In the United States Court of Federal Claims

No. 04-1282 V
VACCINE CASE
Filed March 22, 2007
TO BE PUBLISHED

JUSTINE ADAMS, a minor, by her parents, STEPHEN and OLIVIA ADAMS,	*	
Petitioner,	*	Causation In Fact;
	*	*De Novo* Review;
v.	*	National Vaccine Injury Act,
	*	42 U.S.C. §§ 300aa-10, *et seq.*;
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,	*	Vaccine Rule 3(b).
Respondent.	*	

Clifford J. Shoemaker, **Renee J. Gentry**, Shoemaker and Associates, Vienna, Virginia, for petitioner.

Michael Milmoe, United States Department of Justice, Civil Division, Washington, D.C., for respondent.

MEMORANDUM OPINION AND FINAL ORDER[1]

On November 27, 2006, a Special Master of the United States Court of Federal Claims ("Special Master") issued an Entitlement Decision under the National Childhood Vaccine Act of 1986, 42 U.S.C. §§ 300aa-10, *et seq.* (2000) ("the Vaccine Act"), denying Petitioner's claim. *See Adams* v. *Sec'y of Health and Human Servs.*, 2006 WL 3616951 (Fed. Cl.) ("*Adams*"). The court has determined that the Special Master erred, because Petitioner met the statutory burden of establishing causation in fact by a preponderance of the evidence. Assuming *arguendo* that burden was not met, the Government failed to establish alternative causation.

The court also has determined that the Special Master erred and abused her discretion by engaging in a substantive off-the-record *ex parte* communication with the Government's expert

[1] This Memorandum Opinion and Final Judgment are issued on an expedited basis to facilitate any appellate review that respondent ("the Government") may wish to pursue. *See* House Report 99-908, 1986 U.S.C.C.A.N. at 6344 ("House Report") (awards are to be "made to vaccine-injured persons quickly, easily and with certainty and generosity").

during the hearing and denying Petitioner an opportunity to respond to independent research evidence proffered by the Special Master *sua sponte* during the hearing. *See Blank* v. *Dep't of the Army*, 247 F.3d 1225, 1229 (Fed. Cir. 2001) (citing *Stone* v. *Fed. Deposit Insurance Corp.*, 179 F.3d 1368, 1377 (Fed. Cir. 1999)) (holding that "the introduction of new and material information by means of *ex parte* communications to the deciding official undermine the . . . constitutional due process guarantee of notice and . . . the opportunity to respond."); *see also* Vaccine Rule 3(b) (A Special Master "shall determine the nature of the proceedings, with the goal of making the proceedings expeditious, flexible, and less adversarial, while at the same time affording each party a *full and fair opportunity* to present its case and creating a record sufficient to allow review of the special master's decision.") (emphasis added).[2]

I. RELEVANT FACTS.[3]

A. Petitioner's Medical Records.

Petitioner was born on January 30, 2001, following a normal full term pregnancy, with some bleeding. *See* Ex. 1 at 13; *see also* TR 5. On February 1, 2001, when Petitioner was two days old, her pediatrician, Dr. Lauren Burkhart, described Petitioner as a "normal newborn." *See* Ex. 1 at 18.

On February 15, 2001, when Petitioner was two weeks old, Dr. Burkhart's assessment was that Petitioner was "healthy." *See* Ex. 1 at 9. On that occasion, Petitioner received a Hepatitis B vaccination,[4] without incident. *Id*.

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[2] Unfortunately, the court previously has had to correct arbitrary and capricious actions of the Special Master that have prejudiced other Vaccine Act petitioners. *See Campbell* v. *Secretary of Health and Human Servs.*, 69 Fed. Cl. 775 (2006) (holding that the Special Master's refusal to hold an evidentiary hearing, rejection of affidavits and medical reports proffered by petitioner, but *sua sponte* introducing her own independent research into the record, was "fundamentally unfair"; and the Special Master's rulings were "either inadequately explained or arbitrary and capricious."); *see also Cook* v. *Sec'y of Health and Human Servs.*, No. 00-331V (Fed. Cl. June 23, 2005) (remanding, because the Special Master added *sua sponte* evidence to the record and denied petitioner's request for a hearing, thereby failing to give petitioner a "full and fair opportunity" to present a case).

[3] The relevant facts herein were derived from: Petitioner's August 13, 2004 Petition Against Secretary of Health and Human Services; Petitioner's Exhibits ("Ex. 1-18"); the Government's October 7, 2005 Motion to Dismiss ("Gov't Mot. Dis."); the Government's Exhibits ("Ex. A-C"); the October 13, 2006 hearing ("TR 1-224"); the Special Master's Exhibit ("C. Ex. 1"); the November 27, 2006 Entitlement Decision ("*Adams*"); Petitioner's December 19, 2006 Motion for Review ("Pet. Mot."); and the Government's January 18, 2007 Response ("Gov't Resp.").

[4] Guillain-Barré Syndrome ("GBS") is an "acute idiopathic polyneuritis." DORLAND'S ILLUSTRATED MEDICAL DICTIONARY (W.B. Saunders Co., 30th ed. 2003) ("DORLAND'S") at 1819. In 1994, the Institute of Medicine advised the medical community and the public that:

On March 30, 2001, when Petitioner was two months old, Dr. Burkhart's assessment again was that Petitioner was "healthy." *See* Ex. 1 at 8. On that occasion, Petitioner again received Hepatitis B, diphtheria-tetanus-pertussis ("DTP"),[5] Haemorphilus influenza B ("Hib"),[6] inactivated poliovirus ("IPV"), and Prevnar™[7] ("Prevnar") vaccinations, without incident. *Id.; see also* Ex. 2.

On May 30, 2001, when Petitioner was four months old, Dr. Burkhart assessed her as "healthy." *See* Ex. 1 at 7. On this occasion, Petitioner also received DTP, Hib, and IPV vaccinations, without incident. *Id.; see also* Ex. 2.

> There are reports of [GBS] following [Hepatitis B] vaccination, but it is difficult to determine whether the frequency is greater than expected. There is some *biologic plausibility* for this association in terms of the occurrence of GBS following hepatitis B infection, the occurrence of demyelinating disease following vaccination in general[.] . . . The evidence [, however,] is inadequate to accept or reject a causal relationship between hepatitis B vaccine and GBS.

Adverse Events Associated With Childhood Vaccines: Evidence Bearing On Causality, INSTITUTE of MEDICINE REPORT (1994) ("1994 IOM REPORT") at 219 (emphasis added).

The record reflects that Petitioner's mother "may have GBS positive, and maternal laboratories [at Petitioner's birth] were also significant for an abnormal triple screen. However, an amniocentesis was done which was normal." Ex. 4 at 544.

[5] In 1994, the Institute of Medicine 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 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.

[6] In 1994, the Institute of Medicine further observed that: "Prior to the introduction of [Hib] vaccine, Hib was the leading cause of bacterial meningitis in the United States among children younger than 4 years of age. There are no data specifically bearing on the biologic plausibility of a causal relationship between Hib vaccinations and GBS." 1994 IOM REPORT at 236.

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

On June 11, 2001, Petitioner received IPV, DTP, Hib, and Prevnar vaccinations, without incident. *See* Ex. 2.

On August 23, 2001, when Petitioner was seven months old, Dr. Burkhart assessed Petitioner as "healthy." *See* Ex. 1 at 6. Petitioner again received Hib, Hepatitis B, and Prevnar vaccinations. *Id.; see also* Ex. 2. During the night, Petitioner's mother noticed "some tactile fevers after immunizations, during the course of the evening, but did not actually document fever[.]" *Id.* at 177. Around 4:00 a.m., Petitioner's mother observed Petitioner experiencing a full body seizure, lasting between one to ten minutes, with blue lips. *Id.* at 17; *see also* TR 9. Petitioner's father testified that Petitioner was "shaking" and "had a staring/glazed look." *See* TR 103; *see also* Ex. 13 at 1. Petitioner was taken to the San Diego Palomar Medical Center Emergency Room ("Palomar ER") and examined by Dr. Keri L. London, who reported that Petitioner "presented to the emergency department with signs and symptoms consistent with a febrile seizure." Ex. 1 at 172; *see also* Ex. 7 at 327 (upon examining Petitioner after her second seizure, Dr. London reported: "At the time that [Petitioner] seized last, she had been given an immunization and was described to have tactile fever. It was thought that this was a febrile seizure, although the diagnosis was questionable."). Petitioner's physical examination, conducted at about 5:49 a.m., indicated her temperature was 97.6°. *See* Ex. 1 at 178-79. Nevertheless, Petitioner was diagnosed as having an "acute febrile seizure." *Id.* at 161, 172; *see also* TR 20-21. Later that day, Petitioner was examined by Dr. Burkhart, whose notes stated: "Seizure - doubt febrile - Ø documented ↑ temp. - *? Prevnar related*." Ex. 1 at 17 (emphasis added); *see also* TR 19-20.

On October 26, 2001, Petitioner received an electroencephalogram ("EEG")[8] at the San Diego Children's Hospital and Health Center ("Children's Hospital") that was "normal." Ex. 1 at 126. On October 30, 2001, when Petitioner was nine months old, Dr. Burkhart's assessment was that Petitioner was "healthy." *Id.* at 5. Petitioner received DTP and IPV vaccines. *Id*. Shortly thereafter, Petitioner experienced a second seizure that lasted seven minutes, without fever. *Id*. at 26.

On November 21, 2001, Petitioner experienced a third seizure that was characterized as a "tonic clonic seizure[9] lasting seven minutes." Ex. 7 at 327; *see also* Ex. 13 at 1; TR 22-31. Petitioner was first seen at the Palomar ER, but was transferred to Children's Hospital. *Id*.

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[8] An EEG is a test "recording . . . the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain . . . Fluctuations in potential are seen in the form of waves, which correlate well with different neurologic conditions and are used as a diagnostic criteria." DORLAND'S at 596.

[9] 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.

On December 20, 2001, Petitioner experienced a fourth seizure during a visit to her paternal grandparents in Texas. *See* TR 33. This was a lengthy seizure lasting about 45 minutes, experienced on the left side of Petitioner's body, and described as "a left sided focal seizure."[10] Ex. 1 at 165; *see also* Ex. 8 at 7; Ex. 13 at 1; TR 34. Petitioner experienced a fifth seizure the next day, lasting approximately 30 minutes, and was not responsive to intervention. *See* Ex. 8 at 9; *see also* TR 35. Petitioner was transferred to intensive care and a coma was induced. *Id.* The Dismissal Summary, issued by Cook Children's Medical Center in Ft. Worth, Texas, described Petitioner as having "an episode of prolonged partial status epilepticus." *Id.* at 7. On December 26, 2001, Petitioner's parents followed up with Dr. Burkhart, who noted that Petitioner had developed a "Seizure Disorder." *See* Ex. 1 at 27.[11] On December 28, 2001, Petitioner was examined by Dr. Rayburn R. Skogland, a neurologist at Children's Hospital. *See* Ex. 1 at 161. His notes indicated "[Petitioner] has a history of a seizure early morning following an immunization the day before. . . . Impression: Seizure disorder." *Id.* at 161-62.

During January 2002, Petitioner experienced three to four whole body seizures and was seen at Children's Hospital on at least one occasion with a 102° temperature. *See* Ex. 13 at 1.

On February 13, 2002, Petitioner was just over one year old. *See* Ex. 1 at 4. Dr. Burkhart's examination notes reported that Petitioner had experienced seizures with fever in early January 2002. *Id*. Although Petitioner had a food allergy[12] and was experiencing sinusitis, Dr. Burkhart administered Hib, and measles, mumps & rubella live ("MMR") vaccines, and a purified protein derivative ("PPD") to test for tuberculosis. *Id*. On February 22, 2002, Petitioner was admitted to the Palomar ER after a fever of 100.7° and vomiting. *See* Ex. 7 at 303. While at the ER, Petitioner experienced a seizure that lasted about two minutes. *See* Ex. 1 at 30, 34, 37.

On March 5, 2002, a seizure took place after Petitioner's evening bath and lasted two to three minutes. *Id.* at 36-37; *see also* Ex. 13 at 1. Petitioner was seen at the Palomar ER. *Id.*; *see also* Ex. 7 at 291-93. On March 10, 2002, Petitioner again experienced a seizure after Petitioner's evening bath that lasted two minutes. *Id*. On March 17, 2002, Petitioner had a seizure that lasted for 18-20 minutes, in which Petitioner "clearly progressed from being only visually distracted to not responding to sounds and not moving." Ex. 13 at 1; *see also* Ex. 1 at 35. Petitioner's seizure was observed by a nurse, and thereafter, Petitioner was examined by an unidentified neurologist. *Id.* On

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[10] A "focal seizure" is a seizure that is "partial." DORLAND'S at 1676.

[11] Petitioner's maternal cousins also had experienced febrile seizures, but there is no history of epilepsy. *See* Ex. 4 at 44, 543.

[12] On September 13, 2001, Petitioner experienced hives after ingesting peanut butter and was taken to the emergency room where EpiPen was administered. *See* Ex. 1 at 23, 26. Dr. Burkhart's records contained the following notes: "Peanut Allergy – anaphyloric probable – Epipen prescribed by ER – demonstrated use in __ Ø peanuts or containing products Ø wheat Ø dairy Ø eggs. Will likely need allergy testing @ some point." Ex. 1 at 26.

March 20, 2002, Petitioner again was examined by Dr. Skogland. *See* Ex. 1 at 160; Ex. 13 at 1. His notes indicate that Petitioner experienced seizures in mid-January 2002, on February 21, 2002, and on March 5, 10, and 17, 2002, only two of which were associated with fever. *Id.* at 160.

On April 8, 2002, Petitioner had a seizure at night that lasted "about a minute." Ex. 13 at 1. On April 19, 2002, Petitioner had magnetic resonance imaging ("MRI") of her brain, that was reported as being "within normal limits." Ex. 1 at 123; *see also* Ex. 13 at 1.

On May 5, 2002, Petitioner had a 7 ½ minute seizure described by Petitioner's father as "twitching of fingers on left hand – threw up – stopped breathing – jaw very tight – had to give air[.]" Ex. 13 at 1-2. On May 6, 2002, Petitioner experienced a seizure and was admitted to the emergency room. Ex. 1 at 44; *see also* Ex. 13 at 2. On May 7, 2002, Dr. Burkhart noted that Petitioner was seen at the emergency room "still having seizure/last week – after seconds/last night 15 minutes – color change – vomited/15-20 seizures since January [2002]." *Id*. Subsequently, Petitioner received an EEG at Children's Hospital. Ex. 1 at 122. The diagnostic report, prepared by Dr. Doris A. Trauner, a neurologist at Children's Hospital, concluded that Petitioner's EEG was "Abnormal" and "consistent with the clinical history of seizure with the suggestion of more abnormalities in the right frontal region." *Id*. On May 8, 2002, Petitioner experienced a seizure that lasted 14 ½ minutes during which she stopped breathing. *Id*. at 48. On May 16, 2002, Petitioner had a follow-up examination with Dr. Trauner who diagnosed Petitioner's condition as "Partial Complex seizures with multiple seizures." *Id.* at 158.

On June 8, 2002, Petitioner experienced two consecutive seizures and was examined at the Palomar ER. *See* Ex. 1 at 159; Ex. 7 at 277-79 (diagnosing Petitioner with "febrile seizure" and "acute breakthrough seizures."); Ex. 13 at 2. On June 24, 2002, Petitioner experienced a seizure, lasting about 10 minutes, and was described as "in and out of staring spells." *See* Ex. 1 at 49; *see also id*. at 56; Ex. 13 at 2. Because Petitioner's breathing stopped, Diastat was administered. *Id*. She was transported to the Palomar ER. *Id.* at 30-31, 34, 38; *see also* Ex. 7 at 263-65 (noting Petitioner had experienced 14 seizure episodes within 10 months). On June 25, 2002, Petitioner was examined at Children's Hospital by Dr. Trauner, where she experienced two brief seizures that were reported as "her eyes deviating to the left and her eyelids twitching . . . and she spaced out and was unresponsive for about 10 seconds." *See* Ex. 1 at 153. Otherwise, Petitioner's "development still seems to be normal." *Id.* On June 28, 2002, Petitioner experienced a seizure that lasted 25 minutes with "rhythmic, hiccough-like convulsions on the left side of her body . . . . After the seizures stopped, she had . . . paralysis of her left leg and arm," that cleared up within three hours. *See* Ex. 1 at 107; *see also* Ex. 7 at 247-49; Ex. 13 at 2.

On or about July 1, 2002, Petitioner had a seizure for 25 minutes and again was examined at Children's Hospital. *See* Ex. 1 at 54. On July 12, 13, and 14, 2002, Petitioner experienced "drifting/staring spells" that her father observed lasted two to four seconds and "largely, though not exclusively, coincide with rowdy or excited activity." Ex. 1 at 105; *see also* Ex. 13 at 2. On July 17, 2002, when Petitioner was almost 17 months old, she received an EEG at Children's Hospital. Ex. 1 at 120. The diagnostic report, prepared by Dr. Mark Nespeca, indicated that Petitioner "was

admitted for recent onset of frequent nonconvulsive brief seizures with upward eye rolling." *Id.* The EEG was "abnormal . . . [evidencing] both generalized and focal epileptiform abnormalities, supporting a clinical diagnosis of seizures. The staring spells appear to be associated with generalized epileptiform potentials without any focal epileptiform disturbances preceding them." *Id.*; *see also* Ex. 13 at 2.

On August 15, 2002, when Petitioner was 26 months old, she had a routine pediatric examination with Dr. Leslie J. McCormick, who diagnosed Petitioner as having a "Seizure Disorder." Ex. 1 at 2. On August 23, 2002, since Petitioner had been free of seizures for the prior two weeks, she received a PPD test, although it was noted that "immunizations in past triggered seizures." *Id.* at 3. About two hours later, Petitioner had a seizure and was helicoptered to Children's Hospital. *Id.* at 51; *see also* Ex. 13 at 2 (Petitioner had a 30 minute seizure that her father described as: "started slow. Limp. Breathing gradually decreased. Had to give rescue breaths. Not much success. Oxygen down to 50% by the time paramedics arrived. Eyes and head to the right. Over time twitching of right hand and both eyebrows twitching. At one point she began to curl up into the fetal position. Threw up and pooped. Temp of 104, possibly secondary to the seizure. Gave Diastat. Didn't seem to help. Helicopter and admitted to Children's. Allergic reaction to TB test given approximately 1 hour prior."). On August 28, 2002, Petitioner experienced a seizure in Dr. Burkhart's waiting room, that Dr. Burkhart witnessed and characterized as "tonic-clonic, generalized." Ex 7 at 230. Oxygen was administered. *Id*. This seizure lasted approximately two to three minutes. *Id*. Petitioner again was transported to the Palomar ER, where she experienced another episode of "seizure-like activity . . . with a rightward gaze and unresponsiveness and appeared to have apnea lasting about 20 seconds." Ex. 7 at 231. The attending physician diagnosed Petitioner with "seizures associated with fevers . . . with known epilepsy[.]" *Id*. at 232. The attending physician also noted that Petitioner was hospitalized at Children's Hospital "approximately two weeks ago after having a TB skin test which apparently precipitated a febrile reaction with exacerbation of her seizure disorder." *Id*.

On September 3, 2002, Petitioner again was examined by Dr. Trauner for "intractable epilepsy." Ex. 1 at 149. Dr. Trauner's notes reported that Petitioner "continues to have multiple seizure types, but the seizure frequency has decreased significantly since Depakote was added. She now has between zero and three seizures per week, most of which are grand mal type seizure, but occasionally she has absence seizures[13] as well. Last week, she had 2-to-3-minute seizures." *Id*. On September 23, 2002, Petitioner was 20 months old. *Id.* at 45. On or about that date, Petitioner experienced a seizure and was seen at Children's Hospital. *Id*.

On October 7, 2002, Petitioner's father reported "two seizures during this week four minutes and breathed OK and one to two minutes w/jaw clinched some breathing difficulty." Ex. 13 at 2.

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[13] An "absence seizure" is "the seizure seen in absence epilepsy, consisting of a sudden momentary break in consciousness of thought or activity, often accompanied by automatisms or clonic movements, especially of the eyelids." DORLAND'S at 1676.

On November 13, 2002, Petitioner was admitted to the Palomar ER, because "[t]he patient's mother also felt that the child was slightly warm. She took her temperature and found it to be 99. She was given a dose of ibuprofen and [had] repeat seizure activity which lasted 20 minutes." Ex. 7 at 190. Petitioner was transferred to Children's Hospital. *Id*. at 192; *see also* Ex. 13 at 2.

On December 3, 2002, following an examination, Dr. Burkhart reported: "Seizure disorder; OM-resolved to [plan] to go to John Bastian to consider issue of further vaccines." Ex. 1 at 45. Petitioner's 26 month and 38 month examinations also noted that Petitioner had a "seizure disorder." *Id.* at 4. In addition, Dr. Burkhart indicated that Petitioner still needed MMR, Varivax, DPap, and IPV vaccines, but they could not be administered until Petitioner was "more stable." *Id.* at 3.

On January 5, 2003, Petitioner was admitted to the Palomar ER following a 20 minute seizure and with a viral urinary tract infection. *See* Ex. 7 at 177-78; *see also* Ex. 13 at 3.

On February 21, 2003, Petitioner was admitted to the Palomar ER for a seizure, "lasting 10-15 minutes," with "tonic-clonic activity." Ex. 7 at 165; Ex. 13 at 3.

On March 3, 2003, the Children's Primary Care Medical Group noted that Petitioner was having 50 second staring episodes, frequent onset of mild fevers, and frequent absence seizures that "can lead to grand mal seizures." Ex. 1 at 62. On March 18, 2003, Petitioner was admitted to the Palomar ER for a seizure lasting 45 minutes. Ex. 7 at 154. The examination notes indicated that Petitioner "has a known seizure disorder and has petit mal seizures on nearly a daily basis . . . will occasionally have up to 20 petit mal seizures. She has complex seizures about once a month . . . [that are] generalized . . . very commonly focal on the right nondominant side." *Id.* On March 24, 2003, the Children's Primary Care Medical Group recorded that Petitioner had experienced "1 long grand mal seizure" the prior week. Ex. 1 at 59.

On May 8, 2003, Petitioner was admitted to the Palomar ER for a 10 minute focal seizure, characterized by twitching of the left eye. Ex. 7 at 140. On May 27, 2003, Petitioner was admitted to the Palomar ER with an acute fever and a 15-minute seizure. *Id.* at 129; *see also* Ex. 13 at 3.

On June 6, 2003, Petitioner was examined by Dr. John F. Bastian, an allergist at Children's Hospital. *See* Ex. 1 at 151. Dr. Bastian reported: "Review of system reveals [Petitioner] has a chronic seizure disorder[.] . . . She has got no further immunizations since 8 months she had a DTaP and following that her seizure disorder started[.] . . . While she was in the clinic, she did have one episode of an absence seizure. The parents state these are frequent[.] . . . I also spoke with [the father] about immunizations. I thought because of the proximity of the seizure disorder with the immunizations that *it was reasonable that [s]he should not receive further immunizations as these may trigger further seizures*." *Id.* at 151-52 (emphasis added).

On June 24, 2003, Petitioner was 26 months old. *Id.* at 57. She was examined at Children's Primary Care Medical Group with a "fever, febrile seizure" and diagnosed as having a "Viral Syndrome." *Id.* During a follow-up examination with Dr. Trauner, Petitioner experienced two

seizures: "The first one consisted of the eyes deviating to the left and her eyelids twitching a little bit, and she spaced out and was unresponsive for about 10 seconds. The second seizure was similar except her eyes did not deviate to the left quite so much, and she had slightly more eyelid twitching." *Id.* at 153-54.

On July 6, 2003, Petitioner was admitted to the Palomar ER for an acute seizure lasting 10 minutes. *See* Ex. 7 at 117. The examination notes state: "The patient had some initial postictal paralysis consistent with Todd's paralysis[14] that she has had in the past[.]" *Id.* at 118; *see also* Ex. 13 at 3. Petitioner's father noted she also had seizures on July 16, 20-21, 24-25, 27-28, and 30, 2003. *See* Ex. 13 at 3.

On August 3, 9, 10-11, 21, 27, and 30-31, 2003, Petitioner's father noted seizures. *See* Ex. 13 at 3.

On September 18, 2003, Petitioner was examined at Children's Hospital with fever following two "tonic clonic seizures," each lasting approximately three to five minutes. Ex. 1 at 145; Ex. 13 at 4.

On October 4, 2003, Petitioner was admitted to the Palomar ER "actively seizing." Ex. 1 at 142. This seizure was described as "left-sided Todd's Paralysis" that lasted 15 minutes. *Id.* at 143; *see also* Ex. 13 at 4. On October 9, 12, 15, 27, and 29, 2003, Petitioner's father noted continued seizure activity. *See* Ex. 13 at 4.

From November 10-12, 2003, Petitioner was admitted to Children's Hospital where she had multiple short seizures. *See* Ex. 4 at 625-28. Petitioner's father also reported seizures on November 17-18, 27, 2003. *See* Ex. 13 at 4.

On December 4, 2003, Petitioner was examined again by Dr. Trauner for "intractable seizures." Ex. 1 at 140-41. In the three prior weeks, Petitioner had "several major motor seizures," including "one 18-minute" seizure on December 3, 2003 and an increase in "petite mal seizures."[15] *Id.* at 140. On December 7, 2003, Petitioner was admitted to the Palomar ER for a "focal motor seizure lasting about 15 minutes." Ex. 7 at 93; *see also* Ex. 13 at 4. Petitioner's father also noted seizure activity on December 16 and 25, 2003. *See* Ex. 13 at 5.

On January 10, 2004, Petitioner had an intractable seizure that initiated on the left side with tonic-clonic activity. *See* Ex. 4 at 532; *see also id*. at 542; Ex. 13 at 5. On January 15, 2004,

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[14] "Todd's Paralysis" is a "hemiparesis (muscular weakness or partial paralysis affecting one side of the body) . . . lasting for a few minutes or hours or occasionally several days, after an epileptic seizure." DORLAND'S at 1366.

[15] A "petite mal seizure" is "epilepsy characterized by absence seizures, usually having its onset in childhood or adolescence[.]" DORLAND'S at 628.

Petitioner was admitted to the Palomar ER with a "generalized seizure." Ex. 1 at 136. The treating physician's notes indicated that Petitioner's last generalized seizure took place during the prior week. *Id.* During the examination, Petitioner had another active seizure that was characterized as "more of a right-sided seizure than generalized." *Id.* at 137; *see also* Ex. 5 at 19. The diagnosis was "acute status epilepticus." Ex. 1 at 138.

On February 3, 2004, Petitioner was examined by Dr. Trauner for "intractable partial and generalized seizures." *Id.* at 134. Dr. Trauner's notes indicated that Petitioner had "2 prolonged seizures in January and 6 in December [2003]." *Id.*; *see also* Ex. 13 at 5. On February 13, 2004, Petitioner was admitted to the Palomar ER for a "prolonged seizure." *See* Ex. 7 at 65; *see also* Ex. 13 at 5.

On March 8-9, 2004, Petitioner's father observed seizure activity. *See* Ex. 13 at 5.

On April 2, 7, 9, and 25, 2004, Petitioner's father also noted additional seizures. *See* Ex. 13 at 5. On April 29, 2004, Petitioner was three years and two months old. *See* Ex. 1 at 1. Following a routine examination, another pediatrician, Dr. McCormick, diagnosed Petitioner as having "WV, Seizure Disorder, Possible AR" and noted Petitioner's father's concern about Petitioner's motor skills, *i.e.*, "clumsily falls & trips, climbs poorly, poor fine motor coordination." *Id.*

On May 10, 2004, Petitioner was 39 months. *Id.* at 132. She was again examined by Dr. Trauner for "intractable epilepsy," *i.e.*, "A long flurry of seizures every week or so. During these, she fades out and her head turns on one side." *Id.* Petitioner was diagnosed with "intractable epilepsy of unclear etiology, with what appears to be a focus in the frontal lobe." *Id.* Petitioner's father also noted seizures on May 13-14, 23, and 24, 2004. *See* Ex. 13 at 5-6.

On June 5, 2004, Petitioner was admitted to the Palomar ER for an acute "tonic clonic seizure, right side." Ex. 7 at 49-50; *see also* Ex. 13 at 6. On June 11, 2004, Petitioner was examined by Children's Hospital to determine the need for occupational therapy, since her seizure disorder was continuing and it was "common for [Petitioner] to have unilateral weakness following seizures." Ex. 1 at 129. In addition, Petitioner's parents reported that she was "clumsy, bump[s] into things & getting ahead of herself." *Id.* The examination confirmed that Petitioner "demonstrates significant difficulty [with] balancing, strength + coordination which appears to affect the quality + control of her movements." *Id.* at 130; *see also* Ex. 13 at 6.

On July 3, 2004, Petitioner was admitted to the Palomar ER following a "grand mal seizure." Ex. 7 at 47; *see also* Ex. 13 at 6. On July 15, 2004, Petitioner was examined by Dr. Trauner. *See* Ex. 4 at 418. Dr. Trauner's unsigned notes stated: "[Petitioner] has partial complex seizures, as well as very long absence seizures. She occasionally has grand mal seizures as well[.] . . . She is having approximately one long partial complex seizure per week with post-ictal Todd's paralysis for 1 to 2 hours and absence seizures that last . . . up to 1 to 2 minutes approximately every other day." *Id.* On July 22-23, 26, 29, and 31, 2004, Petitioner's father noted seizures. *See* Ex. 13 at 6. On July 22, 2004, a Physical Therapy Pediatric Evaluation from Children's Hospital and Health Center ("Pediatric Therapy") noted that Petitioner "continues to have seizures daily." Ex. 3 at 19. On July

23, 2004, Petitioner was admitted to the Palomar ER following a 22.5 minute seizure. *See* Ex. 7 at 23. Her examination "did not reveal any focal neurologic abnormalities. There is no underlying cause for the seizure event at this point such as a subdural hematoma, meningitis, or toxic problems." *Id*. at 24; *see also* Ex. 13 at 6.

On August 10, 2004, Petitioner was admitted to the Palomar ER with a tonic-clonic seizure, lasting 22 minutes. Ex. 3 at 9; *see also* Ex. 13 at 6. Petitioner's father noted other seizures on August 23, 26, and 28, 2004. *See* Ex. 13 at 6.

On September 13, 2004, Pediatric Therapy records indicate that Petitioner is "more clumsy." *See* Ex. 3 at 17. On September 22, 2004, Petitioner's mother observed a seizure during a therapy session. *See* Ex. 3 at 9. On September 23, 2004, Dr. Trauner examined Petitioner for "intractable epilepsy." *Id.* at 6-7. An unsigned copy of Dr. Trauner's notes reported that "[Petitioner] has had progression of her neurological abnormalities associated with her seizure disorder of unknown etiology, and she now has fallen behind her chronological age in terms of cognitive functioning[.] . . . Because of this I am quite concerned about trying to get better control of the seizures, and I have discussed a vagus nerve stimulation, as well as a possible seizure surgery with her parents." *Id.* at 7. A series of tests was recommended. *Id*. On September 24, 2004, Petitioner also may also have experienced one or two seizures during therapy. *Id*.

On October 20, 2004, Pediatric Therapy reported that Petitioner "[P]ossibly is having 1 or 2 seizures during sessions." *Id.* at 9. On October 25, 2004, Petitioner had another seizure. *Id.* at 15.

From November 3-8, 2004, Petitioner was admitted to Children's Hospital for a series of tests. *See* Ex. 4 at 14, 233, 242-43. During this time, Dr. Nespeca again examined Petitioner, but this time stated that she had a "history of intractable epilepsy with multiple admissions for seizures[.] . . . Her parents describe three different types [of seizures] including versive, or head turning seizures,[16] absent seizures, and generalized tonic seizures . . . at times [Petitioner] gets dusky appearance with her seizures . . . she has between 5 and 20 absent seizures a day and about one versive seizure occurring every couple of months." *Id.*; *see also id.* at 35-36. Dr. Nespeca's notes also indicated that on November 3, 2004, Petitioner experienced a two-minute versive seizure. *Id*. at 16. The final video EEG Monitor Report:

> does not support the existence of a unifocal localization of seizure onsets in this patient. The study documents the existence of generalized absence seizures, photosensitive seizures with either generalized or generalized and then partial evolution of seizure patterns, spontaneous left hemiclonic seizures, and leftward or rightward spike and wave complexes after evolution into left hemisphere or right hemisphere electroencephalographic seizure patterns. *There were no myoclonic*

[16] A "versive seizure" is "characterized by sustained forced conjugate ocular and cephalic and/or truneal deviation." STEDMAN'S MEDICAL DICTIONARY (28th Edition 2006) ("STEDMAN'S) at 1744.

seizures observed to occur during this study, and the child's parents do not report the existence of any myoclonic seizures.[17]

Id. at 84 (emphasis added).

On January 2, 6, 8, 13-14, 24-25, 28, and 31, 2005, Petitioner's father noted seizure activity. Ex. 14 at 1.

On February 3, 9, 13, 16, 19, and 27, 2005, Petitioner's father also noted seizure activity. *Id*.

On March 5, 13, 15, 19, 22, 25, 27, 29, and 31, 2005, Petitioner's father noted continued seizure activity. *Id*.

On April 7-8, 16, 18, and 22-23, 2005, Petitioner's father also noted seizure activity. *See* Ex. 14 at 2.

On May 7-8, 13-14, 22, 24, 28, and 31, 2005, Petitioner's father noted seizure activity. *Id*.

On June 4, 6-7, 15, and 17, 2005, Petitioner's father noted continued seizure activity. *Id*. On June 20, 2005, a vagal nerve stimulator was implanted in Petitioner. *See id.*; *see also* TR 42-43. Seizure activity was noted by Petitioner's father on June 23, 26, and 28, 2005. *See* Ex. 14 at 3-4.

On July 2, 11, 16, 20, 25-26, and 29, 2005, Petitioner's father noted seizures. *Id.*

On August 1, 5, 10, 13-14, 20, 22, 25, 27, and 29, 2005, Petitioner's father noted seizures. *Id.*

On September 1, 3, 4, 9, 13, 17-18, 20, 24-25, and 27-29, 2005, Petitioner's father noted seizures. *Id.*

On October 1, 8, 12, 14, 15, 17, and 22-23, 2005, Petitioner's father noted seizures. *Id.*

On November 2, 2005, Petitioner was examined by Dr. William W. Sutherling, Medical Director of the Epilepsy and Brain Mapping Program, that is affiliated with Huntington Hospital, Huntington Medical Research Institutes, and the California Institute of Technology. *See* Ex. 16 at 1. Dr. Tatiana Malura, a "Diplomate of the American Board of Psychiatry and Neurology, with special competence in pediatric neurology," also participated in the consultation. *Id*. The Initial Neurological Impression and Preliminary Working Diagnosis reported the "onset of convulsive seizures 24 hours after vaccination." *Id*. at 5. Petitioner was diagnosed with "Progressive Mixed

[17] Even though Petitioner did not have myoclonic seizures, Petitioner's parents were informed that she could get a test for the SCN1A, a gene associated with Dravet's Syndrome, if they wanted to rule out the possibility of myoclonic epilepsy. *See* TR 56-57.

Seizure Disorder with Generalized Tonic, Partial Versive, Absence and Photosensitive Absence Documented on Video EEG." *Id*.

By the October 13, 2006 evidentiary hearing, Petitioner was over 5 ½ years old and had impaired language skills, for which she received speech therapy and occupational therapy at a school for children with special needs. *See* Ex. 1 at 13; *see also* TR 40-41. In describing a typical day, Petitioner's father informed the Special Master that:

> [it] largely consists of my wife and I essentially doing something to manage [Petitioner's] care or helping to watch out for her safety. I did a per count last night. I call it my care team. There are 19 different people that I have to work with to keep things going . . . a neurologist, a pediatrician, Ms. Gentry, counsel of my care team, nurses, therapists, one-on-one aids, a very long list of people.
>
> So we're either filling out forms on psychologists and behavioral specialists, two that come to mind. That requires the most of our time. So what we do with [Petitioner] is we basically go from appointment to appointment, or, you know, preparing for a behavioralist to come over, or this was the homework from the psychologist, or her homework for school is done.
>
> We spend a great deal of time in any given day, every day, ensuring [Petitioner's] safety. She can certainly walk, but she's extremely atoxic. So she will stumble a lot or she in any slight bauble which another child might recover from, she might fall down. So we spend a great deal of time watching out for her safety.
>
> She has not developed, her own sense of her own safety, it does not occur to her that[:] ["M]y balance is off. I better not try the stairs.["] So we're constantly on guard for that. That's our day . . . In a nutshell, our lives have been very much – it's really all about taking care of [Petitioner] right now.

TR 46-47.

Petitioner takes five different medications each day. *See* TR 46, 52.

B. Expert Reports.

1. Petitioner's Expert – Dr. Carlo Tornatore, Resident Director Of The Department Of Neurology, Georgetown University Medical Center.

Petitioner's expert, Dr. Tornatore, is and has been a board-certified neurologist by the American Board of Psychiatry and Neurology for sixteen years. *See* Ex. 17 at 1; *see also* TR 61. Since June 1999, Dr. Tornatore has served as the Resident Director of the Georgetown University Medical Center Neurology Program and as an Assistant Professor at the Georgetown University Medical Center in the Department of Neurology. *See* Ex. 17 at 13. During 1990-1994, Dr.

Tornatore was a Senior Fellow at the Section of Molecular Virology and Genetics at the Laboratory of Viral and Molecular Pathogenesis at the National Institute of Neurological Disorders and Stroke at the National Institute of Health. *See* Ex. 17 at 2; *see also* TR 60. Dr. Tornatore received a B.A. from Cornell University in Neurology and a M.S. in Physiology and M.D. from Georgetown University. *See* Ex. 17 at 12. Dr. Tornatore also completed an internship in Internal Medicine at the Department of Medicine, Providence Hospital, and completed his residency at Georgetown University Hospital in the Department of Neurology. *Id*. In addition, Dr. Tornatore has received numerous awards and honors in the neurology field and his work has been published widely. *Id*. at 3-10. At the evidentiary hearing, Dr. Tornatore emphasized that during his six-year term at NIH his work focused on pediatric neurology research, and in his current position at Georgetown University Hospital, he is responsible for overseeing the training of all residents in pediatric neurology. *See* TR 60-61, 128.

In this case, Dr. Tornatore's July 29, 2005 Report concluded that:

> to a reasonable degree of medical certainty, it is my opinion that [Petitioner's] seizure disorder[18] was the direct result of the August 23, 2001 vaccinations.

Ex. 11 at 3; *see also* TR 64; *see also id*. 60-133 (entire testimony).

Dr. Tornatore based this opinion on: an examination of the three volume set of Petitioner's medical records; his expertise in neurology; and knowledge that a "vaccine induced fever with subsequent seizure, is a well recognized phenomena." *See* Ex. 11 at 3 (citing PEDIATR. INFECT. DIS. J. Aug. 2002, 21(8): 781-86).

2. Respondent's Expert – Dr. Max Wiznitzer, Associate Pediatrician And Associate Neurologist, University Hospital Cleveland, Ohio And Director Of Autism Center At Rainbow Babies And Children's Hospital.

The Government's expert, Dr. Wiznitzer, is and has been a board-certified neurologist by the American Board of Psychiatry and Neurology, with a special qualification in Child Neurology, for 21 years. *See* Exhibit B at 5; *see also* TR 135-36. 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. *Id*. 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, 2. Dr. Wiznitzer also has received numerous awards and honors in the neurology field and his work has been widely published. *Id*. at 4-5, 12-42.

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[18] Dr. Tornatore's Report also described Petitioner's condition as "an intractable seizure disorder and progressive neurologic abnormalities." *See* Ex. 11 at 2.

In this case, Dr. Wiznitzer's November 20, 2005 Report concluded that:

> [Petitioner's] first seizure that occurred on 8/24/01 was brief in duration and was not associated with any documentation of fever. If the seizure had been provoked by fever, I would expect an identifiable fever in the emergency room because of the short time period between the seizure and arrival at the hospital. Feeling warm to the touch at some earlier time is not sufficient to conclude that fever as present. Therefore, one cannot conclude that seizure was fever-related. This and subsequent seizures (with a diagnosis of epilepsy) were not a consequence of the immunizations of 8/23/01, either by consideration of the Vaccine Injury Table or of presumed direct causation of the vaccines.

Ex. A at 2;[19] *see also* TR 140-45, 50; 134-220 (entire testimony).

II. PROCEDURAL HISTORY.

On August 13, 2004, Petitioner's parents[20] initiated an action on her behalf in the United States Court of Federal Claims, under the Vaccine Act.

On August 2, 2005, Petitioner filed Dr. Carlo Tornatore's Expert Report. On November 29, 2005, the Government filed Dr. Matt Wiznitzer's Expert Report.

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[19] Dr. Wiznitzer's Report also commented on three articles that were relied on by Dr. Tornatore: Robert P. Wise, *Postlicense Surveillance For 7-Valent Pneumococcal Conjugate vaccine*, JAMA 2004, 1702-10; Frederic E. Shaw Jr., *Post-Marketing Surveillance For Neurological Adverse Events Reported After Hepatitis B Vaccination*, AM. J. EPIDEMIOL 1988, 127: 337-52; and Constance M. Vadheim, *Effectiveness and Safety of an Haemophilus Influenzae Type B Conjugate Vaccine (PRP-T) in Young Infants,* PEDIATRICS 1993, 92: 272-79. *See* Ex. A at 2. Dr. Wiznitzer summarized his understanding of the scope and recommendations of these articles as follows:

> While seizures are described after the immunizations, these articles are either not applicable to children, do not show a cause-effect relationship or do not describe a true increased risk of seizures with the vaccines that were administered to [Petitioner]. Therefore, Dr. Tornatore's conclusion that [Petitioner's] seizure disorder was the result of the August 23, 2001 vaccinations is not supported by the medical records or the submitted articles.

Id. However, the United States Court of Appeals for the Federal Circuit has held: "requiring medical literature . . . contravenes section 300aa-13(a)(1)'s allowance of medical opinion as proof." *Capizzano*, 440 F.3d at 1324 (quoting *Althen III*, 418 F.3d at 1280).

[20] Petitioner's father is a Project Manager for Intuit. *See* Ex. 1 at 161. Petitioner's mother is a software writer. *Id*. When Petitioner's parents are not present, Petitioner is cared for by her grandmother. *Id*. at 146.

On October 13, 2006, over two years after the Petition was filed, an evidentiary hearing was held.

On November 27, 2006, the Special Master issued an Entitlement Decision, determining that Petitioner failed to prove that: "but for Prevnar vaccine Petitioner would not have SMEI.[21] Petitioners have not proved a prima facie cause of causation." *Adams* at *16. On December 19, 2006, Petitioner filed a timely Motion for Review. On January 18, 2007, the Government filed a Response.

III DISCUSSION.

A. Standard of Review.

Congress requires the United States Court of Federal Claims to analyze conclusions of law made by a Special Master under the Vaccine Act *de novo*, *i.e.*, pursuant to a "not in accordance with law" standard. *See* 42 U.S.C.§ 300aa-12(e)(2)(B). "The 'not in accordance with the law' aspect of the standard of review is . . . involved . . . [where there is] dispute over statutory construction or other legal issues." *Hines* v. *Sec'y of Health and Human Servs*., 940 F.2d 1518, 1527 (Fed. Cir. 1991).

B. The Elements and Burden of Proof in Vaccine Act Cases.

The Vaccine Act provides that a petitioner may qualify to receive compensation and other relief under the Vaccine Injury Compensation Program ("Program"), if injury can be established either by causation in law or causation in fact. Causation in law is established if one of the vaccines, listed in the Vaccine Injury Table at 42 U.S.C. § 300aa-14(a) ("Table"), was administered to a petitioner and the "first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths" of specific adverse medical conditions, associated with the use of each vaccine and listed in the Table, occurred within a time period specified in the Table. *See* 42 U.S.C. § 300aa-14(a); 42 C.F.R. § 100.3(a). The Table is to be read

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[21] The National Institute of Neurological Disorders and Stroke states that Dravet's Syndrome or "severe *myoclonic epilepsy* of infancy (SMEI), is a severe form of epilepsy. It appears during the first year of life with frequent febrile seizures that, by definition, are rare beyond age 5. Later, other types of seizures typically arise, including myoclonus (involuntary muscle spasms) . . . In 30 to 80 percent of cases, Dravet's Syndrome is caused by defects in a gene, required for the proper function of brain cells." NINDS Dravet Syndrome Information Page, *available at* http://www.ninds.nih.gov/disorders/dravet_syndrome/dravet_syndrome.htm (last visited 3/12/07) (emphasis added).

"Myoclonus" is defined as "shocklike contractions of a portion of a muscle, an entire muscle, or a group of muscles, restricted to one area of the body or appearing synchronously or asynchronously in several areas." DORLAND'S at 1213.

and interpreted by reference to "Qualifications and aids to interpretation," that define the key terms used in the Table. *Id*.

Congress also decided to afford a petitioner the opportunity to receive relief under the Program, even if the time period for the first symptom or manifestation of a specified injury is not satisfied. *See* 42 U.S.C. § 300aa-11(c)(1)(C)(ii), § 300aa-13. Under these circumstances, however, a petitioner must establish causation in fact under a traditional tort analysis, *i.e.*, first, by establishing a *prima facie* case offering evidence of sufficient facts to establish each element of the claim and then by meeting a burden of proof as to each element of the claim under a "preponderance of the evidence" standard. *See* 42 U.S.C §§ 300aa-13. Accordingly, a non-Table Vaccine Act petitioner must proffer at least some evidence as to each element of the claim and sufficient evidence to persuade the special master or court by a preponderance or "greater weight" of evidence that each fact asserted is more probable than not.

In interpreting the Vaccine Act, the United States Court of Appeals for the Federal Circuit has held that a petitioner must proffer evidence that meets a "preponderance of evidence" burden of proof in non-Table causation in fact cases: "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury. To prove causation in fact, a petitioner must proffer a medical theory that explains the causal connection between the vaccination and illness manifested. Causation in fact requires proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury. A reputable medical *or* scientific explanation must support this logical sequence of cause and effect." *Grant* v. *Sec'y of Health & Human Servs*., 956 F.2d 1144, 1148 (Fed. Cir. 1992) (citations omitted) (emphasis added); *see also Bunting* v. *Sec'y of Health and Human Servs.,* 931 F.2d 867, 873 (Fed. Cir. 1991) ("petitioner's burden is not to show a generalized 'cause and effect relationship' with listed illnesses, but only to show causation in the particular case[.] [Otherwise,] a different and greater burden [would be placed] on petitioners than was enacted by Congress.").

In *Capizzano* v. *Sec'y of Health & Human Servs.*, 440 F.3d 1317 (Fed. Cir. 2006), the United States Court of Appeals for the Federal Circuit re-affirmed the three-part test for determining causation in fact in non-Table cases, endorsed in *Althen* v. *Sec'y of Health and Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005) ("*Althen III*"), requiring that a petitioner must:

> show by preponderant evidence that the vaccination brought about [the] injury by providing:
>
> (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 proximate temporal relationship between vaccination and injury.

Capizzano, 440 F.3d at 1324 (quoting *Althen III*, 418 F.3d at 1278).

If a petitioner is able to establish legal causation or causation in fact, then the burden of proof shifts to the Government to establish that a factor unrelated to the vaccine was the actual cause of the petitioner's injury. *See* 42 U.S.C. § 300aa-13(a)(1)(B); *see also Althen III*, 418 F.3d at 1278; *Jay* v. *Sec'y of Health and Human Servs*., 998 F.2d 979, 984 (Fed. Cir. 1993).

C. The Special Master's Determination Of Causation In Fact Was Erroneous As A Matter Of Law.

1. Petitioner Proffered A Reliable Medical Theory "Causally Connecting" Her Vaccinations And The Onset Of A Seizure Disorder That Has Developed Into Epilepsy.

At the evidentiary hearing, Petitioner's expert, Dr. Tornatore, testified that Petitioner's vaccinations were the cause of her first seizure on August 24, 2001 and "probably the cause of the subsequent seizures and then the intractable seizure disorder." TR 64. Dr. Tornatore's opinion was based, not only on Petitioner's extensive and well documented medical history, but also on reliable medical theory.

The first theory Dr. Tornatore discussed was a molecular mechanism immune response or "molecular mimicry" of at least one of Petitioner's vaccinations, that irritated Petitioner's brain as manifested by seizures:

> DR. TORNATORE: [T]he nature of [a] vaccination is that it's meant to induce an immune response. That's what it is. It's a viral protein as well. And those viral proteins can do very few things. They can either induce an immune response. The immune response then attacks the protein and becomes memory cells or some of those may actually cross into the brain and start to irritate the brain and then they may go away.
>
> As we'll see in the VAERS data, there are actually cases of kids who had a very extreme form of this from the vaccination called the ADEM[.] And so there is a biologically plausible reason as to why a vaccination will then lead to a generalized convulsion because there's this immune response that develops. In fact, this is [Petitioner's] third -- and so her immune system is now primed.[22] And so

[22] This was Petitioner's fourth DTP vaccination, fourth Hib vaccination, third Prevnar vaccination, and third Hepatitis B vaccination. *See* Ex. 1 at 6, 7, 9; Ex. 2.

when she sees the vaccine for the third time, her immune response will be very fast. And so we will see things within a matter of hours.

But certainly these are very rare, but that's the nature of why we're here. We'll see the VAERS data suggests that perhaps it's not all. And so these types of immune-mediated issues certainly could be one possibility.

TR 69-70.

* * *

SPECIAL MASTER: When you were giving a possible medical theory as to the vaccine as a viral protein, you form an immune response to it, part of that response goes into your brain. You made an analogy to acute – encephalomyelitis, which she doesn't have, otherwise known as ADEM but you continue and that's the cause of subsequent seizures. Now, we're dealing with pneumococcus.

DR. TORNATORE: But, I mean, these are microbiological proteins. So whether it's a viral protein or a bacterial protein, it's immaterial to the nervous system. When it's given, the protein is broken down into little bits and pieces. And for the immune system for that particular viral or bacterial organism.

The results are the same. Once the immune system recognizes it and gets turned out, it will then be activated and starts circulating. And sometimes, there are other antigens in the brain that may look like those same proteins which form *molecular mimicry*[23] and then they

[23] Molecular mimicry is a "phenomenon wherein, two separate peptides or proteins are not identical, but because of the structure or their component of amino acids, in terms of . . . the way they may look to the immune system, they appear to be identical[.]" *Althen II*, 58 Fed. Cl. at 276 n.16.

will start to attach that particular tissue or potentially attack it.

TR 79-80 (emphasis added).

During the Government's cross-examination, Dr. Tornatore provided a more detailed explanation of molecular mechanism immune response or "molecular mimicry":

GOVERNMENT'S COUNSEL: I just wanted to ask you a couple of questions about your theory. I think you said that there are molecular mechanisms at play here, and that you believe that [Petitioner] suffered from an immune process which is plausible here. Is that a fair characterization of your testimony?

DR. TORNATORE: That's pretty close.

GOVERNMENT'S COUNSEL: Okay. Why didn't you mention the molecular mechanisms of the immune-related process in your report that was written? It's not dated, but it was faxed from your department back in July of 2005.

DR. TORNATORE: Let me see what I got. I've got – mechanism of vaccine-induced fever with subsequent seizures that's a well-recognized phenomenon. That's just one mechanism. I didn't put all of them down. But by extension, a vaccine-induced fever with subsequent seizures, there has to be a *molecular mechanism* behind that. And then the fever is either due to the vaccine interaction the MCH-1 in the presentation and then subsequent downstream mechanisms. . . . But the *idea is that when you give a vaccine, the T-cells, what they have to do is that protein has to actually bond on the outside of the T-cells and macrophages, and then they actually talk to each other, but they do it with the special proteins that are started on the outside of the cells called MHC, major histocompatibility complex*. And then they present the protein to the cells, and those

cells then react against it. It's sort of like they're serving it up as a dish to the other cells, if you will. They need a platter to do it on, and the platter happens to be MCH complex. . . . So the protein that's given in this vaccine, for instance, once it goes into the tissue what happens is macrophages come in. They chew it up and then it comes up on the surface of the macrophage next to these MHC proteins. And then the T-cells which are coming around, they will join up with the macrophages, and the macrophage will then stimulate the T-cell, but you need these other proteins for all of this to happen properly.

And in fact there are *certain people whose MHC is very wobbly, and so that they're always presenting protein inappropriately to T-cells. Those are people who start to develop autoimmune diseases*. That is the idea behind certain NHC subcategories like HLA DR2 in particular.

SPECIAL MASTER: What did you say?

DR. TORNATORE: There's a certain HLA and then D-R-A. It has a very hard propensity for autoimmune. People who have that have a lot of autoimmune disease.

SPECIAL MASTER: I assume you're not saying that [Petitioner] has an autoimmune problem, just a – problem.

DR. TORNATORE: No. I was just saying that there are *certain genetic backgrounds that are predisposed to it.*

SPECIAL MASTER: To what?

DR. TORNATORE: To *autoimmune disease.*[24]

TR 118-21.

The Special Master, apparently, did not recognize that the theory of a molecular mechanism immune response or "molecular mimicry," as discussed by Dr. Tornatore, essentially was the same medical theory relied on by the United States Court of Federal Claims in *Althen II*:

> The medical theory on which [Petitioner's expert] based his . . . opinion is known as the *theory of "degeneracy,"* resulting from growing knowledge about "*molecular mimicry*." [Petitioner's expert] explained . . . that "the reason one gives vaccinations is in order to create memory cells, T cells, B cells that will respond to the pathogen that is being vaccinated against in the future." The body's T cells, however, can "degenerate" and mistakenly respond to non-specific or non-native antigens, such as CNS myelin antigens, rather than the vaccine's antigen. This mistake can then trigger an inflammatory response, which ultimately manifests itself as a demyelinating disease through "epitope spreading,"[25] resulting in a chronic condition, such as that developed by petitioner. [Petitioner's expert] reported that the *degeneracy of T cells is "a widely recognized principle in medicine, accepted in the field of neuroimmunology and supported by the [medical] literature."*

Althen II, 58 Fed. Cl. at 276 (emphasis added) (internal citations omitted). More importantly, the United States Court of Appeals for the Federal Circuit held that this theory "provided the requisite showings of a medical theory causally connecting the vaccination and the injury[.]" *Althen III*, 418 F.3d at 1282.

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[24] The fact that Petitioner's mother had a history of hyperthyroidism, an autoimmune condition, further supports Dr. Tornatore's theory that Petitioner's seizures may have been initiated by a molecular mechanism immune response or "molecular mimicry." *See* Ex. 1 at 13; Ex. 9 at 20, 22.

[25] An "epitope" is the "simplest form of an antigenic determinant, on a complex antigenic molecule, which can combine with antibody or T cell receptor." STEDMAN'S at 610. "Epitope spreading" is a "process that was described in the experimental model for MS and has been repeated many times; whereby, an immune response that is initially very restricted to a few different types of T cells with a few different T cell receptors over time, because of continuing inflammation, can become more widespread and involve more different T cells, more different antigens." *Althen II*, 58 Fed. Cl. at 276 n.17.

A second, related theory is that the vaccinations in combination with a toxin provoked Petitioner's seizures:

> DR. TORNATORE: The other is whether the pneumococcal protein or a *combination* of the pneumococcal protein and the other viral proteins has mixed with some kind of [toxin], and that's what caused the temperature to go up.[26] My suspicion is there is an immune response. That's why she was lukewarm and that is why, or that was the sense, and then [Petitioner] had the seizure probably because of some irritation that was caused.
>
> And then subsequently, there are changes in the brain that can linger from this kind of irritation. And then, several months later, we don't know why . . . another seizure happens, but again it's prolonged again suggesting that in this particular case, this these seizures are really related to one another. The subsequences really speak to that they're all related to one another for sure.
>
> So the second seizure again is prolonged. . . . [P]rior to that second seizure [Petitioner] is normal, which was good and [Petitioner] was developing normal, which is fine. So that's says that it's an event that may have caused an irritation that's still around the brain stem to develop.
>
> And then the third seizure, which is Exhibit 1, page 169, this is 35 – and so we can see again no antecedent event that apparently caused

[26] Dr. Tornatore reviewed Petitioner's medical and exhaustive seizure history and concluded that there were several intervening events that may have accounted for the fact that Petitioner did not have a fever by the time she was examined at the emergency room. *See* TR 65-67, 80-81. Dr. Tornatore gave more weight to Petitioner's parents' description of the fact that she was warm to the touch, contemporaneous with her seizure. *See* TR 67. In addition, Dr. Tornatore was impressed by Petitioner's high white blood cell count at 15.5, which is an indication of a prolonged seizure, and high MCV and MCH (corpus clan hemoglobin) levels. *See* TR 65-66.

> this, but very clearly another prolonged seizure. The child had two seizures which were previously rather prolonged as well.
>
> And then, as [Petitioner's father] testified, there were a whole host of seizures that subsequently developed and the type of the seizures sort of changed as time goes by. And certainly the extent of the seizures and their intensity would suggest that now [Petitioner] is having injury to the brain, and as Dr. Sutherling noted the changes in her cognition may actually be due to the seizures.

TR 70-71.

The third medical theory, proffered to explain how Petitioner's vaccinations caused the onset of a seizure disorder that developed into epilepsy was "kindling in epilepsy":

> DR. TORNATORE: [I]f you have one seizure, the brain will then take compensatory mechanisms to shut it down. But if you have a second seizure, then it's like a fire. That is why it's called kindling. You're putting more kindling into the fire. And so it then becomes a little bit more intractable. There's a larger area that is now irritable.
>
> And then when something else triggers a seizure and it's more prolonged – these are very prolonged, 13 minutes. We know that a nerve really only can go without oxygen for about seven minutes and after that it becomes irreversibly injured. More importantly, a nerve which is constantly firing, then in and of itself quickly uses up its oxygen and energy storage, it may start to die off or it may actually work erratically in the future. And then with each episode, it becomes more and more likely to fire.

TR 78.

* * *

SPECIAL MASTER: [L]et's assume Prevna[r] caused the first seizure. It's three months until she has the second seizure, and then it's a month until she has the third seizure on the fourth, a day later, and then once you are in January 2002, there are four of five seizures every month. There is a difference in tempo here and I don't understand why.

DR. TORNATORE: Well, I think it's not uncommon in people who have seizures that the brain has compensatory mechanisms, that there is maybe a small focus that is irritated. But the brain is very plastic and so it will try to shut down that area. That may linger because then it subsequently happens again.

And then something happens, the baby doesn't sleep well, maybe she didn't get enough sleep, ate something funny, who knows, but there was something that then caused the nerve – remember the nerves are very dynamic. They are electrical organisms that fire all the time, and they are very dependent on the chemical milieu that they're in, and that can change pretty dramatically, if you don't get enough sleep, if you have a fever, if you have an infection, and that's enough to then change the electricity or electrical conduction of those nerves – happens.

The next time, as it's happened, the nerves around it may become further injured. They may have recovered the first time, but norther's a second hit. Now they're more prone to firing a little bit more rapidly.

TR 77-78.

* * *

DR. TORNATORE: And so you can almost, in [Petitioner], I can see it. There's a kindling effect. The first seizure is there. Then three months go by. There's more focus. Something caused the second one to happen. Okay? But it's pretty prolonged. And so that focus is probably a bit more problematic. Then in December, I guess – something else happens there[.]

TR 79.

The Special Master's analysis of this testimony first focused on whether Petitioner did or did not have a fever on August 24, 2001, *i.e.*, whether Petitioner's initial seizure was "febrile." *Adams* at *13-14. In doing so, the Special Master failed to recognize that the theory of molecular mechanism immune response or "molecular mimicry" is not dependant on whether or not Petitioner in fact had a fever. *See Althen II*, 58 Fed. Cl. at 276. Moreover, although Dr. Wiznitzer rejected the theory that the Prevnar vaccine alone could cause Petitioner's seizures, he conceded that the Prevnar vaccine in combination with other vaccines may have that effect. *See* TR 186. (DR. WIZNITZER: "So I see that this point is here [in the Brighton Collaboration *see* TR 187]. I buy the fact that ADEM is here. That's all I can say. I can't say there is a causal relationship with Prevna[r]. I will just say that it happened. Maybe it was due to one of the others [vaccinations] that were present."). Dr. Wiznitzer's concern about the immune-response theory was that Petitioner "should have had multiple[] areas of the brain that [were] injured by the immune system[.] . . . We have no encephalopathy there that anyone reports in the medical records." TR 184. Dr. Wiznitzer recognized, however, that: "This is an area that people are doing a lot of intense research in, and it's not as simplistic as coming on and saying, this is what's causing it." *Id.* (emphasis added). Here, both Dr. Wiznitzer and the Special Master confused the relationship between the burden of proof and causation. The Vaccine Act does not require the petitioner to establish precise causation. As the Untied States Court of Appeals for the Federal Circuit recently stated, "the purpose of the Vaccine Act's preponderance standard is to allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body." *Capizzano*, 440 F.3d at 1324.

As a result, the Special Master's causation analysis primarily was based on her subjective view that Dr. Wiznitzer's experience with "neurologic conditions" in children, professionally trumped that of Dr. Tornatore. *See Adams* at *14. The court does not accept the Special Master's premise that Dr. Wiznitzer had "far superior knowledge . . . of childhood epilepsy *and* Dravet's Syndrome, and his understanding of what is and is not a febrile seizure." *Compare Adams* at *16 with TR 62-64. The court has determined that both experts were extraordinarily well qualified. *See* Ex. 17; Ex. B. Nevertheless, assuming *arguendo* that the Government's expert had more experience with children, that fact is irrelevant to whether Petitioner's expert proffered "a medical theory causally connecting the vaccination and the injury." *Capizzano*, 440 F.3d at 1324. Dr. Tornatore proffered three medical theories "causally connect[ing] [Petitioner's] vaccination[s] with her injury,"

i.e., the onset of a seizure disorder that has developed into epilepsy. Since two of these theories were not persuasively rebutted,[27] Petitioner satisfied the first element of *Capizzano*/*Althen III*.

2. Petitioner Established "A Logical Sequence Of Cause And Effect" Between Her Vaccinations And The Onset Of A Seizure Disorder That Has Developed Into Epilepsy.

The Special Master also concluded that: "Dr. Tornatore's testimony does not provide a logical sequence of cause and effect because he assumes that there is no other underlying reason for [Petitioner's] seizure disorder except for Prevnar vaccine." *Adams* at *16. In doing so, the Special Master erred in assuming that the testifying expert's role is to establish a "logical sequence of cause and effect." To the contrary, as the Federal Circuit has stated: "*Althen III* explained that *medical records* and *medical opinion testimony* [from "treating physicians"] are favored in vaccine cases, as [they] are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Capizzano*, 440 F.3d at 1326 (citing *Althen*, 418 F.3d at 1280) (emphasis added); *see also* 42 U.S.C. §§ 300aa-13(a)(1).

In this case, Petitioner's medical records fully document a "logical sequence" of the cause and effect between Petitioner's vaccinations and the onset of a seizure disorder that has developed into epilepsy. *See* Ex. 1-18. In addition, on August 24, 2001, the same day as Petitioner's initial seizure, her primary treating physician and pediatrician, Dr. Burkhart, had the following first impression: "? *Prevnar related*." Ex. 1 at 17 (emphasis added). This causal link is significant, because Dr. Burkhart made this observation, even though she was not sure whether Petitioner's seizure occurred with or without a fever; her concern was whether Prevnar may have caused Petitioner's seizure. *Id*. On December 2, 2002, after witnessing Petitioner's seizures for one year, increasing both in frequency and significance, Dr. Burkhart referred Petitioner to Dr. John F. Bastian, an allergist at Children's Hospital "to consider [the] *issue of further vaccines*." Ex. 1 at 45 (emphasis added). Dr. Burkhart made this referral, because she believed that Petitioner needed to receive further vaccinations, but decided to delay administration until Petitioner was "more stable." Ex. 1 at 3. On June 6, 2003, Dr. Bastian also confirmed Dr. Burkhart's concern about a link between Petitioner's vaccinations and now "chronic seizure disorder," observing that:

> [Petitioner] has [received] no further immunizations since 8 months she had a DTaP and following that her seizure disorder started[.] . . . While she was in the clinic, she did have one episode of an absence seizure. The parents state these are frequent [.] . . . I also spoke with [the father] about immunizations. I thought because of the proximity

[27] Dr. Wiznitzer's critique of the "kindling" theory was well-taken, because this theory apparently was based on a "mouse model [and] there is still major controversy as to whether it's truly applicable to the human." TR 181-82.

of the seizure disorder with the immunizations that *it was reasonable that [s]he should not receive further immunizations as these may trigger further seizures*."

Ex. 1 at 151-52 (emphasis added). Significantly, Dr. Wiznitzer did not question the logical sequence posited by either of these treating physicians.

Accordingly, in this case, Petitioner's medical records and treating physicians established, by a preponderance of evidence, a logical sequence of cause and effect between Petitioner's vaccinations and the onset of a seizure disorder that has developed into epilepsy.

3. Petitioner Established A "Proximate Temporal Relationship" Between Her Vaccinations And The Onset Of A Seizure Disorder That Developed Into Epilepsy.

The United States Court of Appeals for the Federal Circuit also requires that a petitioner show, by a preponderance of evidence, a temporal relationship between the vaccination and onset of injury: "Evidence demonstrating petitioner's injury occurred within a medically accepted time frame bolsters a link between the injury alleged and the vaccination, at issue under the 'but-for' prong of the causation analysis." *Pafford* v. *Sec'y Health and Human Servs*., 451 F.3d 1352, 1358 (Fed. Cir. 2006) (citing *Capizzano*, 440 F.3d at 1326).

In this case, Petitioner established the requisite temporal relationship:

PETITIONER'S COUNSEL:	And finally with respect to the vaccine in [Petitioner]'s case as well as the statistics mentioned in the article on Prevna[r], would you say that there is a striking temporal relationship in this case between the vaccination and the onset of the neurological event?
DR. TORNATORE:	I think there is a very striking in a certain sense with the article stating that almost half the patients who had neurologic sequelae had it within the first 24 hours. So again that fits very nicely.
SPECIAL MASTER:	So you're saying it's a medically appropriate timeframe.
DR. TORNATORE:	The timeframe is absolutely appropriate.

TR 107.

* * *

PETITIONER'S COUNSEL:	There is in your opinion a striking temporal relationship?
DR. TORNATORE:	Yes, absolutely. The eight hour difference and the fact that it was within 24 hours. And again going back to the table, it shows that half of all of the average neurologic events occurred within 24 hours again makes perfect sense from a time standpoint.

TR 132; *see also* Ex. 16 at 5.

The Special Master begrudgingly acknowledged as much: "As for the third *Althen* criterion of medically appropriate time frame, 24 hours seems to fulfill the criterion." *Adams* at *16.

D. The Government Did Not Establish Alternative Causation.

In the Entitlement Decision, the Special Master misapplied the *Capizzano/Althen III* test, concluding that "[p]etitioners have not proved that but for Prevnar vaccination [Petitioner] would not have SMEI." *Adams* at *16; *see Althen III*, 418 F.3d at 1278 ("If [petitioner] satisfies [three-prong] burden, she is entitled to recover *unless the [government] shows*, also by a preponderance of evidence, that the injury was in fact caused by factors unrelated to the vaccine.") (citations omitted) (emphasis added)). In addition, the Special Master erred in perceiving that her role in Vaccine Act cases is to identify "a medical explanation." *Adams* at *13 ("In essence, the Special Master is *looking* for a medical explanation[.]"). To the contrary, the role of the Special Master is to weigh the evidence proffered by Petitioner of causation in fact and, *if a prima facie* case is established, only then to weigh evidence proffered by the Government of alternative causation. *See Capizzano*, 440 F.3d at 1324 (quoting *Althen III*, 418 F.3d at 1278).

As previously discussed, since Plaintiff satisfied all three required elements of *Capizzano/Althen III*, it was appropriate for the Special Master to allow the Government to introduce evidence of alternative causation. In this case, however, the Government did not do so through Dr. Wiznitzer's Report or otherwise.

Recognizing this failure of proof, early in the evidentiary hearing, the Special Master participated in an *ex parte* off-the-record discussion with the Government's expert as to whether Petitioner may have Dravet's Syndrome. *See* TR 91-92; *see also* Pet. Mot. at 6-7. Then, the Special Master distributed an article that she obtained from independent research discussing Dravet's Syndrome. *See* Pet. Mot. at 7 (citing Ingrid E. Scheffer, *Severe Infantile Epilepsies: Molecular Genetics Challenge Clinical Classification*, *available at* http://brain.oxfordjournals.org/cgi/content/full/126/3/513) ("Scheffer Article").

The fact that there was no medical evidence that Petitioner experienced myoclonic seizures typical of Dravet's Syndrome did not deter the Special Master. *See* Ex. 4 at 94. When the hearing resumed, the Special Master decided to pursue her diagnosis with Petitioner's expert:

SPECIAL MASTER:	I know that Dr. Wiznitzer mentioned this *off the record*, and he hasn't testified yet, but I just thought I'd ask you, have you ever heard Dravet syndrome, French pronunciation, D-R-A-V-E-T-, Dravet Syndrome?
Dr. TORNATORE:	Yes, I'm familiar with that.
SPECIAL MASTER:	Can you tell me if you think that [Petitioner] has it?
DR. TORNATORE:	I don't think so. . . . To be fair, it is one of the syndromes that has many different manifestations. *But she's not had monoclonic seizures which is seen in many of the patients that have it*. Again, there are many patients who don't have that. I think probably most importantly is that Dr. Sutherling [Petitioner's doctor] makes no comment to that degree, and this is somebody who is an eminent epileptologist who is very well regarded. Certainly, if he felt that was the case, he would have certainly looked at that as an issue. So I think the treating physicians didn't have, at least this particular physician didn't have a suspicion that was the case.

TR 91-92 (emphasis added).

After this testimony, the Special Master convened another recess, during which she distributed another article: Charlotte Dravet, *Dravet's Syndrome (severe myoclonic epilepsy in infancy)* ("Dravet Article"). *See* Gov't Resp. at 4; *see also* C. Ex 1. The Special Master justified her actions by explaining that she would not place the article in the record, unless it was mentioned during the hearing. *See* Pet. Mot. at 4.

When the proceedings resumed, the Special Master, nevertheless, introduced her exhibit and attempted to have the Government's expert adopt her diagnosis that Petitioner had Dravet's Syndrome:

SPECIAL MASTER:	Was it your testimony earlier that Justine has Dravet Syndrome?
DR. WIZNITZER:	*Insufficient data*. May I explain?
SPECIAL MASTER:	Yes.
DR. WIZNITZER:	I am familiar with the article that Special Master –
SPECIAL MASTER:	All right. *Now that you brought it up, I submit Court's Exhibit No. 1, an article on Dravet Syndrome, written by the person for whom Dravet [S]yndrome is named, Charles Dravet, otherwise known as severe myoclonic epilepsy in infancy.*
DR. WIZNITZER:	It has another name, too. It's called polymorphic epilepsy in infancy.
SPECIAL MASTER:	Polymorphic?
DR. WIZNITZER:	Polymorphic.
SPECIAL MASTER:	Because it keeps changing its form?
DR. WIZNITZER:	No, because the EEG has discharges for multiple sites. And those kids, if you look in the literature about severe monoclonic epilepsy, then you look and find polymorphic epilepsy. Those kids are actually Dravet syndrome kids. It's how you look at things as to what name you want to give it. So a group came together to give it a name. Now they've agreed on this name. Before that, you called it what you thought it was. I have patients with Dravet syndrome, and I guess the first to say is what always bothered

me greatly is the kids clearly had a clinical history of Dravet syndrome with a clinical history that fit very nicely. But a few of them ever had monoclonic seizures.

And if you read this article, Dr. Dravet says you don't need to have a monoclonic seizure . . . which he describes as the natural history of Dravet syndrome is – let me just give you the natural history description and then we'll see the question about [Petitioner] here.

TR 161-63 (emphasis added).

* * *

DR. WIZNITZER: And the reason that I actually mentioned to [Government's counsel] this morning long before the hearing started that, irrespective of what we talked about at the hearing today, I had a strong sense that we should check for Dravet syndrome, is that when you look at – should be evaluated, when you look at [Petitioner's] history, she starts with seizures that are deeper, general clonic, shaking all over, or one side is shaking, that are full-blown in nature, *some provoked by fever*. She has adequate development for a period of time. Then she starts developing other seizure types which are described in the medical records as absence seizures and as aversive seizures, which are the commonest of seizures which are occurring.

TR 166-67 (emphasis added).

* * *

DR. WIZNITZER: And my concern is that when you come into the Court today and say, *all alternative causations have been excluded*, and just because some other doctors didn't identify it,

you can't come to that. You always have to keep an open mind as to what's going on. *It is possible that this is Dravet's*.

TR 168.

* * *

SPECIAL MASTER: So is the reason that *you are not diagnosing [Petitioner] with Dravet* syndrome is that they haven't this test for SCN-[1A]?[28]

DR. WIZNITZER: Yes. If you were to say, Dr. Wiznitzer, clinically, does she fit the criteria? Does she fit the profile? I would say, yes, Special Master, she does.

SPECIAL MASTER: Now, it seems to me that Dravet syndrome is not a cause. It's a description of symptoms.

DR. WIZNITZER: Right, but there's a genetic basis to it and that's the whole point.

TR 169-70 (emphasis added).

The end game is that Dr. Wiznitzer did not testify that Petitioner "had Dravet's Syndrome." *See Adams* at 10. He testified only that "she fit the profile." TR 178.[29] In contrast, none of Petitioner's treating physicians, none of the doctors that examined Petitioner in three different hospital emergency rooms, and none of the doctors that administered EEGs, MRIs, or other tests ever diagnosed Petitioner with Dravet's Syndrome. *See* Ex. 1. As Dr. Tornatore confirmed:

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[28] Dravet's Syndrome is often caused by the spontaneous mutation of the gene SCN1A. *See* TR 169. In November 2005, after the Petition was filed in this case, Petitioner's parents discussed the issue of the SCN1A gene with Dr. Sutherling. *See* Ex. 16 at 5. Dr. Sutherling, like Dr. Nespeca, also rejected Dravet's Syndrome as the cause of Petitioner's injury: "It is less likely that there is a genetic abnormality or other . . . there is no definite indication at this time of any progressive metabolic or inborn error or other problems such as this to produce patient's seizures." *Id.*; *see also* Ex. 4 at 94.

[29] On October 27, 2006, after the hearing the Special Master allowed the Government to file an article mentioned by the Government's expert during the hearing: S. Berkovic, *et. al.*, *De-Novo Mutations of the Sodium Channel Gene SCN1A in Alleged Vaccine Encephalopathy: A Retrospective Study*, 5 LANCET 488-92 (2006) ("Berkovic Article"). *See* R. Ex. C.

PETITIONER'S COUNSEL: Is there any place in this rather massive record that indicates that any doctor or anyone else attributed these seizures to any other cause?

DR. TORNATORE: No, there's not.

TR 132.

Accordingly, the Government failed to establish by a preponderance of the evidence any alternative cause for the onset of Petitioner's[30] seizure disorder that developed into epilepsy, including that Petitioner had Dravet's Syndrome.

IV. CONCLUSION.

Petitioner has proffered: reliable medical records, a reputable medical opinion of at least one, if not three medical theories; a logical sequence of cause and effect, including detailed assessments of her "treating physicians"; and a strong temporal relationship, all causally connecting the Petitioner's vaccinations to the onset of a seizure disorder that has developed into epilepsy. In other words, Petitioner established that it is more likely than not (greater than 50%) that, but for her vaccinations, the onset of her seizure disorder, that has developed into epilepsy, would not have occurred. In addition, Petitioner has established that it is more likely than not (greater than 50%) that vaccinations were a substantial factor in causing the onset of her seizure disorder that has developed into epilepsy. Accordingly, Petitioner has met the statutory burden to establish causation in fact under 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I) and 42 U.S.C. § 300 aa-13(a)(1)(A) and is entitled to relief under the Vaccine Act, including compensation, reasonable attorney fees, and other costs.

Therefore, Petitioner's Motion for Review is granted and the November 27, 2006 Entitlement Decision of the Special Master is reversed and vacated. The case is remanded to the Special Master for an award of compensation to Petitioner, together with reasonable attorney fees, and other costs. The Clerk of the United States Court of Federal Claims will enter judgment accordingly.

IT IS SO ORDERED.

s/Susan Braden
SUSAN G. BRADEN
Judge

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[30] In defending the Special Master's findings on Dravet's Syndrome, the Government failed to recognize that, as a matter of law, it would need to concede that Petitioner met the requirements of *Capizzano*/*Althen III* before an alternative causation inquiry is even relevant. *See* Gov't Resp. at 13-20.