

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 99-669V

Filed: August 23, 2007

DR. ROBERT G. and JACQUELINE K. *
SHARKEY, as parents and natural *
guardians of RYAN REID SHARKEY, *

Petitioners, *

v. *

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

Respondent. *

Hepatitis B vaccine followed by
hypotonia; inflammatory
myopathy

ORDER TO SHOW CAUSE¹

Petitioners filed a petition dated August 5, 1999, on behalf of their son, Ryan Reid Sharkey (hereinafter, "Ryan"), under the National Childhood Vaccine Injury Act, 42 U.S.C. §300aa-10 et seq., alleging that hepatitis B vaccine administered on June 7, 1995 and August 22, 1995 caused Ryan to suffer adverse effects. Pet. at 1. Petitioners allege that shortly after Ryan

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.

received his first hepatitis B vaccination, he became hypotonic and began to have difficulty feeding. Dr. Wes McRae of the Mayo Clinic, stated that the theory behind Ryan's hypotonia was that the hepatitis B vaccination was related to the development of neurologic sequelae.

Petitioners are ORDERED TO SHOW CAUSE by **Monday, October 22, 2007** why this case should not be dismissed.

FACTS

Ryan was born on May 28, 1995.

Ryan was the product of a normal pregnancy except that Mrs. Sharkey went into preterm labor at 33 ½ weeks gestation. Med. recs. at 1013. She was thereafter placed on Terbutaline. *Id.* At delivery, Ryan was intubated due to a small amount of meconium present below the cords and a moderate amount from the stomach and nares. Med. recs. at 1015.

On May 31, 1995, Ryan saw his doctor at three days of age. Mr. and Mrs. Sharkey described Ryan as an angel during the day and a terror at night. Med. recs. at 18. She would breast feed for two to four hours. Ryan was to have a repeat of his bile test after the first results came in. *Id.*

On June 7, 1995, at the age of 10 days, Ryan received his first hepatitis B vaccination at his two-week well-child visit during which Ryan was described as being well. Med. recs at 16, 20; Ex. A attached to petition.

On June 26, 1995, Ryan visited Dr. Irwin Kash because he was crying all day and had been crying for five previous days while awake (putting onset of crying at June 20, 1996). He did not cry when nursing or sleeping. Ryan was described as waking up screaming which continued all day. His body was rigid and his extremities straight. He would pull his hair and

was consolable for only up to 20 minutes. Med. recs. at 15. On examination, Ryan was alert and calm. His head, ears, eyes, nose, throat, neck, and lungs were normal. His abdomen and extremities were normal. The doctor diagnosed him with probable colic. *Id.*

On August 2, 1995, during Ryan's two-month checkup, he was noted to be sleeping for long periods of time at night and had a decrease in muscle tone. Med recs. at 14. He had an increase in head lag, but normal deep tendon reflexes (DTRs). Mrs. Sharkey had mastitis three days previously and Ryan seemed cranky and less interested in feeding since then. Mrs. Sharkey took Augmentin. *Id.* The doctor diagnosed hypotonia and failure to thrive. *Id.*

On August 4, 1995, Ryan saw Dr. Kash again for a follow-up regarding his weight. Med. recs. at 13. Dr. Kash noted that Ryan's hypotonia had persisted. *Id.* Ryan would breastfeed for two to three hours. He would sleep 10 hours at night. Ryan did not call out to eat. The doctor diagnosed persistent failure to thrive and hypotonia. *Id.*

On August 9, 1995, Dr. Kash saw Ryan for another follow-up on his weight. *Id.* Ryan had excellent eye contact. His weight had increased three ounces in three days. *Id.*

On August 10, 1995, Ryan was seen by Dr. John D. Osterman at the request of Dr. Kash. Med. recs. at 895. The history notes that Ryan appeared normal for the first eight weeks or so of life (approximately the end of July 1995). Then over a two-day period of time, he seemed to become sleepy and hypotonic, and stopped sucking and feeding well. *Id.* The sleepiness resolved, but the hypotonia and the poor breast feeding persisted. *Id.* Weakness was noted to be proximal, involving shoulder and hips more than distal extremities. *Id.* There was no apparent illness at the time of the decline, such as intercurrent fever, runny nose, cough, vomiting, or diarrhea. There was also no constipation or pupillary dilatation. *Id.* Ryan remained alert and

sociable. He would smile receptively, laugh, and coo. He would bat at a mobile and even grasp at objects. *Id.* Family history was negative for neuromuscular disease, other than a paternal great aunt with polio. Med. recs. at 896. Specifically, there was no history of nerve or muscle disease, developmental delay, or seizures. *Id.* Ryan's height was in the 75th percentile, his weight in the 15th percentile, and his head circumference in the 35th percentile. General examination was remarkable for Ryan's thin habitus and generally depleted and flabby muscle mass. He was in no acute distress. Neurologically, Ryan was alert and bright-eyed, and he tracked and smiled receptively. His cry was weak and bottle feeding not vigorous. *Id.* He did not cough, gag, or choke. He handled secretions fine. Pupils were equal, round, and full. He did not have nystagmus or ptosis. Neck musculature was markedly decreased with poor head control and marked head lag on traction response. Truncal weakness was noted on ventral suspension. Appendicular tone was decreased with decreased proximal movement and more spared distal movement of the extremities. DTRs were difficult to elicit in the upper extremities, 1-2/4 at the knees and ankles. Moro and grasp reflexes were present and symmetric. Grasp was strong. Tonic neck reflex was absent on either side. Positive support reflex and strep reflex were absent. *Id.* Dr. Osterman felt that, at this point, there was no clear involvement of the central nervous system, but rather a disorder of the motor unit. Med. recs. at Ex. 897. A diagnosis of exclusion would be benign congenital hypotonia. Med. recs. at 897.

On August 11, 1995, Dr. Kash saw Ryan for another follow-up visit. Med. recs. at 13.

On August 14, 1995, Dr. Kash notes that Ryan had gained weight tremendously in the prior two days with an increase of almost three ounces. Med. recs. at 12. Ryan was sociable and

extremely alert, but all the physical findings of hypotonia persisted. He was thought to have benign congenital hypotonia because of his alertness and his normal DTRs. *Id.*

On August 22, 1995, Ryan received his second hepatitis B vaccination. Med. recs. at 20; Ex. A attached to petition..

On August 31, 1995, Ryan was seen by Dr. Osterman for a follow-up regarding his hypotonia. Med. recs. at 893. Dr. Osterman reported that a number of studies had been obtained and showed mildly elevated CPK with normal isoenzymes; moderately elevated LDH with normal isoenzymes; negative UA; mildly elevated lactic acid; normal heart size and vascularity; normal EKG; negative stool culture for *Clostridium botulinum*; and normal thyroid function. *Id.* Dr. Osterman also noted that the exam showed proximal muscle weakness and hypotonia, but that Ryan had improved since he was seen three weeks earlier. His head control had some improvement. He was more active with his arms and legs. He was very sociable. He laughed, smiled, and cooed. He was alert and bright-eyed. He could track by turning his head as well as moving his eyes. His height was in the 80th percentile, weight in the 25th percentile, and head circumference in the 40th percentile. *Id.* He had also improved in feeding and weight gain. Ryan's DTRs were normal and symmetric. Med. recs. at 894.

On September 5, 1995, Ryan was referred by Lee Memorial Health Systems Rehabilitation Department to the Early Intervention Program for a developmental evaluation. Med. recs. at 343. Ryan presented with low energy, but had excellent tracking and visual exploration. Med. recs. at 342-43. According to his performance on the Bayley Scales of Infant Development, Ryan's motor quality factor score was non-optimal due to his low muscle tone and physical weakness. Med. recs. at 343-44.

Also on September 5, 1995, Ryan visited Dr. Margie Morales with the Early Intervention Program. The medical records note that Ryan was doing well until approximately six to eight weeks of age when the parents noticed that he did not want to feed or suck and slept most of the night. He began losing weight and was evaluated. He seemed to be weak but there was no evidence of gagging, choking, ophthalmoparesis, or ptosis. Med. recs. at 346. There had been no recent illness, fever, hospitalizations, allergies, accidents or blood transfusions. His diet consisted of breast milk plus supplement and Polyose. His immunizations were up to date. His hearing and vision were good. Med. recs. at 347.

On September 21, 1995, Ryan had been vomiting for the prior two weeks, becoming worse in the prior six days. He had vomited six times over the past five days. He was afebrile and fussy prior to vomiting. Med. recs. at 11.

On October 5, 1995, Ryan was still having trouble with his feeding, but he was “acting fine.” *Id.*

On October 6, 1995, the medical records note that Ryan had been vomiting for three weeks. Med. recs. at 10. He was not taking formula or breast milk well. *Id.* Ryan had been using medicine for thrush. Mrs. Sharkey had tried Mylanta but that had also made him vomit. *Id.*

On October 8, 1995, Ryan had taken 17 1/4 ounces of formula on October 7th. He took eight ounces on October 8th and then vomited. Ryan was acting a little more sleepy, but fine otherwise. *Id.*

On October 9, 1995, the medical records note that Ryan “seems okay.” *Id.* He had taken 18 ounces the day before. Mrs. Sharkey was giving him soy and cereal. *Id.*

On October 16, 1995, Ryan was referred to Dr. Jose Javier Muniz, a pediatric gastroenterologist, for poor feeding and an episode of hematochezia. Med. recs. at 879. Ryan had a history of hypotonia of undetermined etiology. Ryan's intake the prior day and the day before was only a little over 12 ounces a day. *Id.* Gastroesophageal reflux and esophagitis were thought to be a strong possibility, and Ryan was started on Carafate and Propulsid. The possibility of intussusception was entertained and a barium enema was done and found to be negative. *Id.* Dr. Javier Muniz thought Ryan's feeding refusal and hematochezia were two separate problems. Med. recs. at 880. He started to refuse feedings a couple of weeks before he was put on Isomil. After he was on Isomil for four days, he developed mucousy, bloody stools, possibly indicating colitis. His hematochezia resolved since he went back on cow's milk formula. His refusal to eat and history of vomiting might indicate GER with esophagitis. *Id.*

On October 17, 1995, Ryan was admitted to the pediatric intensive care unit at Lee Memorial Hospital because of a congenital myopathy and aspiration with cyanosis. Med. recs. at 671. The history as reported by Dr. Eduardo Riff, the consulting physician, was that Ryan started to develop hypotonia at approximately two months of age. At that time, Ryan presented with difficulty feeding. Since that time, he has had a slowly progressive decrease in muscle tone. *Id.* Around October 1, 1995, Ryan was noted to have some arching episodes and not wanting to feed. These episodes only occurred during feeding. Ryan would also have some crying and some apparent agitation. It was remarkable because Ryan rarely cried or became agitated. *Id.*

According to the Discharge Summary, Ryan was seen on routine follow-up by his pediatrician at two weeks of age, and at that time the pediatrician had remarked to his colleagues that the child appeared to be hypotonic. Med. recs at 657. In the few weeks prior to the hospital

admission, Ryan had had poor oral intake and no weight gain. *Id.* The day of the hospitalization, Ryan was given Carafate, which was started for possible gastritis as the cause of the decreased oral intake. *Id.* Ryan was seen to aspirate on the medication and was immediately brought to his father who is an ER physician. Ryan appeared to be diffusely cyanotic and diaphoretic, with nasal flaring, grunting and choking. By the time Ryan reached the emergency room, he was in much better shape. Med. recs. at 667. Upon admission, Ryan was intubated for respiratory failure associated with pronounced hypercarbia and metabolic compensation. Med. recs. at 658. The neurologic exam remained remarkable for pronounced weakness and hypotonia. *Id.*

According to the history and physical records taken by Dr. Kash on the day of admission, Ryan had been known to be hypotonic since the first couple of weeks of age. Med. recs. at 664. On October 17, 1995, Dr. Osterman provided a neurology consultation per Dr. Kash's request, and noted that Ryan was a four-month-old infant male with a history of pronounced hypotonia since birth. Med. recs. at 667. Dr. Osterman also noted that Ryan was last seen by him six weeks previously. Ryan had been making steady gains prior to that visit and for the first two weeks subsequently. Over the past three to four weeks, he developed new problems, however. First, he developed postprandial emesis for which reflux precautions and thickened feeds were instituted. Over the past three weeks, his oral intake had been poor, decreased from 21 to 15 ounces daily with only an increase of three ounces body weight over the prior three weeks. *Id.* Dr. Osterman's impression was that Ryan had a congenital muscle disease and questionable gastroesophageal reflux/esophagitis. Med. recs. at 892.

On October 18, 1995, Cathy Maxwell, a speech pathologist, saw Ryan as requested by Ryan's pediatric gastroenterologist, Dr. Jose Muniz-Quinones. Med. recs. at 733. She reported

that Ryan had been admitted to the Children's Hospital at Healthpark, Florida after an episode of choking. She stated that, most notably, he had been hypotonic since the first few weeks of age but the source of this neuromuscular disorder had not been diagnosed at this time. *Id.*

On October 23, 1995, Dr. George Kalemeris sent a letter to Dr. Rebecca Flokerth at Brigham and Women's Hospital requesting her review of Ryan's muscle biopsy. Med. recs. at 678. Per Dr. Kalemeris' history, Ryan was a four-month-old infant with a history of pronounced hypotonia since birth and suspected congenital muscle disease. Ryan has had difficulty feeding and developed an episode of aspiration. Ryan was immediately brought by the father who is an emergency room physician to the hospital where Ryan was noted to be diffusely cyanotic and diaphoretic with nasal flaring, grunting, and choking. *Id.*

On November 24, 1995, Ryan's DNA was tested for changes found to be associated with spinal muscular atrophy (SMA). Med. recs. at 949. The test found that Ryan has at least one intact SMN gene. Ryan could be among the 2% of children with SMA that do not have deletions of both SMN genes. Alternatively, he may have a disorder other than SMA. Id.

On December 10, 1995, Ryan was transferred to the Mayo Clinic in Rochester, Minnesota. Med. recs. at 735.

A December 10, 1995 neuropsychiatric record from the Mayo Clinic notes that Ryan was screaming at four weeks with the possibility of colic. He was evaluated then and may have been hypotonic. His crying resolved. He was definitely hypotonic at two months and seen by a neurologist at two and one-half months who suspected myopathy. Med. recs. at 754.

The Mayo Clinic Dismissal Summary notes that Ryan was transferred from Fort Meyers, Florida via air ambulance for EMG and muscle biopsy for evaluation of a neuromuscular

disorder. At approximately two months of age, Ryan was noted to be hypotonic with poor head control and body tone. He was evaluated by a neurologist at two and one-half months of age who suspected a myopathy. At three months of age, he was noted to have proximal hypotonia and weakness with marked involvement of neck and trunk, upper extremities more involved than lower, and very poor reflexes. Med. recs. at 812. At four months of age, he continued to be hypotonic with associated developmental delays and gross motor skills. He was admitted to the hospital and intubated on October 18, 1995 for possible aspiration after given a medication, and he became cyanotic. He had reached and surpassed catch up growth. Over the last two weeks, the parents thought Ryan was improving in strength. He was kicking, and could raise his arms off the bed. *Id.*

On December 15, 1995, Ryan was transferred back to Lee Memorial Hospital. Med. recs. at 910. At this time, Ryan was tolerating continuous gastrostomy tube feedings with good, consistent weight gain. Due to a poor response to steroids, Ryan was given Intravenous Gamma Globulin (IVIG) over the course of five days. After the five days of therapy, Ryan was placed on a weekly dose of IVIG. *Id.*

On February 4, 1996, Ryan was transferred to Children's Memorial Hospital in Chicago, Illinois. Med. recs at 42.

On February 7, 1996, Ryan's differential diagnosis included myositis, post Guillain-Barré Syndrome, and chronic inflammatory demyelinating polyneuropathy (CIDP). Med recs. at 45. An MRI of the cervical and thoracic spine taken on 11/17/95 and an MRI of the brain taken on 10/20/95 showed no abnormalities. Med. recs. at 201. A review on February 6, 1996 of a

muscle biopsy done at the Mayo Clinic was remarkable for inflammation. The muscle showed a mild amount of myopathic change. Med. recs. at 212.

On February 14, 1996, Ryan was scheduled to have chromosomal studies done for Prader Willi syndrome. Med. recs. at 68. The results of this testing were negative for Prader Willi, but there was the suggestion that Ryan's parents have DNA studies done to rule out uniparental disomy, if clinically indicated. Med. recs. at 190.

On February 19, 1996, Ryan underwent a tracheostomy and GT replacement. Med. recs. at 75-78. At this time, Ryan was an 11-month-old male with a two-month history of progressive muscular weakness and ventilatory failure. Multiple muscle biopsies and diagnostic investigations had failed to reveal a diagnosis. Ryan had failed to extubate and wean from a ventilator after several attempts. A tracheostomy was deemed necessary due to Ryan's ongoing need for ventilatory support. Med. recs. at 236.

On February 23, 1996, a care conference was held where the doctors agreed that no diagnosis could be given with complete certainty, but that GBS was the most likely diagnosis. Med. recs. at 95.

In the March 12, 1996 transfer summary, it is noted that Ryan's discharge diagnosis from the Children's Memorial Hospital was hypotonia of unknown etiology. Med. recs at 131. The history states that Ryan received hepatitis B vaccine at 10 days of age. At the beginning of the fourth week of life the mother reported that he began crying constantly and was thought to have colic. By the fifth week of life, he was noted not to be feeding as well. *Id.* By two months of age, he appeared floppy and seemed to have lost the small amount of head control that he had gained. At four months of age, he was failing to thrive with significant decrease in amount of

feedings. At approximately five months of age, he had an episode of aspiration. Shortly afterwards, he required intubation secondary to respiratory failure and hypotonia. *Id.* An extensive work-up was performed which ruled out congenital myopathies, myasthenia gravis, and mitochondrial interim abnormalities. A muscle biopsy at Mayo Clinic showed minimal inflammatory processes so that Ryan was started on IVIG and Prednisone. *Id.* The discharge summary notes that there was concern about the relationship between hepatitis B vaccine and the development of Ryan's neurologic sequelae. This could not be completely supported but was the theory behind this hypotonia. Med. recs. at 31.

On March 12, 1996, Dr. Wes McRae, the attending pediatric neurologist, wrote a Neurology Summary letter and stated that Ryan had received his regularly scheduled second hepatitis B vaccine and appeared to do well until one to two weeks later. His parents reported an acute onset of irritability and inconsolability lasting a few days. There was no evidence of an infectious process at that time and the episode was assumed to be colic. Med. recs. at 136. He seemed to recover. However in retrospect, the parents noted his crying changed and he eventually had difficulties feeding. There did not appear to be gross hypotonia or weakness at that time from the parents' recollection. *Id.* Dr. McRae notes in this letter that evidence for the possible diagnosis of GBS was the "occurrence after immunization (seen with GBS)." Med. recs. at 138. He concluded that, after a great deal of debate and discussion the diagnosis of GBS must remain a diagnosis of exclusion absent direct evidence. Med. recs. at 140. However, he noted that Ryan's nerve conduction velocities and CSF protein were normal. Med. recs. at 138.

On March 13, 1996, it is noted in the progress notes that “Ryan should not have any live virus immunizations at all.” Med. recs. at 143. [Hepatitis B vaccination is not a live virus vaccine.]

On March 13, 1996, Ryan was transferred back to Lee Memorial Hospital. Med. recs. at 884. The consultation record notes that no specific diagnosis was confirmed by the Mayo Clinic. The possibility of GBS or some mixture of GBS and an inflammatory myopathic process due to an autoimmune response was posed. *Id.* In another report, Dr. Eduardo Riff notes that Ryan “was seen on routine follow-up by the pediatrician at two weeks of age and was noted to be somewhat hypotonic at that time.” Med. recs. at 887. Dr. Osterman saw Ryan on March 13, 1996 at Lee Memorial Hospital at the request of Dr. Riff and diagnosed him with neuromuscular weakness and hypotonia of unknown etiology. Med. recs. at 884. It was felt that Ryan was too weak for the degree of inflammation found on the Mayo Clinic muscle biopsy to call what he has a primary inflammatory myopathy. *Id.* Ryan continued to be alert and appropriate for age. Med. recs. at 885. He had pronounced hypotonia and weakness about the neck, trunk, and upper extremities greater than lower extremities, proximal greater than distal in distribution. There was complete head lag on traction response. There was poor truncal support when Ryan was placed in a sitting position. His DTRs were absent in the upper extremities but present and normal in the lower extremities. His plantar responses were flexor bilaterally. Ryan’s severe neuromuscular disease of unknown origin appeared non-progressive. His poor breathing was thought due to inefficient respiratory status rather than a primary neuromuscular basis. *Id.* Ryan’s knee jerks were clearly evident and normal. Dr. Osterman believed his ankle jerks were present and normal. *Id.*

On March 21, 1996, Ryan was discharged from Lee Memorial Hospital. Med. recs. at 904.

On April 17, 1996, Ryan saw Dr. Osterman. Med. recs. at 882. He had some improvement in spontaneous activity over the past month. *Id.* He made mouthing movements and said Dada. He imitated facial movements and would give a high-five and play patty cake and peek-a-boo. He used a pop-up toy effectively. He was alert and playful. Med. recs. at 883.

On January 27, 1997, Dr. Osterman wrote a letter to Dr. Jean Aicardi at Miami Children's Hospital requesting his assistance in evaluating Ryan. Med. recs. at 850. Dr. Osterman stated he first saw Ryan at two and one-half months of age because of hypotonia and difficulty feeding. "It is not clear how normal or abnormal his motor function was prior to that, though I do believe that there was some concern on the part of the primary physician following the two-week routine exam." *Id.* Dr. Osterman states that when he first evaluated Ryan at two and one-half months, his reflexes were absent in the upper extremities, one to 2/4 in the lower extremities, and gradually became more brisk, actually developing a few beats of clonus at the ankles over many months. Med. recs. at 851. Ryan never developed a sensory level or bowel or bladder dysfunction. *Id.* At the Mayo Clinic, an EMG showed classic changes of a rather severe myopathy. *Id.* Muscle biopsy showed an active inflammatory myopathy. *Id.* Ryan did not make functional progress on IVIG and did not benefit under Prednisone. Med. recs. at 852. At Children's Memorial Hospital in Chicago, Ryan's muscle MRI was normal with no evidence of inflammation. *Id.* EEG and BAER were normal. MRI of brain, cervical and thoracic spine were normal. Ophthalmologic examination was normal. Repeat nerve conduction studies and EMG were normal. *Id.* Ryan was too weak clinically for the relative paucity of inflammation found on

the Mayo Clinic muscle biopsy to call what he had a primary inflammatory myopathy. B-cells and other markers for myositis were unremarkable. *Id.* Dr. Osterman summarizes Ryan's case by stating that Ryan "is a 20-month-old infant who, in retrospect, was already showing signs of hypotonia and weakness beginning at two weeks of age and feeding difficulties by two months of age, followed by need for ventilatory support by four months of age." *Id.* On examination, Ryan showed profound, diffuse hypotonia and weakness, except for his ankles where his tone is increased and clonus intermittently elicited, while areflexic in the arms and hyporeflexic at the knees. His toes are downgoing bilaterally. He was at the 95th percentile for height, 75th percentile for weight, and 50th percentile for head size. *Id.*

Petitioners mention in their petition at paragraph 29 that Ryan saw Dr. Aicardi on February 27, 1995, but they have not filed this record (or the undersigned has not found it in the medical records).

Petitioners mention in their petition at paragraph 33 that Ryan saw Dr. Harold G. Marks on May 10, 1999, but they have not filed this record (or the undersigned has not found it in the medical records).

DISCUSSION

This is a causation in fact case. To satisfy their burden of proving causation in fact, petitioners 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, 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).

Petitioners must show not only that but for the vaccine, Ryan would not have had whatever he has, but also that the vaccine was a substantial factor in bringing about whatever he has. Shyface v. Secretary of HHS, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

In the instant action, at three days of age, Ryan’s parents regarded him as a terror at night. Thirteen days after his first hepatitis B vaccination which was administered at 10 days of age, Ryan was screaming all day, but not when he nursed and not when he slept. His pediatrician diagnosed him with probable colic. At Ryan’s two-month well-baby visit, his pediatrician diagnosed him with hypotonia and failure to thrive. His mother had had mastitis three days before and, since then, Ryan had lost interest in eating. His deep tendon reflexes were normal. Dr. Osterman, who was the first pediatric neurologist to see Ryan,, diagnosed benign congenital

hypotonia by exclusion. He saw no clear involvement of the central nervous system, but rather a disorder of the motor unit. He subsequently diagnosed Ryan with a congenital muscle disease.

The undersigned is aware that Dr. Wes McRae, a neurologist at the Mayo clinic, reached a diagnosis of exclusion of Guillain-Barré syndrome, but in light of Ryan's DTRs being normal at the time of the onset of his hypotonia, a diagnosis of GBS is unlikely. Moreover, Ryan's cerebrospinal fluid protein was always normal. The only solid diagnosis was inflammatory myopathy and this seemed not an explanation for Ryan's condition because of his clinical weakness. IVIG and Prednisone were not beneficial to him. Ryan's EMG and nerve conduction studies did not show demyelination. Because Ryan did not have a demyelinating disease, the findings of the Omnibus proceedings appear not to apply to his case.

Petitioners are ORDERED TO SHOW CAUSE by **Monday, October 22, 2007** why this case should not be dismissed. If petitioners intend to proceed with this case, they shall file Dr. Jean Aicardi's records for Ryan's February 27, 1997 visit (and any other visits to Dr. Aicardi) and Dr. Harold G. Marks' records for Ryan's May 10, 1999 visit. If these records are already in the massive volumes of records, petitioners shall identify where they are. If they are not in the volumes, petitioners shall file them by **October 5, 2007**.

IT IS SO ORDERED.

Dated: August 23, 2007

/s/ Laura D. Millman

Laura D. Millman
Special Master