OFFICE OF SPECIAL MASTERS

No. 96-294V

(Filed: June 15, 2001)

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RAGINI RAJ, a Minor, by her Parents and	*	
Guardians, RAJENDRA RAJ and SAMU RAJ,	*	
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	*	**TO BE PUBLISHED**
Petitioners,	*	
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND	*	
HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	
* *	*	

DECISION

GOLKIEWICZ, ***Chief Special Master.***

I. PROCEDURAL BACKGROUND

On May 28, 1996, petitioners filed a claim on behalf of their daughter, Ragini Raj, under the National Vaccine Injury Compensation Program (hereinafter Athe Vaccine Program@ or Athe Program@).[1] Petitioners claim that Ragini suffered seizures and encephalopathy as a result of the Diphtheria-Pertussis-Tetanus (ADPT@) vaccine she received on March 12, 1994. Petition (hereinafter APet.@) at 2.

On August 26, 1996, respondent filed her responsive report pursuant to Vaccine Rule 4(b) contesting petitioners= entitlement to compensation. Respondent=s Report (hereinafter AR. Rpt.@) at 3. In her report, respondent contended that petitioners failed to meet the revised Vaccine Injury Table definition of encephalopathy and, in the alternative, failed to prove that the DPT

vaccination actually caused Ragini=s seizure disorder. Id. at 5. Moreover, respondent noted that petitioners had not obtained an expert report or provided any medical support for their claim. Id. at 6.

Subsequently, petitioners filed expert reports from Dr. Mark Geier, filed on February 27, 1997, Dr. Marcel Kinsbourne, filed on May 27, 1997, and Dr. Ronald Gabriel, filed on June 15, 1999. Dr. Geier asserted that this is an off-Table, i.e., cause-in-fact, case of DPT causing encephalopathy and residual seizure disorder.[2] Petitioners= Exhibit 15 (hereinafter AP. Ex. __@) at 24. He also contended that the issue of whether Ragini had infantile spasms or myoclonic seizures is not important because Ainfantile spasms are virtually indistinguishable from myoclonic spasms.@[3] Id. at 15. In his report, Dr. Kinsbourne argued that infantile spasms are not a distinct clinical category. P. Ex. 16 at 2. In addition, he posited that studies examining the relationship between DPT and infantile spasms, which failed to find a causal relationship between the two, are inconclusive on the issue of causation because the studies are limited in sample size. Id. at 2. Finally, Dr. Gabriel argued that the DPT vaccination caused Ragini to experience an Aunspecified seizure disorder@ which Acannot be classified as ... classical ... infantile spasms.@ P. Ex. 17 at 2, 3.

On August 11, 1997, respondent filed an expert report from Dr. Yuval Shafrir. Dr. Shafrir contended that infantile spasms is an acceptable classification of seizures. R. Ex. B at 4. Moreover, Dr. Shafrir concluded, based upon the medical records and the parents= description of the seizures, that Ragini suffered from infantile spasms starting within two days after her second DPT vaccination. Id. at 1-3.

Respondent and petitioners filed pre-hearing briefs on October 10 and 17, 2000, respectively. In her brief, respondent noted that the issue of infantile spasms was important because of the Institute of Medicine=s (hereinafter AIOM@) finding that the available scientific evidence does not support a causal relationship between the DPT vaccine or the pertussis component of DPT and infantile spasms. Respondent=s Pre-Hearing Memo (hereinafter AR. PH Memo@) at 1. Petitioners, in their brief, listed three main issues to be decided in this case: 1) did Ragini experience an encephalopathy and a residual seizure disorder; 2) did Ragini have infantile spasms; and 3) was Ragini=s condition causally related to the vaccination she received? Petitioners= Pre-Hearing Memo (hereinafter AP. PH Memo@) at 1.

An evidentiary hearing was conducted on October 30, 2000. At the hearing, the court heard testimony from Ragini=s mother, two experts for petitioners, Drs. Geier and Gabriel, and respondent=s expert, Dr. Shafrir. The hearing transcript was filed on December 5, 2000.[4]

Thereafter, on January 24, 2001, petitioners filed a Motion for Judgment on the Record (hereinafter AP. MJR@). In this motion, petitioners argued that, based upon respondent=s expert=s, Dr. Shafrir=s, testimony that Ragini suffered an encephalopathy within 72 hours of the vaccination and that he would have hospitalized her if he had seen her during this time period, they have demonstrated that Ragini suffered a Table injury under the Vaccine Program. P. MJR at 1. In response, respondent argued that petitioners misconstrued Dr. Shafrir=s testimony.

Respondent=s Opposition to Petitioners= Motion for Summary Judgment (hereinafter AR. Opp.@) at 1. Dr. Shafrir, according to respondent, testified that he did not believe Ragini suffered a Table encephalopathy. Id. at 2-3. Moreover, respondent contended that Dr. Shafrir=s statement, that he would have hospitalized Ragini, does not relieve petitioners of their burden to prove that Ragini suffered an acute encephalopathy as defined in the Table. Id. In their reply, petitioners reaffirmed their argument that Ragini suffered a Table injury. Petitioners= Reply (hereinafter AP. Reply@) at 2.

The record is now complete and the case is ripe for decision. After considering the entire record, the court finds that petitioners are not entitled to compensation. The court=s reasoning follows.

II. FACTUAL BACKGROUND

Ragini was born on November 13, 1993. Pet. at 2. She was the product of a 38 week gestation period that was unremarkable. R. Rpt. at 1. At birth, she weighed seven pounds and three ounces and her Apgar scores were 9(1) and 9(5). P. Ex. 5 at 3, 5. Her newborn admissions profile revealed no abnormalities. Id. at 3-5.

By all accounts, Ragini developed normally during the first four months of her life.[5] Ragini=s mother described her as Apretty healthy@ during this time period. Tr. at 9. On January 13, 1994, Ragini had a two month checkup where her pediatrician, Dr. Carole Gervais, described her as a A well child.@ P. Ex. 10 at 20. During this office visit, Ragini received her first DPT vaccination. Id. Approximately two months later, at Ragini=s four month checkup on March 12, 1994, Dr. Gervais again described Ragini as a Awell child.@ Id. at 19. It was during this office visit that Ragini received her second DPT vaccination. Id.

On March 14, 1994, within 48 hours of the second DPT vaccination, Ragini started to manifest spasms. P. Ex. 1 at 1. Ragini=s mother described the spasms in the following way: AWhile sitting in her infant seat, [Ragini=s] head would drop, her arms would flail, and her eyes would roll back .... Sometimes she would also draw up her legs with these episodes.@ Id. at 1-2. These episodes, according to the mother, would last a few seconds and occurred 10 to 15 times per day. Id. at 2.

Ragini saw Dr. Gervais again on March 17, 1994. P. Ex. 10 at 19. Dr. Gervais examined Ragini but observed no spasms and referred her to Dr. David Kaufman, a pediatric neurologist. Id.

Dr. Kaufman examined Ragini on May 5, 1994. P. Ex. 2 at 23. On at least five occasions during the exam, Dr. Kaufman noted that Ragini had an Aisolated episode in which her head would drop forward, her arms went out, and her legs came up in a typical flexor spasm position.@ Id. at 24. Dr. Kaufman reported that while Ragini=s EEG was diffusely abnormal and approaching a hypsarrhythmic pattern, it did not meet the criteria for full hypsarrhythmia. Id. A computed tomography (CT) brain scan was normal. Id. Dr. Kaufman diagnosed Ragini with infantile spasms, admitted her to Mount Sinai Hospital, and placed her on adrenocorticotropic hormone (ACTH). Id.

On September 14, 1994, Ragini was evaluated by Dr. Hart deCoudres Peterson. P. Ex. 11 at 1. Dr. Peterson reported that Ragini=s treatment, which consisted of 20 units of ACTH twice a day for approximately one month, had failed to stop her seizures. Id. When her dose was increased to 30 units twice a day, the seizures worsened. Id. When the dose was reduced, however, her spasms decreased and her EEG, performed on June 2, 1994, was said to be nearly normal. Id. Dr. Peterson reported that Ragini=s ACTH treatment was discontinued on June 14, 1994. Id. Thereafter, a number of other treatments were tried with no real success, including Klonopin, Felbamate, and Depakote. Id. Dr. Peterson concluded that Ragini=s neurologic condition A presents a curious paradox. Poorly controlled myoclonic seizures, but apparently normal neurologic development and an EEG, which may have shown hypsarrhythmia initially, but now is more or less normal.@ P. Ex. 11 at 2.

Ragini saw Dr. Kaufman again on March 9, 1995. P. Ex. 3 at 4. He confirmed the ACTH treatment had failed and reported that Ragini=s subsequent treatment had included Valproic Acid, Felbatol, and Klonopin. Id. He noted that Ragini was on the Ketogenic diet and taking Klonopin. Id. In his report, Dr. Kaufman stated that while Ragini appeared more alert and responsive, she still had occasional seizures. Id.

On March 20, 1995, Ragini had a developmental pediatric evaluation which showed she was exhibiting AGlobal Developmental Delays.@ P. Ex. 12 at 2. Ragini=s seizures finally stopped in December of 1995, and she went off medication sometime in 1997. Tr. at 17-18. Ragini=s mother reported at the hearing on October 30, 2000, that Ragini, who turned seven on November 13, 2000, was functioning at a level somewhere between a four and six year-old. Id.

III. DISCUSSION

Petitioners can prove they are entitled to compensation under the Program in one of two ways: through a statutorily prescribed presumption of causation or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act. First, petitioners may prove that Ragini suffered an injury or condition listed in the Vaccine Injury Table within the statutorily prescribed time period. ' 11(c)(1)(C)(i). If petitioners establish that Ragini suffered such injury by a preponderance of the evidence, they are entitled to a presumption of causation. ' 13(a)(1)(A). If Ragini qualifies under this presumption, she will be said to have suffered a A Table injury.@ Once petitioners show that they are entitled to a presumption of causation, the burden shifts to respondent to prove that the injury or condition Ais due to factors unrelated to the administration of the vaccine described in the petition.@ ' 13(a)(1)(B).

Second, in the event petitioners fail to satisfy the requirements under the Act for demonstrating a Table injury, petitioners may prove by a preponderance of the evidence that the vaccination in question, more likely than not, caused the alleged injury. '' 11(c)(1)(C)(ii)(I) and (II). This causation-in-fact standard, according to the Federal Circuit, requires proof of a Alogical sequence of cause and effect showing that the vaccination was the reason for the injury.@ Grant v. Secretary of HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

In the present case, petitioners allege that Ragini suffered a Table injury, or in the alternative,

that the DPT vaccination was the actual cause of Ragini=s seizure disorder.[6]

A. Table Encephalopathy

As stated above, petitioners can prove entitlement to compensation by proving, by a preponderance of the evidence, that Ragini suffered an encephalopathy as defined by the Table. In 1995, the Department of Health and Human services modified the Table definition of encephalopathy in order to clarify its meaning because many experts believed the original definition was Atoo vague@ and failed to reflect current medical knowledge of the condition.[7] 60 Fed. Reg. 7678, 7687 (Feb. 8, 1995). The resulting definition, described below, significantly narrowed the meaning of encephalopathy under the Table. See id. at 7686-7688. This modified definition of encephalopathy, as set forth in the 1995 revised Table, is applicable in the present case because it applies to all petitions filed on or after its effective date of March 10, 1995.[8] See ' 14(c)(4).

The 1995 revised Table lists encephalopathy as a Table injury for the DPT vaccine if it manifests itself within 72 hours after the vaccination. 42 C.F.R. ' 100.3(a)(II). The Qualifications and Aids to Interpretation (hereinafter AQAI@), which interprets the conditions listed as Table injuries, provides that Aa vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy.@ Id. ' 100.3(b)(2). According to the QAI, an encephalopathy is Aone that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred).@ Id. ' 100.3(b)(2)(i). For children less than 18 months of age who present following a seizure, the QAI explains, an acute encephalopathy is demonstrated Aif their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.@ Id. ' 100.3(b)(2)(i)(A). The QAI defines a A significantly decreased level of consciousness@ as follows:

> A Asignificantly decreased level of consciousness@ is indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (see paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):
> (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
> (2) Decreased or absent eye contact (does not fix gaze upon family members or other individuals); or
> (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

Id. ' 100.3(b)(2)(i)(D).

In sum, in order to qualify under the Table definition of an acute encephalopathy, petitioners must prove by a preponderance of the evidence that, within 72 hours of the DPT vaccination, Ragini experienced Aa significantly decreased level of consciousness@ which persisted beyond 24 hours.

In the present case, petitioners argue they have demonstrated that Ragini suffered a Table injury under the Act based largely upon the following testimony of respondent=s expert, Dr. Shafrir: (1) Dr. Shafrir agreed that Ragini suffered an encephalopathy within 72 hours of her DPT vaccination, (2) Dr. Shafrir testified that he would have hospitalized Ragini if he had seen her within 72 hours of the DPT vaccination, and (3) Dr. Shafrir testified that, more likely than not, Ragini=s EEG was abnormal within 72 hours of the DPT vaccination.[9] P. MJR at 1, 2.

Petitioners argue Dr. Shafrir=s testimony that Ragini experienced an encephalopathy within 72 hours of the vaccination and that her EEG was probably abnormal during this time period is conclusive evidence that Ragini suffered an encephalopathy. See id.; P. Reply at 2. Petitioners explain that under the QAI, seizures alone are insufficient to constitute a diagnose of encephalopathy; additional evidence is needed. P. MJR at 2. According to petitioners, Dr. Shafrir=s statement regarding Ragini=s EEG constitutes the needed additional evidence. Id. Finally, petitioners assert that Dr. Shafrir=s testimony stating he would have hospitalized Ragini proves she suffered an acute encephalopathy because the QAI defines acute encephalopathy as one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred). Id.; P. Reply at 2.

Respondent, in her response, counters that petitioners misconstrued Dr. Shafrir=s testimony and failed to establish that Ragini suffered an acute encephalopathy as defined by the Table. See R. Opp. 2-4. First, concerning Dr. Shafrir=s testimony that Ragini suffered an encephalopathy, respondent argues Dr. Shafrir=s testimony was based on a broad understanding of the term encephalopathy, not on the definition set forth in the Vaccine Injury Table. Id. at 2. In support of this argument, respondent points out that Dr. Shafrir testified he did not believe Ragini met the Table definition of an acute encephalopathy because it requires Amuch more severe changes in consciousness or behavior.@ Id.; Tr. at 117. Moreover, according to respondent, Dr. Shafrir testified Ragini had Aspecific encephalopathy called infantile spasms,@ which is a slowly progressive disease, not acute encephalopathy. R. Opp. at 3; Tr. at 130.

Second, respondent argues Dr. Shafrir=s testimony that he would have hospitalized Ragini does not relieve petitioners of their burden to prove the requirements for an acute encephalopathy as set forth in the Vaccine Injury Table. R. Opp. at 3. Respondent asserts that, in addition to the seizures, the statute requires petitioners to show that Ragini suffered a decreased level of consciousness which lasts for at least 24 hours and cannot be attributed to the seizures. Id. at 4. In the present case, respondent argues, the only symptoms Ragini suffered within 72 hours of the DPT vaccination were the seizures. Id. As a result, respondent maintains petitioners failed to prove that Ragini suffered an acute encephalopathy. Id.

After reviewing the entire record in this case, the court finds that petitioners failed to show that Ragini suffered an acute encephalopathy as defined by the Table. As stated earlier, in order to prove a Table injury, petitioners must prove that Ragini suffered an acute encephalopathy within 72 hours of her DPT vaccination. See 42 C.F.R. ' 100.3. The statute defines an acute encephalopathy as one which is Asufficiently severe so as to require hospitalization,@ id. ' 100.3(b)(2)(i), as indicated Aby a significantly decreased level of consciousness lasting ... beyond 24 hours [which] cannot be attributed to [the seizure].@ Id. ' 100.3(b)(2)(i)(A).

In the present case, petitioners failed to produce any evidence to show that Ragini experienced a decreased level of consciousness as described by the Table. A Asignificantly decreased level of consciousness@ is indicated by a decreased or absent response to the environment, decreased or absent eye contact, or inconsistent or absent responses to external stimuli, for at least 24 hours. Id. ' 100.3(b)(2)(i)(D). In Ragini=s case, the only reported symptoms she experienced during the 72- hour post-vaccination time period were the seizures. Pet. at 2. Under the Table, however, seizures alone are not enough to constitute a diagnosis of acute encephalopathy. 42 C.F.R. ' 100.3(b)(2)(i)(E). The QAI states A[i]n the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of an acute encephalopathy.@ Id. The court is not persuaded by petitioners= argument that Dr. Shafrir=s statement, namely that Ragini=s EEG was probably abnormal during the 72-hour post-vaccination period, satisfies the Aother evidence@ required by the statute. First of all, the statement is speculative. Second, and more importantly, when asked by petitioners= counsel whether Ragini=s EEG, which Dr. Kaufman performed nearly two months after Ragini=s DPT vaccination, was evidence of an encephalopathy, Dr. Shafrir replied it was evidence of infantile spasms, not acute encephalopathy. Tr. at 130.

Moreover, petitioners= reliance on Dr. Shafrir=s testimony to prove a Table injury in this case is misguided. First, Dr. Shafrir=s statement that he would have hospitalized Ragini if he had seen her within 72 hours of the vaccination only satisfies part of the definition of a Table encephalopathy. The QAI states that Aa vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests ... an injury meeting the description below of an acute encephalopathy.@ 42 C.F.R. ' 100.3(b)(2). That description, according to the QAI, includes the requirements that the acute encephalopathy is Aone that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred),[10] id. ' 100.3(b)(2)(i), and, for children like Ragini who are less than 18 months of age and present following a seizure, is indicated by a Asignificantly decreased level of consciousness [which] persists beyond 24 hours.@ Id. ' 100.3(b)(2)(i)(A). Furthermore, the legislative history, in explaining the reasoning behind the hospitalization requirement, notes that A[**i]n order** to demonstrate a Table encephalopathy, the petitioner must prove that the injury was indeed serious enough to warrant hospitalization.@ 60 Fed. Reg. 7678, 76780 (Feb. 8, 1995)(emphasis added). Based on the above, the court finds that the hospitalization requirement is a necessary condition to proving a Table encephalopathy, but not sufficient, in and of itself, to prove a Table injury because petitioners still have to show that Ragini suffered a decreased level of consciousness for at least, and in this case beyond, 24 hours during the 72-hour post-vaccination period. Simply put, the fact that a person has an injury which is severe enough to warrant hospitalization does not mean that he or she has met the full definition of a Table encephalopathy. The definition of a Table encephalopathy is clear and is mandatory; petitioners failed to meet that definition.

Second, Dr. Shafrir=s testimony that Ragini suffered an encephalopathy within 72 hours of the DPT vaccination fails to satisfy the statute=s requirement that petitioners show a Adecreased level of consciousness@ for at least 24 hours during the 72-hour post-vaccination period. As stated earlier, the clinical signs listed in the QAI, which petitioners needed to prove in order to show a A decreased level of consciousness,@ include a decreased or absent response to environment, decreased or absent eye contact, or inconsistent or absent response to external stimuli. 42 C.F.R.

100.3(b)(i)(2)(D). In the present case, however, petitioners offered no evidence to show that Ragini suffered a Asignificantly decreased level of consciousness@ as described above. Furthermore, Dr. Shafrir exposed the disingenuousness of petitioners= argument concerning his statements at trial when he testified that he did not believe Ragini suffered a Table encephalopathy because it requires Amuch more severe change[s] in consciousness and behavior. @ Tr. at 117. Rather, Dr. Shafrir stated he believed Ragini suffered from a Aspecific encephalopathy called infantile spasms.@ Id. at 130.

In sum, the court finds that petitioners failed to prove Ragini suffered an acute encephalopathy as described in the Table. The record shows that Ragini did not experience a Asignificantly decreased level of consciousness@ as mandated by the QAI. Her only symptoms, according to her mother and the medical records, were the seizures. Moreover, the court rejects petitioners= inaccurate depiction of Dr. Shafrir=s statements at trial as a meritless attempt to satisfy the Table definition of an acute encephalopathy.

B. Causation-in-Fact

Petitioners= alternate theory of entitlement to compensation in this case is causation-in-fact. Under this theory, petitioners must prove by a preponderance of the evidence that the DPT vaccination, more likely than not, caused Ragini=s injury. In Liable v. Secretary of HHS, No. 98-120V, 2000 WL 1517672 (Fed. Cl. Spec. Mstr. Sept. 7, 2000), the court set forth a logical framework, with which the undersigned concurs, for examining causation-in-fact cases involving DPT and its association with neurological illness.[11] In that case, the court reviewed the pertinent research concerning whether the DPT vaccine can cause neurologic damage to a vaccinee, including the 1981 British study entitled the National Childhood Encephalopathy Study (ANCES@),[12] the Institute of Medicine=s (AIOM@) 1991 Report,[13] and the IOM=s 1994 Report.[14]

The NCES examined the relationship between the DPT vaccine and neurological illnesses in infants and children. 1991 IOM Report at 100. The study addressed two major questions about DPT immunization: 1) Does DPT immunization cause an increase in serious acute neurologic events in children; and 2) Does DPT immunization cause permanent brain damage? Id. at 101. The study found that children vaccinated with DPT had a risk of experiencing a severe acute neurologic illness during the seven day period following vaccination. Id. This risk was about 3.3 times as great as the risk that a non-vaccinated child of similar age would have of experiencing a severe acute neurologic illness within a given seven day period. Id. The study also found that permanent damage as a result of DPT immunization is a Avery rare event and attribution of a cause in individual cases is precarious.@ NCES Report at 149.

The 1991 IOM Report, which was produced by a committee of physicians selected by the IOM,[15] examined the available medical and scientific literature regarding the possible adverse consequences of the pertussis and rubella vaccines.[16] Specifically, and particularly relevant to the present case, the committee considered the evidence concerning the potential relationship between the DPT vaccine and neurologic injury. Liable, 2000 WL 1517672, at *3. The

committee concluded, based in large part upon the NCES, that the evidence is Aconsistent with a causal relation between DPT vaccine and acute encephalopathy.@ Id. The study, however, also concluded that the available evidence was insufficient to base a conclusion as to whether the DPT vaccine causes chronic or permanent neurologic injury. Id.

Moreover, the committee concluded, after examining all of the available evidence concerning the possible relation between the DPT vaccine and infantile spasms, including the NCES, case reports, case series, and other epidemiologic studies, that the Aevidence does not indicate a causal relation between the DPT vaccine or the pertussis component of DPT and infantile spasms.@[17] 1991 IOM Report at 77. The committee explained that the risk estimates for these studies were not consistent, varied widely across studies, and failed to reach statistical significance. Id. at 76.

For example, the committee examined the NCES data and explained that the NCES researchers measured the risk of infantile spasms associated with immunizations by utilizing the following four post-immunization time intervals: 0 to 6 days, 7 to 13 days, 14 to 20 days, and 21 to 28 days. Id. at 73. The committee found that immunization with the DPT vaccine was not statistically significantly associated with an increased risk of infantile spasms in any seven-day interval.[18] Id. Furthermore, the committee compared the Aestimates of risk of infantile spasms done separately for DPT and DT vaccinees.@ Id. at 74. Such comparisons showed nearly identical results for children who received the DPT and DT vaccines.[19] Id. According to the committee, this suggests that exposure to the pertussis component of the DPT vaccine does not increase the risk of infantile spasms. 1991 IOM Report at 74. Thus, while the 1991 IOM Report concluded that the NCES Aresults suggest that DPT immunization is associated with an increased risk, within 7 days, of seizures and encephalopathy,@ id. at 101, it found no such relation between DPT and infantile spasms. Id. at 77.

The 1994 IOM Report, which is a published analysis of the 1993 NCES follow-up study[20] and the 1991 IOM Report, found that the medical evidence is Aconsistent with a causal relation between DPT and the forms of chronic nervous system dysfunction described in the NCES in those children who experience a serious acute neurologic illness within seven days after receiving [the] DPT vaccine.@ 1994 IOM Report at 13.

Based upon the 1994 IOM Report, the court in Liable set forth the following theory, which it called the A1994 IOM causation theory@:

> If a neurologically-intact vaccinee (1) suffers, within seven days after a pertussis vaccination, a neurologic episode that would have qualified as a Aserious acute neurologic illness @ under the NCES; (2) goes on to experience chronic neurologic dysfunction of the type described in the NCES; and (3) no other cause for that dysfunction can be identified; then it is appropriate to causally attribute the chronic neurologic dysfunction to the vaccination.

Liable, 2000 WL 1517672, at *8.

The term Aserious acute neurologic illness@ within the meaning of the 1994 IOM Report has been interpreted by this court to mean any one of the five neurologic events suffered by case children under the NCES. Id. at *10. The original NCES included children who were between the ages of two and 36-months-old and were hospitalized between 1976 and 1979. The NCES asked participating doctors to report the admission of children with one of the following conditions:

(1) acute or subacute encephalitis, encephalomyelitis, or encephalopathy;
(2) unexplained loss of consciousness;
(3) Reye=s syndrome;
(4) convulsions with a total duration of more than half an hour, or followed by coma lasting 2 hours or more, or followed by paralysis or other neurologic signs not previously present and lasting 24 hours or more;
(5) infantile spasms (West syndrome).

Id. at 3.

Thus, in applying the A1994 IOM causation theory@ to the present case, the pertinent question becomes whether Ragini suffered a neurologic episode that would have qualified as a Aserious acute neurologic illness@ under the NCES within seven days of her DPT vaccination. Petitioners argue that Ragini=s seizure disorder was an acute encephalopathy that qualifies her for the NCES.[21] Respondent, on the other hand, argues that Ragini suffered from infantile spasms, which are an expression of chronic, not acute, encephalopathy. This issue is important because, as stated earlier, the 1991 IOM Report determined that the evidence does not indicate a causal relation between the DPT vaccine and infantile spasms. 1991 IOM Report at 5. Therefore, if the court determines that the evidence shows Ragini suffered from infantile spasms, then petitioners would lose the causal link provided by the A1994 IOM causation theory@ and, thus, would not be entitled to compensation unless they could prove that the DPT vaccination caused Ragini=s infantile spasms; such proof being problematic due to the 1991 IOM Report finding no such causal relationship. See supra n. 15, at 11 (discussing the deference this court gives to the IOM=s findings).

The facts show that Ragini suffered seizures within the seven-day period following her vaccination. Ragini=s mother stated that within 48 hours of the DPT vaccination, while sitting in her infant seat, Ragini=s Ahead would drop, her arms would flail, and her eyes would roll back. These episodes would last for just a few seconds.@ P. Ex. 1 at 2. This description comports with Dr. Shafrir=s testimony at trial that infantile spasms are associated Awith a sudden, massive body jerk@ that last for a few seconds, as opposed to myoclonic seizures, which last Aanywhere up to 400 milliseconds.@ Tr. at 138, 144. Moreover, when Dr. Kaufman diagnosed Ragini with infantile spasms on May 5, 1994, he noted that, on at least five occasions during the exam, Ragini had Aan isolated episode in which her head would drop forward, her arms went out, and her legs came up in a typical flexor spasm position.@ P. Ex. 2 at 24. During the trial, Dr. Shafrir explained that this is a classical description of infantile spasms. Tr. at 108. Furthermore, when petitioners= counsel pointed out that Dr. Kaufman did not indicate how long these episodes

lasted, Dr. Shafrir explained that it did not matter because Dr. Kaufman used the term Atypical flexor spasm@, and A[f]lexor spasm is a neurological term. It means infantile spasm.@ Id. at 145-46.

Notwithstanding the above, petitioners allege that Ragini=s seizures were not infantile spasms, but rather myoclonic seizures or an unspecified seizure disorder. P. Ex. 15 at 10; P. Ex. 17 at 3. Their argument is predicated on Ragini=s non-hypsarrhythmic EEG, her failure to respond to ACTH treatment, and the conflicting reports by various physicians regarding the character of her seizures. P. Ex. 17 at 2. Respondent, conversely, contends that Ragini suffered from infantile spasms based on the mother=s and Dr. Kaufman=s descriptions of the seizures, Dr. Kaufman=s diagnosis of infantile spasms, and literature supporting the notions that infantile spasms can occur without hypsarrhythmia in the EEG and failure to respond to ACTH treatment does not preclude a diagnosis of infantile spasms. See R. Rpt. at 4-5; R. Ex. B at 1, 4; R. Ex. F; R. Ex. G; 1991 IOM Report at 65. For the reasons stated below, the court finds, after examining the entire record in this matter, that the seizures Ragini suffered within the seven-day period following her DPT vaccination were infantile spasms.

First, petitioners emphasize that when Dr. Kaufman saw Ragini on May 5, 1994, he noted that Ragini=s EEG was Adiffusively abnormal ... approaching a hypsarrhythmi[c] pattern[,] but the background pattern was reasonably good so [he] did not feel that it met the criteria for a full hypsarrhythmi[c] EEG.@ P. Ex. 2 at 24. Petitioners= expert, Dr. Gabriel, testified that one of the reasons he did not believe Ragini had infantile spasms was because of Dr. Kaufman=s notation regarding the non-hypsarrhythmic EEG. Tr. at 100. Later on, however, Dr. Gabriel testified that hypsarrhythmia is not required to diagnose infantile spasms.[22]

Respondent submitted literature congruent with Dr. Gabriel=s testimony that hypsarrhythmia is not needed to diagnose infantile spasms.[23] Moreover, respondent=s expert, Dr. Shafrir, explained that new technology, namely a video EEG, has shown that hypsarrhythmia sometimes does not appear between seizures.[24] Tr. at 165. Rather, hypsarrhythmia may appear just before the appearance of the seizure, then it may go away. Id. at 109-10, 165. Therefore, because hypsarrhythmia is not a requirement in the diagnosis of infantile spasms, the court finds petitioners= argument concerning Ragini=s non-hypsarrhythmic EEG unpersuasive.

Next, petitioners contend that Ragini=s failure to respond to ACTH is evidence that she did not have infantile spasms. See P. Ex. 17 at 2. Petitioners= expert, Dr. Gabriel, testified that virtually all people with infantile spasms will respond to ACTH. Tr. at 90. Subsequently, however, when asked whether he had any literature to support such a proposition, Dr. Gabriel intimated to the court that he had no such support. Id. at 102. He testified that he was speaking from his own personal experience. Id. Moreover, Dr. Gabriel warned the court that his statement was predicated on Ragini receiving adequate levels of ACTH. Id. at 151.

Respondent=s expert, Dr. Shafrir, rebutted the proposition that lack of response to ACTH rules out the diagnosis of infantile spasms. According to Dr. Shafrir, the only controlled study on the issue is the Glaze study.[25] Id. at 130. In that study, the researchers used low doses of ACTH, 20 to 30 units per day, which is the same dose that Dr. Kaufman used to treat Ragini. Id. at 111.

The study, according to Dr. Shafrir, had a no response rate of 30 to 40 percent. Tr. at 110. Based on the above, the court finds that Ragini=s non-response to ACTH treatment fails to adequately support petitioners= contention that Ragini did not suffer from infantile spasms.

Finally, petitioners posit that the conflicting reports by various physicians concerning the nature of Ragini=s seizures supports their contention that she did not have infantile spasms. Specifically, petitioners note that, on May 5, 1994, Dr. Kaufman, after examining Ragini and witnessing the seizures, diagnosed her with infantile spasms. P. Ex. 2 at 24. Approximately four and one-half months later, on September 20, 1994, Dr. Peterson examined Ragini and concluded that she Apresents a curious paradox. Poorly controlled myoclonic seizures, but apparently normal neurologic development and an EEG, which may have shown hypsarrhythmic initially, but now is more or less normal.@ Id. Petitioners= argument, ostensibly, is that Dr. Kaufman=s diagnosis of infantile spasms must be wrong in light of Dr. Peterson=s subsequent characterization of Ragini=s seizures.

Petitioners= own expert, Dr. Gabriel, however, offered a potential explanation for the inconsistent diagnoses when he testified that A[i]t is typical for infantile spasms to transition.@ Tr. at 99. He explained, A[w]ith further maturation of the brain, the typical infantile spasm seizures and typical EEG pattern transition to a different seizure pattern and a different EEG abnormality. @ Id. at 99. Although Dr. Gabriel testified that Dr. Peterson diagnosed myoclonic seizures at a time when infantile spasms should still have been apparent, id. at 100, he subsequently acknowledged the possibility that a transition occurred. Id. at 154. Moreover, when asked whether Ragini had infantile spasms or myoclonic seizures, Dr. Gabriel concluded that he Acould not rule out infantile spasms as a primary diagnosis.@ Id. at 157.

Respondent=s expert, Dr. Shafrir, in contrast, admitted that he was not sure what happened to Ragini=s seizures between Dr. Kaufman=s diagnosis of infantile spasms and Dr. Peterson=s diagnosis of myoclonic seizures. Id. at 140. What he did know, however, according to his testimony, was that Ragini had infantile spasms when Dr. Kaufman examined her in May and that she continued to have seizures thereafter. Tr. at 140. In addition, respondent submitted literature supporting the notion that infantile spasms disappear, with or without treatment, or evolve into other types of seizures. R. Ex. F; 1991 IOM Report at 65. The literature also states that hypsarrhythmia disappears in the majority of cases over weeks to months, irrespective of treatment. R. Ex. F at 670. Therefore, based on the above, the court logically must reject petitioners= argument as speculative and unsupported by not only the literature, but also by petitioners= own expert=s testimony.

In sum, the court finds that during the 72-hour post-vaccination period, Ragini suffered from infantile spasms. Ragini=s mother=s and Dr. Kaufman=s descriptions of the seizures, as well as Dr. Kaufman=s diagnosis of infantile spasms, support respondent=s contention that Ragini had infantile spasms. Petitioners= arguments against such a diagnosis, namely Ragini=s non-hypsarrhythmic EEG, failure to respond to ACTH, and the doctors= apparent inconsistent diagnoses, when viewed in the aggregate, fail to persuade this court to second-guess Dr. Kaufman=s original diagnosis of infantile spasms. The testimony and literature submitted in this case clearly show that hypsarrhythmia is not needed for a diagnosis of infantile spasms and that

not everyone with infantile spasms responds to treatment with ACTH. In addition, assuming Dr. Peterson=s diagnosis of myoclonic seizures, nearly four and one-half months after Dr. Kaufman=s diagnosis of infantile spasms, is accurate, a reasonable explanation for the inconsistency is found in the literature which shows that infantile spasms often transition into other seizures. Therefore, because the evidence shows that Ragini suffered from infantile spasms, the 1991 IOM Report found no causal relationship between the DPT vaccine and infantile spasms, and petitioners failed to submit any evidence to the contrary,[26] the court finds that petitioners are not entitled to compensation in this matter.

As a final note, the court feels compelled to discuss the quality of expert testimony in this case. Petitioners= experts, to say the least, were unpersuasive. First of all, Dr. Geier is wholly unqualified to testify concerning the two major issues in this case: whether Ragini had a Table encephalopathy and whether she had infantile spasms. Concerning the Table encephalopathy issue, the undersigned, in Salmond, 1999 WL 778528, at *10, found Dr. Geier unqualified to testify as to whether a petitioner had an acute encephalopathy within seven days following her DPT vaccination because he is neither board certified nor has formal training in pediatrics and pediatric neurology. Concerning the infantile spasms issue, Dr. Geier admitted at trial that he has no experience treating or diagnosing seizure disorders. See Tr. at 46, 47. Petitioners= other expert, Dr. Gabriel, while board certified in pediatrics and neurology, challenged Dr. Kaufman=s original diagnosis of infantile spasms utilizing, at best, questionable rationales. The court found both experts to be non-objective advocates whose testimony played fast and loose with the facts and literature. In contrast, the court found respondent=s expert, Dr. Shafrir, to be credible. While the court recognizes that Dr. Shafrir had some bias against DPT causing injury, he nevertheless testified consistently with the facts, statute, literature, and medicine. Dr. Shafrir=s testimony was clearly far superior to petitioners= experts.

CONCLUSION

Based on the foregoing, the court finds, after considering the entire record in this case, that petitioners are not entitled to compensation under the Vaccine Act. Petitioners failed to offer persuasive proof that Ragini suffered an acute encephalopathy within 72 hours of her DPT vaccination, as defined by the Table, or, in the alternative, that the DPT vaccination caused-in-fact her injury. Therefore, for the reasons discussed above, petitioners fail to qualify for an award under the Program. The Clerk is directed to enter judgment accordingly.

IT IS SO ORDERED.

Gary J. Golkiewicz
Chief Special Master

[1]The National Vaccine Injury Compensation Program comprises Part 2 of the National Vaccine Injury Act of 1986 (hereinafter Athe Vaccine Act@ or Athe Act@), as amended, 42

U.S.C.A. '' 300aa-1 et seq. (West 1999 & Supp. 2000). Hereinafter, individual section (') references will be to 42 U.S.C.A. ' 300aa of the Act.

[2]Dr. Geier posited, however, that Ragini was sick enough to have been hospitalized, and, if she had been, she would have met the definition of a Table injury under the Program. P. Ex. 15 at 24.

[3]This argument was refuted not only by respondent=s expert who stated that infantile spasms is a separate entity in the ILAE classification of epileptic syndrome, Respondent=s Exhibit B (hereinafter AR. Ex. ___A) at 4, but also by petitioners= other expert, Dr. Gabriel, who testified that he recognizes the difference between infantile spasms and myoclonic epilepsy. Tr. at 157.

[4]Citations to the October 30, 2000, hearing transcript will be referenced as ATr. at ___.@

[5]Ragini initially saw her pediatrician, Dr. Carole Gervais, on November 18, 1993. P. Ex. 10 at 21. During this office visit, Dr. Gervais reported that Ragini had mild jaundice and a normal physical exam. Id. On November 30, 1993, during Ragini=s second office visit, Dr. Gervais noted that the jaundice had resolved and described Ragini as a Awell child.@ Id. On December 12, 1993, Dr. Gervais diagnosed Ragini as having viral enteritis. Id. at 20. Subsequently, on January 13 and March 12, 1994, Dr. Gervais examined Ragini and described her as a Awell child.@ Id. at 19, 20.

[6]The court notes that, according to the Revised Vaccine Injury Table, effective March 10, 1995, residual seizure disorder is no longer listed as a vaccine-related injury for the DPT vaccine. 60 Fed. Reg. 7,678, 7,694 (Feb. 8, 1995).

[7]Section 14(c) and 14(e) of the Act permits the Secretary of the Department of Health and Human Services to amend or modify the Vaccine Injury Table upon a finding that a Acertain illnes[s]@ or Aconditio[n] ... can reasonably be determined in some circumstances to be caused or significantly aggravated by certain vaccines.@ See The National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table - II, 62 Fed. Reg. 7685, 7685 (Feb. 20, 1997)(codified at 42 C.F.R. ' 100.3); Terran v. Secretary of HHS, 195 F.3d 1302 (Fed. Dir. 1999), cert. denied, Terran v. Shalala, 121 S. Ct. 45, 68 USLW 3699 (U.S. Oct. 2, 2000)(No. 99- 1749)(holding the Secretary=s authority to promulgate the revised Table constitutionally permissible, as her authority does not offend the Presentment Clause or the nondelegation doctrine involving the separation of powers between the legislative and executive branches of government).

[8]The Secretary also modified the Table in 1997. See 62 Fed. Reg. 7685 (Feb. 20, 1997). The present case, however, does not fall under the 1997 revisions because petitioners filed their claim on May 26, 1996, well before the effective date of the 1997 revisions.

[9]In addition, Dr. Shafrir testified that there was no evidence of an encephalopathy before Ragini=s DPT vaccination, that there was no evidence of an alternate cause of Ragini=s encephalopathy, and that Ragini=s encephalopathy persisted for more than 6 months. Tr. at 129-130, and 135.

[10]The legislative history explains that this requirement was meant simply to exclude those conditions, such as excessive crying and sleepiness, which are not serious enough to warrant medical attention. 60 Fed. Reg. 7,678, 7,681 (Feb. 8, 1995).

[11]The court notes that this court=s cause-in-fact test set forth in Stevens v. Secretary of HHS

, No. 99-594, 2001 WL 387418 (Fed. Cl. Spec. Mstr. March 30, 2001), is not applicable in the present case because an epidemiological study, the NCES, is available. Furthermore, the court believes that the 1994 IOM Report, see infra p. 12, which analyzed the NCES data, is based on reliable scientific evidence, and the court agrees with the Liable court=s interpretation of that study.

[12]See R. Alderslade, et al., The National Childhood Encephalopathy Study: A Report on 1000 Cases of Serious Neurological Disorders in Infants and Young Children from the NCES Research Team, in Whooping Cough: Reports from the Committee on the Safety of Medicines and the Joint Committee on Vaccination and Immunization (Department of Health and Social Security, London: Her Majesty=s Stationary Office, 1981)[hereinafter NCES Report].

[13]See Christopher P. Howson et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines (National Academy Press, 1991)[hereinafter 1991 IOM Report].

[14]See Kathleen R. Stratton et al., Institute of Medicine, DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis (National Academy Press, 1994)[hereinafter 1994 IOM Report].

[15]In promulgating the Act, Congress mandated that the IOM conduct scientific reviews of the possible adverse consequences of vaccines covered under the Program. Stevens, 2001 WL 387418, at *30. Thus, pursuant to the Act, the IOM created the Committee to Review the Adverse consequences of Pertussis and Rubella Vaccines. Salmond v. HHS, No. 91-123V, 1999 WL 778528, at *5 n.10 (Fed. Cl. Spec. Mstr. Sept. 16, 1999). This committee assembled experts in Ainfectious diseases, pediatrics, internal medicine, neurology, epidemiology, biostatistics, decision analysis, biologic mechanisms of vaccines, immunology, and public health.@ 1991 IOM at vi-vii. While the special masters are not legally bound by the IOM reports, the Institute=s conclusions have been afforded great deference and authority in vaccine cases given its Congressional mandate and independent role in reviewing existing literature relating to the adverse consequences of vaccines. See Asche Robinson v. HHS, No. 94-1096V, 1998 WL 994191, at *7-*8 (Fed. Cl. Spec. Mstr. Dec. 22, 1998).

[16]The IOM committee examined 17 adverse events for the pertussis vaccine B infantile spasms; hypsarrhythmia; aseptic meningitis; encephalopathy (including acute encephalopathy and chronic neurologic damage); deaths classified as sudden infant death syndrome (SIDS); anaphylaxis; autism; erythema multiforme or other rashes; Guillain-Barré syndrome (polyneuropathy); peripheral mononeuropathy; hemolytic anemia; juvenile diabetes; learning disabilities and hyperactivity; protracted inconsolable crying or screaming; Reye=s syndrome; shock and Aunusual shock-like state@ with hypotonicity, hyporesponsiveness, and short-lived convulsions (usually febrile); and thrombocytopenia B and three adverse events for rubella vaccine B arthritis (acute and chronic); radiculoneuritis and other neuropathies; and thrombocytopenic purpura. 1991 IOM Report at 2.

[17]In the present case, the court notes that petitioners did not contest the 1991 IOM findings concerning the DPT vaccine and infantile spasms. When asked whether he agreed with the IOM=s conclusion regarding infantile spasms, petitioners= expert, Dr. Gabriel, stated AI can only offer you my opinion with respect to my analysis of that subject. Their [the IOM=s] opinion speaks for itself.@ Tr. at 98. In the absence of any contrary persuasive authority, the court credits the IOM=s findings on the lack of a proven relationship between the DPT vaccine and infantile spasms.

[18]The relative risk for the four time periods 0 to 6, 7 to 13, 14 to 20, and 21 to 28 days were 1.2, 0.6, 0.4, and 0.6, respectively, following DPT immunization. 1991 IOM Report at 73. The NCES had sufficient statistical power (80 percent) to detect a relative risk of 2.0 to 2.4. 1991 IOM Report at 76. A relative risk greater than two has been found sufficient to establish Amore probable than not@ in a given case. See Daubert v. Merrell Dow Pharm., Inc., 43 F.3d 1311, 1321 (9th Cir. 1995).

[19]The relative risk for the four time periods 0 to 6, 7 to 13, 14 to 20, and 21 to 28 days were 1.3, 0.7, 0.8, and 0.5, respectively, following DT immunization and, as stated earlier, 1.2, 0.6, 0.4, and 0.6 respectively, following DPT immunization. 1991 IOM Report at 73.

[20]The 1993 follow-up study examined Acase children@ from the original NCES, 10 years later. Liable, 2000 WL 1517672, at *3. The study found that Acase children@ were significantly more likely than non-case children to suffer from chronic neurologic dysfunction. Id.

[21]Petitioners= expert, Dr. Geier, testified that if Ragini had been hospitalized, she A potentially would have been [included] in the NCES.@ Tr. at 58. He explained that Ragini does not fit the NCES criteria for a seizure because her seizure was not long enough, but that she A might well fit [the NCES] criteria for an encephalopathy.@ Id. at 69. Dr. Gabriel, petitioners= other expert, testified that Ragini sustained an acute seizure disorder which meets the NCES criteria for a serious neurologic injury. See id. at 97.

[22]Dr. Gabriel discussed a 1985 Texas study which found that 25 percent of children with infantile spasms did not have hypsarrhythmia. Tr. at 150. He argued that today, because of more sophisticated EEG technology, the percentage would be lower. Id. at 151. The court presumes that the new technology Dr. Gabriel is referring to is the video EEG to which Dr. Shafrir testified. Dr. Shafrir explained that a video EEG should have been done in this case. Id. at 109. No firm conclusion can be drawn from this line of testimony, except that a certain percentage of children with infantile spasms will not have a hypsarrhythmic pattern on EEG.

[23]See 1991 IOM Report at 65 (stating that Aapproximately 80 percent of infants with infantile spasms have, at some time, a characteristic EEG pattern of hypsarrhythmia.@). In addition, the court notes that only 64 percent of the case children in the NCES who were diagnosed with infantile spasms had typical or atypical hypsarrhythmia. Id. at 73.

[24]In an article submitted by respondent entitled Myoclonus and Myoclonic Seizures, by Tallie Baram, the author reports that a prolonged EEG or a video EEG may be required for diagnosis of infantile spasms because hypsarrhythmia may not be present early in the course of infantile spasms, or it may be present only during deep sleep. See R. Ex. F at 670.

[25]See Daniel Glaze, et. al, Prospective Study of Outcome of Infants with Infantile Spasms Treated During Controlled Studies of ACTH and Prednisone, 112 Journal of Pediatrics 389 (Mar. 1988).

[26]Petitioners expert, Dr. Geier, submitted numerous articles and case studies in this matter. See P. Exs. A-Z. At trial, Dr. Geier explained to the court that he filed theses articles in order to show that DPT can cause encephalopathy. Tr. at 78. The only article, however, that speaks to the issue of whether DPT can cause infantile spasms is an article from 1957, by Baird and Borofsky, entitled Infantile Myoclonic Seizures. See P. Ex. E. In this article, the authors concluded that the evidence showing DPT immunization may be a factor in causing infantile myoclonic seizures is suggestive but not clear-cut. Id. at 107. The court finds that this evidence

fails to meet petitioners' burden of proving causation-in-fact by a preponderance of the evidence.