In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

* *		
JOHN CHRISTIANSEN and	*	
CATHERINE CHRISTIANSEN,	*	
parents of W.C., a minor	*	No. 08-244V
	*	Special Master Christian J. Moran
	*	
Petitioners,	*	Filed: November 13, 2012
	*	Reiussed: December 20, 2012[1]
v.	*	
	*	Entitlement; diphtheria, tetanus,
SECRETARY OF HEALTH	*	acellular pertussis vaccine (DTaP);
AND HUMAN SERVICES,	*	developmental delays, seizures,
	*	infantile spasms; significant
Respondent.	*	aggravation.
* *		

John Christiansen, Bellmore, NY, for petitioners, pro se;
Lisa A. Watts, United States Dep't of Justice, Washington, D.C., for respondent.

PUBLISHED DECISION DENYING COMPENSATION

Mr. and Mrs. Christiansen ("petitioners"), on behalf of their minor son W.C., filed a petition on April 7, 2008, alleging that W.C. was harmed by the diphtheria, tetanus, acellular pertussis ("DTaP") vaccine, which is a component of the Pediarix

[1] When this decision was originally issued, the parties were notified that it would be posted in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17,2002). The parties were also notified that they may seek redaction pursuant to 42 U.S.C. § 300aa-12(d)(4)(B); Vaccine Rule 18(b). Petitioners made a timely request for redaction and this decision is being reissued with the name of the minor child redacted to initials and the child's date of birth redacted to the year of birth.

vaccine he received on July 12, 2005.[2] The petitioners seek compensation pursuant to the National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-10 et seq. (2006).

W.C. suffers from a devastating disease known as infantile spasms. A preponderance of the evidence shows that he started manifesting the infantile spasms prior to receiving the Pediarix vaccine on July 12, 2005. Therefore, the vaccination did not cause the infantile spasms. Further, a preponderance of the evidence shows that the DTaP vaccine did not significantly aggravate W.C.'s condition, but that his course followed the normal course of infantile spasms. In short, the petitioners have not established that the DTaP vaccine adversely affected W.C. and therefore, are not entitled to compensation.

I. Procedural History

The petitioners filed their petition on April 7, 2008. The petition was filed within 36 months of when W.C. received his third set of vaccinations, which was on July 12, 2005. The petition alleged that the July 12, 2005 DTaP vaccination administered to W.C. caused him to suffer from an encephalopathy. Although required to be filed with the original petition, the petitioners did not submit medical records until June 20, 2008, and they filed additional medical records in July, September, and October, 2008. Exhibits 1-19; see 42 U.S.C. § 300aa-11(c) (stating medical records must be submitted with the initial petition filed with the court).

On October 8, 2008, the Secretary filed her report pursuant to Vaccine Rule 4, concluding that petitioners were not entitled to compensation. The Secretary argues that W.C. did not suffer an acute encephalopathy following the DTaP vaccination. Instead, the Secretary states that W.C. suffered from severe developmental delay and neurological problems before the July 12, 2005 vaccination date. Further, the Secretary states that W.C.'s treating physicians did not relate his neurological deficits and infantile spasms to his July 12, 2005 vaccination. Resp't Rep't at 8. The Secretary concluded that W.C.'s seizure condition manifested before the July 12, 2005 vaccination, and therefore he should be denied compensation.

[2] Pediarix is a combination vaccine, which includes the DTaP, hepatitis B, and inactivated polio vaccines. Dorland's Illustrated Medical Dictionary (32nd ed. 2012) at 1400.

A status conference was held on October 24, 2008. During the status conference, petitioners were ordered to file the journal articles they used to develop their theory of the relationship between W.C.'s seizures and the vaccination. Petitioners also discussed the possibility of retaining an attorney.

On January 8, 2009, petitioners filed a status report that discussed a medical theory for the claim that W.C.'s injuries occurred due to administration of the DTaP vaccination. Petitioners asserted that the DTaP vaccine can cause an encephalopathy in infants because of the pertussis component. Pet'r Status Rep't at 3. This status report made no mention of retaining an expert, but was filed with journal articles that petitioners claimed supported their medical theory.

A status conference was held on January 16, 2009. During the call, petitioners discussed their progress in retaining an expert and were encouraged to continue exploring experts to support their claim.

Nearly two years later, petitioner submitted the report of Dr. Chone Ken Chen. Dr. Chen practices pediatric neurology in New York University Downtown Hospital, as well as at the Chang Comprehensive Health Center. Exhibit 22 (Dr. Chen's curriculum vitae). Dr. Chen's report stated that W.C. was a healthy child who did not exhibit developmental delays until after the administration of the vaccine and he suggested an autoimmune mechanism for W.C.'s injuries. Exhibit 20 at 6.

On January 14, 2011, the Secretary filed a responsive expert report from Dr. Russell Snyder, who practices pediatric neurology and has clinical experience with epilepsy and infantile spasms. Exhibit B (Dr. Snyder's curriculum vitae). Dr. Snyder's report claimed that seizures and developmental delays were present prior to the immunizations. His report further stated that the seizures that occurred after the July 12, 2005 vaccination were the continuance of infantile spasms, coupled with already present developmental delays. Exhibit A at 1-4.

A status conference was held following the filing of the expert opinions. During this conference, petitioners were ordered to submit a supplemental report from Dr. Chen to address inconsistencies between his report and Dr. Snyder's report regarding the onset of W.C.'s developmental delays.

Petitioners filed Dr. Chen's supplemental report on March 28, 2011. Dr. Chen claimed that W.C. displayed adverse, moderate symptoms of "few days crying on/off" when he was first exposed to DTaP on December 10, 2004, and that

W.C. "deteriorated significantly shortly after receiving that particular vaccine" (referring to the July 2005 vaccine). Thus, Dr. Chen concludes that the July 2005 dose of DTaP significantly aggravated W.C.'s "prior existing developmental delay." Exhibit 23 at 5.

During a status conference held on April 25, 2011, a hearing was scheduled for October 24, 2011, and both parties were ordered to submit prehearing briefs. Petitioners filed their prehearing brief on August 30, 2011, restating their claim that the July 12, 2005 DTaP administration caused W.C. to suffer developmental injuries.[3] In response to the Secretary's claim that W.C. suffered seizures prior to the vaccination, petitioners claimed that a normal MRI and EEG, conducted on June 22, 2005, supported their contention that W.C. did not suffer from seizures before the vaccination. Pet'r Prehr'g Br. at 3 (citing exhibit 5 at 4-6). The Secretary filed her prehearing brief on September 14, 2011 stating that the petitioners have not established that the vaccine "either caused [W.C.'s] infantile spasms or significantly aggravated a pre-existing neurologic disorder." Resp't Prehr'g Br. at 12.

A hearing was held in New York, New York on October 24, 2011. Dr. Chen and Dr. Snyder testified in person. Following the hearing, both parties requested the opportunity to submit posthearing briefs.

In petitioners' brief, they maintained their original claim that the July 12, 2005 DTaP vaccination caused W.C.'s seizure disorder. However, in addition to their original claim, petitioners introduced a claim that the July 12, 2005 vaccination significantly aggravated W.C.'s pre-existing medical condition. Pet'r Posthr'g Br. at 4. In the Secretary's brief, she advocated that petitioners' claims be dismissed because petitioners did not meet their burden of proof. Resp't Posthr'g Br. at 10, 13. With the submission of these briefs, this case is now ready for adjudication.

II. Facts

W.C. was born a twin, via cesarean section, in 2004. He weighed 4 lbs. 7 oz., while his brother, T.C., weighed 6 lbs. 10 oz. Exhibit 1 (medical records of Dr. John Cafaro) at 3. W.C. was born at 36 weeks due to breech presentation and

[3] Petitioners' prehearing brief did not allege significant aggravation. Petitioners' brief claimed the third dose of the DTaP vaccine only caused W.C.'s injury.

had Apgar scores of 9 and 9 and with a two vessel cord.[4] W.C. was discharged from the hospital after four days. Exhibit 1 at 33, 39.

W.C. had his two-month well-child examination on December 10, 2004, at Pediatric Healthcare of Long Island. During the check up, it was reported that W.C. was relatively healthy and that he had good weight gain. During this visit, W.C. received the DTaP and Prevnar vaccines. Exhibit 2 at 15.

Almost a month later on January 6, 2005, W.C.'s mother phoned the doctor to report that W.C. had been experiencing "few days crying on/off." Although she reported the crying, the record noted that W.C. did not have a fever and had experienced no change in his sleep patterns. Id. Dr. Chen stated that W.C.'s crying was an adverse reaction to the December 10, 2004 DTaP vaccination. Dr. Chen explained that the December vaccination could have possibly been the inciting agent. Exhibit 20 at 6.

On January 13, 2005, W.C. received the hepatitis B vaccine and the inactivated polio vaccine. Following these vaccinations, W.C.'s mother reported that W.C. was irritable and experiencing gas. W.C.'s mother also noted that W.C. was starting to exhibit symptoms of reflux and continued to cry. Exhibit 2 at 15.

On February 10, 2005, W.C. received the haemophilus influenza type b ("HIB") vaccine and a second dose of the DTaP vaccine. W.C. then received the Prevnar and hepatitis B vaccines on March 24, 2005 and reported no complaints following the vaccinations. Id. at 17-18.

On April 10, 2005, W.C. was seen in the emergency room because of an increase in crying and loose stools. He was diagnosed with gastroenteritis. On April 18, 2005, W.C. was seen in the pediatric gastroenterology and nutrition department of Winthrop Hospital. W.C. had a history of symptoms including irritability, gassiness, occasional vomiting, diarrhea, and constipation while taking Prevacid and Zantac with no relief. W.C. was ordered to start Prilosec at 10mg

[4] An infant with a two-vessel cord has a single umbilical artery, as opposed to the normal three-vessel cord with two arteries. "A single umbilical artery occurs in fewer than one percent of cords in singletons and five percent of cords in at least one twin." Twenty percent of infants with a two-vessel cord are reported to have "fetal anomalies." Exhibit E (Beal, MH & Ross, MG, "Umbilical Cord Complications," http://emedicine.medscape.come/article/262470-overview (Updated Sept. 1, 2010)) at 2.

and given instructions to continue with his formula while eating "Stage I foods." Id. at 4-7.

W.C. saw Dr. Pamela Banks on April 29, 2005, for his six-month examination. Dr. Banks noted that W.C. was a twin, born with a 2-vessel cord, and had a possible hiatal hernia at birth. She also noted that W.C. was a poor feeder and sleeper, had a twitch, and suffered from constipation. After her examination, Dr. Banks recorded that W.C. was unable to focus, could not keep his head up, and was unable to reach for objects. Following the examination, Dr. Banks recommended early intervention and a neurology consultation. Exhibit 3 at 1.

On May 5, 2005, W.C. received an eye examination from Pediatric Ophthalmology of Greater New York. After testing, Dr. Barry Pinchoff noted that W.C. had significant visual and developmental delays. Dr. Pinchoff concluded that "the lack of visual responsiveness with the developmental delays and the absence of nystagmus is suggestive of neurologic abnormalities." W.C. was referred for further neurologic consultation. Exhibit 3 at 61.

W.C. was seen at the Division of Pediatric Gastroenterology and Nutrition on May 12, 2005. A physical examination revealed that W.C. had poor head control and lacked the ability to follow objects with his eyes. He was diagnosed with constipation and minimal gastrointestinal reflux, and started on laxatives. Id. at 57-58.

On May 31, 2005, Dr. Vijaya L. Atluru conducted a neurologic examination of W.C. He was seven months old. During the exam, Dr. Atluru observed that W.C. had "significant developmental delay functioning at 2-3 month level. Neurologic findings suggestive of central dysfunction." Dr. Atluru recommended an "MRI brain [scan] to rule out structural abnormalities" and an "EEG to rule out seizures." Id. at 56.

On June 10, 2005, a second pediatric neurologist, Dr. Freddie Marton, examined W.C. Dr. Marton noted that W.C.'s "growth and development were fine for the first 3 months," however, after this point, W.C.'s parents became concerned about his inability to focus and also reported stiffness in his body compared to his twin brother. Dr. Marton observed that W.C. was not able to "sit, roll, crawl or stand," and his final impression of W.C. was that he had a "clinical picture consistent with global developmental delay and encephalopathy of unknown etiology." Id. at 54, 55.

Dr. Marton suggested W.C.'s eye-rolling and shaking might suggest a possible seizure disorder. Dr. Marton recommended an MRI and electrocardiogram and that W.C. see a geneticist. Id.

The MRI and electrocardiogram were performed on June 22, 2005. The results of both tests were normal. Exhibit 5 at 4-5. W.C. returned to Dr. Atluru's office on July 5, 2005. Dr. Atluru recorded that developmentally, W.C.'s head control was better, although not normal, and he was still not able to roll over or sit. Dr. Atluru also noted that W.C. still did not reach for objects and was not babbling similar to a child of his age. Dr. Atluru concluded that W.C. suffered from "probable static encephalopathy with severe global developmental delay, functioning at 2-3 month level. MRI brain was normal. Metabolic disorders including a leukodystrophy, carnitine deficiency considered." Dr. Atluru recommended that W.C. consult a metabolic specialist and continue physical therapy, occupational therapy, and feeding therapy. Exhibit 5 at 4-6.

On July 12, 2005, W.C. visited Dr. Banks for his nine-month checkup. Dr. Banks noted that W.C. was "grossly delayed" and proceeded to schedule W.C. for an endocrine and metabolic workup. During this appointment, W.C. received the Pediarix vaccine, which is the subject of this petition. W.C. was scheduled to return to Dr. Banks at 12 months. Exhibit 3 at 3.

On July 19, 2005, Dr. Lydia Eviatar, a neurologist at Schneider Children's Hospital, examined W.C. to assess his neurological issues. During her examination, she noticed "very little visual tracking and very poor interactive behavior." In addition to the poor visual tracking, Dr. Eviatar also noted that W.C. occasionally darted his eyes and stiffened his upper extremities including tightening his whole body. She characterized W.C.'s condition as dystonia,[5] and noted scissoring in W.C.'s lower extremities. Dr. Eviatar recorded that some of W.C.'s "episodes appeared to be seizure-like." Exhibit 6 at 2-10, 87-89.

On August 9, 2005, three weeks after being examined by Dr. Eviatar, W.C. was admitted to the hospital for video EEG monitoring to rule out the possibility of neurotransmitters disorder or W.C. being epileptogenic.[6] The results of this

[5] Dystonia is defined as "a disorder of movement characterized by sustained muscle contraction, frequently causing twisting and repetitive movements or abnormal postures." Nelson's Textbook of Pediatrics (19th ed. 2011) at 2058.

[6] Epileptogenic is defined as "producing epileptic attacks." Dorland's at 641.

monitoring revealed episodes in W.C.'s sleep, which were consistent with "generalized epilepsy." These findings prompted Dr. Eviatar to start W.C. on Zonegran, an anticonvulsant medication. Id. at 2-10, 87-89.

On August 19, 2005, W.C.'s mother phoned Dr. Banks to report that W.C. had a 30-minute seizure at home. He was admitted to Schneider Children's Hospital and treated with Phenobarbital and Vigabatrin. Exhibit 3 at 3. Following the seizure, W.C. had a normal brain MRI on August 20, 2005. Subsequent EEGs performed on August 30, 2005 and September 20, 2005, indicated the presence of bilateral cerebral dysfunction, with a classification of hypsarrhythmia.[7] Exhibit 6 at 13, 16, 73-74.

On September 2, 2005, W.C. underwent a neurologic follow-up with Dr. Eviatar. An examination revealed that W.C. suffered from cortical blindness, spastic quadriparesis, and the most severe form of cerebral palsy.[8] Follow-up appointments with Dr. Eviatar[9] revealed similar findings, including that W.C. suffered from infantile spasms and was now legally blind. W.C. was started on Topamax, in addition to the Phenobarbital and Vigabatrin. On November 8, 2005, W.C. was started on a ketogenic diet. Id. at 86-100.

W.C. continued to undergo neurological follow-up examinations. Id. at 102-06, 111-115. On January 30, 2006 W.C. saw Dr. Rami Grossman, a pediatric neurologist. After a physical examination, Dr. Grossman concluded that W.C. suffers from, "severe intractable seizure disorder; infantile spasms; life threatening reaction to ACTH; severe global developmental delay; borderline microcephaly; and hypotonia." Exhibit 7 at 1-3.

Dr. Grossman ordered an EEG, ambulatory recorder, a MRI and MRA with contrast, and a blood test. He recommended that W.C.'s Vigabatrin dose be increased to 500mg in the morning, and 1000mg in the evening, and that W.C.'s ketogenic diet and Klonopin dosage continue. Id.

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[7] Hypsarrhythmia is an electroencephalographic abnormality, most commonly found in cases of jackknife seizures. Dorland's at 908.

[8] Amended records from Dr. Eviatar state that W.C. "carries the diagnosis of Cerebral Palsy, cortical blindness, and infantile spasms." Exhibit 6 at 119.

[9] Follow-up appointments with Dr. Eviatar took place on September 20, 2005, October 6, 2005, October 11, 2005, November 1, 2005, November 8, 2005, and November 17, 2005.

An EEG conducted on January 30, 2006 returned abnormal, a finding indicative of the potential for a severe seizure disorder according to Dr. Grossman. A subsequent EEG, performed on May 22, 2006, was again abnormal, and now indicated "the presence of an active seizure disorder and a diffuse cerebral dysfunction." Id. at 4, 9.

At four years old, W.C. could not communicate or ambulate. Exhibit 4 at 10. At the hearing, petitioners did not present any evidence that W.C. improved, and given the severity of infantile spasms, improvement is, unfortunately, not likely.

III. Standards for Adjudication

There are at least three distinct parts to evaluating whether a petitioner is entitled to compensation. One part is to articulate the elements of the petitioner's case. These elements are "what" petitioner must establish. A separate part of the analysis is the quantum of evidence that a petitioner must introduce, which is the burden of proof. A final aspect is the process of weighing the evidence that is submitted. These three portions are discussed separately.

A. Elements of Petitioner's Case

The Vaccine Act sets out five elements for entitlement to compensation, listed in paragraphs (A) through (E) of section 11(c)(1). This case raises issues relating to paragraph (C), which requires a showing that a covered vaccine either caused or significantly aggravated an injury. The ways that petitioners can establish that a vaccine was the cause of an initial injury or that the vaccine significantly aggravated a pre-existing condition are discussed in section IV below.

B. Burden of Proof

For the elements that petitioners are required to prove, their burden of proof is a preponderance of the evidence. 42 U.S.C. § 300aa−13(a)(1). The preponderance of the evidence standard, in turn, has been interpreted to mean that a fact is more likely than not. Moberly v. Sec'y of Health & Human Servs., 592

F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between "preponderant evidence" and "medical certainty" is important because a special master should not impose an evidentiary burden that is too high. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing special master's decision that petitioners were not entitled to compensation); see also Lampe v. Sec'y of Health & Human Servs., 219 F.3d 1357 (2000); Hodges v. Sec'y of Health & Human Servs., 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with dissenting judge's contention that the special master confused preponderance of the evidence with medical certainty). In this regard, "close calls regarding causation are resolved in favor of injured claimants." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005).

C. How to Weigh Evidence

The remaining issue is how to evaluate evidence submitted to meet the standard of proof on those elements. Three authorities generally instruct special masters in how to evaluate evidence. They are Congress, the United States Court of Federal Claims, and the United States Court of Appeals for the Federal Circuit.

Congress is the first authority for instructions about how to weigh evidence. In enacting the National Vaccine Injury Compensation Act, specifically section 13, Congress provided some instructions about how special masters should analyze the evidence. Among other provisions, section 13 dictates that the special master should consider "the record as a whole." Section 13 also provides that the special master shall consider "any diagnosis, conclusion, medical judgment or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition or death." Nevertheless, "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court."

The second authority is the United States Court of Federal Claims, in its capacity as rule maker. Congress authorized the Court of Federal Claims to promulgate rules of procedure for cases in the Vaccine Program. 42 U.S.C. § 300aa−12(d)(2). Collectively, the judges of the Court of Federal Claims have issued the Vaccine Rules. The Vaccine Rules, in turn, provide that the special

master "must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties." Vaccine Rule 8(b)(1).

The third authority is the United States Court of Appeals for the Federal Circuit. Decisions by the Federal Circuit are binding precedent. 42 U.S.C. § 300aa−12(e). Within the Vaccine Program, the Federal Circuit expected that special masters would "consider[] the relevant evidence of record, draw[] plausible inferences and articulate[] a rational basis for the decision." Hines ex rel. Sevier v. Sec'y of Health & Human Servs., 940 F.2d at 1528. The Federal Circuit expects that a special master will present a reasonable basis for rejecting the opinion of an expert. Lampe, 219 F.3d at 1361; Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993).

These standards will be used to determine whether the petitioners have established entitlement to compensation. For the reasons explained below, the evidence does not support an award of compensation to the petitioners.

IV. Analysis

The petitioners are presenting alternative causes of action. The petitioners' primary cause of action is that W.C.'s seizure disorder and developmental delay developed after he received the third DTaP vaccination on July 12, 2005, and that the vaccine caused his condition. The alternative theory of relief assumes that W.C. was suffering from developmental delay and seizures when he received the third dose of the vaccine. In this theory, the petitioners maintain that the vaccine significantly aggravated his condition.

The preliminary step in adjudicating the petitioners' claim is to resolve when W.C. first exhibited seizure symptoms. This finding will determine if petitioners' causation-in-fact theory is viable. If W.C. was already suffering from infantile spasms when he was vaccinated in July 2005, then the vaccine cannot have caused his infantile spasms. See Locane v. Sec'y of Health & Human Servs., 685 F.3d 1375, 1381 (Fed. Cir. 2012) (stating that "[g]iven the Special Master's finding that the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness"); W.C. v. Sec'y of Health & Human Servs., 100 Fed. Cl. 440, 451 (2011) (stating that "[i]f [petitioner] became ill before receiving the vaccine, a fortiori, he cannot show that . . . the vaccine was a 'but-for' cause of his [disease]"), appeal docketed, No. 2012-5058 (Fed. Cir. Jan. 27, 2012).

A. Causation-in-fact: Did W.C.'s vaccination on July 12, 2005 cause his seizure disorder?

Petitioners claim that although W.C. suffered from developmental delays before the vaccination date, W.C.'s seizures were caused by the July 12, 2005 vaccine. The Secretary argues that W.C. exhibited seizure-like symptoms including infantile spasms prior to the vaccination date, negating the July 12, 2005 vaccine as the cause of his infantile spasms. A preponderance of the evidence supports a finding that W.C. was already suffering from developmental delay and infantile spasms before he received the third dose of the vaccine. As explained below, W.C.'s clinical course before vaccination was consistent with how infantile spasms typically present. See exhibit A (Dr. Snyder's report) at 5.

Infantile spasms are a form of epilepsy found in infants and characterized by brief, symmetrical contractions of the musculature of the neck, truck, and extremities. These spasms normally last up to five seconds and occur in clusters. Exhibit N (John M. Pellock et al., "Infantile spasms: A U.S. consensus report," 1991 Epilepsia 51(10)) at 2175–76.

Infantile spasms typically start during the first year of the child's life, with the first occurrence between the third and eighth months. The peak onset of infantile spasms is between four to six months. Exhibit H (Glauser, TA & Morita, DA, Infantile Spasm (West Syndrome), http://emedicine.medscape.com/article/1176431-overview (Updated 4/26/10)).

Physical symptoms can be minimal during the early stages of infantile spasms, and the patient may have normal findings after general examinations. If physical symptoms are present during the manifestation of infantile spasms, they can be as subtle as head nodding or as severe as powerful contractions of the body. The spasms typically occur just before sleep, or shortly after the infant is awakened. Id.

Most cases of infantile spasms have a dreadful outcome. Dr. Chen stated "once you have infantile spasms the chances of being developmentally normal is practically nil." Tr. 116. In Dr. Snyder's view, mental retardation occurs in 90 percent of children with infantile spasms. Tr. 222.

Both experts testified that early detection of infantile spasms is difficult. Dr. Chen testified that symptoms of infantile spasms are typically subtle at first, and that early EEG findings may show "little or nothing" before becoming more

progressively obvious. Tr. 111. Similarly, Dr. Snyder stated in his report that infantile spasms are difficult to diagnose due to a subtle onset and are often not diagnosed until the "the jerks become more forceful or the child begins to lose developmental skills." Exhibit A at 5 (citing exhibit K (EH Kossoff, "Infantile Spasms," 16 The Neurologist 69-75 (2010) at 69).

In this case, both experts reviewed the medical records documenting W.C.'s health. Each expert reached the same conclusion – W.C. was manifesting signs and symptoms of infantile spasms before his July 12, 2005 vaccination. Dr. Chen testified that the onset of symptoms could be traced to the two-month, December 10, 2004 dose of the vaccine.[10] He testified: "I state now even more adamantly that this process of the response, we can attribute it to the vaccine having an effect on the 12th of July, then the similar process should have been started when he [W.C.] was two months old." Tr. 105; accord tr. 140-42; tr. 150-51.

Dr. Chen testified that, although not documented as seizures, W.C. exhibited behavior indicating infantile spasms prior to the July 12, 2005 dose of the vaccine. Tr. 105-06. These symptoms included upward rolling of the eyes, twisted hands, and lack of visual tracking. Dr. Chen referenced a report from Dr. Atluru, dated May 31, 2005, in which Dr. Atluru noted these signs and recorded that W.C. was suffering from "significant developmental delay function at 2-3 month level." Tr. 104-06; see also exhibit 3 at 56. Dr. Chen agreed with this finding, testifying that W.C. suffered significant developmental delay prior to the July 12, 2005 dose of the vaccine. Tr. 102.

Dr. Snyder also testified that symptoms of seizures manifested prior to July, 2005. Dr. Snyder indicated that W.C. was probably manifesting infantile spasms as early as April 2005. Dr. Snyder referred to a record from Dr. Banks, dated April 29, 2005, which indicated that W.C. suffered from a positive twitch and developmental delay. Dr. Snyder viewed this twitch as an early manifestation of W.C.'s infantile spasms. Tr. 295; see also exhibit 3 at 1-2.

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[10] The statute of limitations prevented the petitioners from pursuing Dr. Chen's theory that the December 10, 2004 vaccination *caused* W.C.'s infantile spasms. See 42 U.S.C. § 300aa-16; Cloer v. Sec'y of Health and Human Servs., 654 F.3d 1322, 1335 (Fed. Cir. 2011) (en banc) (citing Markovich v. Sec'y of Health and Human Servs., 477 F.3d 1353, 1360 (Fed. Cir. 2007)).

The statute of limitations appears to have forced Dr. Chen to render an opinion that focused on the third dose of the DTaP vaccine, rather than either of the first two doses. See tr. 104, tr. 107, tr. 149.

Here, both experts agreed that W.C. exhibited symptoms of infantile spasms and global developmental delays prior to the July 12, 2005 dose of the vaccine. Tr. 111 (Dr. Chen); tr. 224-230 (Dr. Snyder). Thus, a preponderance of the evidence supports finding that the vaccine did not cause W.C.'s injury.

Petitioners' argument that W.C. started suffering from infantile spasms after his July 12, 2005 vaccination is based upon the fact that W.C. was actually diagnosed with infantile spasms after the vaccination. See Pet'r Posthr'g Br. at 3-4. This argument is not persuasive. Both experts testified that because of the subtle presentation of infantile spasms, an infant may display manifestations of that dreadful disease long before the disease is diagnosed. Tr. 111 (Dr. Chen); tr. 223 (Dr. Snyder). Thus, it is the date of onset that is significant to this analysis, not the date of diagnosis.[11]

Despite petitioners' argument, the undisputed medical evidence weighs strongly in favor of finding that W.C. was manifesting infantile spasms well before July 12, 2005. Consequently, the petitioners cannot proceed on their claim that the July 12, 2005 vaccination caused W.C.'s infantile spasms. See Locane, 685 F.3d at 1381.

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[11] The difference between the date of onset and the date of diagnosis has been recognized in a variety of cases. E.g. White v. Sec'y of Health & Human Servs., No. 04-337V, 2011 WL 6176064, at *11 (Fed. Cl. Spec. Mstr. Nov. 22, 2011) (autism); Porter v. Sec'y of Health & Human Servs., No. 99-639V, 2008 WL 4483740, at *16 (Fed. Cl. Spec. Mstr. Oct. 2, 2008) (autoimmune hepatitis), motion for review granted sub nom. Rotoli v. Sec'y of Health & Human Servs., 89 Fed. Cl. 71 (2009), decision reinstated, 663 F.3d 1242, 1254 (Fed. Cir. 2011); Locane v. Sec'y of Health & Human Servs., No. 99-589V, 2011 WL 3855486, at *6 (Fed. Cl. Spec. Mstr. Feb. 17, 2011) (Crohn's disease), motion for review denied, 99 Fed. Cl. 715, 726 (2011), aff'd, 685 F.3d 1375 (Fed. Cir. 2012); W.C. v. Sec'y of Health & Human Servs., No. 07-456V, 2011 WL 4537877, at *6-8 (Fed. Cl. Spec. Mstr. Feb. 22, 2011) (multiple sclerosis), motion for review denied in relevant part and granted in non-relevant part, 100 Fed. Cl. 440, 451 (2011), appeal docketed, No. 2012-5058 (Fed. Cir. 2012); Cloer v. Sec'y of Health & Human Servs., No. 05-1002, 2008 WL 2275574, at *7-9 (Fed. Cl. Spec. Mstr. May 15, 2008) (multiple sclerosis), aff'd, 85 Fed. Cl. 141, 148-49 (2008), rev'd, 603 F.3d 1341 (2010), aff'd on rehearing en banc, 654 F.3d 1322, 1339-40 (Fed. Cir. 2011) (en banc), cert. denied, Cloer v. Sebelius, 132 S.Ct. 1908 (2012).

B. Significant aggravation

Although the petitioners cannot establish that the third dose of the vaccine caused W.C.'s condition, the petitioners would be entitled to compensation if they established that the vaccine significantly aggravated his condition. 42 U.S.C. § 300aa-11(c)(ii)(I). The Secretary introduced this theory of recovery in her prehearing brief, and this theory was further discussed at the hearing and in the posthearing briefs.

The Vaccine Act defines "significant aggravation" as a "change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42 U.S.C. § 300aa-33(4). Elements for a claim based upon significant aggravation are set forth in Loving v. Sec'y of Health & Human Servs., 86 Fed. Cl. 135, 144 (2009).[12] One part of an analysis of a significant aggravation claim is evaluating whether the vaccine made the person worse than the person would have been but for the vaccination. In doing so, the natural course of the disease must be considered. Locane v. Sec'y of Health & Human Servs., 99 Fed. Cl. 715, 731 (2011) (finding that the special master was not arbitrary in denying compensation when the petitioner "failed to present persuasive evidence that separates [her] problems from an expected course" of the disease afflicting her), aff'd 685 F.3d at 1382; Hennessey v. Sec'y of Health & Human Servs., No. 01-190V, 2009 WL 1709053, at *41-42 (Fed. Cl. Spec. Mstr. May 29, 2009), motion for review denied, 91 Fed. Cl. 126 (2010).

[12] The following elements must be proved by a preponderance of the evidence:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a "significant aggravation" of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

1. Did the third dose of the DTaP vaccine significantly aggravate W.C.'s developmental delay and seizure disorder?

Here, a preponderance of the evidence demonstrates that W.C.'s course was consistent with the natural course of infantile spasms and was not affected by the third dose of the DTaP vaccine. The medical record and petitioner's expert fail to offer any persuasive basis for finding that the third dose of the vaccine made W.C.'s condition worse than it otherwise would have been.

To support their significant aggravation claim, petitioners essentially present two arguments. First, petitioners compare the results of studies of W.C.'s brain before and after vaccination. Pet'r Posthr'g Br. at 9 (citing exhibit 5 at 6). On June 22, 2005, W.C. underwent an MRI brain scan and sedated EEG. The results were normal. Petitioners contrast these tests results with other tests given to W.C. after the vaccination. Dr. Eviatar concluded that W.C. had "an abnormal EEG consistent with symptomatic generalized epilepsy." Pet'r Posthr'g Br. at 9 (citing exhibit 3 at 88); see also exhibit 6 at 10.

Dr. Snyder explained that this sequence of EEGs does not suggest that an intervening event (like the vaccination) worsened the infantile spasms. He testified that in persons with infantile spasms, it is common for an EEG to return a normal result initially, and to evolve into an abnormal EEG later. Tr. 233-34; see also exhibit D (Tallie Z. Baram, "Myoclonus, myoclonic seizures, and infantile spasms," Pediatric Neurology: Principles & Practice 1067 (Kenneth F. Swaiman et al. eds., 4th ed. 2006)).

Dr. Chen agreed that an EEG can be normal early in the course of infantile spasms. Tr. 122. Dr. Chen forthrightly explained that EEGs that monitor a person for a relatively short time can miss seizure activities. Tr. 19-21. He also stated that "even though the EEG was normal, it doesn't mean that the child was normal. It could have been that he was having infantile spasms, the very beginning of it, but it's just that the evidence was not there at that moment in time." Tr. 109.

Dr. Chen also agreed with Dr. Snyder's discussion of how infantile spasms progresses. Dr. Chen testified that the natural evolution in infantile spasms is from mild to severe. He testified that the manifestation of infantile spasms "has a normal evolution in time course" and that "the natural evolution" is from mild to severe. Tr. 145. He explained that these spasms do not resolve, but rather "evolve into something else." Tr. 116.

The experts' explanations suggest that W.C.'s course did follow the natural course of the disease. Thus, because W.C.'s condition was evolving from a milder form of infantile spasms to a more severe state, it is not unusual that W.C. received a normal EEG result before the third dose of the vaccine, and then received an abnormal result after the vaccine.

Petitioners' second argument is that W.C. worsened developmentally after receiving the third dose of the vaccine. Pet'r Posthr'g Br. at 5. In support of this argument, Dr. Chen relied upon a July 19, 2005 record from Dr. Eviatar. Tr. 120-21. He stated that because Dr. Eviatar's clinical description of W.C. was "intense, more descriptive, [and] a lot longer" than the picture presented by Dr. Atluru and Dr. Martin prior to the vaccine, he concluded that W.C.'s condition worsened. Tr. 128-29. However, Dr. Chen struggled to identify new signs or symptoms that W.C. developed after the vaccine. He testified that scissoring, hyporeflexia, and upgoing toes were new symptoms, but then clarified that upward toes and scissoring may not have been new. Additionally, Dr. Chen stated that there is some confusion as to whether Dr. Eviatar meant hyporeflexia or hyperreflexia, so hyporeflexia may also not be a new symptom. Tr. 131-33.

Dr. Chen stated that W.C. would be "somewhat better" if he had not received the July 12, 2005 dose of DTaP, but that the damage to W.C. had already occurred. Tr. 197-99. When asked specifically if W.C. would have been able to walk if he had not received the third dose, Dr. Chen stated, "I would say it's a coin toss. I wouldn't really know." Tr. 200.

Dr. Snyder testified that W.C.'s condition represented the natural "evolution of the infantile spasm process," and thus did not worsen due to the third dose of the vaccine. Tr. 230. Additionally, Dr. Snyder did not find any new signs or symptoms to suggest a worsening of W.C.'s pre-existing condition. Dr. Snyder testified that W.C. did not have a fever and did not exhibit changes in behavior post-vaccination. In response to Dr. Chen's suggestion that scissoring of the legs and upward toes were new signs, Dr. Snyder stated that scissoring would be a nonspecific sign and that upward toes "are normal at this age." Tr. 232-33.

The medical records and the expert testimony do not constitute persuasive evidence that W.C.'s condition was aggravated following his receipt of the third dose of the vaccine. Persuasive evidence suggests that the vaccine did not play any role in W.C.'s course. Dr. Chen failed to identify ways that W.C. was worse than expected. Dr. Chen could not identify any new signs or symptoms following W.C.'s July 12, 2005 vaccination, and admitted that symptoms he thought might

be new may also be reoccurring symptoms. Dr. Snyder explained that W.C.'s course matched the natural process for infantile spasms. For all these reasons, there is not preponderant evidence that W.C.'s infantile spasms were significantly worse than they would have been if he had not received the third dose of DTaP.

Thus, a discussion of the other prongs from Althen and Loving is not needed. However, for the sake of completeness, a brief discussion follows.

2. Prong One from *Althen*: Did petitioners present a persuasive medical theory showing that the DTaP vaccine can significantly aggravate infantile spasms?

In an off-Table significant aggravation case, petitioners are required to show "a medical theory causally connecting such a significantly worsened condition to the vaccination." Loving, 86 Fed. Cl. at 144, relying on Althen, 418 F.2d at 1278. This element of petitioners' case is sometimes referred to as answering the "can it" question. Pafford v. Sec'y of Health & Human Servs., No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), aff'd, 64 Fed. Cl. 19 (2005), aff'd, 451 F.3d 1352 (Fed. Cir. 2006).

Here, Dr. Chen essentially brought out two different theories to explain how a vaccine can significantly aggravate infantile spasms.[13] Early in his testimony, he stated that when individual vaccines are combined into one product (as with Pediarix), "the total is greater than the sum of those parts." Dr. Chen hypothesized the combined vaccine may "become too strong, too much of a good thing" and cause the individual receiving the combined vaccine to have a greater immune response. Tr. 57-61; tr. 63; see also exhibit 23 at 8-9. When asked by the undersigned to explain his reasoning for this statement, Dr. Chen testified that "it's pure chemistry." Tr. 190.

[13] To be more precise, Dr. Chen discussed theories by which the DTaP vaccine could cause infantile spasms. He did not set forth any alternative theory by which the DTaP vaccine could significantly aggravate infantile spasms. Nevertheless, given the petitioners' pro se status, it is assumed that the petitioners intended that Dr. Chen's theories explaining causation would also explain significant aggravation. Likewise, Dr. Snodgrass's opinions about why the evidence does not support a theory for causation are accepted as opinions why the evidence does not support a theory for significant aggravation.

Later in this testimony, Dr. Chen stated that his "entire theory is based on autoimmune mechanisms." Tr. 141. He explained that "so many autoimmune processes have been associated with vaccinations that we can go on and on . . . [but that he is] open to the suggestion that one of the causes could be autoimmune-related vaccine reactions." Tr. 213-14; see also exhibit 20 at 8a and exhibit 23 (Dr. Chen's report) at 8-9.

With respect to either the "too many vaccines" theory or the autoimmune theory, petitioners did not present any evidence showing "some indicia of reliability to support the assertion of the expert witness." Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010). Rather, Dr. Chen repeatedly referenced the package insert for Pediarix, which summarizes results from a German study on the safety of Pediarix. See tr. 24; tr. 47-50; tr. 73-77; tr. 174.

The package insert's summary of the German safety study contains four sentences. It states that 4,666 people (presumably infants) received Pediarix. From this group six subjects had seizures. Of these six, two of those children had afebrile seizures and infantile spasms. Other children had seizures with and without fever. Exhibit 24 at 106-07. Dr. Chen found significance in these results because of his comparison between the incidence of infantile spasms and the incidence of seizures. Tr. 30-32; tr. 156 (Dr. Chen stating "So the ratio is much higher than I would expect compared to 'the background.' This is just a gut feeling."); tr. 176 (Dr. Chen stating "That's how I'm making the inference.").

The package insert states that the administration of Pediarix is contraindicated in people with "progressive neurological disorders, including infantile spasms." Exhibit 24 at 101. Dr. Chen sees this contraindication as supporting a conclusion that Pediarix can aggravate infantile spasms. Tr. 26. However, this warning is not an admission that Pediarix worsens those progressive neurological disorders. See Werderitsh v. Sec'y of Health & Human Servs., No. 99-319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005) (quoting 21 C.F.R. § 600.80(l) as saying "[a] report or information submitted by a licensed manufacturer . . . does not necessarily reflect a conclusion by the licensed manufacturer or FDA that the report or information constitutes an admission that the biological product caused or contributed to an adverse effect"). The recommendations on the package insert constitute, according to Dr. Snyder, "defensive medicine on the part of the package insert people." Tr. 299. It appears that the package insert's contraindication does not guide practice in the field because, according to Dr. Snyder, most pediatricians would have vaccinated W.C.

in July 2005, despite his showing of some symptoms of a neurological disorder. Tr. 254-55.[14]

Likewise, the German study has limited persuasive value. As Dr. Snyder pointed out, the study as reported in the package insert did not "take into account the inciden[ce] of infantile spasms which is about one to 2,000 live births to one to 4,000 live births." Thus, in a population of approximately 4,000 infants, "you would expect two cases of infantile spasms, which is what they found." Tr. 234.

Although Dr. Chen is not an epidemiologist, tr. 170-71, he recognized the background incidence of infantile spasms is important to understanding the results found in Germany. Dr. Chen testified:

> [I]t's a statistical association, six cases of seizures out of 4,666 and two cases of infantile spasms out of 4,666. I don't know offhand what the actual statistics are in reference to the general population, the number of cases of infantile spasms that occurred annually on a per thousand or per hundred thousand cases. I don't have the statistics.

Tr. 49; accord tr. 153-55. Without some showing that the incidence of infantile spasms in children who received Pediarix was more than the expected incidence of infantile spasms, it is difficult to give much weight to the German safety study. See Watson v. Sec'y of Health & Human Servs., No. 96-639V, 2001 WL 1682537, at *14-15 (Fed. Cl. Spec. Mstr. Dec. 18, 2001) (discussing report of Institute of Medicine describing need for background rate); cf. Arkansas Game and Fish Comm'n v. United States, 87 Fed. Cl. 594, 629-32 (2009) (using background mortality rate of trees to assess whether flooding harmed a forest), rev'd, 637 F.3d 1366 (Fed. Cir. 2011), reh'g and reh'g en banc denied, 648 F.3d 1377 (Fed. Cir. 2011), certiorari granted, 132 S.Ct. 1856 (2012).

Information that is more meaningful comes from studies that took into account the background rate for infantile spasms. Dr. Snyder cited two studies that

[14] Dr. Snyder's own preference would have been to recommend a delay in W.C.'s vaccination. Tr. 255; tr. 286. Upon questioning by the petitioners, Dr. Snyder explained that his caution was based upon his experience that vaccinations can cause "various legal activities," not that vaccinations can cause injuries. Tr. 300.

assessed whether the change in vaccination schedule affected the incidence of infantile spasms in Denmark. Exhibit A at 4 (citing exhibit L (J.C. Melchior, "Infantile spasms and early immunization against whooping cough, 52 Archives of Disease in Childhood 134 (1977)) and exhibit P (W. Donald Shields et al., "Relationship of pertussis immunization to the onset of neurological disorders: A retrospective epidemiologic study," 113 No. 5 Journal of Pediatrics 801 (1988)); tr. 244; tr. 247. These studies did not find that the vaccination schedule caused any change. These studies were among the reasons why Peter Camfield, who is a distinguished neurologist, concluded that "any relationship [between DTP immunization and brain damage] is likely a temporal coincidence because DTP is administered several times in infancy." Exhibit F (Peter Camfield, "Brain Damage from Pertussis Immunization," 1992 American Journal of Diseases of Children 146) at 327. Dr. Camfield's work and other publications may explain why, by Dr. Chen's admission, the theory that Pediarix can cause (or significantly aggravate) infantile spasms is not commonly accepted. Tr. 166.

In sum, through Dr. Chen's testimony, petitioners have advanced theories that the Pediarix vaccine can cause (or significantly aggravate) infantile spasms. For each point made by Dr. Chen, Dr. Snyder explained why Dr. Chen's opinion was not reliable or supported. Consequently, the petitioners have failed to meet their burden of producing a reliable theory explaining how the Pediarix vaccine can cause (or significantly aggravate) infantile spasms. See Knudsen ex rel. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548 (Fed. Cir. 1994) (petitioners' theory of causation must be supported by a "sound and reliable medical or scientific explanation").

3. Prong Two from *Althen*: Did the DTaP vaccine W.C. received significantly aggravate his infantile spasms?

Another element of a significant aggravation case is "a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation." Loving, 86 Fed. Cl. at 144, relying on Althen 418 F.3d at 1278. This prong has been interpreted to mean an inquiry into whether the vaccine "did cause" the injury to the vaccinee. Pafford, 451 F.3d at 1354. Under this prong, the relevant evidence tends to be evidence specific for the petitioner, as opposed to evidence about causation in general. In particular, statements from treating doctors that a vaccine caused their patient's injury can be quite probative. Moberly, 592 F.3d at 1323; Capizzano, 440 F.3d at 1326.

As a matter of logic, the first and second prongs relate to each other. See Capizzano, 440 F.3d at 1327 ("We see no reason why evidence used to satisfy one of the Althen III prongs cannot overlap to satisfy another prong."). If it is found that the vaccine "did cause" an injury, then the vaccine must be capable of causing the injury. Conversely, if there has not been a showing that the vaccine "can cause" an injury, then the vaccine cannot be said to have caused the injury for a specific petitioner. See Caves v. Sec'y of Health & Human Servs., 100 Fed. Cl. 119, 145 (2011), aff'd, 100 Fed. Appx. 932 (Fed. Cir. 2012).

This case falls into the latter category. Because Dr. Chen has not presented a reliable theory to show that the vaccine can cause (or significantly aggravate) infantile spasms, it cannot be said that the vaccine caused (or significantly aggravated) infantile spasms in W.C.

At times during Dr. Chen's testimony, he struggled to express an opinion that the vaccine harmed W.C. When petitioners asked Dr. Chen whether he could "make a cause and effect link between the vaccination and aggravation of [W.C.'s] preexisting medical condition to cause seizures," Dr. Chen responded negatively. He stated: "I would say no, that certainly he had a preexisting condition before July 12. Whether that condition was due to the umbilical vessel disease disorder that's postulated or might be due to an earlier vaccine." Tr. 82. When petitioners followed up on this response, Dr. Chen stated that the he would rate the acellular pertussis vaccine "slightly higher than the two-vessel umbilical" cord disease. Tr. 83. In this context, petitioners pressed Dr. Chen to state there was a cause and effect relationship and Dr. Chen, again, equivocated. He testified: "I wouldn't say a cause and effect. I would say a correlation. It's a little softer. It's more probable than not as I said earlier, but is there a direct cause and effect relationship because cause and effect implies medically something much stronger." This response led to the following exchange between the petitioners and Dr. Chen:

> Q: So you would say it's probable.
> A: It's probable.
> Q: Thank you.
> A: It may just be 51 to 49, but it's more than 50/50, let's put it that way. But how much more than that, 51 [to] 49, or 55 [to] 45, it's hard to say.

Tr. 84. While Dr. Chen ultimately agreed that his opinion was "probable," the overall context suggests that Dr. Chen was not confident in his opinion. Later Dr. Chen could not explain how the vaccine affected the course of W.C.'s

development, which, as discussed above, was already impaired because of the infantile spasms. See tr. 197-200.

Additionally, a treating physician did not conclude that the vaccine caused or significantly aggravated W.C.'s infantile spasms. Dr. Chen confirmed "none of W.C.'s treating physicians ever suggested that his infantile spasms were caused or aggravated by the July 12, 2005 vaccine."[15] Tr. 141. W.C. was seen by Dr. Eviatar seven days after receiving the third dose of the vaccine. Dr. Eviatar observed that some of W.C.'s episodes appeared to be "seizure-like" and she had him admitted for video EEG monitoring, which returned results suggestive of atypical infantile spasms. Exhibit 6 at 88. However, Dr. Eviatar does not make any statement connecting W.C.'s condition to his recent receipt of the vaccine.

4. Prong Three from *Althen*: Did W.C.'s injury occur within a medically acceptable timeframe after the vaccination to infer causation?

A third element of a significant aggravation case is "a showing of a proximate temporal relationship between the vaccination and the significant aggravation." Loving, 86 Fed. Cl. at 144, relying on Althen, 418 F.3d at 1278. The Federal Circuit has elaborated that the third prong of the Althen test requires "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." Bazan v. Sec'y of Health & Human Servs., 539 F.3d 1347, 1352 (Fed. Cir. 2008). Thus, the two components of this prong are the

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[15] Dr. Chen makes a conclusory statement that there is a logical sequence of cause and effect based on the fact that there is an absence of information showing W.C.'s condition was caused or aggravated by another factor. Pet'r Prehr'g Br. at 13-14 (quoting exhibit 20 at 8a) ("[T]he absence of any contravening evidence of hypoxic ischemia at birth and the absence of neurometabolic or genetic disorder together support the logic of the Petitioner's argument that the Pediarix vaccine combination caused significant aggravation of [W.C.'s] severe developmental delay and together demonstrate a …very probable and logical cause and effect relationship of the vaccination of July 12, 2005 and the acute seizure aggravation of July 19, 2005.").

Mere conclusory statements and opinions are not enough to establish, by a preponderance of the evidence, causation or significant aggravation. See Doyle v. Sec'y of Health & Human Servs., 92 Fed. Cl. 1, 8 (2010).

timeframe for which it is "medically acceptable to infer causation," and the onset of the aggravation.

Here, Dr. Chen's opinion regarding timing varied. When he was presenting a theory that Pediarix caused W.C.'s infantile spasms, Dr. Chen stated that seven to 14 days is an appropriate interval between the vaccination and the onset of infantile spasms. Tr. 102; see also tr. 35-37. On cross-examination, Dr. Chen was asked about an article by Mary Anne Guggenheim that Dr. Snyder had cited. Dr. Guggenheim concluded that the latency between the arguably inciting event and the manifestations of infantile spasms was 6 weeks to 11 months. Exhibit I (Mary Anne Guggenheim et al., "Time Interval from a Brain Insult to the Onset of Infantile Spasms," 38 No. 1 Pediatric Neurology 34 (2008)) at 35. Dr. Chen's direct response was that he agreed with the Guggenheim article. Tr. 149-50.[16]

Dr. Snyder discussed the Guggenheim article in his testimony. He stated the Guggenheim article "refutes the claim that a close temporal association between an immunization and the onset of infantile spasms establishes causation." Tr. 242.

In his rebuttal testimony, Dr. Chen changed to focus his opinion on whether DTaP significantly aggravated W.C.'s infantile spasms. In this context, Dr. Chen appeared to accept, again, the results of Guggenheim study. Dr. Chen stated that for a vaccine to cause the onset of infantile spasms, seven days is "unlikely or less than probable." However, Dr. Chen stated that seven days is an appropriate interval for the acceleration of a pre-existing condition. Tr. 210-11; see also exhibit 23 at 4. Dr. Chen did not explain why aggravation could occur much more quickly than direct causation.

Other than the Guggenheim article and Dr. Chen's testimony discussed above, the parties elicited almost no evidence about the appropriate medical interval. The parties' briefs are similarly short. See Pet'r Br., filed Feb. 29, 2012, at 15-16; Resp't Br., filed March 22, 2012, at 12; Pet'r Reply, filed June 1, 2012, at 6.

[16] Dr. Chen elaborated that the interval found in the Guggenheim study (6 weeks to 11 months) was consistent with Dr. Chen's opinion that the first or second doses of the pertussis-containing vaccines caused W.C.'s infantile spasms. In Dr. Chen's words, the alternative "acute exacerbation argument is entirely artificial." Tr. 150.

Under these circumstances, resolving whether seven days is an appropriate amount of time for vaccinations to aggravate infantile spasms is unnecessary. Even if petitioners were to have established that seven days is appropriate, timing is not enough. It has long been true in the Vaccine Program that for off-Table cases, a vaccination "'is not the cause of every event that occurs within the ten day period.'" Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992), quoting Hasler v. United States, 718 F.2d 202, 205 (6th Cir. 1983).

Here, the events that occurred after W.C.'s July 12, 2005 vaccination represent the ordinary and terribly unfortunate evolution of infantile spasms. In the final analysis, there is relatively little dispute about the decisive issues. Both Dr. Chen and Dr. Snyder agree that W.C.'s behaviors before July 2005, were consistent with infantile spasms. And both experts agree that infantile spasms almost always leave the child severely retarded. While one can postulate that DTaP somehow made W.C. worse than he would have been but for the vaccination, petitioners have failed to present a persuasive theory for how this could have happened and have failed to present a persuasive showing that this did happen.

V. Conclusion

Petitioners presented two claims for compensation for their son, W.C. Their first theory is that the July 12, 2005 dose of DTaP caused W.C. to suffer from seizures. This claim is not sustainable because W.C. actually was suffering from infantile spasms before he received the third dose of DTaP.

Petitioners' second theory is that the DTaP vaccination significantly aggravated W.C.'s condition. This claim is also not sustainable because neither the medical records nor the expert testimony was able to show persuasively that W.C. was any worse because of the third dose of the vaccine. Instead, the evidence showed that W.C.'s course followed the natural progression of infantile spasms.

The Clerk's Office is instructed to enter a judgment in accord with this decision unless a motion for review is filed.[17]

IT IS SO ORDERED.

Christian J. Moran
Special Master

[17] The undersigned reaches this decision notwithstanding Mr. Christiansen's and Mrs. Christiansen's love for W.C. The evidence simply compels findings that infantile spasms is a horrible disease that affected W.C. before the vaccination and the infantile spasms continued its awful course after the vaccination.

Mr. Christiansen's concern for his son motivated him to represent his son pro se. Mr. Christiansen handled this case with diligence and competence. Given what medical science knows about infantile spasms, it is extremely unlikely that a licensed attorney could have achieved a different result for W.C.