OFFICE OF SPECIAL MASTERS

No. V

(Filed: December 22, 1998)

* *		
IRENE BAKER GRUBER,	*	
a Minor, by and through her Parents and	*	
Natural Guardians, MICHAEL GRUBER and	*	
LANA BAKER,	*	
	*	
Petitioners,	*	**TO BE PUBLISHED**
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND	*	
HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *		

Timothy B. Saylor, Canton, Ohio, for petitioners.

Mark W. Rogers, U.S. Department of Justice, Washington, D.C., for respondent.

DECISION ON ENTITLEMENT

GOLKIEWICZ, *Special Master*.

Petitioners, Michael Gruber and Lana Baker, filed a petition for compensation under the National Vaccine Injury Compensation Program on January 13, 1995.[(1)] Petitioners allege that their daughter, Irene Baker Gruber ("Irene") suffered a significant aggravation of an underlying neurologic disorder as the result of a diphtheria-pertussis-tetanus ("DPT") vaccination she received on January 16, 1992. Transcript of Hearing ("Tr.") at 11-12. On April 12, 1995, respondent filed

a report recommending that the court dismiss this case based on the lack of evidence to support a finding that Irene's condition is vaccine-related.

An evidentiary hearing was held on December 11, 1997, in Florence, Kentucky. At that time, petitioners presented the testimony of Michael Gruber, Irene's father, and Dr. Tracy Glauser. Testifying for respondent was Dr. Mary Anne Guggenheim. Petitioners filed a post-hearing brief on April 6, 1998, to which respondent filed a responsive brief on June 18, 1998. This case is now ripe for decision.

FACTS

The pertinent facts are not in dispute. Irene was born on July 23, 1991, at Grant Medical Center in Columbus, Ohio, following a pregnancy remarkable only for borderline gestational diabetes. Petitioners ("P.") exhibit ("ex.") 1 at 6. At birth, Irene weighed 7 pounds, 14.8 ounces and measured 20 inches in length. Her APGAR scores were eight and nine.[(2)] P. ex. 1 at 20.

Irene was noted by her pediatrician, Dr. Roach, to be a well baby at her first few appointments. P. ex. 2 at 4-5. She received her first set of immunizations on September 18, 1991, and her second set on November 20, 1991. P. ex. 2 at 5. Michael Gruber, Irene's father, testified that in late November or early December 1991, he and his wife noticed that Irene was experiencing very subtle episodes of eye fluttering. Tr. at 14-15; *see also* P. ex. 2 at 7 (pediatrician's records confirm time of onset of episodes). Mr. Gruber described these episodes as "just a brief double blink of the eyes" that did not occur on a daily basis but could be seen most frequently when Irene was just waking from a nap. Tr. at 15. Mr. Gruber did not believe the episodes to be unusual because they were infrequent and subtle. Tr. at 38. By early January 1992, Mr. Gruber testified, he and his wife noticed an increase in the frequency of the episodes, which were no longer associated only with waking. However, petitioners were still not concerned for Irene's health at that time. Tr. at 16.

Mr. Gruber testified that on January 16, 1992, when Irene was taken to Dr. Roach for her third DPT vaccination, petitioners mentioned the eye-fluttering episodes to Dr. Roach. Tr. at 19-20. According to Mr. Gruber, Dr. Roach observed several of the episodes at that time, but felt that they were startles, a normal response to Irene's environmental stimuli. Tr. at 20. Dr. Roach's notes indicate Irene was a well baby at that appointment and she received her third DPT shot that afternoon. Tr. at 20-21; P. ex. 2 at 5.

The Grubers did not notice anything unusual about Irene on the evening of January 16. Tr. at 21. However, Mr. Gruber testified that the next morning his wife was changing Irene's diaper when Irene's body began to jerk. *Id*. Mr. Gruber did not observe the first part of the episode, but did witness the rest of it. He described Irene as "somewhat rigid and had -- had jerking motions. She was, you know, sort of gazing off at that point." Tr. at 23. He continued, "I believe it was her right arm was basically, you know, stiff, and her -- the hand pumping, as I recall. And her legs seemed somewhat stiffened." Tr. at 24. Mr. Gruber testified that was the first such episode he and his wife witnessed. Tr. at 24, 32. Petitioners suspected the jerking was a seizure and consulted a child medical book. The book instructed that a seizure lasting less than five minutes was not a medical emergency, so petitioners did not call 911. They did call Dr. Roach's office, however, and were instructed to bring Irene to the office. Tr. at 21-22. Petitioners arrived at the medical office at about 8:45 a.m., and Irene was examined by Dr. Royhans. According to Mr. Gruber, Dr. Royhans believed the episode to be a seizure and scheduled an EEG for Irene for February 4. Tr. at 22-23.

Dr. Royhans' records of January 17, 1992, are as follows:

PC [(present complaint)] Mom [des]cribes jerking movements [started] in one leg -- to rest of body lasting 5 min. Dad tried to hold leg still but it cont. to jerk. Eyes remained open --- baby was drowsy after & slept for short time. Irritable & fussy now.

No temp. noted 98.5 Ax [(axillary)] after seizure[.] Mom changed diaper at 7:30 A -- started jerking as above[,] no cyanosis[,] started on leg ® jerking then [indecipherable] body to arms (both) stopped on own.

P. ex. 2 at 6. The doctor's impression was "seizure - time related to DPT." *Id*. Another notation instructs that no further "P" (pertussis) is to be given and that MMR is to be withheld as well. *Id*. A Vaccine

Adverse Events Reporting System (VAERS) form was completed on January 17, 1992, reporting the events as described above. P. ex. 11 at 1.

Mr. Gruber referred to notes made by petitioners contemporaneously with Irene's birth and development (P. ex. AA, filed at hearing) to confirm that Irene had other seizures on January 29 and February 2. Tr. at 25. The handwritten notes report the following:

1st seizure - Day after DPT 1-17-92 During diaper change right leg began to jerk

2nd 1-29-92 incident last approx. 40 sec. on back playing with toys. Walked over [and] saw arm jerking it seemed to dissipate after I held onto it. Only in arm on R side. Had been awake from nap 15-20 mins. Had hiccups during seizure. Eyes open, quiet but seemed aware.

Overall appears to jerk and startle more easily

3rd 2-2-92 5:53pm5:57p.m. Irene had been up from her nap about ½ hour. She had been sitting up on my lap. I laid her down to change her and her right arm tightened up and was jerking. Her head seemed to stiffen [and] pull up to left. Duration of approx 3 min.

P. ex. AA at 29. Mr. Gruber testified that his wife made the entries describing the first and second seizures and he made the entry regarding the third seizure. Tr. at 26. Irene's pediatrician's notes report those seizures as well. P. ex. 2 at 6. There are also handwritten records of seizures occurring on February 13, and March 14, 1992. P. ex. AA at 30.

Mr. Gruber recalled the change in Irene's seizure activity following the January 16th vaccination, describing it as sudden rather than a consistent increase or smooth continuum. Tr. at 41-42, 46. "The -- both the frequency increased dramatically, as well as her head would start jerking. You know, she would jerk her head back. It would -- and she would throw her arms back, which it never occurred prior to that time." Tr. at 27. He continued:

Where -- where I referred to as the November through January 16th time period where I would say things were subtle and barely noticeable, after January 16th, it basically came right at you and hit you squarely between the eyes. There was no question as far as that she was, you know, having -- having a problem.

Tr. at 41.

An EEG was performed on February 4, 1992, recording activity during waking and sleep states, and was reported to be abnormal. "Generalized spike and wave discharges appeared during the waking state, appeared to be further increased during photic stimulation, and were also seen during sleep." P. ex. 12 at 2-3. An extended EEG with video monitoring was performed on February 18, 1992. That EEG was also abnormal. P. ex. 12 at 38-39. A prolonged 24-hour EEG telemetry recording was also conducted that same day, following the EEG. The results were as follows:

[T]he patient had a very large number of clinical episodes identified by the parent as the typical clinical episodes of concern. These occupied much of the waking recording especially for the hour or so following awakening from sleep. These were generalized myoclonic seizures. They were associated with a generalized atypical spike and wave discharge. Apparently this was one of the two types of clinical episodes of concern as possible seizures. The other type was not recorded.

P. ex 12 at 40.

Irene was admitted to Children's Hospital in Columbus, Ohio on March 6, 1992, following a twenty-minute seizure that resolved spontaneously in the emergency room. During the hospitalization, an EEG was performed which recorded a large number of clinical episodes of generalized myoclonic seizures. Irene did well overnight and was discharged on March 8, 1992. P. ex. 12 at 92, 282.

On March 22, 1992, Irene experienced her first episode of status epilepticus. Children's Hospital records note that "generalized clonic seizures lasted for 50 min. before valium and dilantin stopped her seizures." She required intubation following valium-induced apnea. P. ex. 12 at 104. An EEG conducted during that hospitalization on March 25, 1992, was abnormal, showing "moderate to severe generalized slowing of the cerebral activity." P. ex. 12 at 128. Irene was discharged from the hospital on March 30, 1992. P. ex. 12 at 174; Tr. at 32.

Mr. Gruber and his wife noticed that Irene had an increased sensitivity to light sometime after February 1992. According to Mr. Gruber, sometimes just going outside would be enough to trigger a seizure in Irene. They kept cardboard in their windows. "To take her to the doctor's office, we had to put a coat over her head, put cardboard up in the windows of our car." Tr. at 36.

Over the next few months, Irene's seizure activity continued in the form of multiple myoclonic seizures and generalized tonic-clonic seizures. P. ex. 12 at 222; P. ex. 2 at 11-20 (pediatrician records). On August 5, 1992, Dr. Roach's notes indicate Irene's parents reported a "different" type of seizure. She was described as having three to four minutes of continuous eye blinking followed by five minutes of eye deviation to the right, limpness, then 15 minutes of intermittent deviation. Afterward, Irene vomited and became pale. P. ex. 2 at 18.

On July 1, 1992, Irene was reported to be "growing normally, along the 75th percentile for height and weight and 50th percentile for head circumference." P. ex. 7 at 1. On August 27, 1992, she was noted to have cognitive, social, and behavioral skills at an age-appropriate level. Her neurodevelopmental functioning was also thought to be age-appropriate. Her general fine/gross motor skills, however, were equivalent to those of a ten-month old. P. ex. 12 at 302. Pediatrician notes of September 21, 1992, report that Irene could pull to a stand and was cruising. She could say "Ma Ma" and "Da Da" and had words for body parts. P. ex. 2 at 20. An evaluation on October 22, 1992, reports that Irene sat alone at five to six months and started to say words at 11 months. At that time, she could not walk, but was cruising along furniture. P. ex. 6 at 2.

On October 22, 1992, Irene was evaluated by Dr. Blaise Bourgeois of The Cleveland Clinic Foundation. He noted that she was experiencing three different seizure types at the time: 1) "generalized myoclonic seizures . . . [that] occur almost every few minutes"; 2 "generalized, predominantly clonic seizures, occasionally with a tonic phase . . . usually last[ing] less than one minute, but on occasions, have persisted for up to an hour"; and 3) "focal seizures." P. ex. 6 at 1-2. Irene's seizures continued over the next few years, requiring medication and hospitalization.

A momentous event in Irene's clinical history occurred on March 11, 1996, when Irene was admitted to Columbus Children's Hospital for a generalized tonic clonic seizure which progressed to status epilepticus. Irene developed liver failure and was transferred to Children's Hospital Medical Center in Cincinnati, Ohio, for a possible liver transplant, which became unnecessary when her liver enzymes normalized. However, Irene remained hospitalized for nearly two months, until May 5. P. ex. 12 (second P. ex. 12, filed Aug. 14, 1996) at 22; P. ex. 13 at 10-11. Mr. Gruber testified that after her liver failure, Irene lost any developmental gains she had made and became severely mentally retarded. Irene is

currently in a wheelchair, unable to stand or walk. She has no upper body control and cannot speak. She cannot control her bowel functions and is entirely dependent upon her parents for care. Tr. at 37-38; P. ex. 15 at 3.

MEDICAL EXPERT EVIDENCE

Dr. Glauser

Dr. Tracy A. Glauser, board certified in pediatrics and neurology, with special competence in child neurology, and one of Irene's treating physicians since July of 1993, testified on behalf of petitioners.(3) Dr. Glauser believes that Irene suffered an "abnormal reaction" to her January 16, 1992, DPT vaccination that resulted in a distinct and significant worsening of her seizures. Tr. at 60; P. filings of Aug. 15, 1997, and April 28, 1997 (expert reports of Dr. Glauser).

First, Dr. Glauser testified that Irene has a very rare "syndrome," known as Severe Myoclonic Epilepsy ("SME")--a complex of symptoms, for which the etiology is unknown.(4) Tr. at 62, 96, 102. In 1992, only 172 cases had been reported and, according to Dr. Glauser, that number is not significantly higher now. Tr. at 65; P. ex. 15. Dr. Glauser describes the prognosis for SME as consistently "catastrophic." Tr. at 84. SME patients are often normal initially but virtually all end up being severely retarded, according to Dr. Glauser. Tr. at 82, 84, 122-23. The condition usually begins with the development of one type of seizure and then other types of seizures develop. Tr. at 85. Typically, the seizures of SME patients are resistant to any kind of treatment during the first years of evolution, requiring numerous hospitalizations. Tr. at 84-85.

While Dr. Glauser believes that the onset of Irene's SME predated her third DPT vaccination, as manifested by the seizures beginning in late November or early December, he argues that the January 16, 1992, DPT vaccination caused a significant worsening of her seizures. Tr. at 96-97; P. filing of Aug. 15, 1997. Dr. Glauser testified that, based on petitioners' videotape of Irene between November 20th and December 1st, Irene was experiencing myoclonic seizures.(5) Tr. at 53. Based on a videotape of Irene after January 17th, Dr. Glauser believes Irene was still suffering myoclonic seizures, but that they were "much worse" in nature, dramatically increased in frequency and in duration. Tr. at 54-56, 59, 68-69. Dr. Glauser testified that the post-vaccinal tape shows a child who was having almost continual brief seizures. Tr. at 114-15. He found it "very hard to watch those videotapes, because I saw that she was having so many seizures, and I knew Mom didn't recognize them at the time." Tr. at 61. According to Dr. Glauser, on January 17th, Irene suffered a "partial onset seizure" and thereafter her condition became substantially worse to the point where she was unable to function because of the continuous nature of the seizures. Tr. at 68, 68-69.

Dr. Glauser testified that it is difficult to say with specificity what course or progression is characteristic of SME because there are so few cases. While it is typical for an SME patient's seizures to increase in severity and frequency, Dr. Glauser does not know within what time frame the deterioration occurs or whether the deterioration is very quick, or slow and steady.(6) Tr. at 82, 86, 94, 104-05. While the course of SME is far from established, Dr. Glauser testified, "I still think that the intensity and the frequency of the seizures that we saw in the video is more than I would have expected [for SME], having read the literature about it." He attributes that markedly increased severity in Irene's condition to the vaccination. Tr. at 117, 120. In addition, Dr. Glauser believes DPT can aggravate SME, based on a medical article that suggests a temporal relationship may exist between vaccination and afebrile seizures.(7) P. ex. 15 at court-numbered p. 8 (Charlotte Dravet, *et al.*, "Severe Myoclonic Epilepsy in Infants", chpt. 8, Epileptic Syndromes in Infancy, Childhood and Adolescence, 75, 77 (2nd ed. 1992) (hereafter "SME in Infants"));

Tr. at 64.

Dr. Guggenheim

Dr. Mary Anne Guggenheim, board-certified in pediatrics and neurology, with special competence in child neurology, testified on behalf of respondent.[8] Dr. Guggenheim believes that Irene's course was not significantly aggravated by her third DPT vaccination but, rather, that her course reflects a progression consistent with SME.[9] Tr. at 139; R. ex. A at 3.

Based on petitioners' videotapes of Irene, Dr. Guggenheim believes, retrospectively, that the first symptom of Irene's SME appeared around Thanksgiving as myoclonic seizures. Tr. at 129, 133. Subsequently, in the beginning of January, Irene developed, in addition to the rapid eye fluttering, some "funny mouth movements" and "a little bit of a body jerk." Tr. at 133. The duration of the seizures also increased, according to Dr. Guggenheim, from a half a second to a couple of seconds at that time. Tr. at 134. According to Dr. Guggenheim, the seizure Irene suffered after her third DPT vaccination was simply the first episode of a second type of seizure, and since the nature of SME is to have three to five different types of seizures, that episode cannot be considered a significant deterioration of Irene's condition. Tr. at 139, 144.

Dr. Guggenheim does not believe the progression of Irene's course was atypical for SME. While the literature provides little data about a typical time course for the progression of SME, Dr. Guggenheim believes that over the period of one year, SME becomes apparent. Tr. at 132. By late January or early February, Dr. Guggenheim testified, Irene's seizures were much more obvious because they were much more frequent and clinically much worse. Tr. at 136-38. However, that increase in noticeability of Irene's seizures was an indication to Dr. Guggenheim that Irene's underlying disorder, SME, was becoming more obvious, not that it had worsened. Tr. at 135.

STATUTORY REQUIREMENTS

Petitioners may establish causation in one of two ways. First, petitioners may demonstrate what is commonly referred to as a Table case. The Vaccine Injury Table lists vaccines covered by the Act and certain injuries and conditions that may stem from those vaccines. §14. If the special master finds that a person received a vaccine listed on the Table and suffered the onset or significant aggravation of an injury listed on the Table within the time period prescribed by the Table, then the petitioners are entitled to a presumption that the vaccine caused the injury. §13(a)(1)(A). The respondent may rebut the presumption of causation with a preponderance of the evidence that the injury or condition was due to a factor unrelated to the administration of the vaccine.[10] §13(a)(1)(B).

Second, petitioners may establish causation by proving, by a preponderance of the evidence, that the vaccine actually caused the alleged injury. Actual causation requires proof of a "logical sequence of cause and effect," using a medical or scientific theory to causally connect the vaccination and the injury. *Strother v. Secretary of HHS*, 21 Cl. Ct. 356, 370 (1990) (*citing Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir. 1983)), *aff'd without opinion*, 950 F.2d 731 (Fed. Cir. 1991).

Petitioners' theory of recovery in this case is that Irene suffered a Table injury, namely, the significant aggravation of a seizure disorder. Petitioners' burden in a significant aggravation case is to prove that the vaccine recipient:

sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with [a Table vaccine] . . ., and the first symptom or manifestation

of the onset or of the significant aggravation of any such illness, disability, injury, or condition . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table . . . .

Section 11(c)(1)(C)(i). In this case, petitioners must prove that the first symptom or manifestation of the alleged significant aggravation of Irene's seizure disorder occurred within 72 hours of the DPT vaccination in issue. §14(a)(I).

The interpretation of the term "significant aggravation" has been the subject of numerous cases arising under the Program. The Vaccine Act provides that the term "significant aggravation" means "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." § 33(4). The legal interpretation of the term has changed significantly since the first attempts to define and apply it to Program cases. The Court of Appeals for the Federal Circuit, recognizing the difficulty with which the term has been construed and applied, enunciated a test for evaluating whether a petitioner has successfully demonstrated a *prima facie* Table significant aggravation claim under the Act. *Whitecotton v. Secretary of HHS*, 81 F.3d 1099 (Fed. Cir. 1996). The test is not a stringent one, requiring only that the special master:

(1) assess the person's condition prior to administration of the vaccine, (2) assess the person's current condition, and (3) determine if the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination within the meaning of the statute. If the special master concludes that the person has suffered a significant aggravation, the special master must then . . . (4) determine whether the first symptom or manifestation of the significant aggravation occurred within the time period prescribed by the Table.

Id. at 1107. This case is measured against the above criteria.

DISCUSSION

There are a number of points upon which both medical experts agree regarding Irene's condition, including the nature of SME and the role it played in Irene's circumstances. First, the experts believe that the eye-fluttering episodes Irene experienced beginning around Thanksgiving of 1991 were myoclonic seizures. There is also no dispute that the onset of a second type of seizure, partial onset, appeared in Irene the day after her third DPT vaccination.

The experts both testified that the myoclonic seizures appearing in 1991 represent the onset of SME, which, according to the doctors, could not possibly have been diagnosed prior to Irene's third DPT vaccination.[(11)] The experts agree that the prognosis for SME is very bad and that the clinical outcome is always poor. Finally, the experts do not dispute that Irene's current condition was caused by her SME. Tr. at 96-97 (Dr. Glauser); R. ex. A at 3, Tr. at 139 (Dr. Guggenheim).

Where the experts differ in opinion concerns the role of the January 16, 1992, DPT vaccination in Irene's seizure disorder. Dr. Glauser believes the DPT vaccination significantly worsened Irene's seizures. Dr. Guggenheim believes the vaccination had no effect on Irene's course and that the course of her illness is attributable only to the SME which progressed as Dr. Guggenheim would expect. That disagreement essentially encompasses the issues before the court--whether Irene's third DPT vaccination significantly aggravated her preexisting condition within the meaning of the Act and, if so, whether SME is a "factor unrelated" to the administration of the vaccination so as to defeat petitioners' claim.

From the outset, it may seem incredible that petitioners' expert advances the following two concepts in support of petitioners' attempt to gain compensation for a vaccine-related injury--that the DPT

vaccination significantly aggravated Irene's underlying seizure disorder, but that Irene's medical course did not deviate from the expected course of SME. If the court accepts Dr. Glauser's suggestions, it would seem, intuitively, that petitioners could not prevail. Yet, strangely enough, those two seemingly irreconcilable propositions do not hinder petitioners' claim given the facts of this particular case as analyzed under the current state of the law, as will be explained. In fact, the court concludes that petitioners are entitled to compensation under the Program and provides its reasoning below.

Table Injury

The Court must first resolve whether Irene suffered a significant aggravation of her underlying seizure disorder within the Table time period following her January 16, 1992, DPT vaccination. The court makes this determination using the *Whitecotton* test, set forth *infra*, p. 9. The *Whitecotton* test requires the court to first assess Irene's condition prior to the vaccination and then to assess her current condition.

There is no dispute that prior to her vaccination (step one of the *Whitecotton* test), Irene suffered myoclonic seizures. When the seizures began in late November or early December of 1991, they were subtle, manifested only as very brief episodes of eye blinking or fluttering. They were never considered to be seizures by Irene's parents or even, initially, by her pediatrician. In the beginning, the episodes did not occur on a daily basis, and they were associated primarily with waking. The petitioners noticed an increase in the frequency of those episodes by early January and Mr. Gruber testified that the eye blinking was no longer associated only with waking. Still, petitioners were not alarmed because the episodes were subtle and, they presumed, innocuous. Aside from those episodes, Irene appeared to be a healthy, normal child prior to vaccination.

Tragically, Irene's current condition is very poor (step two of the *Whitecotton* test). There is no question that she is severely compromised--profoundly mentally retarded, wheelchair dependent, and completely reliant on others for all of her needs.

Step three of *Whitecotton* requires petitioners to demonstrate that the current condition is significantly worse than it was before vaccination. The Federal Circuit was clear that step three of the test is a simple comparison of the pre- and post-vaccination conditions of the vaccinee.[(12)] In the facts of that case, Maggie Whitecotton was a relatively normal baby prior to vaccination. Aside from difficulty swallowing, she was microcephalic, meaning her head size was smaller than normal. At the time her claim was brought before the court, Maggie was severely disabled both mentally and physically. 81 F.3d at 1101-02. In its application of step three of the test, the Federal Circuit made an uncomplicated comparison. "[W]e can discern from [the special master's] factual findings as a whole that Maggie's present condition certainly constitutes a significant aggravation of her pre-vaccination condition within the meaning of the statute, since she presently suffers from 'greater disability, pain, [and] illness' than she did before her inoculation." *Id.* at 1108.

The court follows the guidance of the Federal Circuit and, making a simple comparison in this case, concludes that step three has been satisfied. Irene's current condition is strikingly worse than her pre-vaccination condition. Where she once appeared a healthy child, consistently gaining developmental milestones, and at least overtly unaffected by her seizures, she is now profoundly impaired both mentally and physically. Clearly, Irene's current condition constitutes a significant aggravation of her preexisting seizure condition.[(13)]

The court must next determine whether the first symptom or manifestation of the significant aggravation occurred within the Table time period, *i.e.*, within 72 hours of the DPT vaccination (step four of

Whitecotton test). If the first part of the test for significant aggravation appears relatively simple and straightforward, step four is anything but, at least according to respondent. Before the application of step four to the facts of this case, the court will address respondent's arguments and discuss the shift in the law and the resulting implications under *Whitecotton*.

Respondent argues that several important issues were not addressed by the Federal Circuit in *Whitecotton*. First, respondent contends that the most important issue left open concerns the standards for determining whether a petitioner has fulfilled the requirements of step four, that is (in respondent's words), "whether a particular sign or symptom following vaccination is the first symptom or manifestation of a *significant aggravation* of the preexisting disease, or merely a sign of the continued existence of a disease." R. Closing Argument, ("R. Argument") at 4, filed June 18, 1998. Respondent asserts that,

[a] child who suffers a neurological disease such as SME appears normal at first, but, as a matter of course, appears increasingly abnormal after the onset of clinical symptoms. For such diseases, the special master must carefully consider whether a new development is a sign of onset of a 'significant aggravation' of the condition, or, rather, simply one more manifestation of the inexorable downward course of the condition.

Id. at 4-5.

Respondent urges the special master to consider reliable scientific evidence regarding the nature and expected course of the underlying disease because "[i]f the symptom which follows vaccination is consistent with the usual course of the preexisting disease, it is obviously not a sign, first or otherwise, of a deterioration in that condition." *Id*. at 5, 9. In this case, respondent asserts, Irene's post-vaccinal seizure was simply the next expression of a disease whose clinical course and outcome is predictable, not a change for the worse in her SME. *Id*. at 10-15.

While respondent's arguments may be logical, they are not meritorious. Respondent attempts to persuade the special master to consider the underlying or preexisting disorder in the court's application of *Whitecotton.* Intuitively, it does seem reasonable that, in determining whether a significant aggravation has occurred, one would *have* to consider whether the preexisting condition may not have been aggravated by DPT, but, rather, progressed in a predictable manner. Presumably, if the vaccinee's current condition was no worse than would have been reasonably expected absent vaccination, it would be fair to conclude that DPT had no role in aggravating the underlying disorder. This inquiry would seem especially relevant if the underlying disorder was progressive in nature as opposed to static. Because a condition deteriorates does not necessarily mean that the condition was actually aggravated--the apparent worsening could simply be the expression of the progressive nature of a disease. However, *Whitecotton* relieves petitioners of the burden, essentially, of demonstrating that the preexisting condition was aggravated and requires a far simpler showing.

The Federal Circuit addressed the issue of significant aggravation in *Whitecotton,* rejecting an analysis in use at the time. Prior to *Whitecotton*, a court-formulated test, articulated in *Misasi v. Secretary of HHS*, 23 Cl. Ct. 322 (1991), was used to analyze significant aggravation claims under the Act. The *Misasi* test required petitioners to compare the vaccinee's current condition with the vaccinee's predicted condition had the vaccine not been administered. Compensation would be awarded to petitioners only if the actual condition represented a significant aggravation of the expected condition. The Federal Circuit in *Whitecotton* held that the *Misasi* scheme effectively required petitioners to prove that the vaccination caused the aggravation of their injuries. The *Misasi* test was therefore improper because it "contradicted the statutory table-injury scheme whose purpose was to remove from petitioners the difficult burden of proving causation." *Whitecotton*, 81 F.3d at 1106.

The effect of this change in legal analysis was a shift from a focus on the nature or process of the condition predating vaccination (*Misasi*) to a focus only on the *symptoms* suffered by the vaccinee (*Whitecotton*). In other words, under the current state of the law, when the court is considering whether there has been a vaccine-related Table significant aggravation of a preexisting condition, the court may *not* take into consideration any facet of the nature of the disease process of the underlying condition. Only consideration of the *symptoms* suffered before and after vaccination is permitted. In practical terms, the inquiry boils down simply to a determination of whether the vaccinee's objective condition deteriorated, and when the first symptoms of that deterioration occurred. For these reasons, petitioners may establish a *prima facie* case even though Dr. Glauser attributes Irene's current condition to SME and does not believe DPT had any effect on her final outcome. At this stage, the court must ignore the fact that Irene has SME, and had it prior to vaccination; only her *symptoms*, not the SME, are to be scrutinized at this point. Medically speaking, Irene may not have been affected ultimately by the vaccination. Legally, she was.

Respondent's arguments are an attempt to resurrect the *Misasi* test. Clearly, under *Misasi*, petitioners' claim would fail. There is no dispute between the parties that Irene would have likely had the same level of impairment due to her SME absent the administration of her third DPT vaccination. However, *Whitecotton* articulates the standard by which significant aggravation cases are to be judged now. The test is much less onerous, and the result is much more favorable to petitioners.[(14)]

The test is not, as respondent asserts, "whether a particular sign or symptom following vaccination is the first symptom or manifestation of a *significant aggravation* of the preexisting disease, *or merely a sign of the continued existence of a disease*." R. Argument at 4 (second emphasis added). Respondent's wording effectively appends language to the test that would require petitioners to show that the preexisting condition was *not* the cause of Irene's deterioration. To impose that burden on petitioners would be to reinstate the *Misasi* standard and run afoul of *Whitecotton*. *Whitecotton* makes it very clear that petitioners, in their *prima facie* case, are not required to prove that the significant aggravation was *not* due to the preexisting condition or, in other words, to show that the significant aggravation of the condition appearing after vaccination would not have occurred absent the vaccination.

Nor is it appropriate for the special master to consider scientific evidence regarding the expected outcome of a disease process in making a determination about step four of the test. Respondent argues that *Whitecotton* "cannot be read so broadly . . . [as] to prohibit consideration of valid, medically reliable evidence regarding the known outcome of a preexisting condition for any and all purposes under the Act." R. Argument, n. 5 at 4. This argument represents another attempt by respondent to subvert the intent of *Whitecotton*. At this stage of the analysis, it is irrelevant that the post-vaccinal seizure may have been the next and expected expression of SME. As noted above, *Whitecotton* shifted the focus from the disease process (*Misasi*) to the symptoms suffered by the individual. Medical and scientific evidence about SME is properly introduced by respondent in its rebuttal only after petitioners have established a *prima facie* Table case, or by petitioners once respondent has met her burden of showing alternate causation. *Whitecotton*, 81 F.3d at 1106-07. *See also*, *Plavin v. Secretary of HHS*, 40 Fed. Cl. 609 (1998) (tuberous sclerosis found to be factor unrelated after petitioners established *prima facie* case).

As for the timing of the onset of the significant aggravation in this case, for purposes of step four, it is undisputed that on the morning of January 17, 1992, Irene suffered the *first episode* of a *new type* of seizure for which medical advice was sought. The appearance of a different seizure type within the Table time period is very significant to the court.[(15)] That seizure marked the beginning of partial onset seizures which continued in Irene, along with more pronounced and prolonged myoclonic seizures, in a progressively deteriorating course, characterized by seizures so frequent and sometimes severe that the

quality of her life was profoundly diminished. Dr. Glauser testified that there was a distinct and sudden change in Irene's seizure disorder following vaccination; where her seizures had been brief and intermittent prior to January 17, 1992, they were virtually continuous following vaccination. Tr. at 60, 115-21. Accordingly, the court concludes that the first symptom or manifestation of the significant aggravation occurred within 72 hours of the DPT vaccination.

Petitioners meet the requirements, under *Whitecotton*, for demonstrating a Table significant aggravation claim and are accorded the presumption of causation. They are entitled to an award in this case unless respondent is able to establish that a factor unrelated to the vaccination is responsible for Irene's condition.

Factor Unrelated

Once a petitioner has established a *prima facie* case, the government may still prevail if it can show, by a preponderance of the evidence, 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. §13(a)(1)(B); *Whitecotton*, 1099 F.3d at 1107. Respondent's proof must meet the exacting standards required for causation in fact under the Vaccine Act. *Knudsen v. Secretary of HHS*, 35 F.3d 543, 549 (Fed. Cir. 1994).

Respondent argues that SME is responsible for Irene's current condition, not the DPT vaccination in issue, because Irene's condition deteriorated in a manner and to an end consistent with the expected progression and outcome of SME.[(16)] Petitioners argue that because the cause of SME is unknown, it cannot be considered a factor unrelated to the vaccination so as to defeat petitioners' presumption of causation. P. Post-Hearing Brief at 8.

There is no dispute between the experts, Dr. Glauser and Dr. Guggenheim, that the prognosis for SME is poor. The condition typically starts with one type of seizure and progresses with the development of several other seizure types which normally increase in severity and frequency through the course of the illness. SME patients are eventually severely physically and mentally impaired. While both experts speculate that the cause of SME is more likely intrinsic than extrinsic, they also agree that SME is idiopathic. Notably, the experts do not dispute that SME is the cause of Irene's current condition, that the onset of that illness pre-dated her third DPT vaccination, and that the progression of her SME was not necessarily atypical.[(17)]

It would seem, then, that if there is no disagreement that Irene's current condition was caused by SME, which indisputably arose before the shot in question, and if petitioners' expert concedes that there is nothing necessarily distinctive or atypical about Irene's course, it would be fairly simple for respondent to carry its burden. However, that the *cause* of SME is unknown is problematic for respondent.

There are limitations as to what may be considered a "factor unrelated." Section 13(a)(2) states as follows:

[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.[(18)]

Respondent asserts that SME is a "condition that is sufficiently well-described in the literature, and because it logically eliminates the vaccine as the cause of Irene's current injuries, it is non-idiopathic within the meaning of the Vaccine Act." R. Argument at 20. To classify SME as idiopathic, respondent argues, would require the government to prove the "cause of a cause" and would yield absurd results. *Id*.

The Federal Circuit was clear in its first *Whitecotton* decision, that disorders of unknown etiology cannot constitute the basis of a factor unrelated defense by the government. 17 F.3d 374, 377-78 (Fed. Cir. 1994); *see also Whitecotton*, 81 F.3d 1099, 1107, at n. 13 (Fed. Cir. 1996) (referring to first *Whitecotton* opinion regarding factor unrelated defense). In *Koston v. Secretary of HHS*, 974 F.2d 157 (Fed. Cir. 1992), respondent attempted to show that Rett Syndrome, and not a DPT vaccination, was responsible for petitioner's daughter's condition. The Federal Circuit in *Koston* classified Rett Syndrome as an idiopathic illness, disqualifying it as a factor unrelated to the administration of the vaccine. The court based its holding on the fact that, while Rett Syndrome is a *suspected* genetic disease, its genetic basis had not been established.(19) *Koston*, at 160-61.

The only exception to the restriction that a disorder of unknown origin cannot qualify as a factor unrelated is found in §13(a)(2)(B) which provides that a factor unrelated may include infection, toxin, trauma or metabolic disturbance unrelated to the vaccination. In *Knudsen v. Secretary of HHS*, 35 F.3d 543 (Fed. Cir. 1994), the Federal Circuit found that a viral infection, proven to be present and responsible for the vaccinee's injury, *but not specifically identified*, qualifies as a factor unrelated under §13(a)(2)(B) for purposes of the Act. *See also Vant Erve v. Secretary of HHS*, No. 92-341V, slip op. at 10-11 (Fed. Cl. Spec. Mstr. Dec. 3, 1998, Westlaw cite pending) ("[T]he statute specifies four types of 'factors unrelated'--i.e., 'infection, toxins, trauma * * *, or metabolic disturbances'--that appear to *automatically* pass the 'idiopathic' test. §300aa-13(a)(2)(B). . . . [I]f the respondent demonstrates that a Table injury was caused by one of the specified four causes, such cause should not be considered an 'idiopathic' factor.") (*citing* Knudsen, 35 F.3d at 548-59).

Like Rett Syndrome (the disorder in issue in *Koston*), SME does not qualify for the §13(a)(2)(B) exception because it cannot be classified as an infection, toxin, trauma, or metabolic disturbance.(20) Also like Rett Syndrome, the cause of SME is unknown. In fact, the evidence regarding the cause of SME is far less substantial than the evidence regarding the cause of Rett Syndrome. Therefore, even though it is undisputed that the syndrome known as SME existed in Irene prior to the administration of the DPT vaccination, and is ultimately responsible for her current medical condition, respondent's claim of alternate causation fails. SME is an idiopathic condition which, it is well-established, cannot qualify as a factor unrelated pursuant to §13(a)(2)(A).(21)

OTHER STATUTORY REQUIREMENTS

As a final matter, respondent argues that petitioners have not shown that Irene suffered the "residual effects or complications" of a Table significant aggravation for more than six months after vaccination as required by statute.(22) Nor, respondent asserts, have petitioners demonstrated that Irene's current condition is a sequela or acute complication of a vaccine injury. R. Argument at 17. Respondent's

argument is a thinly-veiled attempt to relitigate, under the guise of sequela, the four-step *Whitecotton* test. That effort fails.

The inquiry by which a Table significant aggravation determination is made essentially invalidates respondent's concerns because the analysis *includes* a consideration of Irene's current condition. The finding that Irene suffered a significant aggravation does not mean that Irene's 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 is 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. In addition, because over six years have passed since the onset of Irene's injury, petitioners fulfill the six-month statutory requirement as well.

Petitioners have successfully demonstrated that their daughter Irene suffered a Table significant aggravation of her underlying seizure disorder. Respondent was unsuccessful in its attempt to show that the aggravation was due to a factor unrelated to the administration of the DPT vaccination in issue. Petitioners are entitled to an award under the Program.

FINDINGS OF FACT

1. As the parents of their minor daughter, petitioners have the requisite capacity to bring this action. §11 (b)(1)(A); Petition at 2.

2. Petitioners have not previously collected an award or settlement of a civil action in connection with any alleged injury sustained by Irene due to the administration of the DPT vaccine in question. §11(c)(1) (E); Petition at 3.

3. Irene received a vaccine listed in the Vaccine Injury Table. §(c)(1)(B)(i)(I); P. ex. 11 at 1.

4. Said vaccine was administered in the United States, in Columbus, Ohio. §11(c)(1)(B)(i)(I); P. ex. 11 at 1.

5. There is a preponderance of the evidence that Irene suffered a significant aggravation of a seizure disorder as defined by the Vaccine Injury Table with onset within 72 hours of the administration of the DPT vaccination on January 16, 1992.

6. There is a preponderance of the evidence that petitioners expended in excess of $1000 in unreimbursed medical expenses as a result of Irene's vaccine-related injury. §11(c)(1)(D)(i); P. ex. A-2.

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

CONCLUSION

Based on the foregoing, the undersigned finds, after considering the entire record in this case, that petitioners are entitled to compensation in this case 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.

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Gary J. Golkiewicz

Chief Special Master

1. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C. §300aa-1 *et seq*. (1991 and Supp. 1998). For convenience, individual sections of the Act will be sited without reference to 42 U.S.C. §300aa.

2. An APGAR test measures heart rate, respiration, muscle tone, responsiveness to stimulation, and skin color. Generally, two tests are performed at exactly one minute and five minutes after birth. The maximum score is ten. The Merck Manual 1858 (15th ed. 1987). The score taken at one minute is an index of asphyxia, while the five minute score is an index of the likelihood of death or neurological residua. Nelson Textbook of Pediatrics 362 (13th ed. 1983). The accuracy of the score for the prediction of long-term outcome, however, is inconsistent. R Summitt, Comprehensive Pediatrics 370 (1990).

3. Dr. Glauser is currently employed by the Department of Neurology at the Children's Hospital Medical Center in Cincinnati, Ohio. Tr. at 48-49, 59. In addition to being a treating physician in this case, Dr. Glauser specializes in seizure disorders. The court benefitted from Dr. Glauser's testimony in a previous case and finds that his testimony is well-reasoned and highly credible.

4. Dr. Glauser noted that Children's Hospital sees about 20 children a year with myoclonic seizures, but in the past five and a half years he has been there, Irene has been the only patient with SME. Tr. at 78.

5. According to Dr. Glauser, there are two main types of seizures--partial and generalized. A generalized seizure is one that starts on the whole surface of the brain. There are a number of types of generalized seizures, including myoclonic and clonic seizures. Myoclonic seizures are characterized by massive muscle contraction in one part of the body, such as an arm, or the whole body. Clonic seizures are characterized by rhythmic jerking with an occasional stiffening, known as a tonic phase. Tr. at 51-52.

6. Dr. Glauser believes the primary reason the seizures increase in intensity is because SME patients develop photosensitivity which triggers seizures much more easily as patients get older. Tr. at 86.

7. However, Dr. Glauser testified that it is not known what events could cause SME to worsen. Tr. at 110-11.

8. Dr. Guggenheim currently practices pediatric neurology at St. Peter's Community Hospital in Helena, Montana. She is also a clinical professor of Pediatrics and Neurology at the University of Colorado

School of Medicine. R. ex. B. This court has heard from Dr. Guggenheim in previous cases. The court has always been impressed with the quality of her testimony and finds her to be a highly credible expert witness.

9. Dr. Guggenheim has had experience with two SME patients in her medical career. Tr. at 129.

10. 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. §11(c)(1)(D)(i); (2) that petitioners incurred in excess of $1000 in unreimbursable vaccine-related expenses. §11(c)(1)(D)(i); (3) that the vaccine was administered in the United States. §11(c)(1)(B)(i)(I); (4) that petitioners did not previously collect a judgment or settlement in a prior civil action for damages for such vaccine-related injury. §11(c)(1)(E); and (5) that the action be brought by the injured person's legal representative. §11(b)(1)(A).

11. Dr. Guggenheim believes the very earliest Irene could have been diagnosed with SME was in April 1992. Tr. at 144, 154, 155. Dr. Glauser believes it is reasonable to expect the diagnosis of SME in this case to have been made when it was, that is, in November 1992 Tr. at 86-87, 123-24.

12. Respondent argues, but is incorrect, that petitioners must demonstrate a link between the worsening of the preexisting condition and any greater disability, pain, or illness. Specifically, respondent claims that the phrase "results in," from the definition of significant aggravation, requires petitioners, in their *prima facie* case, to demonstrate a link between the "change for the worse" and the alleged "greater disability." R. Argument at 5. In other words, respondent contends, "[i]f the change which begins following vaccination does not *result in* 'greater disability,' it cannot qualify as the 'first symptom or manifestation' of a presumptively vaccine-related 'significant aggravation' under the Act." *Id*. *Whitecotton* found such a requirement to be tantamount to requiring petitioners to prove actual causation. *See* discussion supra, at 13-14.

13. This objective comparison has been utilized consistently by the special masters following *Whitecotton*. *See Hoag v. Secretary of HHS*, No. 94-67V, 1998 WL 408783, at *9 (Fed. Cl. Spec. Mstr. April 22, 1998), *aff'd*, (Oct. 15, 1998) (simple comparison of pre-and post-vaccination condition for *Whitecotton* step three analysis); *Goodwin v. Secretary of HHS*, No. 90-1347V, 1998 WL 78718, at *8 (Fed. Cl. Spec. Mstr. Jan. 20, 1998) (comparison of vaccinee's current encephalopathic condition found to be significantly worse than condition just prior to vaccination); *Evans v. Secretary of HHS*, No. 90-3142V, 1997 WL 429719, at *12 (Fed. Cl. Spec. Mstr. July 15, 1997) (compared current condition--mental retardation and developmental delay--to apparently normal prevaccination condition and concluded significant aggravation); *Gershenson v. Secretary of HHS*, No. 90-4005V, 1997 WL 79874, at *6 (Fed. Cl. Spec. Mstr. Feb. 10, 1997), *aff'd*, 40 Fed. Cl. 298 (1998) (vaccinee found to have no significant aggravation where he had minor neurologic problems before and after shot); *Houtz v. Secretary of HHS*, No. 90-3039V, 1996 WL 734676, at *7 (Dec. 5, 1996) (significant aggravation found where child's prevaccination condition consisted of seizures but otherwise normal development and condition post-vaccination was severe mental and physical handicap); *Fowler v. Secretary of HHS*, No. 91-214V, 1996 WL 512613, at *4 (Fed. Cl. Spec. Mstr. Aug. 27, 1996) (vaccinee's current condition significantly worse than condition prior to vaccination even though neurologist might have predicted, based on prior condition, a course consistent with that suffered by vaccinee).

14. This court is not unsympathetic to respondent's position. As noted above, judged purely from a medical standpoint, it is fair to say that neither doctor believes the DPT played a role in Irene's current condition. However, the Act, as interpreted in *Whitecotton*, presumes a role in the situation presented in this case. *See Hoag*, n. 9, at *9.

15. *Prima facie* significant aggravation has been demonstrated in other Program cases where the vaccinee exhibited symptoms that were different from pre-vaccination symptoms, although related to the preexisting condition. *See, e.g., Evans v. Secretary of HHS*, No. 90-3142V, 1997 WL 429719 (Fed. Cl. Spec. Mstr. July 15, 1997) (child with preexisting tuberous sclerosis but no previous seizures suffered seizures within the Table time period following MMR vaccination); *Kono v. Secretary of HHS*, No. 93-123V, 1995 WL 779598 (Fed. Cl. Spec. Mstr. Dec. 21, 1995) (significant aggravation found where child with preexisting encephalopathy developed on-Table seizures following DPT vaccination); *Suel v. Secretary of HHS*, 31 Fed. Cl. 1 (1993) (initial onset of seizures during Table time period following vaccination in a child with latent tuberous sclerosis found to constitute significant aggravation of preexisting condition); *Downing v. Secretary of HHS*, No. 90-1134V, 1993 WL 120641 (Fed. Cl. Spec. Mstr. April 2, 1993) (significant aggravation found where child with preexisting encephalopathy but no previous seizures suffered on-Table seizures following DPT vaccination).

16. Respondent does not outright assert SME as a factor unrelated to the vaccination because it so vehemently advocates SME as a bar to the finding of a *prima facie* Table case. However, respondent claims that SME does qualify as a "factor unrelated" as a statutory matter and presents argument to that end.

17. When pressed, Dr. Glauser admitted that nothing stands out about Irene's illness as different or unexpected for the course of SME because the normal or expected course is unknown. Tr. at 116, 118, 120. Dr. Glauser acknowledged the following:

SPECIAL MASTER GOLKIEWICZ: When you view this picture of Irene, is what we're seeing here even a normal expected course of SME?

THE WITNESS: . . . Looking normal, having -- starting to have brief seizures in November/December, early January, and then all of a sudden having continuous seizures. I guess it's within the realm of possibility. I'm not -- I'm just not sure what the designated or what the agreed upon time frame is for deterioration. . . .

* * *

SPECIAL MASTER GOLKIEWICZ: Is there anything, looking at this picture here, that is different than what you read about in the literature? I thought that that was the expectancy -- the expected progression of [SME], that there is a change in both the nature of the seizures and the frequency of them. You start out with a certain type of seizure, then it does change at some point in time.

THE WITNESS: Correct. And the only thing I don't know is how you go from A to B. Do you go quickly? Do you go in fits and starts? Or is it a slow deterioration?

SPECIAL MASTER GOLKIEWICZ: And you don't know that because --

THE WITNESS: -- it's not in the literature.

SPECIAL MASTER GOLKIEWICZ: --it's not in the literature?

THE WITNESS: Right.

SPECIAL MASTER GOLKIEWICZ: So go back to my original question. If you took a look at this clinical picture here, is there anything different that would jump out at you and say that this is different

than what we know about SME?

THE WITNESS: The answer would be no . . . .

Tr. at 116-18.

18. The Federal Circuit, in its initial decision in *Whitecotton*, stated that the statutory language describing a "factor unrelated," applies also in significant aggravation cases. "The Act does not limit its prohibition of idiopathic, or unknown, causes to those demonstrably arising after administration of the suspect vaccine; it forbids the use of any such cause to defeat a petition." *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).

19. Rett Syndrome is described in the medical literature as a progressive neurological disorder that consists of a set of distinctive symptoms and that follows a fairly predictable course. It has been described only in girls and is believed to be caused by a metabolic disorder. A specific metabolic defect for Rett Syndrome, however, has never been identified so the cause of the condition remains unknown. For that reason, Rett Syndrome could not support a finding of alternate causation.

20. SME, like Rett Syndrome, is not even a disease, *per se*, but, more properly, a "syndrome"-- "a condition, a group of symptoms, a symptom complex due to some underlying cause . . . ." Tr. at 96; SME in Infants at 87 (Dr. Glauser testified that this article represents the state of medical knowledge at this time about SME, and the authors are responsible for articulating the standard description of the syndrome. Tr. at 65-66.). The difference between a syndrome and a virus (albeit an unspecified one as in *Knudsen*) is that a virus is a pathologically defined, identifiable affliction. The presence of a virus can be detected and confirmed by laboratory cultures. Even without being able to identify the *specific* virus, it is possible to say that a patient has a virus because there is concrete evidence or proof of its existence. That is not the case with a syndrome. A syndrome is a sort of default categorization. A collection of symptoms and a pattern of clinical expressions may characterize it, but no laboratory test or study can confirm its presence.

21. Legislative history indicates 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).

22. While respondent presents this argument in its post-hearing brief (R. Argument at 6-7, 15-17), respondent failed to develop the argument in any meaningful way. The court does its best to interpret and address respondent's position.