OFFICE OF THE SPECIAL MASTERS

No. 99-128V

(Filed: February 6, 2001)

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ANISSA BELL, by her Mother and Next Friend, JODELL BELL,	*	
Petitioner,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Ronald C. Homer, Boston, MA, for petitioner.

R. Lynne Harris, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

On March 12, 1999, Jodell Bell, on behalf of her daughter, Anissa Bell (hereinafter "Anissa"), filed a petition for compensation under the National Childhood Vaccine Injury Act of

1986[1] (hereinafter the "Vaccine Act" or the "Act"). Pursuant to 42 U.S.C. § 300aa-11(c), petitioner has satisfied the requirements that: (1) she has not previously collected an award or settlement of a civil action for damages arising from the alleged vaccine injury, and (2) DPT vaccination was administered to Anissa in the United States.

Petitioner initially alleged that Anissa had an on-Table encephalopathy and chronic nervous system dysfunction following her second administration of DPT vaccine. Subsequently, petitioner changed her allegation to causation-in-fact seizures.

A hearing was held on October 6, 2000. Testifying for petitioner were Mrs. Jodell Bell and Dr. Marcel Kinsbourne. Testifying for respondent was Dr. John MacDonald.

FACTS

Anissa was born on October 21, 1995. She was not discharged from the hospital until October 28, 1995. She had had decelerations and failure to progress. Med. recs. at Ex. 3, p. 6a. On November 6, 1995, she saw the pediatrician because she could not hold down formula. Anissa had gained three ounces between the date of discharge from the hospital and her visit to the doctor on November 6, 1995. Med. recs. at Ex. 4, p. 1. On November 10, 1995, her pediatrician Dr. Antonio E. Frias noted that Anissa was doing well, but was still throwing up. She gained six ounces in four days. Med. recs. at Ex. 4, p. 2. By November 13, 1995, she was spitting up less. Med. recs. at Ex. 4, p. 3.

[1] The statutory provisions governing the Vaccine Act are found in 42 U.S.C.A. § 300aa-1 et seq. (West 1991). The National Vaccine Injury Compensation Program comprises Part 2 of the Vaccine Act. For convenience, further reference will be to the relevant subsection of 42 U.S.C. § 300aa.

She received her first DPT at the age of three months on January 22, 1996. During her well-baby visit at four months of age on March 12, 1996, she was noted to have an upper respiratory infection (URI). On a chart listing milestones, her developmental milestones were circled: she had a social smile, put her hands together, laughed, held her head up 90°, and sat with her head steady. The only four-month skill that she did not have was rolling over, but she had two skills that were six-month milestones: reaching for objects and turning to a voice. P. Ex. 13, p. 2. She received her second DPT on March 12, 1996 at the age of four and one-half months. Med. recs. at Ex. 4, p. 4.

On March 13, 1996 at 6:52 a.m., Anissa was brought to the Wilford Hall Medical Center Department of Emergency Medicine (ED) because she had had a brief generalized seizure. She then had another one at the ED. P. Ex. 27, p. 3. The history given was that she had had URI symptoms for a few days beforehand, but here was no antecedent fever. That morning, she shook, stared, and turned blue, all of which lasted three to four minutes. Then, she returned to normal. Anissa's temperature at the ED was 102.5° F. P. Ex. 27, p. 2. On physical examination, she was happy, smiling, and non-toxic. Her pharynx was normal. Her second seizure lasted two and one-half minutes. Id. The assessment was apparent febrile seizure. The diagnosis was multiple febrile seizures. P. Ex. 27, p. 3.

While in the ED, Anissa had four seizures. P. Ex. 27, p. 3. Anissa was prescribed Tylenol to be taken every four to six hours, as needed. P. Ex. 27, p. 4. She was admitted to the Pediatric Intensive Care Unit (PICU). P. Ex. 27, p. 3.

The clinical record of March 13, 1996 indicates a history of present illness as recorded by the resident of the ED, Captain Maria W. Davison. Anissa was in her usual state of health until four

to five days earlier when she developed a runny nose (which ran clear) and chest congestion. At about 1:00 a.m. on March 13, 1996, she was noted to have trouble breathing, requiring bulbar suction to clear secretion. Mrs. Bell thought Anissa was cyanotic at the time, but she improved and went back to sleep. P. Ex. 27, p. 5.

At about 6:00 a.m., Mrs. Bell noticed that Anissa was having trouble breathing, her extremities were jerking, and she was staring, all of which lasted three to four minutes without loss of bladder or bowel control. She slowly came back to normal. In the ED, she had a temperature of 102.5°. She was about to be discharged when she had three seizures without return of consciousness between each seizure for a total of twenty minutes. Afterward, she was awake and alert. The ED doctor noted Anissa's eye movements with her seizures were deviated, sometimes to the left and sometimes to the right. At other times, she had no lateral nystagmus. There was no focal etiology or loss of bowel or bladder function. P. Ex. 27, p. 6. She vomited the previous day in the clinic. P. Ex. 27, p. 8.

On physical examination, Anissa's anterior fontanelles were flat. P. Ex. 27, p. 9. She had a positive yeast-like rash in her neck folds. Id. Her nose was clear with rhinorrhea. Id. Dr. Davison's impression was that Anissa's seizure activity was atypical for febrile seizures given their length and no increase in temperature afterward. There was no focality. Possible diagnoses included generalized seizure disorder, febrile illness, metabolic abnormality, and infection. She suspected a viral etiology. Anissa was admitted for observation. P. Ex. 27, p. 10.

The Nursing Admission Note of March 13, 1996, at 12:45 p.m., states that Anissa had her four-month immunizations the day before and had had URI symptoms. Anissa had two seizures lasting 30 to 45 seconds each. She had a third seizure lasting three minutes. Her temperature at the

ED was 102°. P. Ex. 27, p. 11. On March 14, 1996, the nurse removed thick green secretions from Anissa's nose with a bulb syringe. Anissa had multiple sneezing episodes. P. Ex. 27, p. 12.

The PICU staff notes of March 13, 1996, at 2:30 p.m., state that Anissa's recurrent seizure episodes had only a moderate temperature elevation. She had a normal neurological examination and no focal signs. P. Ex. 27, p. 14. A PICU resident's note of March 14, 1996, at 7:30 a.m., notes slight nasal congestion. P. Ex. 27, p. 15.

Col. William W.C. Young, a pediatric neurologist, wrote a consultation report entertaining possible etiologies including the effect of her pertussis vaccination since the seizure occurred within 24 hours of vaccination. He suggested avoiding pertussis vaccine in the future. P. Ex. 27, p. 22. On examination, she had normal bulk but a slightly decreased tone, manifested by head lag and poor traction when pulled to a sitting position. She had decreased right upper extremity movement. P. Ex. 27, p. 23.

Anissa was discharged on March 15, 1996. All her cultures were negative except her initial blood culture which was later negative. Her seizure was not consistent with a benign febrile seizure. She had mild hypotonia which could be due to a postictal state or anti-convulsants. She had decreased right upper extremity movement, which was due either to her intravenous site or Todd's paralysis (a postictal state). Her EEG was normal. On discharge, she moved all four extremities spontaneously but had head lag on pull to sit. Otherwise, she was normal. It was recommended that Anissa avoid further pertussis vaccinations. The discharge summary recommended Tylenol for temperatures over 100.4°. Additionally, it stated that Anissa was to return to the clinic for any further seizures, temperatures in excess of 101°, increased irritability, decreased appetite, decreased urine output or parental concern. P. Ex. 27, p. 21.

On March 26, 1996, Anissa was started on Phenobarbital secondary to recurrent seizure activity. She still did not roll over. Med. recs. at Ex. 4, p. 13. She had slight motor delay and positive tone as manifested by head lag. Med. recs. at Ex. 4, p. 13a.

On April 11, 1996, Anissa had an EEG which showed diffusely slow background and absent alpha rhythm, suggestive of global encephalopathy. Med. recs. at Ex. 5, p. 24.

On April 18, 1996, she had seven seizures. Six were staring episodes lasting 30 to 120 seconds. One was tonic-clonic lasting two minutes with color change to the lips and grunting. She had had seven seizures the day before. She was sleepy with a slightly decreased appetite. Dr. Young started her on Carbamezapine. Med. recs. at Ex. 4, p. 17. She had a prominent head lag with arm traction. An EEG showed a left temporal seizure for 29 seconds which was clinically confirmed. Med. recs. at Ex. 4, p. 17a.

On June 14, 1996, Anissa had an EEG which was abnormal and recorded epileptic activity from both hemispheres. Med. recs. at Ex. 5, p. 63. She was at Wilford Hall Medical Center from June 22 to 24, 1996 because of increasing frequency of seizure activity. She had had 16 seizures in the past 24 hours lasting 30 to 60 seconds, which were tonic-clonic. During the past week, she had had two to three seizures a day. Med. recs. at Ex. 5, p. 64.

An MRI was done on July 23, 1996 and interpreted by Captain Charles E. Johnson. Anissa's myelin was normal for her age (nine months), but not yet complete. She had decreased size of the frontal subarachnoid spaces. There was interval myelination of the peripheral occipital lobe white matter. P. Ex. 26.

An EEG done on August 19, 1996 showed moderate to severe global encephalopathy. Med. recs. at Ex. 5, p. 70. An EEG done on October 31, 1996 showed severe epileptic encephalopathy. At least some of Anissa's seizures emanated from her left occipital area. Med. recs. at Ex. 5, p. 79.

An MRI was done on September 8, 1998 (Anissa was two years and ten months old) and interpreted by Dr. Nikhil Patel. There appeared to be delayed myelination which could be secondary to a demyelinating or dysmyelinating process. Anissa's level of myelination seemed to be approximately that of a ten-month old. There were also findings consistent with minimal cerebral atrophy. The corpus callosum appeared to be slightly atrophied. P. Ex. 24.

On June 23, 1999, Anissa saw her treating pediatric neurologist, Dr. Young, who recorded that she had a three-year history of refractory seizures. She took continuous nighttime feedings through a G-tube, but refused to swallow liquids. She was unable to roll over or sit up without support. She had conjugate random eye movements and did not fix her gaze. She was vocally loud through the day and sometimes at night. She might have some vision. She had spastic extremities, but worse in the arms. Dr. Young diagnosed static encephalopathy, probably secondary to recurrent status epilepticus, with severe global developmental delays, recurrent seizures, but better controlled, bilateral spastic hemiparesis, microcephaly, mild visual impairment, and mild lumbar scoliosis. P. Ex. 19, p. 1.

Anissa had an MRI on June 23, 1999 at Wilford Hall Medical Center which was interpreted by Lt. Col. Christopher J. Lisanti,. Her peripheral frontal, temporal, and occipital white matter is not myelinated on the T2 sequences. Her temporal white matter is not myelinated on the T1 sequences. Her central white matter is myelinated appropriately. There is mild prominence of the cerebrospinal

fluid spaces, particularly the frontal horns, which may be secondary to atrophy. Dr. Lisanti's impression was delayed white matter myelination. P. Ex. 19, p. 4.

Dr. Young saw Anissa on January 3, 2000 in her home. She was having increased seizures, up to eight to ten per week. P. Ex. 19, p. 8.

Dr. Young wrote a letter dated March 1, 2000, stating that "[d]elayed myelination occurs when an insult to the developing brain occurs anytime from the second trimester of pregnancy (at 13 weeks gestation) up until about 8 months of age. . . . As a result, delayed myelination can occur from an insult to the fetus. . . or anytime within the first 8 months of age." Dr. Young thought that the two MRIs strongly suggest that Anissa's myelination pattern became abnormal after the onset of repeated episodes of prolonged seizures, i.e., status epilepticus, which began at age four months within the first 24 hours of her second DPT vaccination.

Dr. Young wrote that, because Anissa's first MRI was normal and her subsequent MRI was abnormal, showing delayed myelination, that would suggest her problems with delayed myelination did not occur before four months of age. That Anissa had normal well-baby examinations at ages two weeks, two months, and four months of age, with normal head circumference and developmental milestones, is further confirmation that her brain was normal prior to her second DPT vaccination.

Dr. Young stated:

> Myelin is the covering of the long axons of the neurons which make up the individual cells of the central nervous system. The process of myelination involves the production and laying down of this covering, which is used to enhance the transmission of electrical impulses along the axon of the individual nerves. Any kind of insult to the developing brain at the critical period of myelination can cause <u>delayed myelination</u>. Such insults include central nervous system infections, strokes, lack of oxygen, toxins, drugs, malnutrition, and uncontrolled seizures. [emphasis included]

P. Ex. 23.

TESTIMONY

Mrs. Jodell Bell testified first for petitioner. Tr. at 4. She used to live 20 to 25 minutes away from Wilford Hall Air Force Base Hospital where she went for treatment. Tr. at 6. When Anissa was born, she had hypoglycemia and was put on a drip. Tr. at 7. Anissa was really healthy, but spat up formula. *Id.* She had thrush in November 1995 for which she received medication. Tr. at 7-8.

Anissa had a cold but no fever three to four days before she received her second series of immunizations on March 12, 1996. Tr. at 9. Anissa was congested, had a runny nose and a cough. *Id.* Mrs. Bell gave her Tylenol, nasal saline drops, and suctioned her nose and mouth. *Id.*

They went to the doctor at 9:00 or 9:30 a.m. on March 12, 1996. Tr. at 10. The doctor examined Anissa and prescribed Tylenol. Tr. at 11. They went to the pharmacy for the Tylenol, then went to the immunization department. *Id.* Anissa received her inoculations around 1:00 p.m. and she and Mrs. Bell remained in the waiting room for 20 to 25 minutes to see if she had an adverse reaction. Tr. at 12. Afterward, Mrs. Bell bought groceries. *Id.*

Anissa felt warm in the car seat. *Id.* Mrs. Bell suctioned her. *Id.* She checked Anissa's temperature, but does not recall what it was except that she was warm. *Id.* It was not a high fever. Tr. at 13. They arrived home around 4:30 or 5:00 p.m. Tr. at 12.

Mrs. Bell gave Anissa Tylenol. Tr. at 13. Anissa was a little fussy, whiny, and cranky. *Id.* Mrs. Bell held Anissa for one to one and one-half hours to calm her. *Id.* Anissa calmed down and went to sleep at 6:00 or 6:30 p.m. without a bottle. Tr. at 13-14. Her normal bedtime was 7:30 to 8:00 p.m. Tr. at 15. She slept until 11:30 p.m. Tr. at. 14. It was unusual for her to sleep for five

hours. Tr. at 15. She would normally wake at 11:00 or 11:15 p.m. for a bottle. Tr. at 15-16. Anissa awoke at 11:30 p.m. with a strange stare. Tr. at 14. She was not blinking. *Id.* Her right arm and leg were elevated and her body stiff. Tr. at 17. This lasted two to three minutes. Tr. at 15. Mrs. Bell suctioned Anissa's nostrils and mouth, and she went back to sleep. *Id.* Anissa's breathing, which was loud, scared her. Tr. at 16. At about 11:45 p.m., Anissa had another episode, which lasted less than one minute. Tr. at 18. Mrs. Bell suctioned her nostrils and mouth. *Id.* Anissa went back to sleep. *Id.*

At 2:00 a.m., Anissa opened her eyes. Tr. at 19. Her right arm and leg elevated, her tongue clicked, her body jerked, and she grunted. *Id.* This lasted three to five minutes. *Id.* She went completely limp. *Id.* She was very warm at this time. *Id.* On the way to the emergency room, Anissa had a clicking noise. *Id.* Mrs. Bell pulled over to the side of the road. *Id.* The episode lasted two to three minutes. *Id.* At the emergency room, she was told that Anissa's temperature was 102 degrees Fahrenheit and that she was seizing. Tr. at 20. Anissa had a seizure in the emergency room and they gave her medication which stopped it. *Id.* She had three to four seizures when she was going to be discharged. Tr. at 21.

Mrs. Bell told the emergency room doctor that she had taken Anissa's temperature and she was feverish, and she also told him of the other episodes at home. Tr. at 29. Anissa had fever before she seized. Tr. at 25. In the emergency room, Anissa was limp and had fallen asleep. Tr. at 29. She denied that Anissa was happy and smiling on physical examination. Tr. at 30. Anissa remained congested until March 16, 1996. Tr. at 30-31. Her nose secretion was mucous, but not green or yellow. Tr. at 31.

Anissa still has seizures and fever precipitates them. Tr. at 22. Mrs. Bell gives her Tylenol or Motrin. *Id.* Occasionally, Anissa's seizures are afebrile, but the majority occur with fever. Tr. at 22-23. In 1996, half her seizures were febrile and half were afebrile. Tr. at 33. Anissa is delayed. Tr. at 62. She cannot roll over and does not walk. *Id.* She is like an early infant. Tr. at 63.

Dr. Marcel Kinsbourne testified next for petitioner. Tr. at 38. His opinion is that DPT caused Anissa's seizures and brain damage. Tr. at 40. His basis is that she had onset of fever followed by multiple seizures, including a 20-minute seizure, within 24 hours of her DPT. *Id.* She was given anti-epileptic drugs. *Id.* Anissa's seizures were unusually severe, and atypical in length and recurrence. *Id.* Dr. Kinsbourne opined that Anissa would have qualified to be part of the NCES or the National Childhood Encephalopathy Study (NCES).[2] *Id.* The association of her DPT with her seizures is well above chance. *Id.* He testified that the Institute of Medicine ("IOM") endorses this view.[3] Tr. at 41.

Anissa had clonic and tonic seizures. *Id.* Some of the time, she jerked, and other times, she was stiff. *Id.* The limbs were not doing the same thing at the same time. *Id.* Anissa has multiple seizure types. *Id.* The damaging agent is diffuse in its action over a period of time. Tr. at 42.

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[2] Alderslade, R., et al., "The National Childhood Encephalopathy Study, Whooping Cough: Reports from the Committee on Safety of Medicines and the Joint Committee on Vaccination and Immunization," 79-184 (London 1981). P. Ex. 28, Tab A. (Children with convulsions lasting more than 30 minutes were included in the study.)

[3] Stratton, K.R., et al., "DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis. A Report of the Committee to Study New Research on Vaccines," Pre-Publication Copy (Washington, DC, 1994). P. Ex. 28, Tab C. (There is a causal relationship between DPT and febrile seizures. Children experiencing serious, acute neurologic illness within seven days of DPT vaccination may have chronic nervous system sequelae. Id. at 8, 16.)

Dr. Kinsbourne testified that fever alone can lower the seizure threshold and cause seizures. *Id.* Fever here played the precipitating role. *Id.* Anissa's seizures were out of proportion in their severity and typicality. *Id.* Dr. Kinsbourne testified that DPT caused Anissa's fever. *Id.* She had had a runny nose for three to four days without fever. Tr. at 43. Her nose discharge was clear, indicating she had a probable virus. Tr. at 44. Dr. Kinsbourne's opinion is that Anissa's URI played no role in her seizure condition. *Id.*

When Anissa was in the emergency room, her fever was 102.5 degrees Fahrenheit. Tr. at 45. Seizures themselves may generate fever, but to do so, they must make considerable metabolic demands on the body. Tr. at 46. Brief seizures do not do so, but status epilepticus does. *Id.*

Benign, febrile convulsions are common. Tr. at 53. They are manifested by symmetrical jerking of the limbs and are not followed by more seizures or epilepsy. *Id.* Anissa did not have benign febrile seizures. *Id.* She had five febrile seizures, which were long, asymmetrical, and mixed. *Id.* She had complex febrile seizures, which are related to brain damage. Tr. at 53-54.

Anissa's 20-minute seizure did not stop by itself. Tr. at 54. She needed intravenous and rectal treatments to stop seizing. *Id.* This was the first time Anissa had had a fever. *Id.* But something in addition to the fever was going on. Tr. at 55. Anissa's fever indicates that DPT had an adverse effect on her. Tr. at 56. It lowered her seizure threshold. *Id.* Dr. Kinsbourne said DPT is known to cause fever, referring to the Cody article.[4] *Id.*

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[4] Cody, C.L., et al., "Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children," *Ped* 68:650-60 (1981). P. Ex. 29. Within three and six hours post-vaccination, 46.5% of the vaccinees had fever. Id. at 652. Nine convulsions were reported within 24 hours of vaccination, of which seven children had elevated temperatures. Children who manifested seizure activity were also noted to be either fussy or irritable. Id. at 653. The authors state, "Convulsions appear to be the most common more serious reaction observed following pertussis immunization." Id. at 656. They recommend that those who

Anissa's MRI scans do not help with a diagnosis. *Id.* Her 1996 scans were normal. *Id.* Her 1998 scan showed delay in myelination of the white matter (it is white because of myelin). Tr. at 61. Some of Anissa's seizures were severe and caused cumulative brain damage. Tr. at 57. In the alternative, DPT vaccine caused negative effects on the brain neurons she was not yet using. *Id.* White matter is under grey matter and sends information to the spinal cord. Tr. at 60. Dr. Kinsbourne would be surprised if Anissa's grey matter were normal. *Id.* Dr. Kinsbourne surmises that Anissa must have white and grey matter damage. Tr. at 63. Her seizures probably arise from her grey matter. *Id.*

Fever is so common after DPT that doctors prescribe Tylenol as an anti-pyretic. Tr. at 66. Fever was a substantial factor in Anissa's seizures as was the pertussis toxin, and Dr. Kinsbourne attributes Anissa's brain damage to both her seizures and DPT. Tr. at 65-67.

Dr. Kinsbourne interprets Mrs. Bell's telling the emergency room doctor that Anissa had no antecedent fever to mean no fever before she received her second DPT vaccination. Tr. at 72-73. It does not mean she did not have a fever after the vaccination and before she seized. *Id.* However, he admits it is ambiguous. Tr. at 72. Anissa was in the emergency room for three hours on March 13, 1996 and remained afebrile for the rest of her hospitalization, which is consistent with a DPT-caused fever, which peaks and resolves quickly, within less than 24 hours. Tr. at 73.

The NCES counted a series of recurring seizures as one seizure if the patient did not regain consciousness between the individual seizures. Tr. at 74. Thus, although Anissa had three seizures, Dr. Kinsbourne counts it as a 20-minute seizure because she did not have an intervening recurrence of consciousness between them. *Id.* He testified that if Anissa had not developed a fever after her

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experienced convulsions receive Dt vaccine in future. Id. at 657.

DPT vaccination, her condition would have been less severe. Tr. at 75. Fever facilitates seizures. *Id.* Fever alone can cause seizures but not seizure disorders. Tr. at 79.

DPT's toxic changes to her brain may not show up on MRI. *Id.* He had two explanations for Anissa's 1998 and 1999 MRIs: (1) DPT damaged her white matter which developed more slowly, i.e., her maturation decelerated, and (2) multiple seizures can destroy grey matter and, when grey matter is destroyed, white matter will be destroyed also. Tr. at 80-81. Grey matter destruction might not appear on an MRI. Tr. at 81. Her atrophy might be due to grey matter destruction. *Id.* Anissa's brain is not normal due to her grey matter. *Id.* Dr. Kinsbourne has no explanation for why Anissa was discharged from the hospital without medication. Tr. at 82.

Dr. John MacDonald testified for respondent. Tr. at 84. His opinion is that he does not think that Anissa had a fever before she seized based on the history Mrs. Bell gave in the emergency room that she had no antecedent fever. Tr. at 87. He attributes her temperature in the emergency room to the metabolic demands of her seizures, which can be tremendous. Tr. at 88-89. Three hours later, her temperature was normal. Tr. at 90. No medical record notes she had a fever before she seized. Tr. at 92.

Dr. MacDonald testified that fever is not relevant to Anissa's outcome. *Id.* Her seizures were not febrile seizures. *Id.* Anissa has chronic seizure and brain problems. *Id.* Fevers can cause isolated seizures but not epilepsy. Tr. at 93. He cited Dr. Nelson's Collaborative Perinatal Project which recorded 1400 febrile seizures. Tr. at 94. A small group had status epilepticus yet had normal intelligence.[5] *Id.*

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[5] Hirtz, D.G., Nelson, K.B., and Ellenberg, J.H., "Seizures following childhood immunizations," *Ped* 102:14-18 (1983). R. Ex. I. The authors followed 39 children who had post-vaccinal seizures. None developed epilepsy. Of the 39, 36 had fever after vaccination. In

Anissa has a disorder of the grey and white matter on MRI. Tr. at 95. Her seizures are a sign of grey matter involvement. *Id.* She has a multisystem disorder resulting in developmental problems. *Id.* Dr. MacDonald does not know the cause of her condition. *Id.* She has epilepsy whose onset was in the subsequent year following the onset of her seizures. *Id.* Wilford Hall Medical Center discharged her without medication because they assumed her brief seizures were without consequence. Tr. at 99. Epilepsy means recurrent seizures of any length. Tr. at 100. But recurrent seizures do not necessarily damage the brain. Tr. at 100-01. If they do damage it, they damage the grey matter in the area of the hippocampus. Tr. at 101.

If DPT had caused a toxic event in 1996, Anissa should have had some change in her grey matter on MRI from April or July 1996. Tr. at 101-02. To posit brain damage, Dr. MacDonald would need to see an acute encephalopathy and there is none here. Tr. at 103. Mrs. Bell's

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25, the fever was over 102° F. The authors state, "Pertussis antigen is a pyrogen; in addition, it is capable of causing histamine sensitization and the release of insulin. A rise in mean plasma insulin concentration has been documented in a small series of children following DPT immunization." Id. at 17. They note that "hyperthermia accelerates neuronal damage" as does hypoglycemia. Id. "Immunization with DPT, in addition to its pyrogenic effect, may cause a few children to experience hypoglycemia. A lengthy febrile seizure might be associated with hypoglycemia in those few attacks that are followed by lasting deficit." Id.

Respondent also filed four other articles: Berg, A.T., et al., "Childhood Onset Epilepsy With and Without Preceding Febrile Seizures," *Neur* 53:1742-48 (1999); Knudsen, F.U., et al., "Long Term Outcome of Prophylaxis for Febrile Convulsions," *Arch Dis Child* 74:13-18 (1996); Rich, S.S., et al., "Complex Segregation Analysis of Febrile Convulsions," *Am J Human Genetics* 41:249-57 (1987); and Kendig, E., et al., "Consensus Statement of the National Institutes of Health Consensus Development Conference on Febrile Seizures," *Ped* 66:1009-12 (1980). R. Exs. D, E, F, and G. In the last article, the preface states that there are two significant risks associated with febrile seizures: a 30 to 40% risk of recurrent febrile seizures and a slightly increased risk of later epilepsy. R. Ex. G, p. 1009. The first article states that "children who have experienced febrile seizures are at increased risk of developing later unprovoked seizures and epilepsy compared with children without febrile seizures." R. Ex. D, p. 1742.

description of Anissa's episode at 11:30 p.m. might have been difficulty breathing or a seizure. Tr. at 103-04.

In April 1996, a neurologist noted recurrent breakthrough seizures but no mention of fevers. Tr. at 104-05. The seizures came in clusters. Tr. at 105. This is a typical record of an epileptic child who has difficult to control seizures. *Id.* By June 1996, Anissa was on five medications. *Id.* Anissa is epileptic and has little chance of remission. *Id.*

The fever had no bearing on her seizures or chronological neurologic picture. Tr. at 106. From April to June 1996, her epilepsy was not related to fever. *Id.* Her 1998 MRI showed very mild change in her myelin. Tr. at 110. There are genetic diseases of myelin development. *Id.* This was not secondary to an acute insult on March 12, 1996. *Id.*

Anissa did not have status epilepticus in March 1996. Tr. at 111. She later developed innumerable status epilepticus episodes, which can cause damage and which her treating physician, Dr. Young, thought did cause damage. Tr. at 111-12. Dr. MacDonald thinks Anissa's status epilepticus is part of global brain damage rather than its cause. Tr. at 112. He disagrees with a subsequent diagnosis in the record that she had DPT encephalopathy. Tr. at 113.

Anissa had normal grey matter on MRI. Tr. at 112. Most epileptics have grey matter that does not work well, but no structural defects, i.e., anatomical damage. Tr. at 114. Anissa became microcephalic. Tr. at 115. Many children with recurrent seizures and chronic encephalopathy become microcephalic. *Id.* Dr. MacDonald does not know why this occurs. *Id.* However, Anissa's MRI from July 23, 1996 was normal. *Id.*

Anissa's white matter developed poorly later on, but this was a mild problem. Tr. at 116. Her developmental delay and seizures are clinical evidence that her grey matter does not work properly. *Id.* Normal MRIs did not reflect her abnormal clinical state. Tr. at 117.

Anissa's first seizure was on March 12, 1996, at 11:30 p.m., at home when she stiffened and her right arm jerked. *Id.* She was warm and feverish, but this was not documented. Tr. at 117-18. Her fever was documented only in the emergency room. Tr. at 118. Dr. MacDonald does not dispute that Anissa was warm at home. Tr. at 118-19. He assumes there was fever at 5:00 p.m. March 12, 1996, four hours after vaccination. Tr. at 119. The cause of her fever was either the DPT, her upper respiratory infection, or a combination of the two. *Id.* However, three hours after admission to the hospital, she was no longer febrile. *Id.*

DPT can cause fever, which lasts 24 hours. Tr. at 120. Anissa's fever is not consistent with a DPT-related fever. *Id.* DPT can cause febrile seizures. Tr. at 121. It can damage the brain if there is an acute encephalopathy immediately after the vaccination. *Id.* The doctors treated Anissa's 20-minute seizure as a prolonged seizure, not as status epilepticus, and did not prescribe Phenobarbital or Dilantin. Tr. at 122. The Nelson study about which Dr. MacDonald spoke would not have included Anissa because one needed seizures lasting one hour in order to get into the study. Tr. at 122-23.

Anissa has true epilepsy and a brain which does not work. Tr. at 124. Seizures are symptoms of bad brain function, not the cause of it. *Id.* Before her first seizure, Anissa was normal. Tr. at 125. She would not have been included in the NCES because they were looking for status epilepticus, which she did not have. Tr. at 125. Her seizures were all described as brief. *Id.* A 20-

minute seizure is not diagnostic of status epilepticus. *Id.* He does not know the cause of her problems. Tr. at 127.

DISCUSSION

To satisfy her burden of proving causation in fact, petitioner must offer "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." See Grant v. Secretary, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992); Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

"[E]vidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149. Mere temporal association between vaccination and injury is insufficient to establish causation. Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984). The court must determine that the evidence makes causation in fact "legally probable, not medically or scientifically certain." Knudsen, supra, at 548-49. The Federal Circuit in Knudsen gave as an example of finding causation in vaccine cases if epidemiological evidence and the particular vaccinee's clinical picture substantiate that conclusion "without detailed medical and scientific exposition on the biological mechanisms." Id., at 549.

Petitioner must not only show that but for the vaccine, he or she would not have had the injury, but also that the vaccine was a substantial factor in bringing about his or her injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

Petitioner alleges that Anissa's second DPT vaccination caused in fact her seizure disorder and current condition. This court has previously held that DPT vaccine can cause a fever which in turn causes the onset of a seizure disorder. McMurry v. Secretary, HHS, No. 95-682V, 1997 WL 402407 (Fed. Cl. Spec. Mstr. July 27, 1997). In McMurry, the vaccinee had a high fever and seized for fifty or more minutes following her DPT. Id. at *1-2. In addition, she was unresponsive and in status epilepticus. Id. Based on the occurrence of the fever as well as the onset of severe seizures, the court held for petitioners. McMurry, supra, at *8-9.

McMurry and this case are quite similar. Here, Anissa seized briefly a few times in the context of a fever. Although Mrs. Bell did not recall Anissa's temperature during the night when she started seizing, she testified that Anissa was warm and that she became hotter as she continued to seize. She had been giving Anissa Tylenol before she became feverish and she was not feverish before she received the DPT vaccination. Anissa was also fussy and irritable, just like the children in the Cody article who seized in the context of fever within 24 hours of receiving DPT vaccination.

By the time Anissa reached the ED, her temperature was 102.5°. The doctors diagnosed her with febrile seizures, but recognized they were atypical, i.e., not benign, because of their duration and type. Moreover, her temperature did not increase after the seizures, which they would have expected with febrile seizures. Anissa was ultimately diagnosed with epilepsy, and she has continuing intractable seizures, microcephaly, loss of developmental milestones, and severe mental retardation.

Anissa was put on Phenobarbital to control her seizures just two weeks after she received DPT. She was diagnosed by EEG with global encephalopathy within a month of receiving DPT. Her MRIs showed a failure to myelinate brain cells, stopping at about the ten-month level, as well

as some cerebral atrophy. Dr. Young, her treating pediatric neurologist, attributes her delayed myelination to an insult to the brain which can be caused by, *inter alia*, uncontrolled seizures. Myelination enables brain cells to function. Dr. Young diagnosed Anissa as having status epilepticus whose onset was when she was four-months old, within 24 hours of receiving DPT vaccine.

Contrary to respondent's defense of Anissa's initial seizures being innocuous, she had a steady, uninterrupted decline in her condition dating from the beginning of her intractable seizures. Petitioner's medical evidence, through the medical records, Dr. Young's opinion, and Dr. Kinsbourne's testimony, shows a logical sequence of cause and effect sufficient to satisfy her burden of proving causation in fact: DPT caused Anissa to have fever (her first fever), the fever caused her to seize, her seizures did not stop, her intractable seizures caused a failure to myelinate the cells in her brain, her brain damage led to a diagnosis of global encephalopathy and status epilepticus, and she is now in a condition of total helplessness.

Respondent's expert Dr. MacDonald has various attacks on petitioner's proof. First, he does not believe that Anissa had fever before her first seizure, although he did concede that she had fever the evening of the vaccination. Second, he thinks that whether or not she had fever is irrelevant because a benign, febrile seizure does not cause harm. Third, he opines that her development of epilepsy had nothing to do with her initial febrile seizures. Fourth, he denies that she had status epilepticus and opines that she did not have epilepsy until a year later. Finally, he views seizures as not damaging to the brain.

The undersigned believes that Anissa had fever prior to her first seizure. Mrs. Bell testified credibly that Anissa was warm and then got very warm, and the medical literature which both sides accept is that post-DPT vaccine fever is quite common. Moreover, Mrs. Bell's telling the emergency

room doctor that Anissa did not have any antecedent fever was in the context of giving a pre-vaccination history of upper respiratory infection, Anissa's neonatal history and progress since she was born, Mrs. Bell's medical condition during pregnancy, and other relevant details. The emergency room doctors diagnosed Anissa as having febrile seizures, although atypical for duration and type. Their discharging her without anti-convulsant medication is consistent with their diagnosis of febrile seizures, i.e., they anticipated they would not recur because febrile seizures are typically benign.

The undersigned does believe that fever makes a difference. Even Dr. MacDonald had to admit that fever can provoke a seizure. Clinicians and the medical literature, such as the Cody article, accept that one of the most common adverse reactions to DPT is fever, occurring in almost half the vaccinees. Both sides also agree that fever can provoke seizures and, according to Dr. Kinsbourne and the medical records, it did so in this case.

The undersigned disagrees that Anissa's initial seizures are unrelated to her later-diagnosed status epilepticus. First, her own treating pediatric neurologist diagnosed her as having status epilepticus beginning at age four months. She was prescribed anti-convulsant medication (Phenobarbital) just two weeks post-vaccination when it became apparent that her febrile seizures were not benign and self-limiting. She was diagnosed with global encephalopathy on April 11, 1996, almost a month after the onset of her seizures. She became microcephalic, meaning her head became small because her brain was not growing. The first MRI performed after she was ten months of age showed a failure to myelinate beyond the ten-month level. When the brain cells are not fully myelinated, they do not communicate nerve impulses appropriately in order to function normally.

Not surprisingly, Anissa has had a continual loss of skills that she had had when she was four months of age and has failed to gain milestones.

The undersigned does not find Dr. MacDonald's testimony credible in light of the evidence in this case. He would have the court believe that Anissa has, in essence, two unrelated seizure disorders: her initial seizures and then, at some point, epilepsy, neither of which damaged her.

The court accepts Dr. Kinsbourne's testimony that DPT is a substantial factor causing Anissa's brain injury due to the effect of her seizures and of the toxicity of the vaccine on her brain. There may be something wrong with Anissa's brain that preceded her vaccination, but we will never know what it is. Congress's intent in creating the Vaccine Program was to benefit those who are susceptible to the components of the vaccine in ways we do not understand:

> The Vaccine Act established a federal "compensation program" under which awards are to be "made to vaccine-injured persons quickly, easily, and with certainty and generosity." House Report 99-908, [99th Cong., 2d Sess.] at 3, 1986 U.S.C.C.A.N., at 6344. The program is supposed to be "fair, simple, and easy to administer." *Id*. at 7, 1986 U.S.C.C.A.N. at 6348.... The program stems from Congress's recognition that "[w]hile most of the Nation's children enjoy great benefit from immunization programs, a small but significant number have been gravely injured." *Id*. at 4, 1986 U.S.C.C.A.N. at 6345.

Knudsen, supra, at 549.

The Federal Circuit holding in Knudsen does not require petitioner to prove specific biologic mechanisms for her injury. Id. at 549. She needs to prove only legal probability, not medical or scientific certainty. Id. at 548-49. Moreover, under Shyface, supra, the Federal Circuit stated that petitioner needs to prove only that the vaccine was a substantial factor in her injury. The vaccine does not have to be the only or even the predominant factor.

Petitioner has shown in this case that DPT is a substantial factor in Anissa's injury: her epilepsy, seizures, chronic encephalopathy, delayed myelination, microcephaly, status epilepticus, and current mental and developmental retardation. Petitioner has satisfied her burden of proving causation in fact for her vaccine injury and sequelae.

Respondent has not proved a known factor unrelated is the cause of Anissa's current condition. 42 U.S.C. § 300aa-13.

CONCLUSION

The parties shall confer with the undersigned about filing life care plans. The undersigned encourages the parties to engage in the settlement of damages and offers alternative dispute resolution as a possible means of doing so in this case.

IT IS SO ORDERED.

DATE: _____ _____

Laura D. Millman
Special Master