OFFICE OF SPECIAL MASTERS

No. 95-451V

(Filed: January 23, 1998)

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| MICHELE Y. TERRAN, as legal representative of JULIE F. TERRAN, a minor, | * | |
| Petitioner, | * | |
| v. | * | PUBLISHED |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | |
| Respondent. | * | |
| * * * * * * * * * * * * * * * * * * * * * * * * | * | |

*Andrew W. Dodd, Esq.*, Torrance, California, for petitioner.

*Claudia Gangi, Esq.*, United States Department of Justice, Washington, D.C., for respondent.

**ENTITLEMENT DECISION**

**ABELL,** Special Master:

On 12 July 1995, petitioner filed a claim under the National Childhood Vaccine Injury Compensation Act (Vaccine Act or Act)[(1)] for the alleged vaccine-related injuries of her minor daughter, Julie F. Terran. Petitioner claims that the pertussis toxin component of the diphtheria-pertussis-tetanus (DPT) vaccine, administered on 10 August 1992, caused Julie's residual seizure disorder (RSD) and encephalopathy.

On 10 October 1995, respondent filed a report concluding that petitioner is not entitled to compensation under the Act. On 5-6 March 1997, the court conducted an evidentiary hearing in Los Angeles, California. Petitioner presented the testimony of Dr. Gary Berebitsky, treating physician of Julie, and Dr. John Menkes, pediatric neurologist. Dr. Robert Baumann, pediatric neurologist, testified on behalf of respondent.

Following a review of the entire record, and for the reasons stated *infra*, the undersigned finds that petitioner is not entitled to compensation under the Act.

## I. FACTS[(2)]

Julie was born on 10 February 1992 in Phoenix, Arizona. Pet.Aff., at 2. Her APGAR scores were eight/nine and she was discharged in good health from the hospital on 11 February 1992. Pet.Ex. 1, at 19. She received her first DPT vaccination on 27 March 1992 at two months of age. Tr. at 22. She received her second DPT vaccination on 3 June 1992 at three and one-half months of age. Tr. at 22. She received her third DPT vaccination on 10 August 1992 at six months of age. Tr. at 22. Her fourth DPT vaccination, administered on 22 September 1993, unlike the three previous DPT vaccinations, was an acellular DPT vaccine. All of these vaccines were given by Dr. Gary Berebitsky, Julie's pediatrician, at her well-baby care checkups. Tr. at 22. The third DPT vaccination is the one that is at issue in this case.

The day after her third DPT vaccination, on 11 August 1992, Julie suffered a seizure episode lasting approximately seven seconds in which one of her arms became stiff. Pet.Aff., at 2. On 12 August 1992, Julie experienced four afebrile seizures, each about one minute in length. Tr. at 109; Pet.Ex. 4, at 333. Following her 12 August 1992 seizures, Julie was rushed to Phoenix Children's Hospital (PCH) at Good Samaritan Medical Center via ambulance. Pet.Aff., at 3. She played with her oxygen mask during the trip, and was noted as alert, active, and non-toxic. Pet.Ex. 4, at 203-4; Pet.Ex. 10, at 436. Julie was admitted to PCH for observation and remained hospitalized from 12-14 August 1992. In the presence of hospital personnel, on 13 August 1992, Julie suffered another seizure lasting approximately five and one-half minutes. Pet.Aff., at 3; Pet.Ex. 4, at 235. The hospital personnel administered the anti-convulsant Phenobarbital to Julie. Tr. at 105; Pet.Ex. 4, at 235. Julie experienced approximately a total of twelve minutes of seizure activity in the seven days following her third DPT vaccination. Tr. at 109. Julie continued to have seizures throughout the next year. On 12 September 1992, she suffered from a seizure lasting approximately fifty minutes despite being on Phenobarbital medication at the time. Pet.Aff., at 3. Her seizures continue today.

Julie's neurological condition is well documented in the medical records. Thirteen months after Julie's third DPT, Dr. Berebitsky noted on 13 September 1993 that Julie was "well appearing" and "neurologically intact." Pet.Ex. 2, at 42. It was not until November 1993 that Dr. Berebitsky first noted a problem with Julie's neurological condition. He indicated she had a borderline passing score on the Denver Developmental Screening Test. Pet.Ex. 2, at 45. Julie currently is mentally retarded.

Because Julie had a meningocele lump removed from her skull as a young child, her doctors performed several tests to see if there was any permanent brain damage. These tests were completed prior to her third DPT vaccination and concluded she had no brain abnormalities. She had an MRI scan on 18 May 1992 which reported her brain structure as normal. Pet.Ex. 2, at 174; Tr. at 33. Her lump was checked for cancer, and the test came back reporting there was no cancer. Dr. Manwaring, a board certified

pediatric neurosurgeon, did the follow up and he found Julie's pre-immunization neurological condition to be unremarkable except for moderate strabismus. Pet.Ex. 4, at 338. After the vaccination, Julie had MRIs on 21 May 1993 and 13 August 1993 which showed no structural pathology in her brain. Pet.Ex. 2, at 174-76. Dr. Allen Kaplan, the Director of Pediatric Neurology, Phoenix Children's Hospital said in a letter to another doctor the meningocele lump was not the cause of the seizures. Pet.Ex. 4, at 349. Respondent requested Julie undergo two separate genetic workups, on 28 June 1995 and 29 July 1996, and those results were entirely normal. Pet.Ex. 29.

## II. FACT WITNESS

In this case, only Dr. Gary Berebitsky was called as a fact witness. It was unnecessary to have other fact witnesses inasmuch as the records speak for themselves, they are not at issue, and additional fact testimony would be redundant.

### A. Dr. Gary Berebitsky

Dr. Gary Berebitsky is Julie's primary care physician and a board certified pediatrician. Tr. at 14. He testified that prior to her 10 August 1992 vaccination, Julie was a healthy child except for a small pea-sized meningocele lump in the skull and being cross-eyed. Tr. at 19. She was reaching her developmental milestones and evidenced no seizure activity prior to her third DPT vaccination. Tr. at 19. Finally, Dr. Berebitsky confirmed that the vaccination given to Julie on 10 August 1992 was manufactured by Connaught and had a lot number of 2k31068. Tr. at 24; Pet.Ex. 15.

## III. EXPERT WITNESSES

**A. Dr. John Menkes**[(3)]

Dr. John Menkes testified on behalf of the petitioner as an expert witness. He is board certified in pediatrics and neurology. He is also a consultant for the Committee on Adverse Vaccine Reactions for the Institute of Medicine. Tr. at 59. He opined that to a reasonable degree of medical probability, the pertussis vaccine triggered a seizure disorder that has proved resistant to medical therapy and this has caused progressive intellectual deterioration in Julie. Tr. at 37-38. He defined an encephalopathy as an "altered abnormal state of the brain." Tr. at 38. He explained the significance of the National Childhood Encephalopathy Study (NCES), which establishes an association between the pertussis vaccine and encephalopathy, and opined that Julie would have been included in the parameters of the study because she had a "complicated seizure" which occurred within seven days of the vaccination. Tr. at 40-41; 93. The complicated seizure is apparent because she required hospitalization. Tr. at 42. On cross-examination, he admitted he did not know that the test subjects in the NCES had to have seizures totaling more than thirty minutes within seven days of the vaccination to be included in the study. Tr. at 75-76.

Next, Dr. Menkes discussed how different vaccine lots can vary up to forty-fold in immunogenicity or in effectiveness of inducing an immune response in the recipient. Tr. at 42. Some batches have far greater adverse effects and neurological symptoms than other batches. Tr. at 43. The neurological reactions are a result of the pertussis toxin in the whole-cell vaccine. Tr. at 44. He explained that the pertussis toxin couples to G proteins. G proteins are found within a cell and are instrumental in initiating inter and intra-cellular signals. The toxin alters the G proteins and their signals within a cell and from one nerve cell to another. Tr. at 44. The pertussis toxin causes the cells to confuse inhibitory signals with accentuating signals. Tr. at 45. The result is the nerve cells do not signal properly. Tr. at 45. As a result of the pertussis toxin in the brain cells, the inhibitory cells are depressed and the excitatory impulses are enhanced. Tr. at 51. Since the brain functions by electrical signals from one cell to another, the pertussis toxin coupling with the G proteins causes damage to the functioning of the brain. Tr. at 51. The brain's nerve cells begin to stimulate themselves to death. Tr. at 53. This can cause a seizure disorder and encephalopathy. Tr. at 50. Tests done on animals have unequivocally shown that pertussis toxins couple with G proteins. Tr. at 44. In fact, this is such a predictable and verifiable reaction that pertussis toxin is now commonly used in a number of studies that are primarily designed to elucidate this inter and intra-cellular signaling system. Tr. at 45. This medical theory is supported by nerve cell preparations, tissue slices, cellular suspensions, and several hundred medical articles, Tr. at 45, and has been established beyond any contention. Tr. at 49. However, on cross-examination, Dr. Menkes admitted that the theory that the pertussis toxin can cause a seizure disorder with a potential evolution to retardation is not generally accepted in the medical community. Tr. at 79. He speculated that a paper advancing the theory could be published in Europe. Tr. at 80. He believed that about twenty percent of American pediatric neurologists would concur with the theory and that older pediatric neurologists are more likely to agree with the theory than younger pediatric neurologists. Tr. at 82.

Dr. Menkes testified that once a person has a seizure, a subsequent seizure becomes more likely. The brain remembers having a seizure and it becomes easier and easier for it to have another seizure. This process is called "kindling" other seizures. Tr. at 50. Dr. Menkes explained that a seizure disorder caused by a vaccine is intractable and not easily cured by anti-convulsants (which is unique since only one-half to one percent of seizures are intractable and persistent). Tr. at 63. Seizures caused by pertussis toxin occur shortly after vaccination and are afebrile. Tr. at 63. The child must be normal prior to the vaccination in order to implicate the pertussis toxin. Tr. at 63.

Normally, according to Dr. Menkes, a protective system called the blood-brain barrier keeps toxins out of the brain. Tr. at 45. The pertussis toxin is able to enter the brains of young children (under 6 months)

because the blood-brain barrier is not yet operative. Also, the development of the blood-brain barrier may be delayed in some infants. Tr. at 46. This has been established by evidence that most new born children have bilirubin (the normal degenerative product of red cells) in the brain. This causes yellow jaundice, but is not serious unless excessive bilirubin gets into the brain. When the child gets older, the blood-brain barrier matures and bilirubin no longer can pass into the brain. Tr. at 47. In addition, the pertussis toxin can also enter the brain of a young child with a developed blood-brain barrier because of the anti-toxins in the vaccine. These anti-toxins, or a bacterial infection, can lower the blood-brain barrier through a process called pinocytosis[(4)] and allow the pertussis toxin to enter the brain even though the child has a developed blood-brain barrier. Tr. at 47.

Dr. Menkes' testimony then focused on Julie's particular case. He opined to a reasonable degree of medical probability that the pertussis toxin breached the blood-brain barrier and got into Julie's brain. Tr. at 49. He did admit, on cross-examination, that with the current state of medical technology, there is no way of knowing for certain if the pertussis toxin got into Julie's brain. Tr. at 86. Presently, there is not a clinical test to see if the toxin had breached the blood-brain barrier. Tr. at 86. He said the fact that she was given a vaccine from a lot with over two hundred reported adverse reactions, including four deaths, gives weight to his conclusion. Tr. at 49. According to Dr. Menkes, Julie did not react to her first or second whole-cell pertussis vaccinations because they were probably from a different lot, Tr. at 88, and she did not react to her fourth vaccination because it was an acellular pertussis vaccine. Tr. at 88. Once Julie had one seizure, she became susceptible to another seizure and this resulted in a seizure disorder. Tr. at 50. The fact that Julie had a normal EEG prior to the vaccine, and then showed a deterioration over time in her EEGs supports his theory. Tr. at 52. In addition, the fact that Julie's seizures are intractable, afebrile, and started shortly after the vaccination also lends support to Dr. Menkes' conclusions. Tr. at 63. Finally, the meningocele lump Julie had on the occipital area of her skull is unassociated with any seizures or any other abnormality and is not diagnostically significant in this case. Tr. at 58-59.

In the NCES study in England, subjects had to meet the criteria of at least one of the categories for inclusion in the study. Dr. Menkes believes Julie would have been included in the NCES seizure study because she meets the criteria of having "complicated" seizures. She has complicated seizures because they are afebrile, Tr. at 95, and recurrent. Tr. at 96. Dr. Menkes also believed Julie might have been included through the criteria of having seizures for more than thirty minutes, even though she in-fact only had twelve minutes of seizure activity seven days after vaccination, because the reason Julie did not seize for more than thirty minutes within seven days of the vaccination is because she was taking anti-convulsants. Tr. at 91, 168.

Dr. Menkes opined that Julie does not meet the new table criteria for an encephalopathy. Tr. at 65. However, Dr. Menkes stated Julie has an encephalopathy because she has an altered state of brain function. Tr. at 65. The new table definition of encephalopathy is too restricted. Tr. at 70. The word encephalopathy means "diseased brain." Tr. at 67. A majority of pediatric neurologists would agree with him that a chronic seizure disorder fulfills that definition. Tr. at 67. In Julie's case, the encephalopathy started with one seizure (as the first sign or symptom) and each succeeding seizure caused a continuing disruption until it evolved into an encephalopathy. Tr. at 65. This explains her global developmental delay and retardation. Tr. at 77. On cross-examination, Dr. Menkes admitted Julie would not have been included in the NCES encephalopathy study because she did not have changes in alertness within seven days of the vaccination. Tr. at 78.

**B. Dr. Robert Baumann**[(5)]

Dr. Robert Baumann was called to testify by respondent as an expert witness. He is board certified in

pediatrics and neurology. He opined to a reasonable degree of medical certainty that Julie's seizure disorder is unrelated to the immunization. Tr. at 112-13. He believes Julie had an underlying anomaly, manifested in the meningocele lump, that caused her current condition. Tr. at 113. In addition, Julie's seizures were brief and she was not encephalopathic during the period of the seizures. This is not what a doctor would expect if her illness was caused by a toxin. Tr. at 113. Her EEGs showed no abnormalities until she was 15 months of age. Tr. at 114.

According to Dr. Baumann, Julie would not have been included in the NCES study because she does not meet the operational criteria of the study. Tr. at 114. She did not met the requirement of having in excess of thirty minutes of seizures within seven days of vaccination. He said that "complicated seizures" were not a criteria used for including children in the study. Tr. at 115. Also, even if "complicated seizures" were a criteria, the term is too vague to mean anything. Tr. at 115.

Dr. Baumann testified that the vast majority of the scientific community agrees with the Institute of Medicine's position[(6)] that an encephalopathy can be the sequela to an immunization of DPT. Tr. at 116-17. However, Julie did not suffer an acute encephalopathy as a result of her third DPT. Tr. at 119. The medical records are clear she did not have a clouded level of consciousness. Between her seizures she was awake, alert, appropriate, and fed. Tr. at 120. She may have a chronic encephalopathy today. Tr. at 120.

Dr. Baumann believes Julie's seizures are not a result of her immunization. Instead, she has a cognitive disorder that developed *in utero*. Tr. at 122. The meningocele lump was the first manifestation of the cognitive disorder and the subsequent manifestations are the seizures and her current diminished capacity. Tr. at 22. He acknowledges that Julie had an MRI after the surgery to remove the lump and another follow up MRI one year later and both of those MRIs showed Julie to be normal, but he does not believe this contradicts his opinion because a lot of children with normal MRIs later develop seizures. Tr. at 128. In light of her underlying disorder, it is normal for a child with a meningocele to behave normally until six months of age but later develop symptoms of developmental delay. Tr. at 129. The vaccination did not significantly aggravate her condition because it is normal for Julie to show a gradual deterioration in her EEGs. Tr. at 130. However, Dr. Baumann was not aware of any studies that show what percentage of children with a meningocele later experience seizures or developmental delay. Tr. at 133. Lastly, Dr. Baumann did not believe it was medically relevant that the particular vaccine batch given to Julie had more adverse reactions than other batches. Tr. at 138.

On cross-examination, Dr. Baumann readily agreed that the underlying abnormality he opines caused the meningocele lump, seizures, and developmental delay cannot be demonstrated on an MRI, or by any chemical test, or visualized by any radiographic technique, may not show up in an autopsy, and in fact does not even have a specific name. Tr. at 139-42. Also, the lump is made up of the meningeal material that covers the brain. It is not composed of brain cell material. Tr. at 149. All of the articles submitted by the doctor say the pathogenesis of meningoceles are unknown. Tr. at 151. He said neurology is mostly unknown causes. Tr. at 151. He refers to the disease as an "underlying anomaly" that is unknown, but he refused to call the disease idiopathic. Tr. at 160-61.

Dr. Baumann said petitioner's expert, Dr. Menkes, "gave the most lucid presentation I have ever heard. A first rate presentation. And yet, I think even with a presentation of that quality, I think over eighty percent would think it's a[n un]tenable hypothesis." Tr. at 118. Dr. Baumann was not familiar with the literature on the use of pertussis toxin to produce certain electrical signals in the brain, but said "if Dr. Menkes tells me you can use this experimentally, I'm sure that's quite true." Tr. at 144.

## IV. STATUTORY REQUIREMENTS

The Vaccine Act permits establishment of causation in one of two ways: either through the statutorily prescribed presumption of causation or by proving causation-in-fact. The Vaccine Injury Table lists specific vaccines and certain injuries or conditions that may occur as a result of a vaccine's administration. If the onset of those injuries or conditions is found to occur within a prescribed time period, a rebuttable presumption is created that the vaccine caused the condition.(7)

In the case at bar, petitioner alleges her third DPT, administered on 10 August 1992, caused her residual seizure disorder and encephalopathy. Inasmuch as RSD is an injury not listed in the new Vaccine Table, (8) petitioner's thesis under the Act is one of causation-in-fact. Encephalopathy is still a table-injury. However, petitioner concedes she does not meet the criteria of an onset of an encephalopathy as defined in the new Vaccine Table(9)

and thus her thesis again is one of causation-in-fact.

Causation-in-fact is an acceptable thesis under the Act. Petitioner may establish entitlement to an award through traditional tort methods. Causation-in-fact cases include injuries not listed on the Table or injuries that are listed but occurred outside the temporal parameters of the Table. Entitlement in such cases is dependent upon proof by a preponderance of the evidence that the vaccine actually caused the injury.

Causation-in-fact delves directly into the continuing controversy of whether the DPT vaccine can cause permanent neurological disorders. Thus, a petitioner's prima facie case is more difficult to establish. Not only is proof of injury necessary but petitioner also bears the burden of linking the injury directly to the vaccine. Ruling out other potential causes is an essential element but does not itself establish causation. Thus, the proffered theory of causation must not only be shown to be possible but also must be shown to have occurred in this particular case.

It should be noted that in analyzing a contention of causation-in-fact, the presumptions available under the Vaccine Injury Table are inoperative. The burden rests on the petitioner to show that the vaccination in question more likely than not caused the specific injury, *under the same standards which apply in traditional tort litigation*, in which the same "preponderance of the evidence" standard applies. *Hines v. Secretary of the DHHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Strother v. Secretary of the DHHS*, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). The preponderance of the evidence standard requires that the trier of fact "believe that the existence of a fact is more probable than its nonexistence before (he) may find in favor of the party who has the burden to persuade the (judge) of the fact's existence." *In re Winship*, 397 U.S. 358, 371-72 (1970)(Harlan, J., concurring)(quoting F. James, *Civil Procedure* 250-51 (1965)). Mere conjecture or speculation does not meet the preponderance standard. *Snowbank Enterprises v. United States*, 6 Cl.Ct. 476, 486 (1984).

The Federal Circuit in *Grant v. Secretary of the DHHS*, 956 F.2d 1144 (Fed. Cir. 1992) summarized the legal criteria required to prove causation-in-fact under the Vaccine Act. The court noted that 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 the vaccination was the reason for the injury. A *reputable medical or scientific explanation* must support this logical sequence of cause and effect.

*Id*. at 1148 (citations omitted)(emphasis added); *see also Hines v. Secretary of the DHHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991); *Strother v. Secretary of the DHHS*, 21 Cl. Ct. 365, 370 (1990); *Carter v. Secretary of the DHHS*, 21 Cl. Ct. 651, 654 (1990); *Novak v. United States*, 865 F.2d 718, 724 (6th Cir.

1989); *Hasler v. United States*, 718 F.2d 202, 205-06 (6th Cir. 1983). Temporal association alone is *not* sufficient. *Strother v. Secretary of the DHHS*, 21 Cl. Ct. 365, 370 (1990). "Similarity of petitioner's injury to injuries listed on the Table does not show causation in fact. Encephalitis, seizure disorders, and other Table injuries can have causes other than administration of a vaccine." *Strother v. Secretary of the DHHS*, 21 Cl. Ct. 365, 370 (1990). Moreover, in an off-Table case, where the injury or death in question is idiopathic, and no cause can be determined, the petitioners' claim must fail. *Hines v. Secretary of the DHHS*, 21 Cl. Ct. 634, 650 (1990), *aff'd*, 940 F.2d 1518 (Fed. Cir. 1991).

To support a causation-in-fact allegation, petitioner's expert must do more than suggest a possible correlation based on a temporal relationship between vaccination and the injury; he must explain *how* and *why* the injury occurred. *Strother*, 21 Cl. Ct. at 370. If petitioner's expert views the temporal relationship as "key," the claim must fail. *Thibaudeau v. Secretary of the DHHS*, 24 Cl. Ct. 400, 403 (1991).

A reputable medical or scientific explanation does not simply mean, however, any theory that a medical expert is willing to espouse. In construing the Federal Rules of Evidence, the Supreme Court recently held that it is the trial judge's responsibility to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786, 2795 (1993); *see also* Vaccine Rule 8(b)(the trier of fact is obliged to consider "all relevant, reliable evidence."). Rule 702 provides that an expert witness may testify to his "scientific, technical, or other specialized knowledge." The term "knowledge," however, "connotes more than subjective belief or unsupported speculation." *Daubert*, 113 S.Ct. at 2795. Thus, the expert's proposition must have been "derived by the scientific method." *Id.* This requires that the proponent demonstrate that there is "some objective, independent validation of the expert's methodology." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995)(Kozinski, J.), *on remand from* 113 S.Ct. 2786 (1993). 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.

*Id.; see also Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786, 2796-97 (1993). The overall touchstone is "whether the analysis undergirding the experts' testimony falls within the range of accepted standards governing how scientists conduct their research and reach their conclusions." *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1316 (9th Cir. 1995).

Other prerequisites to compensation include: (1) that the injured person suffered the residual effects of a vaccine-related injury for more than six months after the administration of the vaccine, § 11(c)(1)(D)(i); (2) that the petitioner incurred in excess of $1000 in unreimbursable vaccine-related expenses, § 11(c)(1)(D)(i); (3) that the vaccine was administered in the United States, § 11(c)(1)(B)(i)(I); (4) that the petitioner did not previously collect a judgment or settlement in a prior civil action, § 11(c)(1)(E); and (5) that the action be brought by the injured person's legal representative, § 11(b)(1)(A).

## V. DISCUSSION

In assessing any inconsistencies between medical records and oral testimony, the undersigned first looks to the issue of the credibility of the fact witnesses. The undersigned thoughtfully observed the demeanor,

comportment and presentment of Dr. Gary Berebitsky and has concluded he is a credible witness. Any inconsistencies between his testimony and the medical records are at worst *de minimus*.[(10)]

This is a case where the medical facts are not greatly in dispute.

In the case at bar, petitioner alleges her third DPT, administered on 10 August 1992, caused her residual seizure disorder and encephalopathy. Inasmuch as residual seizure disorder is an injury not listed in the new Vaccine Table,[(11)] petitioner's thesis under the Act is one of causation-in-fact. Encephalopathy is still a table-injury. However, petitioner concedes she does not meet the criteria of an onset of an encephalopathy as defined in the new Vaccine Table[(12)] and thus her thesis again is one of causation-in-fact. The analysis in this matter divides into the following three queries: (1) Does Julie suffer from a seizure disorder and/or chronic encephalopathy? (2) Can pertussis toxin/DPT cause a seizure disorder and/or chronic encephalopathy? And (3), did pertussis toxin/DPT in this case cause Julie's seizure disorder and/or chronic encephalopathy?

**A. Diagnosis: Does Julie suffer from a seizure disorder and/or chronic encephalopathy?**

Petitioner contends that Julie suffers from a seizure disorder. Julie had her first seizure, lasting about seven seconds, the day after her third DPT. The next day she experienced four seizures lasting each about one minute and was rushed to the hospital. The following day, she had a five and one-half minute seizure in the hospital. About one month later, she suffered from a seizure lasting approximately fifty minutes despite being on Phenobarbital. She continued to have seizures throughout the next year. Her seizures continue today. The court finds, by a preponderance of the evidence, that Julie suffers from a seizure disorder.

Petitioner also contends that Julie suffers from an encephalopathy. Withal, petitioner concedes that she does not meet the criteria of an onset of an encephalopathy under the new Vaccine Table. The new Vaccine Table gives very precise criteria which petitioners must meet. Because the petitioner concedes she does not meet the criteria of the new table, she must proceed with causation-in-fact for an off-table injury. The relevant statutory language states the petitioner may recover if the petitioner sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine. § 11(c)(1)(C)(ii)(II). The petitioner can recover for any illness caused by the vaccination. Unless otherwise defined, "the words of a statute must be given their usual and ordinary meaning." *State v. Thiele*, 736 P.2d 297, 301 (Wash.Ct.App. 1987). The statute does not define what constitutes an "illness" or an off-table encephalopathy. Petitioner's expert medical doctor defined an encephalopathy as a "diseased brain" or "an altered state of brain function." Tr. at 65, 67. Respondent's expert medical doctor defined an encephalopathy as a "clouded level of consciousness." Tr. at 120. An encephalopathy is "any degenerative disease of the brain." *The Sloane-Dorland Annotated Medical-Legal Dictionary* 250 (1987); *Dorland's Illustrated Medical Dictionary* 550 (27th ed. 1988). Julie's treating pediatrician, Dr. Berebitsky, has diagnosed Julie with an encephalopathy.[(13)] Petitioner's expert medical doctor opined that Julie has an encephalopathy. Respondent's expert medical doctor opined that Julie did not have an acute encephalopathy at the time of the first seizures, but today she has a chronic encephalopathy. Currently, Julie is mentally retarded and developmentally delayed. The court finds, by a preponderance of the evidence, that Julie suffers today from a chronic encephalopathy.

**B. Theory of Causation: Can pertussis toxin/DPT cause a seizure disorder and/or chronic encephalopathy?**

Having established that Julie suffers from a seizure disorder and an encephalopathy, the next issue to be decided is whether the DPT vaccination of 10 August 1992 actually caused Julie's current condition. That determination requires the court to decide whether pertussis toxin/DPT can cause a seizure disorder and/or chronic encephalopathy. The undersigned responds in the affirmative.

The Act establishing this Program charged the Institute of Medicine (IOM) of the National Academy of Sciences to review the medical and scientific literature on possible adverse consequences of pertussis and rubella vaccines and to prepare a report on the results of its review. A committee was formed, conducted the review, and published its report: Institute of Medicine, *Adverse Effects of Pertussis and Rubella Vaccines* (Nat'l Academy Press 1991)(hereinafter 1991 IOM Report). The Act likewise mandated a periodic review of possible adverse events associated with DPT vaccination. The next committee's report was published in 1994: Institute of Medicine, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* (Nat'l Academy Press 1994) (hereinafter 1994 IOM Report).[(14)] Considering the charge given to the IOM and the scope of its review, the court considers its conclusions to be authoritative on the issue and subject to great deference in this Program.

The 1991 IOM report concludes "(a) that the evidence indicated a causal relation between DPT and *febrile* seizures, (b) that the evidence *did not indicate* a causal relation between DPT and *afebrile* seizures." Institute of Medicine, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* 3 (Nat'l Academy Press 1994)(summarizing 1991 IOM report)(emphasis added). The 1994 IOM report examined the relationship between DPT and chronic nervous system dysfunction (an encephalopathy and seizure disorder in Julie's case). It concluded:

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 vaccination. . . . The *evidence remains insufficient to indicate* the presence or absence of a causal relation between DPT and chronic nervous system dysfunction under any other circumstances. That is, because the NCES is the only systematic study of chronic nervous system dysfunction after DPT, the committee can only comment on the causal relation between DPT and those chronic nervous system dysfunctions under the conditions studied by the NCES. In particular, it should be noted that the chronic nervous system dysfunctions associated with DPT followed a serious acute neurological illness that occurred in children within 7 days after receiving DPT.

Institute of Medicine, *DPT Vaccine and Chronic Nervous System Dysfunction: A New Analysis* 15-16 (Nat'l Academy Press 1994)(emphasis in original). The undersigned concludes that the 1991 & 1994 IOM reports establish, by a preponderance of the evidence, that DPT can cause acute *febrile* seizures within seven days of vaccination,[(15)] but there is an insufficiency of scientific evidence to conclude that DPT can cause *afebrile* seizures, and DPT can cause chronic nervous system dysfunctions (seizure disorders and encephalopathy) in cases which met the criteria established by the NCES.[(16)] The National Childhood Encephalopathy Study[(17)] is a comprehensive epidemiological study done in the United Kingdom finding statistically significant risk for neurological injury for up to seven days following a DPT vaccination. The criteria of the NCES requires the child to have an acute encephalopathy, or at least thirty minutes of seizure activity within seven days of the vaccination, or to have "complicated" seizures. The parties debated vigorously over the meaning of the word "complicated" seizures. The evidence in this case requires this court to conclude that the term "complicated" is shorthand for a longer phrase used in other places in the NCES study. *Ergo*, the term "complicated" means complicated "by [a] coma lasting 2 hours or more, or followed by paralysis, or other neurological signs not previously

present, lasting 24 hours or more." R. Alderslade et al., *The National Childhood Encephalopathy Study* 146-47, 157 (Her Majesty's Stationary Office 1981).

In the case at bar, petitioner proffered an additional theory of causation slightly different from that enumerated in the 1991 & 1994 IOM reports. While the court accepts the theory of causation proffered in the 1991 & 1994 IOM reports, the court does not find, by a preponderance of the evidence, that the theory of causation proffered by petitioner meets the standards of scientific reliability enunciated in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786, 2795 (1993).[(18)]

There are four factors listed in *Daubert* as guideposts for this court to follow to determine if a scientific theory is reliable. The four factors are (1) general acceptance in the scientific community; (2) whether it's been subjected to peer review and publication; (3) whether it can and has been tested; (4) 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).[(19)] In the case at bar, petitioner's theory, as explained by Dr. Menkes, is that the pertussis toxin in the DPT vaccine is able to breach the blood-brain barrier in a child either because the barrier is underdeveloped in infancy or because of endotoxins in the pertussis toxin. Once in the brain, the pertussis toxin causes the nerve cells to fire erratically and results in an afebrile seizure. The first seizure causes more seizures and the result is a seizure disorder and an encephalopathy.

Examined in the light of the four guideposts enumerated in *Daubert*, the court must conclude that petitioner's theory of causation is not based on reliable scientific evidence. First, petitioner's theory is not generally accepted in the scientific community, as admitted by both Dr. Menkes and Dr. Baumann. Tr. at 79, 118. Second, the theory has not been subjected to peer review publication because Dr. Menkes said it is not generally accepted and would not get published in the United States. Tr. at 79. Third, the theory has not been satisfactorily tested. Finally, the error rate of the tests is not known at all (because of the lack of test results).

For these reasons, the undersigned concludes that the preponderance of the evidence supports the IOM conclusion that a causal relationship exists between DPT and acute *febrile* seizures within seven days of DPT vaccination, but not *afebrile* seizures. Also, a causal relationship exists between DPT and chronic nervous system dysfunctions (encephalopathy and seizure disorders) in cases which met the criteria established by the NCES.[(20)] A petitioner can satisfy the criteria established by the NCES by meeting the requirements of any one of the three categories for inclusion in the study. The injured child, within seven days of vaccination, must either: (1) experience an acute encephalopathy, defined as an "altered level of consciousness, confusion, irritability, [or] changes in behaviour," R. Alderslade et al., *The National Childhood Encephalopathy Study* 157 (Her Majesty's Stationary Office 1981); or (2) have more than thirty minutes of seizure activity, *id.*; or (3) have seizures complicated by a coma lasting two hours or more, or followed by paralysis, or other neurological signs not previously present, lasting twenty-four hours or more. *Id.*

**C. Application of Theory: Did pertussis toxin/DPT in this case cause Julie's seizure disorder and/or chronic encephalopathy?**

Having found that it is medically possible for DPT to cause a seizure disorder and encephalopathy, the final query is whether DPT caused Julie's seizure disorder and/or encephalopathy in this particular case. The undersigned responds in the negative.

The 1991 IOM report concludes that DPT can cause febrile, but not afebrile seizures. Julie's seizures immediately after the vaccination were afebrile. Since her first seizures were not febrile, there is a lack

of evidence to conclude that Julie's initial seizures were caused in fact by her DPT vaccination.

This court must also conclude that Julie's seizure disorder and encephalopathy were not caused-in-fact by her third DPT vaccination because she does not meet even one of the three criteria of the NCES. The 1994 IOM report which concludes that DPT can cause chronic nervous system dysfunction expressly states the conclusion is only valid in cases which met the NCES criteria.[(21)] The criteria for the NCES study were cases where the child had (1) an acute encephalopathy, as defined by the NCES, or (2) at least thirty minutes of seizures, or (3) had seizures "complicated" by a coma lasting two hours or more or followed by paralysis or other neurological signs not previously present, lasting twenty-four hours or more. In Julie's case, she did not have an acute encephalopathy following her DPT vaccination. Julie did not exhibit the "altered level of consciousness" required by the NCES. In fact, Julie was alert and active in the ambulance and hospital. Petitioner's expert medical doctor admitted that Julie would not have been included in the NCES encephalopathy study. In addition, Julie only had twelve minutes of seizure activity within seven days of her vaccination. This is far short of the thirty minute NCES requirement. It is too speculative to conclude that absent the Phenobarbital Julie's seizures would have lasted more than thirty minutes. Finally, Julie didn't have a "complicated" seizure because she didn't lapse into a coma after her vaccination, nor exhibit any paralysis. To the contrary, after her first seizure, Julie was alert and active in the ambulance and hospital and played with her oxygen mask in the ambulance. Because Julie does not meet the criteria of even the NCES, the court concludes that petitioner has failed to prove by a preponderance of the evidence that Julie's injuries were caused-in-fact by her third DPT vaccination of 10 August 1992.[(22)]

## VI. CONCLUSION

1. As the parent of her minor daughter, petitioner has the requisite capacity to bring this action. Section 11(b)(1)(A); Pet.Exh. A, at 1.

2. Petitioner has not previously collected an award or settlement of a civil action in connection with Julie's alleged vaccine-related injury. Section 11(c)(1)(E); Pet.Exh. A, at 4.

3. Julie was administered a vaccine listed in the Vaccine Injury Table. Section 11(c)(1)(B)(i)(I); Pet.Exh. A, at 2.

4. Said vaccine was administered in the United States. Section 11(c)(1)(B)(i)(I); Pet.Exh. A, at 2.

5. There is a preponderance of the evidence that Julie suffered the residual effects of her alleged injury for more than 6 months after the administration of the vaccine. Section 11(c)(1)(D)(i); Pet.Exh. A to Pet.Exh. 37.

6. There is a preponderance of the evidence that petitioner incurred unreimbursable expenses due in whole or in part to such injury in an amount greater than $1,000. Section 11(c)(1)(D)(i); Pet.Exh. A, at 3-4.

7. There is not a preponderance of the evidence that Julie's 10 August 1992 DPT vaccination caused-in-fact her seizure disorder or encephalopathy.

Based on the foregoing, the undersigned finds that petitioner is not entitled to compensation in this case. In the absence of a motion for review[(23)] filed pursuant to RCFC Appendix J, the clerk of court is directed to enter judgment dismissing this case with prejudice.

**IT IS SO ORDERED.**

_____

Richard B. Abell

Special Master

1. The statutory provisions governing the Vaccine Act are found at 42 U.S.C. §§ 300aa-1 to 300aa-34 (1991 & Supp. 1997). Hereinafter, for ease of citation, all references will be to the relevant subsection of 42 U.S.C. § 300aa.

2. Reference to the transcript of the 5-6 March 1997 evidentiary hearing will be made as "Tr. at __."

3. Dr. Menkes received his A.B. from the University of Southern California in 1947, his M.S. from the University of Southern California in 1951, and his M.D. from Johns Hopkins University School of Medicine in 1952. He completed his internship at Children's Medical Center, Boston, Massachusetts in 1954 and his residency in pediatric neurology at the Neurological Institute of New York, Columbia-Presbyterian Medical Center in 1960. He has served as Associate Professor of Pediatrics at Johns Hopkins and Professor of Neurology and Pediatrics at UCLA. He is board certified in pediatrics and neurology. His *curriculum vitae* lists 124 publications to his credit. His name appears in numerous places as a contributor to the IOM reports.

4. Pinocytosis is "the imbibition of liquids by cells, especially the mechanism by which cells ingest extracellular fluid and its contents.... It is thought to be a method of active transport across the cell membrane." *Dorland's Illustrated Medical Dictionary* 1296-97 (27th ed. 1988).

5. Dr. Baumann received his B.S. from Tufts University, Medford, Massachusetts in 1961 and his M.D. from Western Reserve University, Cleveland, Ohio in 1965. He completed his internship at the Department of Pediatrics, University of Chicago in 1966 and his residency at the Department of Pediatrics, University of Chicago in 1967. He is currently a Professor of Neurology and Pediatrics at the University of Kentucky. He is board certified in pediatrics, psychiatry and neurology, and epidemiology. His *curriculum vitae* lists 48 publications to his credit.

6. The conclusions of the IOM are contained in the "DISCUSSION" section, *infra*.

7. [7] Section 11(c)(1)(C)(i); section 14(a).

8. Under the change in the regulations, 42 C.F.R. §§ 100.1-100.3 (1995), effective 10 March 1995, petitioners who file on that date or later must comply with the new Vaccine Table. The new Vaccine Table no longer lists RSD as a table injury and the definition of an encephalopathy has become more demanding.

9. The applicable provisions of 42 C.F.R. § 100.3 state:

(b) *Qualifications and aids to interpretation*. The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table ....

***

(2) *Encephalopathy*. For purposes of paragraph (a) of this section, a vaccine recipient shall be considered to have suffered an encephalopathy only if such recipient manifests, within the applicable period, an injury meeting the description below of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination.

(i) An acute encephalopathy is one that is sufficiently severe so as to require hospitalization ....

(A) Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

***

(D) 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 ...:

(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).

(E) The following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in either mental status or level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle. Seizures in themselves are not sufficient to constitute a diagnosis of encephalopathy. In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy.

42 C.F.R. § 100.3 (1995).

10. The following standard has been applied when testimony is *in conflict* with medical records:

It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight. *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947); *Montgomery Coca-Cola Bottling Co. v. United States*, 615 F.2d 1318, 1328 (Ct. Cl. 1980); *see also* 32A C.J.S. *Evidence* § 1033 (1964). That rule has been followed in Program cases. *See, e.g., Flynn*

*v. Secretary of HHS*, No. 89-54V, 1990 WL 293364 (Cl. Ct. Spec. Mstr. May 17, 1990). The rule should not be applied blindly, however. Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent. Records which are incomplete may be entitled to less weight than records which are complete. . . . Further, it must be recognized that the absence of a reference to a condition or circumstance is much less significant than a reference which negates the existence of the condition or circumstance. Since medical records typically record only a fraction of all that occurs, the fact that reference to an event is omitted from the medical records may not be very significant. *See Clark v. Secretary of HHS*, No. 90-45V, 1991 WL 57051 (Cl. Ct. Spec. Mstr. Mar. 28, 1991).

*Murphy v. Secretary of HHS*, 23 Cl. Ct. 726, 733 (1991).

11. *See* footnote 8.

12. *See* footnote 9.

13. Because of the personal contact between physician and patient, as a general rule the court gives greater weight to treating doctors than to those whose evaluation is limited to a review of the records in anticipation of a hearing. *See*, *e.g.*, *Bastian v. Secretary of HHS*, No. 90-1161V, 1994 WL 551465 (Fed. Cl. Spec. Mstr. Sept. 22, 1994).

14. Pet.Exh. 26.

15. "Febrile seizures are the single most common adverse reaction to pertussis immunization." Gerald M. Fenichel, *Clinical Pediatric Neurology: A Signs and Symptoms Approach* 62 (3rd ed. 1997).

16. The conclusion of this court is in accordance with the following cases: *Elsener v. Secretary of the DHHS*, No. 90-3361V, at 7-8 (Fed.Cl.Spec.Mstr. Oct. 30, 1997(unpublished); *McMurry v. Secretary of the DHHS*, No. 95-682V, 1997 WL 402407, at * 5 (Fed.Cl.Spec.Mstr. June 27, 1997).

17. R. Alderslade et al., *United Kingdom Department of Health and Social Security, Whooping Cough: Reports from the Committee on Safety of Medicines and the Joint Committee on Vaccine and Immunization, The National Childhood Encephalopathy Study* 79-184 (Her Majesty's Stationary Office 1981); Resp.Exh. I.

18. The theory of causation proffered by petitioner was not accepted as reliable by the United States Court of Federal Claims in the case of *Mobley v. Secretary of the DHHS*, 22 Cl.Ct. 423, 429 n.9 (1991). In that case, Dr. Kinsbourne testified:

The best available information is that the pertussis vaccine contains two agents which singly or, more probably, in conjunction can in occasional or rare cases be severely damaging to brain cells and damage them permanently. And these are the pertussis toxin and the pertussis endotoxin, which is also described as a lipopolysaccharide. Now, it has been shown by chemical studies that if pertussis toxin is allowed to come into contact with neurons, the basic cells that do the work of the brain, then, that toxin is capable of interfering with the neuron's energy metabolism.

*Id; cf. Misenko v. Secretary of the DHHS*, No. 92-0013V, 1995 WL 761436, at *15 (Fed.Cl.Spec.Mstr. Dec. 7, 1995)(Special Master found pertussis toxin and endotoxin results in low blood pressure and hypoglycemia which ultimately causes an encephalopathy).

19. These four factors come from the *Daubert* block quotation on page 10 of this decision.

20. Petitioner also advanced the theory that Julie's injuries were a result of the administration of a vaccine from a "hot lot" that had a history of causing injuries in children. Julie was given a vaccination manufactured by Connaught that had a lot number of 2k31068. Petitioner submitted four articles on the batch-to-batch variability of DPT vaccines. Pet.Exhs. 34-37. Petitioner also submitted the FDA adverse reaction file in reference to lot number 2k31068. Pet.Exh 14. It showed that there have been 22 serious, including 4 fatal, injuries reported to have occurred in conjunction with the administration of the vaccine lot given to Julie. However, presumably, there are random adverse reactions unrelated to the administration of a vaccine with every batch of several thousand vaccines. While the court finds this probative evidence to weigh heavily in favor of petitioner's claim, it does not find the evidence to be determinative of the issue because it is too conjectural as to this specific immunization.

21. *See* block quote from the 1994 IOM report on page 13-14 of this decision.

22. Since this court has already ruled that petitioner has not met the requirements of § 13(a)(1)(A), it is unnecessary to determine if she also meets the "factor unrelated" requirements of § 13(a)(1)(B), but a little *dicta* never hurt anyone. This court concludes that there is not a preponderance of the evidence to prove that Julie's seizure disorder or encephalopathy is due to any factor unrelated to the administration of the vaccine. Section 13(a)(1)(B) states:

compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole--

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

***

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine" --

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition.

§ 13(a)(1)(B) & (2)(A). This court can not think of a better example of an idiopathic disease then the one proffered by respondent. Respondent's "underlying disorder" cannot be observed chemically, radiographically, electrically, genetically, or even visually upon death. The disorder doesn't even have a name (in an age when every malady of the human condition has a name - *e.g*. "road rage disorder"). The proffered disease meets the Greek definition of the word which is "hidden." For these reasons, this court concludes that Julie's injuries were not caused by a factor unrelated, and even if they were, the disease proffered by respondent is idiopathic and *ergo* insufficient as a matter of law. It is important to note that this court does not draw any conclusions about the actual etiology of Julie's injuries because the court was not presented with sufficient evidence to form a conclusion.

23. Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by each party filing a notice renouncing the right to seek review.