In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 99-667V

Filed: October 16, 2007

JAMES P. MUSARRA, JR. and PATRICIA MUSARRA as parents and natural guardians of FRANKLIN MUSARRA,	*	
Petitioners,	*	
v.	*	Hepatitis B vaccination, followed by acute lymphocytic leukemia; neuropathy and areflexic bladder four months later; third hepatitis B vaccination followed one month later by UTI which ameliorated
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., alleging that hepatitis B vaccine caused an unspecified

[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.

adverse reaction. Petitioner is ORDERED TO SHOW CAUSE by December 10, 2007 why this case should not be dismissed.

FACTS

Franklin Musarra (hereinafter "Franklin") was born on April 30, 1990 and weighed eight pounds, nine ounces. Med. recs. at 2.

According to the records from Kings Bay Pediatrics, Franklin received his first hepatitis B vaccination on October 18, 1994. Med. recs. at 1. He appeared normal. Med. recs. at 10. His appetite was fair. Med. recs. at 13.

On November 24, 1994, Franklin received his second hepatitis B vaccination Med. recs. at 1. At the time, he was doing well and not having any problems. Med. recs. at 14.

On December 4, 1994, Franklin was admitted to Baptist Hospital. Med. recs. at 135. Dr. Arcenio Chacon noted that Franklin was a four-year-old child who was referred to him by Dr. Padama Gupta with a history of congestion, cough, and respiratory distress which gradually increased during the past week. His past medical history was unremarkable. The family history revealed that Franklin had two siblings who had viral illnesses, respiratory in nature, during the last few days. Med. recs. at 138. He had recovered from a URI two weeks earlier. Med. recs. at 206. On arrival, Franklin was agitated, grunting, and in severe respiratory distress. Med. recs. at 138. In the Emergency Room, it was noted that Franklin had a very abnormal chest x-ray with a very enlarged pleural effusion on the right side and a very small effusion on the left side. Med. recs at 135. The pleural fluid was tapped and sent for multiple studies. Franklin's initial white blood cell count was 53,000 with many atypical lymphocytes noted in it. He also had a mediastinal mass which was noted on the chest x-ray after the initial tap. *Id*. A consultation with

Dr. Gaghastani, a pediatric oncologist, was requested. His initial assessment was leukemia versus T-cell lymphoma. *Id*. Franklin underwent bone marrow aspiration on December 5, 1994 and also had a retap of the right pleural effusion. On December 5, 1994, Franklin was transferred to Jackson Memorial Hospital Pediatric Intensive Care Unit for chemotherapy. *Id*.

On December 6, 1994, Dr. Marianna Horn sent a letter to Dr. Gupta updating her on Franklin's progress. Med. recs. at 25. The letter states that Franklin was admitted to Baptist Hospital on December 3, 1994 for a one-week history of cough, decreased appetite, and progressive respiratory distress. *Id*. There was no history of fever. A chest x-ray at Baptist Hospital emergency room. revealed a marked right pleural effusion. *Id*. A follow-up chest x-ray showed a large upper mediastinal mass. Franklin was then admitted to the pediatric intensive care unit. Franklin's past medical history was totally unremarkable. *Id*. His immunizations were up-to-date and he had a history of varicella zoster infection. *Id*. A physical examination revealed a well-developed, well-nourished four-year-old male in no acute distress on two liters of oxygen by nasal cannula. *Id*. His chest had decreased breath sounds on the lower right with diffuse bilateral wheezing but very good air exchange. His abdomen was soft and tender, but he had a spleen palpable to the umbilical line and a liver four centimeters below the right costal margin. His CBC showed a white blood cell count of 53.9, with hemoglobin of 13.4 gm/dl, and a hematocrit of 40%. His platelet count was 245,000 with 95% blasts in the differential. *Id*.

On January 24, 1995, Dr. Horn wrote a letter to Dr. Gupta stating that Franklin had completed his month of induction chemotherapy and had had a bone marrow aspirate done on December 27, 1994 which showed a remission marrow. Med. recs. at 29. He then continued with chemotherapy with vincristine, and ara-c followed by asparaginase three times per week on

the week of December 30, 1994 and vincristine again with triple intrathecal chemotherapy on January 3, 1995. *Id*.

Thereafter, Franklin had an admission for fever and neutropenia with a urine culture positive for staph. epi. and otitis media in addition to an interstitial right middle lobe infiltrate. He was treated with vancomycin and ceftazidime and, on G-CSF, his counts improved promptly and he was discharged on January 15, 1995 on oral Macrodantin. *Id*.

He returned to the clinic on January 19, 1995 for re-admission for his first consolidation chemotherapy with intermediate dose of methotrexate and IV 6-MP which he was currently receiving. *Id*.

On March 15, 1995, Dr. Horn wrote a letter to Dr. Gupta regarding Franklin's progress. Med. recs. at 30. Franklin had begun the cyclic maintenance portion of his chemotherapy as of March 2, 1995. He was tolerating his treatment very well. *Id*.

On April 17, 1995, Franklin was admitted to Jackson Memorial Hospital for rehabilitation. Med. recs. at 20. A brief history states that Franklin had been diagnosed with acute lymphoblastic leukemia when he was hospitalized in December. *Id*. His stool cultures while in the hospital were positive for enterovirus. *Id*. He received chemotherapy in-house and was transferred to rehabilitation. *Id*. His strength actually worsened during the hospitalization involving his upper extremities somewhat. He was discharged on April 20, 1995 from pediatric rehabilitation. Med. recs. at 21.

On June 7, 1995, Dr. Horn wrote a letter to Dr. Gupta updating her on Franklin's progress. Med. recs. at 32. On March 20, 1995, Franklin presented to the out-patient clinic with a history of having been unable to walk for several days with buckling of his knees when he

stood up. *Id*. He complained of some tenderness but also of severe weakness with inability to bear weight. He related no history of paresthesias, and no history of back pain, other muscular pain, or weakness. *Id*. On physical exam, he appeared to have decreased deep tendon reflexes throughout with 4-5/5 strength in the bilateral upper extremities, with significantly decreased 2-3/5 strength in the bilateral lower extremities, and with decreased sphincter tone. *Id*. He was admitted and neurology was consulted. He had an MRI which showed no abnormalities. There were no changes consistent with demyelination. He had a lumbar puncture with CSF showing a glucose of 55, protein 19, white blood cells 2, none of which were blast cells and no red blood cells. *Id*. The myelin basic protein was normal. EMG showed a central polyaxonal pattern. It was the opinion of the neurologist that he might have Guillain Barré Syndrome (GBS) or that the defect might be secondary to myelopathy induced by intrathecal Methotrexate which is rare and unpredictable. *Id*. Franklin was continued on systemic chemotherapy but was not given further Vincristine or any further intrathecal chemotherapy. The doctors did vast literature searches and consulted multiple leukemia experts and it did appear that intrathecal Methotrexate was the cause of Franklin's neuropathy especially in light of the fact that despite several doses of gammaglobulin and the passing of approximately eight weeks, he had had no evidence of improvement, which one would expect with GBS. *Id*. Franklin's parents decided to continue Frank off his systemic chemotherapy. He was admitted to the hospital with neutropenia and fever. Med. recs. at 33.

On July 21, 1995, Dr. Richard Curless saw Franklin. Med. recs. at 34. The neurologic examination revealed an areflexic, flaccid paraplegia. Franklin had no loss of somatic sensation. He had poor bowel and bladder function, although his father noticed that Franklin's sphincter

control had improved slightly over time. Id. His upper extremities were thin, but appeared to be normal. He had no cranial nerve palsies. *Id*. Franklin had a complete work up during his hospitalization in an effort to discover the cause of his paraplegia. He was presented to a pediatric neurology conference to discuss the possible etiology. *Id*. The doctors were not in agreement as to whether this was a result of the leukemia, the intrathecal drug, or a severe motor neuropathy. *Id*.

Also on July 21, 2005, Rosemary De Mello, Frank's physical therapist, wrote a letter to Dr. Cullen. Med. recs. at 76. Her letter states that Frank was making steady progress with minor setbacks periodically due to decreased endurance as expected from chemotherapy. *Id*. However, she became very concerned during the July 10th week when she noted decreased activation in the gluteus quads and gastrocs. *Id*. Her major concern was muscle atrophy of both lower extremities as well as the decreased motion at the ankle. *Id*. She requested that Frank be seen by the pediatric orthopedist as soon as possible. *Id*.

On July 26, 1995, Franklin was seen by Dr. Robert Cullen for a neurology follow-up consultation. Med. recs. at 38. Franklin was the product of a full-term pregnancy born via a Caesarean section because of a prior Caesarean section with a birth weight of 8 pounds 12 ounces and a length of 19 ½ inches. *Id*. There was no active labor. No forceps were used. There was no premature rupture of membranes and no nuchal cord. *Id*. The intrauterine fetal activity was described as good. The neonatal period was unremarkable. As for illnesses, he had had varicella and roseola. *Id*. He did have a head injury at age two where he jumped off a bunk bed. He may have had a loss of consciousness. No x-rays were done. *Id*. He had a Mediport put in. He had a history of fracture of his right foot, and no allergies. *Id*. Growth and

developmental milestones show that he walked at nine months, sat at four to five months, used words by 14 months, sentences at two years old, and was toilet trained at two years old. *Id*. Franklin's family history showed his mother was living and well with a basal cell carcinoma. His father was living and well but he had hepatitis on two occasions. *Id*. There was a nine-year-old brother and a three-year-old brother both of whom were living and well. Significant family illnesses included the father's mother with hypertension and rheumatic fever, a paternal cousin with Down syndrome, the father and the father's mother with depression, and the father's mother with diabetes. Med. recs. at 39.

Around December 3, 1994, Franklin was diagnosed as having an ALL T-cell type of leukemia. He had been in remission since January 1995. *Id*. His last marrow was about nine weeks before and he was still in remission. *Id*. He had not had any central nervous system involvement. In early March 1995, they noted that he was dragging his left leg. Then he got progressively weaker and both legs became markedly weak. *Id*. He was incontinent. There was a question of some involvement of his upper extremities. *Id*. He had no difficulty breathing, swallowing, or chewing. Prior to this illness, he was ambulatory. *Id*. He did have a lumbar puncture. At that time, a younger brother had varicella and Franklin received SIG. *Id*. He was worked up at JMH and was felt to have GBS. An EMG was said to have been abnormal. He had physical therapy four days a week, and occupational therapy four days a week. *Id*. He had improved. His upper extremities were about 100%. He was still weak. He did not walk or crawl. *Id*. His bowel and bladder were a little bit better, but not completely normal. He did not have any sensory losses. At that time, he was treated with intravenous gammaglobulin. *Id*. Along the way, he had also received Vincristine, Cytoxan, Adriamycin, and Granucytic colony

stimulating factor. Physical examination showed Franklin to be a fairly adequately nourished, but thin five year old. Med. recs. at 40. The general physical examination showed that he had alopecia, probably related to his chemotherapy. He had a Mediport beneath the left clavicle. He had a markedly exaggerated lordosis[2] evident when he sat. *Id*. He had considerable atrophy of the musculature below the knee. There were no heel cord contractures. He had somewhat loose hip abduction. *Id*. There was a scar in the region of the occiput from a prior fall. Neurologically, he was alert and cooperative. *Id*. Motor examination showed a general decrease in muscle bulk with atrophy in the lower extremities. He had almost no movement in the lower extremities and could only wiggle his hips slightly. *Id*. The strength in the upper extremities was 5/5 bilaterally. Grasp, traction, and head control were reasonably good when being pulled to a sitting position. He did have the exaggerated lordosis when sitting to maintain his balance. When placed standing, he made no effort to bear weight on his feet. When placed in a crawling position, he was unable to crawl. A cerebellar examination showed fairly good finger-to-nose type movements. *Id*. He had no abdominal reflexes except for the left lower quadrant of the abdomen. He had no cremasteric reflexes. He did have what appeared to be a weak anal wink. *Id*.

On September 6, 1995, Franklin had a neurologic evaluation. Med. recs. at 66. On physical examination, his upper extremities had full active ROM, and fairly normal strength. His spine was normal and there was no tenderness. His trunk strength was fair. *Id*. The lower extremities revealed no motor function at the hips/knees/ankles. He had absent reflexes at the

---

[2] "An abnormal increase in the curvature of the lumbar and cervical spine as viewed from the side...." Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1067.

knees/ankles. He had 1 to 2+ over 4+ reflexes at the elbows/wrists, and vascular status was normal. *Id*. The impression was paraplegia, etiology under investigation.

On November 3, 1995, Franklin was seen for a routine follow up. Med. recs. at 16. He had been diagnosed as having acute lymphoblastic leukemia on December 3, 1994. Franklin had been under the care of oncologist Dr. Marianna Horn at JMH. He was in remission and required maintenance chemotherapy. Franklin apparently developed severe weakness of both lower extremities in March 1995 soon after he was exposed to his brother with chickenpox. *Id*. According to Mrs. Musarra, Franklin initially had some weakness of upper extremities also but that had improved and now he had only weakness of the legs. Franklin had very poor bladder and bowel control. He had had one episode of urinary tract infection in the past. *Id*. On physical examination, he was afebrile, in no distress, and alert. Both legs were flaccid and the muscles seemed to be atrophic in the legs. DTR was absent. Franklin had some tightening at both heels. Med. recs. at 17.

On March 6, 1996, Dr. Horn wrote a letter to Dr. Gupta updating her on Franklin's progress. Med. recs. at 42. He was doing well on his chemotherapy protocol. He had completed approximately 44 weeks of chemotherapy and in the last 5 months had been tolerating his chemotherapy well without major complications. He was continuing to receive physical therapy and was attending school. *Id*.

On April 9, 1996, Franklin was seen for a neurologic evaluation. Med. recs. at 66. He had tightness in the knees/feet. An examination revealed popliteal angle of zero degrees, and significantly increased tone in the hip flexors especially on the right. His feet were tight and he could barely get the left/right side to neutral. *Id*.

On May 20, 1996, Franklin had a physical therapy evaluation. Med. recs. at 105. The history stated that Franklin had T-cell acute lymphoblastic leukemia. Three months into his chemotherapy treatment, weakness developed in the lower extremities with subsequent paralysis. This was diagnosed as GBS, though his oncologist felt that it was Methotrexate[3] toxicity. *Id*. At the time, Franklin was participating in a chemotherapy program that was a three-week/six-week on/off program. Mrs. Musarra reported that Franklin's weakness developed rather quickly beginning in the feet (he was awkward in the morning) and within three days he could not walk at all. *Id*. He was hospitalized for 44 days in an attempt to identify the cause of the paralysis. *Id*. At this time, it was still unclear whether the true diagnosis was GBS toxicity secondary to the chemotherapy. *Id*.

On May 30, 1996, Franklin was seen for an evaluation at Miami Children's Hospital. Med. recs. at 67. He was progressing in terms of function but still had fairly dense paraplegia with no lower extremity function. *Id*.

On June 5, 1996, Franklin's casts were removed and new casts were applied. Med. recs. at 67.

On June 19, 1996, Franklin had developed blisters in the posterior aspect of both heels. Med. recs. at 68. He was still tight in the heel cords, which seemed to have developed after starting the half casts. *Id*.

---

[3] Methotrexate is a folic acid antagonist that acts by inhibiting synthesis of DNA, RNA, thymidylate, and protein. It is used as an antineoplastic in treatment of a wide variety of malignancies, including acute lymphocytic leukemia. Dorland's Illustrated Medical Dictionary, 30th ed. (2003) at 1144-45.

On July 9, 1996, the blisters had healed. Med. recs. at 69. He was to resume stretching and bivalve cast application. *Id*.

On August 2, 1996, Franklin was maintaining ankle motion, although the rigidity of the ankles was still there. *Id*. Motor return was beginning to be noticeable. *Id*.

On September 13, 1996, Franklin was progressing well and walking in his AFOs without much support. *Id*. His tone had increased, but his left side was still tight. *Id*.

On December 17, 1996, Franklin was progressing fairly well, although he still lacked strength more than fair minus to the lower extremities. *Id*. He was to continue aggressive physical therapy. *Id*.

On January 2, 1997, Franklin was admitted to Jackson Memorial Hospital for another course of chemotherapy. Med. recs. at 421. On the evening of admission, however, Franklin had a fever up to 103 degrees. Therefore his chemotherapy was held off and he was begun on antibiotics. Med. recs. at 422. The blood culture that was drawn at the time showed two days later a staph EPI bacteremia. Frank defervesced by day three and by day five, it was felt that Franklin's chemotherapy could safely be started. *Id*. He had no complications from his chemotherapy and the rest of his hospital course was uncomplicated. *Id*.

On January 23, 1997, Franklin was admitted for another round of chemotherapy. Med. recs. at 624. A physical examination revealed Franklin to be afebrile with stable vital signs. The rest of his physical examination was unremarkable, except for his bilateral lower extremity paralysis and muscle wasting. Med. recs. at 625.

On April 15, 1997, Franklin returned to Dr. Gupta's office for a follow up. Med. recs. at 18. He was walking in his walker and was doing extremely well. Med. recs. at 18. He had a trace of quadricep function, no motors below the knee, and weak function of the hamstrings. *Id*.

On May 19, 1997, Dr. Robert Shebert wrote a letter to Dr. Rosemarie Rine regarding Franklin's progress. Med. recs. at 44. Franklin was seven years old. He was status post chemotherapy for acute lymphocytic leukemia and had had a total of 26 months of therapy including intramuscular, intravenous, and intrathecal therapy. *Id*. He received methotrexate and intreathecal ara-C. Franklin had had subacute development of muscle weakness at which time, Dr. Shebert believed he may have had GBS due to a dysimmune etiology. *Id*. His vaccinations included hepatitis B shortly after which he developed his acute lymphocyte leukemia. His symptoms of GBS occurred approximately four months later. On examination, his mental status and cranial nerves were normal. *Id*. Motor examination revealed that his muscles were thin but strong in the upper extremities. In the lower extremities, he had rather dramatic leg weakness with iliopsoas and quads being 0-1/5. Hamstrings were not much better. Glutei were 1-2/5. He had some inversion of the foot and toes in the lower extremities but no other movement. Deep tendon reflexes were curious. *Id*. They were absent in the upper extremities and relatively hyperactive in the lower extremities. There was no Babinski response. *Id*. His gait was markedly affected and he used braces and a walker. *Id*.

On August 19, 1997, Franklin was seen for a follow-up visit by Dr. Gupta. Med. recs. at 18. He had problems keeping knee extension and with hyperlordosis of the lumbar spine. He was receiving regular physical therapy and was demonstrating progress. *Id*.

On October 28, 1997, Franklin was seen by Dr. Rine for a physical therapy evaluation. Med. recs. at 51, 49. She noted that his trace abilities were evident in calf musculature when he was attempting to maintain a sitting position on either a T stool or when sitting on a round therapy ball with weight bearing through the lower extremities. Med. recs. at 51. He was also able to maintain good weight-bearing through the lower extremities in these positions with verbal cueing to do so. Lower abdominal strength was continuing to improve and currently was in the fair plus to good range. His tolerance to electrical stimulation had also improved dramatically. *Id*.

On January 21, 1998, Franklin was seen at Kings Bay Pediatrics. Med. recs. at 2. As noted during this visit, Franklin's developmental history was normal until December 1994 when he was diagnosed with T-cell ALL. In March of 1995, he was diagnosed with GBS and had had lower body paralysis since. *Id*. This diagnosis was questionable. He had progressed slowly since then, going from a wheelchair to braces and a walker and was currently being trained with crutches. *Id*.

On April 2, 1998, Franklin was cleared for his vaccinations and received his third hepatitis B vaccination and second MMR vaccination. Med. recs. at 4.

On May 1, 1998, Franklin had a symptoms of a urinary tract infection for two to three days and a rash in his groin area. Med. recs. at 5.

On May 20, 1998, a handwritten note described a phone conversation with Franklin's father in which they discussed the hepatitis B vaccine regarding timing - one week prior to the diagnosis of ALL and now one month prior to recent UTI. *Id.* At the time of the phone call, the urine culture had cleared but Franklin's urinary incontinence persisted. Mr. Musarra questioned

whether Franklin had exacerbation of nerve damage in light of the recent reports on hepatitis B vaccine. *Id*.

On June 10, 1998, Franklin saw Dr. Trevor J. Resnick, a developmental neurologist. Med. recs. at 769. Dr. Resnick noted that Franklin was a previously healthy child who, in December 1994, was diagnosed with T-cell leukemia. He was treated according to protocol until March 1995 at which time he developed a subacute ascending paralysis. *Id*. He was on ARA-C hydrocortisone and intrathecal Methotrexate at that time. His weakness involved mostly the legs and to a lesser extent the arms. *Id*. Over a period of three to four months, he recovered totally in terms of his arms and trunk, but essentially was left a paraplegic with bowel and bladder symptoms. His control over bowel movements resolved and pretty much his bladder control also resolved, although he still had urgency and accidents. In April of 1998, he had a hepatitis B vaccination. For about one month after the vaccine, he had a worsening of his bowel and bladder symptomatology, which subsequently resolved back to baseline. Med. recs. at 770. He had had MRIs of the spinal cord which were normal, but no MRI of the brain. The current issue was whether the key to the intrathecal chemotherapy caused a myelitis or whether it was a secondary and unrelated autoimmune disorder or possibly an independent condition, such as either GBS or a polio-like syndrome in association with his altered immune status. *Id*. Of note was the fact that during his treatment regime, it was noted that he had a marked decrease in his immunoglobulins. *Id.*

Dr. Resnick examined Franklin and found that he had a normal general examination other than complete hypotonia of his lower extremities. *Id.* The presence of intact reflexes, intact sensory modalities, and devastating weakness was more consistent with a polio or GBS-like

syndrome. But it would be unlikely to be GBS because of Franklin's lack of recovery. He thought it was more likely a polio-like syndrome because of Franklin's residual deficits and the fact that he was immunologically compromised at the time of his symptoms. *Id*. Either way, he did not believe that Franklin's symptomatology was suggestive of any possible recurring autoimmune entity. *Id*. Furthermore, Franklin's MRIs did not show any patchy demyelination. *Id.*

On March 24, 1999, Franklin saw his pediatrician with the bladder and bowel problem of urgency. He often could not make it to the bathroom in time. Med. recs. at 7. He had leg braces and difficulty removing his clothing. *Id.*

Other Submitted Material

In addition to the medical records, Franklin's parents have submitted affidavits. P's Exs. B and C. The affidavits state that Franklin was a heathy, happy, and active boy. He began walking at nine months and thereafter learned to run. *Id*. On October 18, 1994, Frank received hepatitis B vaccination. *Id*. Frank had a chronic cough for the rest of October 1994 until the middle of November 1994. During this time, Franklin's appetite decreased and he complained of soreness in his arms. On November 24, 1994, Franklin received his second hepatitis B vaccination. *Id*. Within days of the shot, he began complaining of being extremely tired, experienced difficulty breathing, constantly attempted to clear his throat, and had a pain in his stomach. *Id*. On December 3, 1994, Franklin became unable to breathe, and Mrs. Musarra rushed him to the emergency room. Franklin's lungs had completely filled with fluid and a post-drain x-ray revealed a large upper mediastinal mass. *Id*. On December 4, 1994, Frank was diagnosed with T-cell lymphoblastic leukemia and was started on a two-and-one-half year course

of chemotherapy. On or about March 15, 1995, while Franklin was still undergoing chemotherapy, he began complaining of pain in his legs. *Id*. He gradually became weaker and by March 20, 1995, he was unable to walk. *Id.* Frank was admitted to the hospital where he was diagnosed with GBS with associated bowel and bladder incontinence. Over the next year, Franklin was able to regain control of his incontinence with only an occasional accident. *Id*. One year after chemotherapy was ended, Franklin was cleared to resume his immunizations. He received the third Hepatitis B vaccination on April 2, 1998. *Id*. Within a few days following this vaccination, Franklin became incontinent again. He must now wear diapers on a regular basis. *Id*. Urological testing has revealed that Frank can empty only half of his bladder when he urinates and he therefore frequently suffers from urinary tract infections. *Id*.

DISCUSSION

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 1317, 1325 (Fed. Cir. 2006), the Federal Circuit said "we conclude that requiring either epidemiologic studies, rechallenge, the presence

of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect is contrary to what we said in Althen...."

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).

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

This case was transferred to the undersigned on January 11, 2006. Also in January 2006, the undersigned was transferred the Omnibus proceeding concerning hepatitis B vaccine and demyelinating diseases such as GBS, MS, transverse myelitis, and chronic inflammatory demyelinating polyneuropathy. The undersigned ruled in the four paradigm cases that hepatitis B vaccine could cause demyelinating diseases (GBS, MS, TM, and CIDP) if the onset of the disease occurred within three to 30 days post-vaccination based on the testimony of petitioners' Dr. Vera Byers and respondent's Dr. Roland Martin.

Petitioners are ORDERED TO SHOW CAUSE why this case should not be dismissed for the following reasons:

1. Hepatitis B vaccine does not cause acute lymphoblastic leukemia.

2. The interval between Franklin's second hepatitis B vaccination and the onset of his neurologic difficulties was four months. This is three months beyond the period of time that the

undersigned has held is appropriate for linking vaccination to an autoimmune disease, based on the testimony of petitioners' expert Dr. Byers and respondent's expert Dr. Martin at the Omnibus proceeding.

3. Franklin's onset of neurologic difficulties in March 1995 arose in the context of his brother's having chickenpox. Franklin's immune system was already compromised by his ALL. Viruses, such as chickenpox, can lead to neurologic difficulties such as paraplegia and areflexic bladder.

3. Franklin's urinary tract infection which occurred one month after his third hepatitis B vaccination had resolved by the time Franklin saw Dr. Resnick, a neurologist, one month after the onset of Franklin's UTI, according to Dr. Resnick's June 10, 1998 record. If *arguendo* hepatitis B vaccine had caused a significant aggravation of Franklin's pre-existing areflexic bladder, the sequelae of that significant aggravation did not last for more than six months as the Vaccine Act requires for compensation. 42 U.S.C. § 300aa-11(c)(1)(D)(i). A subsequent record from his pediatrician in March1999 states that because of his leg braces and removing his clothing, Franklin sometimes could not make it to the bathroom in time. The undersigned has not seen any neurologist's report stating that Franklin's bladder problems are significantly worse neurologically after the third hepatitis B vaccination and because of the third hepatitis B vaccination.

Petitioners shall respond by **December 10, 2007** why this case should not be dismissed.

IT IS SO ORDERED.

Dated: October 16, 2007

/s/ Laura D. Millman
Laura D. Millman
Special Master