OFFICE OF SPECIAL MASTERS

No. 99-436V V

(Filed: March 23, 2003)

KATHERINE A. THOMPSON, a minor, by her grandmother, BONNIE THOMPSON, and her mother, JAMIE THOMPSON,	*	
Petitioners,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Clifford J. Shoemaker, Vienna, VA, for petitioners.
Althea W. Davis, Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

Petitioners filed a petition on July 2, 1999 under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that their daughter and granddaughter Katherine Allison Thompson (hereinafter, "Allison") suffered an adverse reaction to hepatitis B vaccinations. Allison received hepatitis B vaccinations on September 14, 1996 and November 13, 1996.[1] She received DPT, HiB, and polio vaccinations on November 13, 1996 and January 20, 1997. The onset of her infantile spasms was February 3, 1997. She was hospitalized on February 6, 1997.

[1] The petition confuses the dates of the hepatitis B vaccinations with other vaccinations Allison received.

Petitioners changed their allegations to causation-in-fact encephalopathy following Allison's second DPT vaccination on January 20, 1997, causing infantile spasms 14 days later.[2]

On November 18, 2002, the undersigned held a hearing. Testifying for petitioners were Jamie Lynn Thompson, Bonnie Lee Thompson, and Dr. Carlo Tornatore. Testifying for respondent was Dr. Russell D. Snyder.

At the hearing, petitioners's expert referred to four exhibits (P. Exs. 25 through 28) which petitioners had not filed and which the court, respondent, and respondent's expert Dr. Snyder had not seen. After the hearing, on January 2, 2003, petitioners filed Exhibits 25 through 28. On January 29, 2003, respondent filed Dr. Snyder's response to P. Exs. 25 through 28.

On February 28, 2003, petitioners filed an unsigned response to Dr. Snyder's analysis of P. Exs. 25 through 28. Not only did this response have no signature, but also there was no letterhead or printed name to indicate who had written it.

The undersigned issued an Order dated March 17, 2003 that petitioners had either to refile this response with the signature of the author or to file the author's name. Petitioners' counsel telephoned the undersigned's law clerk to inquire if it was sufficient to obtain Dr. Tornatore's statement that he agreed with the unsigned response to Dr. Snyder. The undersigned conveyed the answer that it was not sufficient. On March 28, 2003, petitioners filed Dr. Mark Robin Geier's statement that he had written the previously unsigned response to Dr. Snyder's analysis of P. Exs. 25 through 28.

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[2] Petitioners' medical expert put the onset of Allison's infantile spasms as one to two days after the second DPT vaccination.

On April 24, 2003, respondent moved to strike Dr. Geier's response to Dr. Snyder's analysis of P. Exs. 25-28 because he was not a witness in the case, respondent had had no opportunity to cross-examine him, and it was patently unfair and in violation of Rule 8(c) of the Vaccine Rules of the United States Court of Federal Claims, RCFC, Appendix B, that these proceedings be "governed by principles of fundamental fairness to both parties."

On May 2, 2003, petitioners opposed respondent's motion to strike Dr. Geier's response to Dr. Snyder's analysis of P. Exs. 25-28 (which petitioners now term Exhibit 29), asking leave to file the exhibit (which the undersigned notes is already filed; hence the motion to strike), and expressing a willingness to reopen the record so that additional evidence from Dr. Geier and Dr. Snyder may be taken, and respondent may have the opportunity to cross-examine Dr. Geier.

The undersigned's determination of respondent's motion to strike will be discussed below in the DISCUSSION section of this opinion.

FACTS

Allison was born on September 13, 1996. She received her first hepatitis B vaccination a day later. She received her first set of vaccinations (2nd hepatitis B, 1st DPT, HiB, and polio) at the age of two months on November 13, 1996. Med. recs. at Ex. 4, p. 4. On December 27, 1996, she had a cough, and congestion. She was crying and gagging on phlegm. Med. recs. at Ex. 4, p. 5. On December 31, 1996, she was on Amoxicillin and was afebrile. Her cough was much worse and kept her up at night. She had paroxysms of coughing. Id.

On January 4, 1997, Mrs. Thompson called the doctor. Allison was on Amoxicillin first, and then sulfa-Albutatrol syrup. Then, she had diarrhea and was not eating. Med. recs. at Ex. 4, p. 6.

On January 20, 1997, at four months, her face was red with a rash and she had cold symptoms. She had finished Pediazole two weeks previously and was on Ventolin. She also had a diaper rash. She was administered her 2nd DPT, 2nd HiB, and 2nd polio. She was diagnosed with an upper respiratory infection. Med. recs. at Ex. 4, p. 5.

Seventeen days later, she returned to the doctor on February 6, 1997, with a temperature of 99° rectally and a history of episodes of jerking and straightening her body before sleep and waking up, which had become progressively more frequent. Mrs. Thompson denied that Allison twitched. She jerked only once and then the episode was over. She had no other symptoms and was afebrile. Her appetite was slightly depressed and she had a change in personality. On physical examination, Allison was alert and well-appearing. Mrs. Thompson and her mother reported an increase in fussiness. Allison was acting differently. She had had as many as 20 episodes in the prior 24 hours. Her color and respiratory pattern had not changed. The episodes occurred always around times of sleep. The episodes were described as flexion of the arms and legs and turning of the head to the right side. There were no repetitive motions, i.e., no tonic-clonic movements. Med. recs. at Ex. 4, p. 6.

Allison went to the Alamance Regional Medical Center Emergency Department on February 6, 1997 at 6:00 a.m. Med. recs. at Ex. 14, p. 5. She had an increase in crying every day and tightened her muscles periodically. Mrs. Thompson stated that Allison had had cold symptoms since November. She had muscle spasms each week. She had crying and pulling at her ears on February 5th. The child was sleeping in the Emergency Department and her color was good. At 6:40 a.m., she was discharged. Id.

A history taken was that Allison had been fussy since 2:30 a.m. She had occasional jerks when she was going to sleep. She had a decrease in appetite. Med. recs. at Ex. 14, p. 6.

On February 6, 1997, Allison was admitted to The North Carolina Memorial Hospital. The Intern Admit Note of February 6th states that Allison had a new onset of spasm on Monday, February 3, 1997, while waking consisting of tilting and turning her head to the left. There were no eye deviation, lip smacking, or extremity involvement. She had been irritable on Saturday, February 1, 1997, through Monday, February 3rd. She had decreased appetite for two days. On Monday, February 3rd, she had decreased level of activity, increased irritability, and decreased intake by mouth. Her urinary output and bowel movements had not changed. Then, on February 4th, she had four episodes in the evening. Each began when she wakened from short naps. She turned her neck and head to the left and had lots of gas during the spasm, but no bowel movement or urinary output. She was slightly less irritable. Med. recs. at Ex. 6, p. 15.

On February 5th, the spasms started at 2:00 p.m. Allison's grandmother thought they happened more often when Allison was exhausted. She did not have head movements or a facial expression of being frightened or in pain. She tightened her whole body. Allison had spasms when going to sleep or waking. She went to sleep at 8:00 p.m. and woke screaming at 2:00 a.m. the day of admission. She fell back to sleep and was kicking her legs during sleep. Then at 2:30 a.m., she awoke screaming and did not settle down until she was in the car at about 5:00 a.m. She was seen in Alamance Regional Hospital and diagnosed with colic.

Her grandmother called the pediatricians who saw Allison. The case was discussed with Dr. Greenwood and she was taken to UNC for admission. Allison did not have any fever. She had a dry

cough and some mucous discharged from her nose and throat. Mrs. Thompson had early cold symptoms as well. Id.

On neurological examination, Allison was alert, active, responsive, playful, and reached for toys. She moved all extremities well. Her reflexes were symmetric and she had no gross deficits. She was diagnosed with infantile spasms. Med. recs. at Ex. 6, p. 16.

Developmentally, Allison cooed, raspberried, reached for objects, rolled to both sides and sat independently. Her paternal aunt (her father's half-sister) has a history of seizure/twitching, and eye deviation. Her maternal uncle has a history of febrile seizures. Her maternal grandmother has a history of seizures. Med. recs. at Ex. 6, p. 17. The doctor described Allison as vigorous. Id.

Dr. Robert S. Greenwood, the pediatric neurology admitting physician, wrote a note on February 6th, stating that Allison was admitted for spells of jerking which began three days previously (or February 3, 1997) during an upper respiratory infection. The spells were characterized by slight head turning and flexion of the extremities and neck. They were very brief but occurred in clusters around sleep. On February 5, 1997, she had 10 to 15 of these jerks. She had been more irritable and cried more on February 6th. Her appetite and activity had declined over that week (February 6th was a Thursday). Her parents felt she had developed normally and more rapidly than her siblings. On physical examination, Allison was alert and in no distress. Her temperature was 35.9° C (or 96.6° F). Med. recs. at Ex. 6, p. 5.

On neurological examination, Allison was alert and oriented. She appeared to have normal development. She had normal tone, bulk, and strength. Her coordination was normal, without tremor or movement disorder. The diagnosis was infantile spasms. Id.

The neurologist noted that Allison had a longstanding history of upper respiratory infection whose first spells, lasting one to two seconds, were on February 3, 1997 during the evening. She had had an upper respiratory infection with coughing and sneezing since November 1996. Developmentally, Allison was normal. She cooed, smiled, laughed, used her head well, and sat by herself. Her father's sister had seizures at ages 10 to 13, but none since and her aunt's EEG was normal. Med. recs. at Ex. 6, p. 18.

Allison woke at 2:00 a.m. and screamed for two to three hours straight. She continued to have spasms that afternoon for a total of 8 to 10. Supposedly, she had a frightened look, but no gross head deviations, eye deviations or respiratory problems. Id. She had a good appetite and no irritability or lethargy. Med. recs. at Ex. 6, p. 19.

At 4:00 p.m. on February 6, 1997, Allison had her eyes open, and she was attentive and interactive. She visually tracked and fixed to auditory and visual cues. She cooed. Id.

Allison's EEG, which Dr. Michael Tennison and Dr. Joseph Handler performed on February 6, 1997, showed a diffusely high amplitude and slightly chaotic slow background with multifocal but generally synchronous spike and sharp wave activity. The diffuse background slowing was suggestive of bihemispheric dysfunction as in encephalopathy due to toxic, metabolic, or primary neuronal disorders. Multifocal epileptiform activity was also suggestive of a generalized or partial onset seizure disorder. In combination, the findings were consistent with the definition of hypsarrhythmia. Med. recs. at Ex. 6, p. 4.

Allison's MRI of her brain, which Dr. Jill E. Thompson did on February 7, 1997, resulted in the interpretation that Allison's corpus callosum was slightly thin although normally myelinated. Of note was a non-specific prominence of the extra-axial cerebrospinal fluid (CSF)- containing

spaces. Allison's cerebral hemispheres were slightly asymmetrical with the left being larger than the right. Med. recs. at Ex. 6, pp. 66-67.

An x-ray of Allison's chest on February 9, 1997 showed cardiomegaly (enlargement of the heart).[3] Med. recs. at Ex. 6, p. 69.

In a pulmonary evaluation of Allison's persistent cough, the parents first noted Allison to cough in November 1996 in association with upper respiratory symptoms. The upper respiratory symptoms resolved but Allison had been coughing since, primarily when going to sleep or awakening. She was prescribed several antibiotics without effect. She had a clinical diagnosis of respiratory syncytial virus (RSV) in early January. She had wheezing with this illness and was prescribed oral Albuterol. Allison had a history of spitting up about once a day. She did not cough or choke with her feeds. She had had a more acute component of her cough in the last few days. Her cough had become moist with some rattling in her chest. She had modest rhinorritis. Mrs. Thompson also had some bronchitis recently.

On examination, Allison was alert and vigorous. Her respiration was comfortable. The doctor's impression was a mild upper respiratory infection accounting for the change in her cough characteristics. Med. recs. at Ex. 6, p. 71.

She was discharged from the hospital on February 9, 1997 and prescribed ACTH. Med. recs. at Ex. 6, pp. 73-74.

On February 12, 1997, Allison returned to her pediatrician with cold symptoms and gagging on phlegm. She had more frequent episodes of spasms and decreased sleep and appetite, but was

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[3] Stedman's Medical Dictionary, 27th ed. (2000) at 290.

afebrile. She had had six days of congestion without fever. She was taking the bottle well, but had difficulty sleeping. She had a mild wheeze. Med. recs. at Ex. 4, p. 6.

On August 27, 1997, Allison had an MRI of her brain done. Dr. Suresh K. Mukherji saw abnormal pineal region masses. The subarachnoid spaces and ventricles were prominent. Med. recs. at Ex. 8, p. 51.

A PET scan done on March 10, 1998 showed mild, asymmetrically diminished uptake in the left temporal lobe that suggested an interictal seizure focus. Med. recs. at Ex. 20, p. 59.

Allison was at the Duke University Medical Center, from May 5 to 9, 1998, with a diagnosis of infantile spasms, and secondary diagnoses of developmental coordination disorder and autosomal deletion syndromes. Med. recs. at Ex. 20, p. 8. Her abnormal video EEG pointed to left temporal region abnormalities. Med. recs. at Ex. 20, p. 28. A PET scan showed abnormal uptake in the left temporal region. Id.

The discharge summary from Duke, dated May 9, 1998, and written by Dr. Mark Wainwright, states that Allison had a maternal aunt with a history of seizures until menarche. Med. recs. at Ex. 20, p. 53. Allison had a narrow, sloping forehead and pointed chin. The philtrum (the groove in the midline of the upper lip)[4] was elongated. There was a single 3 cm. café au lait spot in her mid-lumbar region. Id.

On July 10, 1998, Allison had an EEG which was abnormal. There was evidence of focal neuronal dysfunction or the presence of a structural lesion in the left posterior quadrant which was potentially epileptogenic in nature. Med. recs. at Ex. 20, p. 92. On July 28, 1998, an MRI showed no evidence of cortical dysgenesis. Med. recs. at Ex. 20, p. 108.

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[4] Stedman's, supra, at 1368.

On June 29, 1999, Allison was evaluated at the Developmental Evaluation Center in Greensboro, NC. Med. recs. at Ex. 15, p. 2. In the family medical history section is noted that Allison's mother required special reading classes in elementary school and Allison's father had significant learning difficulties in school and speech and language difficulties. There is a paternal family history for learning difficulties, speech and language delays, seizures (not infantile spasms), depression, and drug/alcohol abuse. There is a maternal family history for mental retardation, alcohol abuse, and muscular dystrophy. Med. recs. at Ex. 15, p. 3.

Submissions

Petitioners filed Exhibit 23, consisting of medical articles to which Dr. Tornatore referred in his expert report to support his point that pertussis toxin is an excitatory neurotoxin. These articles are:

1. "12-Hydroxyeicosatetrenoate (12-HETE) Attenuates AMPA Receptor-Mediated Neurotoxicity: Evidence for a G-Protein-Coupled HETE Receptor," by A.J. Hampson and M. Grimaldi, 22 *J Neuroscience* 1:257-64 (2002).

2. "HIV-1 Tat through phosphorylation of NMDA receptors potentiates glutamate excitotoxicity," by N.J. Haughey, et al., 78 *J Neurochemistry* 457-67 (2001).

3. "Agonist Stimulation of the Serotonin1A Receptor Causes Suppression of Anoxia-Induced Apoptosis via Mitogen-Activated Protein Kinase in Neuronal HN2-5 Cells," by T. Adayev, et al., 72 *J Neurochemistry* 1489-96 (1999).

4. "mGluR7-like metabotropic glutamate receptors inhibit NMDA-mediated excitotoxicity in cultured mouse cerebellar granule neurons," by M Lafon-Cazal, et al., II *European J of Neuroscience* 663-72 (1999).

On January 2, 2003, after the hearing in this case on November 18, 2002, petitioners filed Exs. 25 - 28 containing an article and three abstracts to which petitioners' expert Dr. Tornatore referred at the hearing, but which petitioners had not provided to either respondent or the undersigned until the hearing:

1. Ex. 25 - Goodman, M., Lamm, S.H., and Bellman, M.H., "Temporal relationship modeling: DTP or DT immunizations and infantile spasms," 16 *Vaccine* 2/3:225-31 (1998). The authors concluded that DPT has no effect on the causation of infantile spasms. Id. at 229.

2. Ex. 26 - (abstract) Kuno-Sakai, H. and Kimura, M., "Epidemiology of Pertussis and Use of Acellular Pertussis Vaccines in Japan," 89 *Dev Biol Stand* 331-32 (1997).[5] In Japan, in 1970, a compensation system for vaccine adverse reactions was started. The authors attached to their 24-line abstract Table 1 showing the frequency of reported severe adverse events in applications to the compensation system for payment following whole cell and acellular pertussis vaccination per 10 million doses administered. From 1970 to 1980, out of 44.9 million doses of whole-cell pertussis, there were reported to the compensation system 1.3 cases of infantile spasms per ten million doses (or 5.8 total infantile spasm cases–1.3 x 4.49=5.8) for a probability (or P) value of 0.013. There were no cases reported to the compensation system of infantile spasms among 62.6 million doses of acellular DPT from 1981 to 1993. Id. at 332.

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[5] Volume 89 of *Developments in Biological Standardization* is actually a book published in June 1957, edited by Fred Brown, whose title is "Pertussis Vaccine Trials: Istituto Superiore Di Sanita, Rome, Italy October 30-November 1, 1995." It contains 410 pages, is published by S. Karge, and is available on www.amazon.com for $339.25. Its ISBN is 3805564813. Http://www.amazon.com/exec/obidos/t...02-7420251-0144168?v=glance&s=booksA "This book contains the proceedings of the International Symposium on Pertussis Vaccine Trials, held in Rome in October 1995. The meeting was organized following the almost simultaneous release of the results of five clinical trials and two other clinical studies…" http://www.mioti.com/cat/condition/condition.asp?Cat=Pertussis

3. Ex. 27 is an excerpt from the National Childhood Encephalopathy Study (NCES),[6] pp. 1-78 (see R. Ex. E for the remainder of the NCES).

4. Ex. 28 consists of two abstracts. The first is "Pertussis encephalopathy with high cerebrospinal fluid antibody titers to pertussis toxin and filamentous hemagglutinin," by C.C. Grant, et al., 102 *Ped* 4 (Pt 1): 986 (1998). A 7-year-old girl who had wild pertussis, not DPT vaccination, had an encephalopathy. She also had pertussis antibodies in her cerebrospinal fluid (CSF), indicating entry of pertussis antigen into her central nervous system. The second abstract is "Epidemiological features of pertussis in hospitalized patients in Canada, 1991-1997: report of the Immunization Monitoring Program–Active (IMPACT)," by S.A. Halperin, et al., 28 *Clin Infect Dis* 6:1238 (1999). It discusses the disease pertussis and its complications.

Respondent filed excerpts from Adverse Effects of Pertussis and Rubella Vaccines, Institute of Medicine (IOM) (1991), chapter 4, "Evidence Concerning Pertussis Vaccines and Central Nervous System Disorders, Including Infantile Spasms, Hypsarrhythmia, Aseptic Meningitis, and Encephalopathy," pp. 65-82. R. Ex. B. After reviewing the medical literature concerning DPT and infantile spasms, especially the NCES, the IOM concluded that "evidence does not indicate a causal relation between DPT vaccine or the pertussis component of DPT and infantile spasms." Id. at 77.

Respondent filed Dr. Snyder's response to P. Exs. 25 to 28 since he did not have an opportunity to read them before trial. R. Ex. F. In particular, regarding the Bellman article, P. Ex. 25, Dr. Snyder stated that the probability (or P) value for infantile spasms 0-6 days after DPT

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[6] Alderslade, R., Bellman, M.H., Rawson, N.S.B., Ross, E.M., and Miller, D.L. "The National Childhood Encephalopathy Study," in *Whooping Cough: Reports from the Committee on Safety of Medicine and the Joint Committee on Vaccination and Immunisation* (London: Her Majesty's Stationery Office, 1981). R. Ex. E.

immunization was 0.14, meaning it was not statistically significant. The number of subjects was seven, being quite small. The authors of the study stated none of the data fit an association model between DPT and infantile spasms.

If the undersigned were to accept the statements of Dr. Geier, petitioner's "stealth witness," filed unsigned and unacknowledged as "A Reply to Dr. Russell Snyder's Comments" (P. Ex. 29), the gist of Dr. Geier's comments is that statistical significance is unimportant since the court needs a standard of only more likely than not to rule for petitioners. Dr. Geier fails to understand that the undersigned accepts data which are persuasive to individuals in the field at issue (epidemiology, here) in order to accept their conclusions. An association which would not persuade the medical authors of a study investigating a causal association of DPT and infantile spasms similarly does not persuade the undersigned.

Additionally, Dr. Geier speculates that if only there had been larger numbers of cases and controls, there would have been statistical significance. The undersigned does not reach decisions based on speculation. Dr. Geier provided an article written in 1957 concluding that it is "suggestive but not clear-cut" that DPT "may be a factor" in the production of infantile myoclonic seizures, and "it seems possible that DPT immunization could be responsible for this convulsive disorder." The close following of onset of seizures in their nine patients after immunization suggested to the authors of this study that causation "would have to be considered." However, three of the nine children had a history of difficulty prior to their onset of seizures. "Infantile Myoclonic Seizures," by H.W. Baird and L.G. Borofsky, 50 *Ped* 332-39, 337, 338 (1957). (Attachment D to Dr. Geier's report.) The undersigned rules based on probability, not possibility, and mere temporal association is legally insufficient to prove causation. The authors of this study conclude: "Although a large number of

infantile myoclonic seizures seem to be prenatally determined, some would appear to have their origin in encephalopathies of various etiologies. In the latter group, pertussis immunization should be considered as an etiological possibility." Again, the standard for the undersigned is probability, not possibility.

TESTIMONY

Mrs. Jamie Lynn Thompson testified first for petitioners. Allison was a very alert baby, fed well, and played with toys. Tr. at 8. But she would have projectile vomiting from drinking too quickly. Tr. at 9. After Allison's two-month vaccinations at 1:30 p.m. on November 13, 1996, Mrs. Thompson was on the second shift at 3:00 p.m. Tr. at 10. Her mother-in-law called and said that Allison was screaming out of control and her leg was swollen and red. Id. Her mother-in-law called the doctor's office, which recommended ice, a warm bath, and Tempra for several hours. Tr. at 11. After five hours, Allison calmed down. Id. She did not seem as happy as before. Tr. at 12.

Allison got RSV around Christmas, December 23rd, and was horribly sick. Tr. at 12. She was choking and coughing from congestion. Id. She was sick all through Christmas. Id. She was diagnosed with RSV on December 27th. Id. The RSV lasted 63 days. Tr. at 13. Allison slept in a car seat so she would not choke. Id.

Allison would have had her four-month check-up on January 13, 1997, but she was terribly sick and had a rash around her mouth. Tr. at 13. Her immunizations were postponed. Id. On January 20, 1997, Mrs. Thompson took Allison in for a sick visit because she was not improving. Tr. at 14. She had a lingering cough and rash. Id. The doctor said Allison had no fever and would be fine. Id. He suggested giving Tempra before administering the immunizations for DPT, HiB, and polio, at 1:30 p.m. Tr. at 15. Mrs. Thompson went to work and dropped Allison at her mother-in-

law. Id. Mrs. Thompson received phone calls from her mother-in-law that Allison was screaming, her vaccination site was very painful, and Mrs. Thompson wanted to take her to the emergency room. Tr. at 16. By 11:25 p.m., Allison was fine. Id. She had calmed down and they were ten minutes to home. Tr. at 17.

Allison was very cranky afterwards. Tr. at 17. One to two days afterward, she would pull her legs in. Id. Mrs. Thompson thought Allison had stomach aches. Id. No stomach pain drops comforted her. Id. She did not smile as much and was not as interested in her toys. Tr. at 18. This lasted two weeks. Id.

On February 3, 1997, Mrs. Thompson's mother-in-law saw Allison jerk. Tr. at 18. On February 4, 1997, she saw Allison jerking on one side two to three times. Id. The mother-in-law called the doctor. Tr. at 19. Allison had a doctor's appointment on February 6, 1997. Id. At 11:45 p.m. on February 5th until 4:00 a.m. on February 6th, Allison was screaming. Id. They went to the ER at Alamance County Hospital. Tr. at 20. Allison was asleep and the doctor told her that she had colic. Id. She saw Allison jerking on one side during the night. Tr. at 21. They saw Dr. Duffy who drew blood and called Chapel Hill Hospital and a neurologist there. Tr. at 22. At Chapel Hill, Allison had an MRI and EEG, and was diagnosed with infantile spasms. Tr. at 23. They prescribed ACTH, but Allison's RSV was so bad that they could not give her ACTH since it affects the immune system. Id. She had seizures every few minutes and was screaming. Tr. at 24. She had no rest. Id. Her seizures lasted one second and ran from 10 per day to 30-40 per day. Tr. at 25.

ACTH had no effect on Allison until she was given a maximum dose, and the seizures stopped. Tr. at 28. Allison drank 8 bottles of fluid a night and "blew up." Tr. at 26. ACTH caused Allison's blood pressure to rise and breathing difficulties. Tr. at 27. She was weaned off ACTH on

which she had been grumpy but seizure-free. Tr. at 28. Within two days of being off ACTH, Allison seized again. Id. They have tried 24 medications. Id. Allison does not have a focal point for her seizures and thus cannot have a brain resection. Tr. at 29. She does not say much. Tr. at 30. She began to walk at 16 months. Id. She has balance problems and wears a helmet with a face guard. Tr. at 31. She has been diagnosed with Lennox-Gastaut syndrome.[7] Tr. at 32. She has never cried as she did after both DPT vaccinations. Id. She screamed loudly from February 5 - 6, 1997. Id. On January 4, 1997, Mrs. Thompson called the doctor because Allison had diarrhea since January 1, 1997. Tr. at 49. Allison had had stomach aches prior to February 1, 1997, but they were smaller ones. Tr. at 53. Mrs. Thompson's brother had febrile seizures. Tr. at 66.

Bonnie Lee Thompson testified next for petitioners. Her daughter Nicole had a reaction to DPT consisting of a rash and her further doses were reduced 1/4. Tr. at 71-72. Mrs. Thompson babysat Allison from 3:00 to 11:00 p.m. Tr. at 74. She was a happy, contented baby. Id. She babbled, held her bottle, did raspberries, and played patty cake. Id.

At 3:00 p.m., after her first DPT on November 13, 1996 at 1:00 p.m., Allison screamed at the top of her lungs for 30 minutes. Tr. at 75. Mrs. Thompson checked her diaper. Id. Allison's leg was swollen, huge, hot, and red. Id. Mrs. Thompson gave her Tempra. Id. Allison kept screaming and would not take her bottle. Id. After 5 hours, she calmed down and went to sleep. Tr. at 76. She recovered after the first DPT. Id. Then, she developed an infection. Tr. at 78. On December 23, 1996, she was coughing, choking, and had phlegm. Tr. at 79. On December 27th and

[7] "Lennox-Gastaut syndrome is characterized by the triad of seizures ..., slow spike-wave complexes on EEG, and mental retardation." Clinical Pediatric Neurology. A Signs and Symptoms Approach, 3d ed. (1997) by G.M. Fenichel, at 22.

30th, 1996, she saw the doctor. Id. Allison had low-grade fever, mucous came up, it was hard to put her down, and she slept in the car seat. Id.

On January 13, 1997, they cancelled the doctor's appointment for immunizations. Tr. at 80. On January 20, 1997, Mrs. Thompson and her daughter-in-law took Allison in to see the doctor because she was not getting better from her RSV. Id. They saw Dr. Scott. Tr. at 81. Allison did not have any fever, but could not lie down. Tr. at 82. She had a rash around her mouth and cold symptoms. Id. The nurse gave Allison Tempra and then her second DPT. Tr. at 85. Allison's leg swelled again and she screamed for five hours, but was then okay. Id. She screamed all night long, and her legs tightened up. Tr. at 87. Allison was not happy, would not smile, and pulled her legs up. Id. She was not losing weight and urinated normally. Id. After the second DPT, Allison did not know her. Tr. at 88.

On February 3, 1997, Mrs. Thompson saw a jerk. Tr. at 90. A day later, she saw three jerks and scheduled a doctor's appointment on February 6, 1997. Id. They were at the ER at 4:30 a.m. on February 6, 1997, where they were given a diagnosis of colic. Tr. at 91. Allison started ACTH at the end of February and finished it in mid-April. Tr. at 96. She tapered off ACTH, but the seizures came back. Id.

Dr. Carlo Tornatore, an adult neurologist who specializes in molecular pathogenetics and viruses, testified next for petitioners. Tr. at 122. He spends 50% of his clinical practice working on demyelinating and inflammatory disorders such as multiple sclerosis, vasculitis, epilepsy, and Parkinson's. Tr. at 124. He devotes the other 50% of his time to education and research. Id. His only experience with infantile spasms is the two cases he saw as a medical resident. Tr. at 124-25.

He has almost no experience with RSV. Tr. at 126. He has extensive experience with encephalopathy in adults. Tr. at 127.

Dr. Tornatore stated that acute encephalopathy is a sudden change in behavior. Tr. at 129. When Allison screamed for 5 hours, it was with a different kind of scream. Id. This is how an immature brain manifests encephalopathy. Tr. at 130-31. Dr. Tornatore testified that Allison had two episodes of acute encephalopathy, one after each DPT, but "this is total speculation on my part." Tr. at 130. Her brain was too immature at two months to manifest infantile spasms, unlike her more mature brain at four months. Tr. at 131-32. He thinks the onset of Allison's infantile spasms was very shortly after the January 20, 1997 vaccination. Tr. at 132. He interprets Allison's screaming as an acute encephalopathy and her bringing her legs up as really an infantile spasm that no one recognized. Tr. at 133. However, Mrs. Thompson also testified that she brought her legs up after the first immunization, and Dr. Tornatore was "hard pressed to say that was an infantile spasm" because, at two months, she would have been too young. Id. So he ascribed her bringing her legs up at two months to a spasm related to the pain. "That's total speculation," he stated. Id.

The EEG done on February 6, 1997 showed hysarrhythmia which Dr. Tornatore stated did not begin overnight but earlier. Tr. at 134. Her MRI was normal. Id. He testified that encephalopathy and infantile spasms are symptoms of an injured brain. Tr. at 135. He considered Allison's swollen leg important, showing a very adverse reaction. Tr. at 136. She also had eczema and a diaper rash as well as RSV. Tr. at 137. If Allison had a viral syndrome, she should not have been given a vaccination. Tr. at 136. She was prescribed monilia which is microstatin cream against fungus. Tr. at 137.

Dr. Tornatore does not interpret the NCES as concluding that DPT does not cause infantile spasms. Tr. at 140. He believes that the incidence of infantile spasms reported to the NCES was lower than the actual number of cases because the NCES relied on hospitalizations for its cases. Tr. at 144. The undersigned mentioned to Dr. Tornatore that Allison was hospitalized. Id. Dr. Tornatore testified that Allison would have been included in the NCES in the encephalopathy part and in the infantile spasms part of the study. Tr. at 144-45.

In the NCES, screaming was the third most common neurological event reported and infantile spasms was the second. Tr. at 145. Screaming preceded other neurologic events. Id. Referring to the Melchior analysis of Danish data, Dr. Tornatore acknowledged that a change in pertussis vaccine schedule from five, six, and 15 months of age to five weeks, nine weeks, and ten months of age made no difference in the overall age of onset of infantile spasms. Tr. at 147. Looking just at the earlier age of onset, he said there was an increased incidence of infantile spasms following DPT, but it did not reach the level of statistical significance. Tr. at 147-48.

In the 1983 Bellman study[8] using the NCES data on infantile spasms, from zero to six days after immunization, the odds ratio was 2.31, but the number of cases was small, making the probability (or P) value 0.14 (not statistically significant). Tr. at 150. The odds ratio for the first six days after immunization was much higher than during the subsequent weeks. Id. Dr. Tornatore opined that the P value would have been higher if the NCES had had more cases. He stated that

[8] Although the undersigned's question to Dr. Tornatore concerned the 1983 Bellman article, Dr. Tornatore's answer and petitioners' subsequent filing were of the 1998 Bellman article which revisited the NCES analysis of infantile spasms and reached the same conclusion of no causality from DPT.

Allison fits into a group that would have had a higher odds ratio of association if they had been "teased" out. Tr. at 151.

Dr. Tornatore said the Kimura paper showed a statistically significant rate of infantile spasms after whole-cell pertussis vaccine as compared to no infantile spasm cases after acellular pertussis. Tr. at 151-52. He considered that if the incidence of infantile spasms were unrelated to DPT, the rate after both whole-cell and acellular vaccinations would have been identical. Tr. at 152.

Dr. Tornatore said Allison's screaming was a direct effect of the immunization. Tr. at 156. Both the screaming and the infantile spasms suggest that there was injury to the brain. Allison cried after both vaccinations. Tr. at 157. The second DPT was a rechallenge. Tr. at 158. Allison's grandmother then testified that Allison's crying after the vaccinations was high-pitched and scared her. She had never heard it before. Id.

Allison had the RSV infection for over 60 days and never had an infantile spasm. Tr. at 162-63. Dr. Tornatore thinks the infection had a synergistic effect and alone would not have caused the infantile spasm. Tr. at 163. But the rechallenge with pertussis vaccine was a substantial factor. Tr. at 162-63. Explaining biologic plausibility, Dr. Tornatore said that people in laboratories use pertussis toxin and toxoid as a toxin for nerves. Tr. at 164. At the molecular level, people use it to block a series of different channels and secondary messengers. Id. It makes sense to Dr. Tornatore that pertussis toxin can be toxic to the brain. Tr. at 164-65.

He recalled a paper concerning a child who had wild pertussis who developed infantile spasms. Tr. at 165. He said he could bring a reference.[9] Id. In the glass test tube (in vitro),

[9] The first abstract petitioners later submitted as part of their Exhibit 28 concerns a seven-year-old girl who had wild pertussis and, subsequently, her CSF was found to contain antibodies to pertussis, showing entry of pertussis antigen into her central nervous system, but the

pertussis toxin is very potent and does not require a great deal to cause changes. Id. "In vivo [in a living body], we don't know." Id. His assumption is that DPT has not only pertussis toxin, but also some endotoxin that allows the pertussis toxin to enter the brain more quickly. Id. The timing in Allison's case fits with the toxic effect because she immediately began to feel bad and had significant enough injury to her brain to start screaming. Id.

Once the neurotoxin enters the brain, it injures it, causing kindling where the seizures feed on themselves and are very difficult to stop. Tr. at 166. This results in developmental delay, profound mental retardation, and intractable seizures. Id. Because the MRI is normal, the toxic effect is very small and not a gross effect on the whole brain. Id.

Dr. Tornatore is not a pediatric neurologist and does not treat babies. Tr. at 175. He sees adults primarily with immune-related disorders (MS and vasculitis), and 5% of his patients are adolescents. He was not sure how many patients he sees. Tr. at 178, 179. From 5 to 10% of his patients have seizure disorders. He sees no pediatric patients with seizure disorders. Tr. at 179. Most of his publications concern HIV. His first paper was on vaccines. Id. He deals with live viruses in his laboratory, not toxoided viruses, although some may have been inactivated in some way. Tr. at 180.

Dr. Tornatore has not published anything on infantile spasms. Tr. at 181. In his practice, he has not seen anyone with infantile spasms. Id. His opinion is that Allison's infantile spasms began within a couple of days after her second DPT but were misinterpreted as colic. Tr. at 183. His opinion is that Allison's EEG was consistent with encephalopathy as well as hypsarrhythmia. Tr.

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abstract does not mention that she had infantile spasms. It mentions only that she had pertussis encephalopathy. Petitioners never filed any article that would support Dr. Tornatore's testimony that a child had infantile spasms after wild pertussis infection.

at 185. The EEG is incapable of distinguishing between an acute and a chronic encephalopathy. Tr. at 186. He believes Allison had a severe insult to her brain after her first DPT at two months of age. Tr. at 188. He explained the lack of any notation of neurological injury to Allison's brain in the medical records between the ages of two and four months as due to a "subtle injury" to her brain. Id. She made new milestones. Id. She sat up at four months. Id. He would agree this was a transient injury and not permanent damage. Id.

Dr. Tornatore testified that we really do not know neurologically what happened to Allison after her first DPT when she stopped crying. Tr. at 189. She continued to develop, but perhaps there were "more subtle things" that someone could have found. Id. Allison did not manifest seizures at two months because her brain was too immature. Id. When asked about the situation where a neonate has seizures from birth, Dr. Tornatore responded that it does not always happen. Tr. at 189-90. Usually something is so profoundly wrong with the brain that the brain gives up and the child has a seizure disorder. Tr. at 190. Infantile spasms do not occur until four months going until eight months. Tr. at 191-92. He admitted that, although unusual, a two-month-old could manifest infantile spasms. Tr. at 192. He continued, "That is why we're here today. We're talking about unusual things that could happen. If we want to talk about that, then you're going to support our case." Id.

On December 31, 1996, Allison had paroxysms of coughing and the doctor wondered if she had the disease pertussis. Tr. at 193-94. The doctor diagnosed RSV, but nothing in the record confirms either diagnosis. Tr. at 194-95. The doctor prescribed Pediazole, but Dr. Tornatore was unfamiliar with it. Tr. at 194. Pediazole would be used to treat pertussis since it contains erythromycin. Tr. at 196. Venalin is a bronchodilator. Tr. at 196.

Allison's chronic infection probably stimulated her T and B cells. Tr. at 201. A vaccination will challenge an activated immune system, causing fever and profound problems. Id. However, Allison did not have fever. Id. Referring to the Bellman paper again, Dr. Tornatore stated that the data for the first week was suggestive of a relationship between DPT and infantile spasms even if it did not reach statistical significance because the numbers were small. Tr. at 206. Dr. Tornatore stated, "I can never prove this case on a statistical basis." Tr. at 208. To Dr. Tornatore, infantile spasms and convulsions are essentially the same, being manifestations of injury to the brain or an encephalopathy. Id. Therefore, he does not think the NCES study actually says that there was not sufficient proof that DPT causes infantile spasms because the study links convulsions to DPT. Id. His opinion is that the reason infantile spasms did not rise to the level of causation (which convulsions had done) is that infantile spasms were underreported. Tr. at 208-09.

Dr. Russell D. Snyder testified for respondent. Tr. at 218. He is a pediatrician and pediatric neurologist. Id. He is board-certified in pediatrics, neurology, and neurology with special competence in child neurology. Id. He has been practicing pediatric neurology for 36 years. Id. He currently sees patients one day a week. Id. He went to part-time practice in 1998. Id. He is on a faculty full-time. Id. Fifty percent of his patients have seizure disorders. Tr. at 219. He has treated 50 patients with infantile spasms, or two to three a year. Id.

Infantile spasms are a peculiar type of seizure in an age group with an EEG showing hypsarrhythmia. Tr. at 220. In 50 to 60% of the cases of infantile spasms, one knows the etiology (symptomatic infantile spasms). Id. In 40 to 50% of the cases of infantile spasms, one does not know the etiology (cryptogenic infantile spasms). Id. The onset occurs usually over several days

and is frequently mistaken for colic. Tr. at 220-21. Infantile spasms have devastating sequelae. Tr. at 221.

Dr. Snyder testified that Allison's onset of infantile spasms was on February 4, 1997. Tr. at 221. He pointed to the written intern admission note of February 6, 1997 that indicated a February 4th onset. Tr. at 223. Nowhere in the pediatric medical records is there any notation of Allison's reacting to her two DPT vaccinations. Tr. at 222. On January 20, 1997, when she received her second DPT, she had cold symptoms. Tr. at 223. This is unrelated to her later diagnosis of infantile spasms. Id.

Dr. Snyder testified that Allison did not have symptoms of encephalopathy between January 20, 1997 when she received her second DPT and February 6, 1997 when she was diagnosed with infantile spasms. Tr. at 223. A brief period of crying is not acute encephalopathy. Tr. at 224. She did not have encephalopathy on admission to the hospital. Tr. at 226. Based on the medical records, Allison did not have an acute encephalopathy at any time. Tr. at 227.

In Dr. Snyder's opinion, Allison's RSV did not play any role. Tr. at 228-29. Her immune system was not primed. Tr. at 229. The medical literature is overwhelmingly against ascribing infantile spasms to DPT. Id. The Institute of Medicine says there is no association. Tr. at 230. Allison would fit into Bellman's second column (onset of infantile spasms in the second week after DPT) rather than in Bellman's first column (onset of infantile spasms in the first week after DPT). Id. In the second week, those with DPT had a lower rate of infantile spasms than those inoculated with Dt (tetanus). Tr. at 231. Bellman and his co-authors concluded that there is no proof that DPT causes infantile spasms. Tr. at 230. In the NCES, infantile spasms were overdiagnosed because so many recovered completely. Tr. at 233. Dr. Snyder also opined that Allison's upper respiratory

infection did not cause her infantile spasms. Tr. at 235-36. On cross-examination, Dr. Snyder admitted that, according to the NCES, screaming can be a neurological manifestation. Tr. at 235.

DISCUSSION

Petitioners have two options under the Vaccine Program: (1) to proceed under the theory of a Table injury or (2) to proceed on a causation in fact theory. Petitioners have opted for causation in fact. Petitioners allege that both of Allison's DPTs caused encephalopathy because she screamed after each one and, after her second DPT, she had infantile spasms a day or two later also caused by DPT.

The first question is whether or not Allison had an acute encephalopathy after either DPT vaccination. The medical records are totally silent as to any symptomatology of encephalopathy. On seeing her pediatrician on February 6, 1997, Allison had jerking and straightening of her body, a slight decrease in appetite, and a change in personality. But on physical examination, she was alert and well-appearing. Mrs. Thompson and her mother-in-law reported an increase in fussiness and a change in behavior.

Allison went to the Alamance Regional Medical Center Emergency Department, with a history of increased crying every day and tightening her muscles periodically. Mrs. Thompson stated that Allison had cold symptoms since November and muscle spasms each week. She was crying and pulling at her ears since the prior day. The hospital staff diagnosed colic.

On admission to The North Carolina Memorial Hospital, Allison's mother and grandmother noted the new onset of spasms on February 3, 1997, and prior irritability starting on February 1, 1997 with a decreased appetite for two days. On Monday, February 3, 1997, she had decreased level of activity, increased irritability, and decreased eating. Her urinary output and bowel movements did

not change. She woke up screaming at 2:00 a.m. on February 6th and continued screaming for three hours. Allison was afebrile. She still had cold symptoms, a dry cough and some mucous discharge. Mrs. Thompson had early cold symptoms also.

On neurological examination, Allison was alert, oriented, responsive, playful, vigorous, and reached for toys. She moved all extremities well. She had symmetric reflexes and no gross deficits. The neurologist diagnosed her with infantile spasms. Her family history was positive for neurologic problems. Her father's half-sister had a history of seizure/twitching with eye deviation. Her maternal uncle had a history of febrile seizures. Her maternal grandmother had a history of seizures. Allison's mother required special reading classes in elementary school and Allison's father had significant learning difficulties in school and speech and language difficulties. There is a paternal family history for learning difficulties, speech and language delays, seizures, depression, and drug/alcohol abuse. There is a maternal family history for mental retardation, alcohol abuse, and muscular dystrophy.

Dr. Tornatore subscribes to the thesis that screaming means neurologic injury, i.e., encephalopathy. Yet, he also recognized that Allison was in pain. Mrs. Thompson and her mother-in-law testified that, after each DPT, Allison's leg was swollen, huge, hot, and red. Dr. Tornatore called Allison's leg spasm after her first DPT a pain spasm. He called the same movement after her second DPT, when her leg was again swollen, hot, huge, and red, her first infantile spasm.

Allison's grandmother testified that Allison recovered after hours of screaming. Her onset of RSV symptoms made for a difficult 60 days. It was this illness that sent Allison back to the doctor between the DPT vaccinations. The doctor did not record any symptoms of encephalopathy.

It is impossible to diagnose someone who is responsive, oriented, happy, alert, reaching for toys, vigorous, and playful (as the medical records note Allison to be) as having an acute encephalopathy. Dr. Snyder, respondent's pediatric neurologist expert, is more credible than Dr. Tornature in opining that Allison never had an acute encephalopathy. It is not surprising, however, that, as Dr. Tornatore recognized, a swollen, hot, red, and huge leg will be painful and cause crying as well as leg spasms.

The second issue is whether Allison's second DPT caused her infantile spasms. Allison's grandmother testified, and the records support her, that the onset of Allison's jerks was February 3, 1997. She also testified that a day or two after her second DPT, Allison had some leg jerks, and it is these that Dr. Tornatore testified were the onset of her infantile spasms. These early jerks are not reflected in the medical histories that Mrs. Thompson and her mother-in-law gave at two hospitals and to the pediatrician.

Dr. Tornatore is not qualified to diagnose the onset of infantile spasms in this case. He is not a pediatric neurologist. He treats adults, primarily with demyelinating illnesses, and has some adolescent patients. The only two infantile spasm cases Dr. Tornatore has personally seen were when he was a medical resident. His testimony amounts to nothing more than speculation, to which he admitted repeatedly. When faced with the overwhelming medical literature that shows no causal association between DPT and infantile spasms, Dr. Tornatore's response was that infantile spasm cases were underreported or never hospitalized. He ignores the NCES researchers' active pursuit of cases, with questionnaires sent to all hospital personnel and monthly reminders. He also ignores the NCES' distinction between convulsions lasting more than 30 minutes and infantile spasms. The NCES found a statistically significant increase of prolonged, febrile convulsions in the week

following DPT vaccination, but did not find the same with infantile spasms. Dr. Tornatore, saying infantile spasms are convulsions and therefore the NCES actually posits causation for infantile spasms, totally misreads the NCES and obliterates the very real difference neurologically between prolonged, febrile convulsions and infantile spasms. Allison never had fever and an infantile spasm is not a prolonged seizure. Dr. Tornatore's twisting of medical literature analysis and pediatric neurologic principles bodes ill for his credibility as an expert witness.

The only literature, if one could call it that, in support of a statistically significant number of infantile spasms after DPT is the Kimura abstract, published in a book describing proceedings concerning vaccine trials. These 5 or 6 cases of infantile spasms consisted of applications for compensation from the Japanese no-fault system for adverse reactions to vaccines. Kimura did not provide data in his abstract as to whether the diagnoses of infantile spasms were correct, what the onsets were, and whether compensation was provided. Such a skeletal listing of data can hardly satisfy petitioners' burden of showing credible evidence in support of causation.

The undersigned in numerous opinions has held that DPT does not cause infantile spasms. See Barnes v. Secretary of HHS, No. 92-0032V, etc., 1997 WL 620115 (Fed. Cl. Spec. Mstr. Sept. 15, 1997). Barnes was affirmed on appeal under the names Hanlon v. Secretary of HHS, No. 90-1334V, 40 Fed. Cl. 625 (1998) and Plavin v. Secretary of HHS, No. 91-1555V, 40 Fed. Cl. 609 (1998). The Federal Circuit affirmed the undersigned's decision as well in Hanlon v. Secretary of HHS, 191 F.3d 1344 (Fed. Cir. 1999), cert. denied sub nom. Hanlon v. Shalala, 530 U.S. 1210 (2000); and Plavin v. Secretary of HHS, 184 F.3d (Fed. Cir. 1999). See also, Turner v. Secretary of HHS; Flanagan v. Secretary of HHS, 268 F.3d 1334 (Fed. Cir. 2001) (consolidated appeal). These were all cases dealing with tuberous sclerosis in which the vaccinees had the benefit of the then-

statutory presumption of causation of seizures. Nevertheless, the undersigned found after due consideration of all the evidence that their underlying neurological illness was the cause of their conditions.

See also, Snead v. Secretary of HHS, No. 01-337V, 2002 WL 1906505 (Fed. Cl. Spec. Mstr. June 28, 2002), in which the undersigned ruled that DPT did not cause the vaccinee's infantile spasms. Other cases holding that petitioners did not prove DPT causes infantile spasms are: Raj v. Secretary of HHS, No. 96-294V, 2001 WL 963984 (Fed. Cl. Spec. Mstr. July 31, 2001); and Jackson v. Secretary of HHS, No. 90-1903V, 1995 WL 120210 (Fed. Cl. Spec. Mstr. Mar. 3, 1995).

In Raj, supra, the same counsel that represented petitioners there represents petitioners here with Dr. Geier as one of petitioners' experts (just as he is here, though as a "stealth witness"). The chief special master held in Raj that DPT did not cause the vaccinee's infantile spasms, whose onset was two days after vaccination. Petitioners also alleged a Table encephalopathy in Raj. The chief special master held that petitioners failed to prove that the vaccinee had a Table encephalopathy. Referring to the Institute of Medicine (IOM) report, the chief special master stated, at *8:

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

The IOM report is respondent's Exhibit B in this case.

Petitioners' whole case here rests on a slim reed–the Kimura abstract which has a very small Table attached to one paragraph. Here, and only here in all of the medical literature, is there a statistically significant rate of infantile spasms following DPT. But the authors do not give confidence limits, and the cases are tiny compared to an enormous number of doses (5.8 infantile spasms cases out of 44.9 million doses of DPT). Moreover, the case retrieval was not similar to the NCES which sent questionnaires with monthly reminders to doctors asking for their participation in reporting cases of hospital admission. See R. Ex. E, pp. 101, 155. The Kimura cases came from applications for compensation from a no-fault system, hardly a reliable source of data.

The undersigned notes that, in the instant action, the interval between vaccination and onset of infantile spasms is 14 days (from January 20, 1997 to February 3, 1997). Dr. Tornatore's attempt to "backdate" the onset to within a day or two of vaccination is not supported by the records of the pediatrician, Alamance ER, and North Carolina Memorial Hospital.

Dr. Tornatore referred in his testimony to "our case." He apparently takes a highly personal view of his testimony so that he has become a team player. In order to make "his" case, Dr. Tornatore ignores the medical records and creates facts which support his assertions which, in themselves, are not based on his clinical practice or knowledge. He has done this before. See, Morris v. Secretary of HHS, No. 99-412V, 2002 WL 31965739 (Fed. Cl. Spec. Mstr. Dec 18, 2002), appeal docketed (Fed. Cl. Jan. 17, 2003), and Bruesewitz v. Secretary of HHS, No. 95-0266V, 2002 WL 31965744 (Fed. Cl. Spec. Mstr. Dec. 20, 2002) (DPT does not cause afebrile seizures).

He (and the stealth witness Dr. Geier) posit to this court that the court need not regard statistical significance as meaningful since the burden of proof in a civil hearing is by a

preponderance of the evidence. But the undersigned relies upon those knowledgeable in the field and what is persuasive to them in order to evaluate the credibility of a conclusion as to causation.

In Haim v. Secretary of HHS, No. 90-1031V, 1993 WL 346392 (Fed. Cl. Spec. Mstr. Aug. 27, 1993), a case before the undersigned, Dr. Geier again testified, even 10 years ago, that statistical significance was not important in finding a causal relationship. The undersigned rejected his testimony, id. at *11, emphasizing that reliability of data is vital in finding an opinion credible. In reaching her decision, the undersigned relied upon the United States Supreme Court's decision in Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 US 579 (1993). The Supreme Court stated that the first criterion for accepting scientific evidence is that the expert's testimony pertaining to scientific knowledge be not only relevant, but reliable. Secondly, the "scientific" aspect of the testimony must be grounded in the methods and procedures of science. Thirdly, the "knowledge" aspect of the testimony must rely on more than subjective belief or unsupported speculation. Id. at 590.

The Supreme Court further stated:

> [I]n order to qualify as "scientific knowledge," an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation--*i.e.*, "good grounds," based on what is known.

Id.

Daubert focuses on evidentiary reliability. The Supreme Court stated: "In a case involving scientific evidence, *evidentiary reliability* will be based upon *scientific validity*." Id. at n.9 (emphasis included). The expert's opinion should have a "reliable basis in the knowledge and experience of his discipline." Id. at 592.

The Supreme Court instructed trial courts to assess preliminarily whether the reasoning or methodology underlying the expert's testimony is scientifically valid as well as "whether that reasoning or methodology properly can be applied to the facts in issue." Id. at 593.

A key consideration in assessing the scientific reliability of testimony is whether the theory at issue can be or has been tested. Id. Another consideration is whether the theory proffered has been accepted after peer review and in publications. Although not essential to establish reliability, peer review, i.e., the scrutiny of the scientific community, represents "good science" because it detects more likely substantive flaws in methodology. Id.

Further, when a particular scientific technique is at issue, the court should ordinarily consider the known or potential rate of error and the standards controlling the technique's operations. Id. at 594. The Supreme Court stated that a trial court may be properly skeptical about a known technique the scientific community only minimally supports. Id. "The focus ... [of the trial court] must be solely on principles and methodology, not on the conclusions that they generate." Id. at 595.

The Supreme Court, recognizing the difference between the quest for truth in the courtroom and the quest for truth in the laboratory, emphasized that scientific inquiry advances "by broad and wide-ranging consideration of a multitude of hypotheses," whereas the trial court is not intent on "the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes." Id. at 597.

In conclusion, Daubert stands for the principle that a trial judge's task is to ensure that an expert's testimony both rests on a reliable foundation and is relevant to the issues of the case. "Pertinent evidence based on scientifically valid principles will satisfy those demands." Id.

Here, we have overwhelming evidence in epidemiologic and medical articles, based on extensive research in various countries, concluding that there is no valid proof that DPT causes infantile spasms. By contrast, petitioners submit the Kimura abstract, based on applications for compensation to the Japanese no-fault system. This is not a case-control (NCES) or cohort analysis. This is nothing but a listing of alleged 5.8 cases of infantile spasms among 44.9 million doses of DPT, without any evidence of reliability or proper methodology.

The United States Supreme Court in Kumho Tire Co. v. Carmichael, 526 US 137, 141 (1999), stated that "scientific expert testimony... is admissible only if it is both relevant and reliable." This is important in order "to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Id. at 152.

Intellectual rigor is missing from Dr. Tornatore's testimony and the stealth witness Dr. Geier's submission after trial. They both posit causation based on the speculation that there are more cases of infantile spasms out there than the NCES and other researchers detected and that, in any event, since the undersigned is looking only for a preponderance of the evidence, statistical significance should not even be relevant here. But it is relevant since professionals in the field of epidemiology rely upon statistical significance in order to reach valid, credible conclusions.

The undersigned might comment that not only is Allison's onset of 14 days after vaccination too far after her vaccination even to be countenanced as causally related to it (and even if it were as close in time as Dr. Tornatore testified, it still is unrelated to DPT because infantile spasms are not related to DPT), but also she never had a fever. One of the most frequent symptoms accompanying reactions to DPT vaccination, and even seizures, is fever. The undersigned has held repeatedly that

DPT does not cause afebrile seizures, based on the NCES, the IOM, and other literature. See Bruesewitz, supra; Clements v. Secretary of HHS, No. 95-484V, 1998 WL 481881 (Fed. Cl. Spec. Mstr. July 30, 1998); O'Connell v. Secretary of HHS, No. 96-63V, 1998 WL 64185 (Fed. Cl. Spec. Mstr. Feb. 2, 1998), aff'd, 40 Fed. Cl. 891 (1998), aff'd by unpub. opinion, No. 98-5134 (Fed. Cir., Nov. 1, 1999); Haim, supra. The IOM also concluded that DPT does not cause afebrile seizures. Adverse Effects of Pertussis and Rubella Vaccines (1991). The IOM did a meta-analysis of febrile and afebrile seizures and concluded that "even pooling available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccination." Id. at 115.

As for respondent's motion to strike the stealth witness Dr. Geier's report, the undersigned denies that motion solely for the purpose of not prompting petitioners to appeal based on how important Dr. Geier may be to their case. It is better to evaluate Dr. Geier's contribution now rather than on remand. Frankly, petitioners' counsel knew it was wrong to submit Dr. Geier's report after the hearing. That is why he submitted it without any indication of who wrote it. When the undersigned ordered that either the author submit his name or petitioners refile the exhibit with his name, petitioners' counsel telephoned to inquire if it was sufficient to satisfy the Order if he filed a statement from Dr. Tornatore that he agreed with the report. This was not sufficient and, thus, Dr. Geier emerged from the shadows to proclaim his handiwork.

Dr. Geier has a long history of testifying in this Program. As the chief special master stated in Raj, supra, "Dr. Geier is wholly unqualified to testify concerning the two major issues in this case [encephalopathy and infantile spasms]. [H]e is neither board certified nor has formal training in

pediatrics and pediatric neurology." 2001 WL 963984, *12. The undersigned had a similar impression of Dr. Geier in Haim, supra, at *11:

> The court holds that Dr. Geier's testimony does not reach the level of evidentiary reliability that Daubert requires because it is not based upon scientific validity, valid methodology, peer review or testing, and more than minimal support within the scientific community. [T]the court points out that Dr. Geier's expertise as a doctor in the fields of genetics and obstetrics is of no relevance to the issues in the case.

To summarize, petitioners have failed to satisfy their burden of proving that Allison had an acute encephalopathy after either of her DPT vaccinations. She was seen medically between the first and second vaccinations, primarily for RSV, and there was no notation of symptoms of an acute encephalopathy. The testimony of her grandmother establishes that she recovered from her hours of crying after her leg was swollen, hot, huge, and tender. After her second DPT, again according to Allison's grandmother and mother, her crying went away after some hours. The interval of time between vaccination and onset of infantile spasms was two weeks, according to the medical records.

Contemporaneous medical records are considered trustworthy because they contain information necessary to make diagnoses and determine appropriate treatment:

> Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events.

Cucuras v. Secretary, HHS, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Secondly, petitioners have failed to provide credible evidence that, more likely than not, DPT causes infantile spasms, and that it caused Allison's infantile spasms. To satisfy their burden of proving causation in fact, petitioners must offer "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, HHS, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Agarwsal v. Secretary, HHS, 33 Fed. Cl. 482, 487 (1995); see also Knudsen v. Secretary, HHS, 35 F.3d 543, 548 (Fed. Cir. 1994); Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993).

Without more, "evidence showing an absence of other causes does not meet petitioners' affirmative duty to show actual or legal causation." Grant, supra, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. Hasler v. US, 718 F.2d 202, 205 (6th Cir. 1983), cert. denied, 469 U.S. 817 (1984).

Petitioners must not only show that but for the DPT vaccine, Allison would not have had the injury, but also that the vaccine was a substantial factor in bringing about her injury. Shyface v. Secretary, HHS, 165 F.3d 1344 (Fed. Cir. 1999).

It is regrettable that the Thompsons have an ill child whose needs will be lifelong. But they have not proved that DPT caused Allison's infantile spasms. Neither Dr. Tornatore nor Dr. Geier is qualified to testify about infantile spasms, and their testimony is filled with speculation that is directly contrary to the conclusions reached in well-respected and numerous epidemiologic and medical studies ranging over two decades.

Petitioners have not prevailed on a theory that Allison had an acute encephalopathy which DPT caused in fact and that DPT or acute encephalopathy caused her infantile spasms.

CONCLUSION

Petitioners' petition is dismissed with prejudice. In the absence of a motion for review filed pursuant to RCFC Appendix B, the clerk of the court is directed to enter judgment in accordance herewith.

IT IS SO ORDERED.

_____ _____

DATE Laura D. Millman
Special Master