In the United States Court of Federal Claims

No. 02-0411V
(Filed With Parties: October 6, 2008)
(Reissued: October 21, 2008)[1]
TO BE PUBLISHED

JOHN DOE 21,	*	
Petitioner,	*	Burden of Proof;
	*	Causation in Fact;
v.	*	De Novo Review;
	*	National Childhood Vaccine Injury Act
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	of 1986, 42 U.S.C. §§ 300aa-1-300aa-34 (2000).
Respondent.	*	

John H. McHugh, New York, New York, Counsel for Petitioner.

Michael P. Milmoe, Washington, D.C., for Respondent.

MEMORANDUM OPINION AND FINAL ORDER.

BRADEN, *Judge*.

On April 30, 2002, a Petition was filed for compensation and other relief, pursuant to National Childhood Vaccine Act of 1986, 42 U.S.C. §§ 300aa-1-34 (2000) ("Vaccine Act"), and was assigned to now-retired Special Master E. LaVon French. On April 30, 2004, the statutory 240-day deadline for issuance of a decision expired. *See* 42 U.S.C. § 300aa-12(d)(3)(A)(ii). For reasons that escape the court, it took seven months for the case to be re-assigned. Special Master John F. Edwards ("Special Master") then proceeded to take an additional four years to issue a May 22, 2008 unpublished "Fact/Witness/Medical Expert Witness Credibility Ruling," denying Petitioner's causation-in-fact claim by requiring Petitioner to rebut one of the Government's alternative theories of causation, contrary to *Althen* v. *Sec'y of Health & Human Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005) ("*Althen*"). *See John Doe 21* v. *Sec'y Dep't of Health and Human Servs.* at *2-26 (Fed. Cl.

[1] An unredacted version of this Memorandum Opinion And Final Order was issued to the parties on October 6, 2008. The parties were given the opportunity to propose redactions. The substitution of Petitioner's name was requested.

Spec. Mstr. May 22, 2008) ("*John Doe 21*"). As discussed herein, this was not Special Master Edwards' only error.

By any measure, these proceedings were not "expeditious." RCFC Appendix B(II) Rule 3(b). These proceedings were not "flexible." *Id.* These proceedings were not "less adversarial," nor did they provide Petitioner with a "full and fair opportunity to present [his] case[.]" Id. This Memorandum Opinion and Final Order, issued on an expedited basis, vacates Special Master Edwards' May 22, 2008 "Credibility Ruling." This case is remanded to recently-assigned Special Master Christian Moran with a directive to reopen the record to allow: Petitioner's expert Dr. Shane to complete his July 20, 2007 testimony; Dr. Eviatar to address Special Master Edwards' "suspicions" regarding her October 26, 2004 note that Petitioner's "intermittent vertical nystagmus" was "most likely secondary to post DPT encephalopathy" (*id*. at *25); and such rebuttal as the Government requires. A final decision will issue no later than 90 days thereafter, *i.e.*, Wednesday, January 21, 2009. *See* 42 U.S.C. § 300aa-12(e)(2)(C). No party will be afforded any extension of time.

I. RELEVANT FACTS.[2]

[2] The relevant facts recited herein were derived from: October 2, 2002 Defendant ("Government" or "Gov't") Notice of Filing with Ex. 1 – 9/1/02 Declaration of Mr. Doe; Exhibit 2 – 9/19/02 Letter from Dr. Victor Turrow, M.D., F.A.A.P., Pediatrician; Exhibit 3 -- July 2002 Declaration of Angela Rose Dazzo; Exhibit 4 – Undated Certification of Loretta Costello; Exhibit A – 5/11/99 Birth Certificate; Exhibit B – Records of North Shore University Hospital; Exhibit C – Records of Mark N. Goldstein, M.D., F.A.C.S., F.A.A.P., Pediatric Opthomology; Exhibit D – Records of Dr. Mark J. Kupersmith, M.D., New York Eye and Ear Infirmary, Institute for Neurology and Neurosurgery Beth Israel Medical Center; Exhibit E – Records of Dr. Michael L. Slavin, M.D., Residency Program Director, Chief Neuro-Opthaomolohy, Medical Retinal Diseases, Long Island Jewish Medical Center; Exhibit F – Records of Dr. Robert J. Gould, M.D., Metropolitan Pediatric Neurology, P.C.; Exhibit G – Records of Dr. R.R. Branccio, M.D., Bayridge Dermatological Assoc.; Exhibit H – Records of Dr. Robert Hayman, M.D., F.A.A.P., Pediatric Dermatology; Exhibit I – Letter from Dr. Neil S. Sadick, M.D. Sadick Aesthetic Surgery & Dermatology; Exhibit J – Records of Dr. R.R. Branccio, M.D., Bayridge Dermatological Assoc.; Exhibit K – Records of Nassau County System (New York) – Children's Health Network Early Intervention Program; Exhibit L – Records of North Shore - Long Island Jewish Health and Manhasset Schools; Exhibit M – Records of Dr. Mark J. Kupersmith, M.D., New York Eye and Ear Infirmary, Institute for Neurology and Neurosurgery Beth Israel Medical Center; Exhibit N – Records of Dr. Neil S. Sadick, M.D., Sadick Aesthetic Surgery & Dermatology; October 10, 2002 Petitioner Exhibit (September 20, 2000 letter from Dr. Steven Pavlakis, M.D.); July 29, 2005 Petitioner Exhibits A (**"**May 16, 2005 operative note of Dr. Neil A. Feldstein, New York Presbyterian Hospital-Columbia") and B ("April 28, 2005 Consultation Report, Neurosurgical Associates, New York, Presbyterian Medical Center, New York"); September 12, 2005 Exhibit (records from the Columbus Presbyterian Medical Center) (302-93); October 27, 2005 hearing limited to fact testimony (10/27/05 TR 4-147); October 28, 2005, hearing limited to medical testimony (10/28/05 TR 203-380); October 31, 2005, Petitioner filing

A. Petitioner's Medical Records.

On May 11, 1999, Petitioner was born after a routine pregnancy. *See* 10/2/02 Gov't Ex. B at 2-25. At birth, Petitioner weighed six pounds, 12 ounces, and measured 19 ½ inches in length. *Id*. at 3; *see also* 7/11/06 Pet. Ex. A at 1. On May 24, 1999, Petitioner had a "healthy" two week examination and was beginning to hold his head and was responding to sound and light. *See* 10/2/02 Gov't Ex. B at 30. On June 10, 1999, Petitioner had a one month examination that was normal, except for constipation, but otherwise was "alert comfortable." 7/11/06 Pet. Ex. A at 5.

On July 20, 1999, Petitioner's constipation continued, but Petitioner's pediatrician from General Pediatrics, North Shore Hospital Division, noted that Petitioner "roll[ed] side to side, lifts head very well, coos vocalizes, focuses on face, turns to voice, smiles." 10/2/02 Gov't Ex. B at 34. Petitioner's assessment was "healthy." *Id.* On that date, Petitioner received diphtheria-tetanus-pertussis ("DTP"), inactivated poliovirus ("IPV"), and COMVAX™,[3] Hib, and Hepatitis B vaccinations. *Id*. at 32.

On the evening of July 20, 1999 at 9:47 p.m., Petitioner was admitted to the North Shore University Hospital Emergency Department with a fever of 101°F. *Id*. at 34B. The primary complaint "per mother" was "crossed eyes, moaning, acting unusual." *Id*. The triage nurse noted that Petitioner received a DPT vaccine on that same date and developed a fever. *Id*. at 34B.[4] The

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including prescriptive pad note of Dr. Eviatar and two photographs of Petitioner; November 4, 2005, Government Exhibits C and D; December 29, 2005 Petitioner Filing with Ex. 1 – 12/29/05 Nassau Radiologic Group, P.C.; Ex. 2 – 6/23/00 Nassau Radiologic Group, P.C.; Ex. 3 – 5/10/05 Long Island Jewish Medical Center, Department of Radiology; Ex. 4 – 6/7/05 Neurological Associates at New York Presbyterian Medical Center in New York; Ex. 5 – 11/21/05 Dr. Steven Pavlakis letter; Ex. 6 – 11/21/05 Dr. Eugene B. Spitz, M.D., Diagnostic & Treatment Center for Central Nervous System Disorders, Inc.; July 11, 2006, Petitioner's Exhibit A (1-96); Exhibit B (records of Dr. Palvakis); Exhibit C (note from Dr. Marvin Boris); July 24, 2006, Petitioner's Exhibit A (Report of May 3, 2002 MRA) and Exhibit B (Report of May 2, 2002 MRI); November 13, 2006, Petitioner's Exhibit A (Expert Report of Dr. Steven Pavlakis) and Exhibit B (Expert Report of John D. Shane); January 30, 2007, Petitioner's Exhibit (records from Beth Israel Medical Center); February 15, 2007, Government Supplemental Expert Report of Dr. Wiznitzer; July 20, 2007, continuation of hearing limited to medical testimony. *See* (7/20/07 TR 383-478).

[3] "COMVAX™" is a "trademark for a combination preparation of *Haemophilus* b conjugate vaccine and hepatitis B vaccine (recombinant)." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 403 (27th ed. 1988) ("DORLAND'S").

[4] In 1994, the Institute of Medicine ("IOM") also reported that:

> DPT [has] been known to cause fever, they have been associated with the occurrence of acute febrile seizures [*i.e.*, "those associated with high fever, occurring in infants

resident physician examination noted a rectal temperature of 101.3°F, with an "enlarged thyroid" and "adenopathy."[5] *Id*. at 34B. The attending physician noted: "fever & a 10 minute episode of eye crossing, without tonic/clonic activity,[6] drooling[.]". *Id*. Subsequent tests, including blood and urine samples were negative. *Id.* at 36-44, 46-47. A neurological examination showed no "focal deficits" and a regular flat fontanelle.[7] *Id.* at 34B. Petitioner was diagnosed with a fever, advised to take "Tylenol," and Ms. Doe was instructed to "follow up with" Petitioner's pediatrician "in the morning." *Id.* at 34D. Petitioner was released from the Emergency Room around 11:00 p.m. in "satisfactory" condition. *Id*.

Petitioner's fever, however, did not abate. *Id.* at 45. On July 21, 1999, Petitioner's mother reported her son still had a temperature of 101°F. *See* 7/11/06 Pet. Ex. A at 8.

On July 28, 1999, Petitioner's medical records show that both eyes had "no tears' and were "crusty," but Petitioner was "alert; awake . . . [and his] neck was supple." 10/2/02 Gov't Ex. B at 48.

During an August 19, 1999 examination when Petitioner was 3 ½ months, he experienced another fever episode of 101°F, was "cranky," but "alert" and "active," with a "neck supple." *Id*. Other tests were unremarkable. *Id*. at 48. Because Petitioner's older sister was ill,[8] the physician assumed the cause of these symptoms was a "viral syndrome." *See* 7/11/06 Pet. Ex. A at 8.

On September 14, 1999, a physician from the North Shore University Hospital Division of Pediatrics determined that Petitioner was "well," except for a "discharge" from the left eye that could possibly be a duct "obstruction," but noted that Petitioner "sits, holds [his] head," "babbles," and

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> and children." DORLAND'S at 415]. Febrile seizures alone do not lead to a residual seizure disorder . . . there are no data directly nearing on the biologic plausibility of a relationship between diphtheria or tetanus toxins and residual seizure disorder.

1994 IOM REPORT at 79.

[5] "Adenopathy" is the "swelling or morbid enlargement of the lymph nodes." STEDMAN'S MEDICAL DICTIONARY 755 (28th ed. 2006) ("STEDMAN'S").

[6] A "generalized tonic-clonic seizure" is a "seizure of grand mal epilepsy, consisting of loss of consciousness and generalized tonic convulsions followed by clonic convulsions." DORLAND'S at 1676. "Grand mal epilepsy" is a "symptomatic form of epilepsy often preceded by an aura; characterized by loss of consciousness with generalized tonic-clonic seizures." *Id*. at 628.

[7] A "fontanelle" is "[o]ne of several membranous intervals between the angles and margins of the cranial bones in the infant." STEDMAN'S at 755.

[8] Petitioner had a sister, born on May 29, 1995. *See* 10/2/02 Gov't Ex. B at 32.

otherwise was "social." 10/2/02 Gov't Ex. B at 51. On this occasion, DtaP, IVP, and COMVAX vaccinations were administered, but the pertussis[9] portion was not administered, because of the July 20, 1999 "hypotonic-[illegible] episode."[10] *Id*. at 52; *see also* 7/11/06 Ex. A. at 1.

From September 23 to October 7, 1999, Petitioner was examined by physicians at North Shore University Hospital Division of General Pediatrics at least five times for otitis[11] and thrush.[12] *See* 10/2/99 Gov't Ex. B at 53-55. On September 23, 1999, Petitioner's parents reported that he would not take a bottle, was up all night crying, with coughing and congestion, but had no fever. *Id*. The diagnosis was "nasal thrush" and a prescription for Nystatin™[13] was issued for one week. *Id*. On September 24, 1999, Petitioner's physician noted that Petitioner was "more cranky - fever today." *Id*. Augmentin™,[14] an antibiotic was prescribed, and Nystatin™ was suspended. *Id*.

On October 4, 1999, Petitioner's physician noted a "l[eft] strabismus"[15] or "psuedostrabismus,"[16] and recommended an opthalmologic consultation. *Id.* at 54. On October 5, 1999, Petitioner was reported to be "kvethcy all night," exhibiting "blurred eyes," and "reddened ears." *Id*.

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[9] Pertussis vaccine is "a suspension of killed *Bordetalla pertussis* organisms (whole cell vaccine) or a fraction thereof (acellular) either fluid (pertussis vaccine [USP] or absorbed on aluminum hydroxide or aluminum phosphate and resuspended (pertussis vaccine absorbed [USP]); used for routine immunization against pertussis (whooping cough). It is generally used in a mixture of diphtheria and tetanus toxoids. (DTP or DTaP)" DORLAND'S at 1999.

[10] "Hypotonia" is "a condition of diminished tone of the skeletal muscles; diminished resistance of muscles to passive stretching." DORLAND'S at 900.

[11] "Otitis" is an "inflammation of the ear." STEDMAN'S at 1394.

[12] "Thrush" is an "[i]nfection of the oral tissues with *Candida albicans* . . . common in normal infants who have been treated with antibiotics." STEDMAN'S at 1986.

[13] "Nystatin™" is a "polyene antifungal agent . . . used in the treatment of . . . candidal infections[.]" DORLAND'S at 1296.

[14] "Augmentin™" is a "trademark for combination preparations of amoxicillin and clavulanate potassium." DORLAND'S at 179.

[15] "Strabismus" is "[a] manifest lack of parallelism of the visual axes of the eyes." STEDMAN'S at 1841.

[16] "Psuedostrabismus" is "[t]he appearance of strabismus caused by epicanthus, abnormality in interorbital distance, or corneal light reflex not corresponding to the center of the pupil." STEDMAN'S at 1593.

On November 8, 1999, Petitioner was diagnosed with an "u[pper] r[espiratory] i[llness]" and "nasal congestion." *Id.* at 56. Although, the physician observed that Petitioner had not rolled over yet, and could not "sit up [without] support," Petitioner was diagnosed as a "well infant," because he exhibited "good head control" and was able to grab "onto objects well." *Id.* On that date, a DT vaccine was administered, but without pertussis. *Id*. at 32, 57; *see also* 7/11/06 Ex. A at 1.[17] Petitioner also was referred to Dr. Strove for a left eye "deviation medially." 10/2/02 Gov't Ex. B at 57.

On November 10, 1999, Dr. Steven E. Rubin, MD, a pediatric ophthalmologist, found Petitioner to be a "healthy 6 month old baby with a suspected esotropia"[18] and noted "crusting from the left eye." *Id.* at 59. Dr. Rubin, however, found no evidence of strabismus and suggested that the esotropia "would probably spontaneously resolve over the next several months." *Id.*

On November 15, 1999, Petitioner was admitted to the North Shore University Division of General Pediatrics with eye crusting, nasal discharge, chest congestion, and fever of 101°F, but was diagnosed with a viral syndrome and conjunctivitis. *Id*. at 58. Nasal suctioning, a humidifier, and eye drops were prescribed. *Id*. On November 22, 1999, Petitioner was examined for nasal congestion, a continuing cough, and vomiting twice on November 21, 1999. *Id*. Petitioner was diagnosed with otitis media and prescribed Augmentin™. *Id*.

On December 4, 1999, Petitioner cried all night, with aches and fever. *Id*. at 61. Petitioner's records indicated teething, but Petitioner also was experiencing thrush. *Id*. Significantly, however, plagiocephaly[19] was observed. *Id.* at 61. An appointment was recommended to examine Petitioner's head circumference and "development." *Id*.

On December 10, 1999, Petitioner was "cranky and up all night; the examination confirmed the right ear had a yellow bulging effusion." *Id*. Cefzil™,[20] a different antibiotic, was prescribed. *Id*. On December 22, 1999, Petitioner's ear was rechecked and still found to be "mucusy," despite

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[17] Petitioner's November 8, 1999 medical records indicated that Pertussis should not be administered, because of Petitioner's adverse reaction on July 20, 1999. *See* 10/2/02 Gov't Ex. B at 57.

[18] "Estropia" is a form of strabismus involving "manifest deviation of the visual axis of an eye toward that of the other eye." DORLAND'S at 583.

[19] "Plagiocephaly" is an "unsymmetrical and twisted condition of the head, resulting from irregular closure of the cranial sutures." DORLAND'S at 1301.

[20] "Cefzil™" is a "trademark for cefprozil" a "synthetic broad-spectrum, second-generation cephalosporin effective against a wide range of gram-negative and gram-positive organisms, used in the treatment of otitis media and infections of the respiratory and oropharyngeal tracts, skin, and soft tissues; administered orally." DORLAND'S at 315; *see also* 314.

having taken Cefzil™. *Id*. at 62. In addition, Petitioner had "mucusy eyes," with redness, haziness, but no pus. *Id*. On December 24, 1999, a Ceftriaxone[21] shot #2 (400 mg) was administered to Petitioner's thighs, together with a prescription for Gantrisin™.[22] *Id*. On December 27, 1999, Petitioner was examined and received a third shot of Ceftriaxone. *Id*. at 63.

On January 3, 2000, Petitioner's physician reported that: "Petitioner was crying all day [January 2, 2000]; experienced a fever of 101-102◦F; was sneezing and coughing; with congestion evident." *Id*. On January 8, 2000, Petitioner again was crying non-stop, with a low-grade temperature, despite being on Gantrisin™. *Id*. The antibiotic was changed to a combination of Amoxicillin[23] and Augmentin™. *Id*. On January 14, 2000, Petitioner was re-checked, to ascertain his reaction to the new antibiotics. *Id*. at 64. On January 19, 2000, Petitioner's physician observed that Petitioner's infection was improved, and re-instated Gantrisin™. *Id*.

On January 31, 2000, Petitioner received a Hepatitis B immunization. *Id*. at 65. On January 31, 2000, Petitioner's physician observed that Petitioner could: sit without support; use a "pincer grasp;" speak; wave; and play "peek-a-boo." *Id*. Petitioner was diagnosed as "well," despite the fact he could not pull "to stand" or "cruise." *Id.*

On February 7, 2000, Petitioner was examined for a possible ear infection, being irritable all day and night, with mild nasal congestion and decreased appetite. *Id*. at 66. On February 17, 2000, Petitioner experienced vomiting, intermediate diarrhea, a "wet cough," and fever. *Id*. at 67. By February 19, 2000, Petitioner still was not keeping food down, was "very cranky," had a bad cough, and was very congested. *Id*.

On March 8, 2000, when Petitioner's ear was re-checked, his physician also noted potential increased "tone" [24] in Petitioner's extremities and noted concern about Petitioner's "developmental progression." *Id*. at 68. On March 16, 2000, Petitioner was examined for chronic coughing, congestion, and crying and was referred to an Ear Nose and Throat ("ENT") specialist. *Id*. at 69.

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[21] "Ceftriaxone" is a "semi-synthetic, broad-spectrum, third generational cephalosporin antibiotic, which acts by inhibiting enzymes responsible for cell-wall synthesis; effective against gram-positive and gram-negative bacteria; administered intravenously and intramuscularly." DORLAND'S at 314-15.

[22] "Gantrisin™" is a "trademark for preparations of sulfisoxazole." DORLAND'S at 755. "Sulfisoxazole" is a "short-acting sulfonamide used as a antibacterial in the treatment of a wide variety of infections, particularly in the urinary tract[.]" *Id*. at 1791.

[23] "Amoxicillin" is a :semisynthetic derivative of ampicillin . . . used . . . in the treatment of infections[.]" DORLAND'S at 64.

[24] "Tone" is the normal degree of vigor and tension, in muscle, the resistance to passive elongation or stretch." DORLAND'S at 1919.

On March 17, 2000, Petitioner also had a "head ultrasound" for "enlarged head size." *Id*. at 70. The ultrasound revealed "[p]rominent extra-axial spaces" consistent with "benign external hydrocephalus."[25] *Id.* at 70.

On March 27, 2000, Petitioner was examined for crying, cough, running nose, and recurrent otitis. *Id*. at 69. On March 29, 2000, Petitioner was examined by an ophthalmologist and ENT, and for the first time "vertical nystagmus"[26] was noted. *Id.* Petitioner also was examined by Dr. James Fagin, M.D., from the Nassau County Early Developmental Intervention Program, who concluded Petitioner had "fine & gross motor developmental delay." 10/2/02 Gov't Ex. L at 240.

On March 29, 2000, Petitioner was examined by the Louise Oberkotter Early Childhood Center, where he was evaluated in "eight areas of development: Gross Motor; Fine Motor; Relationship to Inanimate Objects; Language/Communications; Self-Help; Relationship to Persons; Emotions and Feeling States; and Coping Behavior." *Id.* at 219-23. Petitioner's scores in the categories of Gross Motor, Fine Motor, Language/Communication, and Emotions and Feeling States were "Of Concern." *Id.* at 221-22. "Physical Therapy services to address delay in gross motor skill acquisition" was recommended. *Id.* at 223. In addition, monitoring Petitioner's "fine motor function" and "Speech and Language development" was recommended. *Id.*

On March 30, 2000, Petitioner's physician noted that Petitioner's mother observed her son's "vertical nystagmus, seems to be getting worse." 10/2/02 Gov't Ex. F. Subsequently, Dr. Robert J. Gould, M.D., a pediatric neurologist, ran a series of tests, but was unable to observe any "vertical nystagmus." 10/2/02 Gov't Ex. B at 71; *see also* 10/2/02 Gov't Ex. F at 179. Dr. Rubin's re-examination on April 5, 2000 also did not evidence nystagmus. *See* 10/2/02 Gov't Ex. B at 72.

On April 24, 2000, Dr. Mark N. Goldstein, M.D., a pediatric otolaryngologist ("Dr. Goldstein"), scheduled Petitioner for a bilateral myringotomy[27] and placement of tubes due to "effusions"[28] in Petitioner's ears. *Id*. at 75. On April 24, 2000, Dr. Goldstein and Dr. Rubin's recommendations were reviewed by a physician from the Department of Pediatrics at North Shore University Hospital. *Id*. Although this physician agreed that a myringotomy procedure was indicated, he also recommended a neurological evaluation. *Id*. Subsequently, Petitioner entered an

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[25] "Hydrocephalus" is a "condition marked by an excessive accumulation of cerebrospinal fluid resulting in dilation of the cerebral ventricles and raised intracranial pressure; it may also result in enlargement of the cranium and atrophy of the brain." STEDMAN'S at 910.

[26] "Nystagmus" is the "[i]nvoluntary rhythmic oscillation of the eyeballs, either pendular or with a slow and fast component." STEDMAN'S at 1350.

[27] A "myringotomy" is "the creation of a hole in the tympanic membrane[.]" DORLAND's at 1217.

[28] An "effusion" is "[t]he escape of fluid from the blood vessels or lymphatics into the tissues or a cavity." STEDMAN'S at 616.

early intervention physical therapy program to address his developmental delay. *See* 10/2/02 Gov't Ex. L at 236.

On April 28, 2000, Dr. Steven G. Pavlakis, M.D., Director, Division of Pediatric Neurology and Developmental Medicine and Professor of Pediatrics, Mount Sinai School of Medicine ("Dr. Pavlakis"), examined Petitioner for occasional "up and down eye fluttering" and "upper eyelid fluttering," without "alteration of consciousness." 10/2/02 Gov't Ex. B at 78-79. Dr. Pavlakis noted that Petitioner regularly was alert, active, and interactive for someone his age, but also was delayed "in regard to motor milestones." *Id.* Dr. Pavlakis concluded that Petitioner had mild hypotonia,[29] but had "trembling in both arms" and "mild tremors." *Id.* Dr. Pavlakis was not overly concerned with Petitioner's eye and eyelid fluttering and, after reviewing a video of Petitioner's "atypical eye movements," did not believe they were "seizures." *Id.* at 79.[30] Dr. Pavlakis, however, did consider these episodes "a little atypical." *Id* at 79. Petitioner, however, was referred to Dr. Mark J. Kupersmith, a neuro-ophthalmologist ("Dr. Kupersmith"), because Petitioner in fact may have had "epilepsy." *Id.* at 78-79, 144.

On May 8, 2000, Dr. Goldstein conducted pre-admission testing, a medical history, and an examination in preparation for a double myringotomy procedure, because of fluid in Petitioner's middle ear. *See* 10/2/02 Gov't Ex. L at 144-46. Dr. Goldstein was aware that Petitioner's past medical history noted "? seizure after DPT. Delayed fine motor skills, now in early intervention." *Id*. at 144.

On May 22, 2000, Petitioner again had a fever with transient vomiting/diarrhea. *Id*. at 82. His vaccines were re-scheduled for 1-2 weeks later. *Id*. Petitioner was diagnosed as having "developmental delay." *Id*. Petitioner also had an EEG as requested by Dr. Pavlakis. *Id*.

On May 24, 2000, Petitioner had a 103°F fever, vomiting, and diarrhea. *Id*. at 83. He was alert, but "clingy and lethargic." *Id*. On May 31, 2000, Petitioner continued to experience crankiness, but his ears seemed to be better, after having tubes inserted. *Id*.

On June 7, 2000, Dr. Kupersmith, M.D., Chief of the Division of Neuro-Opthomology at the Institute for Neurology, Beth Israel Medical Center in New York, examined Petitioner for the "abnormal or involuntary" movement of his eyes and eyelids. *See* 10/2/02 Gov't Ex. F at 119. Dr. Kupersmith did not observe any irregular activity, but observed a video tape provided by Ms. Doe that showed Petitioner during an episode. *Id.* at 168. Nevertheless, Dr. Kupersmith did not believe that Petitioner's irregular eye movements were related to a seizure, but concluded that the activity was "upper lid retraction," rather than "any significant eye muscle involvement or nystagmus." *Id.*

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[29] "Hypotonia" is "[a] condition in which there is a diminution or loss of muscular tonicity." STEDMAN'S at 939.

[30] *See* Pl. 10/10/02 letter from Dr. Pavlakis explaining that on April 28, 2000 Petitioner did experience "an event consistent with seizure." It appears that the symptom was not "eye fluttering," but a "trembling" and "mild tremor." *See* 10/2/02 Gov't Ex. B at 78-79.

Nevertheless, Dr. Kupersmith was concerned about Petitioner's "head size," and recommended a Magnetic Resonance Imaging ("MRI") to determine whether Petitioner had "hydrocephalus, causing posterior third ventricle dilation." *Id.* On June 13, 2000, Petitioner had an EEG that was reported to be "within the normal limits." 10/2/02 Gov't Ex. B at 85.

On June 12, 2000, at 13 months, Petitioner was sitting, recently crawling, still raking his hands, clapping and waving, and understood "no." *Id*. at 84.

On June 13, 2000, Petitioner also had an Electroencephalography Study ("EEG") at North Shore Hospital. *Id*. at 85. Petitioner had to be sedated, because he was experiencing "fluttering eye and hand shaking." *Id*. The responsible physician reported that Petitioner also may have exhibited signs of "hypnogogic hyper synchrony,"[31] but the photic stimulation was not abnormal and no clear epileptiform activity was seen. *Id*. On June 22, 2000, Dr. Joseph L. Zito ("Dr. Zito") performed a cranial MRI that also revealed "no evidence of mass effect" in the "ventricular system and subarachnoid spaces," and "no extraaxial mass or fluid collection." *Id; see also* 12/29/05 Pet. Ex. at 4 . Dr. Zito concluded that Petitioner's MRI was "normal." 10/2/02 Gov't Ex. B at 85*; see also* 12/29/05 Pet. Ex. at 4.

On June 26, 2000, Petitioner was examined for an eye infection. *Id*. at 84. On June 27, 2000, Petitioner had a follow-up examination regarding the bilateral myringotomy and tube insertion. *See* 10/2/02 Gov't Ex. L at 143. Petitioner again was reported as experiencing "some blinking of the eyes upon arising." *Id*.

On July 12, 2000, Petitioner received a measles-mumps-rubella ("MMR") immunization and a VARIVAX immunization. *Id.* at 102. On July 26, 2000, Petitioner was examined for diarrhea and some spitting up. *Id*. at 102.

On August 11, 2000, Petitioner was diagnosed with an upper respiratory infection. *Id*. at 103. More importantly, Petitioner's "vertical nystagmus" was of sufficient concern that he was referred to a neurologist. *Id*.

On September 6, 2000, Petitioner was examined for crankiness and crying in his sleep, and the physician concluded that those symptoms were attributed to teething. *Id*. at 103.

On September 13, 2000, Petitioner was observed to have "developmental delay," but was "progressing." *Id.* at 99. The physician also noted "intermittent but daily vertical nystagmus." *Id.* On that date, DT vaccination was administered again, without pertussis, because of Petitioner's prior reaction. *Id.* at 32, 99. In addition, an IPV vaccine was administered. *Id*.

On September 26, 2000, Dr. Pavlakis examined Petitioner and recommended a 24-hour EEG and another evaluation by Dr. Kupersmith. *Id*. at 104. Petitioner was examined for being "cranky"

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[31] This term is not defined either in DORLAND'S or STEDMAN'S. "Synchrony," however, is defined as "[t]he simultaneous appearance of two separate events." STEDMAN'S at 1887.

and "pulling his ear," but no fever or drainage was evident. *Id*. By September 28, 2000, however, Petitioner had developed a fever and an ear infection. *Id*. On September 30, 2000, a new antibiotic was prescribed. *Id*.

On October 6, 2000, another EEG was conducted with some "episodes of eye fluttering." *Id*. at 105. Nevertheless, the EEG was determined to be normal. *Id*. at 134. On October 12, 2000, Dr. Rubin examined Petitioner for a follow-up of his eye fluttering. *Id.* at 106. During the examination, Dr. Rubin "confirmed the presence of an infrequent, *intermittent upbeat nystagmus*[32] *which had apparently evaded detection at [Petitioner's] many prior examinations*." *Id*. at 106 (emphasis added). Dr. Rubin referred Petitioner to a neuro-ophthalmologist for further examination of Petitioner's "intermittent vertical nystagmus." *Id.* at 109-110.

On October 23, 2000, Petitioner was evaluated by the Therapy Services of Greater New York and diagnosed with "gross motor and fine motor deficits." *Id*. at 234. The "quality of [Petitioner's] movement was also constantly compromised due to poor grading of tone." *Id*. at 235.

On October 30, 2000, Petitioner had a flu, was "very cranky," and was examined for an ear infection. 10/2/02 Gov't Ex. B at 105. Amoxicillin was prescribed. *Id*.

On November 7, 2000, Petitioner was examined by Dr. Michael J. Slavin, M.D., Chief Neuro-Ophthalmology, Medical Retinal Diseases at the Department of Opthomology at the North Shore Long Island Jewish Health System in Great Neck, New York ("Dr. Slavin"). *Id*. at 109. Dr. Slavin noted that Petitioner's "milestones" were delayed, but did not observe any vertical nystagmus and described the examination as "normal." *Id.* Dr. Slavin, however, had a question about a "lucency seen in the interpedancular cistern" in Petitioner's MRI. *Id*. Dr. Slavin noted, however, that after consulting with Dr. Zito, he felt that the MRI "lucency" was a "flow artifact" and not a "lesion." *Id*. at 110.

On November 16, 2000, Petitioner exhibiting crying, cranky behavior. *Id*. at 111. Although Petitioner completed the course of Amoxicillin, he still had "mucosy eyes." *Id*. On November 17, 2000, Petitioner had drainage from his ear. *Id*. On November 27, 2000, Petitioner exhibited no eye "fluttering," but was "walking with a wide gait." *Id.* at 112. The physician scheduled an

[32] "Upbeat nystagmus" is a vertical nystagmus with the fast phase upward occurring in lesions of the vermis cerebelli." DORLAND'S at 1296. The "vermis cerebelli" is the "narrow median part of the cerebellum, between the two lateral hemispheres." *Id*. at 2033. The "cerebellum" is part of the brain "that occupies the posterior cranial fossa behind the brain stem and is concerned in the coordination of movements." *Id*. at 336.

"ortho[pedic] eval[uation]," because of "developmental issues." *Id*. Prevnar™[33] and HIB vaccines were administered. *Id.*

On December 12, 14, 16, 20, 2000 and January 8, 2001, Petitioner continued to receive medical care for fever, nasal infection, coughing, sinusitis, rash, and yeast infections. *Id*. at 113-14.

On January 10, 2001, Petitioner was tested and evaluated by Ms. Amy Bogatch, M.S.-CCC, Speech/Language Pathologist at the Nassau County Early Intervention Program in Mineola, New York ("Ms. Bogatch"). *See* 10/2/02 Gov't Ex. K at 199-201. She observed that Petitioner "exhibits significant delays in both receptive and expressive language abilities . . . Further weaknesses were noted in the area of oral-motor skills and feeding as [petitioner] is unable to chew and swallow solid foods or drink from a cup. Drooling is apparent." *Id*. at 201.

From January 11, 2001 to February 27, 2001, Petitioner was seen by Dr. Neil Sadick, M.D. and Dr. Robert Hayman, M.D. for scabies and eczema. *See* 10/2/02 Gov't Ex. B at 115-19, *see also* 10/2/02 Gov't Ex. N at 278-82.

On February 16, 2001, Petitioner was examined for swollen glands and "developmental delay" was noted. *See* 10/2/02 Gov't Ex. B at 120.

On March 8, 2001, Petitioner underwent a "functional visual evaluation" at the Long Island Infant Developmental Program. *See* 10/2/02 Gov't Ex. K at 141-42. Despite numerous prior examinations by Dr. Rubin, an opthomologist, and Dr. Kupersmith, a neuro-opthomologist, Petitioner was now diagnosed with "vestibular problems"[34] and "demonstrated a 25%+ delay in visual-motor skills." *Id*. at 242.

On May 14, 2001, Dr. Rubin evaluated Petitioner, because of observations of "nystagmus" and "esotropia" in the preceding few weeks. *See* 10/2/02 Gov't Ex. B at 124. Dr. Rubin noted that Petitioner "was slightly more hyperopic[35] than other children." *Id.*

On May 18, 2001, Petitioner received another Prevnar™ vaccination. *Id.* at 32, 127. The attending physician noted that Petitioner was still undergoing physical therapy, occupational therapy, and speech therapy and was working with a specialist for the visually[-]impaired to address

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[33] "Prevnar™" is a "trademark for a preparation of pneumococcal heptavalent (or 7 valent) conjugate vaccine." DORLAND'S at 1505. This vaccine is used for immunization of children who are "high risk for pneumococcal infection, including those with . . . immunocompromising conditions. *Id*. at 1999.

[34] "Vestibular nystagmus" is "nystagmus due to disturbance of the vestibular system; eye movements are rhythmic with a slow and fast component." DORLAND'S at 1296.

[35] Hyperopia is "[l]ongsightedness; that optic condition in which only convergent rays can be brought to focus on the retina." STEDMAN'S at 923.

"disorientation in movem[en]ts." *Id*. at 126. On May 19, 2001, Petitioner was examined in the emergency room for fever, "draining" ears and "goopy eyes," and was prescribed Amoxicillin. *Id*. at 128. On May 22, 2001, Petitioner continued to experience a fever with mouth sores, and his ear tubes were "draining profusely." *Id*. A different antibiotic, Ceftin™ was prescribed.

On June 7, 2001, Petitioner experienced a rash that was treated as potential scabies. *Id.* at 130.

On June 20, 2001, Petitioner had a pediatric cardiology examination, of no consequence. *Id*. at 129.

On July 26, 2001, Petitioner was examined by Sheila McElhern, M.S. Ed., TVI, at the Nassau County Early Intervention Program, Nassau County Department of Health, who reported that Petitioner "has been diagnosed with intermittent vertical nystagmus and vestibular problems of undetermined cause." 10/2/02 Gov't Ex. L at 243. His MRI and other neurological tests were inconclusive. *Id.* He demonstrates frequent squinting and head tilts, poor balance, and trips and falls frequently." *Id*.

On July 3, 2001, Dr. Steven B. Ritz, M.D., Associate, Pediatric Cardiology at the Children's Heart Center at North Shore Hospital reported no cardiology concerns, but noted that Petitioner had a "paradoxial reaction following his 2-month pertussis vaccination." 10/2/02 Gov't Ex. B at 131. In addition, Petitioner had a "history of developmental delay and intermittent horizontal nystagmus." *Id*.

On July 11, 2001, Petitioner was examined for "not walking right - foot turns in and he seems to be favoring his right foot." *Id*. at 137. In addition, Petitioner's left foot was "considerably warmer" than his right foot, but no swelling was detected. *Id*. His "gait" was "absolutely normal." *Id*. On July 23, 2001, another possible ear infection was noted. *Id*.

On August 14, 2001, Dr. Lydia Eviatar, M.D., Professor of Pediatric Neurology at the Long Island Campus of the Albert Einstein College of Medicine ("Dr. Eviatar"), conducted a "neurological consultation," to evaluate issues regarding Petitioner's "poor balance and episodes of upward gaze nystagmus with eye fluttering[.]" *Id.* at 134. Petitioner's past medical history indicates he was "doing well until 6 months of age, until he received a Pertussin shot." *Id*. The emergency work-up, however, was unremarkable, other than a CT scan showing a "slightly enlarged subarachnoid space." *Id*. Dr. Eviatar's evaluation concluded that:

> Neurological examination reveals [Petitioner] has a fleeting gaze, but is interactive, playful and nonverbal. Cranial nerve examination is normal and the parents had to elicit an episode of eye flutter, which was very brief by waking him up as he was falling asleep and shaking him around. There was no nystagmus or opsoclonus elicited during the examination. Motor tone is decreased and there is hyperlaxity of the ligaments. He is reaching for objects with no overt dysmetria, but has difficulty stacking blocks. A mild tremor is noted while doing so. He appears to be primarily left-handed. As mentioned, there is a broad-based ataxic gait and poor gross motor

> coordination. Self-stimulatory behaviors, such as jumping or running back and forth when excited are noted, as well as preservation of objects that can be spun or by Barbie dolls, which he can wave back and forth to see their hair move.
>
> My diagnostic impression is that the youngster has generalized gross motor and fine motor delays, as well as speech and language delay and some very mild pervasive developmental disorder features. *The onset of eye movements immediately after the Pertussin shot is puzzling. We do see episodes of flutter or opsoclonus and developmental delay as a result of autoimmune encephalitis known as encephalopathy.*

Id. at 135-36 (emphasis added).

On September 20, 2001, Ms. Bogatch reported a REEI-2 reveals Petitioner's "receptive language at 14-16 month level . . . His expressive language appears to be at a 18-20 month level." 10/2/02 Gov't Ex. L at 245. Ms. Bogatch reported that she had spoken to Petitioner's occupational therapist and recommended that the services of a special education teacher be obtained. *Id*. Petitioner's "attention skills and his ability to focus to task are limited, his conceptual development is below age expectance, and his play skills are immature." *Id*.

On October 5, 2001, Ms. Joanne C. Villian, Physical Therapist with the Therapy Service of Greater New York reported Petitioner's gross motor skills were at the 21 month level, although he was 28 months old. *Id.*

On October 22, 2001, Petitioner had a two year examination with Dr. Rubin. 10/2/02 Gov't Ex. B at 138. No nystagmus nor strabismus was evident. *Id*. Dr. Rubin concluded: "At this point I can provide no help in my search of any underlying diagnosis for [Petitioner.]" *Id*.

On November 5, 2001, Petitioner was examined for a sore throat, with cough and fever. *Id*. at 139.

In November 8, 2001, a comprehensive evaluation by the Early Childhood Development Program at Schneider Children's Hospital, North Shore - Long Island Jewish Health System was conducted. 10/2/02 Gov't Ex. L at 249 "[C]oncerns include sensory-vestibular issues, speech and language, gross and fine motor development. All developmental milestones were reported delayed." *Id.* Petitioner's development was at a 23 month old level. *Id.* at 237. Petitioner's cognitive skills, were tested on the Bagley Scale of Infant Development and reported as "within the Significantly Delayed range of functioning[.]" *Id*. at 237. Petitioner's physical development examination reported: gross motor skills per the *Developmental Profile for Young Children* were "within the 20 month level, representing a 33% delay in balance and coordination skills. [Petitioner] demonstrates significant attentional difficulties which impede functional performance . . . He appears to have difficulty integrating and tolerating vestibular stimulation. He appears to under-react to tactile stimulation and displays difficulty with body awareness. He demonstrates delays in self-help skills

in the area of feeding with regard to adequate use of a utensil, cup drinking and tolerating hard textures of food." *Id*. at 238. Petitioner's "Language and Communication Development" examination reported:

> [Petitioner] inconsistently established appropriate eye contact with the evaluators. At times it appears that [Petitioner] lost eye contact and would stare beyond the person seated in front of him. This occurs throughout the evaluation, as [Petitioner] would appear related and focused one minute and then he would suddenly appear distant and disconnected from the environment and his surroundings. Receptive language skills were judged to be at the 1 year, 8 month level, indicating a 33% delay. Expressive language skills were judge to be at the 1 year, 11 month level, indicating a 23% delay. Informally, overall intelligibility was judged to be good at the single word level for both known and unknown contexts. At the phrase level, overall intelligibility was judged to be fair-poor for known contexts and poor for unknown contexts. Intelligibility was compromised by [Petitioner's] use of jargon. Oral motor weaknesses and feeding concerns were noted as well.

Id. at 239.

The "Adaptive Behavior" examination reported:

> [Petitioner] obtained a standard score of 66, 1st %ile on the *Vineland* which places his self-help skills within the Low range of functioning and more than two standard deviations below the norm. He is not toilet trained, nor does he indicate a soiled diaper. He will eat and tolerate a variety of foods, and self feeds with a spoon and fork, although with some spillage. . . Reportedly, [Petitioner] displays difficulty lateralizing his tongue, and often uses his fingers to push foods back into his mouth, as they often spill out. He is unable to competently drink from an open cup (without much spillage) but can drink from a sippy cup, suck from a straw and continues to drink two bottles per day. Assistance is needed with dressing and undressing, although [Petitioner] will extend his arms appropriately and can remove his hat, coat, and gloves independently. He requires assistance with tooth brushing, face washing, and does not yet actively participate in bathing.

Id.

On November 8, 2001, Cheryl Seltzer, OTR, reported that Petitioner's status demonstrated "mildly low muscle tone in his trunk and face. Frequent drooling is observed . . . He demonstrates asymmetry with regard to arm and hand function as well as increase tone in his right upper extremity . . . Overall movement patterns appear to display limited trunk rotation and lack of integrated movement patterns. Movement quality is immature when negotiating his environment." *Id*. Under sensory motor processing, Petitioner was described as having "difficulty integrating and tolerating vestibular stimulation . . . appear[ing] to under-react to tactile stimulation." *Id.* at 258. Petitioner's gross motor and fine motor-perceptual skills both evidenced a 33% delay. *Id.* Petitioner's "gross motor skills . . . represent [] a 33% delay in balance and coordination. *Id*. at 257.

Petitioner's "fine motor - perceptual skills . . . represent [] a 33% delay. He demonstrates difficulty with bilateral integration skills, coordinated use of both sides of his body as well as decreased hand strength required for use of refined hand skills. He demonstrates difficulty with visual-perceptual skills. He demonstrates significant attentional difficulties which impede functional performance." *Id*. at 258. He demonstrates some difficulty due to motor planning and difficulty tolerating movement experiences." *Id*. at 259.

On November 13, 2001, Petitioner was examined for a "wet" cough and possible strep infection. *See* 7/11/06 Pet. Ex. A at 62.

On December 4, 2001, Petitioner was examined for not eating and fever. 10/2/02 Gov't Ex. B at 140. A virus was suspected. *Id*. On February 5, 2002, Petitioner was examined for fever and vomiting. *Id*. at 63. A virus was suspected. *Id*.

On February 23, 2002, Petitioner again was evaluated by Dr. Rubin for an "increased frequency of episodes of vertical nystagmus with a chin-up head position" that Petitioner's mother documented with a home video. *See* 10/2/02 Gov't Ex. B at 142. Dr. Rubin concluded that examination was, "essentially normal," but another neuro-opthomologist examination was recommended. *Id.*

On February 28, 2002, Dr. Kupersmith conducted a "neuro-ophthalmic follow[-]up," and concluded that Petitioner had a history of "some encephalopathy of some sort." *Id*. at 175. Dr. Kupersmith did not see any remarkable change from his June 2000 evaluation, but confirmed nystagmus on Petitioner's right eye and that his left gaze, was "conjugate jerk nystagmus." *Id*.[36] Dr. Kupersmith suggested that Petitioner's condition "may be some type of neuronal discharge phenomenon" and recommended that Petitioner try an anticonvulsant or Baclofen[37] under pediatric neurologist supervision. *Id.*

Sometime in March 2002, Petitioner's mother died of a stroke. *Id*. at 204; *see also* 7/11/06 Pet. Ex. A at 71.

On March 26, 2002, Petitioner had a low-grade fever, coughing, and runny nose and was diagnosed with a virus. *See* 7/11/06 Pl. Ex. A at 64. On March 27, 2002, Ms. Bogatch reported that Petitioner continued to exhibit "overall delays in language, articulation, and oral motor skills. 10/2/02 Gov't Ex. K at 209. Petitioner experienced "delays of up to and greater than 33% in both receptive and expressive language skills." *Id*. at 209-210.

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[36] "Jerk nystagmus" is defined as "nystagmus which consists of slow movement in one direction, followed by a rapid return movement in the opposite direction[.]" DORLAND'S at 1296.

[37] "Baclofen" is an "analogue of y-aminobutyric acid administered . . . as a muscle relaxant and antispastic in treatment of spacity of spinal origin . . . it is used also . . . to treat spacity of cerebral origin[.]" DORLAND'S at 191.

On April 11, 2002, Petitioner was examined for swelling of the right eye and was diagnosed with and treated for conjunctivitis. *See* 7/11/06 Pl. Ex. A at 63. On April 12, 2002, Petitioner's left eye continued to be swollen with a discharge. *Id*. at 64. Conjunctivitis was diagnosed. *Id*. On April 18, 2002, Petitioner had a temperature and experienced another seizure. *Id*. at 65.

On April 17, 2002, following an "event that was consistent with seizure," Dr. Pavlakis examined Petitioner and noted that he experienced "alteration of consciousness over a long period of time, lasting 20 minutes to hour," and showed "some change in color." 10/10/02 Pet. Ex. at 2. Dr. Pavlakis concluded that this episode was similar to the July 20, 1999 episode and recommended another EEG. *Id.*

On April 30, 2002, Petitioner filed a Petition, pursuant to the Vaccine Act, 42 U.S.C. § 300aa-1, in the United States Court of Federal Claims.

* * *

On May 1, 2002, at a pre-op for an EEG, MRI, and MRA, Petitioner's physician noted he had been on Klonopin™[38] until five days ago, that was stopped because of nystagmus and sleepiness. *Id*. at 66.

On May 3, 2002, in order "[t]o rule out aneurysm, [on April 18, 2002]" Petitioner had a magnetic resonance angiography ("MRA"). 7/24/06 Pet. Ex. A at 1. The MRA was determined to be "unremarkable, because it revealed "[n]o intracranial vascular anomalies." *Id.*

On May 10, 2002, Plaintiff had a temperature of 102°F, was vomiting mucus and breathing heavily. *See* 7/11/06 Pl. Ex. A at 66. A virus was suspected since a strep test was negative. *Id*. at 66-67. On July 9, 2002, Petitioner was experiencing fatigue, no appetite, cough, and irritability. *Id*. at 69. A virus was suspected. *Id*. On July 15, 2002, a urine test for metabolic screening was negative. *Id*.

On July 24, 2002, Ms. Bogatch reexamined Petitioner. *See* 10/2/02 Gov't Ex. at 203-04. She reported that Petitioner's expressive language appears to be at 22-24 month level with scattering of skills up to 28 months. *Id*. at 203. Significantly, she reported that Petitioner:

> exhibits numerous articulation errors, which consist of substitutions of one sound for another, omissions of sounds in the initial, medial, and final positions of words, and simplifications of blends. Intelligibility is judged to [be] severely delayed.
>
> James's mother passed away approximately 3 months ago. James's speech and language skills have been affected by this tragedy. He also experienced a seizure

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[38] "Klonopin™" is a trademark for a "preparation of clonazepam." DORLAND'S at 982. "Clonazepam" is a "benzodiazepine used as an anticonvulsant in the treatment of atonic and myoclonic seizures[.]" *Id*. at 377.

> approximately 8 weeks ago. After the seizure, his speech became extremely unintelligible and it did not improve for approximately 3-4 weeks. His speech and language skills have been improving over the last 6 weeks.

Id. at 203-04. CPSE services were approved. *Id*. at 204. In late September 2002, Petitioner began attending "Variety Preschoolers Workshop," a Preschool Special Education Service set up by the Public School District of Manhasset, New York. *See, e.g., id*. at 204.

On August 9, 2002, during his three year examination, Petitioner's nystagmus was reported as improved, but was evidenced when Petitioner was tired. *See* 7/11/06 Pl. Ex. A at 71. No suspicious seizure activity was reported. *Id*. Petitioner's physician, however, noted "developmental delay," as Petitioner was not toilet trained, had gross motor weakness, and some speech difficulty. *Id*. On August 11, 2003, Petitioner's physician noted Petitioner was "making progress." *Id.* at 79.

On August 12, 2004, Petitioner had a five year examination, before starting kindergarten in an "inclusion prog[ram]" at "Shelter Rock," where he would continue to receive occupational, physical, and speech therapy. *Id.* at 85. A "DT pediatric" vaccine and an IPV were administered, without incident. *Id.* at 86.

On April 27, 2005, in response to symptoms of vertigo, a radiologist reviewed the May 3, 2002 MRI, saw "no evidence of temporal lobal pathology," but found "evidence of bilateral tonsillar herniation of the cerebellar tonsils[39] of approximately 7-8mm." 7/24/06 Pet. Ex. B at 2.

On April 28, 2005, Dr. Neil A. Feldstein, a neurosurgeon at the Presbyterian Medical Center in New York City ("Dr. Feldstein"), examined Petitioner and observed that he exhibited "a mild upbeat nystagmus," as well as an extension of his head at the neck. *See* 10/24/05 Gov't Ex. at 13. Dr. Feldstein reviewed previous MRIs. *Id*. at 13-14. According to Dr. Feldstein, the first MRI in 2000 "shows fullness to the posterior fossa without tonsillar herniation." *Id.* at 13. The second MRI, a scan from 2002, however, "is consistent with Chiari malformation," including "a 6-7 mm tonsillar herniation and significant deformation and compression of the inferior portion of the cerebellum at the level of foramen magnum." *Id.* Dr. Feldstein suggested that Chiari malformation was the sole explanation that tied Petitioner's symptoms together. *Id.* at 14. Dr. Feldstein requested a MRI of the entire spinal cord, "to reassess the anatomy in the posterior fossa." *Id.* He believed that Petitioner's condition would improve with a "suboccipital decompression."[40] *Id.*

On May 10, 2005, Petitioner had another MRI of his brain, cervical/thoracic/lumbar spine, and a cerebrospinal fluid flow study. 12/29/05 Pet. Ex. at 5-6. The MRI results were "consistent

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[39] "Tonsil of the cerebellum" is a "rounded lobule on the underside of each cerebellar hemisphere, continuous medially with the uvula of the cerebellar verones." STEDMAN'S at 1999.

[40] "Suboccipital" refers to "[b]elow the occiput or the occipital bone. 2. Denoting certain muscles, nerves, a nervous plexus, or triangle of the neck below the occipital bone." STEDMAN'S at1856.

with Chiari I Malformation[41] with 9mm of inferior cerebellar tonsillar ectopia." *Id.* The fluid study showed "less flow" possibly "below the foramen magnum compared to above the foramen magnum." *Id.* at 6..

On May 16, 2005, Dr. Feldstein performed an "elective suboccipital decompression" on Petitioner at Columbia Presbyterian Medical Center. 9/15/05 Pet. Ex. at 368. Dr. Feldstein used "B[rain stem] A[uditory] E[voked] R[esponse] and S[omato] S[ensory] E[voked] P[otential] monitoring." *Id.* at 392. The monitorings and "pulsation of the cerebellum and upper cervical canal" improved during the suboccipital bony decompression. *Id.* at 393. After the surgery, Petitioner was taken to the pediatric intensive care unit "for post-op management." *Id*. at 368. Petitioner remained stable during his hospital stay and was released on May 18, 2005. *Id*. at 368.

On June 7, 2005, Dr. Feldstein conducted a "first post-op check." 12/29/05 Pet. Ex. at 7. Petitioner did not report any specific post surgery complications, and Dr. Feldstein noted that Petitioner was "healing nicely," despite "minor pain and irritability." *Id.*

On September 13, 2005, Petitioner's six year examination showed much improved balance and fine motor skills. *See* 7/11/06 Pet Ex. at 93. Although Petitioner was attending the first grade, he continued to receive special education services, but was improving in "cognitive issues." *Id.*

B. Expert Opinions Of The Parties.

1. Petitioner's Expert-Dr. Eugene Spitz, M.D.

Dr. Spitz has been the Chief Pediatric Neurosurgeon at the Children's Hospital of Philadelphia for many years and estimated that he has seen over 15,000 pediatric neurological patients during his career. *See* 11/28/05 TR at 207. Dr. Spitz's residency was with Dr. H. Houston Merritt at Montefiore Hospital in New York. *Id*. at 209, 225. At the University of Pennsylvania, he

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[41] "Chiari I Malformation" is "a *congenital* anomaly in which the cerebellum and medulla oblongata, which is elongated and flattened, protrude down into the spinal canal through the foramen magnum." DORLAND'S at 438 (emphasis added).

In a letter dated November 21, 2005, Dr. Pavlakis stated that at "no time during the period that I was following [Petitioner], did I think [Petitioner] had a clinically relevant Chiari malformation." 12/29/05 Pet. Ex. at 8. On that same date, Dr. Spitz addressed a letter to Petitioner's attorney concluding "[t]he attempt to blame a non-existent Arnold-Chiari Syndrome for the neurological and developmental abnormalities, after the vaccination, is moot." *Id* at 10.

In a letter dated November 30, 2005 addressed to Petitioner's attorney, Dr. Zito offered a reading of Petitioners' June 2000 and May 2002 MRIs. Dr. Zito found "that neither [MRI] shows any abnormality in the brain stem or spinal court...[and] no evidence of Chiari I malformation". 12/29/05 Pet. Ex. at 3. "[T]he MRI's show no condition of the brain, brain stem or spinal cord, which would explain encephalopathy." *Id.*

also worked with Dr. Marburg, a neuroanatomist, and Dr. Charles Davidson, a neuropathologist. *Id*. at 207.

Dr. Spitz reviewed Petitioner's entire record and examined Petitioner in 2002, at which time, Petitioner exhibited "neurologic difficulty," *i.e.*, "[p]oor coordination, problems with communication, things that led me to think of the possibility of a chronic onset to an acute disease." *Id*. at 211. Dr. Spitz testified that it was "very likely" that Petitioner's post vaccine response was indicative of encephalopathy, which "by definition has an involvement of the brain itself." *Id*. at 216; *see also id*. at 212. Following the July 20, 1999 initial vaccination, in Dr. Spitz's opinion, Petitioner suffered an encephalopathy, *i.e.*, a reduced level of consciousness that lasted more than 24 hours: "I think that's a fact, but not the only fact." *Id*. at 217.

PETITIONER'S COUNSEL:	Okay. What other facts are there?
DR. SPITZ:	The neurological signs themselves, the changing skin tone, color, the reaction to the environment, all are significant.
PETITIONER'S COUNSEL:	And what reaction are you referring to? By skin tone, what are you referring to?
DR. SPITZ:	Well, they all reduced over time.
PETITIONER'S COUNSEL:	[A]pparently over the next week there was a distinct difference in the feel of his body. They referred to it as muscle tone, and it became spongelike. Would that be consistent with encephalopathy?
DR. SPITZ:	It certainly could be. . . . An encephalopathy involves portions of the brain that control muscle tone, it will show up at that time.
PETITIONER'S COUNSEL:	Okay. And would that be consistent with his lack of coordination later on?
DR. SPITZ:	It certainly can be, yes.
PETITIONER'S COUNSEL:	Okay. Would it be consistent with his stumbling as he tried to [walk]?
DR. SPITZ:	I think all of this is part of it.

PETITIONER'S COUNSEL: Okay. And there was testimony that he developed a nystagmus of the eye. Is that consistent with –

DR. SPITZ: That certainly is neurological.

PETITIONER'S COUNSEL: Is that consistent with his having suffered from an encephalopathy?

DR. SPITZ: Yes, it is.

Id. at 217-18.

* * *

PETITIONER'S COUNSEL: Dr. Spitz, when you [saw Petitioner] two years ago, did he show signs of a continuation of the disability due to the encephalopathy?

DR. SPITZ: As we mentioned, there were signs of it, yes, the clumsiness.

PETITIONER'S COUNSEL: And what were those signs?

DR. SPITZ: He just was not up to par that you would expect of a boy who is normal.

PETITIONER'S COUNSEL: And his inability to swallow his baby food, is that a sign of the encephalopathy?

DR. SPITZ: Not necessarily.

PETITIONER'S COUNSEL: Okay. His inability to swallow?

DR. SPITZ: That's neurologic.

PETITIONER'S COUNSEL: Okay. Would that be a continuation of the encephalopathy?

DR. SPITZ: It certainly could be.

PETITIONER'S COUNSEL: And I understand he just recently learned to throw a ball. Is that a sign of the encephalopathy?

DR. SPITZ: In the tests that were done before they started the therapy, occupational therapy, they give him a ball to throw, and how he uses that ball, catches it and throws it and so on is significant . . . He didn't do it well.

PETITIONER'S COUNSEL: And you read the entire medical record for [Petitioner], did you not?

DR. SPITZ: Some time ago, yes.

PETITIONER'S COUNSEL: Did it indicate that this disability had continued for a period of more than six months?

DR. SPITZ: Yes.

PETITIONER'S COUNSEL: And it continued for more than two years?

DR. SPITZ: Still continuing.

Id. at 219-21.

On cross examination, Dr. Spitz explained why he gave less deference to Petitioner's medical records than Petitioner's parents' observations.

GOVERNMENT COUNSEL: Your testimony is based on what, on the fact testimony that you've heard from the Petitioner's [father] and the affidavits that were contained in the petition, or on the medical records themselves?

DR. SPITZ: On everything that I had, including the conversations with the father.

GOVERNMENT COUNSEL: Okay. If you just had the medical records, if you just had the stack of documents and left out the affidavits and your conversations with Mr. Doe, would you be able to come to the same diagnosis?

DR. SPITZ: Generally speaking, and particularly true here, the records that were kept were very poor. Some of them really could not be read. I don't think they ever reflect the true picture of the

child. Pediatricians are too hurried and too quick.

GOVERNMENT COUNSEL: Okay.

DR. SPITZ: And they don't listen.

GOVERNMENT COUNSEL: So is that a no, if you just had these records and you didn't have the information that has come in from the affidavits and the conversations, would you be able to say that [Petitioner] suffered an encephalopathy?

DR. SPITZ: You can't separate the two. What I heard from the parents is very significant.

Id. at 230-31.

* * *

GOVERNMENT COUNSEL: Well, from your review of these records, do you have an opinion as to whether Jimmy suffered a significantly decreased level of consciousness that persisted for 24 hours or more within three days of his vaccination?

DR. SPITZ: It's possible.

Id. at 232-33.

* * *

DR. SPITZ: May I make a comment?

SPECIAL MASTER EDWARDS: Yes, you may.

DR. SPITZ: What's being done is going through page after page of material that I don't think is pertinent to the question, and . . . it's placing me at odds to what the father told me. So in every instance either the father is not telling me the truth or these reports are not accurate.

SPECIAL MASTER EDWARDS: And that is a decision that is left of me to make, Dr. Spitz, and I appreciate your position

as an expert here, appearing for Mr. Doe, that you have looked at the records, and you have taken a history from Mr. Doe. You have reviewed the affidavits from the other fact witnesses, and you have decided to accord greater weight to the fact witnesses' description of the child, and that is upon what you base your opinion that the child suffered an acute encephalopathy, is that correct?

DR. SPITZ: That is correct.

SPECIAL MASTER EDWARDS: And your position is that these medical records are not reliable?

DR. SPITZ: I'm afraid that's so.[42]

Id. at 239-40.

* * *

PETITIONER'S COUNSEL: And do you find that a mother's analysis of whether her child is normal is more accurate [than] that a doctor's analysis of whether a child is normal, as to what the child is doing or how the child is presenting itself?

DR. SPITZ: Unfortunately, yes. The mother's interpretation generally is more accurate, more dependable.

PETITIONER'S COUNSEL: So an emergency room physician could find a child alert and the mother not find that same child alert, is that correct?

DR. SPITZ: That's correct.

PETITIONER'S COUNSEL: Can you tell me why that is, in your experience?

[42] Dr. Spitz also pointed our several mistakes in the medical records to evidence why he did not rely on them in this case. *See* 11/28/05 TR at 247-49.

DR. SPITZ: It's a question, I think, of how you practice your medicine, how much time you have to give to it, how much detail you go into, and I've learned the hard way with all these years to listen to mothers. Mothers are much more dependable than the physician.

Id. at 249-50.

* * *

On re-direct, Dr. Spitz testified:

PETITIONER'S COUNSEL: Dr. Spitz, referring to the medical records, do the entirety of the medical records confirm that [Petitioner] is developmentally delayed in a serious fashion?

DR. SPITZ: Yes.

PETITIONER'S COUNSEL: Okay. And does the entirety of the medical records indicate that before July 20th of 1999, [Petitioner] was a normal baby.

DR. SPITZ: Yes.

PETITIONER'S COUNSEL: And that can be found and confirmed in the medical records?

DR. SPITZ: Yes.

PETITIONER'S COUNSEL: Can it be confirmed in the medical records that following July 20th of 1999, [Petitioner] was no longer a healthy baby?

DR. SPITZ: That's correct.

Id. at 246.

* * *

PETITIONER'S COUNSEL:	Dr. Spitz, there was a discussion of hypertonic spell, and I didn't get a clear definition of exactly what a hypertonic spell is. Do you know what it's purported to be?
DR. SPITZ:	It describes a child who is flaccid, who is not responsive on a temporary basis, and could be any number of things. What it is not according to the testing that is done, it is not a seizure.
PETITIONER'S COUNSEL:	Is the diagnosis of hypertonic spell inconsistent with the finding of encephalopathy?
DR. SPITZ:	No.
PETITIONER'S COUNSEL:	One could be the other?
DR. SPITZ:	One could be the other.

Id. at 251.

2. The Government's Expert-Dr. Max Wiznitzer, M.D.

The Government's expert, Dr. Wiznitzer, is a board-certified neurologist by the American Board of Psychiatry and Neurology, with a special qualification in Child Neurology. *See* 11/28/05 TR at 259-60. In addition, Dr. Wiznitzer is certified by the American Board of Pediatrics. *Id*. Since 1986, Dr. Wiznitzer has been an Associate Pediatrician and an Associate Neurologist at University Hospital of Cleveland, Ohio. *See* 2/28/05 Gov't Ex. B at 2. And, since 1992, Dr. Wiznitzer has been Director of the Autism Center at Rainbow Babies and Children's Hospital in Cleveland, Ohio. *Id*. at 3. During the past 24 years, Dr. Wiznitzer also has been an Associate Professor of Pediatrics and Associate Professor of Neurology at Case Western Reserve University. *Id.* at 2. Dr. Wiznitzer completed his residency in Pediatrics from Children's Hospital Medical Center in Cincinnati and served as a Fellow in Developmental Disorders, Pediatric Neurology, and Higher Cortical Functions. *Id* at 1. Dr. Wiznitzer also has received numerous awards and honors in the neurology field and his work has been widely published. *See* 2/28/05 Gov't Ex. B at 4-5, 12-42.

Dr. Wiznitzer has testified for the Government in a number of vaccine cases. *See* 11/28/05 TR at 257-58, 312-13; *see e.g.*, *Adams* v. *Sec'y of Health & Human Servs.*, 76 Fed. Cl. 23, 33-34 (2007).

In this case, Dr. Wiznitzer testified:

DR. WIZNITZER: According to the table definition, which is an acute encephalopathy that persists for at least 24 hours, [Petitioner] did not have a condition that fulfilled the table criteria.

GOVERNMENT COUNSEL: And can you tell us what the basis for your opinion is in that regard?

DR. WIZNITZER: Well, the basis for my opinion is built basically on information from the medical records which incorporates information from the family.

Number one, there clearly was an event that occurred on the evening after his vaccination . . . associated with fever, an episode of crossed eyes. Whether we take the event as being some sort of lethargy or loss of tone or impairment of consciousness is not very well – is not elaborated here simply because it states in the medical record that the baby was alert as per mother during episode. This is the note written by the resident as well as the note written by the nurse.

But taking into account, and let's take into account that [Petitioner] did have an event [in] which there was an impairment of consciousness, limpness, color change in association with fever. It's clear in the medical record from North Shore University Hospital when he came to the emergency room that there is documentation by multiple medical personnel, not just one, not just two, but basically three, a nurse, a resident and an attending physician, that he was alert.

By being defined as alert, you can't be encephalopathic. These two terms are mutually exclusive.

Number two, there was no evidence of low tone at the time of that examination. Basically, the attending physician in his notes says motor negative, without focal deficits.

Motor negative, I think, is pretty clear that there is no significant abnormality in terms of movement. There is no significant abnormality in terms of tone.

The resident checked off boxes about the right upper extremity, left upper extremity, right lower extremity, left lower extremity, which basically lists normal. There is a whole little sequence of boxes which appears to pertain to the entire area there, which would include any abnormalities of tone.

GOVERNMENT COUNSEL: Just before you go on, would you expect to see if the child was having an acute encephalopathy there to be problems with muscle tone?

DR. WIZNITZER: *Yes. I would normally expect the child who is acutely encephalopathic to have* a significantly decreased level of consciousness, and most times I also find that there is *some alternation [sic] in tone*.

The only reason I'm saying that in this circumstance specifically is because the parents reported that he was limp or whatever terminology was used, or flaccid at home, and if that was a part and parcel of the encephalopathy, it should persist when they are being seen in the emergency room. Yet we don't have any documentation of an impairment of consciousness. We don't have any documentation of an impairment in tone, and according to the available medical records on the emergency room page . . . . There is [no] evidence of cyanosis, which means looking blue. There is no evidence of pallor, which means looking pale. None of that is there.

Unlike my colleague in the room, I find it hard to believe that three separate observers, no matter how rushed they might be, could miss a child with a significant impairment of

consciousness . . . . [I]f we assume that an event did occur, dependant on the timing that's documented in the records, whether we use a timing of 15 minutes or we use 45 minutes or an hour, to me it doesn't matter. There wasn't an acute change in mental status. It was clearly resolved by the time that he was seen in the emergency room.

Therefore, he doesn't meet table criteria because there was not an impairment, a significant *impairment of consciousness* over a period of 24 hours.

11/28/05 TR 266-70 (emphasis added).

* * *

GOVERNMENT COUNSEL: His record seems to indicate that as of April [2000], on the second page it says that he is alert, active and interactive at an age-appropriate fashion.

DR. WIZNITZER: Yes. But at that time he has a *history of being symptomatic because of the eye movements, and he is described as having a mild tremor when excited*, and he is also described at that point as having some *mild hypotonia or low tone*.

Id. at 282.

* * *

GOVERNMENT COUNSEL: Dr. Wiznitzer, you, in your report, ascribe the symptoms that Jimmy did experience the night of the shot to something else. If you believe the -- if the Court accepts the fact witness testimony, and can you explain what that opinion is and how you arrived at it?

DR. WIZNITZER: Yes. That [Petitioner] had what sounds like a hypotonic, hyperresponsive episode based on the description of the family members and friend; that he was limp, unresponsive, had a color change, this was associated with fever,

had a limited duration of time, and then by the time he was in the emergency room this was no longer observed. That event is most consistent with HHE.

GOVERNMENT COUNSEL: Can you tell us in your opinion what an HHE is?

DR. WIZNITZER: Well, hypotonic, hyperresponsive episode is an episode that's been described after vaccinations, specifically after DPT, in which a child does exactly what I described; that there is a change of tone, change of color, change of impairment of consciousness that's of limited duration with a full recovery by the child.

The mechanism of action is not well defined. We know it's not a seizure. We know, to the best of our knowledge, that it's not glued to like low blood sugar attacks. Some people feel that it may be a fainting spell or a syncopal equivalent. We just don't have enough knowledge. They are rare events. I've seen children who have had those spells. I have never seen them during the spell because by the time I'm called to see them, no matter how quickly I see them, the episode has resolved.

By the time they make it to the emergency room, make it to their primary care provider and we're called about, I see a child who basically has an examination similar to what was detailed for [Petitioner] in the emergency room; awake, alert, moving, adequate tone. And then the parents and I just talk about this episode, some evaluations that need to be done of management in the future.

GOVERNMENT COUNSEL: Is HHE a recognized medical condition in the medical community?[43]

DR. WIZNITZER: Yes, it is.

GOVERNMENT COUNSEL: Isn't HHE the same thing as an encephalopathy?

DR. WIZNITZER: No.

Id. at 287-89.

* * *

GOVERNMENT COUNSEL: Okay. Do the records that we have just gone through about [Petitioner's] two-month well baby visit, four-month and six-month baby visit, do those lend credence to the idea that the event that Jimmy suffered that evening, if the fact testimony is accepted by the Court, is more likely an HHE as opposed to an encephalopathy? And if so, why?

DR. WIZNITZER: It is an HHE because according to the available medical records for a period of months after that time from a neurologic standpoint he was asymptomatic on all examinations that were done by physicians.

GOVERNMENT COUNSEL: Okay. Is there anything in the medical records themselves that tend to corroborate the idea that the treating physicians believed that Jimmy had an HHE as opposed to an encephalopathy?

DR. WIZNITZER: Well, there is a note at four months age, you have to excuse me, where it states that "decided to give DT because of previous

[43] In response to questions regarding Petitioner's potential hypotonic-hyporesponsive event, Dr. Spitz defined the condition as one where a child is flaccid and unresponsive on a temporary basis. *See* 11/28/05 TR 251. Dr. Spitz stated that he has never observed a patient with HHE as Dr. Wiznitzer did. *Id*. at 229-30.

hypotonic--" unreadable word, "spell," which appears to suggest that it was an HHE episode. It also suggests that the physicians were quite aware of what had happened in the emergency room and its ramifications.

Id. at 289-90.

* * *

It is clear in the medical record, clear that in March of 2000 he had abnormalities that were reported, which were the eye movements. In April, and also at that time he also had the tremors, episodic tremors, episodic eye movement abnormalities, whether you want to call it eyelid flutter, whether you want to call it nystagmus is immaterial. In April [2000], he was documented as having hypotonia, but that's really the first time that we have a definite corroboration of any kind of obvious neurologic impairment that was present.

Id. at 291.

* * *

Therefore, while I agree that at the present time he has what we would -- as a medical practitioner, *I would say, has a static encephalopathy because he has neurologic problems*. According to the table definition of chronic encephalopathy, he does not meet criteria . . . for two reasons. One is, according to the table, it says, "Individuals who return to a normal neurologic state after the acute encephalopathy," and everyone knows the words. That's basically what happened with [Petitioner] according to the available medical records, and the information that's in the record.

Id. at 292.

Dr. Wiznitzer also proffered an alternative diagnosis of Petitioner's neurologic problems, other than HHE:

DR. WIZNITZER:	So Chiari I malformation is an abnormality in which portions of the cerebellum, which is the balance center of the brain, specifically a lower part of the cerebellum which are known as tonsils, basically slip down lower than they should, putting pressure on the brain stem which is in front of the cerebellum, and then putting pressure on the upper cervical spinal cord as the consens (phonetic) basically slowly work their way down and protrude below the opening of the skull, known as the foramen magnum, which is the opening in the skull through which the spinal cord enters and connects with the brain. So it basically is going into a space where it shouldn't go. It can have a general developmental progress as we know in progressive MRI studies that have been done in children, where you may find evidence of fullness or mild herniation of the cerebella tonsil on the first MRI, and then as time goes on you find that the tonsils go lower into the cervical -- upper cervical cord region. So as a consequence of the cerebellar tonsils protruding lower than they should, basically you get a sequence of abnormalities involving three distinct parts of the brain that are all in that region, which is basically into what's called the posterior fascia and the upper cervical spine.
GOVERNMENT COUNSEL:	Can you tell us what the treatment is for Chiari I malformation?
DR. WIZNITZER:	The accepted treatment is basically surgical decompression.

Id. at 298-300.

* * *

DR. WIZNITZER: But what you can have is dysfunction that localizes to the brain stem, dysfunction that localizes to the cerebellum. The dysfunction can show itself, because there is increased pressure and there is cramping in that space, it many times will present with pain, episodic headache usually in the back of the head. In young children what you will get is episodic irritability because it hurts and they can't tell us that it hurts. They can just cry, and tell us that it hurts.

You will also have other abnormalities. The balance center, which is the cerebellum, may not work right because of the cramped nature there, which means as you start with your motor function your balance will be off, and I think the medical records are replete here in telling us that he had ataxia or unsteadiness of gait or imbalance of gain.

You can have tremor. You can have imbalance of arm use and movement. If there is pressure that's put on motor pathways that are coming down through the brain stem into the upper cervical spine, if there is pressure put on those, you can have an asymmetry or an impairment of strength or function of one or both arms where you may posture abnormally, or you may not have good function. There actually may be muscle wasting that's associated with it.

The cerebellum coordinates movement. The cerebellum coordinates movement not only for the trunk, not only for the extremities, but also for the oral facial region, which means that if we have a problem with coordination of oral motor movement, you are going to have features such as unintelligible speech and speech delay.

> Pressure can be put on nerves that run from the brain stem and into the brain stem in this region, including nerves that deal with hearing, nerves that deal with swallowing, nerves that deal with palatal motion, which is the little floppy area at the top of our mouth, nerves that deal with tongue use, nerves that deal with mouth movement itself, and those obviously would lead to things such as hearing impairment, swallowing problems, easy choking – . . . And you can also get nystagmus. The brain stem and the cerebellum, abnormalities of the brain stem and cerebellum are well known to be associated with nystagmus. In this case, basically a fluttering of the eye movements up and down, up and down, up and down. He had vertical nystagmus. This is a well-known phenomenon described in association with Chiari malformations.
>
> So basically making a list of the features of his clinical complaints, which [were] nystagmus, the wide-based gaits with ataxia or difficulties with balance, hearing loss which may or may not be related, expressive language delay because your speech is unintelligible if you can't coordinate the movements, difficulties with chewing and swallowing and choking on solid foods, difficulties with lip closure on a cup, problems with excessive drooling because you can't control how the mouth works and how you coordinate your swallow, increased tone in the arms asymmetries of arm use, and . . . an episode that [is] basically called a posterior fascia fit. It's not a seizure but we call them posterior fascia fits.

Id. at 301-04

On redirect, Dr. Spitz took issue with Dr. Wiznitzer's diagnosis that Petitioner's chronic health problems were attributed to Chiari I malformation.

PETITIONER'S COUNSEL:	And can you tell me if the Chiari I malformation would cause these symptoms that Dr. Wiznitzer has attributed to the Chiari I malformation?
DR. SPITZ:	Not with the lesion has described, and not with the way it was handled in the operating room.
PETITIONER'S COUNSEL:	Okay. What is the difference between the lesion as described and the lesion that would cause these particular symptoms?
DR. SPITZ:	The Chiari syndrome by definition consists of two types. The first type is the usual one with no signs of pressure and no hydrocephalus. The second type is like the first through misplacement, plus you have hydrocephalus involved.
PETITIONER'S COUNSEL:	And which type was this?
DR. SPITZ:	This was the first type.
PETITIONER'S COUNSEL:	Okay. And what is there about the first type that would not cause these symptoms?
DR. SPITZ:	If there is impingement on the tissue part of the findings. . . When you open up a posterior fascia of a child with an active, ongoing, severe Chiari syndrome, there is a great distortion of the top of the spine, the cervical spine, of the midbrain, of the cerebella tonsils. That was not the case here.
PETITIONER'S COUNSEL:	And did you see –
DR. SPITZ:	As a matter of fact, grossly -- there was no sign of fascia grossly. . . .[F]rom the operative notes, yes.
PETITIONER'S COUNSEL:	Okay. And did you see the MRIs in this case?

DR. SPITZ: I saw -- yes, I did see two of the MRIs.

PETITIONER'S COUNSEL: Okay. And were the MRIs around the surgery, are they consistent with your diagnosis that there was no impingement of the tissue?

DR. SPITZ: Yes.

PETITIONER'S COUNSEL: And what kind of a Chiari would cause these symptoms of nystagmus, wide stance, speech, choking, lip closure, et cetera?

DR. SPITZ: They are associated with hydrocephalus which causes pressure from above, or myelomeningocele which caused tethering, it's traction from below, others pull down or compressed down from above.

PETITIONER'S COUNSEL: Was there any sign in this case of compression?

DR. SPITZ: No.

PETITIONER'S COUNSEL: Was there any sign in this case of tethering?

DR. SPITZ: No.

PETITIONER'S COUNSEL: Is there anything in the doctor's notes that would indicate that he found anything when he opened Jimmy up that would explain any of his symptoms?

DR. SPITZ: No.

Id. at 341-44.

* * *

PETITIONER'S COUNSEL: And so did you see anything in those MRIs that would cause –

DR. SPITZ: We did see the herniation of the cerebella tonsil, but not pathologically to the point of requiring surgery at that point.

PETITIONER'S COUNSEL:	Okay, so it wasn't large enough at that point to do this kind of damage?
DR. SPITZ:	It didn't go down far enough.
PETITIONER'S COUNSEL:	Okay. And that's based on your examination of the MRI?
DR. SPITZ:	That's correct.

Id. at 345-46; *see also* 12/29/05 Pet. Ex. 3 (Dr. Zito found MRI evidenced no sign of Chiari I malformation); *id*. at 8 (Dr. Pavlakis' statement that Petitioner did not have "a clinically relevant Chiari malformation);.

3. Petitioner's Expert – Dr. John J. Shane, M.D.

Because the interpretation reports for the June 2000 and May 2002 MRIs were not available at the October 28, 2005, hearing, the Special Master re-convened the hearing on January 20, 2007. *See* 8/22/07 TR at 384. By that time, however, Dr. Spitz had died. *Id*. at 384. Instead, Dr. John J. Shane was retained by Petitioner to review the MRIs and interpret the reports. *Id*. at 385.

Dr. Shane graduated from Lehigh University and received his M.D. degree from Pennsylvania State University College of Medicine ("Pennsylvania State"). *Id*. at 398. Dr. Shane's rotation residency was at Wilkes-Barre General Hospital, and he served as a four-year resident in clinical and anatomical pathology at Pennsylvania State, focusing on neuropathy and cardiovascular. *Id*. Dr. Shane also worked at the Institute for Cardiovascular Research under the direction of Dr. Warner, a neuropathologist. *Id*. Subsequently, Dr. Shane was a Research Fellow with a grant from the American Cancer Society. *Id*. at 399. Thereafter, he became the Chief of Pathology and Director of Vascular Medicine at St. Agnes Hospital [Pennsylvania] while teaching pathology, first as an Instructor and then as an Assistant Professor. He was also serving at the same time as a phlebologist and neuropathologist at Broad Street Hospital. *Id*. at 399. In 1974, Dr. Shane became Chairman of the Department of Pathology at Lehigh Valley Hospital in Allentown, Pennsylvania, the "seventh most advanced hospital in the country." *Id*. In 1994, Dr. Shane became an Adjunct Professor at Ottoman while maintaining the position of Clinical Professor at Pennsylvania State. *Id*.

The Special Master qualified Dr. Shane as an expert in pathology, with experience in neuropathy. *Id*. at 413.

After reviewing Petitioner's MRIs and the interpretive reports, Dr. Shane testified that:

> [T]here was no significant Chiari I malformation or herniation until the year 2005. In 2005, we see what is a very, very mild and probably minimal Chiari malformation with a descent of nine millimeters. You have to understand that with Chiari there has to be more descent than is normal, and we like to say that up to five millimeters is normal, but even there there's a little bit of variation only because the accuracy with

which you can make these measurements off the MRI certainly does not allow for 100 percent accuracy.

Your measurements are within a millimeter or two, but never completely accurate to the millimeter, so with that you need at least eight or nine millimeters or more of descent before you call this a Chiari at all, and in that circumstance it is a minimum Chiari, and in this case, there is in my opinion no Chiari whatever that is clearly noticeable until the year 2005, and at that point in time, the Chiari is certainly a minimal Chiari.

I am not convinced in correlating even at that point there was any significant symptomatology related to the Chiari malformation, and the proof of the pudding is in the eating, and there is Chiari malformation without syrinx; that means without inscription, without the generation –

Without syrinx the symptomatology is usually relieved major, I mean, 90 percent by a surgery and in this case, this child was decompressed but there was no change whatever in his symptoms . . . there was absolutely no improvement.

Id. at 416-17.

* * *

PETITIONER'S COUNSEL: Dr. Shane, do you recall what symptomology [Petitioner] was demonstrating as of that early period in the spring of 2000, which is March?

DR. SHANE: Yes. [Petitioner] at that point in time had been noticed by his parents to be less attentive. He had poor eye contact with his family, with other people, with his environment. He did not respond normally to these people. He was basically not a happy child. He was a cranky child. He was a child who was described in numerous medical records as cranky . . . not a happy child.

He was a child that lacked good eye contact. He was a child who lacked focus. He was a child that responded to his caregivers, to his contacts in a less than normal fashion.

PETITIONER'S COUNSEL: Okay. With that description and in looking at the 2000 MRI, can you tell us if there was

anything about that MRI that would explain those symptoms?

DR. SHANE: That MRI was totally normal.

PETITIONER'S COUNSEL: Now, I understand that there's some indications that there was a fullness of the posterior tonsils there. Would fullness of the tonsils have anything to do with these kinds of symptoms?

DR. SHANE: Absolutely not. Now, there you are into my area of anatomy, pathology, and let me say that the only way you could do symptoms is with compression, and if you have even the slightest degree of compression that would be to the herniation, the tonsil herniation. There was no herniation at that point in time, and there was zero increased pressure. With zero increased pressure, there were no symptoms.

PETITIONER'S COUNSEL: Now, in any of the MRIs did you see herniation?

DR. SHANE: Not until 2005. In 2005, it's minimal basically.

PETITIONER'S COUNSEL: Now, there was another MRI in 2002. Now, do you recall what Jimmy's symptoms were in 2002?

DR. SHANE: Well, in 2002 he had similar symptomatology. At that point in time, Jimmy was still exhibiting the lack of attention. He was still exhibiting the slow responsiveness, and he was still exhibiting some of the cranky behavior, and certainly there is nothing in the MRI that would explain those symptoms, and certainly I would not ever interpret these symptoms you see in that MRI as the symptoms of Chiari.

It certainly is at a level that you would never, ever even remotely consider doing any decompression. Again, your accuracy in

measuring these on the firm as is one of the basis, and I think it's still within the range of normal.

PETITIONER'S COUNSEL: Now, I understand that Jimmy was sort of clumsy also. Can either of those MRIs explain clumsiness or drooling or the statements?

DR. SHANE: Well, you have to remember that some clumsiness can be the result of posterior fossa junction, so the clumsiness could well have been a symptom of the posterior fossa. *But the nystagmus – the nystagmus in his case was up beating*. In Chiari malformation, the nystagmus is down beating 100 percent of the time.

The only time you have up beating nystagmus is if you have an abnormality with the cervico-medullary junction, and there was no abnormality of the cervico-medullary junction, so hence, the nystagmus that he had was not related to Chiari.

PETITIONER'S COUNSEL: And can you tell us what this junction is? Explain what the significance of it is?

DR. SHANE: Well, cervico-medullary junction is the junction of the T medullary area framed by the cervical cord and at that point in time, he had no abnormality of that junction. There's minor, minor descent. Even in 2005 there's very, very minor descent, and that's not going to produce any abnormality. There was no sryinx, and there was no abnormality of the cervico-medullary junction, and hence the nystagmus that he had was certainly not due to a Chiari.

PETITIONER'S COUNSEL: In the 2002 MRI, was there any indication of pressure?

DR. SHANE: No, no. You can find particularly in children diagnosis of Chiari in infants is extremely

rare. In children, you can get descent with very, very low increase in pressure, and again descent even in 2005, he had three or four millimeters beyond what is customary, and you consider – you consider the difficulties of measuring it.

It's not impressive even when he was operated on, and I think under the circumstances, I would first want to see the surgery, but I would say that certainly it explains why he has no improvement after surgery. The condition of the child before surgery and the condition after surgery doesn't –

PETITIONER'S COUNSEL: Now, you've indicted that the symptoms Jimmy's presented would have been essentially in 2000?

DR. SHANE: Yes.

PETITIONER'S COUNSEL: And the evidence you have of physicians trying to consult these MRIs, is it possible to make any determination as to what causes those symptoms could be based on the medical record themselves?

DR. SHANE: *The symptoms that he has or that he seems to have are cerebral, and you know he had a cerebral event. You know that he had a vaccine reaction*. I would define the reaction as certainly up to the observer. I would define the reaction as something that by any other term is a seizure, and *he had the ongoing symptomatology of a cerebral process, not a cerebellar process, and as a result, on a patient level this cerebral injury, he has the reaction*.

Again, how you define it is up to the observer, and the reaction was to the vaccine, and that would kind of point to – it's difficult. When he first began to exhibit the reversal of his previous neurologic achievements, his

vocalization prior to that event and after that event shows a *decline in his neurologic achievements*.

Id. at 418-22 (emphasis added).

* * *

PETITIONER'S COUNSEL: Now, Doctor, the vaccine table contains a description of an encephalopathy manifesting within 72 hours of the DPAT vaccination. Would you please explain to us from your experience what that encephalopathy is and how it manifests itself in the brain?

SPECIAL MASTER EDWARDS: Mr. McHugh, that really goes beyond the scope of what you presented Dr. Shane for today, and that is to discuss the relevance of the findings on MRI. . . . It is beyond the scope, Mr. McHugh, of what you're presenting Dr. Shane for today. Dr. Shane stepped in to complete the record in the absence of Dr. Spitz. Dr. Shane's role is to review the MRIs and provide rebuttal testimony to Respondent's contention that the MRIs show Chiari I malformations that are responsible for Jimmy's current condition . . . . *Your surrebuttal case rebuts Respondent's contention that the MRIs show Chiari I and that the Chiari I is responsible for the current condition*.

PETITIONER'S COUNSEL: Correct. Correct.

SPECIAL MASTER EDWARDS: You presented Dr. Shane to say that the 2000 and 2002 MRIs are normal. The 2005 MRI shows only slight herniation and that none of the child's symptoms are relatable to a Chiari I malformation. *You don't get beyond in a surrebuttal case to go back to your case in chief to reargue that the child's current condition is related to vaccination*.

PETITIONER'S COUNSEL: It is relevant to emphasize that a vaccination affects the whole brain and would be

	consistent with this type of injury, and the Chiari I type malformation, even if it was present would not be consistent with this message, and it's just a continuation of precisely the same rebuttal. . . .
SPECIAL MASTER EDWARDS:	That's beyond the scope of a surrebuttal case. That's presenting again your case in chief.
PETITIONER'S COUNSEL:	I respectfully disagree, if that's your ruling.

TR 422-23, 425-27 (emphasis added).

II. THE SPECIAL MASTER'S OPINION.

Special Master Edwards determined that, because Petitioner's medical records did not disclose a diagnosis that Petitioner's post-vaccination symptoms met the definition of a Table Injury, compensation was not due. *See John Doe 21* at *14. Likewise, Petitioner failed to proffer expert evidence acceptable to Special Master Edwards, that Petitioner's post-vaccination symptoms met the definition of a Table Injury. *Id*. at *22.

Special Master Edwards also dutifully recited the governing precedent regarding causation-in-fact cases. *See John Doe 21* at *25. The Special Master, primarily relying on the Government's expert, Dr. Wiznitzer, determined that "[a]fter canvassing through the record . . . it is more likely than not that [Petitioner] sustained on July 20, 1999, a vaccine related HHE." *John Doe 21* at *27. Special Master Edwards then proceeded to determine, by a preponderance of the evidence, that Petitioner did not establish that he "suffered the residual effects for more than 6 months after the administration of his July 20, 1999 DTaP vaccine." *Id*. He concluded that "the preponderance of the evidence does not establish that [Petitioner's] vaccine-related HHE is responsible for [Petitioner's] current neurological condition." *Id*.

On July 7, 2008, Petitioner filed a Motion For Review of Special Master Edwards' May 22, 2008 ruling that was assigned to the undersigned judge. On July 16, 2008, Petitioner filed a Memorandum in Support of the July 7, 2008 Motion ("Pet. Br."). On August 6, 2008, the Government filed a Memorandum in Response ("Gov't Resp.").

III. THE ARGUMENTS OF THE PARTIES.

A. The Petitioner's Assertions of Error.

The Petitioner asserts two errors require the United States Court of Federal Claims to reject the May 22, 2008 ruling of the Special Master and award Petitioner compensation. *See* Pet. Br. at 8, 18. First, Petitioner's encephalopathic illness arose prior to January 2000 and the Special Master's finding to the contrary ignored both fact and expert medical opinion. *Id*. at 8-10. Specifically, it was erroneous for the Special Master to construe the lack of documentation of Petitioner's "static

encephalopathy" in medical records as being equivalent to having "*no evidence* of sequella from [Petitioner's] encephalopathy lasting six months." *Id*. at 10 (emphasis added). In fact, a medical record is not even required to support a determination that a table encephalopathy exists. *Id*. at 14 (citing Aids to Interpretation of the Table, 42 C.F.R. § 100.3(D)). Therefore, it is "more likely than not" that Petitioner's "parents' version of the facts is correct and . . . their observations were reported to the doctor." *Id*. at 12. This is particularly so in this case, because Petitioner's illness was apparent as of October 4 and November 8, 1999, approximately four months after the initial series of vaccinations were administered. *Id*. at 17-18.

Second, Petitioner also asserts that the Special Master erred in determining that the ER's decision not to admit Petitioner following his July 20, 1999, post-vaccine reaction evidenced that Petitioner did not experience initial symptoms of "acute encephalopathy." *Id*. at 18-32. To evidence this, Petitioner points out that the ER discharge record did not "check" Petitioner as having "improved." *See* 10/2/02 Gov't Ex. B at 34D. Instead, Petitioner was discharged as a sick baby, with fever, despite having been admitted with the same symptoms. *Id*.

B. The Government's Response.

The Government responds that the Special Master correctly found that Petitioner failed to prove a *prima facie* case of encephalopathy, pursuant to 42 C.F.R. § 100.3(b)(2)(i). *See* Gov't Resp. at 6-13. In addition, the Special Master correctly found that Petitioner failed to prove causation-in-fact. *Id*. at 15-19. The Government argues there is no evidence that Petitioner's "chronic encephalopathy was actually caused by his adverse reaction to the vaccine," because Petitioner presented "no evidence of any kind as to actual causation." *Id*. at 16-17. Second, Petitioner's theory of an initial "adverse reaction being an acute encephalopathy" was "thoroughly discredited by the Special Master." *Id*. at 17 (internal quotations omitted). Third, the Special Master appropriately determined that the "initial adverse reason was an HHE which was not responsible for [Petitioner's] neurological condition." *Id*. (citing *John Doe 21* at *27). Finally, the Government argued that, "[b]ecause petitioner was unable to establish the factual basis for his Table case, he was similarly unable to demonstrate that [Petitioner's] later problems were vaccine-caused." *Id*. at 19.

IV. DISCUSSION.

A. Standard Of Review And Burden Of Proof In Vaccine Act Cases.

In *De Bazan* v. *Sec'y of the Dept. of Health & Human Servs*., 539 F.3d 1347 (Fed. Cir. 2008), the United States Court of Appeals for the Federal Circuit recently restated the standard of review and relevant burdens of proof in cases brought under the Vaccine Act.

> Under the Vaccine Act, the Court of Federal Claims reviews the decision of the special master to determine if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 42 U.S.C. § 300aa-12(e)(2)(B); *Althen* v. *Sec'y of Health & Human Servs*., 418 F.3d 1274, 1277 (Fed. Cir. 2005). We review legal determinations of the Court of Federal Claims de novo. *Althen*, 418 F.3d at 1278. To the extent that the Court of Federal Claims adopts factual findings

made by the special master, we accord them the same deference as the Court of Federal Claims and review them under the arbitrary and capricious standard as provided in the statute. *Munn* v. *Sec'y of the Dep't of Health & Human Servs*., 970 F.2d 863, 870 (Fed. Cir. 1992). When the Court of Federal Claims makes its own factual findings either in the first instance or when it has found the special master's findings arbitrary and capricious, we review those findings for clear error. *Id*. at 871-72; *see also Althen*, 418 F.3d at 1278.

As part of [the] burden of proof, the petitioner must establish that [the] injuries were caused by a vaccine listed on the Vaccine Injury Table ("Table"). *See* 42 U.S.C. § 300aa-11(c)(1)(C). The petitioner may meet this burden as to causation in either of two ways. First, causation is presumed if the petitioner can demonstrate by a preponderance of the evidence that [the] injury meets the criteria in the Table. *Grant* v. *Sec'y of the Dep't of Health & Human Servs.*, 956 F.2d 1144, 1146-47 (Fed. Cir. 1992). The Table lists symptoms and injuries associated with each listed vaccine and a timeframe for each symptom or injury. 42 U.S.C. § 300aa-14. Congress has thus determined that if a petitioner can establish that [petitioner] received a listed vaccine and experienced such symptoms or injuries within the specified timeframes, she has met her *prima facie* burden to prove that the vaccine caused her injuries.

If, as here, the petitioner has suffered an injury that is not listed on the Table, or if the petitioner suffered an injury listed on the Table but not within the specified timeframe, [petitioner] is not afforded a presumption of causation and thus must prove causation-in-fact. *Grant*, 956 F.2d at 1147-48. We have held that causation-in-fact in the Vaccine Act context is the same as "legal cause" in the general torts context. *Shyface* v. *Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Therefore, drawing from the RESTATEMENT (SECOND) OF TORTS, the vaccine is a cause-infact when it is "a substantial factor in bringing about the harm."[44]

We observed in *Shyface* that the "substantial factor" standard requires a greater showing than "but for" causation. 165 F.3d at 1352. The RESTATEMENT addresses "but for" causation by stating that "the actor's negligent conduct is not a substantial factor in bringing about harm to another if the harm would have been sustained even if the actor had not been negligent." RESTATEMENT (SECOND) OF TORTS § 432(1). Therefore, "but for" causation requires that the harm be attributable to the vaccine to some non-negligible degree. But, as we explained in *Shyface*, a merely non-negligible contribution to the harm is insufficient because the vaccine must have been a substantial factor in bringing about the harm. *Shyface*, 165 F.3d at 1352. However, the petitioner need not show that the vaccine was the sole or predominant cause of her injury, just that it was a substantial factor. *Walther* v. *Sec'y of Health & Human Servs*., 485 F.3d 1146, 1150 (Fed. Cir. 2007) (citing *Shyface*, 165 F.3d at

[44] *See* RESTATEMENT (SECOND) OF TORTS § 431(a).

1352). Applying these principles to the Vaccine Act context, we have held that . . . to meet [the] burden as to causation-in-fact, [petitioner] must establish by a preponderance of the evidence: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Althen*, 418 F.3d at 1278.

* * *

Once the petitioner has established a *prima facie* case for entitlement to compensation and thus met [the] burden to prove causation-in-fact, the burden shifts to the government to prove "[by] a preponderance of the evidence that the [petitioner's injury] is due to factors unrelated to the administration of the vaccine described in the petition." *See* 42 U.S.C. § 300aa-13(a)(1)(B); *Walther*, 485 F.3d at 1150. If the government fails to meet this burden, the petitioner is entitled to compensation. So long as the petitioner has satisfied all three prongs of the *Althen* test, [Petitioner] bears no burden to rule out possible alternative causes.

Id. at 1350 (italics added).

A. The Special Master Correctly Determined That Petitioner Did Not Establish A Vaccine Table Injury.

The Vaccine Injury Table provides that a plaintiff, who suffers "acute encephalopathy" within 72 hours after receiving a vaccine including pertussis, is entitled to a presumption of causation or a *prima facie* injury under the Vaccine Act. *See* 42 C.F.R. § 100.3(a)(II).

An "acute encephalopathy" is defined as:

one so severe so as to require hospitalization (whether or not hospitalization occurred).

For children less than 18 months of age who present without an associated seizure event, an acute encephalopathy is indicated by a *significantly decreased level of consciousness lasting for at least 24 hours.* Those children less than 18 months of age who present following a seizure shall be viewed as having an acute encephalopathy if their significantly decreased level of consciousness persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication.

42 C.F.R. § 100.3(b)(2)(i).

* * *

A "significantly decreased level of consciousness" is:

> indicated by the presence of at least one of the following clinical signs for at least 24 hours or greater (*see* paragraphs (b)(2)(i)(A) and (b)(2)(i)(B) of this section for applicable timeframes):
>
> (1) Decreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli);
>
> (2) Decreased eye contact (does not fix gaze upon family members or other individuals); or
>
> (3) Inconsistent or absent responses to external stimuli (does not recognize familiar people or things).

42 C.F.R. § 100.3(b)(2)(i)(D).

In this case, drowsiness, eye crossing, not making eye contact, and fever were reported by Petitioner's parents after receiving his vaccinations on September 19, 1999. *See* 10/27/05 TR at 76-81. Petitioner's contemporaneous medical records, however, do not evidence that Petitioner experienced "a significantly decreased level of consciousness lasting for at least 24 hours," 42 C.F.R. § 100.3(b)(2)(i)(A).

The court does not doubt Petitioner's parents' contrary observations, particularly since they had absolutely no motive for not being entirely truthful with the ER doctors and Petitioner's pediatrician. Without independent medical collaboration of the specific symptoms of acute encephalopathy, as defined in the Vaccine Injury Table, Congress has determined that a petitioner cannot establish a *prima facie* case for compensation. In so finding in this case, Special Master Edwards did not err. *See John Doe 21* at *13-22. That ruling, however, does not preclude Petitioner from qualifying for compensation under the Vaccine Act, if causation-in-fact can be established by a preponderance of the evidence. *See De Bazan*, 539 F.3d at 1347. For that reason, Special Master Edwards proceeded to assess whether Petitioner established causation-in-fact. *See John Doe 21* at *23-25.

B. The Special Master Erred In Ruling That Petitioner Is Not Entitled To Compensation Under The Vaccine Act.

1. The Special Master Failed To Adhere To The Analysis And Burden Of Proof Established By The United States Court Of Appeals For The Federal Circuit In Causation-In-Fact Cases.

The record established and Special Master found that Petitioner had a "documented adverse reaction" to the July 20, 1999 DTaP vaccination. *See John Doe 21* at *26. Petitioner's expert, Dr. Spitz, however, testified that Petitioner's immediate post vaccine reaction was more than just a reaction, but was "acute encephalopathy" that continued to manifest symptoms until 2002, when Dr.

Spitz examined him. *See* 11/28/05 TR at 216-21.[45] The record also contained the notes of Dr. Lydia Eviatar, Professor of Pediatric Neurology at the Albert Einstein College of Medicine, who, following an August 14, 2001 "neurological consultation," observed: "The onset of eye movements immediately after the Pertussin shot[46] is puzzling. *We do* [*, however,*] *see episodes of* flutter[47] or

[45] Dr. Wiznitzer, the Government's expert, agreed that Petitioner currently has "static encephalopathy, because he has neurologic problems," but was of the opinion that Petitioner's post vaccine reaction was indicative of a "hypo-tonic-hyporesponsive" event ("HHE"). *See* 7/20/07 TR 287-90, 337. Dr. Wiznitzer's opinion was based on a notation in a September 14, 1999 medical record indicating that Petitioner had an "hypotonic-(illegible) episode" on July 20, 1999 and Petitioner's pediatrician's decision to administer the second set of vaccines on that date without pertussis. *See* 10/2/02 Gov't Ex. B at 52.

[46] In *Paulimino* v. *Sec'y of Health and Human Servs*., 69 Fed. Cl. 1 (2005), the Special Master recognized that "a febrile seizure [*i.e.*, a seizure characterized by fever] . . . may have been induced by pertussis vaccine." *Id*. at 7; *see also Id.* at 4-6 (discussing medical literature regarding pertussis). Over a decade earlier, in *Mobley* v. *Sec'y of Health & Human Servs.*, 22 Cl. Ct. 423, 429 fn. 9 (1991), Petitioner proffered a similar medical theory by Dr. Kinsbourne. Dr. Kinsbourne obtained his medical degree from Oxford University in 1955, followed by a specialist degree in pediatrics and neurology. After teaching at Duke University for five years as an Associate Professor, he moved to the University of Toronto Medical School where he was a full Professor of Pediatrics and a Staff Physician at the Hospital for Sick Children. *See Mobley* v. *Sec'y of Health & Human Servs.*, 1990 WL 299394, at 3 note 18. He also now serves as the Director of the Division of Behavioral Neurology at the Eunice Kennedy Shriver Center, in Waltham, Massachusetts and a lecturer at Harvard University Medical School. *Id.* Dr. Kinsbourne theorized that: "the best available information is that the pertussis vaccine contains two agents which singlely or, more probably, in conjunction can in occasional or rare cases be severely damaging to brain cells and damage them permanently . . . it has been shown by chemical studies that if pertussis toxin is allowed to come into contact with neurons, the basic cells that do the work of the brain, then, that toxin is capable of interfering with the neuron's energy metabolism." *Mobley*, 22 Cl. Ct. at 429 note 9. Although affirming the Special Master's determination that Table Injury was not established in that case, because the "chemical studies" involved mice, the court made no independent determination about this theory or its relevance in a causation-in-fact cases. *Id*.

[47] *See Markovich* v. *Sec'y of Health & Human Servs*., 477 F.3d 1353, 1357 (Fed. Cir. 2007) (recognizing that an "eye-blinking episode was a symptom of a seizure disorder[.]"); *see also id*. at 1359 (citing January 29, 2002 Mayo Clinic Report establishing that "repeated eye-blinking" was "not only a symptom of seizure activity but also manifested one type of seizure activity.").

opsoclonus[48] and developmental delay as a result of *autoimmune encephalitis*[49] known as encephalopathy." *See* 10/2/02 Gov't Ex. B at 136 (emphasis added). On October 26, 2004, Dr. Eviatar noted that Petitioner's "intermittent vertical nystagmus" was "most likely secondary to post DPT encephalopathy." *See* 10/31/05 Pl. Filing, Exhibit 1.[50]

Instead of first determining whether Petitioner's current condition, that appears to be either an autoimmune or acute encephalopathy, was causally connected to his recognized July 20, 1999 post vaccine adverse reaction per *Althen*, Special Master Edwards required Petitioner to rebut the Government's alternative "HHE medical theory." *See John Doe 21* at *24-26; *compare* 10/28/05 TR at 287-90, 337 *with* 10/2/02 Gov't Ex. B at 34B, 134-36. In doing so, Special Master Edwards erred. This is not the first time Special Master Edwards has committed this error. A year earlier Special Master Edwards was reversed by the United States Court of Appeals for the Federal Circuit for requiring a petitioner to "bear the burden of eliminating alternative independent potential causes." *Walther* v. *United States*, 485 F.3d 1146, 1152 (Fed. Cir. 2007).

2. The Special Master Erred In His Review Of The Record And Made A Credibility Determination Without Seeing The Witness.

It is significant that Special Master Edwards, despite having touted "canvassing thoroughly the record" (*John Doe 21* at *25), did not notice that Petitioner's medical records on July 20, 1999, in addition to a fever, crossed-eyes and irregular eye movement, reported an "enlarged thyroid" and "adenopathy." [51] *See* 10/2/02 Gov't Ex. at 34B. An enlarged thyroid is a recognized indication of

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[48] "Opsoclonus is a "condition characterized by nonrhythmic horizontal vertical oscillations of the eyes, observed in various disorders of the brain stem or cerebellum." DORLAND'S at 1319.

[49] "Autoimmune encephalomyelitis" is also known as "acute disseminated encephalomyelitis" and is "characterized by perivascular lymphocyte and mononuclear cell infiltration and demyelination; it occurs most commonly following an acute viral infection . . . but may occur without a recognizable antecedent. *It formerly occurred as a complication of . . . human diploid vaccines and of smallpox vaccination. It is believed to be a manifestation of an autoimmune attack on the myelin of the central nervous system. Clinical manifestations include fever, headache, vomiting, and drowsiness . . . tremor, seizures, . . . many survivors have residual neurologic deficits*. DORLAND'S at 610 (emphasis added); *see also Adams* v. *Sec'y of Health and Human Servs*., 76 Fed. Cl. 23, 37-40 (2007) (discussing molecular mechanism immune response to certain vaccines); *Althen* v. *Sec'y Health & Human Servs.*, 58 Fed. Cl. 270, 276, *aff'd* 418 F.3d 1274 (2005) (discussing the theory of molecular mechanisms, immune response, also known as "molecular mimicy").

[50] The record does not indicate if Dr. Eviatar had seen the July 28, 2002 report of Dr. Kupersmith that Petitioner "might have had some infantile encephalopathy of some sort." 10/2/02 Gov't Ex. D at 175.

[51] *Supra* note 4.

an autoimmune condition and may help explain why Petitioner's July 20, 1999 fever and unusual eye movements continued for over a month until at least August 19, 1999. This error informs the court that Special Master Edwards' review of the record was not thorough, nor was the review of the Government's expert, Dr. Wiznitzer.

It appears that Dr. Eviatar was the only physician who saw this notation, understood its potential significance, and after examination of Petitioner posited on August 14, 2001, that Petitioner may have "autoimmune encephalitis." 10/2/02 Gov't Ex. B at 134-26.[52] Although Petitioner did not call Dr. Eviatar as a witness, nevertheless Special Master Edwards made a point to call into question the credibility of her October 26, 2004 notes linking Petitioner's current condition with his first set of vaccinations. *See John Doe 21* at *25. Special Master Edwards erred in making a credibility determination, without "seeing the witness." *See Bradley* v. *HHS*, 991 F.2d 1570, 1575 (Fed. Cir. 1993) ("The fact-finder has broad discretion in determining credibility *because he saw the witnesses* and read the testimony.") (emphasis added). Dr. Eviatar should be afforded the opportunity to address the Special Master's concerns directly.[53]

3. The Special Master Erred In Prohibiting Petitioner's Expert From Completing His Testimony.

Special Master Edwards also erred in prohibiting Petitioner's expert, Dr. Shane, from completing his testimony, an event never mentioned in the May 22, 2008 "Credibility Ruling." *See John Doe 21*. Dr. Shane appears to have had a theory about Petitioner's initial vaccines and relationship to his current condition, but Special Master Edwards ruled that Dr. Shane could not state his opinion, as a rebuttal witness. *See* 7/20/07 TR at 427.[54] Congress did not intend for Vaccine Act proceedings to be conducted within the formal structure of the evidentiary framework of federal civil cases. *See* 42 U.S.C. § 300aa-12(d)(2)(A)/(B); *see also Campbell* v. *Sec'y of Health & Human Services*, 69 Fed. Cl. 775, 778 (2006) ("Fundamental fairness" does not require strict adherence to the Federal Rules of Evidence, but does require the Special Master to afford Petitioner an

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[52] On February 16, 2001, Petitioner also was examined with a "two week history of swollen glands" and "developmental delay." *See* 10/2/02 Gov't Ex. B at 120.

[53] If the Special Master was so concerned, he should have taken initiative to require Dr. Eviatar to testify about her October 2004 note. *See* 42 U.S.C. § 300aa-12(d)(3)(B)(iii) ("in conducting a proceedings on a petition, a Special Master may require the testimony of any person[.]").

[54] It is not clear whether Dr. Shane examined Dr. Eviatar's records prior to his July 20, 2007 testimony. As of September 3, 2006, he had not reviewed those records. *See* 11/13/06 Pl. Ex. B at 1-2.

opportunity to present all relevant evidence.). Dr. Shane should have an opportunity to complete his testimony.[55]

The court has considered the July 7, 2008 Petition as having been filed *pro se*. *See Ruderer* v. *United States*, 188 Ct. Cl. 456, 468 (1969) (The United States Court of Federal Claims has a long tradition of examining the record "to see if [a *pro se*] plaintiff has a cause of action somewhere displayed."). Petitioner's counsel's June 20, 2008 "Memorandum of Points of Error," primarily attacked the credibility determinations of the Special Master Edwards that, as a matter of law, are accorded "broad discretion." *Bradley*, 991 F.2d at 1575. In doing so, Petitioner's counsel overlooked obvious legal errors made by Special Master Edwards, in applying the relevant burden

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[55] Special Master Edwards emphasized that: "In his long tenure . . . [he] heard many treating physicians and exceedingly well-credentialed experts testify . . . that even a minimally competent doctor could not mistake clinical manifestations of an acute encephalopathy . . . . The Special Master does not accept that the triage nurse, the resident physician and attending physician were wrong in their evaluation of [Petitioner] on July 20, 1999." *But see* Committee on the Future of Emergency Care in the United States Health System, Washington, D.C.: National Academy Press (2007), at 189-90 ("Physicians, nurses and other clinicians working on the same shift often fail to communicate effectively, further increasing the chance for error to occur. In fact, poor communication and teamwork failures are a significant problem in the [Emergency Department ("ED")] . . . communication issues were associated with 30 percent of the ED risk management files they studied and appeared to contribute directly to adverse medical outcomes in 20 percent of those cases.") (citing White, A.A., *et al.*, "*Cause And Effect Analysis Of Risk Management Files*," ACADEMIC EMERGENCY MEDICINE (2004), at 11(10), 1035, 1041). In this case, we know that neither the triage nurse nor that attending physician appeared to recognize the significance of the resident physician's note of "enlarged thyroid" and "adenopathy," which are relevant to determining whether Petitioner experienced the on-set of "autoimmune encephalitis." 10/2/05 Gov't Ex. B at 34B; *see also John Doe 21* at *19.

Moreover, as the attached "Court Exhibit" shows, five of the six symptoms listed in DORLAND'S for "acute disseminated encephalomyelitis," *i.e.*, fever, vomiting, tremor, seizure, and residual neurological deficits (*supra* note 48), in fact, were observed by Petitioner's doctors between July 20, 1999 and April 28, 2000 alone. *See* attached Court Exhibit (shaded notations from Petitioner's medical records). More importantly, on October 12, 2000, Dr. Rubin, a pediatric opthomologist, who first examined Petitioner on November 10, 1999, four months after the first vaccinations, admitted that "the presence of an infrequent, intermittent upbeat nystagmus . . . apparently evaded detection at Petitioner's many prior examinations." *Id*. at 106; *see also* Committee on the Future of Emergency Care in the United States Health System, Washington, D.C.: National Academy Press (2007), at 193 ("[T]here are a few, typically small studies demonstrating that care is compromised during several stages of an ED visit. For example, providers often triage patients inaccurately . . . . As might be expected, children with special medical needs . . . are significantly more likely to experience a medical error than other children.) (citing Selbst, S.M., *et al.*, "*Preventing Medical Errors In Pediatric Emergency Medicine*," PEDIATRIC EMERGENCY CARE (2004), at 20(10), 702-709, and Slonim AD, et al., "*Hospital-reported medical errors in children*." PEDIATRIC 111(3):617.621. (2003)).

of proof to establish entitlement in causation-in-law cases. *See* Pet. Br. at 8-32. Moreover, Petitioner's counsel failed to argue governing precedent favoring his client's position. For example, the court was urged to follow *Setnes ex rel.* v. *United States*, 57 Fed. Cl. 175 (2003) (holding that the court should not trigger the statute of limitations on the "first symptoms"), although that holding specifically was rejected by the United States Court of Appeals in *Markovich* v. *Sec'y of Health & Human Servs.*, 477 F.3d 1353, 1358 (Fed. Cir. 2007) (recognizing that a "*subtle symptom or manifestation of onset of the injury*, such as a symptom that would be recognizable to the medical professional at large[,] but not to the parent, would be sufficient to trigger the running of the statute.). "[T]he Vaccine Act has consistently been interpreted as *including subtle* symptoms or manifestations of onset of the injury within the ambit of evidence that triggers the running of the statute." *Id*. at 1358 (emphasis added). If "subtle symptoms" recognized by a parent are sufficient to trigger the statute of limitations those same observations do not then become irrelevant or unreliable in determining causation, as occurred in this case. *See John Doe 21* at *19-22. Parental observation is relevant and reliable evidence, but is entitled to even more weight if substantiated by the medical records, reviewed in their entirety. Of course, where parental observation is *in conflict* with medical opinions, it is entitled to "little weight" or deference. *See Cucuras* v. *Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).[56] In this case, parental observation was not in conflict with medical records; the medical records simply were not clear or complete. That fact does not render parental observation irrelevant; only that parental observation alone does not satisfy Plaintiff's burden of proof to establish each of the causation-in-fact elements of *Althen* by a preponderance of evidence. More is required. And, on remand, much more diligence is expected from Petitioner's counsel in representing his client's interest.[57]

For all of the reasons discussed herein, Petitioner's motion is granted-in-part and Special Master Edwards' May 22, 2008 "Credibility Ruling" is vacated. This case is remanded to recently-assigned Special Master Christian Moran with instructions to reopen the record to allow: Petitioner's expert Dr. Shane to complete his July 20, 2007 testimony; Dr. Eviatar to address Special Master Edwards' "suspicions" regarding her August 26, 2001 note that Petitioner's "intermittent

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[56] In 1993, the United States Court of Appeals for the Federal Circuit observed that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . 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." *Cucuras*, 993 F.3d at 1528. Although that might have been true in 1993, the Institute of Medicine issued a Report in 2007 warning that: "Emergency care services are delivered in an environment where the need for haste, the distraction of frequent interruptions, and clinical uncertainty abound, thus posing a number of potential threats to patient safety. Children are, of course, at great risk under these circumstances because of their physical and developmental vulnerabilities, as well as their need for care that may be atypical for providers used to treating adult patients." *Emergency Care for Children: Growing Pains*, Committee on the Future of Emergency Care in the United States Health System, Washington, D.C.: National Academy Press (2007), at 8.

[57] Special Master Moran is expected to consider the court's observations in any fee application submitted by Petitioner's counsel.

vertical nystagmus" was "most likely secondary to post DPT encephalopathy" (*see* 10/2/02 Gov't Ex. B at 136); and any additional rebuttal the Government requires.[58] Special Master Moran's final decision will issue no later than 90 days hereafter, *i.e.*, by Wednesday, January 21, 2009. No party will be afforded any extension.

IT IS SO ORDERED.

This case is remanded, pursuant to 42 U.S.C. § 300aa-12(e)(2)(C), for further action in accordance with the court's direction.

SUSAN G. BRADEN
Judge

[58] Assuming Special Master Moran determines that Petitioner has established, by a preponderance of evidence, "a medical theory causally connecting the vaccination and the injury," the attached Court Exhibit, tracking only the medical records, should assist Special Master Moran in determining "a logical sequence of cause and effect showing that the vaccination was the reason for the injury" and "showing of proximate temporal relationship between vaccination and injury" is established. *See Althen*, 418 F.3d at 1278; *see also Paulimino*, 69 Fed. Cl. at 7("Petitioner has proffered both a scientific temporal relationship and credible medical theory that sets out a logical sequence of cause and effect between the [pertussis] vaccination and [*Paulimino's* seizure event[.]").