OFFICE OF SPECIAL MASTERS

No. 92-764 V

Filed: June 6, 1997

WILLIAM L. McCARREN, SR., and PATRICIA A. McCARREN for WILLIAM L. McCARREN, JR.,	*	
Petitioners,	*	PUBLISHED
v.	*	
SECRETARY OF THE DEPT. OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

E. James Thompson, Jr., Baltimore, Maryland, for petitioner.

Glenn MacLeod, Washington, D.C., for respondent.

DECISION

GOLKIEWICZ, Chief Special Master

I. PROCEDURAL BACKGROUND

On November 3, 1992, Petitioners filed a petition pursuant to the National Childhood Vaccine Injury Act of 1986 (hereinafter referred to as "the Act").[(1)] Petitioners alleged that their son, William L. McCarren, Jr., received a Diptheria-Pertussis-Tetanus vaccine ("DPT") on March 13, 1990, and subsequently suffered a seizure on March 16, 1990. Petition, filed 11/3/92. Petitioners

further alleged that "Since the vaccine D.T.P. was administered starting on March 16, 1990, William L. McCarren Jr. has suffered with an Intractable Seizure Disorder." Pet. At 1. In addition to Petitioners'

formal allegation of a seizure disorder, the medical testimony presented in this case has raised the issue as to whether or not Billy also suffered an encephalopathy in the days following the DPT inoculation. Therefore, the court will address these issues separately.

Respondent contested Petitioners' entitlement under the Act, and moved to dismiss Petitioners' claim. R. Rpt, filed 2/26/93. Respondent's argument was twofold. First, Respondent alleged that Petitioners failed to meet their burden, by a preponderance of the evidence, that Billy suffered a Table injury *within the prescribed time period*.[(2)] Respondent claimed that Petitioners failed to support, with medical records and/or expert testimony, that the first symptom or manifestation of the onset of the residual seizure disorder occurred within the Table's time frame. R. Rpt. at 5-7. Particularly, Respondent states, "[t]he medical records do not support a finding that Billy's first seizure occurred three days after the DPT shot... [Billy] experienced a febrile seizure in the evening of March 16, 1990, approximately 80 hours following his DPT immunization. Consequently, Billy's seizure actually occurred more than three days after the immunization." R. Rpt. at 5-6. Moreover, Respondent states that "the medical records place the onset of Billy's seizures as starting as early as January 1990. Thus the underlying condition which caused Billy's seizure in March 1990 predated his March 13, 1990 vaccination, and his seizures cannot be presumed to have been caused by the vaccine."[(3)] R. Rpt. at 6. Respondent also specifically argued that Billy did not suffer an encephalopathy within the Table period. Instead, Respondent argued that Billy's symptoms following the shot were a common reaction to the inoculation. Respondent relied further on the fact that Dr. Woody, Dr. Frost, and Dr. Lavenstein all stated that Billy did not suffer from an acute encephalopathy within the 72 hours following the DPT vaccination. See R. Post-Hearing Memo., filed 12/8/94, at 4; see also R's Post-Hearing Memo., filed 2/7/97, at 4-8.

Second, Respondent alleged that Petitioners, in the alternative, failed to prove that the DPT vaccination was the cause-in-fact of Billy's injury. Respondent cited Strother v. Secretary of HHS, 18 Cl. Ct 816, 820 (1989), for the following legal standard: "[C]ausation 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." Respondent contended that because "petitioners have failed to provide an expert medical opinion specific to causation in this case...they have not met their burden of proof." R. Rpt. at 7.

Subsequent to Respondent's report, Petitioners filed two expert reports, one by Robert C. Woody, M.D., who began treating Billy in April of 1990 (filed 9/29/94), and another by Ronald S. Gabriel, M.D. (filed 7/5/95), which addressed the causation in fact issue(s). In addition, Petitioners filed medical literature to support their claim. See P. Prehearing Exhibit List, filed 5/6/96, at Exhs. 1-4 (M. Kulenkampff, J.S. Schwartzman and J. Wilson, *Neurological Complications of Pertussis Inoculation*, 49:1 Archives Disease Childhood, Jan. 1974, at 46-49; Ronald Gabriel, Evidence Linking Pertussis Vaccines to Irreversible Encephalopathy, at 1, 5-6, 11-12 (unpublished paper presented before the Institute of Medicine); Deborah G. Hirtz, Karin B. Nelson and Jonas H. Ellenberg, *Seizures Following Childhood Immunizations*, 102:1 J. Pediatrics, Jan. 1983, at 14-18; J.M. Berg, *Neurological Complications of Pertussis Immunizations*, Brit. Med. J., July 5, 1958, at 24-27.

Respondent filed two expert reports as well. A medical opinion by James D. Frost, Jr., M.D., was filed on February 18, 1994, and Dr. Bennett Lavenstein's expert opinion was filed September 14, 1995. In addition, Respondent filed medical literature to support the government's claim. See

R. Prehearing Exh. List, filed 4/22/96, at Exhs. A-C (C. Cody, *Nature and Rates of Adverse Reactions Associated with DTP and DT Immunizations in Infants and Children*, 68 pediatrics, Nov. 5, 1981, at 650-660; institute of medicine, adverse effects of pertussis and rubella vaccines 87-119 (1991); J. Ellenberg, D. Hirtz, et al., *Do Seizures in Children Cause Intellectual Deterioration?*, 24 N. Eng. J. Med. 1085-88 (1986).

Two hearings were conducted in this case. The first was held on October 12, 1994, in Washington, D.C., to determine whether the Act's presumption of causation favored Petitioners, or more specifically, whether the first symptom or manifestation of the onset of Billy's Table injuries occurred within three days of the March 13, 1990, DPT vaccination. 42 U.S.C.A. §300aa-14. Testifying for the Petitioners were Billy's father, William L. McCarren, and the child's former treating physician, Robert Woody, M.D. Dr. James Frost testified for the Respondent. Prior to issuing a decision based upon the evidence adduced at the first hearing, it was determined that a second hearing was necessary to address the cause-in-fact issue raised for the first time in the parties' posthearing briefs.

The second hearing was conducted on November 5, 1996, in Washington, D.C., to address solely whether the DPT vaccination was the cause-in-fact of Billy's intractable seizure disorder. At issue particularly, was whether it was medically plausible that a DPT vaccination could cause the onset of Billy's seizure disorder or encephalopathy within eighty (80) hours of the vaccine's administration, and if so, did it in fact happen in Petitioners' case. Dr. Ronald Gabriel testified as Petitioners' expert; Dr. Bennett Lavenstein testified on behalf of the government. Post-hearing briefs have been submitted by both parties from both hearings and the record is now closed. After reviewing the entire record, and for the reasons set forth below, the court finds Petitioners have failed to carry the burden of proof required under the Act, and thus, are not entitled to compensation. A full discussion follows.

II. FACTUAL BACKGROUND

William L. McCarren, Jr., or "Billy", was born June 23, 1989, in Baltimore, Maryland, after a relatively uneventful pregnancy. M.R. at 5-14. He had an Apgar score of 6 at one minute, and of 9 at five minutes. M.R. at 6. At Billy's July 13, 1989, check-up, "no problems [were] reported". M.R. at 17. On January 10, 1990, Billy was seen by Dr. Nagji J. Suraja for coughing and wheezing, and was diagnosed with pharyngitis, bilateral otitis media, and bronchitis. M.R. at 17.

On March 13, 1990, beginning at 9:25 a.m., Billy was seen at Harbor Hospital Center for purposes of receiving his immunizations. The medical records from that date indicate that Billy had "no previous immunizations" because he was "always sick at shot time."[(4)] M.R. at 19. Indeed, at the time of the immunization on March 13, 1990, these same records indicate that Billy was diagnosed with a mild case of upper respiratory infection, although no fever was present. Nonetheless, the physician administered the DPT and OPV#1 vaccinations, with instructions for Billy to return "in 6 weeks for DPT#2--OPV#2." M.R. at 19. Mr. McCarren testified at the first hearing, when asked what time the vaccination was given on March 13, 1990, that "It would have been some time before 12:00, and I can't pinpoint exactly when." When asked "Did you leave the clinic by 12 o'clock?", Mr. McCarren responded, "I would say so, yeah." Tr. I at 8.[(5)]

On March 13, 1990, following the immunization, Mr. McCarren testified that Billy was "cranky...irritable. He really wasn't moving around that much because of the I guess the pain that he was having in his leg where he got the shot at." Tr. I at 9. In describing Billy's behavior one day following the immunization, on March 14, 1990, Mr. McCarren stated that Billy "slept uneasy", was "very irritable and cranky", and that the clinic, after being informed of Billy's behavior, told the McCarrens to give the child Tylenol. On March 15, 1990, the second day after the DPT shot, Billy seemed, according to Mr. McCarren's testimony, "a little better. He didn't have a fever. He was still very irritable." Tr. I at 9.

On March 16, 1990, the third day after Billy's DPT immunization, Mr. McCarren testified that he returned home from work around 4:00 p.m. and began playing with and tickling his son, who responded with laughter and giggling. Tr. I at 32. Suddenly, he observed the following: "He felt a little bit warm. I told my wife, and we gave him Tylenol. So we continued to play a little bit on the sofa. And at that time he collapsed and began having a seizure...His eyes rolled up into the back of his head, and it sounded like

he was gasping for air."[(6)] Tr. I at 10. Mr. McCarren reports that the seizure lasted "between 10 and 15 minutes" and that an ambulance thereafter transported the child to St. Agnes Hospital. Tr. I at 10-11. By the ambulance's arrival time, Billy had stopped seizing, but was "respond[ing] to pain and was and [sic] very cranky." Tr. I at 11. After a blood test and a spinal tap were performed, Billy was released, with a diagnosis of febrile seizure and "LOM" or left otitis media. Tr. I at 11; M.R. at 37.

In the days following this initial seizure, Mr. McCarren stated that Billy was "irritable; but other than that he was resting normally.. .[and] [h]e didnt have any seizures up until April 18, and then he started jerking." Tr. I at 11-12. According to Mr. McCarren, these jerking or twitching episodes would last about 15 seconds and would occur consistently on a daily basis. Tr. I at 12. Although the McCarrens took Billy to the ER of St. Agnes Hospital soon after the twitching began, he was not admitted. Tr. I at 12. Thereafter, due to the continuing nature of the twitching episodes, Billy was evaluated by Dr. Woody on April 25, 1990. Tr. I 13-14. Dr. Woody recommended an EEG and an MRI; the EEG was normal and the MRI revealed a "cystic structure of the right choroid plexus which probably represents a cyst on the right side." M.R. at 113.[(7)] Billy experienced subsequent seizures on numerous occasions, including 6/26/90, 7/14/90 (twitching), 8/15/90, 9/21/90, 11/11-15/90, 12/21/90, and multiple times thereafter. See M.R. generally. Throughout Billy's young life, he has been evaluated by numerous physicians due to his history of seizures. In June 1990, Dr. Woody definitively diagnosed Billy with a seizure disorder, and this condition exists to this day. M.R. at 114.

III. DISCUSSION

A. Applicable legal requirements

Under the Act, petitioners have two routes to pursue compensation for a vaccine-related injury or death. If their case fits within the statutory parameters of the Vaccine Injury Table, petitioners may take advantage of a statutory presumption of causation. §300aa-14(a).

Alternatively, petitioners may show entitlement under the Act by a preponderance of the evidence that an injury or death was in fact caused by a vaccine set forth in the Vaccine Injury Table. §300aa-11(c)(1)(C)(ii). Causation in fact is the traditional tort standard applicable outside of the Vaccine Act. See Strother v. Secretary of DHHS, 21 Cl. Ct. 365, 369-70 (1990), *aff'd* 950 F.2d 731 (Fed. Cir. 1991).

In order to prove causation in fact,

petitioners 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 v. Secretary of DHHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted).

In the present case, Petitioners alleged that Billy's Table injuries, either an encephalopathy or the onset of Billy's current seizure disorder[(8)], occurred within 3 days following his DPT vaccination. This allegation raises the first issue in this case, which is whether or not the facts, read in conjunction with applicable law, support that Billy suffered a vaccine injury within the time period prescribed in the Vaccine Injury Table for residual seizure disorder or encephalopathy.

B. Petitioners' Case for Presumption of Causation

1.

In order to determine whether Billy suffered the onset or manifestation of encephalopathy or residual seizure disorder within the table time frame, the time period of "3 days" must be defined. This issue appears to be well settled, as the courts have consistently held that the Vaccine Table's use of "3 days", as a time period within which certain injuries must occur in order to grant petitioners the presumption of causation, means 72 hours. See Ultimo v. Secretary of HHS, No. 90-2045V, 1992 WL 392629 (Fed. Cl. Spec. Mstr. Dec. 11, 1992), *aff'd* 28 Fed. Cl. 148 (1993). See also Candelas v. Secretary of HHS, No. 90-759V, 1991 WL 187316 (Cl. Ct. Spec. Mstr. Sept. 5, 1991); Horner v. Secretary of HHS, No. 90-1445V, 1996 WL 544562 (Fed. Cl. Spec. Mstr. Sept. 12, 1996); and Hellebrand v. Secretary of HHS, 999 F.2d 1565 (Fed. Cir. 1993)(wherein the Court, in dictum, interpreted the Vaccine Table's "3 days" time period, for the injury of shock-collapse or hyporesponsive collapse, to mean 72 hours).[(9)] This court sees no basis for deviating from these prior rulings on this issue.

Given this interpretation, the evidence weighs against presumed causation. Petitioners' testimony, as well as the medical records and Dr. Woody's testimony, overwhelmingly support that Billy's first seizure on March 16, 1990, occurred more than 72 hours following his DPT vaccination. The medical records indicate that on March 13, 1990, beginning at 9:25 a.m., Billy was seen at Harbor Hospital Center for purposes of receiving his immunizations. M.R. at 19. Mr. McCarren testified at the first hearing, when asked what time the vaccination was given on March 13, 1990, that "[i]t would have been some time before 12:00, and I can't pinpoint exactly when." When asked, "Did you leave the clinic by 12 o'clock?", Mr. McCarren responded, "I would say so, yeah." On cross examination, Mr. McCarren recollected that the doctor's visit was "somewhere in the morning time." Tr. I at 24. When asked what time the family returned home from the doctor's visit, Mr. McCarren stated, "I would say roughly around 12:00 or a little bit before. I'm not sure. We know it was before 12:00." Tr. I at 26.

Furthermore, Mr. McCarren testified that, on March 16, 1990, the third day after Billy's DPT immunization, he returned home from work around 4:00 p.m. and began playing with and tickling his son, who responded with laughter and giggling. Tr. I at 32. Sometime thereafter however, Billy had a seizure and was rushed to the emergency room at Saint Agnes Hospital. Tr. I at 10-11. The corresponding medical records of the March 16, 1990, incident state "child was well until DPT-OPV#1 giv [given] at Harbour Hosp. Was febrile on Day 1 (101). Was well next 2 days--***until 6 pm tonight***--felt warm--mom gave Tylenol then child had seizure." M.R. at 37 (Emphasis supplied). The Emergency Department record's first recording of the events or treatment is at "1855", or 6:55 p.m. M.R. at 37.

Dr. Woody testified at the first hearing that "[w]hen I got the records, indeed, there had been an immunization in the days right before the onset of the seizures for which I saw him. At that time I counted up the hours; and, indeed, it was something around 80 hours." Tr. I at 53. When asked on cross examination whether Billy suffered a seizure within 72 hours of the DPT shot, Dr. Woody testified, "Well, the chronology that has been given I think in the affidavits and all would suggest no, that not within 72 hours. 80 hours is the most accurate figure that I can determine." Tr. I at 61.

Lastly, Petitioners adopt the medical records in evidence and concede that the onset of the first seizure occurred somewhere between 78 and 80 hours after the immunization. See Jt. Pretrial Stmt, filed 10/3/94, at 2-3 (wherein Petitioners stated: "It is agreed that Billy's first seizure took place approximately 80 hours after his first DPT inoculation."); see also Petitioners' Post Hearing Br., filed 12/5/94, at 2, 4, and 7; Jt. Pretrial Stmt., filed 4/22/96, at 2-3; Pet. Post Hearing Br., filed 1/3/97, at 3. Given the overwhelming evidence outlined above, the court finds that Billy's first seizure occurred outside the 72 hour time frame required by the Vaccine Injury Table. However, the inquiry does not stop there.

In the alternative and in anticipation of the court's ruling in line with its previous decisions, the Petitioners have also alleged that, even if Billy did not suffer the first seizure in the 72 hours following the DPT shot, it is likely that he suffered from "abnormal electrical activity" prior to the occurrence of the

first seizure, and that this activity signified the onset of Billy's seizures, thus providing Petitioners with the presumption of causation. See Jt. Pretrial Stmt., filed 10/3/94, at 3; Petitioners' Post Hearing Br., filed 12/5/94, at 7; Jt. Pretrial Stmt., filed 4/22/96, at 2-3. This argument fails as well and is discussed below.

2.

At the first hearing, Dr. Woody opined that abnormal electrical brain activity was likely occurring prior to the onset of Billy's clinical activity, i.e., his seizure. Tr. I at 54. Stated another way, Dr. Woody explained a seizure as the clinical or motor manifestation of the abnormal electrical activity. Tr. I at 54. Moreover, Dr. Woody testified that it was his experience, as a child neurologist, "that there is interictal electrical abnormalities between seizures". Tr. I at 55. Dr. Woody connected this abnormal activity to brain injuries; and in cases such as Billy's, that "the injury to the brain occurs before the onset of seizures." Tr. I at 74. He further elaborated:

If we propose that there was an injury, of any nature, whether it was head trauma or meningitis or conceivably pertussis immunization, rarely--there would--logically and scientifically, it's only reasonable that there would be the inciting event, whatever that is. And then a propagation of neuronal dysfunction and some correlation of abnormal electrical activity building up, finally manifested by a clinical event [i.e., seizure] that would bring the child to medical attention.

Tr. I at 55.

In relating this to Billy's situation, Dr. Woody stated, "...I'm quite emphatic that something did occur to this child's brain before I saw him, whether it was hours or days or months or years. This child didn't just decide to have a seizure one day and had the seizure. There was some precedent to that. When those precedents occurred, I don't think I can--and in retrospect, no one can today--say exactly when those occurred." Tr. I at 73-74. When asked directly whether the DPT vaccination was the injurious event, Dr. Woody testified, "I can speculate that it was after the DPT" (Tr. I at 66). . ."I think the brain was insulted before the clinical events occurred. Exactly at what time that occurred, I can't say." Tr. I at 73. Pressing further on the immunization's role, respondent's counsel asked Dr. Woody, "[I]s there anything that leads you to believe that it's more likely than not that his [Billy's] brain was injured within--that his brain was injured after the DPT shot as opposed to weeks, days, months before?" In response, Dr. Woody answered, "No, there isn't. He could have had some neurologic problem which was in no way evident before the DPT." Tr. I at 76. It necessarily follows then, that because Dr. Woody could not explain when or what caused Billy's brain injuries, his opinion does not state, to a reasonable degree of medical certainty, that the abnormal activity was not *already* occurring before the DPT shot, or that it even occurred at all within the 72 hour time period.

Dr. Woody was honest about his uncertainty. He stated, "I'm speculating and suggesting that there was paroxysmal electrical activity...that would have preceded by some time the clinical event". Tr. I at 62. But Dr. Woody admitted that because no EEG tests were done in the three days following the immunization, which would reveal the abnormal electrical activity, "there's no way to prove what I'm saying." Tr. I at 55. Dr. Frost agreed with Dr. Woody, and opined that while it is "certainly possible" that Billy experienced abnormal electrical brain activity prior to the first seizure, "we can't determine that either way without an EEG recording having been done during that time." Tr. I at 87. In fact, EEG tests were later done, and Dr. Woody conceded that most resulted in normal readings, despite that Billy endured a number of seizures in the same time frame as the EEG test taking. Tr. I at 62. Particularly, he confirmed

that when he was treating Billy for the arm twitching, which Dr. Woody considered seizure activity, the EEG results at that time were normal. Tr. I at 63. Dr. Frost's testimony revealed this not to be unusual; he stated, "we do see lots of seizures that have EEG signs accompanying the clinical seizure where there is no interictal or no abnormal activity between the seizures." Tr. I at 88; See also Dr. Gabriel's testimony at Tr. II at 18 ("At this age, as often as not, the EEG will be normal despite clear clinical seizure activity.") Dr. Woody provided support for this proposition by introducing a passage from Elaine Wiley's 1993 book on epilepsy treatment, Principles and Practice, which reads: "The interval between the insult and the development of recurrent seizures activity may appear silent, a period during which cerebral function apparently progresses normally. The silent interval can last from weeks to years." Tr. I at 74.

As if to give Petitioners the benefit of the doubt, Dr. Frost theorized that if one looked to later EEG results, many of which were abnormal, one might then expect that "if a lot of interictal abnormal activity had been going on preceding the initial seizure and if it was part of the same process that we would continue to see abnormal activity when it was done in May." Tr. I at 88-89. This suggests that abnormal EEG readings later in Billy's medical history would tend to prove that previous abnormal activity had occurred as well. But even Dr. Frost cautions himself from accepting this theory: "But that's just speculation. And I basically agree with Dr. Woody that there isn't anyway to determine that." Tr. I at 89.

In short, the "abnormal electrical activity" theory put forth by Petitioners, while conceivable, is unsupported by the medical records and to a reasonable degree of medical certainty by the expert testimony. No EEG was performed in the 72 hours following the child's immunization which would provide the proof the court is seeking. In addition, both Dr. Woody and Dr. Frost indicated that absent this contemporaneous testing, the existence of abnormal electrical activity within the 72 hours would be pure speculation. Their opinions clearly suggest, if not explicitly state, that even if EEG testing had been conducted in the 72 hour time period, and abnormal brain activity had been revealed, that result would not definitively show the activity's causal relationship to the DPT; in other words, the activity could have been occurring prior to the vaccination. Therefore, the court rejects this theory and finds that Petitioners have not proven, through this theory and by a preponderance of evidence, that Billy suffered the first symptom or manifestation of onset of the residual seizure disorder within the 72 hours following his DPT immunization.[(10)]

3.

The medical testimony also indicates that Billy did **not** suffer from an acute encephalopathy within the first 72 hours following the vaccination. The term "encephalopathy " is defined in the Vaccine Injury Table as:

any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

42 U.S.C.A. §300aa-14(b)(3)(A).

Examining the expert testimony, Dr. Woody opined that while Billy's symptoms could have been called an encephalopathy, given the fever, irritability, and mild change in behavior, he also stated that *he would not have diagnosed* Billy with encephalopathy in the three days following the inoculation. He reasoned

that the symptoms did not "reach the threshold of events that warrant...a medical diagnosis of encephalopathy. Perhaps it was the most mild form, not even approaching a clinician's threshold of using that term. But, no, I couldn't say encephalopathy in the first 72 hours." Tr. I at 71-72. However, Dr. Woody did testify that he believed Billy suffers from encephalopathy today. Tr. I at 58, 72. Dr. Frost agreed with Dr. Woody that "[t]here's no evidence documented that any specific encephalopathy occurred in the first 72 hours." Tr. I at 87.

Dr. Lavenstein expanded upon the encephalopathic injury:

I don't think of every child as being cranky, irritable and having change in sleeping pattern as being "encephalopathic" with the image that that portends or conveys . . .In any event, do I think that this child was encephalopathic? I think that this child had a change in mental performance, mental status performance, which was self-limited. He did not have an ongoing encephalopathy. He, in fact, rebounded then subsequently was described as looking playful or, in fact, recovered over that 48-hour period. Then subsequently had the emergence of a fever spike and had the presentation of an ear infection that was probably brewing for the previous X number, 24 or 36-hours, and presented on the 16th with a seizure, an otitis. So in a roundabout way what I'm trying to clarify here is not the course of somebody who is acutely brain injured, progressive decline and encephalopathic over a 72-hour and 80-hour period. **But the presentation of a cranky child not unexpectedly very common in children that get immunizations.**

Tr. II at 60-61 (Emphasis added). Dr. Lavenstein also noted that Billy suffers from an encephalopathy today. Tr. II at 63. When asked when Billy suffered the onset of the encephalopathy or the seizure disorder, Dr. Lavenstein testified: "Well, I don't think that he had a congenital encephalopathy. He was certainly normal for the first eight months of his life by all the records. At sometime after this he manifested what I would say is a refractory intractable seizure disorder (Tr. II at 64)...Now the exact time at which that occurred I have difficulty figuring out when that occurred." Tr. II at 65. He further opined:

I believe that William developed, as many children do, an infantile epileptic seizure disorder with developmental delay that is not post-vaccine induced that occurs in children in infancy for which we do not know the cause. For which an adequate explanation is not available in the scientific literature. But, in fact, there is some abnormality of neuronal function or there's disordered brain function that results in a chronic tractable seizure disorder. And, in fact, the SPECT scan that was done that showed evidence of a focal abnormality in the temporal lobe points to an area of abnormal metabolism where seizures may arise very commonly in the developing brain. And may be the source very commonly of a very resistant refractory seizure disorder.... So developmental delay and seizures that go on hand-in-hand in this case are present throughout infancy here. They emerge over time. But I don't believe that they started on March 13th, 14th or 15th.

Tr. II at 65-66.

Only Dr. Gabriel opined that Billy suffered an encephalopathic process sometime in the 24-80 hours following the vaccination. Tr. II at 47. Dr. Gabriel based this opinion on the information provided by the parents. Tr. II at 16-17. On cross examination, Dr. Gabriel was taken step by step through the symptoms Billy experienced. On March 13th, Billy was cranky and had a sore leg--Dr. Gabriel found this compatible with an encephalopathy. Tr. II at 33. On March 14th, Billy was "not doing a whole lot. He didn't respond normally to play. He wasn't satisfied. He wouldn't quiet down. He had a fever...He had soreness at the injection site. He ate sort of well." Tr. II at 34, citing Tr. I at 25. Dr. Gabriel stated that these symptoms "may be" indicative of an acute encephalopathy. Tr. II at 34. On March 15th, Billy's symptoms were the following: "cranky", "afebrile", "[s]leep pattern disrupted. He was restless, couldn't get situated. Would wake up, stir around, lay back down. Upon waking he'd make a brief cry. There was

no seizures, no loss of consciousness noted. Sometime he would eat, sometimes he wouldn't." Tr. II at 36, citing Tr. I at 29. Dr. Gabriel found this symptomology also indicative of an acute encephalopathy, and further testified that whining, and not crying, were "fairly typical" symptoms of an acute encephalopathic reaction. Tr. II at 37, 38. When asked whether an acute encephalopathic reaction is also characterized by the following actions, "to eat [take] a bottle, take food, sleep, wake up, sleep again and not alarm a parent", Dr. Gabriel did not address this question, and simply reiterated that the child had been normal in the eight months prior to the shot, and now his behavior was changed. Tr. II at 38. Lastly, in reviewing the March 16th symptoms, where "Billy seems better. He's not crying as much. There's nothing that occurred out of the ordinary. In the evening he was walking on the sofa responding to his father playing, giggling. Then he felt warm." Tr. II at 38-39, citing Tr. I at 31-32. Dr. Gabriel opined that these reactions may also be encephalopathic and that "[t]he effects of an encephalopathy wax and wane especially if it is not a devastating acute process." Tr. II at 39. Essentially admitting that Billy's symptoms were not devastatingly acute, Dr. Gabriel nevertheless caught himself, and testified that even with subtle signs and symptoms, an encephalopathic reaction could be so severe as to cause a seizure and subsequent seizure disorder. Moreover, Dr. Gabriel reiterated his opinion that, "[a]ssuming the father is accurate in his resume´, this was a significantly sick child during those three days." Tr. II at 39.

Dr. Gabriel admitted that some of the symptoms, at least those of March 14th, could also be indicative of a sick child. Tr. II at 35. After all, the testimony and medical records indicate that Billy had an upper respiratory infection and a left otitis media on March 16th. M.R. at 37. However, when asked, "Why is it more likely than not that it's encephalopathic and not related to just a sick child?", Dr. Gabriel reasoned:

Because we have three aspects in terms of probability (1) the child was given a neurotoxin, i.e., the Pertussis vaccine; (2) there is a continuum of symptomatology in signs between the vaccine and what occurred; and (3) a prolonged 15-minute convulsion. Clearly you can raise the issue of a sore leg, left otitis media and a URI, upper respiratory infection. But generally speaking the Pertussis vaccine does not produce a sufficiently sore leg as to result in the kind of restlessness, poor sleeping patterns and irritability that you're describing from that testimony.

Tr. II at 35. Dr. Gabriel further claimed that the symptoms Billy experienced may not be compatible with a child with an ear infection because "most children with a simple left otitis media described as 'red and dull' will tug at their ear. But this degree of restlessness and irritability is uncommon. It may happen in the presence of an otitis media but this degree of irritability particularly without fever as you indicated on the 15th would be uncommon to attribute it to an ear infection at that point in time." Tr. II at 37.

In the end, what the court is left with is the testimony of four expert witnesses, three of whom unanimously agreed that the symptoms Billy developed in the 72 hours following his vaccination did not rise to the level of an encephalopathic reaction. In contrast, Dr. Gabriel's testimony revealed, simply put, his willingness to stretch routine symptoms following a vaccination into a compensable encephalopathy. The court was unimpressed with the depth and quality of Dr. Gabriel's testimony. It was quite apparent that Dr. Gabriel was willing to fashion his testimony to support a predetermined end result, i.e., a vaccine induced injury. Such slanted testimony is unhelpful and particularly unpersuasive. In contrast, the other three experts gave straightforward, objective testimony, which comports with the testimony this court has heard from numerous experts in other cases. The court was persuaded by their credible testimony. Given the credible testimony of Dr. Woody, Dr. Frost, and Dr. Lavenstein, and given further that their opinions were based on a rational reading of the patient's history before them, as well as proffered to a reasonable degree of medical certainty, the court rejects Dr. Gabriel's speculative testimony on this point and finds that Billy did not suffer an encephalopathy within the Table time period. Because Petitioners cannot meet the criteria for presumed causation under the Act,[(11)] the sole inquiry in this case now becomes whether Petitioners have made the requisite showing in order to prove causation in fact.

C. Petitioners Case for Causation in Fact

In order to demonstrate a logical sequence of cause and effect, this court has determined that petitioners essentially must make a two-pronged showing. First, that it is medically possible for the DPT vaccine to cause the alleged injury[(12)]

, and secondly, that there is a nexus between the proffered "possibility" and the actual injury. See, e.g., Schuler v. Secretary of DHHS, No. 92-140V, 1995 WL 634391 (Fed. Cl. Spec. Mstr. Oct. 13, 1995); McCummings v. Secretary of DHHS, No. 90-903V, 1992 WL 182190 (Cl. Ct. Spec. Mstr. July 10, 1992), *aff'd*, 27 Fed. Cl. 417 (1992), *aff'd*, 14 F.3d 613 (1993), *cert. denied sub nom.*, 114 S. Ct. 1541 (1994). It is important to note that while ruling out other potential causes is an essential element to a successful prosecution of the case, such a showing does not itself establish causation. See Grant v. Secretary of HHS, 956 F.2d 1144 (Fed. Cir. 1992). Nor is a demonstration of temporal association between the vaccine and the injury sufficient. See Strother v. Secretary of DHHS, 21 Cl. Ct. 365, 369-70 (1990), *aff'd*, 950 F.2d 731 (Fed. Cir. 1991). 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. This case is measured against these standards.

1.

The Petitioners offered medical literature[(13)] and expert testimony in an effort to prove the first prong of their causation in fact argument, i.e., that it is medically possible for the DPT vaccine to cause either encephalopathy and/or the onset of a residual seizure disorder outside the 72 hour time period following the vaccination, or more specifically in this case, within **78-80 hours** after the vaccine. In addressing this issue, Dr. Woody confessed that, "I have never been a proponent of pertussis immunization is [as] a likely cause of brain injury." Tr. I at 55. However, he testified not only that he could conceive, albeit in rare situations, that a seizure could occur up to 80 hours following the shot, but also that the medical community, as evident through the National Childhood Encephalopathy Study (NCES) and the 1991 Institute of Medicine (IOM) follow up report, does accept that acute encephalopathy could occur following the DPT inoculation. Tr. I at 55-57. In acknowledging this consensus and causal relationship, Dr. Woody stated, "Now, if you accept that rarely it could be--and I think that the Institute of Medicine accepts that, and I think intellectually, I accept that very rarely it could and that, perhaps, this is one of the rare cases--then there's going to be the inciting event and some time frame before the clinical event." Tr. I at 56. In addressing whether Billy's injuries and the DPT shot could be causally related, Dr. Woody acquiesced, although ever so slightly: "I think there could be. As I say, the strongest I can come down is that this could well be one of the rare cases." Tr. I at 57. This statement, while perhaps more relevant to the second prong of the causation-in-fact test given the specific reference to Billy's case, does demonstrate Dr. Woody's position that it is medically plausible for an encephalopathic reaction and/or onset of a residual disease disorder to occur within 80 hours of the inoculation.

Dr. Gabriel readily accepted the causal link between the pertussis component of the DPT vaccine and an acute encephalopathic reaction. Tr. II at 6-12. Moreover, Dr. Gabriel included seizures and seizure disorders (Tr. II at 10) as examples of an encephalopathic reaction, and addressed the time frame, following the DPT shot, within which an encephalopathic reaction will occur:

Biological systems cannot be bracketed by numbers. This is not a numbers game. Biological systems clearly function independent of any arbitrary or statistical nominations. But as a matter of probability the bulk of the cases will occur anywhere between six and 72 to 96 hours. That is to say the bulk of the cases. I would be uncomfortable if we got beyond five or seven days post-vaccine. The closer we are to the event itself, that is to say the vaccine, the more comfortable I am in establishing a tight temporal relationship. I think that for purposes of probability I will accept anything in the range of up to 96 hours

post-vaccine, understanding that any number you choose is a statistical phenomenon and the difference between 72 hours or 80 hours, as in this case, or 96 hours is not statistically significant. Nevertheless, one has to set some arbitrary standards and those are mine. In this particular case which is 80 hours or less I am very comfortable in terms of probability that this temporal relationship is acceptable.

Tr. II at 11-12.

Respondent's expert, Dr. Lavanstein, opined that the DPT inoculation can cause an encephalopathy, and "an ongoing decline in a child's performance with a progressive deterioration and clear-cut evidence of a major insult to the nervous system." Tr. II at 63. Lastly, the court has consistently recognized and upheld certain medical literature findings on this point, namely that, it is medically possible for an encephalopathic reaction and/or the onset of a residual seizure disorder to occur following a DPT vaccination, and indeed up to 7 days following the shot, as the NCES literature argues. See Wolf v. Secretary of HHS, No. 90-3137V, 1994 WL 142295 (Fed. Cl. Spec. Mstr. April 7, 1994). See also Estep v. Secretary of HHS, No. 90-1062V, 1992 WL 357811 (Fed. Cl. Spec. Mstr. Nov. 3, 1992), *aff'd*, 28 Fed. Cl. 664 (1993), *appeal dism'd* (Unpublished Fed. Cir. Oct. 29, 1993); Sharpnack v. Secretary of HHS, No. 90-983V, 1992 WL 167255 (Cl. Ct. Spec. Mstr. July 28, 1992), *aff'd,* 27 Fed. Cl. 457 (1993), *aff'd*, 17 F.3d 1442 (Fed. Cir. 1994). Given this consensus among the experts testifying, and for purposes of analysis herein, the court will accept the medical possibility that the DPT vaccine can cause the injuries alleged by Petitioners. That having been found, however, the Petitioners must yet establish that, in this case, the DPT caused an encephalopathic reaction and/or the onset of a residual seizure disorder within the 78-80 hour time frame.

2.

Having found that the DPT inoculation could cause the injuries seen in this case, two final issues arise. The first is **(a)** whether the first seizure, which occurred on March 16, 1990, constitutes the onset of the seizure disorder, and the second is **(b)** whether the DPT in fact caused the onset of Billy's seizure disorder and/or his current encephalopathy. Because the expert testimony often intertwined the seizure disorder and encephalopathy discussions, the court will address these injuries together.

a.

In examining the cause of Billy's residual seizure disorder, it is important to address whether his first seizure, which occurred on March 16, 1990, constitutes the onset of the disorder. The medical records indicate that Billy suffered his first seizure on March 16, 1990; however, the second seizure is not documented until April 19, 1990, more than one month after the vaccination. M.R. at 37, 38. Were the court to find that Billy's March 16th seizure is unrelated to this subsequently diagnosed seizure disorder, then Petitioners' claim for this injury would clearly fail under causation-in-fact; simply put, there would be no medical or scientific support for a causal relationship between the shot and a seizure disorder occurring over a month later. However, in reviewing the testimony presented, the court finds that Billy's initial seizure is related to his subsequent disorder. Dr. Woody testified that "it's more than 50/50 that it [the March 16, 1990 seizure] was not a separate febrile seizure but rather that it was part of the subsequent epilepsy which he had." Tr. I at 60. Dr. Gabriel agreed that the March 16th seizure was the beginning of the refractory seizure disorder. Tr. II at 14. Dr. Frost testified with less certainty: "All I can say is that there's a possibility that it is related to the overall process. But I can't put any kind of probability on that. I think it's equally probable that it was a separate type of seizure. Because febrile seizures are not all that uncommon." Tr. I at 92.

Dr. Lavenstein's opinion offered the least support for relating the seizures. Dr. Lavenstein attributed Billy's *initial febrile seizure* to his otitis media. Tr. II at 67. However, Dr. Lavenstein also opined that the

seizure disorder diagnosis would have been properly formed "when the seizures that are recognized are, in fact, idiopathic spontaneous non-febrile. Not the March seizure. Not the April seizure where I believe there was fever also recorded. But subsequently when the child presents with admissions and evaluations as reflected in the medical records of afebrile seizures. So I would tell you that it's beyond April". Tr. II at 75. Dr. Lavenstein expanded upon his opinion and contended that Billy "had seizures with fever where he would get a febrile illness and that would trigger a recurrence of the seizure disorder. But he had a latent ongoing seizure disorder...we know when the symptoms are manifesting themselves but as far as when this non-febrile seizure disorder with developmental delay occurred I really think there's a window". Tr. II at 64-65. He further opined:

I believe that William developed, as many children do, an infantile epileptic seizure disorder with developmental delay that is not post-vaccine induced that occurs in children in infancy for which we do not know the cause. For which an adequate explanation is not available in the scientific literature. But, in fact, there is some abnormality of neuronal function or there's disordered brain function that results in a chronic tractable seizure disorder. [Tr. II at 65]...So developmental delay and seizures that go on hand-in-hand in this case are present throughout infancy here. They emerge over time. But I don't believe that they started on March 13th, 14th or 15th.

Tr. II at 66.

Therefore, while Dr. Lavenstein associated the first seizure with Billy's otitis media, he also testified that Billy had a latent seizure disorder, whose development date was unknown, but could have been manifested by a **febrile illness**. Thus, Dr. Lavenstein recognized the possible relationship between the March 16th seizure and the subsequent residual seizure disorder. While this is an extremely close question with uncertain answers, the court finds that the weight of the expert testimony supports a finding that the March 16, 1990, seizure constitutes the onset of the residual seizure disorder. However, this by no means declares that Billy's March 16, 1990, seizure and the subsequent epilepsy is causally related to the March 13th DPT vaccination---that discussion follows.

b.

There is no question that Billy suffered a seizure on March 16, 1990, about 80 hours following the DPT shot, and that he currently suffers from an encephalopathy. But in order to prevail, causation-in-fact must be established. **It was not**. Dr. Woody stated that "the immunization was the only factor that was occurring in the preceding period that could conceivably be associated with the seizures." Tr. I at 54. In addition, he noted that "this child's epilepsy syndrome became a raging big problem in association with the immunization." Tr. I at 70. Dr. Woody further acknowledged that the pertussis vaccine's impact on the central nervous system, if such were to occur, would logically occur between the insult and the clinical event, seizures in this case. Tr. I at 56. Nonetheless, he also testified, and the case law supports, that a temporal association does not in and of itself establish cause and effect. Tr. I at 54. In the end, Dr. Woody **could not** opine, to a reasonable degree of medical certainty, that Billy's initial seizure, encephalopathy, and subsequent epilepsy were causally related to the DPT vaccination. Dr. Woody testified, "I can speculate that it [the brain injury] was after the DPT, but---and I certainly think he has acquired some functional disability from the frequency and intractability of seizures. But that's hard to quantify other than what the developmental people have measured. Now as far as the exact chronology of how it developed, I can't be any more specific than what I've said." Tr. I at 66. He further testified, "I think the brain was insulted before the clinical events occurred. Exactly at what time that occurred, I can't say." Tr. I at 73. Indeed, although Dr. Woody could not provide the exact, nor a statistically relevant, cause, including an illness, of Billy's injuries, he did opine that Billy's brain could have been injured prior to the DPT[(14)], or "the DPT in some pathophysiologic way precipitated that abnormality" or the "fever in an independent fashion made that preceding neurologic problem evident; and then in pathophysiologic

ways, which we don't understand, it propagated itself [as a seizure]." Tr. I at 73-74, 76. Dr. Woody's frank testimony regarding when Billy's brain was injured and/or the cause of the seizures provides insufficient proof to warrant the court's finding that the DPT vaccination caused Billy's injuries.

The uncertainty of the cause of Billy's seizures was also shared by Dr. Frost. Although he testified that no definite cause had been found for Billy's seizures, he also noted that this lack of explanation was common in the field. Dr. Frost stated that none of the medical records or testimony provided the information he needed to conclude that the DPT caused Billy's seizure disorder. Tr. I at 90, 93, 94. As for Billy's encephalopathic injury, Dr. Frost offered no explanation as to when the current encephalopathy developed; however, he did testify that he found no persuasive evidence to support that Billy's current encephalopathic condition was related to the DPT. Tr. I at 90.

Dr. Lavenstein was more detailed in his explanation of the possible etiology of Billy's *initial seizure*. He conceded that, depending on one's definition of "acute encephalopathy", a seizure could be defined as a "transient disorder of neuronal function" and then fall within the acute encephalopathy's definition of "disordered brain function." Tr. II at 60. Yet, Dr. Lavenstein further opined, "We don't think of febrile seizures as being an "encephalopathy." Tr. II at 60. Instead, Dr. Lavenstein characterized Billy's symptoms following the shot to be a "rather standard, well-known, accepted type of presentation" (Tr. II at 55) rather than an example of "somebody who is acutely brain injured, [with a] progressive decline and encephalopathic over a 72-hour and 80-hour period." Tr. II at 60-61. In support, Dr. Lavenstein testified that once Billy received his Amoxicillin medication for the otitis media, his health improved. Tr. II at 56. Indeed, the medical records reflect no further health concerns until April 19, 1990, when Billy presented to the hospital again with a seizure. M.R. at 38. In short, Dr. Lavenstein opined that due to the otitis media illness, Billy developed a fever, which Dr. Lavenstein declared common with such an illness, and then the fever resulted in a febrile seizure, another common result with otitis media. Tr. II at 56, 67. He further explained that he didn't "think that after the otitis media was diagnosed that this 'endotoxic encephalopathy' would have spontaneously resolved so over the next four weeks prior to the next representation of seizure he would have been, in fact, clinically well. In other words, endotoxin wouldn't have been shut off, marked healing occurred the child would have looked great and everything resolved after he was given Amoxicillin for the otitis media. So I find that hard to believe because actually the brain doesn't behave that way." Tr. II at 63.

In addressing the *disorder's* cause, Dr. Lavenstein attributed the seizure disorder to an abnormal brain or dysgenetic brain. Tr. II at 82. He opined, "It is my belief that this patient has an intrinsic disease of the nervous system and a dysgenetic brain in terms of neurologic substrate and function. In fact, that this is the basis for the emergence of the seizure disorder." Tr. II at 81, citing Dr. Lavenstein's report, filed September 14, 1995, at page 1.

Lastly, Dr. Lavenstein rejected the allegations that Billy suffered an encephalopathy, not only following the vaccination, but following the initial seizure as well. Dr. Lavenstein found "no evidence that the child was encephalopathic or lost milestones or had any evidence of that over the next four weeks [following his initial seizure]." Tr. II at 69. Instead, when asked what evidence Dr. Lavenstein would need to find causation, he testified:

I think what was missing acutely was sort of an intractable crying, an unconsolable child, a child who could not be settled. Who has a course of a very sort of progressive course, if you will, of a child who is sicker, perhaps not feeding well, vomiting, other constitutional symptoms that would have been in the circumscribed period around the time of the DPT. I'd also look for evidence of a fall-off in performance in the child's behavior over the ensuing few weeks, an encephalopathic child...A child who would become less visually attentive. Who would become less alert to the environment. Who would not interact as well with the parents or not be as cuddly or not being able to be handled, would be persistently irritable.

Maybe not to the degree that you'd see in the first 72 hours but a change in the personality of a child who may even, in fact, lose milestones.

Tr. II at 92-93. Further, Dr. Lavenstein testified he'd expect to have seen a child with ongoing difficulty in sleeping, lethargy, and an overall progressive decline in the child's health and behavior. Tr. II at 92, 94, 95.

In contrast, Dr. Gabriel was convinced that Billy suffered an encephalopathy within a medically acceptable time period, which was, along with the initial seizure, causally related to the DPT. He based his opinion not only on the temporal association existing between the shot and the seizure, but on the absence of any other explanations for the injuries in the "pregnancy, labor and delivery, post-partum, genetic, biochemical, metabolic, [or] chromosomal" medical histories. Tr. II at 16-17, 19. Dr. Gabriel supported a causal connection despite acknowledging the following: Billy had otitis media and a fever, the fever indicated that Billy suffered from an infectious process, (Tr. II at 24-26), otitis media is a common result of URI, a fever of 102.2 degrees or less can accompany such illnesses, and otitis media is an important cause of simple febrile seizures. The court notes, however, that Dr. Gabriel consistently rejected the diagnosis, in this case, that Billy experienced a simple febrile seizure on March 16, 1990. Tr. II at 26, 33, and 46. In short, Dr. Gabriel based his opinion on three factors: (1) that Billy received the vaccine, (2) that he developed symptoms thereafter prior to the seizure, and (3) that the initial seizure was 15 minutes in length. Further, he believed that these three factors increased the probability that the symptoms were unrelated to Billy's OM/URI. Tr. II at 35.

In summary, what the court is left with is the following synopsis of the testimony: (1) Dr. Woody and Dr. Frost could not identify an exact cause of the seizures, and neither testified, with any certainty, that Billy's current encephalopathy and/or seizure disorder were related to the DPT, (2) Dr. Woody and Dr. Lavenstein suggested that the seizure disorder could have been a latent phenomenon, (3) Dr. Lavenstein testified that the initial seizure was due to the OM and fever spike, not the DPT vaccination, and the subsequent seizure disorder was due to some abnormality of the brain, also unrelated to the inoculation; moreover, Dr. Lavenstein found no evidence of an encephalopathic injury following the vaccination or in the few weeks following the first seizure, and (4) Dr. Gabriel connected Billy's encephalopathy and initial seizure/subsequent epilepsy to the DPT vaccination.

Despite the uncertainty in the actual cause(s) of Billy's injuries, the court finds the weight of the evidence demonstrates that the DPT vaccination did not cause Billy's March 16th seizure, subsequent seizure disorder, and/or current encephalopathy. In so holding, the court notes that Dr. Gabriel's testimony, although emphatic in its support of the correlation between Billy's injuries and the DPT, was unpersuasive in the end. Simply put, Dr. Gabriel's opinions, when carefully examined, relied essentially on the temporal relationship existing between the shot and Billy's symptoms/seizure, and on the fact that no known or exact cause for the child's injuries had been determined.[(15)] Furthermore, Dr. Gabriel ignored the existence of other probable causes for the injuries, namely the otitis media illness, and/or a cause not yet known. Indeed, Dr. Gabriel acknowledged that at least some of Billy's symptoms following the inoculation could just as easily be attributed to Billy's URI/OM infections. Tr. II at 35.[(16)] Dr. Gabriel also conceded that there's no established "syndrome" for a DPT-related encephalopathic reaction, and that such a reaction is **indistinguishable** from a similar reaction due to some other factor(s) or cause(s), such as an infection. Tr. II at 48.[(17)] In the end, Dr. Gabriel's testimony suffered from the same defects discussed *infra* at pages 14 and 21. Dr. Gabriel's bias in favor of DPT causation overshadows his consideration and discussion of other medical possibilities. His testimony amounts to his own version of presumed causation: a DPT given within 96 hours (see *infra* at pg. 16) of a neurological injury equals causation. Obviously such reasoning is medically and legally deficient. See Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786 (1993) [(18)]. It is also very unpersuasive. In the final analysis, Dr.

Gabriel failed to finger one identifying or distinguishing factor that would lead the court to conclude that it was more likely than not the DPT that caused the injuries in this case. In contrast, the other experts presented credible testimony explaining why they could not ascribe causation to the DPT with any level of certainty. Their testimony was made more reliable by their understanding that, not only are these particular types of injuries difficult to assess, but that they often occur in infancy for inexplicable reasons. The court was convinced that these three experts fairly and objectively considered the medical information and concluded that, for various reasons, the DPT could not be causatively fingered. The court found particularly convincing Dr. Lavenstein's testimony. In any event, Petitioners failed to establish by a preponderance of the evidence the necessary cause and effect linkage between the DPT and Billy's neurological injuries.

IV. CONCLUSION

In conclusion, the Petitioners have not met their burden of proving by a preponderance of evidence that it is more likely than not that the DPT vaccination administered to Billy on March 13, 1990, caused his initial seizure on March 16, 1990, his subsequent seizure disorder, and/or his current encephalopathy. Accordingly Petitioners' claim must be denied as unsupported by either medical records or expert opinion.

Petitioners' claim is hereby dismissed. The Clerk is directed to enter judgment consistent with this decision.

IT IS SO ORDERED.

Gary J. Golkiewicz

Chief Special Master

1. The statutory provisions governing the Act are found at 42 U.S.C.A. §300aa-1 *et seq*. (West 1994 and Supp. 1997). Hereinafter, for ease of citation, individual sections of the Act will be cited without reference to 42 U.S.C.A.

2. The Vaccine Injury Table, contained in §300aa-14(a), requires that the "first symptom or manifestation of onset or of significant aggravation after vaccine administration" for the claimed injuries of encephalopathy and residual seizure disorder occur in "3 days". Incidentally, the injury of residual seizure disorder was later omitted from the Injury Table through the Secretary of HHS's rulemaking authority. See 42 CFR §100.1-100.3 (1995). However, the Injury Table applicable to this case is set forth at §300aa-14(a).

3. References to the medical records attached and filed with the Petition shall be designated as "M.R. at #." Petitioners have marked all medical records with page numbers.

All references to "Tr. I" will refer to the transcript taken from the October 12, 1994, hearing, whereas references to "Tr. II" will refer to the transcript taken from the November 5, 1996, hearing.

In Respondent's R4 Report, filed 2/26/93, Respondent argued that the medical records indicated that Billy suffered a seizure as early as January 1990. See M.R. at 39, 40, 49, 69. This issue was raised and addressed at the October 12, 1994, hearing. Mr. McCarren testified that the medical records were incorrect in their references to any January 1990 seizures. He indicated that he and his wife were

confused and must have miscalculated, when asked at later dates by the medical personnel, the date of onset and/or the age of Billy when he had his first seizure. In any event, Mr. McCarren testified that Billy's first seizure occurred in March 1990. Tr. I at 21-22, 39-44. In further support of their position, Petitioners filed letters from three of the hospitals whose records contained references to a January 1990 seizure history. Those providers stated that Billy was not treated at their facilities in January 1990. See P's Exhibits 8A, 9A, 10A, filed May 28, 1993. With this support from the record, the court finds Mr. McCarren's testimony credible and further finds that Billy's first seizure occurred March 16, 1990.

4. When asked the general health of Billy during his first eight months, his father testified that, "He was generally pretty healthy. He had occasional digestive and respiratory infections; but other than that, he was pretty healthy." Tr. I at 6. Mr. McCarren also testified that his son, at times, experienced fevers with the respiratory and ear infections, that those fevers had reached 101 and 102, but that he never had a seizure with those fevers. Tr. I at 7.

5. Mr. McCarren also testified, when asked on cross examination what time his family returned home from the doctor's office, that, "I would say roughly around 12:00 or a little bit before. I'm not sure. We know it was before 12:00." Tr. I at 26.

6. Mr. McCarren testified that Billy did not experience any comatose states following his vaccination, nor did the parents take him to the doctor's office prior to the first seizure, despite the office's close proximity to their residence. Tr. I at 30. In addition, Mr. McCarren testified that he called his wife during the day of the seizure, but that she had not mentioned that Billy was sick that day, nor did she express any other concerns. Tr. I at 31-32.

7. Despite the MRI's revelation of a cyst, the testifying physicians stated that it was unlikely that the cyst played a significant role, if any, in Billy's seizure activity. Dr. Woody stated, "[I]t was always a question, but no one ever thought that a cyst in the choroid plexus could account for seizure activity which [is] largely a cortical disorder. So we knew it was there, and we followed, and we all speculated. But I don't think anyone seriously thought, either at the time or in retrospect over the whole course, that that cyst was playing a role in the seizures the child had." Tr. I at 49. He further opined, "I would be quite emphatic that I don't think that that cyst relates to his seizures in any way, positive or negative." Tr. I. at 68. See also Dr. Woody's July 6, 1990, report, wherein he stated, "I don't think the cyst has any relationship to the reason the child saw me." M.R. at 115; Dr. Woody's September 21, 1990, letter to the McCarren family: "I have looked at the last MRI and the cystic structure in William's brain appears to be totally harmless." M.R. at 118. Dr. Frost opined that although it was conceivable that the cyst was related to the seizures, he elaborated that, "[i]t's probably unlikely that the cyst was the cause because of the location in the ventricular system and not in the cortex and the fact that the side that the seizures occurred on was not really consistent with where the cyst was." Tr. I at 94. Dr. Lavenstein agreed, and testified, "I don't believe that the cyst is responsible for the seizures or the developmental delay." Tr. II at 68. See also Tr. II at 73. Lastly, Dr. Gabriel opined that the cyst was "of no significance with respect to the seizure disorder and with respect to the child's developmental retardation." Tr. II at 14-15.

8. The parties do not dispute that Billy suffered no seizures prior to March 16, 1990, and that he suffered, within one year after the vaccine's administration, at least two afebrile seizures or seizures accompanied by a temperature of less than 102 Fahrenheit. See 42 U.S.C.A. §300aa-14(b)(2)(B).

9. The interpretation of "3 days" under the Vaccine Injury Table has been taken for granted in the decisions dealing with DPT vaccinations. After an exhaustive search, other than the analysis contained in Ultimo, the court has found that vaccine decisions use the phrases "3 days" and "72 hours" interchangeably, having either relied on Ultimo for support, or having provided no specific basis for the interpretation. Essentially, when discussing DPT-related injuries, the courts have assumed that "3 days"

means "72 hours". The court is unaware of any case law relating to the Vaccine Act which takes the contrary position and the parties have provided none. Lastly, the court notes that while the legislative history relevant to the Vaccine Injury Table applicable in this case provides no assistance in interpreting the time period, comments and discussions relating to subsequent amendments to the Table do. This support can be found in the publication of the Final Rule or revision of the Table which became effective March 10, 1995. Under a discussion of the Medical Issues addressed by the revision, and specifically in reference to the injury of an encephalopathy, the notes to the Final Rule provide that "[t]he revised Table confers a presumption of causation on those individuals who suffer an acute encephalopathy within 3 days after vaccine administration, and who then go on to exhibit 6 months of residual effects, followed by chronic neurological dysfunction." The revision to the Table then lists the time period for the first symptom or manifestation of onset or of significant aggravation after vaccine adminstration to be "72 hours". National Vaccine Injury Compensation Program Revision of the Vaccine Injury Table, 60 Fed. Reg. 7678,7688, 7678, 7694 (1995)(to be codified at 42 C.F.R. pt. 100).

10. Because Petitioners have not shown that abnormal electrical brain activity was occurring within the 72 hours following the vaccine's administration, there is no need to determine whether the alleged abnormal activity medically and/or scientifically amounts to the first symptom or manifestation of the onset of the residual seizure disorder, so as to fall within the Vaccine Injury Table's realm of compensation.

11. *See supra* footnote 2 and accompanying text.

12. If it is not medically possible for the DPT vaccine to cause the injury alleged, it ineluctably follows that Petitioners cannot prove that the vaccine in fact caused Billy's injury.

13. As noted earlier in this decision, both parties submitted medical literature in support of their respective positions. However, none of the four expert witnesses addressed specifically any of the articles, and the studies undertaken by the National Childhood Encephalopathy Study and the Institute of Medicine (1991 follow up to the NCES study) were only discussed through limited questioning. Therefore, without further explanation of the literature from the experts, the court will not address the impact or the significance of the submitted literature on Petitioners' case.

14. Dr. Woody testified in the first hearing:

Q: [I]s there anything that leads you to believe that it's more likely than not that his brain was injured within--that his brain was injured after the DPT shot as opposed to weeks, days, months before?

A: No, there isn't. He could have had some neurologic problem which was in no way evident before the DPT.

Tr. I at 76.

15. Dr. Gabriel was the only expert who declared that in 90% of seizure disorder cases, he could determine the probable etiology. Tr. II at 15. The other experts found this percentage to be significantly less. Tr. II at 83 (Dr. Lavenstein testified, "I don't think there's any epileptologist in the United States that can make an etiologic diagnosis of childhood epileptics, childhood seizure disorders, in 90 percent of the cases."); Tr. I at 89-90 (Dr. Frost opined, "Based upon my own experience, I think certainly far more often it's the case that we cannot identify a specific etiology for childhood onset seizures."); Tr. I at 82 (Dr. Woody stated, "Of my own patients, I guess more than half of them are ideopathic.") Dr. Gabriel

provided no support for his statement. In the court's experience over the past eight years, doctors have routinely testified that in approximately 50% of children's neurological abnormalities, no cause is determined.

16. See generally Gherardi v. Secretary of HHS, 90-1466V, 1997 WL 53449, at *8 (Fed. Cl. Spec. Mstr. Jan. 24, 1997), *appeal pending*, discussing which party has the burden of proving the absence of an alternative cause when the causation in fact theory is pursued by petitioner. As the court noted in Gherardi, "with regard to causation in fact cases, case law appears to assign the burden of showing no competing etiologies to petitioner under traditional tort theories, ...while other cases assign the burden to respondent under the statute's factor unrelated provision." (Citations omitted).

17. Compare Gherardi, *supra* at *8, wherein the court found that epidemiological evidence is necessary to find the polio vaccine causative where the experts could not identify a distinguishing characteristic to assign causation between the vaccine and the alternative cause, wild polio virus. No supportive epidemiological evidence was relied upon by Dr. Gabriel.

18. In Daubert, the Supreme Court held that it is the trial judges' responsibility to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." 113 S. Ct. 2786, 2795 (1993); see also Vaccine Rule 8(b) (The special master 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), on remand from 113 S.Ct. 2786 (1993), cert. den., 116 S.Ct. 189 (1995). 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 or potential rate of error is acceptable.

Id.; see also Daubert, 113 S.Ct. at 2796-97. 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, 43 F.3d at 1317. Dr. Gabriel's testimony fails the Daubert standards.