OFFICE OF SPECIAL MASTERS

December 20, 2002

RUSSELL and ROBALEE BRUESEWITZ, Parents and Legal Guardians of HANNAH BRUESEWITZ,	*	
Petitioners,	*	
v.	*	No. 95-0266V
	*	PUBLISHED
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Clifford J. Shoemaker (with whom Ghada A. Anis is associated), Vienna, VA, for petitioners.
Julia McInerny (with whom R. Lynne Harris is associated), Washington, DC, for respondent.

DECISION

MILLMAN, Special Master

Petitioners filed a petition on April 3, 1995 under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10 et seq., alleging that their daughter Hannah Bruesewitz (hereinafter, "Hannah") suffered an on-Table residual seizure disorder (RSD)[1] and encephalopathy after receipt of her third DPT vaccination. On February 29, 2000, the case was transferred to the undersigned from another special master.

[1/] Effective March 10, 1995, approximately one month before petitioners filed their petition, new regulations deleted RSD as a Table injury for DPT. 60 Fed. Reg. 26,7694 (1995).

On July 9, 2001, this case was set for hearing, by mutual agreement of the parties, on August 28, 2001. At petitioners' counsel's request on August 13, 2001, the hearing was postponed. On January 25, 2002, this case was set for hearing, by mutual agreement of the parties, on March 26, 2002. On February 12, 2002, petitioners' counsel asked for a postponement of the hearing again. On February 21, 2002, the undersigned issued an Order to Show Cause why one of petitioners' experts, Dr. Mark R. Geier, should not have his testimony stricken as irrelevant.

On March 15, 2002, eleven days before the scheduled trial on March 26, 2002, petitioners moved to substitute Dr. Carlo Tornatore, an adult neurologist, for Dr. Marcel Kinsbourne and Dr. Michael Painter, both pediatric neurologists (and the latter one a treating pediatric neurologist) on the ground that Dr. Tornatore is younger with "different experiences" and the other two are senior. The undersigned denied petitioners' motion.

On March 20, 2002, petitioners filed a "Response to Court's Order and Status Report," stating that Dr. Kinsbourne "has chosen to withdraw from this case." Moreover, Dr. Tornatore was unavailable for testifying on the date upon which the parties had previously agreed (March 26, 2002). On March 22, 2002, in deference to petitioners who, in all fairness, were not responsible for the extraordinary and high-handed actions of their counsel, postponed the hearing once again so that petitioners' new expert could be ready and available for trial.

On June 27, 2002, the case was set for hearing on July 23, 2002. Testifying for petitioners were Russell Bruesewitz, Roballee Bruesewitz, Dr. Michael Painter, and Dr. Carlo Tornatore. Testifying for respondent was Dr. John MacDonald. At the end of the hearing, respondent wanted the opportunity to obtain the flow charts from Hannah's initial hospitalization

and all of Hannah's MRIs for Dr. MacDonald to examine. On July 31, 2002, the undersigned issued an Order granting respondent's motion for a subpoena to obtain all of Hannah's MRIs and CTs since 1991. On November 27, 2001, respondent filed Exs. K through N, including Dr. MacDonald's supplementary report saying the MRIs and CTs he reviewed did not reveal any meaningful abnormality (R. Ex. K), and the flow charts for Hannah's hospitalization from April 1, 1992 through April 16, 1992 (R. Ex. N).

FACTS

Hannah was born on October 20, 1991, and received her first DPT vaccination on December 3, 1991, and her second DPT vaccination on February 4, 1992. Med. recs. at Ex. 4, p. 17.

On April 1, 1992, at the age of six and one-half months, Hannah saw her pediatrician, Dr. Jane M. Breck. Mrs. Bruesewitz gave Dr. Breck a history that Hannah had three weeks of a rattle in her throat and a cough at night as well as a runny nose. Hannah was administered her third DPT vaccination. Afterwards, Mrs. Bruesewitz called Dr. Breck and said that Hannah was "not herself." She did not have a fever, but while Mrs. Bruesewitz was feeding her green beans, Hannah began to shudder and "wasn't herself." Hannah had another episode where she screamed and stiffened while falling asleep. Mrs. Bruesewitz said Hannah "gave a jerk." Dr. Breck wrote in her notes: "watch!" Med. recs. at Ex. 4, p. 18.

On April 2, 1992, Dr. Breck notes that Mrs. Bruesewitz called again at 7:30 p.m. on the previous evening. After the DPT the day before during the well child care visit, she was concerned about Hannah's unusual cry and occasional (about two to three) episodes of leg stiffening. Otherwise, Hannah seemed tired. Her breathing was okay, her color was normal, and

she had no other signs of illness or fever. Her drinking was okay. They discussed the question of whether Hannah had had a seizure or just discomfort or an unusual reaction to the vaccination versus another illness. Dr. Breck suggested taking Hannah to the ER, but Mrs. Bruesewitz decided to observe Hannah further to see if any signs appeared or increased that seemed more of concern or were like seizures. If so, she was to go to the ER immediately. Med. recs. at Ex. 4, p. 19.

Hannah was taken to the Children's Hospital of Pittsburgh (CHOP) ER on April 1, 1992, where Mrs. Bruesewitz stated that beginning at 1:00 p.m., Hannah had had intermittent episodes of crying, becoming rigid without clonic movement and, then, brief periods of unresponsiveness without bowel or bladder incontinence. She had one possible apneic spell. The episodes lasted one to two minutes at most. Hannah behaved normally between episodes and ate normally. Med. recs. at Ex. 13a, p. 2.

The Initial Assessment Note stated that her right thigh injection site was slightly reddened and swollen. Hannah's fontanel was soft and flat. Neurologically, she appeared normal. Med. recs. at Ex. 13a, p. 9. Hannah's alteration in consciousness was due to her seizure activity, according to a note written on April 2, 1992. Med. recs. at Ex. 13a, p. 11.

In April 2, 1992, at 12:00 a.m., Dr. J. Martin wrote an Intern Admit Note. Hannah had been well. In the past two weeks, she had had nasal congestion, cough, and sneezing. She received her first two DPT vaccinations previously. At 10:00 a.m. on the day of admission in her pediatrician's office, she received DPT. She went home with her mother. The mother tried to feed her at 12:30 p.m. and Hannah screamed and her arms flew out "like she was stuck with a needle." Mrs. Bruesewitz picked her up and noted her eyes were to the left and Hannah would

not look at her mother for one minute. Afterwards, Hannah slept. At 2:00 p.m. and 5:00 p.m., Hannah had these episodes again. During the day, she had myoclonic jerks several times, lasting one second. At about 7:30 p.m., Mrs. Bruesewitz put Hannah to sleep. At around 8:00 p.m., she heard Hannah scream. She went to see her and found her nonresponsive and floppy. Mrs. Bruesewitz put Hannah on the floor and did not think she was breathing. Mrs. Bruesewitz blew in her mouth, picked her up and hugged her. Hannah looked around but was groggy. Mrs. Bruesewitz called an ambulance. In the ER, Hannah had two episodes from 9:00 to 11:15 p.m. She screamed for about five seconds with her upper extremities increased in extensor tone, and her lower extremities increased in flexor tone. Mrs. Bruesewitz did not feel that Hannah was febrile. She had her last bowel movement four days prior to admission. Hannah had a good appetite. Her sibling had a strep throat which was diagnosed the prior week. Med. recs. at Ex. 13a, pp. 121-22.

Neurologically, Hannah was alert, interactive, babbling, and moving all her extremities well. Her deep tendon reflexes were +2, and she had normal tone and normal strength. Med. recs. at Ex. 13a, p. 123.

Dr. Jane M. Breck, the attending pediatrician on April 2, 1992, at 1:30 p.m., wrote that Hannah did not have any focal findings, was alert, reaching for toys, smiling, and moving all extremities well. She did not have any fever. She had a completely normal examination between episodes. Med. recs. at Ex. 13a, p. 124.

On April 2, 1992, Dr. Harry S. Abram, a pediatric neurologist, saw Hannah and noted that she was doing well except for a mild URI for the prior two weeks. She had an injection in her right thigh at around 10:00 a.m. Her mother fed her at 12:30 p.m. and noted, at 1:00 p.m.,

the first episode. Hannah suddenly screamed, her arms and legs stiffened, and she had diminished responsiveness for one minute. She was dusky in the face and Mrs. Bruesewitz questioned if she had apnea. Afterward, she was slightly groggy, but within several minutes resumed her normal playful self. She had three other episodes at home (at 2:00, 5:00, and 8:00 p.m.). In the ER, she had two spells. Overnight, she had five other episodes. She had no fever, vomiting, or diarrhea. She was generally playful and eating well. Dr. Abrams witnessed one episode: she quickly cried out, tonically stiffened her arms and legs for about five seconds, had a 45-second episode of staring straight ahead and slightly off to the right, and was afterwards groggy. On physical examination, Hannah was alert, complacent, and attentive to her surroundings. She had passive tone mildly diminished. Med. recs. at Ex. 13a, p. 157.

Hannah's complete blood count was notable for an elevated white count of 24,000 with 56 segs and 38 lymphs. Med. recs. at Ex. 13a, p. 158. A blood culture was negative. Med. recs. at Ex. 13a, p. 160. Hannah was admitted to CHOP and discharged on April 16, 1992. Throughout her hospitalization, in between her approximately 125 seizure episodes, she remained alert, awake, playful, and responsive.[2]

[2/] The nurses notes state: 4/2/92 - 8:00 a.m. - awake and alert; 4/2/92 - 6:30 p.m. - alert and playful; 4/3/92 - 5:30 a.m. - awake, alert, smiling, and pleasant; moves all extremities well; 4/3/92 - 8:00 a.m. - awake and alert; 4/3/92 - 9:30 a.m. - awake and alert' 4/4/92 - 9:00 a.m. - awake and pleasant (after having had a 30-minute seizure recorded in an 8:30 a.m. note); 4/4/92 - 12:35 p.m. - awake and pleasant; responds to stimuli and smiles at parents; 4/4/92 - 8:00 p.m. - responds to stimuli; 4/5/92 - 3:35 a.m. - awake and alert; 4/5/92 - 8:30 a.m. - awake and pleasant; respirations easy; 4/5/92 - 10:30 a.m. - awake and pleasant; smiling and playing with father; 4/5/92 - 3:00 p.m. - awake and pleasant; 4/6/92 - 10:15 a.m. - awake and active; 4/6/92 - 9:25 p.m. - awake and oriented; responsive to sound and touch; 4/7/92 - 8:00 a.m. - awake and alert; moves all extremities spontaneously; 4/7/92 - 11:00 a.m. awake; responds to stimuli; 4/7/92 - 1:00 p.m. - awake; responding to stimuli; 4/8/92 - awake and pleasant; respirations easy; 4/8/92 - 10:30 a.m. - awake and alert; 4/8/92 - 1:00 p.m. - awake and alert; 4/9/92 - 9:30 a.m. - awake and alert; 4/9/92 - 12:30 p.m. - awake and pleasant; 4/9/92 - 6:30 p.m. - awake and pleasant; 4/9/92 -

On April 14, 1992, Dr. Ira Bergman, a pediatric neurologist, wrote that she was entirely well until April 1, 1992 when she went for her third DPT and HiB which were given at 10:00 a.m. She did well until 12:30 p.m. when she suddenly began screaming and had a stiffening spell of her arms and legs that lasted for less than one minute. She was mildly groggy afterwards and, then, within a few minutes, was back to normal. She had three further similar spells at 2:00 p.m., 5:00 p.m., and 8:00 p.m., and was admitted to the hospital where she had 5 more spells overnight. A spell was witnessed the next morning and was a typical tonic seizure. An EEG showed two typical spells associated with generalized spike and wave activity, lasting 20 seconds. "Between the spells, she was perfectly normal." Dr. Bergman continued that Hannah had had a mild upper respiratory infection (URI) for the prior two weeks, but she was otherwise well with excellent development. Med. recs. at Ex. 13cc, p. 2.

Over the next three days, Hannah did not improve and was having one seizure per hour. She was loaded with Dilantin and the seizures decreased to one every four hours. On the next day, she was still seizing and was loaded with Phenobarbital. On the following day, the Dilantin was stopped and the seizures increased to one every half hour. She was reloaded with Dilantin.

7:30 p.m. - awake and pleasant; 4/10/92 - 8:00 a.m. - pleasant; respirations easy and unlabored; babbling, smiling, and turning over in crib, playing; 4/10/92 - 12:00 p.m. - alert, pleasant; 4/10/92 - 7:00 p.m. - awake and pleasant; 4/10/92 - 8:00 p.m. - alert, active, and playful; alert and active, moving all extremities and behaving appropriately; 4/10/92 - 8:30 p.m. - alert, active; 4/11/92 - 8:00 p.m. - awake, alert, and playful; 4/12/92 - 2:00 p.m. alert, awake, and playful, out in halls in stroller with family periodically; 4/12/92 - 7:00 p.m. - awake and alert, playing in crib; 4/12/92 - 8:00 p.m. - awake, alert, playful; alert and moving all extremities; 4/13/92 - 6:00 a.m. - awake and pleasant; 4/13/92 - 6:30 p.m. - awake and alert; 4/14/92 - awake and pleasant; respirations easy; 4/14/92 - 9:30 a.m. - awake and alert; 4/14/92 - 5:30 p.m. - awake and alert; 4/16/92 - respirations easy and unlabored; pleasant, babbling, and playing in crib; turning self over; 4/16/92 - 8:30 a.m. - out in stroller, then back to crib with nurse; playing, babbling, pleasant; 9:00 a.m. - Mom in; baby remains as above.

At that point, the character of her seizures changed somewhat and, instead of having stiffening, she would stare with her head turned to the right with mild tremors of her head and perhaps of her right arm. An EEG showed right temporal sharp waves, and two seizures. On the next day, April 9th, she was started on Tegretol. On April 11th, the Dilantin was stopped. She had two staring seizures on the day before, but no seizures yet that day. "The child has remained perfectly normal in between spells." Her review of systems was negative. On physical examination, Hannah was awake and alert with a normal head circumference, normal skin, and a completely normal developmental and neurological examination. She was very pleasant and playful. Med. recs. at Ex. 13cc, p. 3.

On April 21, 1992, Dr. Michael J. Painter, Chief of the Division of Child Neurology at CHOP, saw Hannah for a new onset of seizures. Since her discharge from the hospital on April 16, 1992, she had had three seizures, two on the 16th, and one on the 19th. The seizures were all brief, less than 30 seconds and consisted of head tremor and staring. There were no changes in her respiratory patterns or her color. Over the past five days, she had had low grade fevers of 101 degrees. She was slightly less active than usual, and had had mild URI symptoms. Currently, her mother and father both had URIs. Hannah remained playful and was eating well. She was very attentive to her surroundings and to the examiner. Her Babinski signs were equivocal. Med. recs. at Ex. 13cc, p. 5.

An EEG done on May 5, 1992 was markedly abnormal because of multifocal bihemispheric and generalized epileptiform activity and because of a poorly organized record and bitemporal slowing. Dr. Patricia K. Crumrine wrote that it was not accompanied by clinical events. Med. recs. at Ex. 13cc, p. 12.

A nursing assessment on June 17, 1992, was that Hannah was alert but slightly lethargic. Med. recs. at Ex. 13b, p. 4.

On August 24, 1992, Mr. Bruesewitz remarked that Hannah was more "sedated looking," but Mrs. Bruesewitz related that Hannah's activity level was the same. She was busy and active. Dr. Painter saw Hannah. Med. recs. at Ex. 13cc, p. 16.

On October 28, 1992, Dr. Painter noted that Hannah was quite clumsy and appeared somewhat dazed. Med. recs. at Ex. 13cc, p. 21. An EEG Dr. Crumrine performed on October 28, 1992 was abnormal because of diffuse, bihemispheric slowing and multifocal spike and slow wave discharges which were greatest during the sleep portion and maximum in the more posterior regions. Hannah's seizures consisted of staring for 15 to 20 seconds with associated unsteadiness. Med. recs. at Ex. 13cc, p. 22.

An EEG Dr. Mark Scher performed on November 3, 1992 was abnormal because of multifocal sharp waves, and slowing and disorganization of the background. Dr. Scher noted diffuse encephalopathy. Med. recs. at Ex. 13cc, p. 26.

On November 6, 1992, Hannah was noted not to have had seizures for a week. Her autistic-like features continued. She did not make good eye contact and would not smile. She was much taken with her toys. Each day, however, she improved somewhat and had begun to walk again. Med. recs. at Ex. 13cc, p. 27.

On November 11, 1992, Dr. Painter noted that Hannah was absolutely seizure-free and her development was back to baseline. Med. recs. at Ex. 13cc, p. 30.

On December 6, 1992, Dr. Painter wrote that Hannah continued on Phenobarbital and Tegretol. She was absolutely seizure-free and her development was right on target. She was

saying mama and dada, and waving bye bye. She showed some anxiety to strangers. Med. recs. at Ex. 13cc, p. 31.

On February 3, 1993, Dr. Ammar Katerji noted that Hannah had very good control of her seizure activity but continued to have some seizure breakthroughs. Her last breakthrough was in October 1992 when the Tegretol dose was increased which controlled her seizures very well. Since the last exacerbation of her seizures, she had been doing well. She had had URI symptoms for the prior two weeks with a low grade temperature, but no seizures. She woke that morning and started having seizures consisting of stares, stiffness, and tonic clonic activity, which lasted 30 seconds and then 35 to 60 seconds. She had a total of five seizures since that morning. She was then in a postictal state, but did awaken and respond. Med. recs. at Ex. 13cc, pp. 41, 43.

Also on February 3, 1993, Dr. Bryan J. Lynch performed an EEG which was abnormal because of bifrontal slowing which might be a postictal phenomenon. Hannah had two electroclinical generalized tonic/clonic seizures whose onset appeared generalized. Med. recs. at Ex. 13cc, p. 42.

On March 3, 1993, Dr. Painter noted that Hannah's development was noticeably improved with decreasing Phenobarbital. Med. recs. at Ex. 13cc, p. 45.

On April 8, 1993, Dr. Painter wrote that Hannah was clearly not developmentally appropriate. At 18 months, she was still mouthing things with no words yet and would not name body parts. Med. recs. at Ex. 13cc, p. 58.

On May 10, 1993, Mrs. Bruesewitz told Dr. Painter that Hannah seemed to be making gains developmentally. She was beginning to speak and say isolated words. He was still concerned about the vacuous stare to her face. Med. recs. at Ex. 13cc, p. 59.

On May 17, 1993, Gretchen Probst did an Audiologic Evaluation. Mrs. Bruesewitz reported that Hannah's physicians felt that her general development was on target, but she felt that Hannah's speech and language development might be below age level. Hannah was using only one or two single words expressively and only beginning to respond appropriately to the command "come." Hannah did not yet demonstrate the ability to identify objects or people when they were named and, at times, did not respond at all when called if she were preoccupied. Her hearing was normal. Med. recs. at Ex. 13cc, p. 61.

An EEG that Dr. Abram performed on May 19, 1993 was normal. Med. recs. at Ex. 13cc, p. 63. Dr. Painter wrote on June 11, 1993 that Hannah's EEG was normal but he was concerned about her development. She was then 20 months old but had no discernible speech and comprehended only very simple, one-step commands. She was also irritable, smiled very little, and had a vacuous stare. Med. recs. at Ex. 13cc, p. 64.

On October 27, 1993, Dr. Painter wrote that Hannah was absolutely seizure-free and doing well. She was over the age of two. Med. recs. at Ex. 13cc, p. 65.

On October 29, 1993, an EEG showed she was abnormal most likely due to a postictal state. She had diffuse moderate to high amplitude slowing. She had a number of recent flurries of generalized seizures. Med. recs. at Ex. 13cc, p. 69.

On December 10, 1993, Dr. Painter wrote that Hannah was absolutely seizure-free. Her behavior was much improved, more in the way of facial expression. She now began to interact with her sisters more readily. She was not sleeping as much as she had. She was on valproic acid. Med. recs. at Ex. 13cc, p. 76.

On January 18, 1994, in a Conference Case Report, Dr. Ira Bergman wrote that Hannah was well the day of a DPT without fever. After the DPT, she was well for two hours and then, over the next several hours, had several episodes of staring for 15 to 20 seconds. That evening, she had a similar spell, became dusky and was admitted to the hospital. An EEG showed generalized spike and wave, multifocal spike and wave, and bitemporal slowing. Since then, every three to four months, she has continued to have a flurry of seizures which have changed in their character. At the time of the report, she would have a single jerk followed by total body stiffening and a generalized clonic seizure lasting 30 seconds to one minute. She would have a flurry of 8 to 10 of these over a day or a few days, and then go back to normal. She did very poorly developmentally with a flat affect and poor developmental gains. In November 1992, she was placed on Valproate and did much better developmentally. She had just been admitted two days previously with another flurry of difficult seizures following a mild URI and mild fever. She was somewhat behind in her speech, saying only single words and obeying only the most simple of commands. Her neurological examination showed her to be awake, alert, and playful, with a slightly blunted facial expression. She had no focal deficits. She had a normal MRI. The diagnosis was primary generalized epilepsy. Med. recs. at Ex. 13cc, pp. 79-81.

On February 23, 1994, Dr. Painter wrote that, regarding development, she was speaking isolated words at 28 months of age. She had very good fine motor activity. Med. recs. at Ex. 13cc, p. 88.

On June 22, 1994, Dr. Painter noted that Hannah had flurries of seizures two times in the prior month. The CHOP Child Development Unit felt that she has pervasive developmental disorder (PDD). Med. recs. at Ex. 13cc, p. 98.

On January 9, 1995, she was still having flurries of seizures every month or two. She was developmentally not normal, but making some gains. Med. recs. at Ex. 13cc, p. 64.

On April 24, 1995, she had been seizure-free for two months, but was clearly developmentally delayed. Med. recs. at Ex. 13cc, p. 108.

On June 12, 1995, an EEG done was severely abnormal and showed either a diffuse encephalopathy or a postictal state. Med. recs. at Ex. 13cc, p. 111.

On July 7, 1995, a CT scan of Hannah's head showed diffuse neuronal loss (atrophy). Med. recs. at Ex. 13cc, p. 112.

Submissions

Petitioners filed Dr. Mark R. Geier's first affidavit, dated July 26, 1999. P. Ex. 20. Dr. Geier is an obstetrician-gynecologist. Id. at 7. He is board-certified in genetics and forensic medicine, but not in obstetrics. Id. He is not a pediatrician, neurologist (adult or pediatric), or internist. He concluded that because there was no alternate cause for Hannah's RSD and purported encephalopathy besides the DPT vaccination, DPT must be the cause. Id.

Petitioners filed Dr. Geier's second affidavit, dated August 28, 2001. P. Ex. 22. In it, Dr. Geier confuses Hannah's case with someone else's because he refers to her death and subsequent autopsy. Hannah is still alive. Based on a meta-analysis from the Institute of Medicine (IOM), Dr. Geier concludes that DPT caused her purported encephalopathy. He also refers to the VAERS reports regarding arthritic symptoms and hepatitis and rubella vaccines. (Hannah does not have arthritic symptoms; hepatitis and rubella vaccines are not at issue here.) He remarks that the switch to acellular pertussis vaccine has led to a significant decrease in fever and seizures or convulsions compared to the whole cell pertussis vaccine. Id.

Petitioners filed Dr. Geier's third affidavit, dated September 25, 2001. P. Ex. 24. Dr. Geier justifies his opinion that Hannah had an acute encephalopathy by referring to "Steadman's" [sic] Medical Dictionary, 24th ed., which Dr. Geier states defines an encephalopathy as "any disease of the brain." Id., at 2. He states that "the medical dictionary definition is the one used by the vast majority of the medical world. In fact it is the only definition listed in the medical dictionary." Id. Dr. Geier remarks that it is "obvious" that Hannah suffered an acute encephalopathy immediately following her vaccination. Id. He repeats his review of the IOM's meta-analysis showing DPT causes acute encephalopathy and the VAERS data.

Petitioners filed Dr. Geier's fourth report, dated March 22, 2002. P. Ex. 33. Here, *inter alia*, he discusses the movie "A Beautiful Mind" as evidence that DPT can cause afebrile seizures because the lead character was administered insulin in order to cause him to have afebrile seizures which was hoped to be a cure of his schizophrenia. Dr. Geier thinks DPT lowered Hannah's blood sugar, causing afebrile seizures. Id. at 2. One of the articles Dr. Geier attaches to his fourth report is "Whole Cell but Not Acellular Pertussis Vaccines Induce Convulsive Activity in Mice: Evidence of a Role for Toxin-Induced Interleukin-1ß in a New Murine Model for Analysis of Neuronal Side Effects of Vaccination," by S. Donnelly, et al., 69 *Infection and Immunity* 7:4217-23 (2001). Ex. F to P. Ex. 33. The authors found "that exposure of mice to high ambient temperature following subcutaneous (s.c.) injection of Pw [whole-cell pertussis vaccine] induces seizure-like behavior changes...." Id., at 4218.

Exposure to temperature alone or after injection with acellular pertussis vaccine did not induce behavioral changes in the mice. Id. at 4219. With reference to people, the authors state

"a typical presentation of pertussis vaccine-induced encephalopathy is that of a generalized seizure frequently associated with a high fever within 48 h of pertussis vaccination." Id. at 4220.

Petitioners filed an article by Dr. John T. MacDonald (respondent's expert), entitled "Febrile Convulsions. Current Controversies," 62 *Minnesota Medicine* 433 (1979). He states that typically, the rectal temperature is at least 37.7° C [99.8° F] in a febrile seizure. P. Ex. 38.

Petitioners filed "Pertussis Encephalopathy with High Cerebrospinal Fluid Antibody Titers to Pertussis Toxin and Filamentous Hemagglutinin," by C.C. Grant, et al., 102 *Ped* 4:986 (1998). A 7-year-old-girl who had the disease pertussis (not the vaccine) had encephalopathy. The authors state, "The diagnosis of encephalopathy in this girl was made on the basis of her central hypoventilation and decreased level of consciousness." Id. at 988. The authors also state that "there is no evidence that PT [pertussis toxin], or any of the other toxins or virulence factors produced by *B pertussis*, enter the central nervous system." Id. at 986 [citation omitted]. The girl's "clinical course and EEG were consistent with an acute meningoencephalitis." Id. at 988. P. Ex. 39.

Respondent filed a chapter, "Febrile Seizures," by Shlomo Shinnar, (R. Ex. M) from Pediatric Neurology. Principles & Practice, 3d ed., Vol. One, eds. K.F. Swaiman and S. Ashwal (1999), which states at 676:

> The febrile illness [defining a febrile seizure] must include a patient temperature of greater than 38.4° C [101.1° F]....

Respondent filed Exhibit N, which includes the April 2 - 15, 1992 Seizure Record for Hannah. The chart includes notations for date, time, respiratory distress, oxygen administration,

color, heart rate, loss of consciousness, length of seizure, and length of postictal state.[3] Hannah's postictal periods ranged from none to 5, possibly 10, minutes, with the overwhelming majority of seizures having no postictal periods. Most of her seizures lasted for seconds. Some lasted one to two minutes. On April 3, 1992, at 2:42 p.m., she had a 20-minute seizure. There is a dispute in the records over whether her seizure on April 4, 1992 at 8:30 a.m. was 30 seconds (R. Ex. N, p. 6) or 30 minutes (P. Ex. 13a, p. 19). The experts who testified assumed Hannah had a 30-minute seizure. Presumably, it was 30 minutes because her postictal state was 5 to 10 minutes. P. Ex. 13a, p. 19.

TESTIMONY

Hannah's father and mother testified. Mrs. Bruesewitz has always been told that an axillary temperature of 98.6° was normal. Tr. at 27. Before Hannah received her third DPT, she had about three weeks of a rattle in her throat, a cough at night, and a runny nose. Tr. at 41. Any time Hannah gets a virus now it seems to trigger seizures. Tr. at 37.

Dr. Michael Painter, Hannah's treating neurologist, opined that DPT played a significant role in her having seizures because of the close association in time. Medical literature shows that a vaccinee can have seizures with fever after DPT and seizures with long periods of depressed consciousness. He does not know if DPT causes afebrile seizures. Tr. at 60. He does not know if Hannah had a fever when she had seizures. He knows that infections trigger seizures in Hannah. Tr. at 61. On April 1, 1992, she had three weeks of a rattle in her throat, a cough at

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[3/] "Postictal period. Often, after seizures, normal brain function is not immediately restored and the return to normal mental functioning is gradual. This postictal state is frequently characterized by confusion and lethargy. Occasionally, transient postictal weakness of the affected extremities, known as Todd's paralysis, may be present for minutes or hours." http://www.emsfpg.com/Def/postictal_period.htm.

night, and a runny nose. Some people have an infection and then exposure to something else which leads to seizures. Some children are genetically susceptible to seizing. Tr. at 61-62.

In Hannah's first hospitalization, she had repetitive seizures and was sleepy afterwards, but rebounded and appeared pretty good. His opinion is that Hannah has epilepsy, pervasive developmental delay (which he saw for the first time when Hannah was a year old), and a history of two seizure types (myoclonic and partial). She has had periods of status epilepticus. She had an acute encephalopathy which he defines as a manifestation of abnormal brain activity (seizures). Tr. at 57. It is not unusual not to know the cause of someone's seizure disorder. Tr. at 68. If Hannah did not have a fever with her onset of seizures, he would still opine that DPT caused her seizure disorder because of the close time association. Tr. at 73. Hannah would bounce back quite well between seizures. Tr. at 77. He did not feel comfortable answering the question whether Hannah's neurological condition is related to periods of status epilepticus. Tr. at 77-78.

Dr. Carlo Tornatore testified next for petitioners. He is an adult neurologist interested in viral mechanisms of injury. Tr. at 100. He finds Hannah's case extraordinary. Tr. at 117. She has a focal lesion in her right frontal lobe and all her EEGs were abnormal. Id. She had a preexisting cold before she received her third DPT. His opinion is that, absent any other causes, her third DPT caused a brain insult which led to atrophy and focality which caused a seizure disorder and brain problems. Tr. at 118. Pertussis causes encephalopathy. Her blood oxygen levels went from 90% to 30% causing hypoxic brain injury. Tr. at 122, 144.

Dr. Tornatore's opinion is that Hannah had a fever because her mother had given her Tempra to keep her temperature low, and she had an axillary reading of 36.9° [98.4° F] which is

a core body temperature of 37.9 [100.2° F]. At noon, she had a rectal temperature of 37.8° which is 100° F.[4] Tr. at 145-46. Dr. Tornatore considers a temperature of 37.7° rectally [99.8° F] to be a febrile seizure, referring to an article Dr. MacDonald wrote in 1979 that a temperature of 37.7 is sufficient to diagnose a febrile seizure. Tr. at 146. He testified that on admittance to the hospital, Hannah had an axillary temperature of 37.9° [100.2° F].[5] Tr. at 147.

Respondent's expert, Dr. MacDonald, interjected that if someone has an elevated temperature that persists for a day or so, that could qualify as a febrile seizure. Tr. at 147. He said Hannah had one temperature elevation but no consistent pattern. Tr. at 149. Dr. Tornatore

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[4/] Dr. Tornatore testified that 37.8 degrees Centigrade is 100.2 degrees Fahrenheit, but a device for converting Centigrade into Fahrenheit shows that it is 100 degrees Fahrenheit. http://www.exotictropicals.com/encyclo/information/calculate.htm#Fahrenheit - Celsius Temperature Conversion.

[5/] The Emergency Department Clinical Record at CHOP for April 1, 1992 shows a temperature of 36.9 degrees C or 98.4 degrees F when Hannah was brought in. P. Ex. 13a, p. 2. On admission to CHOP, Hannah's records constantly note she is afebrile, with some elevations of temperature later in her hospitalization: 4/2/92, 8:00 a.m. - afebrile; 4/2/92 - noon- 37.8 rectally (100 degrees F); 4/3/92, 12:30 a.m. - afebrile; 4/3/92 - 8:00 a.m. - afebrile; 4/3/92 - 4:30 p.m. - afebrile; 4/3/92 - 8:00 p.m. - afebrile; 4/4/92 - 2:00 a.m.. - afebrile; 4/4/92 - 12:40 p.m. - afebrile; 4/4/92 - 4:10 p.m. - afebrile; 4/4/92 - 8:00 p.m. - afebrile; 4/5/92 - 1:00 a.m. - afebrile; 4/5/92 - 8:30 a.m. - afebrile; 4/5/92 - 4:30 p.m. - afebrile; 4/5/92 - 8:00 p.m. - afebrile; 4/6/92 - 1:00 a.m. - afebrile; 4/6/92 - 8:15 a.m. - afebrile; 4/6/92 - 4:00 p.m. - afebrile; 4/6/92 - 6:00 p.m. - 38 (100.4 degrees F); 4/6/92 - 8:00 p.m. - afebrile; 4/6/92 - 9:25 p.m. - 37.8 (100 degrees F); 4/7/92 - 2:00 a.m. - 38 (100.4 degrees F); 4/7/92 - 6:00 a.m. - 38.9 (102 degrees F); 4/7/92 - 8:00 a.m. - afebrile; 4/8/92 - 12:00 a.m. - afebrile; 4/8/92 - 7:00 a.m. - afebrile; 4/8/92 - 9:30 a.m. - afebrile; 4/8/92 - 11:00 a.m. - afebrile; 4/8/92 - 2:30 p.m. - afebrile; 4/9/92 - 8:00 a.m. - afebrile; 4/9/92 - 4:30 p.m. - afebrile; 4/10/92 - 5:00 p.m. - afebrile; 4/11/92 - 8:15 a.m. - 38.7 rectally (101.6 degrees F); 4/11/92 - 11:00 a.m. - 37.9 rectally (100.2 degrees F); 4/11/92 - 3:00 p.m. - 38.2 rectally (100.7 degrees F); 4/11/92 - 5:00 p.m. - 38.7 (101.6 degrees F); 4/11/92 - 7:00 p.m. - 37.9 (100.2 degrees F); 4/12/92 - 12:00 a.m. - afebrile; 4/12/92 - 8:00 a.m. - afebrile; 4/12/92 - 4:30 p.m. - 36.9 rectally (98.4 degrees F); 4/13/92 - 8:00 a.m. - afebrile; 4/13/92 - 2:00 p.m. - afebrile; 4/14/92 - 12:00 a.m. - 36.7 rectally (98.06 degrees F); 4/14/92 - 8:00 a.m. - afebrile; 4/14/92 - 5:30 p.m. - afebrile; 4/15/92 - 8:30 a.m. - afebrile; 4/15/92 - 4:00 p.m. - afebrile; 4/16/92 - 8:00 a.m. - afebrile. P. Ex. 13a, pp. 13-40.

testified that she had febrile periods, but he would not anticipate a prolonged febrile period. She had punctuations of spikes in temperature, showing activation of her immune system. Tr. at 149-50. He testified that she had febrile seizures when she arrived at the hospital on April 1, 1992. The site of her vaccination was slightly reddened and swollen. Tr. at 153. She was clearly apneic (poorly oxygenated). Tr. at 153-54. Dr. Tornatore ascribed the medical record notations that Hannah was alert and responsive to her surroundings as "extremely insensitive" observations that did not give a real insight into what was going on in her brain. Tr. at 156. He thinks these were "off the cuff" comments, and that physicians are "eternal optimists." Tr. at 157.

Dr. Tornatore said that pertussis toxin is known to get into the brain and cause encephalopathy. Tr. at 161. He said Hannah had encephalopathy because she was not right, and she was irritable and lethargic. Tr. at 165. Her seizures were a proxy for the same thing. Tr. at 157. In his opinion, this is a case of causation in fact encephalopathy. Tr. at 166. In Hannah's subsequent seizures, infections were a known problem for her. Even minor temperature spikes resulted in seizures because of her lowered seizure threshold due to her brain injury. Tr. at 168.

Explaining the biological mechanisms at work, Dr. Tornatore stated that the pertussis toxin binds to the G protein, changing neuronal function in the brain, leading to seizures. Tr. at 163, 171. Pertussis toxin makes cell membranes more permeable. Tr. at 172. The toxin can cross the blood-brain barrier and lead to encephalopathy. Tr. at 163. When asked why Hannah did not have reactions to her prior two DPT vaccinations, Dr. Tornatore said he did not have an easy answer for that. Perhaps the prior two DPTs sensitized her or because DPT was

administered intramuscularly, more DPT got into the bloodstream. Tr. at 172. The prior two DPT vaccinations were also administered intramuscularly. Tr. at 173.

Dr. Tornatore stated that the Tempra Mrs. Bruesewitz administered to Hannah after her third DPT at 1:00 p.m. would have lowered her temperature if she had one. Tr. at 174. He does not think that Hannah's seizures elevated her temperature because they were so brief, and she had only four temperature elevations during her hospitalization. Id. He guessed that the toxin bound to some "shuttle" that brought it into Hannah's brain because there is no evidence that her blood-brain barrier was breached. Her spinal fluid was relatively normal and her MRI did not show any enhancement of her meninges. Tr. at 177. Dr. Tornatore testified that DPT caused Hannah to have an acute encephalopathy, seizures, and status epilepticus, leading to her ongoing seizures and current condition. Intractable seizures and anoxia lead to brain damage. Tr. at 160, 179.

Hannah's first EEG on April 2, 1992 was severely striking in the slowing of background rate. Tr. at 182. Her delta activity was distinctly abnormal, meaning brain activity slowed. Tr. at 183. The neurons were not firing as rhythmically as they should have been. Tr. at 184. Hannah was having convulsive activity of her brain on EEG without clinically manifesting convulsions. Tr. at 236. Hannah would have been included in the NCES because she had a seizure lasting more than 30 minutes and because he thinks she had an acute encephalopathy. Tr. at 228, 229.

Dr. John MacDonald testified for respondent. He is a pediatric neurologist and has done studies on epilepsy. Tr. at 238. He sees five to six pediatric EEGs a day. Tr. at 239. Discussing Hannah's first EEG on April 2, 1992, Dr. MacDonald stated that encephalopathy relates to the

background rate, but Hannah's background was normal. Hannah awakened in between seizures. Her delta activity was normal for a 5 and ½ month old. Tr. at 241-42. In her April 8, 1992 EEG, her background rhythm was normal. There was no sign of encephalopathy. Tr. at 243.

Hannah's epilepsy is not a particularly unusual presentation in his practice. Tr. at 244. He has patients with 125 seizures in a day, not over several days as Hannah. Id. Desaturation (drop in respiration with cyanotic spells) acutely during a seizure is transient and does not prove there is hypoxic brain damage occurring. Tr. at 245. Because Hannah returned repeatedly to baseline after her seizures means that her seizures did not damage her. Tr. at 246.

Dr. MacDonald does not know the cause of Hannah's current condition. Id. Hannah has an intractable seizure disorder with an autistic-type syndrome and mental retardation. These frequently are of unknown cause and present acutely. Id. She did not have febrile seizures. Id. The article he wrote on febrile convulsions [that 37.7°C (99.8° F) is sufficient for a febrile seizure] is 23 years old. He did not give any references in the article. Current medical opinion is that to diagnose a seizure as febrile, the patient should have persistent temperature elevation that lasts for days. Id. His paper would not be accepted in 2002. Tr. at 301. The current recommendation to diagnose a febrile seizure is 101° F orally. Tr. at 303. He cannot imagine that anyone would call Hannah's seizure disorder a febrile seizure disorder. Id. Hannah had temperature spikes later on in her hospitalization. Intractable seizures do cause temperature elevation. Tr. at 247.

It would be pure speculation, testified Dr. MacDonald, to say that the Tempra Hannah received at 1:00 p.m. and 5:00 p.m. masked her temperature. Id. On April 1, 1992, Hannah had 36.8° rectally [98.2° F] both at 9:30 p.m. when she came to the hospital and at midnight. Tr. at

248. Hannah did not have a febrile seizure because her temperature was not high enough, not persistent, and not documented as fever. Id. and 249. His diagnosis is that she had cluster seizures, from which she recovered quickly, and she did not have status epilepticus. Tr. at 249-50. In order to have status epilepticus, one should have a persistent postictal state, which Hannah did not have. Tr. at 250.

Hannah had a 20-minute seizure at 2:42 p.m., April 3, 1992, and a 30-minute seizure at 8:30 a.m., April 4, 1992. (P. Ex. 13a, pp. 17, 19.) Dr. MacDonald said this was not status epilepticus because she was awake and pleasant afterwards. This was not a medical emergency or she would have been placed on a respirator. Tr. at 250. The hospital managed Hannah's care more conservatively because she rebounded from her seizures. If she had had acute respiratory change, he would have expected decreased oxygen intake. Her duskiness was not an emergency. It was a transient, non-threatening change in color. Tr. at 256.

Acute encephalopathy is a significant change in mental status, not a postictal state due to a seizure. Tr. at 259. In encephalopathy, brain function markedly declines. Tr. at 261. Hannah was very playful, cooing, smiling, and in good color. Then she would be less and less responsive. This is not unusual in a seizure disorder. Tr. at 257-58, 266, 268.

If Hannah had had an acute encephalopathy, one would see other changes on her EEG: sleep patterns would be grossly distorted, voltages would be remarkably low, the slowing would be diffuse. He agreed that Hannah would have been included in the NCES. Tr. at 262. Hannah looked good until she was over a year in age.

Hannah saw the doctor on April 14, 1992 and she was completely normal with no irreversible damage. Tr. at 263-64. She was hospitalized from June 17 to June 24, 1992, and

the notes state she had normal development with no regression. Her seizures had been well-controlled on Tegretol until that day. Tr. at 267-68. In over half of seizure cases, one does not know the cause. Tr. at 271. DPT does not cause afebrile seizures. No medical literature relates DPT to afebrile seizures. Tr. at 272-73.

A dispute arose between the experts over the interpretation of Hannah's EEGs. Dr. Tornatore does not read EEGs in his normal practice. Tr. at 289. Dr. MacDonald stated that in the May 5, 1992 EEG, there was a change in background that was not there a month before. Tr. at 290-91. By the November 1992, Hannah had chronic encephalopathy. Tr. at 291. She was also on medication. Id. Medications have the potential to sedate the child and can cause background changes on the EEGs. Tr. at 295-96. Dr. MacDonald does not know when her encephalopathy began. Tr. at 293. Hannah was not treated for status epilepticus. Tr. at 298. If she had been, she would have been intubated, put in the ICU, and given high doses of medicine, but she was not which was appropriate treatment. Id.

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 both theories in the alternative.

The medical records are replete with references to Hannah as being alert, playful, attentive, pleasant, and completely normal neurologically in between her numerous, short seizures and their brief postictal periods during which she was drowsy, but then rebounded to her responsive, alert self. Even after her 30-minute seizure on April 4, 1992, Hannah was awake and pleasant. P. Ex. 13a, p. 19. A child who is alert, attentive, playful, pleasant, babbling, cooing,

turning herself over, and completely normal neurologically on physical examination does not have an acute encephalopathy. The undersigned holds that Hannah did not have acute encephalopathy after her third DPT.

Not only does Hannah not satisfy the requirements of the Vaccine Act for a Table acute encephalopathy which require "a significantly decreased level of consciousness lasting for 24 hours" which cannot be attributed to a postictal state or medication, Fed. Reg. 60:26, 7694 (Feb. 8, 1995); section 100.3(b)(2)(i)(A), but also she did not have a non-Table acute encephalopathy. Dr. MacDonald's testimony is far more persuasive than Dr. Painter's and Dr. Tornatore's. First, Dr. MacDonald is a pediatric neurologist, whereas Dr. Tornatore is an adult neurologist. Dr. MacDonald has the experience in this area that Dr. Tornatore lacks. The undersigned finds extraordinary and not credible Dr. Tornatore's description of the medical record observations of Hannah's being pleasant, babbling, cooing, responsive to her surroundings, playful, and alert as "extremely insensitive," and "off the cuff" comments because physicians are "eternal optimists." The undersigned holds that the reason the medical staff noted repetitively that Hannah was pleasant, adorable,[6] cooing, babbling, responsive to her surroundings, playful, and alert is that she was. It is Dr. Tornatore who is unbelievable, not the contemporaneous 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.

[6/] The admitting physician noted that she was adorable. P. Ex. 13a, p. 122.

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

Secondly, Dr. Painter's own medical records which are contemporaneous with his treatment of Hannah contradict his testimony. In none of his medical records does he diagnose Hannah as having an acute encephalopathy starting on April 1, 1992. Instead, he emphasized on April 21, 1992 (three weeks after the onset of her seizures) that Hannah was alert, attentive, and playful, and very attentive to her surroundings and to him. P. Ex. 13cc, p. 5. He diagnosed her with epilepsy, etiology unknown, but not with acute encephalopathy. Id. at 6.

Thirdly, medical literature is solidly confirmatory of Dr. MacDonald's testimony that a significant and prolonged depression of consciousness is necessary for diagnosing an acute encephalopathy. Hannah had numerous, mostly brief postictal states, but she always rebounded from them to resume her playful, alert, and responsive self.

That leaves petitioners with the burden of proving that DPT caused in fact Hannah's seizures. 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, Hannah 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).

This whole case, after extensive discovery that petitioners wanted and an extraordinary amount of delay while petitioners asked for repeated postponements of the hearing, boils down to whether or not Hannah had fever with the onset of her seizures.

Both Dr. Tornatore and Dr. MacDonald testified that Hannah would have been included in the National Childhood Encephalopathy Study (NCES) because she had a convulsion lasting 30 minutes. (Dr. Tornatore would have included her also for acute encephalopathy.) A convenient summary of the NCES follows:

> The National Childhood Encephalopathy Study, conducted from 1976 to 1979, examined whether the frequency of vaccination in children with encephalopathy was greater than expected. It compared children aged 2 months to 3 years admitted to a hospital for serious acute neurological disease with a control group of normal children. Based on 11 subjects who appeared to have residua 18 months later, it was estimated that acute encephalopathy with permanent brain damage occurred at the widely quoted rate of 1 per 310,000 doses, with a 95% confidence interval (CI) of 1 in 54,000 to 5,310,000 doses. However, 4 among the 11 with apparent residua had infantile spasms and were subsequently eliminated from consideration when this condition was shown to be unrelated to DTP. Based on the data for the remaining 7 subjects, the relative risk for permanent impairment was 4.7 (95% CI, 1.1-28.0), with an attributable risk of 1 per 330,000 doses (95% CI, 1 case/50,000-18,000,000 doses). However, of these seven children, two had disseminated viral infections and one had Reye syndrome, conditions that are unlikely to be related to inoculation with DTP. In addition, three of the remaining four did not appear to be neurologically impaired on subsequent examination.

"Pertussis Vaccine," by K.M. Edwards, et al., ch 14 of Vaccines, 3d ed., eds. S.A. Plotkin and W.A. Orenstein (1999), at 309. R. Ex. J. The authors, at Table 14-2, quote the "Instititute of

Medicine Conclusions Regarding the Causation of Serious Adverse Events by DTP," that evidence does not indicate that DPT causes afebrile seizures. Id. at 310.

As stated above, the NCES whittled down to four the total number of children whose onsets of illness were within 7 days of receiving DPT, and three of those did not have permanent injuries. Among this selected group of vaccinees were two with prolonged/febrile convulsions. It is unclear if the slant between "prolonged" and "febrile" means "or" or "and." Since the NCES only included a child with a prolonged convulsion (i.e., 30 minutes or more), one would assume that the slant between "prolonged" and "febrile" means "and," but it is unclear. Certainly someone with febrile convulsions that did not last the appropriate 30 minutes would not have been included. But, the NCES does not say. Therefore, it is possible that among the two children included in the study whose onset of 30-minute convulsions occurred within 7 days of receiving DPT were: (1) two children with prolonged febrile convulsions; or (2) two children with prolonged afebrile convulsions; or (3) one child with a prolonged, febrile convulsion and one with a prolonged, afebrile convulsion. One cannot conclude that the NCES supports the idea that DPT causes afebrile prolonged convulsions.[7]

The undersigned finds it irrelevant the Hannah would have been included in the NCES because: (1) she did not have an acute encephalopathy, and (2) the NCES does not specify if

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[7/] See Table V.23 (pp. 133-34; text on 138-39) listing Category 1 B (normal-abnormal) which includes two children with prolonged/febrile convulsions occurring within 7 days of DPT vaccination. R. Alderslade, et al., The National Childhood Encephalopathy Study: A Report on 1000 Cases of Serious Neurological Disorders in Infants and Young Children from the NCES Research Team, in Whooping Cough: Reports from the Committee on the Safety of Medicines and the Joint Committee on Vaccination and Immunization (Department of Health and Social Security, London: Her Majesty's Stationery Office, 1981).

either of the two children with prolonged/febrile convulsions had a prolonged afebrile convulsion.

Moreover, even if Hannah had not only been included in the NCES, but also in the final small number of children discussed in the NCES's conclusions, that does not mean that the NCES authors would have stated that DPT caused her seizure disorder. The NCES authors cautioned that "their study should not be used to show DPT caused a neurologic injury in an individual case. Their confidence limits were too wide to yield reliable results and their derivation of attributable risk suffered from the fact that they performed a case-control study rather than a cohort study." Id. at *11 (pp. 98-99 of the NCES). In a 1993 follow-up to the NCES, the study's authors concluded that they did not prove in the NCES that DPT "was the sole or even the prime cause of either the illnesses or the adverse outcomes in these cases" and "attributions of a cause in individual cases must be speculative." Id.[8]

As to the issue of whether DPT causes afebrile seizures, an examination of Clements v. Secretary, HHS, No. 95-484V, 1998 WL 481881 (Fed. Cl. Spec. Mstr., July 30, 1998), is instructive. Andrew, a 6-and-1/4-month-old, received his third DPT and started seizing within a day. His first documented seizure was 45 minutes long and he had a temperature of 38.5° (101.3° F). Petitioners' expert, Dr. John H. Menkes, a renowned pediatric neurologist, testified that Andrew had an acute encephalopathy, but that his first seizure was not a febrile convulsion because that requires documentation of a temperature of 101.5° or higher. Id. at *5. Dr. Menkes also testified that Andrew would have been included in the NCES. Id.

[8/] D. Miller, N. Madge, J. Diamond, J. Wadsworth, and E. Ross, "Pertussis immunization and serious acute neurological illnesses in children," 307 *Brit Med J* 1171-76, 1175 (1993).

Because the medical records described Andrew as awakening easily, looking around, cooing, and not toxic-looking, and his neurological examination was completely normal, the undersigned held that Andrew did not have an acute encephalopathy. Id. at *11, 12. The undersigned also held that DPT does not cause afebrile seizures.

Dr. Menkes is co-author with Dr. Marcel Kinsbourne, the witness who "has chosen to withdraw from this case," of "Workshop on Neurological Complications of Pertussis and Pertussis Vaccination," 21 *Neuropediatrics* 171-76 (1990), which is attached as P. Ex. S to P. Ex. 17, which are articles that Dr. Painter purportedly relied upon in his affidavit, dated Feb. 13, 1997 (P. Ex. 15.)[9] Dr. Kinsbourne opines in a written report dated Sept. 28, 1996 that Hannah had an acute encephalopathy which DPT caused and DPT caused her afebrile seizures. P. Ex. 14. He states that on April 1, 1992, "Both at 3:00 p.m. and on admission, she was afebrile." Dr. Kinsbourne's opinion that Hannah's initial seizure was afebrile is consistent with Dr. Menkes' testimony about the level of temperature needed (101.5° F) to diagnose a febrile seizure in Clements and with Dr. MacDonald's testimony in the instant action that a temperature of 101° F orally is necessary to diagnose a febrile seizure. Medical literature, such as a standard pediatric neurology textbook (R. Ex. M), confirms that a temperature of 38.4° C (101.1° F) is necessary to categorize a seizure as febrile. But Dr. Tornatore is unlikely to consult a pediatric neurology textbook since he does not practice pediatric neurology.

Petitioners asserted through Dr. Tornatore that Hannah had febrile seizures. In a history Mrs. Bruesewitz gave the admitting doctor on April 2, 1992 at midnight, she said she measured

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[9/] Parts of Dr. Painter's affidavit deal with material with which he is not familiar (particularly paragraph 36). Tr. at 65.

Hannah under her armpit as having a 98.6° temperature, but she did not feel she had a fever. P. Ex. 13a at 122. Dr. Tornatore said that Hannah's rectal temperature would have been higher, 100.3°, and therefore she had a febrile seizure.[10] The first hospital measurement, however, when Hannah was brought in was 36.8° rectally (98.24° F). P. Ex. 13a at 9.

Moreover, Dr. Tornatore based his opinion that Hannah had a febrile seizure (i.e., that fever provoked her seizure and since she just had DPT which commonly causes fever, the DPT caused her seizure disorder) on the assumption that a temperature of 37.7° Centigrade (or 99.8° Fahrenheit) if it persisted for one day was enough to constitute a febrile seizure. But Hannah's supposed initial fever did not persist since, when she entered the hospital, she had a temperature of 36.9° C (or 98.4° F). Therefore, the facts of this case do not satisfy even Dr. Tornatore's criteria for diagnosing a febrile seizure since Hannah's supposed fever did not persist. Even if the undersigned were to accept Dr. MacDonald's 1979 article on febrile seizures in which he states that 37.7° C [99.8° F] is the level of temperature required to have febrile seizures, Hannah's temperature did not reach that level when she was admitted. But Dr. MacDonald disavowed his earlier article and current medical literature does not support it.

Mrs. Bruesewitz herself told the doctors at the hospital that she did not believe Hannah to have had a fever. She testified that Hannah often measured 98.6° F on the axillary thermometer,

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[10/] According to medical literature accessible on the Internet, an axillary or armpit temperature is usually .5 degree or 1 degree Fahrenheit below an oral temperature which is .5 degree of 1 degree Fahrenheit below a rectal temperature. The rectal temperature is deemed most accurate. Health_info.nmh.org/library/...essConditions/topic.asp?hwid=tw9223H. An axillary temperature of 98.6, if Mrs. Bruesewitz's measurement were accurate, would either be 99.6 or 100.6 degrees Fahrenheit rectally. Splitting the difference would yield a temperature of 100.1 degrees Fahrenheit rectally, but considering the permissible range of conversion means Hannah could have had a rectal temperature of 99.6 degrees before she was brought into the hospital.

and Mrs. Bruesewitz considered that to be normal. And all of Hannah's doctors noted afebrile seizures numerous times in the extensive medical records. Hannah's seizure after her DPT vaccination was afebrile, not febrile.

Regarding Dr. Geier, the specialist in genetics and forensic medicine, his affidavits and report are not credible. First, being a board-certified geneticist and forensic medicine specialist does not qualify him to diagnose neurological diseases and offer an opinion as to how doctors who do specialize in neurology define "encephalopathy." Dr. MacDonald's testimony about the definition of acute encephalopathy is more credible than Dr. Geier's and is well-supported in the medical literature. Hannah did not have acute encephalopathy.

In diagnosing Hannah's illness, her physicians used the ICD-9[11] code for convulsions (780.3), not the ICD-9 code for acute encephalopathy (348.3). Med. recs. at Ex. 13a, p. 1. Ultimately, as a consequence of either an underlying brain disturbance or her seizures, Hannah was diagnosed with diffuse encephalopathy, but her seizure onset within two hours of her DPT was not acute encephalopathy and none of her doctors diagnosed her as having acute encephalopathy.

In his discussion of DPT causing seizures, Dr. Geier refers in his second affidavit to the IOM's Adverse Effects of Pertussis and Rubella Vaccines (1991), but significantly omits the IOM's conclusion that DPT does not cause afebrile seizures. Hannah had afebrile seizures. The IOM did a meta-analysis of febrile and afebrile seizures and concluded that "even pooling

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[11/] The International Classification of Diseases, 9th Revision, Sixth Edition, is maintained jointly by the National Center for Health Statistics (NCHS) and the Health Care Financing Agency (HCFA). Ftp.cdc.gov/pub/Health_Stati...ications/ICD9-CM/2001/README02.TXT.

available data provides no evidence of a statistically significant increase in the risk of afebrile seizures following DPT vaccination." Id. at 115.

Dr. Painter, Hannah's treating pediatric neurologist, testified that Hannah had an acute encephalopathy because she had seizures, signifying an abnormal working of her brain. He also testified that DPT caused her acute encephalopathy and her seizures. The basis of his opinion is that DPT can cause seizures, there was a close proximity in time between the DPT and her onset, and he has found no other cause. But, as the Hasler case, supra, states, a mere temporal association is not sufficient legally to prove causation. Moreover, the Federal Circuit in Grant requires affirmative proof to satisfy the legal burden of proving causation. The fact that there is no other known cause does not affirmatively prove that DPT was the cause. Dr. Painter admitted that there are patients with seizures whose cause he does not know. The fact that DPT can cause acute encephalopathy and seizures in others does not prove that DPT caused either or both in Hannah. In the discussion above, the undersigned has rejected Dr. Painter's testimony that Hannah had an acute encephalopathy.

Dr. Painter offered no opinion whether Hannah's seizures were febrile or afebrile and if DPT can cause afebrile seizures. The impression of the undersigned is that Dr. Painter was attempting to help petitioners in a very sympathetic case. Hannah's condition is very unfortunate.

Petitioners have not prevailed on a theory that Hannah had an acute encephalopathy, either Table or non-Table, and/or the onset of febrile seizures that her DPT caused.

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