the opinion of respondent's expert neurologist, the undersigned holds that the vaccinations at issue did not cause them because the purported seizures occurred without fever or an acute encephalopathy. There is no logical sequence of cause and effect that the undersigned in this case accepts that links DPT and/or MMR to a vague sensation or head [redacted] [redacted] days later in the absence of fever or an acute encephalopathy. Similarly, the undersigned holds that MMR did not cause [redacted's] symptoms [redacted] month later of irritability, easy crying when he ate [redacted], and photosensitivity, or exacerbate his pre-existing seizure disorder.

Petitioner has not presented a credible prima facie case that DPaT and/or MMR caused [redacted's] purported seizures or exacerbated his underlying condition.

CONCLUSION

Petitioner's 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.⁸

IT IS SO ORDERED.

DATE

Laura D. Millman
Special Master

⁸ 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.