OFFICE OF SPECIAL MASTERS

(No. 90-2727V)

(Filed June 21, 1999)

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| STANFORD EUGENE and HARRIET EPPS HALEY, as Natural Guardians and Legal Representatives of their Minor Daughter, MARY ELIZABETH HALEY, | * | Publish |
| Petitioners, | * | |
| v. | * | |
| SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |
| * * * * * * * * * * * * * * * * * * * * * * * * * * * * | | |

*James Lee Ford,* Atlanta, Georgia, for petitioners.

*Linda S. Renzi,* United States Department of Justice, Washington, D.C., for respondent.

## DECISION

**WRIGHT, Special Master.**

On October 1, 1990, petitioners filed a claim on behalf of Mary Elizabeth Haley ("Mary Elizabeth"), under the National Vaccine Injury Compensation Program (hereinafter "Vaccine Act" or the "Act").[(1)] Petitioners claim that Mary Elizabeth suffered the onset of a residual seizure disorder ("RSD") and/or an encephalopathy within three days of the administration of a diphtheria-pertussis-tetanus ("DPT") vaccination on November 28, 1984. Alternatively, petitioners argue that the DPT vaccination significantly aggravated Mary Elizabeth's pre-existing brain anomaly, thereby triggering her encephalopathy.

## I.

## PROCEDURAL BACKGROUND

On July 19, 1994, respondent filed a report in this matter recommending compensation be denied since petitioners had not shown that Mary Elizabeth's injuries occurred within the Table time frame and, further, that a factor unrelated to the administration of the vaccination -- an un-named syndrome that caused Mary Elizabeth to be born with structural brain anomalies -- was responsible for her condition. Video depositions of Harriet and Stanford Haley, petitioners herein, as well as Dr. Samuel Haddock, Mary Elizabeth's treating pediatrician, were filed on January 31, 1997. Supplementary telephonic evidence was elicited from Mr. and Mrs. Haley on April 9, 1997. At a hearing in New York City on April 23, 1998, petitioners presented the expert testimony of Dr. Leon Charash. Testifying for respondent was Dr. Jay Selman. Post hearing briefs were filed by petitioners and respondent on June 23, 1998, and July 19, 1998, respectively. On September 14, 1998, petitioners filed a motion to consider additional medical records that were inadvertently omitted from the record herein. That motion was granted on September 21, 1998. The record is now complete and the case is ripe for decision.

Based on all the evidence in the record, I find that petitioners are entitled to compensation for the vaccine-related injury of their daughter, Mary Elizabeth Haley.

## II.

## FACTUAL BACKGROUND

The following evidence is contained in the record in this matter:[(2)]

Mary Elizabeth was born on September 26, 1984, in Anderson, South Carolina. P. Ex. 1. Her parents did not notice anything unusual about Mary Elizabeth during the first two months of her life. Mrs. Haley Dep. at 17. Mrs. Haley described Mary Elizabeth during this time as "bubbly and full of personality." *Id.* at 21. Mary Elizabeth received her first DPT vaccination at the office of her pediatrician, Dr. Haddock, on November 28, 1984 at about 3:30 in the afternoon.[(3)] *Id.* at 17, 22. Mrs. Haley recalled that Mary Elizabeth began to get fussy later during the afternoon of her DPT vaccination. *Id.* at 23. At about 6:30, Mary Elizabeth began to scream inconsolably and did not respond to her parents' futile efforts to calm her. *Id.* at 23-28. According to Mrs. Haley, Mary Elizabeth was "screaming, jerking, carrying on like a wild woman." *Id.* at 29. Mrs. Haley could not recall specifically whether Mary Elizabeth's screaming ceased briefly while she jerked. Tr. I at 8, 30. At the time, Mrs. Haley did not think Mary Elizabeth was having a seizure. Mrs. Haley Dep. at 82. At about 7:00 or 7:30, Mrs. Haley called Dr. Haddock, who returned the call at about 10:00 that night. Dr. Haddock prescribed Butibel and offered to leave some on the back steps of his office. Mr. Haley retrieved the medication from Dr. Haddock's office and they administered it to Mary Elizabeth. By about midnight, Mary Elizabeth finally calmed down and went to sleep. She slept through the night for the first time.[(4)] Mrs. Haley Dep. at 29-31.

Mrs. Haley awakened Mary Elizabeth at about 8:00 a.m. on the morning of November 29, 1984. According to Mrs. Haley, Mary Elizabeth was not the same child as she was before the vaccination. She did not interact with her environment in the manner as before the inoculation. *Id.* at 37. Whereas before she was bright and bubbly, after the inoculation, she did not behave in the same alert fashion, became less responsive, lost her animation, would stare at objects and began to sleep more than she usually did. She also began drooling.[(5)] *Id.* at 21, 37-38, 44-45. Before the vaccination, Mary Elizabeth had achieved a certain amount of head control and would play with her hands and suck her thumbs. That changed after the DPT vaccine. She did not hold her head up in the car seat as she had before and stopped playing with her hands.[(6)] *Id.* at 45-47. In addition, before the immunization, Mary Elizabeth would form her mouth into an "O" and make an "O" sound. After the vaccination, Mary Elizabeth stopped making "O's." Tr. I at 14, 22. "Her brightness left her," and Mary Elizabeth became listless and sleepy. Tr. I at 32.

On December 12, 1984, Mary Elizabeth suffered an episode which caused her to fall out of her car seat. Hrs. Haley Dep. at 48-49; Affidavit of Mrs. Haley, filed December 5, 1994, at 5. The following evening, December 13, 1984, while nursing, Mary Elizabeth's eyes suddenly deviated to the side, her tongue darted and she smacked her lips. Mrs. Haley Dep. at 49-51; Mrs. Haley Aff. at 5. This happened again on December 15th. *Id.* On December 16th, the Haleys took Mary Elizabeth to see Dr. Haddock, who observed Mary Elizabeth suffer a focal seizure. Mrs. Haley Dep. at 52-53; Mrs. Haley Aff. at 5-6.

Mary Elizabeth was immediately admitted to Anderson Memorial Hospital where a diagnosis of infantile spasms was made. P. Ex. H at 50. A CT scan of the brain showed a congenital abnormality of the ventricular system. P. Ex. H at 50. She was then transferred to the Emory University Hospital for further evaluations. Mary Elizabeth was admitted to the Henrietta Egleston Hospital for Children at Emory University, where she stayed from December 18 to December 21, 1984. P. Ex. G at 2. An admission history and physical were recorded, noting the chief complaint as seizures. That note reads:

[P]roduct of an uncomplicated pregnancy and full term delivery. [Patient] had no problems in the neonatal period & has had no other illnesses since birth. However, [about] 1 week ago, mother noted a brief focal seizure of the facial muscles while breast feeding. Then 2 days later, [patient] began having a series of focal seizures for which he [sic] was admitted to Anderson Memorial Hospital & given anticonvulsant.

P. Ex. G at 7. Another CT scan was performed on December 20, 1984. The diagnostician's impression was that Mary Elizabeth's scan revealed agenesis of the corpus callosum ("ACC"), hydrocephalus involving the third and lateral ventricles, and atrophy of the left frontal and left temporal tip. P. Ex. G at 18.

Dr. James F. Schwartz, a pediatric neurologist at Emory Hospital, evaluated Mary Elizabeth at the hospital and later took over her care. He prepared her discharge summary dated December 21, 1984, which states:

This was a twelve week old infant who weighed 7 lb 4 oz at birth, the product of a full term, uncomplicated gestation, with normal labor and delivery. She had done well until about 6 days before admission, when she began having episodes which were, in retrospect, clearly seizures. They initially started as left focal seizures, but subsequently became classical infantile spasms. The onset was about one week after the first DPT. There was no other antecedent illness and no perinatal difficulty.

P. Ex. F at 21.

In a clinic note dated January 28, 1985, Dr. Schwartz stated:

The family relates that the seizures began about one week after her first DPT and at the time of the first DPT she had about 5 hours of incessant, uncontrollable, severe crying. This may be a contraindication to further DPT vaccinations.

P. Ex. F at 19.

In a letter dated January 29, 1985, from Dr. Schwartz to Dr. Gay Haley, Dr. Schwartz, stated:

The CT scan showed absence of the front of the corpus callosum, i.e. agenesis of the corpus callosum, as well as slight dilatation of the third and lateral ventricles. Although agenesis of the corpus callosum is not the cause of seizures, it suggests that there may be other cerebral abnormalities which are not evident on the CT scan and which may be microscopic. Certainly there are normal individuals with normal intelligence without seizures who have agenesis of the corpus callosum but it is a marker that there may well be other congenital abnormalities. There was a slightly enlarged cisterna magna, but I don't think this has any bearing and I really don't think that this is a significant anatomical abnormality.

P. Ex. F at 16.

In July 1985, Mary Elizabeth was seen as an outpatient at Wake Forest University. In a four page summary dated July 9, 1985, Dr. Samir Kabbani, writing for Dr. J. Kiffen Penry, a professor of neurology, noted:

This is a nine month old white baby girl referred here for further evaluation and control of her seizure disorder which started at age 2 months. Basically, the first seizure, according to the father, started about one to two weeks after she had her "DPT shot".

P. Ex. E at 14.

An examination of Mary Elizabeth at Wake Forest University when she was nine and a half months old indicated that she had significant developmental delays. She was unable to roll back to front or front to back, had decreased tone in all muscles, was unable to keep her neck straight when held in a horizontal position, could not pull herself to a standing position, did not turn her attention to the speaker, could not support her weight when in a standing position, and held her thumbs in a cortical position. P. Ex. E at 16.

In March 1988, Mary Elizabeth was evaluated by Dr. Barbara Burton, head of the section of medical genetics at the Bowman Gray School of Medicine at Wake Forest University. An earlier blood test, performed in September 1985, to rule out chromosomal abnormalities, was normal. P. Ex. B at 11. In a letter to Mr and Mrs. Haley dated March 30, 1988, Dr. Burton stated that Mary Elizabeth's serum amino acid analysis was so close to normal it was of no diagnostic significance. P. Ex. B at 35. She continued:

Pertinent points from the history include the fact that the pregnancy was relatively unremarkable and you felt that Mary Elizabeth was normal up until the time of her first DPT shot at 2 months of age. You indicated that you noted a number of changes in her behavior and in her neurologic status on that date and these changes were followed by the development of infantile spasms several days later. Since that time, Mary Elizabeth has continued to have problems related to her seizure disorder and has experienced significant developmental delay as well.

P. Ex. B at 35. Dr. Burton went on to catalogue Mary Elizabeth's brain anomalies as "agenesis of the corpus callosum, marked dilatation of the ventricles and an ill defined abnormality in the cerebellum as well as a number of other non-specific abnormalities."[(7)] *Id.* at 35-36. Although all metabolic and genetic testing was negative and she could not assign any specific syndrome to Mary Elizabeth's condition, Dr. Burton believed that Mary Elizabeth's brain abnormalities had their onset in the early prenatal period and were, "at least in large part, responsible for the neurologic handicaps observed in her." *Id.* at 36. However, Dr. Burton added:

As you point out, it is also possible to have agenesis of the corpus callosum with normal intelligence and no neurologic handicaps so we must assume that in the children who do have handicaps there are other abnormalities in the brain as well, even though these may not always be evident grossly.

There is no doubt in my mind that there was a significant change in Mary Elizabeth's condition on the day that she received her DPT injection. I feel that parents are extremely good judges of their children's behavior and well being and am certainly convinced that you noted a significant change on that date. What is difficult to judge is whether or not this change had anything to do with the DPT injection or was just coincidentally occurring at this same time. Two months is certainly an age at which infantile spasms may first present and other neurologic abnormalities may be seen in association with the actual seizures. Therefore, it is possible that these were simply coincidental events. On the other hand, I certainly could not rule out the possibility that Mary Elizabeth suffered some adverse effects from the DPT injection although we would have to say that this could not be the total cause of her disabilities. The question that I cannot answer is whether or not she might have been uniquely susceptible to injury from the vaccine by virtue of her underlying brain abnormalities. We certainly have reason to believe that this may be the case in some children and for this reason DPT injections are often withheld from children who have certain types of underlying neurologic abnormalities that have been previously recognized. I cannot think of any way of definitively answering this question at the present time, however.

P. Ex. B at 36-37.

Although she is now 14 years old, Mary Elizabeth is profoundly mentally retarded and developmentally delayed. She can roll over on the floor but not creep, crawl, sit, kneel, stand or walk. She sits in a wheelchair. She has no intelligible speech and, other than putting finger foods into her mouth, she is unable to assist in activities of daily living. She cannot dress herself, groom herself and is not toilet trained. She is totally dependent upon others for her care. She has

seizures almost daily, mostly brief but some are prolonged. Tr. II at 16-17, 29.

**III.**

**EXPERT TESTIMONY**

*Dr. Leon Charash*

Testifying on behalf of petitioners was Dr. Leon Charash, a pediatric neurologist.(8) Dr. Charash believes, to a reasonable degree of medical probability, that Mary Elizabeth suffered an encephalopathy and infantile spasms within three days of her November 28, 1994, DPT vaccination. He bases his conclusion on the fact that Mary Elizabeth had a normal prenatal course and delivery and normal development until the time of her November 28, 1994, DPT immunization, when Mary Elizabeth screamed and jerked for hours the evening after her vaccination until she was administered Butibel. Dr. Charash believes the jerking activity represented myoclonic movements. She slept through the night and thereafter never regained her spontaneity. She then began to drool and lost control of her hands and head. On December 13, 1984, Mary Elizabeth suffered an episode in which her eyes deviated to the side, her head swiveled, and she began smacking her lips and darting her tongue. She experienced a similar episode the following Saturday evening and was thereafter diagnosed with infantile spasms. Affidavit of Dr. Charash, filed June 9, 1997; Tr. II at 38.

Dr. Charash defines encephalopathy generally as damage to the brain. Tr. II at 18. He testified Mary Elizabeth has infantile spasms, a type of seizure disorder associated with "hypsarrhythmia," a chaotic pattern of EEG abnormalities. Children with infantile spasms are almost all doomed to have a very poor prognosis. Tr. II at 19-20.

Dr. Charash believes the architectural anomalies in Mary Elizabeth's brain were present in utero. Further, he concedes that such congenital malformations *may* cause infantile spasms. Tr. II at 23-24. However, he testified that there are children and adults who present at autopsy with Mary Elizabeth's specific structural brain anomalies who are perfectly normal otherwise. Tr. II at 24-25, 46. He believes the temporal relationship between the DPT vaccination and the onset of Mary Elizabeth's symptoms makes the likelihood of her brain anomalies causing her infantile spasms to be very improbable. Tr. II at 26.

Dr. Charash based his opinion that Mary Elizabeth suffered the onset of infantile spasms within the Table time period on the record testimony that Mary Elizabeth began to scream and exhibit jerking movements the evening of her vaccination and that this behavior did not abate until she was given Butibel late that evening.(9) Dr. Charash explained that Butibel is a barbiturate and an anticonvulsant and might have the effect of abating seizure activity. Tr. II at 27-28, 42. Even if Mary Elizabeth did not suffer the onset of seizures until seven days after her DPT immunization, Dr. Charash still believes that Mary Elizabeth's symptoms in the Table time period following the vaccination constituted an encephalopathic reaction. Tr. II at 41. He bases this opinion on the description of Mary Elizabeth's behavior following her immunization, as related by Mrs. Haley. Tr. II at 38. Specifically, he noted the change in Mary Elizabeth's reactivity, poor head control and ceasing to perform certain activities she previously did. *Id.* Dr. Charash conceded that the unconsolable crying, alone, would not be indicative of an encephalopathic reaction. Tr. II at 46. Rather, he bases his opinion on the totality of her symptoms, including the "immediate reaction, plus the unique change of events that followed." Tr. II at 50.

Dr. Charash testified that there is a contraindication to administering pertussis vaccine to a child with a known brain anomaly. Tr. II at 31. It was not known at the time that Mary Elizabeth had any structural anomalies in her brain. Tr. II at 32. Dr. Charash believes that the DPT administered to Mary Elizabeth was "more neuro-toxic" because of her abnormal nervous system. Tr. II at 33. He testified, "I think it's not unreasonable to say, number one, that there would be a greater proclivity to have a reaction [among children with abnormal brain development], and if there were a reaction, it might leave the child with a greater disability." Tr. II at 34.

Dr. Charash testified he believes that the myoclonic activity, consisting of "[s]udden, self-limited movement of muscles" that Mary Elizabeth exhibited after the vaccination constituted the onset of her infantile spasms. Tr. II at 42. He also believes that the incessant screaming Mary Elizabeth exhibited the evening of her vaccination indicated she was having a more generalized reaction than soreness from the injection site. Tr. II at 43. He asserted that the uncontrollable crying represented the onset of the alteration in Mary Elizabeth's brain which caused the chaotic EEG pattern later identified as hypsarrhythmia. Tr. II at 42-43.

Dr. Charash also testified he believes Mary Elizabeth suffered a significant change for the worse, resulting in a substantial deterioration in her health in the 72 hours following her immunization. Tr. II at 47. In addition to the hours of incessant crying, Mary Elizabeth lost her head control, was not as reactive, did not regain her spontaneity, began to drool and regressed in the use of her upper extremities. Tr. II at 48. He testified that babies may or may not cry when they experience infantile spasms. *Id.*

*Dr. Jay Selman*

Dr. Jay Selman, a board certified pediatric neurologist, testified on behalf of respondent.[(10)] He believes Mary Elizabeth's seizures did not begin within 72 hours of Mary Elizabeth's November 28, 1984, DPT inoculation, but more likely the date of onset was "in close proximity" to her December 16, 1986, hospital admission. Tr. II at 57-58. He attributes the crying and jerking described by Mr. and Mrs. Haley on the evening of Mary Elizabeth's vaccination to "a reaction to the immunization she had received on the same day." Tr. II at 58. When asked to elaborate, Dr. Selman testified, "It is not uncommon in children who received immunizations that they will be fussy, irritable, out of sorts for several hours following an immunization." Tr. II at 58.

Dr. Selman believes the jerking movements described by Mary Elizabeth's parents were not seizures but rather could have been due to irritability, fussiness or discomfort at the injection site. Tr. II at 59. Moreover, Dr. Selman asserted:

Seizures are not typically accompanying crying. . . .You would not expect to have the same type of crying that you would see with a child who was wet or who was hungary [sic] or who had gas. The cry that you get with an infantile spasm, the best way to understand that is it would be as if someone suddenly punched you in the stomach and you went "ughh" with a sudden kind of a forced grunt. . . . When the infantile spasms become more stronger, there may be more persistent kind of crying, but it has - it has a different character, and certainly early on one would not expect prolonged crying. That would be very, very rare if it occurs.

Tr. II at 59-60.

Dr. Selman is not aware of anyone in his academic position or private practice ever having prescribed Butibel for a child. Further, he believes the dosage Mary Elizabeth received would not have had a therapeutic effect on seizures because she was not given a protective level of the medication.(11) Tr. II at 60-61. Moreover, Dr. Selman asserted, it would be unusual for an initial bout of seizures to be followed for a period of a couple of weeks without recurrences. Tr. II at 61.

Dr. Selman believes Mary Elizabeth did not experience an encephalopathy because he she only had a period of fussiness and crying for five hours with no persisting symptoms. Tr. II at 62. Dr. Selman believes that in order to be a sign of an encephalopathy, unconsolable screaming must last approximately 12 to 24 hours. He believes that the Butibel Mary Elizabeth was administered on the night of her vaccination would have worn off by the next morning.(12) Tr. II at 81. He conceded, "I suspect it may have been something that may be a little bit too powerful to give a two-month old." Tr. II at 83. Dr. Selman was also familiar with the literature suggesting that pertussis vaccine was contra-indicated for children with neurological disorders. Tr. II at 85.

Dr. Selman believes that the onset of Mary Elizabeth's seizures was not until one to two weeks after her inoculation. *Id.* As to the Haleys' descriptions of Mary Elizabeth's diminution in head control and purposeful hand movements, Dr. Selman stated the loss would have to be "profound" in order for it to be a sign of an encephalopathic reaction. Moreover, the onset of drooling, as described by Mrs. Haley, may not be significant because babies "do a significant amount of drooling." Tr. II at 63-64. Finally, if Mary Elizabeth had been encephalopathic following her immunization, Dr. Selman would have expected that there would have been a significant change in her feeding and alertness. Tr. II at 68.

Dr. Selman believes the more likely cause of Mary Elizabeth's condition is the brain anomalies she was born with. According to Dr. Selman, a high percentage of individuals with ACC will have seizures or mental retardation. Moreover, Dr. Selman explained, "[t]he more associated anomalies or other malformations that a child . . . has the greater will be the probability of seizures." Tr. II at 64. As well, the greater the number of anomalies present, the greater the likelihood that some type of syndrome is present. Tr. II at 71.(13) While he could not attach a specific percentage of the population of individuals with Mary Elizabeth's brain anomalies who experience seizures, he opined that perhaps 58 to 70 percent of those persons would. Tr. II at 65. Dr. Selman conceded, however, that there are people with the structural anomalies in Mary Elizabeth's brain who are neurologically normal. Tr. II at 95. The number of such individuals is unknown because "if they are normal, they are usually discovered accidentally" through MRI or CT scans or autopsies. Tr. II at 66. Dr. Selman acknowledged there was no evidence that Mary Elizabeth suffered from any abnormal condition prior to the administration of her November 28, 1984, DPT vaccination. Tr. II at 77-78.

In sum, Dr. Selman believes that ACC was part of a constellation of structural neurological abnormalities that constituted an as yet unnamed syndrome that was the proximate cause of Mary Elizabeth's seizures and developmental delay. Tr. II at 94-95. Dr. Selman further testified that in persons with such abnormalities, there does not necessarily have to be a triggering event to bring on the onset of seizures or mental retardation. Tr. II at 99.

## IV.

## DISCUSSION

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation, or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act.[(14)] The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition.[(15)] A rebuttable presumption also obtains when a petitioner proves that an injury listed on the Vaccine Injury Table has been significantly aggravated, within the Table time period, by a listed vaccine.[(16)] The presumption may be overcome by an affirmative showing that the injury was caused by a factor unrelated to the administration of the vaccine.[(17)]

Petitioners have essentially three theories of recovery here. Petitioners assert that the DPT vaccine Mary Elizabeth received caused her to suffer the onset of either a residual seizure disorder and/or an encephalopathy within the statutorily prescribed time frame for a Table injury. Alternatively, petitioners argue that the DPT immunization significantly aggravated a pre-existing condition, namely, structural brain anomalies.

Under the Table injury route, after petitioners have demonstrated the requirements of Section 13(a)(1)(A), the burden shifts to the respondent to prove the injury was caused by factors unrelated to the vaccination in question pursuant to section 13(a)(1)(B). *Matthews v. Secretary of HHS*, 18 Cl. Ct. 514, 518 (1989); *O'Connor v. Secretary of HHS*, 24 Cl. Ct. 428, 429-30, n. 2 (1991), *aff'd*, 975 F.2d 868.

*Residual Seizure Disorder*

The Vaccine Act provides a rebuttable presumption that a residual seizure disorder that has its onset within the Table time period is causally related to the administration of a DPT vaccine. Specifically, according to the interpretive aids of the Act, a petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer an afebrile seizure prior to the administration of the vaccine, suffered a seizure within three days of the administration of the vaccine and suffered two or more afebrile seizures within one year of the vaccine.[(18)] Section 14(b)(2)(B). While it is clear that Mary Elizabeth suffered many afebrile seizures within the year following her November 28, 1984, DPT vaccination, it is far less clear whether she experienced her first seizure within three days of her immunization.

Mrs. Haley's description of the jerking motions was not particularly precise. She testified Mary Elizabeth screamed, jerked and carried on like a wild woman. She could not specifically remember whether Mary Elizabeth stopped screaming while she exhibited the jerking motions but at the time, it did not cross her mind that Mary Elizabeth may have been suffering from seizures. Mr. Haley added little to the total picture, except to say that Mary Elizabeth bowed her back and jerked her head against his shoulder. He described her as "wiggling and jerking," and pulling up her legs. He testified that Mary Elizabeth couldn't be still.

The totality of the descriptions of Mary Elizabeth's movements leads me to conclude that there is not a preponderance of the evidence that they represented seizure activity. First, neither Mr. nor Mrs. Haley seemed clear on whether Mary Elizabeth stopped screaming during the jerking episodes. Indeed, the impression I got was that the screaming, jerking, wriggling and inability to be still was all of a piece. Moreover, both Dr. Charash and Dr. Selman believed that if Mary Elizabeth was actually screaming during the jerking movements, the likelihood that they represented seizure activity is greatly diminished. Dr. Charash testified that if Mary Elizabeth was screaming during the jerking episodes described by her parents, "then I would attribute the movement of the limbs possibly to being just a voluntary movement, not an involuntary movement. But if those jerks continued over the next days, then I would have to retrospectively say that

the jerks were myoclonic movements at that time." Tr. II at 27-28. Further, Mrs. Haley testified she did not believe at the time that the movements were seizures and she did not describe that the post-vaccinal jerking was similar in any way to the episodes she suffered subsequently which were diagnosed as infantile spasms. Finally, both experts testified that if Mary Elizabeth had the onset of infantile spasms the night of her vaccination, it would have been unusual for a period of one or two weeks to elapse before any more episodes were noticed. Mrs. Haley did not report any further jerking until the episode that occurred on December 12, 1984, during which Mary Elizabeth fell out of her car seat. Consequently, in my view, petitioners have not met the burden of proof by a preponderance of the evidence that Mary Elizabeth's seizures had their onset within 72 hours following her immunization.

*On-Table Encephalopathy or Significant Aggravation of an Underlying Encephalopathy*

As an initial matter, any discussion of whether Mary Elizabeth suffered an encephalopathy or a significant aggravation of an underlying encephalopathy necessarily requires that I address the thorny issue of whether Mary Elizabeth's pre-existing brain abnormalities constituted an underlying "silent" or "static" encephalopathy. That is because it is clear under the Supreme Court's decision in *Shalala v. Whitecotton*, 514 U.S. 268 (1995), that if a person has a pre-existing injury listed on the Vaccine Injury Table -- in this case encephalopathy -- that person cannot suffer a new compensable Table injury of the same type following a listed vaccination. The Supreme Court stated in *Whitecotton:*

If a symptom or manifestation of a table injury has occurred before a claimant's vaccination, a symptom or manifestation after the vaccination cannot be the first, or signal the injury's onset. There cannot be two first symptoms or onsets of the same injury. Thus, a demonstration that the claimant experienced symptoms of an injury during the table period, while necessary, is insufficient to make out a prima facie case. The claimant must also show that no evidence of the injury appeared before the vaccination.

*Whitecotton*, 514 U.S. at 274. The Act makes no distinction between a static and an acute encephalopathy. Accordingly, if Mary Elizabeth's pre-existing brain anomalies are considered a static encephalopathy, under the *Whitecotton* analysis, petitioners may only pursue recovery under a theory of significant aggravation. If, on the other hand, the structural defects in Mary Elizabeth's brain do not amount to a pre-existing encephalopathy, then the case would appropriately be analyzed under a Table encephalopathy theory.

Although there have not been any definitive rulings on whether a structural brain anomaly occurring before birth constitutes an encephalopathy, a number of cases provide some guidance on that issue. The facts of the *Whitecotton* case are instructive. Despite conflicting testimony as to whether Maggie Whitecotton was born with microcephaly or acquired it sometime after birth ("secondary microcephaly" -- implying a post-partum injury to the brain), the special master who initially heard the case determined that Maggie Whitecotton was born with microcephaly which became more pronounced by the time of the DPT vaccination in question. *Whitecotton v. Secretary of HHS*, No. 90-692V, 1991 WL 172187, at *8 (Cl. Ct. Spec. Mstr. Aug. 16, 1991). Maggie suffered seizures within 48 hours of the DPT vaccination in question which continued occasionally over the next five years. She also became severely mentally and physically disabled. The special master, however, was persuaded that Maggie had suffered an encephalopathy "sometime prior" to the administration of the DPT vaccination which allegedly injured her. *Id.* at *4. Accordingly, the special master found Maggie's "original encephalopathy was a not a Table injury which followed the . . . DPT shot." *Id.* Further, employing the then-applicable test for significant aggravation enunciated in *Misasi v. Secretary of Health and Human Services*, 23 Cl. Ct. 322, 324 (1991) (*see* discussion, *infra* at note 33), the special master found that Maggie's injury did not amount to a Table significant aggravation. *Whitecotton*, 1991 WL 172187, at *5 - 8.

The special master's decision was affirmed on appeal to the United States Court of Federal Claims, No. 90-692V (Jan. 14, 1992). The United States Court of Appeals for the Federal Circuit reversed, holding, *inter alia*, that proof of a Table injury did not require a showing that the vaccinee sustained no injury prior to the administration of the vaccination in question. Rather, the court determined that eligibility for a Table injury requires only that the first symptom *after* the vaccination must occur within the Table time period. The Court went on to find Maggie had suffered a Table encephalopathy, the presumption of which could not be defeated by her pre-existing microcephaly, an idiopathic condition. *Whitecotton v. Secretary of HHS*, 17 F.3d 374, 376-77 (Fed. Cir. 1994). On appeal, the Supreme Court, in *Shalala v. Whitecotton*, 514 U.S. 268 (1995), held that if a vaccinee has a pre-existing injury listed on the Vaccine Injury Table, in this case encephalopathy, that person cannot suffer a new compensable Table injury of the same type following a listed vaccination.[(19)]

The line of cases involving vaccinees who are found to have tuberous sclerosis ("TS") is also instructive.[(20)] In *Costa v. Secretary of HHS*, No. 90-1476V, 1992 WL 47334 (Cl. Ct. Spec. Mstr. Feb. 26, 1992) the special master concluded that a Table significant aggravation analysis was not appropriate because the vaccinee was known to have been born with TS. She reasoned:

A non-clinical TS cannot be an encephalopathy under the Act because it is not an acquired abnormality (since a TS child is born with it), nor is it an injury (being the result of inheritance or a genetic mutation) or an impairment (if there are no central nervous system symptoms, the brain is not impaired)."

*Id.* at *20, n. 13. The special master thus determined that a significant aggravation analysis was inappropriate and found that petitioners had satisfied their burden of proving an on-Table residual seizure disorder. On appeal, Judge Tidwell reversed and remanded the special master's finding, giving credence to respondent's expert's opinion that TS "qualifies as an encephalopathy, congenital in origin, because TS is a brain abnormality acquired at birth." *Costa v. Secretary of HHS*, 26 Cl. Ct. 866, 871 (1992). Since then, each of the numerous cases in which the vaccinee has underlying TS has been analyzed under a significant aggravation theory. *See, e.g., Pearson v. Secretary of HHS*, No. 90-988V, 1992 WL 82330 (Cl. Ct. Spec. Mstr. Apr. 8, 1992); *Suel v. Secretary of HHS*, No. 90-935V, 1993 WL 241430 (Cl. Ct. Spec. Mstr. June 18, 1993), *rev'd and remanded on other grounds*, 31 Fed. Cl. 1 (Fed. Cl. Dec. 21, 1993), *on remand*, 1997 WL 617034 (Fed. Cl. Spec. Mstr. Sept. 22, 1997); *Flanagan v. Secretary of HHS*, No. 90-1126V, 1993 WL 264532 (Fed. Cl. Spec. Mstr. June 30, 1993); *Stiefel v. Secretary of HHS*, No. 90-924V, 1993 WL 322059 (Fed. Cl. Spec. Mstr. Aug. 10, 1993); *Barnes et. al. v. Secretary of HHS*, (Omnibus TS Decision) 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997, as amended Sept. 18, 1997).[(21)] *See also Priest v. Secretary of HHS*, No. 95-0134V 1998 WL 928424 (Fed. Cl. Spec. Mstr. Dec. 7, 1998)(special master found the vaccinee had a latent encephalopathy that was significantly aggravated because she had a congenital metabolic disorder which was unmasked by a DPT vaccination); *Downing v. Secretary of HHS*, No. 90-1134V, 1993 WL 120641 (Fed. Cl. Spec. Mstr. Apr. 2, 1993) (underlying hydrocephaly, a structural defect of the brain, was considered to be an encephalopathy for purposes of successfully pursuing a significant aggravation theory).

There is some support for the opposite view, however. In *Hanlon v. Secretary of HHS*, 40 Fed. Cl. 625 (1998), Judge Turner, in dicta, asserted that TS is not listed in the Vaccine Injury Table (in other words, not an encephalopathy as Judge Tidwell believes) and thus petitioners must prove causation-in-fact with respect to their significant aggravation claims. Finally, in *McCollum v. Secretary of HHS*, No. 94-0136V, 1998 WL 338237 (Fed. Cl. Spec. Mstr. June 5, 1998), a case similar to the one at bar, Special Master Millman found that Grant McCollum had suffered a Table residual seizure disorder notwithstanding that he had underlying ACC, as does Mary Elizabeth. In dicta, the special master mused, "There is not much point in discussing significant aggravation because it is unclear from the evidence what exactly DPT would have aggravated in Grant." *Id.* at *11.

Here, considering the broad definition of encephalopathy in the Act, to wit, "any significant acquired abnormality of, or injury to, or impairment of function of the brain,"[(22)] it would be reasonable to conclude that structural defects of the brain would fit within its broad parameters. On an obvious level, structural anomalies certainly represent "abnormalities of" the brain. Even if they have produced no obvious effects and are essentially "silent," they represent an aberrant architecture which may or may not result in deleterious consequences. The fact that the abnormalities were "acquired" in utero has not kept courts from considering structural brain anomalies to represent underlying encephalopathies. *Whitecotton v. Secretary of HHS*, 81 F.3d 1099 (Fed. Cir. 1966)(child born with microcephaly considered to have underlying encephalopathy); *Costa v. Secretary of HHS*, 26 Cl. Ct. 866 (1992)(child born with tuberous sclerosis considered to have underlying encephalopathy). The weight of the caselaw would suggest that this case would most appropriately be analyzed under the construct of significant aggravation. Under that theory, as set forth *infra*, petitioners would prevail. Alternatively, if it were determined that the particular structural anomalies Mary Elizabeth was born with do not represent an underlying encephalopathy, petitioners would similarly succeed under a theory of a Table encephalopathy. An analysis of both theories follows. Because petitioners most strongly advanced a theory of Table encephalopathy, that analysis will be presented first.

*Table Encephalopathy*

Assuming, arguendo, that Mary Elizabeth's brain anomalies are not considered an underlying encephalopathy, petitioners would prevail under a theory of Table encephalopathy. The Vaccine Injury Table's aids to interpretation define encephalopathy as "any significant acquired abnormality of, or injury to, or impairment of function of the brain." Section 14(b)(3)(A). Indications of an encephalopathy may include the following: focal and diffuse neurological signs; increased intracranial pressure; changes lasting at least six hours in level of consciousness; convulsions; high pitched and unusual screaming; persistent, uncontrollable crying; and, bulging fontanel.[(23)] *Id.* It is not necessary that a petitioner satisfy all of the elements listed in the Act's aids to interpretation to be found to have sustained a Table injury.

Dr. Charash believes Mary Elizabeth suffered an encephalopathy with 72 hours of her DPT immunization regardless of whether the onset of her infantile spasms occurred within this period. He bases his conclusion on the unconsolable crying she exhibited the evening after her inoculation and, more importantly, on the dramatic changes in her personality following the vaccination. While he conceded that unconsolably crying, alone, would not lead him to believe Mary Elizabeth suffered an encephalopathy, it was important to Dr. Charash that Mary Elizabeth never regained her spontaneity following the vaccination. She had diminished control over her head and hands, began to drool and changed dramatically in her reactivity to her environment. In short, he looked at the "immediate reaction, plus the unique change of events that followed." Tr. II at 50.

Dr. Selman, on the other hand, testified Mary Elizabeth's DPT reaction was not uncommon in that some children "will be fussy, irritable, out of sorts for several hours following the immunization." Tr. II at 58. Dr. Selman further believes that Mary Elizabeth had no "persistent symptoms" following her immunization until the onset of her infantile spasms one to two weeks later. If she had been encephalopathic, according to Dr. Selman, her uncontrollable crying would have lasted 12 to 24 hours. Moreover, any diminution in her head control and purposeful hand movements would have had to be "profound" in order to signify an encephalopathic reaction.[(24)]

At the outset, it should be noted that I found petitioners to be extremely credible witnesses. This is important because the conclusions of an expert are only as sound as their factual predicate. *Davis v. Secretary of HHS*, 20 Cl. Ct. 168, 173 (1990); *Loesch v. United States*, 645 F.2d 905, 915 (1981), *citing State of Washington v. United States*, 214 F.2d 33, 43 (9th Cir.), *cert. denied*, 348 U.S. 862 (1954); *Fehrs v. United States*, 620 F.2d 255, 265 (1980). Not only was the Haleys' testimony consistent, it was supported in large part by the medical records, which indicate at least five hours of

unconsolable crying following the immunization. Moreover, Mrs. Haley related a history to Dr. Barbara Burton in 1988 which is consistent with her testimony in this proceeding. Dr. Burton was impressed enough with Mrs. Haley's description to indicate she had no doubt there was a significant change in Mary Elizabeth on the date of her DPT immunization.

Dr. Selman attributed Mary Elizabeth's reaction to simple fussiness and irritability. In my view, however, he vastly understated the case. Fussiness and irritability are one thing. Unconsolable screaming that is only relieved by the administration of a powerful central nervous system depressant is a far cry from simple crankiness. When asked if uncontrollable crying and screaming might indicate the onset of an encephalopathic condition, Dr. Selman replied, "It could possibly be related to that." Tr. II at 79. Dr. Selman believed, however, that the screaming would have lasted "[i] n the order of 12 to 24 hours" in order to signify the onset of an encephalopathy. Tr. II at 81.

Dr. Selman apparently did not credit the Haleys' testimony regarding the drastic changes they saw in their daughter immediately after the vaccination. I do not so blithely dismiss the observations of the Haleys. As Dr. Burton so aptly put it in her letter to the Haleys, "I feel that parents are extremely good judges of their children's behavior and well being and am certainly convinced that you noted a significant change on that date." P. Ex. B at 36-37. Mrs. Haley recounted significant changes in the level of Mary Elizabeth's alertness. Whereas before the immunization, Mary Elizabeth was a bright and bubbly child, afterwards she lost her spunk. She no longer interacted with her environment in the same fashion. Mary Elizabeth began to sleep more, drool and lose interest in her surroundings. She evidenced diminished control of her hands and head. These changes are indelibly etched in the Haleys' memories. They signify more, according to Dr. Charash, than a typical vaccine reaction. I found Dr. Charash much more compelling in his testimony on this point than Dr. Selman. The Haleys were concerned enough about the abnormal nature of their daughter's behavior to call Dr. Haddock, who prescribed Butibel. While the administration of that depressant and anti-convulsant might account for the fact that Mary Elizabeth slept through the night for the first time the night of her immunization, it would not account for the continued changes in her affect or the loss of certain developmental achievements.

If one accepts the Haleys' testimony -- as I do -- the indicia that Mary Elizabeth exhibited of a Table encephalopathy were prolonged and persistent crying, lethargy and unresponsiveness, developmental loss of head control and purposeful hand movements and a general neurological deterioration within 72 hours of the immunization in question. Several of these indicia are directly listed on the Vaccine Injury Table's definition of encephalopathy; others are interrelated by Dr. Charash to the same underlying insult -- the immunization -- which resulted in changes in the brain and caused not only the events just mentioned but also Mary Elizabeth's seizures occurring one to two weeks later and her general neurological decline. Considering all of the above and after weighing the testimony of the experts, I find it more likely than not that Mary Elizabeth suffered the onset of an encephalopathy the evening of her DPT vaccination on November 18, 1984, as Dr. Charash testified.

*"Factor Unrelated" and "Sequela"*

The Vaccine Act requires that in order to enjoy a presumption of causation, not only must a Table injury occur within 72 hours of the vaccination in question, but any subsequent injury or death for which a petitioner seeks compensation must be a *sequela* of the injury. Section 14(a)(I)(E). Petitioners have the burden of proving that Mary Elizabeth's current condition is a sequela of a vaccine-related injury.[(25)] In this case, however, such a determination is inextricably intertwined with a further inquiry necessary under the Act -- that is, whether respondent has shown, by a preponderance of the evidence, that Mary Elizabeth's injury was due to a factor unrelated to the administration of the vaccination in question.[(26)] Because both parties agree that Mary Elizabeth was born with brain anomalies which *may* cause the type of seizure disorder and developmental delays she now experiences, the "factor unrelated" question

should logically be addressed first. That is because respondent asserts Mary Elizabeth's structural brain abnormalities caused both her seizure disorder and her current condition.

As noted, once petitioners have established a Table injury, respondent may still prevail if she can show, by a preponderance of the evidence, that the injury was due to a factor unrelated to the administration of the vaccination in question.[(27)] Respondent's burden of proof in this regard is the same as would apply in proving causation-in-fact. *Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994). Thus, in this case, in order to rebut the presumption created by petitioners' successful proof of a Table injury, respondent must not only prove the *existenc*e of the alleged alternative cause, respondent must prove that the *particular* alternative cause asserted, in this case an unnamed syndrome resulting in brain anomalies, also actually caused Mary Elizabeth's injury. *Id.*

Dr. Selman attributed Mary Elizabeth's seizures and current neurological deficits to a malformation of her brain. He testified that a sizable percentage of children with that condition will have seizures.[(28)] He believes Mary Elizabeth most probably suffers from an as yet unknown syndrome which includes ACC, abnormalities of the frontal lobe, an abnormality of the cerebellum and defects in the back of her eyes. He asserted that when one sees a combination of brain abnormalities, such as Mary Elizabeth has, there is a greater probability that they represent a syndrome rather than isolated anomalies. However, Dr. Selman could not identify the syndrome Mary Elizabeth suffered from, nor did the myriad tests conducted on Mary Elizabeth reveal any specific identifiable syndrome, genetic defect or metabolic disorder. In short, the etiology of Mary Elizabeth's brain anomalies is unknown. Moreover, Dr. Selman conceded it is not known how many otherwise healthy people in the general population may have similar brain abnormalities because if they are normal, their structural defects are only discovered accidentally, through autopsy or brain scans.

Respondent may not merely assert a "factor unrelated" defense in order to prevail in rebutting a presumed vaccine-related injury. The Vaccine Act limits what may appropriately be considered a "factor unrelated." Section 13(a)(2) states:

[T]he term "factors unrelated to the administration of the vaccine"--

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

Section 13(a)(2). Dr. Selman believes that Mary Elizabeth most probably suffers from a syndrome which has resulted in her brain anomalies as well as her seizure disorder and related deficits. While acknowledging that Mary Elizabeth was born with structural abnormalities in her brain that were present *in utero*, and that those anomalies *may* cause infantile spasms, based on the totality of the evidence, Dr. Charash does not believe that they caused Mary Elizabeth's seizure disorder and other neurological problems.

In *Koston v. Secretary of HHS*, 974 F.2d 157 (Fed. Cir. 1992), the Federal Circuit held that respondent's offer of Rett Syndrome as an alternative cause or "factor unrelated" must fail because its etiology had not been established. *Id.* at 160-61. Although the medical community suspected that Rett Syndrome was a genetic illness, because it comprises a set of distinctive symptoms only present in girls and follows a relatively predictable course, its genetic origins had not been pinpointed. *Id.* Here, we are presented with architectural anomalies which may, both experts agreed, be benign and which have never even been defined as a syndrome. It goes without saying that the etiology of this *suspected* syndrome is unknown. *See also Whitecotton v. Secretary of HHS*, 17 F.3d 374, 377-78 (Fed. Cir. 1994); *Whitecotton*, 81 F.3d 1099, 1107, at n. 13 (Fed. Cir. 1996). Further, brain anomalies do not fall within the only four exceptions listed in the Act in which an etiology need not be shown. These exceptions include infections, toxins, trauma or metabolic disturbances. Section 13(a)(2)(B). *See Knudsen v. Secretary of HHS*, 35 F.3d 543 (Fed. Cir. 1994) (unidentified viral infection found to qualify as a factor unrelated under section 13(a)(2)(B)). Accordingly, respondent's claim of alternative causation must fail because the brain anomalies Mary Elizabeth was born with are idiopathic and cannot qualify as a factor unrelated under section 13(a)(2)(B).[(29)]

It should be noted that even if the etiology of Mary Elizabeth's brain abnormalities was known, the holding in *Shyface v. Secretary of HHS*, 165 F.3d 1334 (Fed. Cir. 1999) would provide further support for petitioners. In *Shyface*, petitioners attempted to prove that DPT in fact caused the death of Cheyenne Shyface within four days of immunization. Petitioners' expert testified that Cheyenne's death was caused by a high fever resulting from a combination of the DPT immunization and an E. Coli infection. He could not determine which agent was primarily responsible for the death. Respondent's expert argued that the E. coli infection caused Cheyenne's death. Acknowledging that the petitioners' proof of either factor causing Cheyenne's death stood in equipoise, the Federal Circuit, adopting the Restatement (Second) of Torts, held that "an action is the 'legal cause' of harm of that action is a 'substantial factor' in bringing about the harm, and that the harm would not have occurred but for the action." *Id.* at 1352.

Although *Shyface* involved a causation-in-fact claim, it would appear to be equally applicable in any case in which respondent asserts a "factor unrelated" defense. In this case, I find respondent has not met her burden of proving a "factor unrelated" based on two reasons. First, I am not convinced that Mary Elizabeth would, more likely than not, have developed neurological problems from her brain anomalies alone. Secondly, the "factor unrelated" that respondent posits here, ACC and related structural anomalies, does not fit within any known syndrome and its etiology is unknown. However, even if I did not hold those views with the certainty I do, under the *Shyface* analysis, I hold, alternatively, that in Mary Elizabeth's case, the DPT vaccination she received was a substantial factor in bringing about her injury and that her injury would not have occurred but for the DPT vaccination. In so holding, I rely primarily on the testimony of Dr. Charash, who convinced me that Mary Elizabeth's brain anomalies, alone, would not have forecast a catastrophic outcome absent the devastating effects of her DPT vaccination.

The question remains whether petitioners have sustained their burden of proving that Mary Elizabeth's current condition is a sequela of the encephalopathy she evidenced within 72 hours of the DPT immunization in question. "Sequela" is defined in the American Heritage Dictionary as "[s]omething that follows, esp. a pathological *condition resulting from* a disease."[(30)] In the medical sense, sequela is defined as "any lesion or affection *following or caused by* an attack of disease."[(31)] Both definitions imply a progression of events, one leading to the next.

In *Abbott v. Secretary of HHS*, 27 Fed. Cl. 792, (1993), *aff'd in part, rev'd in part and remanded*, 19 F.3d 39 (Fed. Cir. 1994), Judge Wiese had occasion to address the question of sequela in a case in which a child drowned in a bathtub, the result of suffering a vaccine-related seizure. Because "Congress intended this statute to be understood -- and to be applied -- as it would be by a medical professional," the Court in *Abbott* determined the word "sequela" is to be treated as a term of art that carries a "precise and special meaning." The Court defined the term as referring to "somatic

conditions or events recognizable as the pathological sequence or result of an existing disease or disorder or as an independent accompaniment of such a disease or disorder." *Id*. at 794. In that case, the court was clearly attempting to distinguish cases in which there is a recognizable medical theory connecting the injury to death, rather than an intervening event, in that case, drowning.

More recently, in *Hossack v. Secretary of HHS*, 32 Fed. Cl. 769 (1995), Judge Yock stated:

a preponderance of the evidence must show that some logical, direct causal link exists between the presumed Table injury and the alleged sequela. *This is not a difficult burden, and requires far less than medical certainty*. Yet, the petitioners . . . must present some evidence, such as expert testimony, fact testimony, or documentation, to convince the special master that, more likely than not [the alleged sequela was connected to the Table injury].

*Hossack*, 32 Fed. Cl. at 776 (emphasis added). The language in *Hossack* tends to suggest that after a Table injury has been proven, the question of "sequela" should be dealt with generously. As Special Master Hastings noted, in analyzing cases interpreting the "sequela" requirement, "[W]hen a Table injury plainly has occurred, and it is difficult to definitely answer the "sequela" and "result from" questions, the tendency under the Program should be to avoid cutting off Program benefits by a narrow interpretation of those requirements. *Khalsa v. Secretary of HHS*, No. 90-1523V, 1992 WL 158595 (Cl. Ct. Spec. Mstr. June 18, 1992).

As to the question of sequelae, no one disputes that today Mary Elizabeth suffers from an encephalopathy, profound mental retardation, severe developmental delays and a seizure disorder. Nor does anyone conclude that these conditions are severable. Each expert, however, attributes the injuries to a different cause. Dr. Charash attributes them to the DPT vaccination and resulting encephalopathy. He testified that Mary Elizabeth's incessant screaming the night of her vaccination represented a sign that there was an alteration in her brain which, in turn, led to her seizure disorder and severe developmental delays. On the other hand, Dr. Selman believes any reaction Mary Elizabeth had to her DPT vaccination was inconsequential and had no lasting effect. He believes Mary Elizabeth's brain abnormalities were solely responsible for her seizure disorder and her current condition.

In weighing the testimony of the two experts, I find Dr. Charash, again, to be the more convincing on this point. The notion that whatever caused Mary Elizabeth to suffer an encephalopathic reaction the evening of her vaccination also caused her seizure disorder and residual problems presents a logical sequence of cause and effect, particularly if one accepts, as I do, that Mary Elizabeth was never the same after her DPT vaccination. Accordingly, I find, more likely than not, that Mary Elizabeth's seizure disorder and current devastating deficits flowed from the encephalopathy she suffered the evening of her November 28, 1984, DPT vaccination and are sequelae of it.

*Significant Aggravation of Underlying Encephalopathy*

Assuming that Mary Elizabeth's underlying brain abnormalities are considered an underlying encephalopathy, petitioners assert that she suffered a significant aggravation of that encephalopathy within the Table time period. The term "significant aggravation" is defined in the Act as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health."[(32)] The legislative history has discussed the magnitude of deterioration required for petitioners to successfully prove significant aggravation:

The committee has included significant aggravation in the Table in order not to exclude serious cases of illness *because of possible minor events in the person's past medical history*. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), *but is meant to encompass serious deterioration* (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis.)

H. R. Rep. 98, 99th Cong., 2d Sess. Pt. 1 at 15-16, *reprinted in* U. S. Code Cong. & Admin. News 6344, 6356-57 (emphasis added).

The test for determining whether a significant aggravation occurred has changed substantially throughout the Program's history. The Court of Appeals for the Federal Circuit has enunciated a test for evaluating whether a petitioner has successfully demonstrated a *prima facie* Table significant aggravation claim under the Act in *Whitecotton v. Secretary of HHS*, 81 F.3d 1099 (Fed. Cir. 1996). This test is not stringent and establishes four prongs for petitioners to meet their burden: (1) assess the person's condition prior to the administration of the vaccine, (2) assess the person's current condition, (3) determine if the person's current condition is substantially worse than his or her pre-vaccination condition and (4) determine whether the onset of the significant worsening began within the Table time period. If petitioners successfully prove all four prongs, the burden of showing that the preexisting illness is the cause in fact of petitioner's worsened condition passes to respondent. *Id.* at 1107.[(33)]

The first prong of the *Whitecotton* test requires an assessment of Mary Elizabeth's condition prior to the administration of the vaccination. There is no dispute that despite the brain abnormalities she was born with, before November 28, 1984, Mary Elizabeth was happy and apparently healthy. There is also no controversy surrounding what Mary Elizabeth's unfortunate condition is currently. She is entirely dependent on others for care, cannot ambulate or communicate and is profoundly mentally retarded (step-two of the *Whitecotton* test).

Step three of the *Whitecotton* test requires petitioners to demonstrate that Mary Elizabeth's current condition is significantly worse than it was before her November 18, 1984, DPT vaccination. This requirement dictates only a simple comparison of her pre- and post-vaccination conditions. *Gruber v. Secretary of HHS*, No. 95-34V, 1998 WL 928423, at *9 (Fed. Cl. Spec. Mstr. Dec. 22, 1998) (*citing Whitecotton v. Secretary of HHS*, 81 F.3d at 1101-02, 1108). This requirement has been amply satisfied. Before her DPT immunization, Mary Elizabeth was a normal child who reacted normally with her environment. Currently, she is profoundly mentally retarded and severely developmentally delayed with no ability to assist in her activities of daily living. Clearly, her condition is significantly worse than her pre-vaccination condition.

Finally, I must determine if the first symptom or manifestation of the significant aggravation occurred within the 72 hours of her DPT inoculation -- the Table time period. As for whether the fourth step in the *Whitecotton* analysis has been met, it is undisputed that the evening of her DPT vaccination, Mary Elizabeth cried unconsolably for at least five hours. After that, I have found that Mary Elizabeth was no longer the same child. Although the onset of her infantile spasms occurred one to two weeks after her vaccination, Dr. Charash was convincing that they were part of the same course of events set in motion by the insult to her brain on the evening of her vaccination. Accordingly, I find that the first symptom or manifestation of the significant aggravation of Mary Elizabeth's underlying condition occurred within 72 hours of her vaccination, thus satisfying prong four of the *Whitecotton* requirements.[(34)] Petitioners thus meet the requirements for demonstrating a Table significant aggravation under *Whitecotton* and have thus proven a presumptively vaccine-related injury.[(35)] The only way this presumption can be rebutted is if respondent successfully proves that a factor unrelated to the administration of the vaccination in question caused Mary Elizabeth's condition.

*Factor Unrelated*

Once petitioners have established a *prima facie* case, respondent can still overcome the presumption of vaccine-relatedness by showing the evidence preponderates in favor of a finding that a factor unrelated to the administration of the vaccination, including the preexisting condition, was the cause of the vaccinee's post-vaccination significant aggravation. Section 13(a)(1)(B); *Whitecotton v. Secretary of HHS*, 81 F.3d 1099, 1107 ( Fed. Cir. 1996). In order to meet her burden of proof of a "factor unrelated," respondent is held to the standard of proving actual causation under the Vaccine Act. *Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994).

For the same reasons respondent has not met her burden of proving alternate causation under a Table analysis, she is similarly stymied using a significant aggravation construct. That is because there is no known etiology of Mary Elizabeth's brain anomalies. In its first *Whitecotton* decision, the Federal Circuit made plain that the Act's proscriptions against defeating a Table claim with an idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness or condition also apply in cases involving a Table significant aggravation. *Whitecotton v. Secretary of HHS*, 17 F.3d 374, 377 (Fed. Cir. 1994), *rev'd and remanded on other grounds, Shalala v. Whitecotton*, 514 U.S. 268 (1995). Accordingly, because the etiology of Mary Elizabeth's brain anomalies remains unknown, respondent's "factor unrelated" defense must fail.

*Sequela*

While proof of a Table injury of encephalopathy includes a determination of whether a vaccinee's current condition is a sequela of the presumed vaccine-related injury, Special Master Golkiewicz has offered the provocative theory that such an inquiry is inapplicable in cases of Table significant aggravation. He believes that such inquiry is essentially subsumed in the four-part *Whitecotton* analysis. *Gruber, supra*, at *14. Special Master Golkiewicz posited in *Gruber:*

The inquiry by which a Table significant aggravation determination is made essentially invalidates respondent's concerns [regarding proof of sequela] because the analysis includes a consideration of [the vaccinee's] current condition. The finding that [the vaccinee] suffered a significant aggravation does not mean that [her] injury is limited to an event that occurred just within the Table time period following vaccination. It is only the first manifestation or onset of the Table injury that had to have occurred within Table time. Under the third step of *Whitecotton*, significant aggravation is found by the court to have occurred by virtue of a comparison of the pre-vaccination condition and the current condition. Upon a finding of aggravation from that comparison, step four is a determination of the first manifestation or onset of the aggravation. If the onset if found to have occurred within Table time, then it follows ineluctably that the current condition is related to or resulted from the event that occurred within the Table time frame. Sequelae, by definition, arise from the vaccine injury and comprise, or are part of, the current condition. Given these findings, it would be fictitious to consider that the significant aggravation and sequela inquiries are distinguishable and separable; the *Whitecotton* test has in effect merged the inquiries. Thus, petitioners automatically fulfill the sequela requirement by successfully demonstrating a Table significant aggravation of Irene's condition.

*Id*. I find theory this to have merit. However, even if some measure of proof of "sequelae" were required for instances of significant aggravation, I find petitioners have more than met their burden. Using the *Shyface* criteria, I find that the DPT vaccination in question was a significant factor in causing Mary Elizabeth's current condition and that she would not be in such dire straits but for the administration of the vaccination.[(36)]

Based on all of the above, I find that petitioners have successfully demonstrated that Mary Elizabeth suffered a Table significant aggravation of her underlying brain abnormality. In the alternative, and assuming Mary Elizabeth's brain anomalies do not represent an underlying encephalopathy, I find petitioners have shown, more likely than not, that Mary Elizabeth suffered a Table encephalopathy. Under either analysis, respondent did not successfully rebut the presumption petitioners enjoy by proving that a factor unrelated to the administration of the vaccination actually caused Mary Elizabeth's injuries. Finally, petitioners have shown that Mary Elizabeth's current condition is a sequela of her vaccine-related injury. Accordingly, petitioners are entitled to an award under the Program.

**V.**

## FINDINGS OF FACT

1. As the parents of their minor daughter, petitioners have the requisite capacity to bring this action. Section 11(b)(1)(A). Petition at 1, 4.

2. Petitioners have not previously collected an award or settlement of a civil action in connection with any alleged injury sustained by Mary Elizabeth due to the administration of the DPT vaccine in question. Section 11(c)(1)(E); Petition at 4.

3. Mary Elizabeth was administered a vaccine listed in the Vaccine Injury Table. Section 11(c)(1)(A); Petition at 1.

4. Said vaccine was administered in the United States, in Anderson, South Carolina. Section 11(c)(1)(B)(i)(I); Petition at 2.

5. There is a preponderance of the evidence that petitioners expended in excess of $1000 in unreimbursed medical expenses as a result of Mary Elizabeth's vaccine-related injury. Section 11(c)(1)(D)(i).

6. There is a preponderance of the evidence that Mary Elizabeth suffered a significant aggravation of a pre-existing encephalopathy with onset within 72 hours of the administration of the DPT vaccination she received on November 28, 1984.

7. Alternatively, if Mary Elizabeth's brain anomalies are not considered to constitute an underlying encephalopathy, there is a preponderance of the evidence that Mary Elizabeth suffered an encephalopathy as defined by the Vaccine Injury Table with onset within 72 hours of the administration of the DPT vaccination she received on November 28, 1984.

8. There is not a preponderance of the evidence that Mary Elizabeth's injury is due to a factor unrelated to the immunization in question.

9. There is a preponderance of the evidence that Mary Elizabeth's current condition is a sequela of her vaccine-related injury.

## CONCLUSION

Based on the foregoing, the undersigned finds, after considering the entire record in this case, that petitioners are entitled to compensation under the Vaccine Act. An order setting forth the schedule for resolving the damages portion of this case will be issued separately.

**IT IS SO ORDERED.**

_____

Elizabeth E. Wright

Special Master

1. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C.A. §§ 300aa-1 through -34 (West 1991 & Supp. 1998)). References shall be to the relevant subsection of 42 U.S.C.A. § 300aa.

2. The evidence in the record consists primarily of exhibits submitted as part of the petition filed in this case ("P. Ex. ____"), respondent's exhibits filed in this matter ("R. Ex. ____"), video depositions taken of Mr. and Mrs. Haley and Dr. Samuel Haddock on December 5, 1996 , and filed on January 31, 1997 ("Dep. at ___"), evidence taken at the telephonic hearing held in this matter on April 9, 1997 ("Tr. I at ___) and evidence taken at the expert hearing held in this matter on April 23, 1998 (Tr. II at ____") .

3. Notations from this visit indicate only height, weight and head circumference. Nothing abnormal is noted. P. Ex. 3 at 30.

4. Ordinarily, Mary Elizabeth would have awakened for a 1:30 a.m. and a 5:30 a.m. feeding. Mrs. Haley Dep. at 34.

5. Mrs. Haley was not certain when the drooling began but believes it was "a couple of days" after her vaccination. Tr.

I at 13.

6. Petitioners filed a videotaped deposition of Mr. Sanford Eugene Haley, Mary Elizabeth's father, largely corroborating the facts as elicited from Mrs. Haley. Mr. Haley Deposition, filed January 31, 1997. Mr. Haley provided more information about Mary Elizabeth's screaming and jerking spells. He testified she was "wiggling and jerking." Mr. Haley Dep. at 20. According to Mr. Haley, Mary Elizabeth bowed her back and jerked her head against her father's shoulder. He testified, "She would sort of crimp up, not so much with her little hands but her little legs, it was like -- she would pull her legs up almost, and then -- but she just couldn't be still." *Id.* In addition, petitioners filed the videotaped deposition of Dr. Samuel Haddock. Dr. Haddock had no independent recollection of the events described by Mr. and Mrs. Haley but confirmed that he prescribed Butibel during that period of time because his father, also a physician, had used it. He also verified that his handwriting appeared on the label of the bottle of Butibel petitioners brought to the deposition. Dr. Haddock Dep., filed January 31, 1997, at 11, 14, 16.

7. Mary Elizabeth was examined by an ophthalmologist and found to have a cleft of one optic nerve as well as retinal pigmentary abnormalities in both eyes. P. Ex. B at 57-58; P. Ex. B at 36.

8. Dr. Charash received his medical degree from Cornell University Medical College. He is board certified pediatrics but has practiced pediatric neurology from 1958 to the present. From 1958 to 1985, Dr Charash was Clinical Director of Child Neurology at the Nassau County Medical Center, where he remains an attending physician. He is currently an Associate Clinical Professor in the Department of Pediatrics at Cornell University Medical College. He is credited with a number of publications in his field. Curriculum Vitae of Dr. Charash, filed Nov. 18, 1996; Tr. II at 8-9.

9. If Mary Elizabeth was actually screaming *during* the jerking movements, Dr. Charash would attribute the movement of the limbs to be voluntary, rather than reflecting involuntary myoclonic activity. However, "if the jerks continued over the next days, then I would have to retrospectively say that the jerks were myoclonic movements at that time." Tr. II at 27-28.

10. Dr. Selman maintains a private practice in Westchester, New York, where he sees both children and adult neurology patients. Tr. II at 57. Dr. Selman is an attending neurologist at the Northern Westchester Hospital Center in Mount Kisco, New York, and a consulting neurologist in the Westchester County Medical Center in Valhalla, New York. He has authored several publications in his field. R. Ex. B.

11. Later, Dr. Selman conceded he did not know the dosage of Butibel that Mary Elizabeth received. Tr. II at 82.

12. Dr. Selman explained that Butibel is a depressant that contains Tylenol and Phenobarbital. Phenobarbital is an anti-seizure medication which is a central nervous system depressant and was, at one time used as a hypnotic (sleep) medication. Tr. II at 81, 83.

13. Dr. Selman conceded that none of Mary Elizabeth's doctors has been able to name a specific syndrome she might have.

14. Petitioners must prove their case by a preponderance of the evidence, which requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before [the special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." *In re Winship*, 397 U.S. 358, 372-73 (1970) (Harlan, J., concurring) *quoting* F. James, Civil Procedure 250-51 (1965). Mere conjecture or speculation will not establish a probability. *Snowbank Enter. v. United States*, 6 Cl.Ct. 476, 486 (Cl. Ct. 1984).

15. Section 14(a).

16. Section 11(c)(1)(C)(i). If manifestation or significant aggravation of an injury not listed on the Vaccine Injury Table, or if the significant aggravation of an injury listed on the Table but with onset outside the statutorily prescribed time frames occurs, causation is not presumed and petitioner must prove that the vaccine actually caused the injury. Section 11(c)(1)(C)(ii).

17. Section 13(a)(1)(B). Other prerequisites to compensation include: (1) that the injured person suffered the residual effects of a vaccine-related injury for more than six months after the administration of the vaccine. Section 11(c)(1)(D)(i); (2) that the petitioner incurred in excess of $1000 in unreimbursable vaccine-related expenses. Section 11(c)(1)(D)

(i); (3) that the vaccine was administered in the United States. Section 11(c)(1)(B)(i)(I); (4) that the petitioner did not previously collect a judgment or settlement in a prior civil action. Section 11(c)(1)(E); and (5) that the action be brought by the injured person's legal representative. Section 11(b)(1)(A).

18. For purposes of the Vaccine Act, an afebrile seizure is one in which the seizure is not accompanied by a temperature of 102 F or greater. Section 14(b)(2).

19. In a footnote, Justice Souter noted that the Court of Appeals's language could "also be read as casting doubt on the Special Master's conclusion that claimant's microcephaly evidenced a pre-existing encephalopathy. We express no view as to the validity of that conclusion." *Whitecotton*, 514 U.S. at 273, n. 2. On remand, however, the Court of Appeals for the Federal Circuit affirmed the special master's denial of an initial onset claim, finding support for the notion that Maggie Whitecotton's microcephaly constituted a pre-vaccination manifestation of an encephalopathy. *Whitecotton*, 81 F. 3d 1099, 1105 (Fed. Cir. 1996). The court then set forth a new test for determining whether a Table significant aggravation had occurred (*see infra* at p. 23) and remanded the case for further proceedings.

20. Tuberous sclerosis is a genetically determined disorder affecting the nervous system which is principally characterized by tubers in the brain. It is often accompanied by seizures and mental retardation. Dorlands's Illustrated Medical Dictionary 1496 (27th ed. 1988) (hereafter, "Dorland's").

21. The *Barnes* case was an omnibus proceeding comprising 22 separate cases involving vaccinees with tuberous sclerosis.

22. Section 14(b)(3)(A).

23. Although the Act does not differentiate between "acute" and "static" or "silent" encephalopathies, from my years of experience hearing vaccine cases, it would appear that the framers of the Act intended the "frequent manifestations" of encephalopathy listed in Section 14(b)(3)(A) to refer to the acute phase of an encephalopathy. I have heard many cases in which a vaccinee is described as having an underlying "static" encephalopathy, in which none of the listed indicia are present, but the brain has been damaged, leaving sometimes devastating residua.

24. He also believes there would have been a much greater change in her feeding and alertness for Mary Elizabeth to have experienced an encephalopathy.

25. Petitioner bears the burden of demonstrating the facts necessary for an award by a "preponderance of the evidence." Section 13(a)(1)(A).

26. Section 13(a)(1)(B).

27. Section 13(a)(1)(B).

28. Although he could not be precise, he believed that between 58 and 70 percent of individuals with Mary Elizabeth's brain abnormalities would experience seizures.

29. Legislative history states the following:

[T]he Committee recognizes that there is public debate over the incidence of illnesses that coincidentally occur within a short time of vaccination. The Committee further recognizes that the deeming of vaccine-relatedness adopted here may provide compensation to some children whose illness is not, in fact, vaccine-related. . . . Until such time [that research provides more definitive information about the incidence of vaccine injury] however, the Committee has chosen to provide compensation to all persons whose injuries meet the requirements of the petition and the Table and whose injuries cannot be demonstrated to be caused by other factors.

H.R. Rep. No. 99-908, pt. 1, at 18 (1986).

30. The American Heritage Dictionary 1119 (2nd ed. 1985) (emphasis added).

31. Dorland's at 1509 (emphasis added).

32. Section 33(4).

33. The legal construct most widely used before *Whitecotton* was far more rigorous. In *Misasi v. Secretary of Health and Human Services*, 23 Cl. Ct. 322 (1991), Judge Andewelt set forth the criteria he believed were necessary for a petitioner to successfully prove significant aggravation:

To evaluate whether an individual suffered a significant aggravation of a particular condition, it is necessary to (1) assess the individual's condition prior to administration of the vaccine, *i.e.*, evaluate the nature and extent of the individual's pre-existing condition, (2) assess the individual's current condition after the administration of the vaccine, (3) predict the individual's condition had the vaccine not been administered, and (4) compare the individual's current condition with the predicted condition had the vaccine not been administered. [citation omitted] A petitioner satisfies Section 13(a)(1)(A) if he or she establishes by a preponderance of the evidence that the individual's current condition constitutes a significant aggravation of the individual's predicted condition had the vaccine not been administered.

*Id.* at 324.

34. Even if this case were to be analyzed under the more stringent *Misasi* test, petitioners would still prevail, in my view. As discussed *supra*, there are many individuals with brain anomalies similar to Mary Elizabeth's who are perfectly normal throughout their lives. In other words, just because she was born with certain architectural anomalies in her brain, Mary Elizabeth was not destined to become compromised in her mental or developmental functioning. Although the chances of developing seizures or neurological problems were greater for Mary Elizabeth than in the normal population, as Dr. Charash conceded, there was no evidence that convinced me there was any way to accurately assess the probability that Mary Elizabeth would have developed neurological problems. This case is thus unlike *Whitecotton*, in which the special master cited a prominent neurology textbook stating that nearly 100% of microcephalic children will be mentally retarded and medical testimony was elicited supporting that conclusion. As well, in *Gruber, supra,* the vaccinee was diagnosed with a syndrome known as Severe Myoclonic Epilepsy ("SME"), the prognosis for which was consistently catastrophic. *Id.* at *5. In this case, then, unlike the situations in both *Whitecotton* and *Gruber*, there was no predictable and inexorable downward spiral in store for Mary Elizabeth absent the administration of the DPT vaccination.

35. I agree with Special Master Golkiewicz's observation in *Gruber* that even if a post-vaccinal symptom within the Table time frame would comport with the "next expression of a disease whose clinical course and outcome is predictable," such a natural progression of an underlying neurological disorder (in that case, encephalopathy), would not defeat a finding of a Table significant aggravation under the *Whitecotton* analysis. *Gruber, supra,* at *10-11. However, in the instant case, that question need not be reached, because I find that one could not accurately predict what Mary Elizabeth's course would have been absent the administration of the DPT vaccination in question.

36. Consequently, petitioners have also, obviously, met the Act's criterion that Mary Elizabeth suffered the residual effects of her vaccine-related injury for more than six months after the administration of the vaccine, as required by Section 11(c)(1)(D)(i).