OFFICE OF SPECIAL MASTERS

No. 90-134V

(Filed: December 7, 1998)

* *		
CAMILLE E. PRIEST, a Minor, by and through his Mother and Natural Guardian, LYNN M. PRIEST,	*	
Petitioners,	*	**TO BE PUBLISHED**
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Robert M. Scott, Toledo, OH, for petitioners.

Elizabeth F. Kroop, Washington, DC, for respondent.

DECISION AND ORDER

MILLMAN, Special Master

Statement of the Case

On October 20, 1998, the undersigned issued an Order to Show Cause why petitioners are not entitled to compensation. Respondent filed its response to this Order on November 20, 1998. Petitioners replied to respondent's response on December 4, 1998.

The court issues its decision without a hearing. Evidence is sufficient for the undersigned to arrive at a "less-adversarial, expeditious, and informal proceeding for the resolution of [this] petition...." 42 U.S.C. § 300aa-12(d)(2)(A). See also RCFC, Vaccine Rule 8(d) ("A special master may decide a case on the basis of written filings without an evidentiary hearing.")

The court rules on behalf of petitioners on the issue of entitlement on the basis of either of two alternate grounds:

(1) petitioners have a prima facie case of on-Table encephalopathy, residual seizure disorder (RSD), and hypotensive-hyporesponsive shock collapse (HHE), and respondent's defense of a known factor unrelated, i.e., an undefined metabolic disorder, is legally insufficient because respondent cannot show what symptoms Camille E. Priest (hereinafter, "Camille") would have had since respondent does not know what metabolic disorder she has; or (2) again assuming, arguendo, that Camille has an undefined metabolic disorder, petitioners should prevail on the ground of significant aggravation, either on-Table or causation in fact, and respondent's defense of a known factor unrelated is legally insufficient because respondent's expert has opined that DPT "unmasked" the disorder, resulting in Camille's post-vaccinal symptoms, which were substantially worse than her prevaccination condition when she was clinically normal.

The court will discuss these grounds infra.

Statement of the Case

On February 27, 1995, Lynn and Jeffrey Priest, on behalf of their daughter, Camille, filed a petition for compensation under the National Childhood Vaccine Injury Act of 1986[(1)] (hereinafter the "Vaccine Act" or the "Act"). Petitioners have satisfied the requirements for a prima facie case pursuant to 42 U.S.C. § 300aa-119(c) by showing that: (1) they have not previously collected an award or settlement of a civil action for damages arising from the vaccine injury; (2) DPT vaccine was administered to Camille in the United States; and (3) they have incurred $1,000.00 in unreimbursable medical expenses prior to filing the petition.[(2)]

Petitioners allege that Camille suffered an on-Table encephalopathy, HHE, and RSD as a result of her first DPT at the age of two months. 42 U.S.C. §§300aa-11(c)(1)(C)(I); 14(a)(I)(B), (C), and (D). Respondent defends by alleging that Camille has an undefined metabolic disorder, which is a known factor unrelated. 42 U.S.C. §300aa-13(a)(2)(B).

The court did not hold a hearing in this case because the undersigned considers the evidence sufficient for petitioners to prevail upon either of the two alternate grounds described supra.

FACTS

Camille was born on December 20, 1991. Med. recs. at Ex. 1, p. 3. She received her first DPT on February 28, 1992, when she was two months of age. Med. recs. at Ex. 4, p. 1.

The Waterville Fire Department picked up Camille on March 2, 1992, three days after vaccination (1992 was a leap year). Med. recs. at Ex. 19. Their Patient Report describes her as hot, cyanotic, lethargic, tachycardic, and congested. Id.

Camille was hospitalized at Toledo Hospital from March 2 to 31, 1992. Med. recs. at Discharge Summary, p. 2.[(3)] The history Mrs. Priest gave was that Camille received her first DPT on Friday, February 28, 1992, and had a few episodes of non-projectile vomiting during the weekend, but was able to feed. Id. Throughout Monday morning, March 2, 1992, she was playful and asymptomatic, but refused feedings at 9:30 a.m. and 1:00 p.m. Id. At about 1:30 p.m., March 2, 1992, her babysitter found Camille unresponsive in her crib and she was brought to St. Luke's Emergency Room (ER) where they thought Camille was seizing and gave her Valium. Id. They transferred her to Toledo pediatric intensive care unit (PICU) where she was not seizing, but was unresponsive. Id. She had reached developmental milestones for her age. Id. On physical examination, she was lethargic and ill-appearing. Id.

Camille was put on Phenobarbital and Dilantin to control her seizures. Id. at 4. An EEG done on March 3, 1992 indicated seizure activity with right-sided preponderance and profound generalized encephalopathy. Id. A CT scan done on March 4, 1992 showed diffuse bilateral cerebral ischemia vs. cerebritis. Id. A repeat CT scan indicated some improvement, but still showed diffuse hypodensity in cerebellar hemispheres. Id. Tissue samples suggested glycogen storage disease, type I. Id.

Dr. B.U.K. Li, a pediatric gastroenterologist, wrote a letter to Dr. James Huttner on April 30, 1992, stating that Camille was admitted to Toledo Hospital following a life-threatening fever, seizure, and coma which required intubation and ventilation. Med. recs. at Ex. 39, pp. 7-8. Two EEGs dated March 2 and 16, 1992 revealed diffuse encephalopathy. Id. at 7. Two CT scans dated March 4 and 7, 1992 revealed ischemic changes. Id. Two other CT scans dated March 10 and 17, 1992 showed diffuse areas of hypodensity. Id. Camille had possible fatty acid oxidation disorder. Id. at 8. Dr. Li thought her catastrophic course was not related to DPT because the timing was not right. Id.

EVIDENTIARY MATERIAL

Mrs. Lynne M. Priest, Camille's mother, submitted an affidavit dated February 15, 1995, stating that Camille received her first DPT vaccination at 2:45 p.m. on February 28, 1992. P. Ex. 16, p. 2. On Saturday, February 29th, and Sunday, March 1, 1992, she was cranky, irritable, and did not feed well. Id. Also, on Saturday, she had a low grade fever. Id. On Monday, March 2, 1992, she dropped Camille at the home of her babysitter, Tonia Gerity, at about 7:15 a.m. Id.

Mr. Jeffrey J. Priest, Camille's father, submitted a similar affidavit dated February 15, 1995. P. Ex. 17.

Ms. Tonia C. Gerity, Camille's babysitter, submitted an affidavit dated February 15, 1992. P. Ex. 18. She states she had been a licensed practical nurse since 1980 and had been Camille's babysitter since February 1992. Id. at 2. On March 2, 1992, Camille was the only child for whom she babysat. Id. Camille arrived at her home at about 7:15 a.m. and Mrs. Priest advised her that Camille had received the DPT on Friday and might be fussy and irritable as she had been over the weekend. Id. Camille would usually nap between 8:30 a.m. and 9:00 a.m. but she did not do so that day and was "rather fussy" at about 8:30 a.m. Id. Rocking her did not seem to help. Id. Ms. Gerity attempted to feed Camille at around 10:00 a.m., but Camille would only sip at the bottle and again was fussy. Id. Normally, she was an eager feeder and would finish a bottle in 15 to 20 minutes. Id. That day she sipped the bottle for two hours until it was finished. Id. at 2-3. Ms. Gerity put Camille down for a nap at about 11:00 a.m. and Camille fell asleep. Id. at 3.

Between 12:45 p.m. and 1:00 p.m., Camille seemed sleepy. Id. Ms. Gerity began to change Camille's diaper, and noticed her legs were limp. Id. She looked at Camille's eyes and the pupils were fixed and dilated. Id. Her breathing was shallow and irregular. Id. Ms. Gerity attempted to move Camille's arms and upper torso, but Camille did not respond. Id. She called the rescue squad. Id.

Petitioners submitted a report from Dr. B.U.K. Li, Camille's treating pediatric gastroenterologist, dated May 13, 1998. P. Ex. 47. Dr. Li states tests were done on Camille which rule out the possibility of her having a disorder of fatty acid oxidation. Id. He felt there were insufficient data to opine that Camille has a disorder of mitochondrial metabolism, and "[g]iven her unremarkable course beforehand and her stable course afterwards, I think that a mitochondrial aberration is unlikely." Id.

Petitioners also submitted the report of Dr. Lorraine M. Fay, a clinical pediatrician and developmental specialist, dated February 3, 1998. P. Ex. 48. She states that children with metabolic disorders tend to show a pattern of deterioration over time. Id. However, Camille did not show such a decline, has made

slow but steady developmental progress, and is in excellent health. Id. She is on anticonvulsant medications but, since her initial event, has not shown signs of metabolic disturbance, i.e., hypoglycemia, acidosis, elevation of ammonia level. Id.

Dr. Fay does not think that Camille fasted before her post-vaccinal unresponsiveness because her babysitter fed her a bottle at 9:00 a.m., and called for an ambulance just 4 and one-half hours later, at 1:30 p.m. Id. This is too short an interval to be considered a fast which would lead to a metabolic collapse due to MCAD (medium chain acyl carnitine transferase deficiency). Id. Dr. Fay continues:

Camille's parents have consulted with a number of specialists, who have been unable to reach a consensus regarding a diagnosis. Correspondence from her ongoing child neurologist, Dr. Orrechio, expresses doubt that her condition represents metabolic disease. Dr. Kurczynski, a geneticist and neurologist at Medical College Hospital, initially suspected glycogen storage disease, which was later ruled out by liver biopsy by Dr. Hug, in Cincinnati. Dr. Hug also ruled out carnitine deficiency, both total and free. Specific acyl CoA dehydrogenase activity in the liver was measured and also found to be normal, which I would not expect to be the case in MCAD deficiency. Dr. Li, a gastroenterologist in Columbus, reviewed her case and was unable to come to a specific conclusion, recommending specific enzyme studies be considered to rule out mitochondriopathies, if repeat carnitine studies remained equivocal.

Id. at 1-2.

Petitioners also submitted a report from Dr. George Hug, professor of pediatrics, dated May 6, 1992, in which he lists the tests of Camille's liver specimen to measure acyl coenzyme A dehydrogenase. P. Ex. 50. The results were in the normal range of these enzymes. Id.

Petitioners submitted an expert report from Dr. Marcel Kinsbourne, a pediatric neurologist, dated September 8, 1994. Med. recs. at Ex. 21. He states that when Camille was brought to the ER, her temperature was 106 degrees. Id. She was comatose and acidotic. Id. She was intubated for ten days. Id. Currently, she has severe psychomotor delay and spastic quadriparesis. Id. Dr. Kinsbourne opines that Camille had an on-Table HHE which caused hypoxic/ischemic damage to her brain. Id. As a result, she has a static encephalopathy with spastic cerebral palsy. Id. at. 1-2.

Petitioners further submitted a supplemental expert report, dated June 30, 1998, from Dr. Kinsbourne. P. Ex. 51. Dr. Kinsbourne states that Camille had not only an on-Table HHE, but also an on-Table encephalopathy and on-Table RSD. Id. Her HHE caused cerebral ischemia (deficiency of blood in the cerebrum), resulting in irreversible encephalopathy that first manifested in acutely and then chronically. Id. Her encephalopathy was manifested by protracted seizures and prolonged unconsciousness, leaving her cerebrally palsied and mentally retarded. Id. An EEG on March 3, 1992 showed diffuse cerebral damage. Id. A brain CT scan on March 4, 1992 showed diffuse cerebral ischemic changes. Id. A CT scan on March 17, 1992 showed ventricular enlargement, meaning that the damage to Camille's brain was permanent. Id.

Respondent submitted two reports from its expert, Dr. Peter R. Kollros, a pediatric neurologist. R. Exs. A and C. In Dr. Kollros's first report, dated September 30, 1997, he states that Camille has a metabolic disease which caused her neurologic injury. R. Ex. A, p. 1. Her disorder is characterized by lactic acidosis. Id. Her tests show a disorder most consistent with mitochondrial cytopathy. Id. The serum carnitine, although within the normal range, had a short chain esterified fraction with twice the normal value, suggestive of a mitochondrial disorder. Id. Dr. Kollros relies in part on Dr. Li's notation of April 23, 1992 that Camille had a bloated mitochondrial cristae consistent with a Reye's-like syndrome, or

MCAD or another disorder of fatty acid oxidation, i.e., a mitochondriopathy. Id.

Dr. Kollros continues that Camille's vomiting, poor food intake, and poor fluid intake the day prior to her presentation of symptoms "unmasked" her metabolic disorder because she "could not compensate in the face of stresses of decreased carbohydrate and fluid intake." Id. If these stresses (vomiting, failure to eat and drink) had not unmasked her metabolic disorder, some other routine infant stress or illness would have done so and her outcome would not have been substantively different. Id. Dr. Kollros thinks one of Camille's cousins had the same metabolic disorder because that cousin died of SIDS at an age similar to when Camille became ill. Id. at 1-2. Dr. Kollros disagrees with Dr. Kinsbourne because Camille's having HHE 70 hours post-DPT vaccination puts it outside the time within which medical literature describes it occurring.[(4)]

Id. at 2.

Dr. Kollros's supplemental report, dated September 10, 1998, states that Camille had normal profiles of plasma and urine free carnitine and carnitine esters, making it "somewhat less likely" that she has medium chain acyl carnitine transferase deficiency (which he terms MCAT deficiency). R. Ex. C, p. 1. However, Dr. Kollros did not think those normal profiles ruled out such a diagnosis conclusively because they were produced a considerable time after Camille's onset of symptoms. Id. He discounts Dr. Li's and Dr. Fay's opinions because neither is a pediatric neurologist. Id. Dr. Li's information makes Camille's having MCAT deficiency less likely. Id. He finds Dr. Fay's statement that children with metabolic disorders show a pattern of deterioration over time to be "very simplistic. **The patterns of decline and injury from metabolic disorders vary greatly depending upon the specific disorder**." Id. (emphasis added).

In Dr. Kollros's opinion, DPT "imitated an intercurrent illness" in Camille. Id. at 2. Her body responded as if she were fighting off an illness. Id. Often part of this response is to eat and drink less, which is normal. Id. However, children with a wide variety of metabolic disorders are not able to adjust to this because their reserves are so poor that they cannot withstand the stress and they decompensate. Id. The quality of Camille's response, i.e., lactic acidosis and mitochondrial cytopathology, to normal stress and not the severity of her response indicates to Dr. Kollros that she more likely than not had a preexisting metabolic disorder. Id. Dr. Kollros opines that the metabolic disorder caused Camille's encephalopathy. Id.

Dr. Kollros states that if Camille had not received DPT, she would have had some different stress or intercurrent illness which would have unmasked her underlying disorder. Id.

DISCUSSION

Encephalopathy

Petitioners allege that Camille suffered an on-Table encephalopathy after her DPT vaccination. The Vaccine Act includes a section titled "Qualifications and aids to interpretation." 42 U.S.C. § 300aa-14 (b). Subsumed under that section is subsection (3)(A), which states:

The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery,[(5)] or may result in various degrees of permanent impairment.

Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable [sic] crying,

and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

42 U.S.C. § 300aa-14(b)(3)(A).

Dr. Kollros, respondent's expert, admits in his supplemental report that Camille had an acute encephalopathy.[(6)] R. Ex. C. The records are replete with a diagnosis of encephalopathy from the moment that Camille was brought to the hospital. She was comatose, unresponsive, lethargic, with dilated and fixed pupils, and an abnormal EEG and CT scan. In addition, she had seizures.

Petitioners have sustained their burden of proof that Camille had an on-Table encephalopathy.

Residual Seizure Disorder (RSD)

Petitioners allege that Camille suffered an on-Table RSD after her DPT vaccination. The Vaccine Act defines RSD in 42 U.S.C. § 300aa-14(b)(2) as follows:

A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied

by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if--

(B) in the case of any other vaccine [than measles, mumps, or rubella], the

first seizure or convulsion occurred within 3 days after administration of

the vaccine and 2 or more seizures or convulsions occurred within 1 year

after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

Camille sustained her first seizure in the context of a high fever. The records show her fever on hospitalization to be 106 degrees. She suffered subsequent seizures without fever within a year of vaccination. She never had a fever before her DPT vaccination.

Petitioners have sustained their burden of proof that Camille had an on-Table RSD.

Hypotensive-Hyporesponsive Shock Collapse (HHE)

Petitioners allege that Camille suffered an on-Table HHE after her DPT vaccination. The Vaccine Act defines HHE in 42 U.S.C. § 300aa-14(b)(1) as follows:

A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of

muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis,

loss of color or turning pale white or blue, unresponsiveness to environmental

stimuli, depression of consciousness, loss of consciousness, prolonged sleeping

with difficulty arousing, or cardiovascular or respiratory arrest.

Camille was limp and unresponsive when Ms. Gerity, her babysitter, found her early in the afternoon of March 2, 1992. She could not be roused. Her breathing was shallow and irregular. Although medically Dr. Kollros has difficulty with linking HHE to DPT because the onset was 70 hours after DPT vaccination, the statute puts an HHE occurring within 72 hours or three days of vaccination on-Table. 42 U.S.C. §300aa-14(a).

Petitioners have sustained their burden of proof that Camille had an on-Table HHE.

Known Factor Unrelated

The statute provides under 42 U.S.C. §300aa-13(a)(2)(B) that in order for petitioners to prevail, there must not be a known factor unrelated to the vaccine that has caused the vaccinee's illness or injury. The definition of a known factor unrelated is as follows:

[It] may ... include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents **principally responsible for causing the petitioner's illness, disability, injury, condition, or death.**

42. U.S.C. §300aa-13(a)(2)(B) (emphasis added).

Respondent asserts that Camille has an underlying metabolic disorder, although it does not know which one. (Petitioners hotly contest that Camille has a metabolic disorder.) Under the statute, respondent need not identify the precise disorder for that disorder to be a known factor unrelated. However, since the burden of proof is by a causation in fact standard, respondent does need to show what that disorder would cause. Otherwise, it would be impossible for respondent to prove that the known factor unrelated is "principally responsible for causing" Camille's illness.

To satisfy its burden of proving causation in fact, respondent must offer "proof of a logical sequence of cause and effect showing that [the factor unrelated] was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect." See 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).

Respondent's expert, Dr. Kollros, states clearly in his supplemental report, "The patterns of decline and injury from metabolic disorders vary greatly depending upon the specific disorder." The undersigned held to this effect in Connor v. Secretary, HHS, No. 90-3327V, 1998 WL 330938 (Fed. Cl. Spec. Mstr. May 5, 1998). In Connor, the vaccinee, Charles Connor, had an undefined metabolic disorder. Id. at *2. Under the statute, respondent need not identify what metabolic disorder petitioner has to prove a known factor unrelated. But, respondent must prove what petitioner's metabolic disorder would cause in fact in order to defeat the statutory presumption in Connor that MMR caused the seizure disorder. Id. at *12. In

Connor, respondent similarly focused on the vaccinee's symptoms and posited that the undefined metabolic disorder must have caused them because he had them. Id. at *7-8. This was legally insufficient to defeat the statutory presumption. Id. at *12.

This case is even stronger than Connor because, in Connor, the vaccinee did not have any post-MMR symptoms. Without the statutory presumption, petitioner could not have proven causation. In the instant action, respondent's expert has admitted DPT played a role in Camille's illness. Although Dr. Kollros omits any discussion in both of his reports of Camille's high fever (106 degrees), he does concede that Camille's body was reacting to DPT as if it were an intercurrent illness. Hence, this two-month old baby stopped eating and drinking. Moreover, she was vomiting. Because of the stress that her failure to eat and drink produced (not to mention the stress of her subsequent fever), she became encephalopathic and seized. That she had an underlying metabolic disorder, possibly of a transient nature because her current tests show her metabolic levels to be normal, made her more vulnerable to the effects of a DPT reaction. However, and this is crucial, without DPT, Camille would not have had a life-threatening illness on March 2, 1992.

Respondent posits that Camille would have been ill anyway. At some future point in her life, she would have had an intercurrent illness or some similar stress, and then she would have had these symptoms. This is pure speculation. Without knowing what metabolic disorder Camille purportedly has, respondent cannot state what her symptoms would be. In Spence v. Secretary, HHS, No. 95-57V, 1998 WL 211909, *9-*11 (Fed. Cl. Spec. Mstr. April 13, 1998), respondent similarly looked at the vaccinee's post-DPT symptoms and asserted that she would have had similar symptoms anyway, even though no one knew looking forward from her underlying illness what her symptoms would be.

In Spence, the vaccinee, Sarah Spence, had trisomy of her 5p. Id. at *9. Although no one knew what her genetic aberration would cause, she did have an on-Table seizure disorder. Respondent asserted that the pre-existing trisomy 5p must be the cause of her seizures because she had seizures. Id. This court held that such reasoning, while possibly tenable medically, is legally insufficient to defeat the statutory presumption of causation. Id. at *17.

The court has previously held that DPT vaccine can cause a fever which in turn causes the onset of a seizure disorder. McMurry v. Secretary, HHS, No. 95-682V, 1997 WL 402407 (Fed. Cl. Spec. Mstr. July 27, 1997). In McMurry, petitioners alleged a causation in fact seizure disorder.[(7)] Id. at *1. In that case, the child had a high fever and seized for fifty or more minutes following her DPT. Id. at *1-2. In addition, she was unresponsive and in status epilepticus. Id. Based on the occurrence of the fever as well as the onset of severe seizures, the court held for petitioners. Id. at *8-9. Respondent's expert, Dr. Gerald Fenichel, admitted that DPT triggered the vaccinee's seizures, but denied that "trigger" meant the same as "cause." Id. at *7. Even though the vaccinee's underlying condition was idiopathic, Dr. Fenichel was of the opinion that she would have had seizures at some point anyway because, at some later time, she would have had a fever. Id. The undersigned saw no difference between trigger and cause, although this was in the context of an idiopathic factor unrelated.

In the instant action, in the context of a known factor unrelated which is undefined and whose symptoms vary greatly depending upon which metabolic disorder is involved, the undersigned does not consider respondent to have met its burden of proving that the known factor unrelated principally caused Camille's injury. Legally, respondent cannot sustain its burden by looking backward from Camille's symptoms and saying that the metabolic disorder, of whatever type, is the cause of her illness. It is important, also, to recognize that test results currently do not confirm Camille has a metabolic disorder and two of Camille's treating doctors (Drs. Li and Fay) state that they do not believe she has a metabolic disorder.

In another case, McCollum v. Secretary, HHS, No. 94-0136V, 1998 WL 338237 (Fed. Cl. Spec. Mstr. June 5, 1998), respondent defended against on an-Table RSD by asserting that known factors unrelated, cortical dysplasia or microdysgenesis, caused the seizures. Grant McCollum was born with agenesis of the corpus callosum (ACC). Although he had a temperature of 102 degrees after DPT with an on-Table RSD, respondent stated that all his symptoms were due to cortical dysplasia or microdysgenesis because these brain anomalies usually accompany ACC, which, itself, does not cause seizures. Id. at *4.

However, even though Grant had had a brain resection and subsequent biopsy, there was no proof of cortical dysplasia or microdysgenesis. Id. at *9. The neuroradiological experts sharply disagreed in their interpretations of Grant's MRI's. Id. The undersigned held that, without more persuasive evidence that Grant had cortical dysplasia or microdysgenesis, the court would not assume he had either based on respondent's theory that they had to be there in order to explain Grant's post-vaccinal seizures. Id. at *11. Petitioners prevailed.

Contrast these series of cases and the instant action with the case of Matthew Jordan. In Jordan v. Secretary, HHS, No. 91-1344V, 1992 WL 300901 (Fed. Cl. Spec. Mstr. Oct. 2, 1992), aff'd, 38 Fed. Cl. 148 (Fed. Cl. Mar. 31, 1993), appeal dismissed, 1994 WL 745560 (Fed. Cir. Mar. 25, 1994), Matthew was born with an autosomal recessive genetic disorder, the same disorder that afflicted his older sister Kara. Kara and Matthew were born with organs missing and with facial dysmorphism. Id. Kara seized as a neonate. Id. at *4. Matthew seized on-Table after DPT. Id. at *2. He subsequently became mentally retarded. Id. at *2-4.

Kara had an exacerbation of her symptoms after DPT, but these abated. Jordan v. Secretary, HHS, No. 91-0113V, 1998 WL 106131 *3 (Fed. Cl. Spec. Mstr. Feb. 23, 1998). She ultimately died from failure to breathe. Id. The undersigned ruled in both cases that petitioners did not prevail, Kara because her death was unrelated to her DPT-vaccine injury, Matthew because his seizures were part of the autonomic recessive disorder with which he was born.

Testimony at Matthew's trial from respondent's experts, one of whom was a clinical geneticist, showed that Matthew's and Kara's conditions were identical. Kara's neonatal seizures enabled respondent's experts to predict Matthew's course. 1992 WL 300901, at *4-7. Kara seized and was developmentally delayed. Id. at *7. Matthew seized and was developmentally delayed. Id. That DPT had been administered before Matthew's onset of seizures did not remove the underlying known factor unrelated as the principal cause of Matthew's condition. Id. at *12.

Such logical sequence of cause and effect is absent here. The instant action does not permit any type of prediction of symptoms, just as in Connor, Spence, and McCollum. Instead of looking forward from a known disease to easily predictable symptoms, respondent is looking backward from post-vaccinal symptoms and positing that they must have come from the underlying illness. Particularly in the context of an obvious DPT reaction (high fever, HHE, encephalopathy, seizures), this is extraordinary and overreaching.

Respondent has not sustained its burden of proving by a standard of causation in fact that an undefined metabolic disorder principally caused Camille's post-vaccinal symptoms.

On-Table Significant Aggravation

Petitioners do not concede that Camille had a preexisting condition that DPT aggravated. Respondent defends that she does and that DPT did not aggravate it. Assuming, arguendo, that Camille does have a preexisting metabolic disorder, petitioners would still prevail on a theory of on-Table significant

aggravation.

Congress defined "significant aggravation" as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4). In order for this court to hold that DPT vaccine significantly aggravated Camille's metabolic disorder, the undersigned must find that Camille experienced greater disability, pain, or illness accompanied by a substantial deterioration of health within Table time of the vaccination. This is not a difficult task.

Legislative history provides insight into Congress's interpretation of "significant aggravation:"

The committee has included significant aggravation in the Table in order not to exclude serious cases of illness because of possible minor events in the person's past medical history. This provision does not include compensation for conditions which might legitimately be described as pre-existing (e.g., a child with monthly seizures who, after vaccination, has seizures every three and a half weeks), but is meant to encompass serious deterioration (e.g., a child with monthly seizures who, after vaccination, has seizures on a daily basis).

H.R. Rep. No. 99-908 at 31 (1986) , reprinted in U.S.C.C.A.N. 6344, 6356-57.

The language of the statute indicates that onset of an on-Table significant aggravation must occur within three days of a DPT vaccination. "Time period for first symptoms or manifestation of onset or of significant aggravation after vaccine administration: ...3 days...." 42 U.S.C. § 300aa-14(a).

The most authoritative legal holding concerning significant aggravation comes from the United States Court of Appeals for the Federal Circuit in Whitecotton v. Secretary, HHS, 81 F.3d 1099 (Fed. Cir. 1996), which enunciated a test to determine whether a petitioner has proven a prima facie case of on-Table significant aggravation. Under Whitecotton, petitioners must show that: (1) the vaccinee's current condition is significantly worse than her pre-vaccination condition, and (2) the onset of this substantial deterioration occurred within Table time of the vaccination.[(8)] Id. at 1107. Thus, in order for this court to hold that DPT vaccine significantly aggravated Camille's preexisting condition on-Table, I must find that Camille experienced greater disability, pain, or illness accompanied by a substantial deterioration of health whose onset began within Table time of the vaccination. She did and it was.

Camille was vaccinated on Friday afternoon, February 28, 1992 (1992 was a leap year). On the weekend, she had some vomiting and a low grade fever. She was cranky, irritable, and did not feed well. By Monday morning, March 2, 1992, she refused to eat at 9:30 a.m. and 1:00 p.m. and refused her normal 8:30 a.m. nap. She sipped at her bottle for two hours, whereas she normally took fifteen to twenty minutes to finish feeding. She napped at 11:00 a.m.

At around 1:30 p.m., the babysitter found her unresponsive, sleepy, limp, with pupils fixed and dilated, and breathing shallowly and irregularly. The sitter called 911 and the fire department brought Camille to an ER. The fire department report describes her as hot, cyanotic, lethargic, tachycardic, and congested. The ER diagnosed her as seizing and gave her Valium. She was transferred to an intensive care unit at another hospital, where she was lethargic, ill-appearing and unresponsive. She had 106 degrees temperature. She was put on Phenobarbital and Dilantin to control her seizures. An EEG indicated seizure activity and profound generalized encephalopathy.

Currently, Camille has static encephalopathy and cerebral palsy. There could hardly be a starker contrast to her pre-vaccination condition. Since petitioners have satisfied their burden of proving a prima facie

case, the burden of proof then shifts to respondent to show that a known factor unrelated, i.e., the undefined metabolic disorder with which Camille was born, was the cause in fact of her subsequent RSD, encephalopathy, HHE, mental retardation, and developmental delay .

As Associate Justice David H. Souter stated in the U.S. Supreme Court decision in Shalala v. Whitecotton, 514 U.S. 268 (1995), a vaccinee born with an encephalopathy cannot prevail on the theory of on-Table onset of encephalopathy. Since respondent posited that Maggie Whitecotton was born with a chronic encephalopathy because she was born microcephalic, the court can assume that Camille in the instant action was born with a chronic encephalopathy because of her underlying metabolic disorder. If the inevitable effects of Camille's metabolic disorder were to produce encephalopathy, seizures, cerebral palsy, and quadriparesis, then there is no reason for respondent to approach Camille differently than it approached Maggie Whitecotton.

Further clarity may be obtained by looking at the tuberous sclerosis (TS) cases. The undersigned initially tried these cases on a theory of on-Table RSD and on-Table encephalopathy. Respondent objected that the court could analyze the cases only under a theory of significant aggravation. In a test case, Costa v. Secretary, HHS, No. 90-1476V, 1992 WL 47334 (Cl. Ct. Spec. Mstr. Feb. 26, 1992), rev'd, 26 Cl. Ct. 866 (1992), the undersigned ruled for Stephen Costa on a theory of on-Table RSD and on-Table encephalopathy. Respondent appealed and the Honorable Moody R. Tidwell reversed and remanded on that issue, agreeing with respondent that the undersigned had to analyze the case under a theory of significant aggravation. Judge Tidwell held that Stephen Costa had a "latent condition" (encephalopathy and RSD) because he was clinically normal before the DPT vaccination. Costa, supra, 26 Cl. Ct. 866 (1992).

Similarly, in this case, the undersigned could hold that Camille had a latent encephalopathy and a latent RSD before the DPT vaccination since she also had a congenital condition (metabolic disorder) which DPT unmasked.

Because respondent amassed a great deal of evidence to show that TS children with a high number of tubers would inevitably develop afebrile myoclonic seizures, most probably infantile spasms, the undersigned held an Omnibus hearing, resulting in an Omnibus TS Decision, which stated that if a child with TS had a DPT and no symptoms of a vaccinal reaction, i.e., fever, anorexia, screaming, crying, then petitioners would not prevail. If, however, there were symptoms of a vaccine reaction, the undersigned would consider ruling for petitioners.

In the instant action, if Camille had had TS instead of an underlying unknown metabolic disorder, the undersigned would rule for Camille because she had a high fever, was comatose and encephalopathic, in shock (HHE), refused to eat or drink, vomited, was irritable and fussy, and also seized. Stephen Costa developed massive infantile spasms on-Table after DPT, diffuse severe irritability, and continuous crying for which he was hospitalized, not the typical scenario for a TS child. 1992 WL 47334 at *1. Respondent never appealed the Costa decision on remand. Costa v. Secretary, HHS, No. 90-1476V, 1992 WL 365421 (Fed. Cl. Spec. Mstr. Nov. 5, 1992).

Even assuming what petitioners hotly contest herein, that Camille has an underlying metabolic disorder, petitioners prevail on a theory of significant aggravation. Respondent has produced no proof whatsoever of what Camille's symptoms would have been without the vaccination. To do that, respondent would have to know what metabolic disorder she has. The court discussed very thoroughly in Connor the different metabolic diseases there are and the quite varied symptoms they produce. Connor, supra at *10-12. Dr. Kollros admitted the range and variability of symptoms depends on the type of metabolic disorder.

It is legally insufficient for respondent to look at Camille's post-vaccinal symptoms and say those are due to her underlying disorder, without knowing what exactly that disorder is. It is speculative to say that at some point in the future after her vaccination, she would have had some sort of intercurrent illness which would have produced the same stress on her that the DPT did and she would then have manifested the same symptoms and been in the same condition she is in now. It is extraordinarily speculative for Dr. Kollros to support his view that Camille has a metabolic disorder by pointing to her cousin who died of SIDS at about two months of age and state, without any medical records whatsoever, that Camille's cousin must have had the same metabolic disorder he thinks Camille has.

Respondent protested at the last telephonic status conference that petitioners have not proved that Camille's current condition is a sequelae of her vaccine injury. But, as Dr. Kinsbourne stated in his supplemental report, when Camille nearly died from her HHE and encephalopathy, she had cerebral ischemia, manifested on CT scan as ventricular enlargement. This injury led directly to her seizures, mental retardation, quadriparesis, and cerebral palsy.

Even if respondent were to maintain that all these symptoms (mental retardation, cerebral palsy, quadriparesis) were due to her underlying metabolic disorder, that would still not thwart petitioners from recovering under significant aggravation. In Suel v. Secretary, HHS, No. 90-935V, 1997 WL 617034 (Fed. Cl. Spec. Mstr.), aff'd (unpub. order, May 5, 1998), appeal docketed, No. 98-5153 (Fed. Cir. Aug. 18, 1998), the undersigned initially ruled against petitioner. David Suel's eyes rolled back within Table time of his DPT. He did not have any other symptoms. David unfortunately was born with TS. He subsequently developed a seizure disorder, developmental delay, and autism. Petitioners appealed and the Honorable James F. Merow reversed, finding that David had experienced significant aggravation of his TS, and remanded to the undersigned to find damages.

In the meanwhile, respondent had accumulated evidence which it would present in the Omnibus TS hearing. Respondent chose not to ask Judge Merow to reopen his finding of entitlement based on this new evidence. Instead, respondent presented the evidence in the Suel hearing on damages, claiming that petitioners could not prove that David's current condition was a sequela of his vaccine injury.

The court held that the issue of entitlement was before only Judge Merow and that the evidence on sequelae was an attempted end run around the issue of entitlement. It was clear to the undersigned that if DPT legally significantly aggravated David's TS, then petitioners were entitled to receive all the damages for the TS symptoms David manifested which DPT significantly aggravated, i.e., seizure disorder, developmental delay, and autism.

If indeed Camille's current condition is due to her underlying metabolic disorder, then she is entitled to recover compensation for her condition because DPT significantly aggravated her metabolic disorder, "unmasking" (to use Dr. Kollros's term) her latent symptoms (to use Judge Tidwell's analysis in Costa). It seems awfully perverse for respondent to insist that a preexisting condition exists whose symptoms DPT unmasked, causing a clinically normal child to become profoundly abnormal, and yet assert that her symptoms are not compensable under significant aggravation.

For the reasons the undersigned described supra under the on-Table encephalopathy, RSD, and HHE section of this opinion, respondent has failed to satisfy its burden of proof. Petitioners prevail under a theory of on-Table significant aggravation.

Causation in Fact Significant Aggravation

Respondent, in a status conference, and in its Response to Order to Show Cause at 5, posits the defense

that if Camille has a known factor unrelated which is a metabolic disturbance, toxin, trauma, or infection (42 U.S.C. § 300aa-14(b)(3)(B)), petitioners cannot prevail on a theory of on-Table significant aggravation. This is because an on-Table encephalopathy would no longer be considered on-Table in light of the listed known factor unrelated of metabolic disturbance. If respondent's position is legally correct, it would, in effect, eliminate the ability of petitioners to prevail on a theory of on-Table significant aggravation if the factors were metabolic disturbance, toxins, trauma, and infections.

The subsection in question could easily have included on-Table significant aggravation together with on-Table encephalopathy as a precluded legal holding if Congress had so intended to limit the use of on-Table significant aggravation. In a statute that was created for the purpose of easing petitioners' burden of causation, it seems strange that Congress would have intended to make it harder by a convoluted decimation of on-Table significant aggravation.

Respondent's position in the instant action presents the interesting conundrum that petitioners herein could prevail on a theory of on-Table significant aggravation of a latent seizure disorder (using the reasoning of Costa, supra, that Camille's metabolic disorder is a latent seizure disorder) since the qualifications and aids to interpretation do not have a similar provision for RSD that they do for encephalopathy preceded by metabolic disturbance, toxins, trauma, and infections. But petitioners would have to present evidence of causation in fact in order to prevail on a theory of significant aggravation of a latent or chronic[(9)] encephalopathy because of the application of metabolic disturbance, toxins, trauma, and infections to encephalopathy in the qualifications and aids to interpretation. It is bizarre to put petitioners to two different standards of proof concerning the same allegation of significant aggravation. But that is what respondent's position would require. "It is true that interpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available." Griffin v. Oceanic Contractors, Inc., 458 U.S. 564, 575 (1982) (citations omitted).

But assuming arguendo that respondent's interpretation of the Vaccine Act is correct as applied to on-Table significant aggravation, respondent leaves petitioners with one avenue of recovery: proof of causation in fact significant aggravation. In this case, that is not a hard burden.

Dr. Kollros, respondent's expert, opined in his reports that Camille's reaction to her DPT was to stop eating and drinking. Moreover, she was vomiting and had a fever. The stresses that a failure to eat and drink would produce in a normal child would have been de minimus but they were insupportable to Camille, who decompensated and became encephalopathic with the consequence of seizures. All this evidence comes from respondent's expert. Although Dr. Kollros thinks Camille's post-vaccinal reaction insignificant, saying it would have happened anyway at some future time with some other stress, he has provided the very evidence of a logical sequence of cause and effect necessary to satisfy petitioners' burden of proof that DPT caused in fact Camille's substantial deterioration due to a significant aggravation of her preexisting metabolic disturbance.

Even if respondent were to argue that Camille's preexisting metabolic disturbance was not a latent or chronic encephalopathy, respondent would be the first to say that Camille's post-DPT symptoms were the consequence of her having this preexisting metabolic disturbance. The symptoms that DPT induced, provoked, triggered, or unmasked caused the significant worsening of that metabolic disturbance and substantial deterioration from her prevaccination condition. There could hardly be a better illustration of Whitecotton significant aggravation, with a causation in fact analysis rather than on-Table presumption of causation.

This case is similar to Gall v. Secretary, HHS, 1998 WL *** (Fed. Cl. Spec. Mstr. October 30, 1998)

(to be published), in which the special master held that DPT induced, provoked, or triggered the vaccinee's underlying FHL (familial hemophagocytic lymphohistiocytosis)[(10)] which caused in fact her death by a fungal infection. This was proof by a causation in fact analysis.

Petitioners have prevailed in proving a causation in fact significant aggravation.

CONCLUSION

Petitioners have prevailed on a theory of on-Table encephalopathy, RSD, and HHE, and, in the alternative, on a theory of on-Table significant aggravation or, alternately, causation in fact significant aggravation. Petitioners shall file a life care plan ninety days from the date of this Decision and Order, if not sooner. Respondent shall file a responsive life care plan within sixty days of the date of filing of petitioners' life care plan.

IT IS SO ORDERED.

DATE: _____ _____

Laura D. Millman

Special Master

1. The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. §300aa-1 et seq. (West 1991), as amended by Title II of the Health Information, Health Promotion, and Vaccine Injury Compensation Amendments of November 26, 1991 (105 Stat. 1102). For convenience, further references will be to the relevant subsection of 42 U.S.C.A. § 300aa.

2. Respondent has questioned whether petitioners satisfied the $1,000 requirement. Response to Order to Show Cause, p. 3, n.2. Petitioners have submitted documentary proof of unreimbursable expenditures totalling $1,257.67. P. Ex. 16, attached to Mrs. Priest's affidavit. This proof is sufficient to satisfy the statutory requirement.

3. Although the table of contents of P. Exs. 1-21 indicates that the discharge summary is located at Tab 2f, these records are actually located in between P. Exs. 2e and 2f at the Tab marked "Admin/Dis/Misc." In the future, petitioners shall endeavor to label and number each exhibit clearly and carefully to ensure that the court may easily refer to exhibits.

4. An HHE occurring within 72 hours of vaccination would still, however, be within the statutory time limits of an on-Table injury and benefit petitioners with a presumption of causation.

5. One would presume that an encephalopathy which is temporary and results in complete recovery (as described in the aids to interpretation in section 14) would not be compensable pursuant to the Act in contradistinction to an encephalopathy which results in permanent impairment.

6. Respondent in its Response to Order to Show Cause questions whether Camille's onset of symptoms was on-Table. Petitioners, in Petitioners' Reply to Respondent's Response to Order to Show Cause at 2, refute respondent's assertion that onset is off-Table. Camille received her DPT vaccination on Friday,

February 28, 1992, at 2:45 p.m. (P. Ex. 16, p. 2, para. 2). She left the pediatrician's office at 2:55 p.m. (P. Ex. 20, pp. 1 and 4). Her babysitter Tonya Gerrity called for the rescue squad on Monday, March 2, 1992, at 1:25 p.m. (P. Ex. 18, p. 3, and P. Ex. 19, p. 1). This was after finding Camille unresponsive, with fixed and dilated pupils, and shallow and irregular breathing. The Toledo Hospital ER received Camille and found her seizing. Following that, she was admitted as an inpatient at 2:39 p.m. (P. Ex. 2e, p. 7). All of petitioners' allegations occurred within 72 hours of Camille's DPT vaccination. It is disturbing that respondent would assert a position that the medical records refute.

7. Unlike the instant action, petitioners in McMurry did not allege encephalopathy.

8. In Whitecotton, the Federal Circuit set forth a four-prong test for determining whether a petitioner had proven on-Table "significant aggravation," requiring that the following factors be considered: (1) petitioner's pre-vaccination condition, (2) petitioner's current condition, (3) if petitioner's current condition is a significant aggravation of his pre-vaccination condition as prescribed by the statute, and (4) whether the first symptom occurred within Table time. Id. at 1104. This applies obviously solely to an allegation of on-Table significant aggravation. The undersigned has combined the four factors of Whitecotton into two.

9. Respondent took the position in Whitecotton, supra, that Maggie Whitecotton was born with a chronic encephalopathy because she was microcephalic, i.e., she had a small head, indicating a small brain. Respondent posited that she must have had some damage to her brain in utero for the microcephaly to be manifest and any brain damage is chronic encephalopathy. Therefore, since she was born with encephalopathy, she could not claim that her post-DPT seizures were indicative of an on-Table encephalopathy, albeit acute, because she already had the onset from before birth. The U.S. Supreme Court accepted this argument.

10. The vaccinee's underlying illness was also termed HLH (hemophagocytic lymphohistiocytosis).