OFFICE OF SPECIAL MASTERS
No. 99-656V
July 14, 2006

JACOB GONZALES, by his Father and next Friend, FIDEL GONZALES, Petitioner,	*	
v.	*	Hepatitis B vaccination followed by TM months later with intervening colds, fevers, and two or three seizures; no acute illness within appropriate temporal framework
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, Respondent.	*	

ORDER TO SHOW CAUSE[1]

Petitioner filed a petition dated August 5, 1999, under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., on behalf of his son Jacob Gonzales (hereinafter, "Jacob"), alleging that hepatitis B vaccine administered on May 28, 1997 caused him unspecified injury (ultimately, Jacob was diagnosed with transverse myelitis or TM). There are no records of

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

an acute onset of illness at the time of vaccination. Jacob began to develop intermittent fevers two weeks after an operation which itself occurred two weeks after the vaccinations. Jacob began to walk in January 1998, when he was 20 months old. The first appearance of Jacob's altered gait to a medical practitioner was February 14, 1998, nine months after vaccination. Progressive gait disturbance is not TM.

Petitioner is ORDERED TO SHOW CAUSE by September 1, 2006 why this case should not be dismissed.

FACTS

Jacob was born on May 24, 1996. Mrs. Gonzales' first child had cerebral palsy and seizures. Med. recs. at Ex. 1, p. 22. She had an abnormal placenta at about 24.2 weeks. *Id.* Jacob was Mrs. Gonzales' third child. Med. recs. at Ex. 2, p. 170. Jacob received his first hepatitis B vaccination on May 25, 1996. Med. recs. at Ex. 2, p. 167; Ex. 3, p. 4.

On May 30, 1996, Jacob was admitted to Flagstaff Medical Center for lethargy, temperature elevation, and poor feeding secondary to jaundice. Med. recs. at Ex. 2, p. 139. He was discharged on May 31, 1996. *Id.*

On June 14, 1996, Jacob saw Dr. Mark Seby with an upper respiratory infection. He appeared to be doing well. Med. recs. at Ex. 3, p. 24.

On July 31, 1996, Jacob returned to Dr. Seby. He had been doing well in the past month and appeared healthy. His extremities were normal. Med. recs. at Ex. 3, p. 23.

On October 4, 1996, Jacob received his second hepatitis B vaccination. Med. recs. at Ex. 3, p. 4. Jacob appeared happy and playful. He was developmentally normal. His extremities were normal. Med. recs. at Ex. 3, p. 23.

On October 11, 1996, Jacob saw Dr. Seby with yellow drainage from his nose once a day without fever, cough, or pulling at his ears. He was eating well, and alert, and active. Med. recs. at Ex. 3, p. 22.

On December 3, 1996, Jacob saw Dr. Seby with gastroenteritis. His extremities were normal. Med. recs. at Ex. 3, p. 21.

On December 12, 1996, Jacob received his third hepatitis B vaccination. Med. recs. at Ex. 3, p. 4. Jacob had been doing well over the past week, and appeared happy and healthy. His extremities were normal with good muscle tone. Med. recs. at Ex. 3, p. 21.

On February 7, 1997, Jacob saw Dr. Seby. He was doing well without problems. *Id.*

On May 28, 1997, Jacob received his fourth hepatitis B vaccination. Med. recs. at Ex. 3, p. 4. Jacob's parents denied that Jacob had any problems. He was cruising on furniture.

On June 16, 1997, Jacob was admitted to Flagstaff Medical Center for an undescended left testicle. Med. recs. at Ex. 2, p. 85. Dr. Nathan A. Benson, a urologist, took a history that Jacob was one year old and had a past medical history of being treated with phototherapy for hyperbilirubinemia at the time of birth. Otherwise, Jacob was a healthy male who took no regular medications and had no known allergies. A review of systems was essentially negative. He was well-nourished and well-developed, in no acute distress on examination. *Id.* On June 17, 1997, Jacob had surgery for an undescended left testicle and left inguinal hernia. Med. recs. at Ex. 2, p. 98.

On July 15, 1997, Jacob saw Dr. Seby with sinusitis. He had had nasal congestion for the prior few days and a low-grade fever. Med. recs. at Ex. 3, p. 20.

On July 30, 1977, Jacob saw Dr. Seby with diarrhea and fever. Mr. Gonzales said that Jacob had an intermittent fever as high as 101 or 102 for the prior five days. *Id.* He was not as active as usual. He moved all extremities. Med. recs. at Ex. 3, p. 19.

On August 8, 1997, Jacob was brought to Yavapai Regional Medical Center where Dr. Wade E. Kartchner noted in a History and Physical Examination that Jacob had a history of mild illness starting seven to ten days before coming to the ER. He had increased sleepiness, lethargy, and decreased appetite. He saw his primary care physician eight days earlier and was diagnosed with a viral illness. His fever was intermittent. Jacob had a tonic/clonic seizure that day, lasting five minutes. He was taken to the ER where his temperature was measured at 103°. He was somewhat unresponsive and sleeping even up to two hours in the ER. A CT was done which was normal. Med. recs. at Ex. 3, p. 89. Neurologically, Jacob had full range of motion, his deep tendon reflexes were equal and 3 to 4+ in both extremities. *Id.* Dr. Kartchner concluded Jacob had a febrile seizure secondary to a viral illness. Med. recs. at Ex. 3, p. 90.

On August 11, 1997, Jacob saw Dr. Seby. He had been ill for the prior three weeks with intermittent fever, and was brought to Yavapai Regional Medical Center with a high fever and a general seizure. Med. recs. at Ex. 3, p. 19. His lumbar puncture and head CT were negative. He had high lymphocyctes on CBC. He still slept a lot. He had had intermittent loose stools for the past two months. On examination, he appeared sleepy. *Id.* His extremities were normal. Med. recs. at Ex. 3, p. 18. Neurologically, he was intact. He moved all his extremities well and his muscle tone appeared good. Dr. Seby concluded that Jacob's CBC was consistent with a viral infection and recommended he see Dr. William J. Austin. *Id.*

Also on August 11, 1997, Dr. Austin wrote to Dr. Seby that he saw Jacob that day with a history of several weeks of occasional loose stools and some intermittent fever. On Friday, August 8, 1997, Jacob had a grand mal seizure. Lumber puncture and head CT scan were normal. Blood culture was negative. Mrs. Gonzales noticed that Jacob seemed tired over the last week. Physical examination was entirely normal. Med. recs. at Ex. 3, p. 121.

Also on August 11, 1997, Dr. Benson wrote Dr. Seby, stating that Jacob started having fevers about two weeks after his orchiopexy but there was no indication of a wound infection. He examined Jacob that day and he certainly seemed ill. Med. recs. at Ex. 3, p. 120.

On August 20, 1997, the Fire Department EMS/Rescue personnel were called because Jacob had a fever of 103° and a seizure. His fever rose to 104.7°. He was alert, agitated, and crying. Med. recs. at Ex. 2, p. 79. Jacob was brought to Flagstaff Medical Center on August 20, 1997. His seizure lasted about three minutes. Mrs. Gonzales told Dr. Sarah H. Hsia that Jacob had been ill over the past six weeks with low grade fever and malaise. Occasionally he had high fevers every several days. Two weeks previously, his temperature went to 103° and he had a febrile seizure. He was diagnosed with a viral illness. He had a low grade fever to 99.6° and malaise over the past week without symptoms of cold, sore throat, cough, or diarrhea. On August 19, 1997, he had a higher fever. Med. recs. at Ex. 2, p. 68. Jacob's temperature on admission was 101.6°. His tympanic membranes were fairly erythematous. *Id.* His extremities had good range of motion. Med. recs. at Ex. 2, p. 69. The clinical impression was febrile seizure, probable viral illness, although possible early otitis media. *Id.*

On August 20, 1997, Jacob also saw Dr. Seby. Med. recs. at Ex. 3, p. 18. Jacob had his second febrile seizure that day after his temperature went up to 105°. He had a possible ear

infection, but on examination, his tympanic membranes appeared normal. He was alert and playful. *Id.*

On August 21, 1997, Jacob saw Dr. Seby. He was playful and active with a temperature of less than 101°. Med. recs. at Ex. 3, p. 17.

On August 22, 1997, Dr. Seby talked with Mrs. Gonzales. Jacob had increased lethargy that morning. He was going to see Dr. Austin. *Id.*

On August 22, 1997, Jacob went to Flagstaff Medical Center. Med. recs. at Ex. 4, p. 22. Dr. Austin wrote that he had three to four weeks of intermittent fevers, usually low grade, but occasionally to 104°, general lethargy, and two febrile seizures. His lumbar puncture and head CT scan were normal. He had some mild liver function abnormalities which returned to normal. He had had an increase in lymphocytes on CBCs which had been persistent. *Id.* Dr. Austin concluded Jacob had fever of undetermined origin. Med. recs. at Ex. 4, p. 23.

An EEG was done on August 23, 1997 which was normal. Med. recs. at Ex. 2, p. 56. A brain MRI was done on August 24, 1997 which was negative. Med. recs. at Ex. 2, p. 54. Laboratory tests done on August 23, 1997 showed a protein of 33 mg/dl in Jacob's cerebrospinal fluid, a normal result. Med. recs. at Ex. 2, p. 49. Jacob was admitted to Flagstaff from August 22, 1997 to August 25, 1997. Med. recs. at Ex. 2, p. 37. A blood culture done on August 21, 1997 had some gram positive cocci in clusters. Med. recs. at Ex. 2, p. 34. He had an intermittent rash that was lace-like on his extremities which had cleared. *Id.* Jacob had an older sister who had multiple handicaps with seizures and a normal older brother. *Id.*

On August 27, 1977, Jacob saw Dr. Seby. He had a negative lumbar puncture, head MRI, and EEG during his recent hospitalization. He continued to have intermittent lethargy, mixed

with times when he was alert and appeared normal. He did not have his usual energy. He was eating and drinking well. Serum ammonium was slightly elevated. On examination, he was alert, happy, and in no distress. His extremities were normal. Med. recs. at Ex. 3, p. 17.

On September 10, 1997, Dr. Stephen D. Barbour, a specialist in pediatric infectious diseases, wrote to Dr. Austin that he saw Jacob that day in the outpatient clinic to evaluate his episodic illness with fever and sleepiness. His illness extended over the last two months. His development was entirely normal and he had not lost milestones. A blood culture done on August 21, 1997 showed an unknown organism. Med. recs. at Ex. 3, p. 118. On physical examination, Jacob was alert and active. He appeared quite normal. Med. recs. at Ex. 3, p. 119.

On February 3, 1998, Jacob saw Dr. Seby. He had been ill for the past day with several loose stools and with a temperature up to 103.4°. His fluid intake decreased in the past 24 hours. On examination, Jacob appeared tired. His extremities were normal. Dr. Seby concluded that Jacob probably had a viral gastroenteritis. Med. recs. at Ex. 3, p. 15.

On February 5, 1998, Jacob saw Dr. Seby with continued lethargy. He did not have diarrhea and was taking fluids better. On examination, he was alert. His extremities were normal. *Id.*

On February 14, 1998, Jacob saw Dr. Seby. He had a temperature of 103.4° that morning and his father thought he might have had a febrile seizure or that he was delirious. Jacob did not respond well, and his eyes rolled back for about 15 minutes. His parents gave him a sponge bath, his temperature came down, and he became more alert. "For the past week, Dad says he has been acting better, more active, walking. Yesterday he was walking and appeared fine." Med. recs. at Ex. 3, p. 14. Jacob appeared sleepy at times on examination, but at other times, he was alert. He

would walk reluctantly, and when he did walk, he walked slowly and cautiously. His extremities were normal. Neurologically, he moved all extremities well, without focal weakness or tremor. *Id.*

On February 26, 1998, Jacob saw Dr. Seby. He had been ill for the prior two days with fever up to 101°. He had been drinking well and was alert. He was still not walking well, would take a few steps if coaxed and if someone held his hand, but his gait was unsteady. He just started walking the prior month (when Jacob was 20 months of age). *Id.* On examination, Jacob was well-developed, alert, and quiet. His nasal mucosa were mildly inflamed. His extremities were normal. Dr. Seby observed Jacob walking. He could walk slowly, his gait was unsteady, and he needed someone to hold his hand. He definitely preferred to crawl. Dr. Seby suspected a recurrent viral infection causing Jacob's head congestion and fever over the past two days. He was concerned about Jacob's delay in walking and his unsteady gait. Med. recs. at Ex. 13.

On February 27, 1998, Mrs. Gonzales telephoned Dr. Seby. Jacob had been up all night coughing and had fever and green nasal drainage. He was taking liquids well and had mild, intermittent lethargy. *Id.*

On March 6, 1998, Jacob saw Dr. Theodore J. Tarby, a neurologist. He was slow in development, having just begun to walk at 20 to 21 months of age. He was becoming considerably more stable when he had a series of febrile illnesses, most likely viral in origin and associated with vomiting and diarrhea. During these episodes, he became stiff in his lower extremities and gave up the inclination to walk. He became quite immobile and stiff, as well as spastic in his lower extremities. Med. recs. at Ex. 10, p. 39. Dr. Tarby thought this might be ADEM, or TM, or a degenerative disorder such as Leigh's disease. *Id.*

Also on March 6, 1998, Mrs. Gonzales met with a social worker. Mrs. Gonzales was well-known to Children's Rehabilitative Services because of its long term involvement with her daughter Mia who died two and one-half months previously. Med. recs. at Ex. 10, p. 97. Mrs. Gonzales was concerned with Jacob's loss of developmental milestones, walking and sitting, his inability to change his position at times, since he had a series of viruses over the last few months. He had a similar episode over the summer and many tests were done, all of which were negative. *Id.*

On March 7, 1998, Jacob was admitted to the St. Joseph's Hospital and Medical Center because of progressive gait disturbance. He was discharged on March 12, 1998. Med. recs. at Ex. 2, p. 28; Ex. 3, p. 115. He had significant developmental delay. He did not begin to take independent steps until he was 20 months of age. His walking was quite stiff and effortful. He had a mild-to-moderate delay in language. He had a history of two or three seizures with fever. When he was 14 months of age, he had two febrile convulsions and possibly a third around 20 months of age. Over the past couple of months, he had developmental regression and deterioration. Jacob's parents were unable to date this in any specific way. Jacob could not maintain his balance and was unwilling to walk at all. His crawling became significantly impaired. *Id.*

Jacob's sister Mia had a very severe static encephalopathy evaluated in the first two or three months of life which in retrospect was felt due to antenatal ischemic injury to the brain with resultant severe cerebral palsy, developmental retardation, and intractable epilepsy. Med. recs. at Ex. 2, p. 29. Mia died in December 1997 as a result of either acute and/or chronic aspiration leading to respiratory failure. Jacob's brother is normal. *Id.*

On motor examination, Dr. John F. Kerrigan III found Jacob to have definite spasticity, more dramatically in the lower extremities in comparison to the upper extremities. Med. recs. at Ex. 2, p. 30. Deep tendon reflexes were brisk. Jacob crawled slowly whereas, as recently as two to three months earlier, he could crawl quite quickly. Dr. Kerrigan felt that Jacob has had a significant degree of static encephalopathy but also a recent onset of a clearly regressive or degenerative profile. He doubted that Jacob had TM or ADEM, but felt he might have a leukodystrophy or other progressive pathology such as a tumor. *Id.*

On March 8, 1998, Jacob had a brain MRI. Compared with the prior MRI of August 24, 1997, there had been no significant progression in the myelination of the white matter. Dr. C. Roger Bird concluded there was delayed myelination, plus mucosal thickening and inflammatory changes in the paranasal sinuses and the mastoid air cells. Med. recs. at Ex. 11, p. 154.

On March 9, 1998, a physical therapy initial assessment by A. Vappel Bargas revealed that Jacob had a history of neurodegenerative process with decreased standing and decreased crawling for two months. He had fever with seizures in August 1997. His parents stated he had lots of flus the last few months. Med. recs. at Ex. 11, p. 136.

Also on March 9, 1998, an occupational therapist Gina Petty noted Jacob had decreased gross motor ability specifically in walking and balance. His mother stated he had multiple flu/cold viruses in the past six months. Mrs. Gonzales stated, "He did well until he started getting sick so much, his legs go stiff, his balance seems off, he feeds himself with his fingers and uses a spoon." Med. recs. at Ex. 11, p. 138.

Jacob saw Dr. Barbour on March 10, 1998 for an infectious disease consultation. Med. recs. at Ex. 11, p. 113. Jacob had recurrent fevers which were intermittent, with sleeping a lot off

and on, and recent change neurologically over the last month with increased spasticity of his lower body and weakness. He was crawling fast, starting to walk, but had developmental delay with probable regression developmentally, particularly of his motor function. His cerebrospinal fluid had 14 white cells, all lymphocytes. He had a white blood cell lymphocytosis. His MRI showed diffuse white matter enhancement. Dr. Barbour saw Jacob in early September 1977 for his intermittent fevers, recurrent illnesses, and sleeping a lot. At that time (in early September 1997), Jacob did not have a neurologic abnormality, had good muscle strength, and seemed like a normal child. *Id.* Mr. Gonzales told Dr. Barbour that, in retrospect, at 10 months of age, when Jacob received vaccinations, including his fourth OPV vaccination, he seemed to change. *Id.* Dr. Barbour's impression was neurologic nonprogression, perhaps regression, of motor abilities although cognitively, he seemed well; motor developmental delay; white matter enhancement on MRI scan; CSF fluid with 14 white cells, which is elevated to borderline; and unexplained fevers. *Id.* Dr. Barbour also noted unknown illness, probably chronic, which could be metabolic in nature and seemed associated with fevers that were intermittent, sleepiness, and recent onset of motor regression. Jacob also had leg spasticity. Med. recs. at Ex. 11, p. 114. Dr. Barbour found Jacob's case very challenging and very difficult. *Id.*

An EMG and nerve conduction test on March 11, 1978 of Jacob showed no conduction delay or denervation changes. Med. recs. at Ex. 3, p. 116. MRI of Jacob's entire spine was normal. *Id.* Brain MRI when compared with a prior MRI of August 24, 1997 showed delayed myelination with no significant progression. *Id.* Discharge diagnosis was neurologic nonprogression with regression and likely leukodystrophy. Med. recs. at Ex. 11, p. 91.

A lumbar puncture on March 19, 1998 showed a protein count of 23 mg/dl in Jacob's CSF, a normal result. Med. recs. at Ex. 2, p. 23.

On March 20, 1998, Jacob saw Dr. Tarby. It appears there was an acute to subacute change in his lower extremity spasticity. An MRI scan of his brain was normal with the exception of a mild delay in myelination of the supratentorial white matter. The most likely diagnosis was TM. Med. recs. at Ex. 10, p. 37.

Jacob was at St. Joseph's Hospital and Medical Center from March 20 to 24, 1998. Dr. Kerrigan wrote that he was treated with high-dose intravenous gamma globulin for possible transverse myelitis. Jacob seemed to be developing completely normally until roughly 10-12 months of age. Over the past three months, he seemed to have lost motor milestones, particularly gross motor performance. He had not progressed in language and could not walk independently. He had great difficulties crawling. It was felt he had progressive paraplegia from an unknown cause. Recently, he had two spinal taps indicating a slight pleocytosis (total number of white blood cells was 14). Jacob had five days of high-dose IV Ig treatment. His neurologic condition remained unchanged. A repeat spinal MRI was normal. His condition might best be described as progressive non-familial spastic paraplegia. Med. recs. at Ex. 11, p. 222. Over the past week, Jacob had continued to deteriorate, particularly with decreased movement to the lower extremities. He held his legs quite stiffly with the toes rigidly pointing. He had not had any fevers. He had a good appetite. On examination, he was awake, alert, and visually intensive. He was smiling and playful much of the time. Med. recs. at Ex. 11, p. 225.

On March 21, 1998, Dr. Barbour saw Jacob to offer an infectious disease consultation. His impression was developmental delay, regression of one to two months, unclear diagnosis

with possible TM, CSF low grade pleocytosis, and delayed myelinization of the brain. Med. recs. at Ex. 11, p. 235.

A total spinal MRI was done on Jacob on March 21, 1998, and compared with a lumbar spinal MRI done March 10, 1998. The spine was normal. Med. recs. at Ex. 11, p. 254.

On April 2, 1998, Dr. Austin wrote to Dr. Seby that Jacob was hospitalized the prior week for IV gamma globulin which is the treatment for TM even though the diagnosis was still in doubt. The studies done were not definitive of any diagnosis. Dr. Austin's examination of Jacob revealed marked spasticity of the lower extremities with reasonably complete use of his upper extremities. There had been little progression in the last several weeks. Med. recs. at Ex. 3, p. 114.

On April 22, 1998, Jacob saw Dr. Seby with a runny nose. His eating and activity were normal. . Med. recs. at Ex. 3, p. 13.

On April 23, 1998, Dr. Seby telephoned Mrs. Gonzales. Jacob's nasal discharged had increased and his temperature rose. *Id.*

On May 12, 1978, Jacob saw Dr. Phillip W. Mack. According to Mrs. Gonzales, last summer, when he was starting to cruise along a couch, Jacob developed high fevers and weakness and never walked independently. He had an exacerbation of spasticity and loss of function in March 1998. Med. recs. at Ex. 10, p. 47.

On May 15, 1998, Jacob saw Dr. Tarby. Jacob had been evaluated for abnormalities of the immune function, and none had been found. Med. recs. at Ex. 10, p. 33.

On May 19, 1998, Jacob saw Dr. Seby with an upper respiratory infection. He had had nasal congestion and mild cough for the prior few days. His transverse myelitis was improving.

On examination, he was alert and moved his upper extremities well. *Id.* He was weak in the lower extremities. Med. recs. at Ex. 3, p. 12.

On September 9, 1998, Jacob saw Andrea Josephs, a pediatric occupational therapist, at the Arizona Department of Health Services. He had just begun to walk independently in February 1998 at age 21 months when he lost motor function in his lower extremities and was diagnosed with TM. He had been making a steady, but slow recovery. Med. recs. at Ex. 9, p. 3. Ms. Josephs' impression was significant delay in gross motor (on a nine-month level) and moderate speech delay (on a 20-month level). Med. recs. at Ex. 9, p. 4.

On September 21, 1998, Jacob saw Dr. Seby with a history of two days of runny nose and low grade fever. He ate and slept well. He was playful, but intermittently cranky. *Id.*

On December 14, 1998, Jacob saw Dr. Seby with conjunctiva of his right eye for the prior 24 hours. His cold symptoms from the prior week had resolved. *Id.*

On December 15, 1998, Jacob saw Dr. Seby with right ear pain and a temperature of 100.4°. His right eye appeared better. Med. recs. at Ex. 3, p. 11.

On December 28, 1998, Jacob saw Dr. Seby with anemia. He had been pale the past month and seemed more tired in the past two weeks. He ate well but was on a vegetarian diet. He still had weakness in his lower extremities, but crawled well. He had AFO braces bilaterally. On examination, he was alert, active, and crawling frequently on the floor. *Id.* Lab results on December 29, 1998 showed Jacob had mild anemia. *Id.*

On December 30, 1998, Jacob saw occupational therapist Josephs again. He had a diagnosis of possible TM. His motor development was slow but quality of movement was good. He began to walk independently in February 1998, at 21 months of age. Within a few weeks, he

lost motor function in his lower extremities and was not able to crawl. He had made steady but slow progress since March. He had full passive range of motion in his legs. He was often difficult to understand when he talked. Med. recs. at Ex. 3, p. 108.

On January 12, 1999, Dr. Mack at Flagstaff Medical Center examined Jacob. He noted Jacob had TM with onset in December 1997 and exacerbation in March 1998. Med. recs. at Ex. 3, p. 109. His lower extremities were stiff and spastic. *Id.*

On January 27 and February 10, 1999, Jacob was present for speech and language evaluation. He sat unassisted at 8 months of age, crawled at 8 to 9 months of age, walked at 20 months of age, and spoke his first true word at 9 to 10 months of age. He put two words together when he was 20 months of age. At 2 and ½, he used complete simple sentences. Med. recs. at Ex. 3, p. 101. Jacob had average receptive language skills, mildly delayed expressive language skills, and below average speech articulation skills. He had some oral motor deficiencies. Med. recs. at Ex. 3, p. 104.

On February 8, 1999, Jacob saw Dr. Seby with ear pain. Dr. Seby opined he probably had Eustachian tube dysfunction. Med. recs. at Ex. 3, p. 10.

On February 17, 1999, Jacob saw Dr. Austin. The etiology of Jacob's spasticity of his lower extremities and the specific diagnosis were in question for many months. Mrs. Gonzales is convinced that this was a reaction to his immunizations, but many, many studies have been done which have been inconclusive. Med. recs. at Ex. 10, p. 19.

On March 5, 1999, Jacob saw Dr. Seby with a febrile illness for the prior two days with intermittent fever. It was 103.2° two days before and 101° that afternoon. His tonsils were enlarged and red. Med. recs. at Ex. 3, p. 9.

On March 9, 1999, Jacob saw Dr. Jack K. Mayfield at the Phoenix Spine Center. Jacob was well until he was about 1 and ½ years old when he "apparently" had some immunization shots and then developed weakness of the lower extremities. (Jacob was 1 and ½ on November 24 1997; Jacob's fourth hepatitis B vaccination was administered on May 28, 1997, six months earlier.) Med. recs. at Ex. 3, p. 106. There was a question whether Jacob had leukodystrophy but the prevailing diagnosis was apparently TM secondary to viral etiology. Jacob lost the ability to walk, but had shown some improvement over the past number of months. On examination, Jacob had marked spasticity of the lower extremities with scissoring flexion of the knees and internal rotation of the legs with spastic equino varus deformities. He had unsustained clonus of both feet. Dr. Mayfield diagnosed spastic diplegia, and TM by history. *Id.*

On March 15, 1999, Jacob saw Dr. Seby with recurrent fever. In the past few days, his ears had become intermittently red with temperature elevation to 100°. He appeared tired. Med. recs. at Ex. 3, p. 8.

On March 25, 1999, Jacob saw Dr. Seby with recurrent fever. Jacob had been voiding frequently. *Id.* He seemed more alert in the past two days. He was alert and smiling. Med. recs. at Ex. 3, p. 7.

On March 30, 1999, Jacob saw Dr. Austin who noted weakness of his lower extremities with hypertonicity and somewhat less speech than is usual for almost three. However, he had enlargement of his cervical lymph nodes and some fluid by pneumo-otoscopy bilaterally. He had some swelling under the eyelids with some rhinitis. Dr. Austin thought it might be sinusitis or otitis. Med. recs. at Ex. 3, p. 100.

On March 31, 1999, Jacob saw occupational therapist Josephs. His expressive language had improved beautifully and he was using short sentences. He had been making slow progress in standing with support and using his legs separately. In the last month, he developed a fever similar to the initial fever which triggered his disability. It fluctuated and he had been more tired than usual. Med. recs. at Ex. 9, p. 7.

From April 9 to 13, 1999, Jacob was at St. Joseph's Hospital and Medical Center under the care of Dr. Stanley D. Johnsen. Dr. Johnsen's impression was fever of unknown origin, and residual TM. Med. recs. at Ex. 11, p. 14.

On April 10, 1999, Jacob saw Dr. Barbour. Jacob was diagnosed about a year before with TM and felt possibly to have some regressive form of neurologic problem but now seemed to be progressing. His TM was treated with IV immunoglobulin. His parents say he is tired, lethargic, and had waxing and waning temperatures. In March 1998, it appeared he might have a viral illness precipitating it. But he has had good neurologic development. Med. recs. at Ex. 3, p. 98. Dr. Barbour's impression was some unknown neurologic disease with good cognitive and developmental progression, prior diagnosis of TM which was treated, and intermittent fevers of unknown etiology. Med. recs. at Ex. 3, p. 99.

On April 11, 1999, Jacob had a brain MRI which showed improvement when compared to his March 8, 1998 MRI because his myelination pattern was normal. Med. recs. at Ex. 11, p. 6.

On April 15, 1999, Jacob saw Dr. Tarby, who agreed with Dr. Johnsen that there was an unusual fluctuation in Jacob's level of activity in association with relatively mild illnesses and temperature fluctuations that did not get to the febrile state. They did not know if this was a

definable condition. Dr. Johnsen raised the possibility of a mitochondrial myopathy. They disproved that condition in Jacob's sister Mia. Med. recs. at Ex. 10, p. 26.

On May 5, 1999, Jacob saw Dr. Seby with fever the day before of 103.2° and, that day, of 101.8°. He drank only a small amount of juice and rice milk. Dr. Seby diagnosed him with strep pharyngitis. *Id.*

On May 20, 1999, Jacob saw Dr. Seby with a cold. He had a fever of 100°. *Id.* Dr. Seby suspected viral pharyngitis. Med. recs. at Ex. 3, p. 6.

On August 27, 1999, Jacob saw Dr. Tarby. Jacob had spastic paraplegia, most likely secondary to cancerous myelitis. Med. recs. at Ex. 10, p. 24. Dr. Tarby discussed with Mrs. Gonzales the fact that Jacob had had no immunizations since he was one year of age. Mrs. Gonzales was convinced that the immunizations "were responsible in some way for his condition. I tried to do my best to explain to her that this was quite unlikely...." *Id.*

On November 19, 1999, Jacob saw occupational therapist Josephs. She states that in February 1998, he lost the use of his lower extremities probably due to an infection which affected his spinal cord. He had gradually improved and was walking with the aid of a walker and orthotics. Med. recs. at Ex. 9, p. 12.

Other Filed Material

Petitioner's wife Emily Gonzales (she is not a petitioner) executed an affidavit, dated August 8, 2000. Mrs. Gonzales states Jacob progressed well until shortly after his first birthday. She took him for his check-up on May 28, 1997 where he received DPT, HiB, OPV, and hepatitis B vaccinations. Within a couple of hours of his vaccinations, he seemed to be sleeping a lot more and required more naps during the day. He was different and often stared off far away for

long periods of time. Within two weeks of the vaccinations, he also started having stiffness in his right leg when he crawled. Med. recs. at Ex. 12, p. 1.

In August 1997, Jacob had a high fever, started shaking, rolled his eyes back, and grunted. They called 911 and the ER personnel told her Jacob had had a febrile seizure caused by a viral infection. When they brought Jacob home, he developed a chronic fever and extreme lethargy. She had trouble waking him to eat. He had to drink from a baby bottle to obtain fluids. Jacob had a sharp decline of his skills in the summer of 1997. Med. recs. at Ex. 12, p. 2. By early March 1998, Jacob was paralyzed from the waist down, had terrible trunk control, and could not pull himself up or roll over. He could not crawl. Just a couple of weeks before this time, he had started to walk. He was 20 months old and had been delayed in his walking because he was so tired. Med. recs. at Ex. 12, p. 3.

DISCUSSION

This is a causation in fact case. To satisfy his burden of proving causation in fact, petitioner must offer "(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 1274, 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...."

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 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, Jacob would not have had TM (if that is what Jacob had), but also that the vaccine was a substantial factor in bringing about his TM. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In Stevens v. Secretary of HHS, No. 99-594V, 2006 WL 659525 (Fed. Cl. Spec. Mstr. Feb. 24, 2006), the undersigned ruled that hepatitis B vaccine can cause TM and did so in that case. Respondent's expert, Dr. Roland Martin, testified that the appropriate onset interval, if a vaccination were to cause an acute reaction, would be a few days to three to four weeks. *Id.* at *18.

In the instant action, Jacob's onset of fevers and malaise (but not neurologic illness) was in July 1997, over one month after his fourth hepatitis B vaccination. Jacob's contemporaneous medical records do not indicate he had an acute illness the day of or within two weeks of his hepatitis B vaccination, contrary to Mrs. Gonzales' affidavit. Jacob's illness was chronic, proceeding over months with intermittent fevers and two or three seizures. These intermittent

fevers and seizures were not TM. Mrs. Gonzales states in her affidavit that within a couple of hours of his vaccinations, he seemed to be sleeping a lot more and required more naps during the day. She states Jacob was different and often stared off far away for long periods of time. She also states that, within two weeks of the vaccinations, he also started having stiffness in his right leg when he crawled. None of this is in any medical record. There are medical notations in 1998, more than one year after the events to which Mrs. Gonzales alludes, that Jacob was ill at ten months of age (two months before his one-year vaccinations) or one year. But the contemporaneous medical records do not record any illness in May.

On June 16, 1997, the first medical record after Jacob's May 28, 1997 vaccinations, Jacob entered the hospital for surgery that he had on June 17, 1997 for an undescended left testicle and left inguinal hernia. Dr. Nathan A. Benson took a history on June 16, 1997 that Jacob was one year old and had a past medical history of being treated with phototherapy for hyperbilirubinemia at the time of birth. Otherwise, Jacob was a healthy male who took no regular medications and had no known allergies. A review of systems was essentially negative. He was well-nourished and well-developed, in no acute distress on examination Nothing in those records conveys that Jacob was ill, that he was a different child in the prior two weeks, that he slept more, stared off in the distance, and had a stiff right leg. Dr. Benson notes in a different record that Jacob's fevers began two weeks after this operation, which would put onset of his fevers (but not any neurologic condition) at the end of June or beginning of July 1997.

On July 15, 1997, Mrs. Gonzales took Jacob to his pediatrician Dr. Seby. Jacob had sinusitis for the prior few days and a low-grade fever. Mrs. Gonzales did not convey to Dr. Seby that Jacob was ill within hours of his vaccinations or that he slept more, was staring off in the

distance or had a right stiff leg when he crawled. Considering the numerous visits to Dr. Seby that Mrs. Gonzales made with Jacob, it is not credible that she would have omitted details that conveyed, as she put it in her affidavit, that Jacob was a different boy after his vaccinations.

On July 30, 1997, Mrs. Gonzales took Jacob to his pediatrician Dr. Seby because Jacob had diarrhea and fever for the prior five days. Jacob was not as active as usual. He moved all extremities. If Jacob had a stiff right leg, it is astounding that Dr. Seby never discovered this or Mrs. Gonzales never told him of it during Dr. Seby's examination of Jacob.

On August 8, 1997, Jacob went to Yavapai Regional Medical Center where Mrs. Gonzales told Dr. Kartchner that he had a history of mild illness starting seven to ten days before coming to the ER. He had increased sleepiness, lethargy, and increased appetite. Neurologically, Jacob had full range of motion, his deep tendon reflexes were equal and 3 to 4+ in both extremities. If Jacob's right leg were stiff, Dr. Kartchner would have discovered this.

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).

The undersigned can only conclude that the reason Mrs. Gonzales did not give any doctor a history that Jacob was a different child within two weeks of his one-year vaccinations is that his subsequent lethargy, fevers, and eventual walking difficulties occurred over a span of time beginning two weeks after his June 17, 1997 surgery. The first medical notation for low-grade fever and nasal congestion was July 15, 1997. The first notation for higher temperature was July 30, 1997. The first notation of increased sleepiness and lethargy was August 8, 1997. Some time in July 1997, Jacob began to change with intermittent fevers, sleepiness, and lethargy. This is over a month after his vaccinations and does not constitute an acute reaction to his May 28, 1997 vaccinations. Jacob did not manifest in neurologic difficulties until early 1998.

Jacob did not begin to walk until he was 20 months of age (January 1998). The first notation of progressive gait disturbance is in the February 14, 1998 notes of Dr. Seby. Motor delay followed by progressive gait disturbance is not TM. Jacob's progressive gait disturbance did not occur until nine months after Jacob's fourth hepatitis B vaccination.

The undersigned does not believe that petitioner will find an expert to opine that hepatitis B vaccine caused Jacob intermittent fevers that began over a month after vaccination. The undersigned also does not believe petitioner will find an expert to opine that hepatitis B vaccine caused Jacob progressive gait disturbance nine months after vaccination.

Petitioner is ORDERED TO SHOW CAUSE why this case should not be dismissed by **September 1, 2006.**

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master