OFFICE OF SPECIAL MASTERS

No. 91-123V

Filed: September 16, 1999

SUSAN W. SALMOND and WILLIAM J. SALMOND, as Guardians Ad Litem of LISA MARIE SALMOND,	*	
Petitioners,	*	To Be Published
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Curtis R. Webb, Twin Falls, Idaho, for petitioners.

Althea Walker Davis, United States Department of Justice, Washington, D.C., for respondent.

DECISION

GOLKIEWICZ, Chief Special Master.

PROCEDURAL BACKGROUND

On January 28, 1991, petitioners filed a claim on behalf of their daughter, Lisa Marie Salmond ("Lisa"), under the National Vaccine Injury Compensation Program ("Vaccine Act" or the "Act").[1] Initial Petition ("Pet."), filed January 28, 1991; Amended Petition ("Amended Pet."), filed December 7, 1995. Petitioners claim that as a result of a Diphtheria-Pertussis-Tetanus ("DPT") vaccination administered on April 4, 1979, Lisa suffered seizures, resulting in a residual seizure disorder and subsequent attention deficit and learning disabilities. Pet. at 1-4; Amended Pet. at 1-3.

On October 31, 1994, respondent filed a report in this matter contesting the sufficiency of the evidence and recommending compensation be denied. Respondent's Report ("R. Rpt."), filed October 31, 1994. Respondent contended that petitioners failed to demonstrate that Lisa suffered a Table injury, or in the alternative, that the DPT vaccination actually caused Lisa's residual seizure disorder. R. Rpt. at 4-5, 7. Respondent asserted that no expert opinion linked Lisa's condition with the DPT vaccine or her current problems with the events which occurred following the vaccination. R. Rpt. at 7-8. Counsel noted that Lisa's own treating physician, Dr. Arnold P. Gold, denied such a connection and extensive testing failed to discover the etiology of Lisa's seizures. R. Rpt. at 8. An evidentiary hearing was held in this matter on November 12, 1998.[2] Petitioners presented expert testimony from Dr. Mark R. Geier; Dr. Walter Molofsky testified on respondent's behalf.

Pursuant to the court's November 13, 1998 Order, the parties submitted their respective post-hearing briefs. However, after a review of the evidence, the court informed the parties that in the court's opinion, "an analysis of afebrile seizures formed the core of the decision, a subject the parties did not previously brief." Order, filed July 1, 1999, at 1. The court offered the parties an opportunity to review the court's draft decision and to submit supplemental briefs in response to the court's discussion of afebrile seizures. During a status conference conducted on September 2, 1999, petitioners' counsel declined to file a supplemental brief. Thus, the case is now ripe for decision. After considering the totality of the record, the court finds that petitioners failed to show by a preponderance of the evidence that the DPT vaccine in fact caused Lisa's injuries.

II.

FACTUAL BACKGROUND

The parties agreed to the following facts.[3] *See* Stipulation of Facts, filed October 16, 1996. Lisa Salmond was born on January 6, 1979, following a normal pregnancy, labor, and delivery; her subsequent growth, health, and development were considered normal until April 4, 1979. P. Ex. E at 18; P. Ex. M at 281, 287; P. Ex. N at 324. On April 4, 1979, Lisa received a DPT vaccination. P. Ex. G at 53. Four days following her vaccination, on April 8, 1979, at approximately 10:00 p.m., Lisa suffered her first afebrile[4] seizure which lasted about five minutes and was characterized by tonic-clonic activity of the right leg; it first progressed to both legs and then to both legs and the right arm. P. Ex. E at 18, 23; P. Ex. F at 36. Lisa cried hard for fifteen minutes following the seizure and was admitted to Overlook Hospital in Summit, New Jersey, that evening at 11:30 p.m. P. Ex. E at 18, 23; P. Ex. F at 30. Tests conducted during this hospitalization (EEG, skull x-ray, and CBC) returned normal and no cause for her seizure was found. P. Ex. E at 18, 20, 21, 22, 24; P. Ex. F at 28, 47-50. Lisa was discharged the following day, on April 9, 1979, at 4:00 p.m. P. Ex. E at 18; P. Ex. F at 30.

There is no indication of further medical problems until May 6, 1979, nearly one month after Lisa's first seizure, when she suffered two more tonic-clonic seizures involving all four extremities. P. Ex. F at 28; P. Ex. G at 56. The first seizure lasted 3½ minutes; the second convulsion persisted for only 30 seconds. P. Ex. G at 56.

On May 8, 1979, Lisa suffered another seizure which began at 4:30 p.m. with hiccuping, staring, and then aversive movements of her head to the left. P. Ex. G at 56. Subsequently, Lisa's right middle finger and ring finger began to twitch; this was followed by rapid eye blinking, staring to the left, and jerking movements of the right arm. P. Ex. G at 56. Lisa failed to respond to visual or auditory stimuli during this seizure episode and suffered right postictal Todd's paralysis following the convulsion. P. Ex. G at 56.

Lisa was again hospitalized on May 18, 1979, for a 3½ hour episode of status epilepticus. P. Ex. G at 58, 65. Lisa's physicians conducted numerous tests in an effort to determine the cause of her convulsive activity. Metabolic studies, a CT scan, and cerebrospinal fluid analysis returned with negative results, and several EEG's conducted failed to identify the etiology of Lisa's seizures. P. Ex. G at 58, 60, 65. By May 19, 1979, Lisa was seizure-free and remained so throughout her hospitalization. P. Ex. G at 65. Lisa's physicians discharged her on May 30, 1979, on phenobarbital and Dilantin.[5] P. Ex. G at 58, 65.

Lisa's subsequent history reveals she suffered a 2½ minute afebrile grand mal seizure on October 2, 1979, and several seizures in August and November of 1980 associated with varying anticonvulsant levels which were at times toxic. P. Ex. G at 62, 72; P. Ex. H at 151. In July 1981, Lisa suffered mild delays in speech and coordination. P. Ex. 23 attachment at 157 (Dr. Gold's July 29, 1981 neurological consultation report). By second grade, Lisa experienced difficulties with academic performance, especially in math, and had features of an attention deficit disorder. P. Ex. G at 110, 116.

Today, Lisa has a complex seizure disorder with ongoing recurrent seizures which require treatment with multiple anticonvulsants. She evidences attention deficit difficulties and learning and perceptual impairments. No cause has been identified for Lisa's seizure disorder or her learning and attention problems.

III.

THE VACCINE ACT AND RELEVANT JURISPRUDENCE

Causation in Vaccine Act cases can be established in one of two ways: either through the statutorily prescribed presumption of causation, or by proving causation-in-fact. Petitioners must prove one or the other in order to recover under the Act.[6] The Vaccine Injury Table lists certain injuries and conditions which, if found to occur within a prescribed time period, create a rebuttable presumption that the vaccine caused the injury or condition. §14 (a). 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). For purposes of this case, the Table lists residual seizure disorder as a presumptively vaccine-related injury if the onset of the seizure disorder occurs within three days of the administration of the DPT vaccine. §14(a). In the instant case, it is undisputed that Lisa suffered her first seizure on April 8, 1979, four days after her vaccination. Therefore, petitioners failed to satisfy the requirements under the Act for demonstrating a Table injury and, instead, must demonstrate that the vaccination caused-in-fact (*i.e.*, off-Table claim) Lisa's residual seizure disorder to be entitled to compensation.

In order to demonstrate entitlement to compensation in an off-Table case, a petitioner must affirmatively demonstrate by a preponderance of the evidence that the vaccination in question more likely than not caused the injury alleged. §§11(c)(1)(C)(ii)(I) and (II); *Grant v. Secretary of HHS*, 956 F.2d 1144 (Fed. Cir. 1992); *Strother v. Secretary of HHS*, 21 Cl. Ct. 365, 369-370 (1990), *aff'd without opinion*, 950 F.2d 731 (Fed. Cir. 1991). The Federal Circuit in *Grant* summarized the legal criteria required to prove causation-in-fact under the Vaccine Act:

[A petitioner must] show a medical theory causally connecting the vaccination and the injury. Causation-in-fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.

Grant, 956 F.2d at 1148 (citations omitted); *see also Strother*, 21 Cl. Ct. at 370. This requires that petitioner show "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Secretary of HHS*, 165 F.3d 1344, 1352-1353 (Fed. Cir. 1999); *see also Grant*, 956 F.2d at 1148. Petitioner does not meet this affirmative obligation by merely showing a proximate temporal association between the vaccination and the injury. Rather, petitioner must explain *how* and *why* the injury occurred. *Strother*, 21 Cl. Ct. at 370; *see also Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983), *cert. denied*, 469 U.S. 817 (1984) ("inoculation is not the cause of every event that occurs within the ten day period [following it]... [w]ithout more, this proximate temporal relationship will not support a finding of causation"). If petitioner places "singular reliance on the temporal relationship between the administration of the vaccine and the onset of symptoms," the claim must fail. *Thibaudeau v. Secretary of HHS*, 24 Cl. Ct. 400, 403 (1991). Nor may petitioner meet his burden by merely eliminating other potential causes of the injury. *Grant*, 956 F.2d at 1149-1150.

Moreover, petitioner's theory "must be supported by a sound and reliable medical or scientific explanation." *Knudsen v. Secretary of HHS*, 35 F.3d 543, 548 (Fed. Cir. 1994). "[E]vidence in the form of scientific studies or expert medical testimony is necessary to demonstrate causation" for petitioners seeking to prove actual causation. H.R. Rep. No. 990908, 99th Cong. 2d Sess., pt. 1 at 15 (Sept. 26, 1986), *reprinted in* 1986 U.S. Code Cong. and Admin. News 8344, 8356. The general acceptance of a theory within the scientific community can have a bearing on the question of assessing reliability while a theory that has attracted only minimal support may be viewed with skepticism. *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 113 S. Ct. 2786, 2797 (1993). Although the Federal Rules of Evidence do not apply in Program proceedings, the United States Court of Federal Claims has held that "*Daubert* is useful in providing a framework for evaluating the reliability of scientific evidence." *Terran v. Secretary of HHS*, 41 Fed. Cl. 330, 336 (1998), *appeal docketed (on other issues)*, No. 98-5161 (Fed. Cir. Sept. 4, 1998)(citing *Leary v. Secretary of HHS*, No. 90-1456V, 1994 WL 43395, at *9 (Fed. Cl. Spec. Mstr. Jan. 31, 1994)). In *Daubert*, the Supreme Court noted that scientific knowledge "connotes more than subjective belief or unsupported speculation." *Daubert*, 113 S.Ct. at 2795. Rather, some application of the scientific method must have been employed to validate the expert's opinion. *Daubert*, 113 S.Ct. at 2795. Factors relevant to that determination may include, but are not limited to:

whether the theory or technique employed by the expert is generally accepted in the scientific community; whether it's been subjected to peer review and publication; whether it can be and has been tested; and whether the known potential rate of error is acceptable.

Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1316 (9th Cir. 1995) (Kozinski, J.), *on remand from* 113 S.Ct. 2786 (1993); *see also Daubert*, 113 S.Ct. at 2796-2797.

Given these standards, in order to answer the single inquiry of whether, based on the record as a whole, the evidence preponderates in favor of a finding that Lisa's residual seizure disorder was caused by the DPT vaccination, one must pursue a two-step analysis which the court has consistently utilized in addressing cause-in-fact issues in Program cases: (1) *can* the DPT vaccine cause a residual seizure disorder? and (2) *did* the DPT inoculation administered to Lisa on April 4, 1979, in-fact cause her residual seizure disorder? *See Housand v. Secretary of HHS*, No. 94-441V, 1996 WL 282882 (Fed. Cl. Spec. Mstr. May 13, 1996); *Guy v. Secretary of HHS*, No. 92-779V, 1995 WL 103348 (Fed. Cl. Spec. Mstr. Feb. 21, 1995); *Alberding v. Secretary of HHS*, No. 90-3177V, 1994 WL 110736 (Fed. Cl. Spec. Mstr. Mar. 18, 1994).

IV.

DISCUSSION

Can the DPT vaccine cause a residual seizure disorder?

Congress provided, for claims filed before March 10, 1995,[(7)] as this claim was, that a petitioner may be compensated for a presumptively vaccine-related residual seizure disorder under certain circumstances. Congress delineated these instances in the Act's "Qualifications and aids to interpretation" which state:

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if--

. . . .

(B) in the case of any other vaccine [*i.e.*, any vaccine other than the measles, mumps, or rubella vaccines or any combination of such vaccines], the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

§14(b)(2)(B). This section further provides that a seizure or convulsion for purposes of the statutory language may "include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs." §14(b)(4). By explaining the requisite elements for a Table residual seizure disorder, Congress explicitly defined the injury, thereby limiting which seizure disorders petitioners could successfully plead.[(8)] In contrast, in off-Table claims, Congress provided no specific guidance in the legislative history or statutory language defining which injuries could be alleged or explaining what constitutes the particular injury claimed. Instead, petitioners may allege any illness, disability, injury, or condition which they believe results from the administration of the vaccine, regardless of whether it is also listed on the Vaccine Injury Table or defined by the "Qualifications and aids to interpretation." Thus, in off-Table claims, it is petitioners' burden to not only allege an injury which is specific to the facts of their case, but to define and explain the injury as well. In petitioners' case, Lisa's parents alleged that she suffered a residual seizure disorder and subsequent learning disabilities and attention deficit difficulties as a result of the DPT vaccine administered April 4, 1979. Consequently, the court must assess whether the seizure disorder alleged is one which can be caused by the DPT vaccine.[(9)] This inquiry is addressed separately below.

Can the DPT vaccine cause the *type* of seizure disorder Lisa experienced?

Lisa suffered six seizures in the six months following her DPT vaccination on April 4, 1979. *See*, *supra*, at II. Factual Background. While petitioners alleged a residual seizure disorder, the condition requires further examination. From the medical records, it is clear that Lisa suffered from multiple types of seizures, including generalized tonic-clonic, mixed major motor and minor motor variety, grand mal, focal, akinetic, dropping spells, etc. Simply put, her seizures often manifested differently during the various episodes. Although she was diagnosed with a mixed seizure disorder of the major motor and minor motor variety during her late April 1981 hospitalization, Dr. Gold characterized her overall seizure history in 1985 as having no specific pattern. P. Ex. 23 attachment at 160; P. Ex. G at 109. What is evident, however, is that Lisa's seizures were afebrile. For instance, the records demonstrate that Lisa's seizures on April 8, 1979, May 6, 1979, and October 2, 1979, were afebrile. P. Ex. E at 24; P. Ex. F at 28, 36; P. Ex. G at 62. There is also no contest from the experts that Lisa's convulsive activity was anything but afebrile. **Therefore, the issue presented initially to the court is whether the DPT vaccine can cause an afebrile seizure disorder.** After reviewing the evidence in the record, the court concludes that the evidence is insufficient to find that the DPT vaccine *can cause* the type of seizures Lisa experienced. The court relies on the Institute of Medicine's ("IOM") 1991 report, supporting case law, and subsequent administrative changes to the Program as support for this finding and rejects Dr. Geier's testimony on this issue.

Institute of Medicine, Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines (1991 Report)**:** The Institute of Medicine's 1991 report from the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines[(10)] rejected a causal relation between the DPT vaccine and afebrile seizures. R. Ex. 3 at 115, 118. While the committee focused much of its review on the efficacy of the National Childhood Encephalopathy Study ("NCES"), the committee also specifically considered the relationship between the DPT vaccine and different types of seizures, including febrile seizures, epilepsy, infantile spasms, and afebrile seizures.[(11)] The committee concluded that the NCES results "suggest that DPT immunization is associated with an increased risk, within seven days, of seizures and encephalopathy" and determined that the relative risk for convulsions within seven days of the vaccine was 3.3.[(12)] R. Ex. 3 at 101, 107. The reviewers also found a causal relation between the vaccine and febrile seizures.[(13)] R. Ex. 3 at 118. However, the committee found insufficient evidence to indicate such a relation with epilepsy and determined that "[t]he evidence does not indicate a causal relation between DPT vaccine or the pertussis component of DPT and infantile spasms." R. Ex. 3 at 77, 118. More importantly for our purposes, the IOM's experts pronounced that **"the available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccinations" and consequently "the evidence does not indicate a causal relation between DPT vaccine and afebrile seizures."**[(14)] R. Ex. 3 at 115, 118 (emphasis added). In reaching this conclusion, the IOM relied on the results of a meta-analysis[(15)] performed from three controlled studies with defined populations which specifically offered information on afebrile seizures.[(16)] R. Ex. 3 at 115. The IOM stated: "Using the methods described in Appendix D, the pooled RR [relative risk] estimate from these studies is 0.6 (95 CI = 0.4-1.1), assuming a fixed-effects model, and 0.7 (95 percent CI = 0.3-1.5), under a random-effects model. Thus, even pooling of the available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccination." R. Ex. 3 at 115. The committee ultimately concluded that the studies were "consistent in showing no relation to DPT vaccination, although each had limited statistical power to detect risks unless they were on the order of 2.4 or larger." R. Ex. 3 at 115, 118.

Acceptance of the IOM's rejection of the causal relation between the DPT vaccine and afebrile seizures effectively eliminates the NCES's application to this case. This is so even though the NCES made no express findings regarding the causal connection between the vaccine and afebrile seizures. The NCES was launched in 1976 "to assess the risks of certain serious neurological disorders associated with immunization in early childhood." P. Ex. 25 at 80. The NCES investigators requested that participating physicians notify the study of all children between ages 2-36 months who were hospitalized from July 1, 1976, to June 30, 1979, for specifically enumerated acute neurological illnesses.[(17)] P. Ex. 25 at 101, 157. Relevant for our purposes here, treating physicians were specifically asked to report all incidences of convulsions with a total duration of more than about ½ hour, convulsions followed by coma lasting two hours or more, and convulsions followed by paralysis or other neurological signs not previously present lasting 24 hours or more.[(18)] P. Ex. 25 at 155-157. According to the IOM's 1991 report, 904 case children suffered an acute encephalopathic injury or convulsions (non-infantile spasms). R. Ex. 3 at 101. Of this number, 515 children suffered seizures; two-thirds involved febrile convulsions while one-third consisted of seizures of other types. R. Ex. 3 at 101; R. Ex. 4 at 8. In the final statistical analysis, no distinction was made between those children with febrile or afebrile seizures. P. Ex. 25 at 119-121. However, the NCES researchers did indicate the number of participants with a past history of afebrile and febrile seizures and stated that children with a previous history of afebrile seizures were placed in Category II.[(19)] P. Ex. 25 at 103, 114, 115. The researchers also provided the outcome of those in the vaccine-associated group which suffered simple/febrile seizures and prolonged/febrile seizures. P. Ex. 25 at 133-134.

In the end, the NCES researchers concluded *generally* that "[m]ost cases of acute and potentially damaging neurological illness [including those seizures meeting the reporting criteria] in early childhood are attributable to causes other than immunization[, and] [s]uch illnesses occur more frequently within 7 days, and particularly within 72 hours, after DTP vaccine . . . than would be expected by chance. Most affected children made a complete recovery." P. Ex. 25 at 149. They also found that "the onset of these serious neurological illnesses has been shown to 'cluster' at particular time intervals after these two immunizations, which supports a causal association . . . The possibility that causal associations exist between immunization with pertussis . . . and the development of serious neurological disorders is widely regarded as biologically plausible." P. Ex. 25 at 142. Again, in the final statistical calculations, no ultimate distinction was made between those children suffering afebrile seizures and those suffering from other types of convulsions. Thus, while the NCES supports that the DPT can cause seizures, which may then progress to seizure disorders, in some children within seven days following the administration of the vaccine, the IOM's 1991 report modifies this finding with regard to afebrile seizures.

Institute of Medicine, Committee to Study New Research on Vaccines (1994 Report): In December 1993, prompted by the recent publication of the ten-year follow-up report to the NCES,[(20)] 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. R. Ex. 4 at 4-5; *see also* P. Ex. 26 (Miller study). 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 System Dysfunction: A New Analysis.* R. Ex. 4 at 5-6. 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." R. Ex. 4 at 5. 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). Those data have 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." R. Ex. 4 at 3-4. 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. R. Ex. 4 at 3. 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." R. Ex. 4 at 2.

Expert testimony: The experts offered limited testimony on the link between the DPT and afebrile seizures; instead, Drs. Geier and Molofsky focused largely on the issue of whether Lisa would have been notified to and included in the NCES.[(21)] While Dr. Geier recognized that the 1991 IOM report disputed the causal connection between DPT and afebrile seizures, he nevertheless rejected that determination. Dr. Geier explained that in 1991 the IOM was unconvinced of the causal relation between the vaccine and permanent neurological sequela. Tr. at 84-85. He then posited that because afebrile seizures usually indicate permanent damage, the IOM declined in 1991 to relate the DPT to these types of convulsions. Tr. at 84-85. The court questioned Dr. Geier at length regarding the impact of the IOM's 1991 and 1994 findings as they relate to this case. In response, Dr. Geier rejected the notion that petitioners' claim turns solely on the issue of whether the vaccine can cause afebrile seizures. Tr. at 84-85, 128-129. The court and Dr. Geier engaged in the following pointed exchange:

THE COURT: You were asked . . . what is the impact of this case relative to the NCES study in the follow up to the IOM, due to the fact that we have an afebrile seizure, as opposed to a febrile seizure? The '91 IOM found no relationship between an afebrile seizure and DPT. Did that [IOM finding] change?

THE WITNESS: Yeah, I believe that changed when they accepted the long-term. I think if you accept that DPT causes afebrile seizures, you accept that it causes permanent neurologic damage, because afebrile seizures usually are a sign of permanent neurologic --

THE COURT: Didn't the '91 IOM say that there was no relationship, they found no causal relationship for afebrile seizures and DPT?

THE WITNESS: Yes.

THE COURT: In their subsequent reports, did they change that [finding]?

THE WITNESS: I don't recall them specifically changing that, but I believe they would change their position now that they believe that there's permanent damage.

THE COURT: Well, they issued a report after that.

THE WITNESS: I don't recall anywhere in the report where they addressed that.

THE COURT: So, this case could turn on that one item alone? If we find no support in the Institute of Medicine for a causal relationship between afebrile seizures and DPT, doesn't that change your whole opinion, because you're relying on the IOM?

THE WITNESS: No, no, because the IOM's final position was that if it did, the NCES -- I mean, they revised their position. They said that if the child fit in the NCES, then they believed that it was more likely than not due to DPT. And, this child fits into the NCES.

Tr. at 128-129. Dr. Molofsky offered no opinion regarding the direct relationship between pertussis and afebrile seizures although he agreed with the NCES and IOM that the vaccine can cause acute neurological dysfunctions and permanent damage in some children. Tr. at 148, 180; *but see* R. Ex. 1 (Dr. Molofsky's expert report), filed March 25, 1996, at 5 (wherein Dr. Molofsky reported that the literature does not support a causal relation between DPT and chronic seizure disorders or encephalopathies).

The court finds Dr. Geier's arguments unpersuasive and speculative at best. In its 1991 report, the IOM assumed, among other duties, the task of examining the available evidence and from that evidence distinguishing *which types of seizures* could be causally related to the DPT vaccine. The IOM's 1994 report, however, *focused expressly on reviewing and revamping the 1991 report's conclusions regarding the correlation between the vaccine and permanent neurologic damage*. The IOM concluded generally in 1994, following the completion of the NCES ten-year follow-up study, 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."[(22)] R. Ex. 4 at 2. Most meaningful here, however, the 1994 report made no specific adjustment to the previous committee's determinations on afebrile convulsions, as Dr. Geier advocated. While arguably the committee's conclusions in 1994 could be interpreted to encompass afebrile seizure disorders as a form of chronic nervous system dysfunction, in the absence of specific language the court has no basis to read in any modifications to the 1991 report's findings with respect to afebrile seizures. To do so would be pure speculation. That is, it is not reasonable to accept Dr. Geier's hypothesis that the 1994 report revised the 1991 report's findings regarding afebrile seizures thereby accepting the NCES's findings without the modifications adopted by the 1991 IOM committee. As previously mentioned, in reviewing and publishing findings on the relationship between long-term neurological sequela and DPT reactions, the 1994 IOM committee was asked to consider the new information on chronic nervous system dysfunction from the Miller study which was not previously available to the 1991 committee. Thus, the 1994 committee had every opportunity and reason to specifically address the 1991 committee's conclusions on afebrile seizures in the forum provided by the 1994 report. However, in 1994 the IOM did not expressly comment on, change, revise, or reverse its earlier conclusions on the causal relation between DPT and afebrile seizures.

While Dr. Geier asks the court to assume that the 1994 IOM would revise the 1991 findings, the more reasonable interpretation is that the 1994 IOM saw nothing to change in the 1991 findings with respect to the causal relation between the vaccine and *acute injuries* (*i.e.*, afebrile seizures). Instead, armed with the additional information from the Miller study, the 1994 IOM report built upon the 1991 committee's findings with respect to *permanent or chronic neurologic sequela*. In short, Dr. Geier can only speculate that the IOM would change their 1991 opinion on afebrile seizures based on the 1994 findings, and Dr. Geier conceded he could not point to any such statement of revision in the IOM's 1994 report. Dr. Geier simply fails to provide a rational basis for ignoring the IOM's 1991 report rejecting a causal relation between DPT and afebrile convulsions and the IOM's subsequent 1994 follow-up report.

Relevant case law and subsequent administrative changes to the Program: The court's finding here of an insufficient link between the DPT and afebrile seizures is also in line with Special Master Abell's decision in *Terran v. Secretary of HHS*, No. 95-451V, 1998 WL 55290 (Fed. Cl. Spec. Mstr. Jan. 23, 1998), *aff'd*, 41 Fed. Cl. 330 (1998), *appeal docketed (on other issues)*, No. 98-5161 (Fed. Cir. Sept. 4, 1998), wherein the court held that the vaccinee's initial non-febrile seizures were not caused-in-fact by the DPT vaccination since "[t]he 1991 IOM report concludes that DPT can cause febrile, but not afebrile seizures." *Terran*, 1998 WL 55290, at *12. The child in *Terran* similarly suffered multiple, brief, afebrile seizures in the days immediately following the vaccination then a major 50-minute convulsion thirty-two days after her DPT inoculation. *Terran*, 1998 WL 55290, at *1.

Moreover, this ruling is supported by subsequent administrative changes to the Program. Pursuant to the IOM's 1991 report, the Secretary of the Department of Health and Human Services revised the Vaccine Injury Table to exclude a residual seizure disorder as a presumptively vaccine-related injury. The Department noted in its Final Rule that "[i]n its 1994 report, the IOM did not retract any of its 1991 conclusions regarding DTP and seizure disorders. It merely recognized that the NCES included seizures as one of those conditions to be monitored [for] purposes of tracking long-term dysfunction. This recognition does not provide any information one way or the other regarding causation." 60 Fed. Reg. 7678, 7690-7691. The Department further concluded that "there is no basis for providing a legal presumption of vaccine causation for chronic effects based solely on the occurrence of a seizure following DTP immunization. There is simply no need for, nor is there medical evidence to support, a separate presumption for residual seizure disorder in connection with DTP vaccine." 60 Fed. Reg. at 7691. In explaining the relationship between the Table revisions and evolving medicine, the Department noted:

The IOM concluded that "the evidence is insufficient to indicate a causal relation between vaccines containing pertussis" and certain adverse events. Because the evidence was determined as "insufficient," the Department concluded that it could not "reasonably determine" that a causal connection exists, and the Table is being revised accordingly . . . The intent of the regulation is to make the Table consistent with medical knowledge regarding the relationship between vaccines and certain adverse events.

60 Fed. Reg. at 7681, 7682.[(23)]

Based on the whole of the evidence, the court finds the evidence is insufficient to conclude that the DPT vaccine can cause the type of residual seizure disorder suffered by Lisa, to wit an afebrile seizure disorder.[24] In addition, there is no persuasive evidence that Lisa suffered an acute encephalopathy within seven days of her inoculation.[25] Thus, the probability calculations presented by Dr. Geier are valueless, as they rely on the relative risk estimates for an acute encephalopathy. In sum, petitioners' claim fails on the first prong of the causation-in-fact analysis.

V.

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. In so finding, the court notes that its determination rests principally on petitioners' failure to provide persuasive support for their actual causation claim. This decision should not be read to bar future similar claims. Over the last ten years, the causation-in-fact analysis as it relates to DPT claims has been visited on many levels, often in general terms. The current trend in this court involves a more thorough review and analysis of the National Childhood Encephalopathy Study, Institute of Medicine reports, and other relevant literature. Such inspection may provide further developments both in understanding the science and reviewing that understanding in light of the governing law. Therefore, it is conceivable that further discussions regarding the causal relationship of DPT and afebrile seizures could produce a different result. The court is open to such a discussion.

In the absence of a motion for review filed pursuant to RCFC Appendix J, the Clerk of the Court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

Gary J. Golkiewicz

Chief Special Master

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

2. Citations to the November 12, 1998 hearing transcript, filed in this matter on November 17, 1998, will be referenced as "Tr. at ___."

3. The court has provided the citations to the facts contained in the parties' Stipulation of Facts. References to Lisa's medical records will specify both the exhibit letter or number and the consecutive page number, *e.g.*, "P. Ex. E at 13" or "P. Ex. 24 at 16."

4. According to Dorland's Illustrated Medical Dictionary, "afebrile" is defined as "without fever." Dorland's illustrated medical dictionary 35 (27th Ed. 1988)("Dorland's"). A "fever" is defined as "1. elevation of body temperature above the normal; pyrexia. It may be due to such physiological stress as ovulation, excess thyroid hormone secretions, vigorous exercise, central nervous system lesions, or to infection by microorganisms, or to a host of noninfectious processes, as that accompanying inflammation or resulting from release of pyrogenic materials, as in leukemia. 2. any disease characterized by fever." Dorland's at 620.

5. While the parties stipulated that Lisa was discharged on May 31, 1979, the records reflect she was discharged on May 30, 1979.

6. Petitioners must prove their case by a preponderance of the evidence, which requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before [the special master] may find in favor of the party who has the burden to persuade the [special master] of the fact's existence." *In re Winship*, 397 U.S. 358, 372-373 (1970) (Harlan, J., concurring), *quoting* F. James, Civil Procedure 250-251 (1965). Mere conjecture or speculation will not establish a probability. *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (Cl. Ct. 1984).

7. Effective March 10, 1995, the Vaccine Injury Table was amended to exclude residual seizure disorder as a presumptively vaccine-related illness under the vaccine category DPT, pertussis, DT, tetanus-diphtheria toxoid ("Td"), and tetanus toxoid. *See* 60 Fed. Reg. 7678-7696 (Feb. 8, 1995), *codified at* 42 C.F.R. 100.1-100.3.

8. It is this court's opinion that the use of the phrase "residual seizure disorder" is a term of art created by Congress. Despite numerous expert hearings involving cases of seizure disorders, no expert before the undersigned has ever testified that there exists in medicine a *specific condition* called a "residual seizure disorder." Instead, patients suffer from on-going seizure disorders which may have many characteristics and/or causes, and which may even be deemed a specific condition, such as Infantile Spasms Syndrome. Thus, Congress's phraseology is a generalized form of an illness, which is limited in definition by the Act's "Qualifications and aids to interpretation."

9. Upon a finding by the court accepting such a causal relation, the court would then assess whether the learning disabilities and attention deficit difficulties Lisa suffers can be caused by the specific seizure disorder experienced.

10. The IOM created the Committee to Review the Adverse Consequences of Pertussis and Rubella Vaccines in November 1989, pursuant to the Vaccine Act. This committee assembled experts in "infectious diseases, pediatrics, internal medicine, neurology, epidemiology, biostatistics, decision analysis, biologic mechanisms of vaccines, immunology, and public health." Christopher P. Howson, et al., Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines (1991) at *vi-vii*. These experts were responsible for the review of available scientific literature (including the National Childhood Encephalopathy Study) and other information regarding the possible adverse consequences of pertussis. Howson, et al. at *vi*. Specifically, the committee considered the "nature, circumstance, and extent of the relationship, if any, between vaccines containing pertussis (including whole cells, extracts, and specific antigens) and . . . [numerous] illnesses and conditions." Howson, et al. at *vi*. The committee also assessed the causal relation between the pertussis vaccine and permanent neurologic damage. Howson, et al. at *vi*. 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 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 (Fed. Cl. Spec. Mstr. Dec. 22, 1998)*; Cohen v. Secretary of HHS*, No. 94-353V, 1998 WL 408784 (Fed. Cl. Spec. Mstr. July 1, 1998); *Cucuras v. Secretary of HHS*, 26 Cl. Ct. 537, *aff'd*, 993 F.2d 1525 (Fed. Cir. 1993); *Aldridge v. Secretary of HHS*, No. 90-2475V, 1992 WL 153770 (Cl. Ct. Spec. Mstr. June 11, 1992); *Woodcock v. Secretary of HHS*, No. 90-1030V, 1992 WL 92169 (Cl. Ct. Spec. Mstr. Apr. 10, 1992).

11. The committee was not initially asked to report on the causal relation of the vaccine to febrile seizures, afebrile seizures or epilepsy, but undertook this examination since "these conditions are considered by some to be components of encephalopathy." R. Ex. 3 at 118.

12. Relative risk "is the *ratio* of the incidence of a defined condition in those *exposed* to a suspected causal agent in a population to the incidence of the same condition in those who are *not exposed* (in this case, the ratio of the incidence of serious neurological illnesses in immunized children to that in unimmunized children)." P. Ex. 25 at 98. This calculation took into consideration that only 515 of the 904 children experiencing an acute neurological event (non-infantile spasms) had convulsions and only 18 of the 515 had a seizure within seven days of the vaccination. R. Ex. 3 at 101. A relative risk greater than two has been found sufficient to establish causation more probably than not in a given case. *See Daubert,* 43 F.3d at 1321*; see also* Respondent's Posthearing Memorandum, filed January 13, 1999, at 17.

13. The 1991 IOM committee also noted the data suggests that "febrile seizures following administration of DPT vaccine occur during the ages when children are most likely to experience these seizures related to other febrile events" and the "DPT vaccine may cause a doubling or tripling of the febrile seizure rate in the first few days following immunization." R. Ex. 3 at 108 (citations omitted), 118.

14. As the literature submitted by petitioners explains, a finding that the "the evidence does not indicate a causal relation" means that "[t]he evidence, in other words, indicates no causal relation." P. Ex. 36 at 394. This is to be distinguished from a finding that the evidence is insufficient "to indicate the presence or absence of a causal relation" *(i.e.*, "the available evidence [is] insufficient to conclude for or against causation") and from a determination that "the evidence is consistent with a causal relation" (*i.e.*, "the evidence [is] of sufficient quantity and quality to conclude that a causal relation probably exists"). P. Ex. 36 at 394-395.

15. "Meta-analysis," as explained by the IOM, is the "pool[ing] of statistical information from" a "number of sufficiently similar studies of the same adverse event" for the purposes of "develop[ing] an estimate of the relative risk, or the odds ratio, of the event in question that is more precise than the estimates from the individual studies." Howson, et al. at 52-53.

16. These studies were published in 1988 and 1990.

17. While the study's final statistical results attach significance to events occurring within the seven-day period following vaccination or preceding admission, physicians were asked to notify the NCES investigators of the occurrence of the specifically listed acute neurological illnesses as they happened and *without reference to the patient's vaccination history or temporal relationship between the acute illness and the inoculation, unless the illness was definitely deemed by the reporting physician to be a complication of the inoculation.* P. Ex. 25 at 101-102, 155-156.

18. Treating physicians were also directed to report all incidences of acute or subacute encephalitis/encephalomyelitis or encephalopathy; unexplained loss of consciousness; infantile spasms (West's syndrome); and Reye's syndrome (acute encephalopathy with abnormal liver function tests). P. Ex. 25 at 155-157.

19. Category II referred to those children who were considered "Abnormal--Abnormal"; that is, they suffered neurological abnormalities prior to their acute illness and also continued to experience subsequent neurological abnormalities at discharge or on the fifteenth day after their hospital admission

(whichever was sooner). P. Ex. 25 at 107-108.

20. 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.

21. Dr. Geier testified that notification and inclusion in the study's seven-day time period is a prerequisite to using the IOM's statistical analysis to demonstrate in a particular case whether the DPT more likely than not caused the injury alleged. Tr. at 26, 113. He opined that Lisa's ongoing seizure disorder and May 18 convulsion satisfied the notification criteria for, respectively, (1) a seizure followed by neurological signs not previously present lasting for more than 24 hours and (2) a prolonged convulsion. Tr. at 43, 44, 128. He believes Lisa suffered a serious acute neurological illness, as defined by the NCES, on April 8, 1979, within seven days of her DPT vaccine; he further related all of Lisa's seizures to one single pathological process. Tr. at 42, 43, 50, 102-105, 109-112. Dr. Geier believes that his findings of notification and inclusion thereby permitted the usage of the IOM's meta-analysis data to calculate that there is an 83% likelihood that Lisa's illness (which Dr. Geier considered an encephalopathy for purposes of the probability analysis) was caused by the vaccine. Tr. at 33.

Dr. Molofsky agreed Lisa would have been notified to the study based on her May 18 seizure which met the reporting criteria for a convulsion exceeding 30 minutes. Tr. at 160, 161, 176. However, he contested her continued participation in the study based on his belief that she did not suffer an acute event within seven days of her DPT inoculation. Tr. at 159-161, 165. Dr. Molofsky explained that Lisa's seizures were not related via an active or on-going single pathological process such that she suffered a qualifying neurological event within the week following vaccination; instead, he considered the seizures manifestations or sequela of a past event--a prenatal cause. Tr. at 149-150, 159, 160, 173-174, 185-187. While Dr. Molofsky conceded that only epidemiology can demonstrate a causal relationship with DPT, he did not know how this would be achieved and contested that the epidemiological evidence from the NCES and IOM could be used to calculate a percentage of causation in an individual case. Tr. at 163, 166, 167, 180. In any event, he noted that because Lisa did not meet the relevant seven-day time period, she would not be part of the background or basis for the statistical calculation and, thus, no statistical analysis would apply to her case. Tr. at 165, 168.

22. The "serious acute neurological illness" cited in the IOM's 1994 report refers to those illnesses defined and contemplated in the original NCES report. R. Ex. 4 at 11, 13; *see also Lewis v. Secretary of HHS*, No. 95-728V, 1999 WL 476262, at *6 (Fed. Cl. Spec. Mstr. June 14, 1999).

23. The Department noted one commentator's concerns that the Secretary of Health and Human Services should rescind, based on the IOM's 1994 report, some of its findings made after the IOM's 1991 report. 60 Fed. Reg. 7678, 7682 (Feb. 8, 1995)(National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table; Final Rule). The Department responded as follows: "The Department has reviewed these findings again in light of the commentater's [sic] concerns and has determined that the findings remain valid. In fact, the conclusions of the IOM and the NVAC [National Vaccine Advisory Committee] subcommittee

. . . with respect to pertussis vaccine and chronic neurological damage confirm the soundness of [certain] findings . . . The recent IOM report was confined to a review of the Miller study, and is, therefore, limited to the circumstances of that particular study. Given the conclusions articulated by the IOM and the accompanying caveats, and the discussion and conclusions of the NVAC subcommittee, the Department concludes that the findings published with the NPRM [Notice of Proposed Rulemaking] reflect best the state of scientific knowledge." 60 Fed. Reg. at 7682. While this court recognizes that the Secretary is the respondent in this case, she has the dual posture of having been given authority by Congress to make changes to the Vaccine Act. While the court is reticent to base its findings solely on the Department's statements in the Final Rule, the Department's remarks add supportive weight to the court's conclusions.

24. Since the DPT cannot cause afebrile seizures, it follows logically that the vaccine cannot cause an afebrile seizure disorder. Incidentally, the IOM, which defined epilepsy as "[r]ecurrent afebrile seizures," determined that "there is insufficient evidence to indicate a causal relation between DPT vaccine and epilepsy." P. Ex. 31 at 88, 118; R. Ex. 3 at 118.

25. Although Dr. Geier based his statistical calculations on a belief that Lisa developed an acute encephalopathy on April 8, 1979, there is no persuasive evidence in the medical records that support this notion nor has Dr. Geier pointed to any such supporting documentation. Tr. at 26-30, 32-35. Without substantiation from the medical records, Dr. Geier is not qualified to opine whether Lisa suffered an acute encephalopathy within seven days following her DPT vaccination. He is neither board certified nor has formal training in pediatrics and pediatric neurology. Tr. at 54-55. In addition, any role he plays in diagnosing pediatric neurology problems is with the assistance of a team which includes pediatricians and pediatric neurologists; Dr. Geier also does not treat children with neurology problems. Tr. at 55, 64-65. Moreover, Dr. Geier's testimony on neurological issues has been rejected on many prior occasions due to his lack of expertise on the subject. *See Lewis v. Secretary of HHS*, No. 95-728V, 1999 WL 476262, at *4, 9 (Fed. Cl. Spec. Mstr. June 14, 1999). The court finds Dr. Molofsky more qualified to render an opinion on this issue; he is a board certified pediatric neurologist with special certification in child neurology. Tr. at 141. Dr. Molofsky testified that Lisa's May 18 episode of status epilepticus constituted an encephalopathic event, but he rejected that she suffered a systemic illness or an acute or significant encephalopathy (defined as an impairment to or illness of the brain) in the days following her vaccination. Tr. at 149, 150, 161, 192; R. Ex. 1 at 5. He recognized that Lisa expressed irritability following her inoculation but considered this incompatible with the Act's definition of an encephalopathy. R. Ex. 1 at 5. He also noted Lisa appeared normal between her seizures and suffered no prolonged change in mental status. Tr. at 149-150. Dr. Molofsky did believe, however, that Lisa's seizures were manifestations of a prenatal static encephalopathy, unrelated to her DPT vaccine. Tr. at 192; R. Ex. 1 at 5. Accordingly, the court finds based upon Dr. Molofsky's testimony that there simply is no persuasive evidence Lisa developed an acute encephalopathy within seven days following her April 4, 1979 DPT inoculation.