

establish their case that Cassandra suffered an encephalopathy in temporal association with the vaccinations, as is required under the Act to benefit from presumed causation. However, the court raised the possibility of whether Cassandra's seizure disorder, which manifested ten days following the DPT immunization, or on February 17, 1991, was significantly aggravated by the DT administered on March 20, 1991. To that end, the parties provided a second round of expert opinions addressing this medical/legal issue and a second evidentiary hearing was conducted on March 6, 1997, in Boston, Massachusetts. Following the hearing, at the request of the parties, post-hearing arguments limited to the significant aggravation question were heard by telephone. The record is now complete with regard to the issue of petitioners' right to compensation. The court after considering the entire record concludes that petitioners are not entitled to compensation under the Act. The court's reasoning is set forth below.

STATUTORY SCHEME

The Vaccine Act establishes procedures to compensate individuals for injuries or deaths resulting from the administration of specified vaccines. Section 14 of the Vaccine Act, entitled "Vaccine Injury Table," identifies certain vaccines and specifies illnesses, disabilities, injuries, and conditions that have been associated with those vaccines. A petitioner can secure compensation under the Vaccine Act if, inter alia, the petitioner can demonstrate that the administration of a vaccine in fact caused or significantly aggravated a particular condition, whether or not that condition is listed in the Vaccine Injury Table. §§ 11(c)(1)(C)(ii) and 13(a)(1). A petitioner also can secure compensation if the petitioner can demonstrate by a preponderance of the evidence that the vaccine recipient suffers from a condition specified in the Vaccine Injury Table (Section 14(a)) and that "the first symptom or manifestation of the onset or of the significant aggravation of [the condition] occurred within the time period after vaccine administration set forth in the Vaccine Injury Table" (Section 11(c)(1)(C)(I)). If a petitioner makes such a showing, then the petitioner is entitled to compensation unless there is a preponderance of the evidence that the condition "is due to factors unrelated to the administration of the vaccine." § 13(a)(1)(B).

TABLE ISSUE - - ENCEPHALOPATHY⁽³⁾

The medical issue of whether or not Cassandra suffered an encephalopathy in temporal association with her February 7 DPT immunization is dependent upon acceptance of petitioners' factual allegations.⁽⁴⁾ Framed another way, what presents the facts of this case - - the medical records which do not indicate a severe reaction to the DPT, or petitioners' allegations that an immediate, severe, and progressive deterioration in Cassandra's development followed the vaccination. As the court informed the parties at the close of the November 29, 1995, hearing, the court finds that the medical records state the facts.

Petitioners filed a joint affidavit dated July 27, 1994, which they clarified by affidavit dated January 3, 1995. P Rx. at 651- 61.⁽⁵⁾ Petitioners' affidavit describes Cassandra as reacting immediately to the February 7 vaccination by crying. This crying "increased by the hour" and was inconsolable. The Health Department was contacted and petitioners were told to give Tylenol. Cassandra's unusual sleep pattern and unresponsiveness continued through the 16th. On the 17th, Cassandra suffered apnea seizures for which she was hospitalized. Mrs. Hoag expanded on her

descriptions in her testimony. She stated that Cassandra cried for days without any periods of getting better. Transcript of November 29, 1995, Hearing at 19-23 (hereinafter cited as "T1 at _"). She described Cassandra as not waking up to feed or to get her diaper changed and generally unresponsive. T1 at 24. Most importantly, Ms. Hoag stated that Cassandra never returned to normal, as she was prior to February 7. T1 at 34.

The medical records tell a very different story. No effort is made to discuss all of the references to Cassandra's condition following the DPT in this voluminous record. The court simply notes that beginning with the initial histories given at the hospitalization on February 18, Cassandra is described as "well" up until the 16th and as having a DPT without complications. P Rx. at 236. The record states further that "[a]ccording to mother, episodes have abrupt onset." *Id.* One need only look at this one medical history with the extensive details contained therein and ask how is it possible that the family did not report to the medical providers a description of Cassandra's ten days of crying, sleeplessness, unresponsiveness and generally altered sensorium. This court finds it not only illogical but unbelievable. While this one record would suffice to support the court's determination, the evidence does not end here.

First, it is noted that the records contain numerous references to discussions with the family regarding Cassandra's apnea spells. See P Rxs. at 247, 302, 313, and 319. Thus, the family had multiple opportunities following the stressful period of the initial hospitalization to relate the events preceding that hospitalization. No such history was given. Instead, references to being alert, playful and cooing with normal neurology are seen. P Rx at 253-54. Another record states that the apnea episode had an "abrupt onset, no precipitous episode." P Rx at 255. Thus, contrary to petitioners' allegations, the contemporaneous medical records, which in this case contain copious information regarding Cassandra's course of development, not only fail to corroborate petitioners' allegations, the records contradict the claims. The treating doctors also contradict those claims.

Dr. Gilmore saw Cassandra on March 25, 1991, following the second set of apnea spells after the DT shot. Dr. Gilmore testified that as of March 25, Cassandra was not an encephalopathic child. T1 at 182; see P Rx. at 377. She did state that Cassandra had a medical condition characterized by seizures and developmental delay, but she could not determine the onset of that condition. *Id.* at 187. Dr. Duchowney testified that he took a medical history from the parents at their visit on March 30, 1993, and there was no history of a reaction to the vaccination. T1 at 227. While it is clear that the form the family was asked to complete is somewhat general, the family did give an oral history, T1 at 234, and the doctor routinely asked questions which probed the history of the medical problems. T1 at 238-39. No history of a distressed child immediately following the vaccination was reported.

The Court of Appeals for the Federal Circuit has counseled the Special Masters that medical records should be given more weight than conflicting oral testimony offered after the fact. See Murphy v. Secretary of DHHS, 968 F.2d 1226 (Fed. Cir. 1992), cert. den., 113 S. Ct. 463 (1992). The Federal Circuit, when faced with this issue, stated that:

Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical

conditions. With proper treatment hanging in the balance, accuracy has an extra premium.

Cucuras v. Secretary of DHHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

This rule should not be applied inflexibly. Medical records are often incomplete, incorrect, or directed to a different medical issue and thus report different or unrelated information. None of these indicia of unreliability exist in this case. Here, multiple histories were taken by various medical professional probing the onset of Cassandra's apnea spells. The family had the opportunity and the incentive to inform the treating doctors of Cassandra's past medical history. It is clear from the records and the testimony that Cassandra's past medical history was inquired into. Despite these inquiries there is no mention of the type of reaction and downturn in Cassandra's health now alleged. In fact, testimony and records indicate the opposite, Cassandra was not encephalopathic but was alert, happy and cooing.

In the face of these medical records and the testimony of the treating doctors, the court finds the family's testimony not credible. In addition to the incredulous nature of the allegations, the court notes that Ms. Hoag was prompted by a television show regarding DPT reactions to draw a connection to the vaccination. T1 at 44. Also, despite having signed a detailed joint affidavit and having given some rather detailed testimony, Mr. Hoag stated at times that with the passage of time he could not honestly remember specific occurrences from that time other than what was testified to. T1 at 349, 353. The court was not impressed with such selective powers of recall. Lastly, Jean Hoag, the grandmother, stated frankly that she could not recall the events surrounding the February 7, 1991, vaccination. T1 at 208.

The expert opinions and testimony from Dr. Legarda and Dr. Sleasman were predicated on the affidavits and testimony of the family. Dr. Legarda testified that she relied solely upon the affidavits. T1 at 102. Dr. Sleasman stated that his opinion was premised on the parents statements. T1 at 250. Since the court has found the parents information to be unreliable and not credible, petitioners' experts have no factual foundation for their opinions. Based upon the medical records, there is no indication of an encephalopathy following the February 7 DPT. T1 at 257, 259. Respondent's expert, Dr. Schuelein, reached the same conclusion. R Ex. A; T1 at 308.⁽⁶⁾

SIGNIFICANT AGGRAVATION

An alternative route of recovery pled by petitioners was significant aggravation. While some testimony was presented at the first hearing on this issue, the court was not satisfied with the presentation and thus gave the parties an opportunity to supplement the record. Petitioners filed the report of Marcel Kinsbourne on July 10, 1996; respondent filed the responsive report of Dr. MacDonald on August 7, 1996. As noted previously, a second evidentiary hearing dedicated to this issue was conducted on March 6, 1997. As discussed below, the court finds that Cassandra's condition was not significantly aggravated by the DT vaccination administered on March 20, 1991.

The essence of the parties' positions as presented through their respective experts can be gleaned from the experts' reports. Petitioners' expert, Dr. Kinsbourne, states that prior to the March 20 DT immunization, Cassandra suffered from the medical condition residual seizure disorder. Supplemental Report filed July 10, 1996. Following the March 20 DT, Cassandra manifested infantile spasms, a specific type of seizure that carries with it a very poor prognosis for subsequent development. Dr. Kinsbourne states that prior to the manifested infantile spasms, and therefore, prior to the March 20 DT, Cassandra's development could not be predicted as poor. He stated further that the first symptom or manifestation of the infantile spasms was on March 22, 1991, two days following the DT. Cassandra now suffers from severe psychomotor delay which is a typical outcome of infantile spasms, which allegedly began within two days following the March 20 DT.

Respondent's expert, Dr. MacDonald, agreed with Dr. Kinsbourne in many important respects. Thus, there is agreement that Cassandra suffers from infantile spasms. There is also agreement that unfortunately the prognosis for development is very poor. There is also much agreement regarding the medical facts, as they appear in the medical records and will be discussed later. However, Dr. MacDonald disagrees that the seizures seen following the March 20 DT constituted infantile spasm seizures.⁽⁷⁾ More importantly, Dr. MacDonald sees no aggravation of Cassandra's pre-DT condition since Cassandra suffered from what is described as infantile spasms syndrome which was first manifested by the apneic seizures suffered in February of 1991 and evolved expectedly until the classical infantile spasm seizure as seen in May 1991, and the developmental delay that was later exhibited. R Ex. H. From his prospective, Dr. MacDonald saw no aggravation because there was no "major change in the path" of the infantile spasms syndrome from that which would be expected from this syndrome. Id.

The respective experts testified consistently with their written reports at a hearing conducted on April 3, 1997. Dr. Kinsbourne, qualified as an expert by the court, T2 at 14, began his analysis by stating that prior to the DT in March, Cassandra had a seizure disorder which was characterized by apneic spells. T2 at 15. As set forth in the medical records, these spells began in February and were manifested by periods of not breathing for approximately 30 seconds accompanied by mild cyanosis (lips and fingertips turning blue). T2 at 16. Cassandra was hospitalized and treated with phenobarbital. No further spells were reported up to the time of the DT. Id. Important to Dr. Kinsbourne's opinion, at the point of the March 20 DT, while the seizure disorder had yet to "fully declare itself", meaning that there was still a possibility that the seizures could be hard to control, Cassandra at this time had a "relatively good prognosis for mental development." T2 at 17, 19. Dr. Kinsbourne explained that:

I made a distinction between the prognosis for future seizures. I think that I would warn [the parents] that problems with epilepsy or a seizure disorder are very much in the cards for their child. On the other hand, were they to ask me about mental development, I would reassure them that is usually not a major problem.

T2 at 19.

According to Dr. Kinsbourne, this all changed with the seizures suffered after the March 20 DT.

First, the recurrence of seizures constituted "break-through" seizures since they occurred despite the anti-seizure medication phenobarbital. Id. Secondly, the seizures contained a new component, described as "stiffening and arching of the back of the child, and a flexing of one or both arms." T2 at 20. These new components to the seizures were medically important because they were the subtle signs that the "inexorable march of infantile spasms had begun." T2 at 21. An EEG performed on March 25 provided confirmatory evidence in that it showed a hypsarrhythmia electrical pattern, "the classical EEG for infantile spasms." Id. In Dr. Kinsbourne's opinion, the change in the nature of seizures to indicate the presence of the infantile spasms syndrome, which was subsequently confirmed by the appearance of classical infantile spasms seizures in May, portended a very negative prognosis for mental development. T2 at 24-5.

Dr. Kinsbourne clarified the apparent conflict between his testimony and the EEGs performed in March. He explained that the first EEG conducted on March 25 showed the hypsarrhythmia pattern that supported his opinion that the infantile spasms syndrome was present. T2 at 28. However, a video EEG performed on March 29 confirmed the presence of temporal lobe seizures, not infantile spasms. Dr. Kinsbourne stated that the video EEG findings were correct, T2 at 24, and compatible with the child's presentation in February. T2 at 22. These findings are not inconsistent with the March 25 EEG presentation of hypsarrhythmia, however, since in Dr. Kinsbourne's opinion Cassandra was exhibiting two separate seizure conditions, the infantile spasms as evidenced by the jerking and hypsarrhythmic EEG, and the partial complex seizures as seen on the video EEG. T2 at 26. Dr. Kinsbourne supported this view by referencing Dr. Gilmore's letter at P Ex. at 509, which he interpreted to mean that Dr. Gilmore saw components of two seizure types in Cassandra. T2 at 27-8.

On cross-examination, Dr. Kinsbourne clarified that the partial complex seizures appeared in February, prior to the DT, and continued on numerous occasions following the DT. T2 at 31. However, during the same time period following the DT, "there was a new element occurring in Table time after the DT, which was the onset of an infantile spasms disorder, for which I do not detect any antecedent before that vaccination." Id. He did concede that contrary to his direct testimony there was arching reported with the February seizures. T2 at 32. Thus, the arching was not new to the seizures following the DT. However, the jerking was not seen until after the DT. ⁽⁸⁾ T2 at 34.

Dr. Kinsbourne also agreed on cross-examination that the number of seizures Cassandra suffered actually decreased immediately after the DT. Thus, On February 17 she suffered eight apneic spells, while on March 22, two days after the DT, she suffered four spells. T2 at 44. However, Dr. Kinsbourne noted that after the February seizures Cassandra was given phenobarbital to control the seizures. Because of the seizure medication, Dr. Kinsbourne saw the number of seizures as "inconsequential". T2 at 68.

Cassandra was taken off of phenobarbital following the March 22 seizures. She then suffered seizures on March 29 during the video EEG. She was treated with Tegretol, which is used to treat partial complex seizures, not infantile spasms. Dr. Kinsbourne conceded that the treating doctors were impressed with the temporal lobe discharges and treated Cassandra accordingly. T2 at 46. She was in fact diagnosed with partial complex seizures. Id. Cassandra suffered seizures in April, which Dr. Kinsbourne stated were "unmistakable infantile spasm description[s]". T2 at 47.

However, he conceded that there is no indication that infantile spasms seizures were diagnosed at that time and, in fact, were not diagnosed until May. T2 at 48.

Dr. John MacDonald, qualified as an expert in pediatric neurology, T2 at 90, testified for respondent. Dr. MacDonald's opinion is that there was no aggravation of Cassandra's underlying epileptic syndrome in March of 1991. T2 at 91. Dr. MacDonald reviewed briefly the classification of infantile spasms, from its origin as West syndrome, named not surprisingly after Dr. West, to more recent efforts by international organizations to define syndromes by clinical symptoms. T2 at 91-94. He explained that Dr. West in 1845 described a child who exhibited jackknife seizures at an early age which increased in frequency until ultimately decreasing and changing to other types of seizures. The child also suffered from severe mental handicaps. T2 at 92. This classification or understanding remained for over 100 years until international efforts took place to refine the classification. In 1981, efforts to categorize epileptic syndromes for purposes of treatment and prognoses resulted in combining seizure type with EEG abnormalities, age of onset, clinical course and other features. T2 at 93. These classifications were refined in 1985 and 1989. Based upon these classifications efforts by the international epilepsy organizations, Dr. MacDonald stated that:

So, when I'm talking about infantile spasms, I have to differentiate the seizures. And a lot, if not the majority, of infantile spasm patients have multiple seizures, including the classical jackknife seizures that Dr. Kinsbourne has described, and the syndrome, which encompasses, not just the actual seizures, but the entire history of what's going to happen to this child. And, unfortunately, the prognosis is, typically, very poor.

T2 at 94. Dr. MacDonald stated further that the diagnosis of infantile spasms is usually made five to six months after the first symptoms appear, and thus frequently not with the first seizure. Id. He stated that "[t]he seizure pattern evolves, and with all these epileptic syndromes, the feeling now is that most of these are present at birth or, in general, genetically determined. . . ." Id.

As applied to this case, Dr. MacDonald testified that Cassandra appeared normal at birth and nothing medically significant occurred until after February of 1991. T2 at 95. At that time there is a suspicion of seizures, manifested by a blank look, unresponsiveness and apnea. Id. She is hospitalized and an EEG was done. While the EEG was normal, seizure activity was strongly suspected and phenobarbital was prescribed. Id. Dr. MacDonald continued by describing the March seizures after the DT as evidencing arching, some breathing problems and "a little flexion." T2 at 96. He stated that there was no evidence of the dramatic, repetitive jackknife seizures. Id. However, Dr. MacDonald explained that while Cassandra did not evidence the classical infantile spasm seizure at this point in time, she did have the infantile spasm syndrome. T2 at 98. He stated again that:

this is a disorder that is prenatal, developed seizures after birth, and that the seizure, the infantile spasm seizures usually develop between four and 12 months, but the syndrome is a genetic disorder that's present.

T2 at 100.

Dr. MacDonald stated that the treating physicians treatment followed his thought process in evaluating the clinical signs in this case. The physicians saw seizures in March that were not classical jackknife seizures but were accompanied by an EEG that read as hypsarrhythmia. T2 at 103. He speculated that before giving the parents the horrible prognosis attached to infantile spasms and ordering strong medication, the physicians sought confirmation from a video EEG. Id. The video EEG showed temporal lobe seizures that could be treated with routine anti-seizure medications and the difficult family encounter was spared. However, Dr. MacDonald continued that the seizures evolved in a "very typical pattern" for this syndrome until the classical infantile spasm, jackknife seizure, was seen in May. T2 at 104.

Regarding the different seizures Cassandra suffered, Dr. MacDonald stated that the February seizures were brief apnea spells with staring and unresponsiveness. T2 at 109. He stated that the March seizures were "[s]omewhat similar", but more importantly were not a clinical description of infantile spasm seizures. Id. He stated that the seizures were partial complex seizures as described on the EEG. Id. Regarding the April seizures, although they were somewhat repetitive, the mouth movement, described in the records as "churning with mouth", P Rx. at 483, is typical of partial seizures. T2 at 110. Contrary to Dr. Kinsbourne's testimony, Dr. MacDonald stated that flexion movements can be seen in all types of seizures. Coupled with the mouth movements that are not part of infantile spasms, Dr. MacDonald stated that these seizures represented an evolution of the syndrome but not the classical infantile spasm seizure. Id. On May 10, 1991, Cassandra suffered the classical infantile spasm seizure. Both experts agreed.

When asked whether Cassandra's condition was aggravated at any point in time, Dr. MacDonald stated that:

I think she has a syndrome that is defined by these seizure patterns and retardation that, looking at where she is now, and where she started, this is where I would expect she would be. I can't logically say she's worse in any meaningful sense of the word, and that's what you would have to tell these parents early on, that even if the seizures get better, she's going to probably be mentally retarded and very delayed.

That's in the cards. That's part of the syndrome that's set. You're not going to change that. So, I think, she's not worse; she's developing the pattern that would develop.

T2 at 112. Further, when asked if the pattern of evolution seen in this case fits with infantile spasms, Dr. MacDonald replied that this case is "classical for the syndrome." Id. He stated that "[t]his case would fit with the vast majority of the children I've seen over the years. It's very identical." Id.

- - Statutory Requirements

Section 11(c)(1)(C) of the Act provides compensation for petitioners who can prove, by a

preponderance of the evidence, that the injured person:

(i) 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

Thus, petitioner can prove a significant aggravation case by proving that the first symptom or manifestation of a Table injury occurred within 72 hours of the administration of the DT vaccination. Petitioners can also prove that the vaccine caused in fact the significant aggravation if the first symptom or manifestation falls outside of the 72 hour period or if the aggravated injury was not set forth on the Injury Table. §§ 11(c)(1)(C)(ii)(I) and (II). The latter method must be proven by traditional tort causation-in-fact standards.

The Act provides further guidance in its definitional section. Section 33(4) states 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.

The Act's legislative history further explains the meaning of "significant aggravation" as follows:

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. 15-16 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6356-57.

The proper interpretation of this section of the Act has been the subject of numerous decisions. Fortunately, the air has been cleared somewhat with the Court of Appeals for the Federal Circuit's decision in Whitecotton v. Secretary of DHHS, 81 F.3d 1099 (Fed.Cir. 1996). In this decision, the court set forth a four-part test for evaluating whether a petitioner successfully made out a prima facie significant aggravation claim under the Act. Id. at 1107. The court stated that in making the determination, the special master must:

(1) assess the person's condition prior to administration of the vaccine, (2) assess the person's current condition, . . . (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[,] . . . and (4) determine whether the first symptom or manifestation of the significant aggravation occurred within the time period prescribed by the Table.

Id. This case is judged against the above criteria.

- - Discussion

After a complete review of the record in this case, the voluminous medical records, the transcripts from the two hearings, and the transcript of the closing arguments, the court finds that petitioners failed to prove by a preponderance of the evidence that Cassandra's pre-existing seizure disorder was significantly aggravated, either presumptively or in-fact, by the DT vaccination administered on March 20, 1991.⁽⁹⁾ More specifically, the court finds that petitioners failed to meet step four of the Whitcotton test, that is the first symptom or manifestation of that worsening did not occur within the statutory time-frame of three days. The court's reasoning for these findings follows.

In analyzing this case, it is important to note that the respective experts were essentially in agreement on many of the medical issues. Thus, with regard to Cassandra's condition prior to the March 20 DT (step one of the Whitcotton test), the experts agreed that Cassandra had an underlying neurologic disorder. T2 at 15, R Ex. H. Likewise, there is no dispute as to Cassandra's current condition (step two of the Whitcotton test). The experts agree that Cassandra suffers from infantile spasms that carries with it a very poor prognosis for mental development. In fact, Cassandra is manifesting developmental problems. Dr. Kinsbourne's Report filed July 10, 1996; R Ex. H. An objective comparison of Cassandra's current condition to her pre-DT condition shows a clear significant aggravation within the meaning of the statute (step three of the Whitcotton test).⁽¹⁰⁾ See Fowler v. Secretary of DHHS, No. 91-214V, WL (Fed. Cl. Spec. Mstr. Aug. 27, 1996). It is also agreed that Cassandra's condition, at least following the DT immunization, is an evolving medical condition. See, e.g., T2 at 60, 94. Dr. Kinsbourne also agreed with the evolution of different seizure types into the classical jackknife seizure and that the pre-DT seizures "could have unrolled in[to] what happened to this child." T2 at 82. Dr. Kinsbourne further agreed that in retrospect Cassandra's condition could possibly have been "preordained" Id. It is also reasonable to read Dr. Kinsbourne's testimony as agreeing that if the infantile spasm syndrome is diagnosed prior to the March DT, then there would be no aggravation. T2 at 81-84. The dispute thus settles on the question of when the diagnosis of the infantile spasm syndrome can be made. Dr. Kinsbourne viewing the events from the perspective of as they unfolded stated that in February of 1991, "[n]obody could have said 'this is going to develop into infantile spasms.'" T2 at 83. However, in March, following the DT, even though Cassandra had not suffered a classical infantile spasm seizure, the diagnosis of the "infantile spasms disorder" could be made. T2 at 31, 19-21("the inexorable march of infantile spasms had begun"). With that diagnosis, Dr. Kinsbourne opined that a major negative shift in Cassandra's prognosis could be made which constituted a significant aggravation. T2 at 81. Dr. MacDonald strongly disagreed, arguing that the diagnosis could not be made in March, but only in May with the occurrence of the classical infantile spasm seizure that occurred in May 1991. From that perspective, Dr. MacDonald concluded that the course of Cassandra's seizures fit the typical evolutionary course of the infantile spasm syndrome. Since Dr. MacDonald saw no change in the expected course, he logically concluded that there was no aggravation. Analyzing the expert testimony within the

analytic framework of Whitecotton, the court finds that the infantile spasms, and thus the first symptom or manifestation of the worsening of Cassandra's condition, could not be determined more probably than not until the occurrence of the classical infantile spasm seizure that occurred in May 1991.

Dr. Kinsbourne testified that the seizures which occurred two days following the DT shot in March had two components, a continuum of the partial complex seizures first seen in February and a new component, a flexion of one or both arms which portends infantile spasms. T2 at 31, 20. Dr. Kinsbourne stated that the notes of the treating doctors reflected the probability of infantile spasms and the EEG performed on March 25, 1991, showed the hypsarrhythmia electrical pattern confirming the presence of infantile spasms. T2 at 21. In response to the court's questions, Dr. Kinsbourne stated that while the infantile spasms "took center stage" in May, the onset of those spasms was in March. T2 at 25.

Dr. MacDonald took issue with Dr. Kinsbourne's testimony, essentially saying that as of March there was insufficient clinical data to treat Cassandra for the infantile spasms syndrome. T2 at 102-04. Specifically, Dr. MacDonald stated that flexion movements, the new component relied on by Dr. Kinsbourne for a change in the seizure types, can be seen with both generalized and partial seizures. T2 at 110. Regarding the EEG pattern, Dr. MacDonald stated that he has treated patients that with the hypsarrhythmic electrical pattern that have not had infantile spasms. T2 at 120. Dr. Gilmore testified likewise, stating that while classically associated with infantile spasms, this EEG pattern "may also be seen with a wide variety of other seizure types as well." T1 at 196. Most importantly, Dr. MacDonald testified that the treating doctors handled this case consistent with his views, not Dr. Kinsbourne's view that the infantile spasm syndrome is now present.

The court finds Dr. MacDonald's testimony compelling. Reviewing the medical records, the court finds Dr. Kinsbourne's testimony highly speculative and unsupported. In the EEG report for the March 25 test, Dr. Gilmore writes:

Impression: This is an exceptionally abnormal EEG which fits the definition of hypsarrhythmia. The EEG is highly suggestive of the development of infantile spasms (West syndrome).

P Rx at 392. On the same day, Dr. Gilmore writes in her consultant's notes under impression "EEG today [with] modified Hypsarrhythmia. Cannot rule out infantile spasms at this time so ordered video EEG for further evaluation." P Rx. at 377. Treating notes indicate that the doctors were awaiting the results of the video EEG prior to beginning the aggressive treatment for infantile spasms. See P Rx. at 368 (3/26 note - "Will keep on [phenobarbital] for now - after EEG will see if needs ACTH or other therapy); P Rx. at 372 (3/28 note - questionable infantile spasms despite modified hypsarrhythmia on EEG); P Rx. at 373 (3/29 note - indicates that child is currently on video EEG and states that "[i]f patient does have a seizure and it is infantile spasm, we will either initiate ACTH therapy & training immediately. . . ."). These records make it abundantly clear that despite the flexion and the abnormal EEG, the treating doctors were evaluating Cassandra's medical condition further prior to treating her for infantile spasms. This medical course is entirely consistent with Dr. MacDonald's testimony, T2 at 102-04, and is very inconsistent with Dr. Kinsbourne's. Dr. Kinsbourne conceded this inconsistency. T2 at 69.

The video EEG report confirmed partial complex seizures with a temporal focus. P Rxs. at 337, 376. Dr. Gilmore wrote her impression of the video EEG as follows:

Although the clinical history was consistent with infantile spasms, this continuous Video/EEG monitor demonstrates unequivocally that the infant's seizures are right temporal lobe in origin and clinically probably are complex partial in nature.

P Rx. at 394. An attending note on March 31 states that "[i]nfant appears to have partial complex seizures - much better prognosis than infantile spasms." P Rx. at 376. As Dr. Kinsbourne testified, the treating doctors were very impressed with the findings on the video EEG and treated Cassandra, not for infantile spasms, but for the partial complex seizure disorder. T2 at 46.

Dr. Kinsbourne viewed the clinical signs and EEGs following the March 20 DT to indicate one unmistakable thing, Cassandra started down the path of the infantile spasm disorder. However, the factors that he relies upon for this opinion find little support anywhere else in the record. Drs. MacDonald and Gilmore contradict his testimony regarding flexion movements not being seen with other seizures. The same two doctors testified that the hypsarrythmia electrical pattern, while classical for infantile spasms, is not diagnostic. Lastly, it is clear from the medical records that while infantile spasms was considered, consistent with Dr. MacDonald's explanation, it was not treated. In fact, Dr. Kinsbourne recognized that the actions of the treating doctors conflicted with his opinions. T2 at 69. In the final analysis, Dr. Kinsbourne stands alone in the belief that the March seizures signaled the onset of the infantile spasm syndrome.

On this issue the court finds Dr. MacDonald's testimony far more persuasive. Dr. MacDonald's vastly greater experience in treating children and his cogent testimony regarding the care taken in diagnosing infantile spasms given the drastic treatment and prognosis was far more convincing than Dr. Kinsbourne's unsupported speculation as to what should have been diagnosed and treated.

Dr. MacDonald explained convincingly that cases frequently arise that require a retrospective review of the overall sequence of events in diagnosing a neurological condition. T2 at 132. Beyond the need to allow time for the progressive disorder to evolve, Dr. MacDonald offered some very practical reasons for not leaping to a diagnosis. Thus, he explained that the drugs prescribed for treating infantile spasms are very toxic. In addition, before worrying the parents with the poor prognosis for their child, a high level of certainty is called for. He stated that in his experience some patients with hypsarrhythmic EEG's did not develop infantile spasms, thus in order to make a rational judgment one must be convinced of the entire spectrum of symptoms prior to making the diagnosis. T2 at 104. Dr. MacDonald stated that he agreed with the treatment in this case.

Dr. MacDonald buttressed his opinion by comparing his conclusions to the actual treatment of Cassandra. Thus, on cross-examination, Dr. MacDonald traced Cassandra's clinical signs and the treatment of her condition. In February he stated that Cassandra suffered brief multiple seizures that were treated appropriately with the drug phenobarbital. T2 at 140. He stated further that at this point there would be no consideration of treating Cassandra with the drug ACTH for infantile spasm seizures. *Id.* With the March 25 EEG, Dr. MacDonald stated that there could have been a

"heated debate" regarding treatment for infantile spasm seizures. T2 at 141. However, he concluded that more testing and a "clear definition of the problem" was needed prior to treating for infantile spasm seizures. *Id.* When pressed on why he would not treat for infantile spasm seizures at this point, Dr. MacDonald responded with three reasons: (1) the toxicity of the drug treatment; (2) the EEG while suggestive of infantile spasm seizures is not diagnostic; and (3) the clinical description of the symptoms is "at best, atypical, and at worst, not even at all related to infantile spasms." T2 at 142. Thus, Dr. MacDonald concluded that further testing was necessary. In fact, Cassandra was treated with further testing through a video EEG. The video EEG showed partial complex seizures and Cassandra was treated for those seizures, not infantile spasm seizures.

In response to the court's questions, Dr. MacDonald again reviewed Cassandra's seizures and the course of treatment in February and March. He again concluded that while infantile spasms could have been suspected, there was insufficient support for beginning treatment. Dr. MacDonald stated further that:

To look back at this and say, could I have made a diagnosis earlier, this is an evolving pattern. [By analogy] you're going down a road. The seizures may be bumps in the road. There may be many bumps, few bumps, but the road may be set, and where you're going to end up is where you're going to end up, unless something very dramatic occurs that changes the pathway.

T2 at 157. Looking at this record, no deviation from the infantile spasms syndrome pathway is seen.

Dr. Kinsbourne argued that such a deviation is seen from a new component appearing with the March 22 seizures, the abnormal March 25 EEG and based on these two factors a change to a very poor prognosis for mental development. However, there is much evidence in the record that supports an opposite conclusion. Dr. Lagarda and Dr. Sleazman, Cassandra's treating doctors, testified that the seizures in February and in March were similar in their presentation. T1 at 143-44, 282. Dr. Kinsbourne points to the added element of flexion in the March seizures to signal the change and the progression to infantile spasm seizures. However, Dr. MacDonald testified that flexion can be seen in other seizures as well. T2 at 123. Dr. Kinsbourne next cites as support the abnormal March 25 EEG with its hypsarrythmic pattern. Once again, however, Drs. MacDonald and Gilmore testified that while such an EEG pattern is highly suggestive of infantile spasm seizures, it is not diagnostic.

In analyzing Dr. Kinsbourne's opinion that Cassandra's pre-existing neurological condition was aggravated, it becomes apparent that the change in prognosis is premised on clinical evidence that Dr. MacDonald persuasively showed were insufficient or inconclusive to support the signaling, at that time, the manifestation of infantile spasm seizures or the infantile spasms syndrome. Dr. Kinsbourne relied on individual symptoms which were consistent with infantile spasms seizures or the syndrome but were not diagnostic. Dr. MacDonald's testimony was backed by his far more impressive clinical experience, medical literature, and the actual treatment of Cassandra in showing that the symptoms Dr. Kinsbourne relied upon did not carry the medical significance Dr. Kinsbourne gave them. Thus, the court finds based upon Dr. MacDonald's testimony that petitioners failed to meet Whitcotton's step four, *i.e.*, petitioners did not prove that the first

symptom or manifestation of the significant aggravation-occurred within three days after the March DT.

CONCLUSION

As discussed above, petitioners have failed to prove by a preponderance of the evidence that the vaccines either presumptively or in fact caused or significantly aggravated a Table injury.

Therefore, they are not entitled to an award under the Program. The Petition is therefore dismissed. The Clerk shall enter judgment accordingly.

Gary J. Golkiewicz

Chief Special Master

- 1. This Decision was originally entered by the court on April 22, 1998, as an unpublished decision. This reissuance as a published decision follows in response to respondent's written request for publication, filed May 14, 1998, which is hereby granted. In this reissued decision the court corrected a typographical error in footnote 2.**
- 2. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, as amended, 42 U.S.C.A. 300aa-1 et seq. (West 1991 and Supp. 1997). For convenience, individual sections of the Act will be cited without reference to 42 U.S.C.A. 300aa-.**
- 3. Petitioners pled the onset of a Table encephalopathy following both the February 7 DPT and the March 20 DT. The court will analyze only the claim of encephalopathy following the February 7 DPT, since the manifestation of an encephalopathy prior to the March 20 DT, see infra at 6 (Cassandra suffers from a seizure disorder as of February 17); see also transcript of April 3, 1997, Hearing at 67 (hereinafter cited as "T2 at __") (Cassandra suffered from an abnormality of the brain as of February 17), precludes proof of a Table encephalopathy following the March 20 DT. Whitecotton v. Secretary of DHHS, 514 U.S. 268 at 274 (1995).**
- 4. Petitioners bear the burden of demonstrating the facts necessary for entitlement to a Program award by a "preponderance of the evidence." § 13(a)(1)(A). Under that standard, the existence of a fact must be shown to be "more probable than not." In re Winship, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).**
- 5. The medical records for this case have been provided with the petition and also with two amended petitions. The court will cite to the paginated records attached to the Second Amended Petition filed on January 12, 1995.**
- 6. Petitioners also pled that the February 7 DPT caused in fact Cassandra's injuries. However, the experts' opinions on this issue, as limited as they were, fail for the same reason that the opinions**

on the Table case failed, that is the lack of a factual predicate. The experts relied upon the family's testimony, which the court rejected as unreliable. In addition, Dr. Sleasman testified that there is no direct causal link. T1 at 272. Dr. Gilmore stated that the child was developmentally normal as of March 25, T1 at 182, and Dr. Duchowney said there was no history of reaction. T1 at 226. Lastly, Dr. Schulein testified that there was no encephalopathy following either the DPT or the DT. T1 at 308, 315. Clearly, petitioners failed to mount any persuasive case of causation in fact.

7. For the uninitiated, there is a critical distinction that must be understood between the infantile spasm syndrome and infantile spasm seizures. The infantile spasms syndrome defines a condition which is made up of a particular type of seizure - the infantile spasm seizure, coupled with psychomotor retardation or deterioration, and the hypsarrhythmic EEG. J. Aicardi, Epilepsy in Children, p. 17 (1986). The infantile spasm seizure, one component of the syndrome, refers to a repetitive flexion of the muscles in the neck trunk and extremities that is generally bilateral and symmetrical. Id.; see also T2 at 20 (Dr. Kinsbourne describes the classical infantile seizure as the "head jerks forward or back; the eyes roll up; the arms flex; and the legs go up.") It is commonly referred to as a jackknife convulsion or salaam seizures. Id. Other types of seizures commonly precede or accompany the infantile spasm seizures; however, the hallmark of the infantile spasm syndrome is the classical infantile spasm seizure. Id. As discussed infra, Dr. MacDonald testified at length regarding this distinction. It was clear from Dr. Kinsbourne's testimony that he was in full agreement with the distinction between and the description of the seizures and the syndrome. It is also clear from the transcript of the March 6, 1997, hearing that the court, at that time, was confused by the testimony on the differences between the seizures and the syndrome. After a complete review of the record, it is obvious that the confusion was the court's, not the witnesses.

8. Dr. Kinsbourne provided some very confusing testimony regarding the critical added component to the March seizures, namely the flexion. It was this added component, coupled with the EEG report of hypsarrhythmia, that convinced Dr. Kinsbourne that the infantile spasms syndrome was present in this child. T2 at 20, 65. However, at one point in his testimony, Dr. Kinsbourne refers to the added movement as "jerking", not flexion. On cross-examination, Dr. Kinsbourne stated that what he was looking for to distinguish the February and March seizures was "jerking", and that he did not see "jerking before the DT." T2 at 34. This is not a minor point as Dr. Kinsbourne later testified with great care to distinguish between jerking and flexing. T2 at 62. It is also clear in the records that Cassandra had "flexion of one or both arms" but had no "jerky movements." P Rx. at 479. However, given the resolution of this case, it is unnecessary to discuss this matter further.

9. Dr. Kinsbourne stated that he was not offering a causation in fact opinion. T2 at 58.

10. Respondent argued based upon Dr. MacDonald's testimony that there was no significant aggravation under Whitecotton's step three since there was no deviation in the expected course of Cassandra's infantile spasms syndrome. The court found Dr. MacDonald's testimony on this issue compelling. In fact, considering this case from a pure medical standpoint, the court would find against petitioners based upon Dr. MacDonald's persuasive testimony. However, such an argument appears to run afoul of the legal requirements of Whitecotton.

While the court in its discussion of the Misasi test seemed to base its criticism and ultimate rejection of that test on Misasi's reliance on actual vaccine causation as part of a test determining a Table injury (where causation is presumed and thus consideration of the vaccine's role is improper), the court ultimately took a broader swipe at Misasi. The court concluded in its rejection of Misasi that:

the Misasi test improperly required a petitioner to prove, as part of her prima facie case, that petitioners' significant aggravation was not caused by a pre-existing injury.

Whitecotton at 1106.

Thus, in this broader language, it appears that the Federal Circuit has precluded the consideration of the natural course of an underlying condition in determining petitioner's prima facie case of significant aggravation. The question whether or not the natural course could be used to establish a factor unrelated was left open by the court. Id. at 1107, fn.13. Of course, as a factor unrelated, the cause or origin of the underlying disorder must be proven. Id. Given the resolution of this case, it is unnecessary for the court to delve deeper into these issues.