OFFICE OF SPECIAL MASTERS
No. 00-328V
Filed: January 14, 2003

DAPHNE PEREZ, an infant, by and through her next friends and parents, JUAN C. PEREZ and IRMA L. HERNANDEZ, Petitioners, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	TO BE PUBLISHED

Thomas Gibilisco, Los Angeles, California, for Petitioners.
Glenn A. MacLeod, United States Department of Justice, Washington, D.C., for Respondent.

ENTITLEMENT DECISION

GOLKIEWICZ, Chief Special Master

I. PROCEDURAL BACKGROUND

Petitioners, Juan C. Perez and Irma L. Hernandez, filed a claim on June 5, 2000, under the National Vaccine Injury Compensation Program ("Vaccine Program" or the "Program")[1] for injuries suffered by their daughter Daphne Perez allegedly caused by the Diphtheria-Pertussis-Tetanus ("DPT") vaccine. Petitioners allege that Daphne suffered a Table injury – encephalopathy – as a result of the DPT vaccine she received on June 6, 1997. See Petition (hereinafter "Pet.") at 1-2.

[1] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-1 et seq. (West 1991 & Supp. 2002) ("Vaccine Act" or the "Act"). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

On November 6, 2000, Dr. Wendy Mitchell, Daphne's treating neurologist, filed a supplemental affidavit in support of petitioners' claim. Supplemental Affidavit of Wendy Mitchell, M.D. (hereinafter "Pet. Supp. Affidavit"), filed Nov. 6, 2000. In her affidavit, Dr. Mitchell stated that according to her review of the record and the history related to her by Daphne's parents and through Dr. Kunnawuthidee, Daphne's symptoms "manifested within 72 hours of the June 6, 1997 DPT-Hib vaccination and are consistent with onset of encephalopathy and temporally related to the vaccination." Pet. Supp. Affidavit at 3. Dr. Mitchell stated that Daphne's infantile spasms "are by nature an acute encephalopathy." Id. Moreover, Dr. Mitchell stated that she is "of the opinion to a reasonable medical probability that the June 6, 1997 pertussis vaccine triggered, and thus was a substantial factor in causing Daphne's problems ...." Id.

On November 21, 2000, the Secretary of Health and Human Services ("Secretary") filed a report in this matter contesting petitioners' entitlement to compensation. Respondent's Report (hereinafter "R. Rpt."), filed Nov. 21, 2000, at 2, 9. The Secretary contended that Daphne's medical records do not support an on-Table acute encephalopathy as defined by the statute and, in the alternative, fail to prove that the DPT vaccine actually caused Daphne's seizure disorder. Id. at 5-9.

On June 22, 2001, respondent filed an expert report from Dr. Peter Kollros. Respondent's Exhibit A, filed June 22, 2001. Dr. Kollros contended, "Any temporal association between infantile spasms and DPT immunization is thought to be due merely to chance." Id. at 5. Dr. Kollros stated three epidemiological studies had specifically addressed the relationship between infantile spasms and DPT immunization. Id. Dr. Kollros reviewed the three studies in his report and concluded that the "medical evidence is that DPT immunization does not cause infantile spasms." Id. at 6.

During several status conferences, the court informed the parties that on two separate occasions this court addressed similar medical issues in Salmond v. Secretary of HHS, No. 91-123V, 1999 WL 778528 (Fed. Cl. Spec. Mstr. Sept. 16, 1999), and Raj v. Secretary of HHS, No. 96-294V, 2001 WL 963984 (Fed. Cl. Spec. Mstr. June 15, 2001). Both cases were decided against petitioners. Raj specifically presented medical facts and issues very similar to the case at hand. The parties were advised to pay close attention to the Raj decision in presenting their respective cases.

On December 19, 2001, the court conducted an evidentiary hearing on this matter. The court heard testimony from Irma Hernandez, petitioners' medical expert, Dr. Wendy Mitchell, and respondent's medical expert, Dr. Peter Kollros. The hearing transcript was filed on January 7, 2002.[2]

Thereafter, on April 26, 2002, the parties filed post-hearing briefs. Thus, the record is

[2] Citations to the December 19, 2001, hearing transcript will be referenced as "Tr."

complete and the case is ripe for decision. After considering the entire record in this case and for the reasons stated below, the court finds that petitioners are not entitled to compensation.

II. FACTUAL BACKGROUND

The parties agreed to the following facts. See Petitioners' Closing Statement (hereinafter "Pet. Closing"), filed Apr. 26, 2002, at 19-21. Daphne Perez was born on January 23, 1997, following a normal pregnancy, labor, and delivery; her subsequent growth, health, and development were considered normal until June 1997. Pet. Closing at 19; Pet. Ex. 2, 3, 5, and 7. The medical records do not document any significant neurological abnormality prior to June 6, 1997. Pet. Closing at 21. On June 6, 1997, Daphne received a DPT-Hib vaccination. Pet. Closing at 20; Pet. Ex. 6. Within two days after her immunization, Daphne developed a high temperature, a localized reaction, and sudden drops of the head. Pet. Closing at 20; Pet. Ex. 5. Daphne's parents became concerned about Daphne's head drops and visited Dr. Kunnawuthidee. Pet. Closing at 20; Pet. Ex. 5. In August, Dr. Kunnawuthidee examined Daphne again. Pet. Closing at 20; Pet. Ex. 5. Daphne's head drops were unchanged and Dr. Kunnawuthidee referred her to Childrens Hospital Los Angeles for further evaluation. Pet. Closing at 20; Pet. Ex. 8. On August 19, 1997, Daphne was hospitalized at Childrens Hospital. Pet. Closing at 20; Pet. Ex. 8. Daphne's EEG, exhibiting hypsarrhythmia, confirmed the diagnosis of infantile seizures. Pet. Closing at 20; Pet. Ex. 8 at 156.

III. DISCUSSION

Petitioners can prove they are entitled to compensation under the Program in one of two ways. They can prove entitlement 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 Daphne 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 Daphne suffered such injury by a preponderance of the evidence, they are entitled to a presumption of causation. § 13(a)(1)(A). If Daphne qualifies under this presumption, she will be said to have suffered a "Table injury."

If 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 "logical 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). Once again, if petitioners are successful in that showing, the burden shifts to respondent to prove that the injury or condition "is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B).

In the present case, petitioners allege that Daphne suffered a Table injury, or in the alternative, that the DPT vaccination was the actual cause of Daphne's infantile spasms.

A. Table Encephalopathy

As stated above, petitioners can secure entitlement to compensation by proving, by a preponderance of the evidence, that Daphne suffered an encephalopathy as defined by the Table.[3] Once a Table injury has been established by a preponderance of the evidence, the presumption of vaccine-relatedness may be overcome by an affirmative showing that the injury was caused by a factor unrelated to the administration of the vaccine. § 13(a)(1)(B). In this case, an encephalopathy is presumptively related to the DPT vaccine if it complies with the definition at § 100.3(b)(2) and first manifests within seventy-two hours or three days following the vaccination according to § 100.3(a).

According to the Qualifications and Aids to Interpretation ("QAI"), which defines the conditions listed as Table injuries, an acute encephalopathy is "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." § 100.3(b)(2)(i). A child under the age of eighteen months who presents following a seizure is considered to have suffered an acute encephalopathy if her "significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication." § 100.3(b)(2)(i)(A).

> A "significantly 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 time frames):
>
> (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).

§ 100.3(b)(2)(i)(D).

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[3] This claim falls within the statutory revisions set forth in the National Vaccine Injury Compensation Program: Revisions and Additions to the Vaccine Injury Table – II, 62 Fed. Reg. 7685, 7688 (1997) (codified at 42 C.F.R. Pt. 100). Congress extended to the Secretary authority to promulgate revised Vaccine Injury Tables and "Qualifications and aids to interpretation." See § 14(c). See also O'Connell v. Shalala, 79 F.3d 170, 176-77 (1st Cir. 1996); Terran v. Secretary of HHS, 195 F.3d 1302, 1314 (Fed. Cir. 1999), cert. denied, 531 U.S. 812 (2000). Under this authority, the Secretary's administrative revisions are in the form of regulations which are codified in the Code of Federal Regulations. The filing date of one's petition determines whether the case is governed by the statute's (42 U.S.C.A. § 300aa-14) or a regulation's (42 C.F.R. § 100.3) Vaccine Injury Table and "Qualifications and aids to interpretation." Future references to the Secretary's regulation at § 100.3 or its subsections shall be without citation to "42 C.F.R."

Thus, to meet the definition of a Table acute encephalopathy, the Act requires petitioners prove by a preponderance of the evidence that, within seventy-two hours of the DPT vaccination, Daphne experienced "a significantly decreased level of consciousness" which persisted beyond twenty-four hours. Petitioners argue they have demonstrated that Daphne suffered a Table injury under the Act based upon the reports and the testimony of Dr. Mitchell, Daphne's treating neurologist. Pet. Closing at 3-12.

Petitioners argue Dr. Mitchell's report and testimony establish that Daphne experienced an encephalopathy within seventy-two hours of the vaccination. Pet. Supp. Affidavit at 2-4; Tr. 28, 43-45; Pet. Closing at 4. Based on the facts that within days of the vaccination Daphne became irritable, experienced a high temperature, and started having infantile spasms, Dr. Mitchell opined that Daphne "clearly falls within the onset of infantile spasms." Tr. at 36-37. Further, Dr. Mitchell testified that "infantile spasms are definitionally encephalopathic." Tr. at 67. According to Dr. Mitchell, "Daphne had an acute problem which probably should have been referred to us a few days after her shot when she first went back to Dr. K[unnawuthidee]." Tr. at 28; Pet. Closing at 4.

Respondent, in his response, counters that although "Daphne's neurologic condition in the seventy-two hours following her DTP immunization may broadly satisfy the definition of an 'encephalopathy' as expressed in the child neurology literature, her infantile spasms do not meet the definition of a compensable injury contained in the statute." Respondent's Post-Hearing Brief, (hereinafter "R. Post-Hearing Brief") filed Apr. 26, 2002, at 6. Dr. Kollros, respondent's expert, testified that he did not believe that there is evidence that the DTP caused Daphne's infantile spasms and that it is his opinion that Daphne did not suffer a Table injury. Tr. at 69, 84. Dr. Kollros based his opinion on the "lack of evidence that suggests that DPT causes infantile spasms." Tr. at 69. Dr. Kollros also cited the "extensive epidemiological evidence that failed to show a relationship between infantile spasms and the DTP Vaccination." Tr. at 69-70. Further, Dr. Kollros testified, "Infantile spasms can and do occur without evidence of an antecedent cause." Tr. at 75. Respondent argues when the definition of a Table acute encephalopathy is applied to the facts of this case, "Daphne clearly did not experience a Table encephalopathy within 72 hours of her second DTP immunization." R. Post-Hearing Brief at 8.

After reviewing the entire record in this case, the court finds that petitioners failed to show that Daphne suffered an acute encephalopathy as defined by the Table. As stated earlier, in order to prove a Table injury, petitioners must prove that Daphne suffered an acute encephalopathy within seventy-two hours of her DPT vaccination. See § 100.3. The statute defines an acute encephalopathy as one which is "sufficiently severe so as to require hospitalization," § 100.3(b)(2)(i), as indicated "by 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 this case, although Daphne's infantile spasms may fall within the general medical term "encephalopathic," her condition in the seventy-two hours following the DPT vaccine does not meet the criteria of an encephalopathy as defined by the statute. A "significantly 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 twenty-four hours. § 100.3(b)(2)(i)(D). Under the Table, seizures alone are not enough to constitute a diagnosis of acute encephalopathy. § 100.3(b)(2)(i)(E). The QAI states "in the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of an acute encephalopathy." § 100.3(b)(2)(i)(E). Petitioners have failed to provide the "other evidence" required by the statute. Other than a high temperature, a localized reaction, and sudden drops of the head, Daphne did not suffer a "significantly decreased level of consciousness," such as, a decreased or absent response to the environment, decreased or absent eye contact, or inconsistent or absent responses to external stimuli.

Applying the law, Daphne did not suffer an encephalopathy as defined by the law. Dr. Kollros's opinion is consistent with the Act; Dr. Mitchell's utilizes a medically appropriate definition, but one that is contrary to the law. It is not for this court to debate the correctness or appropriateness of the law, but to apply the law. See Watt v. Secretary of HHS, No. 99-25V, 2000 Lexis 268, at *23-*28 (Fed. Cl. Spec. Mstr. Oct. 26, 2000) (distinguishing the medical community's broad definition of encephalopathy from the specific legal definition mandated by the Act's QAI). Accordingly, petitioners' Table case must fail.

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 Daphne's infantile spasms. 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 concurred and adopted in Raj v. Secretary of HHS, No. 96-294V, 2001 WL 963984 (Fed. Cl. Spec. Mstr. June 15, 2001), for examining causation-in-fact cases involving DPT and its association with neurological illness.[4] In Liable, 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, ("NCES Report"),[5] the Institute of Medicine's ("IOM") 1991

[4] The court notes that the undersigned's cause-in-fact test for weighing circumstantial evidence of causation set forth in Stevens v. Secretary of HHS, No. 99-594V, 2001 WL 387418 (Fed. Cl. Spec. Mstr. Mar. 30, 2001), is not applicable in the present case because an epidemiological study, the National Childhood Encephalopathy Study, is available. See Watson v. Secretary of HHS, No. 96-639V, slip opinion, 2001 WL 1682537 (Fed. Cl. Spec. Mstr. Dec. 18, 2001) (Stevens test applies in absence of epidemiological study).

[5] 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

Report,[6] and the IOM's 1994 Report.[7]

The NCES examined the relationship between the DPT vaccine and neurological illnesses in infants and children. 1991 IOM Report at 100. The NCES addressed two significant questions about the DPT vaccine: 1) Does the DPT vaccine cause an increase in serious acute neurologic events in children; and 2) Does the DPT vaccine cause permanent brain damage? Id. at 101. The NCES 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 the seven day period. Id. The NCES also found that permanent damage as a result of DPT immunization is a "very rare event and attribution of a cause in individual cases is precarious." NCES Report at 149.

The 1991 IOM Report, produced by a committee of physicians selected by the IOM,[8] examined the available medical and scientific literature regarding the possible adverse consequences of the pertussis and rubella vaccines.[9] The committee considered the evidence concerning the potential relationship between the DPT vaccine and neurologic injury. Liable, 2000 WL 1517672, at *3; Raj, 2001 WL 963984, at *27. The committee concluded, based in

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Security, London: Her Majesty's Stationary Office, 1981).

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

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

[8] 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. Secretary of HHS, No. 91-123V, 1999 WL 778528, at *5 n.10 (Fed. Cl. Spec. Mstr. Sept. 16, 1999); Raj, 2001 WL 963984, at *27 n.15.

[9] The IOM committee examined seventeen adverse events for the pertussis vaccine - 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 "unusual shock-like state" with hypotonicity, hyporesponsiveness, and short-lived convulsions (usually febrile); and thrombocytopenia - and three adverse events for rubella vaccine - arthritis (acute and chronic); radiculoneuritis and other neuropathies; and thrombocytopenic purpura. 1991 IOM Report at 2.

large part upon the NCES, that the evidence is "consistent with a causal relation between DTP vaccine and acute encephalopathy." Liable, 2000 WL 1517672, at *3; Raj, 2001 WL 963984, at *27. 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. Liable, 2000 WL 1517672, at *3; Raj, 2001 WL 963984, at *27.

After examining all of the available evidence concerning the possible relationship between the DPT vaccine and infantile spasms, including the NCES, case reports, case series, and other epidemiologic studies, the committee concluded that the "evidence *does not* indicate a causal relation between the DPT vaccine or the pertussis component of DPT and infantile spasms." 1991 IOM Report at 77 (emphasis added). Among other things, the committee compared the "estimates 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. 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, despite the 1991 IOM Report's conclusion that the NCES "results suggest that DPT immunization is associated with an increased risk, within 7 days, of seizures and encephalopathy," id. at 101, **the 1991 IOM Report found no such relationship between DPT and infantile spasms**. Id. at 77 (emphasis added).

Thereafter, the 1994 IOM Report, which is a published analysis of the 1993 NCES follow-up study[10] and the 1991 IOM Report, found that the medical evidence is "consistent 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 "1994 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 'serious 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.

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[10] The 1993 follow-up study examined "case children" from the original NCES, ten years later. Raj, 2001 WL 963984, at *31 n. 20 (citing Liable, 2000 WL 1517672, at *3). The study found that "case children" were significantly more likely than non-case children to suffer from chronic neurologic dysfunction. Raj, 2001 WL 963984, at *31 n. 20 (citing Liable, 2000 WL 1517672, at *3).

The term "serious acute neurologic illness" within the meaning of the 1994 IOM Report has been interpreted 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.

At this point, one may be understandably confused as to what controls the outcome of this case, the 1991 IOM report, the 1994 IOM report, Liable or Raj. As discussed with the parties, the court relied upon the IOM's findings of a lack of a proven relationship between the DPT vaccine and infantile spasms in finding no causation in Raj and Salmond. Much attention was given to the discussion of the IOM's findings and the NCES results at the hearing. Tr. at 23-27, 31-32, 36-43, 51-53, 75-77. Let me explain the information evolution.

As explained in Salmond and discussed herein, the 1991 IOM study focused on the NCES study and "specifically considered the relationship between the DPT vaccine and different types of seizures, including ... infantile spasms." Salmond v. Secretary of HHS, 1999 WL 778528, at *18. While concluding that the DPT was associated with an increased risk of convulsions, they determined that the "evidence does not indicate a causal relation between the DPT vaccine or the pertussis component of DPT and infantile spasms." 1991 IOM Report at 77. Thus, while the IOM's 1991 report found the NCES supporting a causal link between DPT and seizures, the 1991 report modified that finding to **exclude** a causal link between DPT and infantile spasms.

Against this backdrop came the 1994 report. See supra n. 7 at 7. In December 1993, prompted by the recent publication of the ten-year follow-up report to the NCES,[11] the IOM's Committee to Study New Research on Vaccines began reviewing the 1991 committee's conclusions regarding the causal relation between the vaccine and permanent neurologic damage. This committee, which was comprised of six experts in the fields of pediatrics, neurology, and epidemiology, published their findings in 1994, entitled DPT Vaccine and Chronic Nervous

[11] The ten-year follow-up report was authored by David Miller, Nicola Madge, Judith Diamond, Jane Wadsworth, and Euan Ross; it is often referred to as the "Miller" study.

System Dysfunction: A New Analysis. In explaining their charge, the IOM stated: "The charge to the committee was to evaluate the contribution of the new data from the NCES to answering the question of whether DPT is causally related to permanent neurologic damage. The [1994] committee's conclusion could be phrased in terms of the impact that it might have on the conclusion of the 1991 IOM report Adverse Effects of Pertussis and Rubella Vaccines regarding the causal relation between DPT and permanent neurologic damage." The committee elaborated: "The inability [of the IOM's 1991 committee] to determine causality between DPT and permanent neurologic damage centered on the incompleteness of the preliminary findings reported from the 10-year follow-up study of the National Childhood Encephalopathy Study (NCES)(Madge et al., 1990). That data has since been reported in full (Madge et al., 1993; Miller et al., 1993). This report reconsiders the causal relation between DPT and permanent neurologic damage in light of the new data from the NCES." The 1994 committee noted that in addition to addressing the evidence available in 1991 on the causal relation between the vaccine and permanent neurologic damage, the 1991 committee also examined the relation between the DPT and various types of seizures, including afebrile seizures. However, the 1994 committee clearly states that its reevaluation relates to the 1991 report's conclusions on the causal relation between the DPT vaccine and permanent neurologic damage. Ultimately, the IOM concluded generally in 1994 that "the balance of evidence is consistent 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 7 days after receiving DPT vaccine." 1994 IOM Report at 2.

There is no indication anywhere in the 1994 report that the findings of the 1991 report regarding infantile spasms were modified or rejected. Therefore, the reasonable interpretation of these documents is that the 1994 IOM's findings that the DPT can cause chronic neurologic damage where an acute neurologic illness occurs within seven days following the DPT vaccination is qualified by the 1991 IOM's findings that **excludes** infantile spasms as related to the DPT vaccination. See Raj, 2001 WL 963984, at *43. Such an interpretation is not only a reasonable and sensible reading of the two IOM reports, it is consistent with recent medical literature that confirms no causal relationship between the DPT and infantile spasms. In his expert report, Dr. Kollros reviewed three epidemiological studies addressing the relationship between infantile spasms and DPT immunization and concluded the "medical evidence is that DPT immunization does not cause infantile spasms." R. Rpt. at 6. The court in fact is aware of no persuasive contrary literature and petitioners' provided none.

Thus the issue in this case devolves to whether Daphne's seizure qualifies for causal coverage under the 1994 IOM report or whether the exclusion finding of the 1991 report relating to infantile spasms applies.

In applying the "1994 IOM causation theory" to this case, the initial question is whether Daphne suffered a neurologic episode that would have qualified her as a "case child" under the NCES within seven days of her DPT vaccination. Petitioners argue that Daphne's infantile spasms (West syndrome) qualify her for the NCES. Pet. Closing at 3-6.

The facts show that Daphne suffered seizures within the seven-day period following her vaccination. Daphne's mother stated that Daphne was "very quiet" following the vaccine and when Daphne would lie down "she would kin [sic] of get stiff and her eyes would roll around." Tr. at 8-9. Petitioners' expert, Dr. Mitchell, testified that Daphne "clearly falls within the onset of infantile spasms within the week that the NCES used." Tr. at 36. Further, respondent concedes Daphne suffers from infantile spasms. Pet. Closing at 20 (memorialization of parties' agreed facts); R. Post-Hearing Brief at 2.

Petitioners contend that because Daphne qualifies as a NCES case child, under Liable, petitioners have met their burden. Petitioners attempt to emphasize the similarities between their case and Liable, while distinguishing their case from Salmond and Raj. Petitioners are correct that like the young girl in Liable, Daphne began to exhibit unusual movements following the DPT vaccination. Pet. Closing at 3. However, the young girl in Liable did not suffer from infantile spasms, but rather suffered a seizure lasting longer than thirty minutes.[12] Liable, 2000 WL 1517672, at *14, *50. The distinction is critical because, as stated above, the IOM specifically addressed the casual relation between infantile spasms and the DPT vaccine following the NCES Report. In fact, in Liable, Special Master Hastings notes that his analysis is consistent with Salmond.[13] Liable, at *66, n. 21. Although Special Master Hastings did not need to address the issue of infantile spasms in Liable, he does state in cases where there was a seizure less than thirty minutes in duration in the seven-day post-vaccination period the 1991 IOM report would apply. Id.

This court has addressed the issue of the causal relationship between infantile seizures and the DPT vaccination before. As previously stated, the IOM committee composed of experts in "infectious diseases, pediatrics, internal medicine, neurology, epidemiology, biostatistics, decision analysis, biologic mechanisms of vaccines, immunology, and public health," 1991 IOM at vi-vii, determined the "evidence does not indicate a causal relation between the DPT vaccine or the pertussis component of DPT and infantile spasms." 1991 IOM Report at 77. While the special masters are not legally bound by the IOM reports, the IOM's conclusions have been afforded great deference and authority in vaccine cases given the IOM's congressional mandate and independent role in reviewing existing literature relating to the adverse consequences of vaccines. See Ashe-Robinson v. Secretary of HHS, No. 94-1096V, 1998 WL 994191, at *7-*8 (Fed. Cl. Spec. Mstr. Dec. 22, 1998); supra n. 8, at 7 (discussing the congressional mandate that the IOM conduct scientific reviews of the possible adverse consequences of vaccines covered under the Program). Respondent cites the IOM's statement that the available scientific evidence remains insufficient to indicate a casual relation between the DPT vaccine or the pertussis component of DPT and infantile spasms. R. Post-Hearing Brief at 2 (citing R. Ex. E).

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[12] The court is not persuaded by petitioners argument that Daphne's mother's testimony, Tr. at 7-9, "is susceptible to the inference that one or more of the seizures lasted thirty minutes or more." Pet. Closing, n.7 at 14.

[13] The Raj decision was filed nine months after Liable was issued.

The facts of this case fall squarely within this court's decision in Raj. In Raj, the court concluded that Ragini Raj did suffer from infantile spasms during the post-vaccination period. Raj, 2001 WL 963984, at *42. After establishing that the evidence demonstrated Ragini suffered from infantile spasms, the court looked to the 1991 IOM Report which found no casual relationship between the DPT vaccine and infantile spasms. Id. at 43. Thus, the court concluded petitioners were not entitled to compensation. Id.

Petitioners attempt to distinguish their case from Raj by arguing: (1) Ragini Raj's condition was not an acute encephalopathy, where Daphne had an acute problem; (2) Ragini's and Daphne's medical courses differed; and (3) the quality of petitioners' experts are different. Petitioners note that in Raj, respondent's expert, Dr. Shafrir, testified that Ragini Raj had a "'specific encephalopathy called infantile spasms,' which is a slowly progressive disease, not acute encephalopathy." Raj, 2001 WL 963984, at *18 (citations omitted); Pet. Closing at 12. Petitioners contend that these facts differentiate the Raj case from their own case because petitioners' expert, Dr. Mitchell, testified that "Daphne had an acute problem which probably should have been referred to us a few days after her shot when she first went back to Dr. K." Tr. at 28; Pet. Closing at 12. Petitioners also point out that Ragini's EEG demonstrated a non-hypsarrhythmic pattern where Daphne showed encephalopathic patterns and petitioners note that Dr. Mitchell testified, "Daphne has had the most refractory infantile spasms I have ever seen." Pet. Closing at 12 (quoting Tr. at 37). Finally, petitioners argue their case is distinct from Raj because their expert, Dr. Mitchell, is "eminently qualified to render opinions," where petitioners' experts in Raj were unpersuasive.

Petitioners' argument that Rajini Raj's infantile spasms were not acute, but Daphne's infantile spasms are an acute problem is unconvincing. At trial, Dr.Mitchell explained that what she referred to as an acute problem was specifically Daphne's infantile spasms. Tr. at 39. Dr. Kollros testified that generally an acute encephalopathy is initially severe and improves over time. Tr. at 71. Dr. Kollros stated that in this case the records present evidence contrary to an acute encephalopathy:

> And that is that when Daphne was seen between the time of her immunization and when she was first diagnosed as having infantile spasms, the concern about her injury was such that, you know, her initial physician said let's wait two weeks and see what happens. It could possibly be a habit. When Dr. Mitchell first saw her, she said that the development seemed to be pretty much on par, maybe not quite as good as you would expect the average child at that age, but it wasn't like there was a severe encephalopathy affecting Daphne's functioning. You know, during that time, she was able to eat. During that time, she responded to people. Dr. Mitchell's notes when she first [saw] her said she smiled, was awake, alert, smiled. And that's not what I would associate with acute encephalopathy, and I don't see evidence that there was really acute encephalopathy ...

Tr. at 71-72. Dr. Kollros's testimony was more persuasive on this issue. Respondent's view is that infantile spasms are a chronic encephalopathy, rather than an acute encephalopathy. R. Post-Hearing Brief at 10 (citing Dr. Kollros's testimony, Tr. at 72-73). As discussed above and at trial, the IOM concluded that there is no relationship between the vaccination, DPT, and infantile spasms. Tr. at 39-42. Although petitioners attempted to analogize the facts of their case to those in Liable, the records and testimony in this case do not support an "acute" encephalopathy.

The court is not persuaded by petitioners argument that Raj is inapplicable to their case because of Ragini's and Daphne's differing medical courses. Ragini's EEG showed a non-hypsarrhythmic pattern where Daphne showed encephalopathic patterns. Pet. Closing at 12. Ragini's non-hypsarrhythmic EEG was an issue in the Raj case because petitioners alleged that Ragini's seizures were not infantile spasms, but were myoclonic seizures or an unspecified seizure disorder. Raj, 2001 WL 963984, at *35. At the Raj trial, petitioner's expert acknowledged that hypsarrhythmia is not required to diagnose infantile spasms and, after reviewing the entire record, the court ultimately concluded that Ragini suffered from infantile spasms. Id. at 37. The distinction between a non-hypsarrhythmic EEG and hypsarrhythmic EEG is of little consequence in this case because petitioners do not contest the diagnose of infantile spasms.

Furthermore, petitioners' argument distinguishing Raj because of poor expert testimony is unconvincing. In Raj, this court did find petitioners' "experts to be non-objective advocates whose testimony played fast and loose with the facts and literature." Raj, 2001 WL 963984, at *44; Pet. Closing at 13. However, in Raj, the court also concluded the respondent's expert testified consistently with facts, statute, literature, and medicine. Raj, 2001 WL 963984, at *45. The court noted the credibility issues within the Raj decision, but weak experts do not render the holding completely inapplicable to later cases. The parties agreed that, Dr. Mitchell, petitioners' expert is well-qualified to testify about the issues presented in this case; she has completed approximately twelve evaluations for the government and she has testified in "about" two vaccine injury cases. Tr. at 18-19, 23. However, Dr. Mitchell relies heavily on the temporal relationship between the vaccination and onset and was unable to provide medical evidence or to cite literature to support her theory. Tr. at 36, 40-41, 48-55, 64-67; Pet. Supp. Affidavit at 3, 4; Pet. Closing at 4-5, 14. The court appreciates Dr. Mitchell's experience and testimony, but her theory was unable to overcome the 1991 IOM Report conclusion that the "evidence does not indicate a causal relation between the DPT vaccine or the pertussis component of DPT and infantile spasms." 1991 IOM Report at 77. Thus, petitioners are unable to prevail in their attempt to distinguish their case from Raj.

During the post-vaccination period, Daphne suffered from infantile spasms. Infantile spasms do allow Daphne to be considered a case child under the NCES. However, the 1991 IOM Report specifically found no causal relationship between the DPT vaccine and infantile spasms. The 1994 IOM Report, a published analysis of the 1993 NCES follow-up study and the 1991 IOM Report, found that the medical evidence is "consistent 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; yet, the IOM did not amend its conclusion that no causal relationship between the DPT vaccine and infantile spasms exists. Petitioners failed to persuade the court to the contrary. The court finds that petitioners are not entitled to compensation in this matter.

IV. 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 Daphne suffered an acute encephalopathy within seventy-two 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.

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Gary J. Golkiewicz
Chief Special Master