In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-318V

Filed: August 23, 2012

KELLY ARANGO, Parent of ISABELA OROZCO, A Minor,	)	TO BE PUBLISHED
Petitioner,	)	Entitlement; Table Injury; encephalopathy; infantile spasms; diphtheria- tetanus-acellular-pertussis (DTaP) vaccine; haemophilus influenza type B (Hib) vaccine; inactivated poliovirus (IPV) vaccine; Prevnar (pneumococcal 7-valent conjugate) vaccine; rotavirus vaccine
v.	)	
SECRETARY OF HEALTH AND HUMAN SERVICES,	)	
Respondent.	)	

David E. Marmelstein, David Marmelstein, Esq., Enfield, CT, for Petitioner;
Ryan D. Pyles, United States Dep't of Justice, Washington, DC, for Respondent.

DECISION ON ENTITLEMENT [1]

LORD, Special Master.

I. INTRODUCTION AND SUMMARY

On May 11, 2009, Kelly Arango ("Petitioner") filed a Petition on behalf of her daughter, Isabela Orozco ("Isabela"), under the National Vaccine Injury Compensation Program (the "Program"). See 42 U.S.C. § 300aa-1-34. The Petition alleged that Isabela suffered the Table injury of encephalopathy following administration of a diphtheria-tetanus-acellular pertussis ("DTaP") vaccine, haemophilus influenza type B ("Hib") vaccine, inactivated poliovirus ("IPV") vaccine, Prevnar (pneumococcal 7-valent conjugate) vaccine, and rotavirus vaccine, on March 28, 2008. Pet. at 1.[2] Petitioner also alleged that the vaccines "caused-in fact" Isabela's "fever, uncontrollable crying,

[1] In accordance with Vaccine Rule 18(b), a petitioner has 14 days to file a proper motion seeking redaction of medical or other information that satisfies the criteria in 42 U.S.C. § 300aa-12(d)(4)(B). Rules of the United States Court of Federal Claims ("RCFC"), Appendix B, Vaccine Rule 18(b). Redactions ordered by the special master, if any, appear in the document as posted on the United States Court of Federal Claims' website.

[2] To receive compensation under the Vaccine Act, a petitioner must prove either that: (1) he suffered a "Table injury" – i.e., an injury falling within the Vaccine Injury Table corresponding to one of his vaccinations; or (2) he suffered an "off-Table" injury that was actually caused by or "caused-in-fact" by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A), 11(c)(1); see also Shalala v. Whitecotton, 514 U.S. 268, 270 (1995).

jerking of [the] arms and legs, and a staring episode," encephalopathy and developmental delay. Pet. at 2, 3.

An entitlement hearing was held on March 25, 2011, in New York City. The parties have submitted post-hearing briefs and the case is now ripe for decision.

The condition from which Isabela suffers is cryptogenic infantile spasms. As Isabela's treating specialist testified, her condition is characterized by initial seizures that can worsen over time, developmental delay and other serious brain dysfunction.

Regarding the allegation of a Table injury, there is no preponderant evidence that Isabela suffered an acute encephalopathy within 72 hours of her vaccination. Based on the entire record, it appears that she suffered seizures following vaccination, but not an encephalopathy as defined in the pertinent regulations by the Secretary.

As to causation-in-fact, the question is whether the evidence preponderates in favor of Petitioner under each of the three prongs set forth in Althen v. Secretary of the Department of Health & Human Services, 418 F.3d 1274 (Fed. Cir. 2005). The strongest evidence presented by Petitioner is that of two caring and able treating physicians. The evidence they provided, in context, does not suffice to prove causation. At hearing, Isabela's pediatric neurologist retreated from an opinion that vaccinations caused Isabela's condition. Isabela's pediatrician raised the possibility of challenge/rechallenge, but the medical record does not support that opinion, as Respondent's expert pointed out. There is little evidence beyond the temporal association to link Isabela's vaccination and her infantile spasms. Accordingly, the Petition is dismissed.[3]

II. BACKGROUND

A. Petition

The Petition alleges that Isabela was the product of an uneventful pregnancy, was healthy at birth and a normally developing child before her vaccinations on March 28, 2008. Pet. at 2. The Petition alleges that Isabela suffered the onset of seizures, which were subsequently diagnosed as infantile spasms, within hours of receiving her vaccinations. Id.

Isabela was sent to Stamford Hospital by her pediatrician on April 3, 2008, where, at the emergency room, she was diagnosed with seizures. Pet. at 2-3.[4] She

[3] I reach this decision with particular reluctance because the circumstances are heartrending and the effort by the two physicians and Petitioner to do everything possible to help Isabela is admirable. These factors do not weigh in the legal balance; unfortunately, I may not make an award of compensation based on my sympathies.

[4] The second page of the Petition on file with the Office of Special Masters is not marked with a page number (i.e., "2"), however, it is assumed to be "page 2" as the text continues and appears to be complete.

received treatment and was discharged on April 5, 2008. Id. at 3. Following an additional hospitalization from May 5-7, 2008, she was sent to Montefiore Epilepsy Monitoring Unit for evaluation and treatment of the seizures. Id. She has continued to experience seizures and suffers from developmental delay. Id.

The Petition states that pediatric neurologist Philip Overby has reviewed Isabela's records and concluded that she suffered an encephalopathy and a seizure disorder within hours after she received the vaccinations. Id. The Petition alleges that "Dr. Overby's opinion is that there is no evidence to suggest a cause" other than the vaccination, and that Isabela's injuries were "temporally related" to the vaccinations. Id. Petitioner states that Dr. Overby also believes that Isabela's encephalopathy and seizure disorder "resulted in Isabela's subsequent developmental delay." Id.

Petitioner contends that Isabela "suffered an encephalopathy and a seizure disorder which was caused-in-fact by the DTAP, Hib, IPV, Prevnar and Rotavirus vaccinations," and that her "developmental delay is a sequelae of that brain injury and seizure disorder." Id. (citing 42 U.S.C. § 300aa-11(c)(1)(C)(ii)(I)).

B. Medical Record

The pertinent facts appear to be undisputed.[5] Isabela was born on November 27, 2007, Pet'r's Ex. 1 at 1, and received hepatitis B vaccines on November 29, 2007, and December 28, 2007, without incident. Pet's Ex. 5 at 1. On January 31, 2008, she was seen for a two-month well-child visit, during which she received IPV, DTaP, Hib, Prevnar, and rotavirus vaccinations, again without incident. Pet'r's Ex. 4 at 78-79; Pet'r's. Ex. 5 at 1.

On March 12, 2008, Isabela was seen for a mild upper respiratory infection. Pet'r's Ex. 4 at 59-60. On March 28, 2008, she was seen for her four-month well-child check up. During this visit, she received IPV, DTaP, Hib, Prevnar, and rotavirus vaccinations. Pet'r's Ex. 4 at 80-81; Pet'r's Ex. 5 at 1.

On April 3, 2008, Petitioner phoned Isabela's pediatrician's office to report that "for the past few days Isabela seems to 'zone out' and eyes roll to the side of her head,

[5] This account of the medical record depends heavily on the submissions of Respondent, but Petitioner does not appear to dispute any of the facts herein. Petitioner filed no pre-hearing statement and a minimal factual statement in her Post-Trial Brief. Petitioner's Post-Trial Brief did, however, contain a potentially confusing statement of fact. The Post-Trial Brief stated that on Sunday and Monday, March 30-31, 2008, Isabela "started having convulsions." Pet'r's Post-Trial Br. at 3. According to the medical records as well as the testimony of Petitioner and the treating physician, Isabela suffered convulsions for the first time on the following Thursday, April 3, 2008. Tr. at 11-13. "And then on Thursday when I had called the doctor, I was getting her ready to take her to the doctor and she had a convulsion." Tr. at 12. Dr. Henkind's testimony was the same: Petitioner phoned the pediatrician's office on Thursday to report the symptoms that had occurred previously. "Not what happened on Thursday but what she was recording from the days prior." Tr. at 32-33. Isabel's symptoms on the Thursday were "much worse than . . . what it was before." Tr. at 12.

doesn't turn her head when mom talks to her, 'snaps out of it' a few minutes later. Has been doing this a few times a day for the past few days." Pet'r's Ex. 4 at 108.

The same day, Isabela was taken to the office of her pediatrician because she had been "shaking all extremities" for about a minute. Pet'r's Ex. 4 at 54. The pediatrician noted that, according to Petitioner, Isabella had "appeared dazed after waking from naps – eyes are glazed. . . . Otherwise pt has been acting well – eating fine, acting like normal self." Id. The pediatrician noted that Isabela had received four-month vaccinations on the previous Friday, six days earlier. Id. While at the doctor's office, Isabela again had rhythmical shaking in all four extremities, "with eyes and head deviating to right and tongue protruding while laying on exam table." Id.

Isabela was then taken to the Stamford Hospital Emergency Room ("ER"). Her history stated that "over the weekend, the child was acting a little bit differently, but no fevers, no coughing, no pointing to ears, no runny nose, no nausea or vomiting ever." Pet'r's Ex. 6 at 1. She was described as having had "[g]eneralized tonic-clonic activity with postictal phase lasting approximately 2 minutes." Id. She was admitted to the hospital for observation and seen by Dr. Overby, a neurologist. Id. He recorded that "[f]ive days prior to the episode, her mother noticed that upon awakening, Isabela seemed somewhat less responsive with eye deviation lasting seconds. The movements occur in both directions laterally. This occurred over the course of 2 days four to five days ago." Pet'r's Ex. 6 at 19. Isabela was diagnosed with a urinary tract infection. Pet'r's Ex. 4 at 52.

On April 23, 2008, a 24-hour electroencephalogram ("EEG") revealed an electro-clinical seizure, non-localizable, and multifocal spikes and poly-spikes. Pet'r's Ex. 6 at 31-32.

Dr. Overby saw Isabella on May 5, 2008. Pet'r's Ex. 6 at 24. In the previous week, she had had seizures lasting several seconds, characterized by "mirthless laughter or smile with tonic stiffening of the trunk," in clusters over a period of four to five minutes. Id. EEG revealed hypsarrhythmia, which is characteristic of infantile spasms. Pet'r's Ex. 8 at 22.[6] Dr. Overby's notes stated, "Given her normal development to date, these are most likely cryptogenic (v. symptomatic) infantile spasms." Id. at 18.

Testing showed "no evidence of . . . chromosom[al] abnormalities." Pet'r's Ex. 6 at 13. Isabela was admitted for evaluation and treatment at the Montefiore Epilepsy Monitoring Unit. Pet'r's Ex. 7 at 1. She was taking the anti-epileptic medications Phenobarbital and Keppra. Id. It was noted that her maternal great uncle had suffered seizures. Id. at 1. There were several notations that her seizures had started shortly after she received her four month immunizations. Pet'r's Ex. 7 at 10, 15. She was

[6] Hypsarrhythmia is "an electroencephalographic [EEG] abnormality sometimes observed in infants, with random, high-voltage slow waves and spikes that arise from multiple foci and spread to all cortical areas." Dorland's Illustrated Medical Dictionary 908 (32nd ed. 2012).

discharged from Montefiore on May 12, 2008, with the diagnoses of infantile spasms – hypsarrhythmia; hypotonia; and developmental delay. Id. at 21.[7]

At Montefiore, Isabela was prescribed adrenocorticotropic hormone ("ACTH"). Id. at 22.[8] On May 20, 2008, Dr. Overby noted that Isabela was having a partial response to ACTH treatment. Pet'r's Ex. 8 at 15. An ACTH taper was recommended, as was a follow-up EEG. Id. at 16.

At six months, Isabela was diagnosed with infantile spasms and developmental delay. Pet'r's Ex. 4 at 38. Another EEG showed hypsarrhythmia and disorganization. Pet'r's Ex. 8 at 22. Dr. Overby described the EEG as "severely abnormal" and stated that the EEG pattern was "most consistent with infantile spasms." Id.

In mid-2008, Isabela's condition appeared to improve significantly. See Pet'r's Ex. 6 at 35. She had responded to her second round of ACTH treatment, her seizures had stopped and she had regained previously lost developmental milestones. Pet'r's Ex. 8 at 14. Dr. Overby recommended a Prednisone taper, ophthalmology evaluation, vaccines "only if not attenuated vaccines," continued treatment with Keppra, and a follow-up in three months. Id.

On July 8, 2008, Isabela was given a Hib vaccine. Pet'r's Ex. 5 at 1. On July 25, 2008, she was noted to be smiling and interactive, without further seizure activity. Pet'r's Ex. 4 at 27. On August 28, 2008, at her nine-month check up, Isabela received a hep B vaccine. Pet'r's Ex. 4 at 26; Pet. Ex. 5 at 1.[9] On September 2, 2008, Petitioner phoned the pediatrician's office to report that following this immunization, Isabela appeared to have a seizure. Pet'r's Ex. 4 at 93. It was noted that Isabela "had two brief seizures after this last vaccine, will hold all further vaccines until done with spasm treatment and has been stable, is now back to her baseline functioning." Id.

An EEG on September 18, 2008, revealed numerous abnormalities, including hypsarrhythmia. Pet'r's Ex. 8 at 20. Dr. Overby noted that a few days after her immunizations in August 2008 Isabela began having recurrent spasms, after a period in which her seizures appeared to have resolved. Pet'r's Ex. 8 at 11. ACTH was restarted and she was also prescribed Topamax, another anti-convulsant medication. Id. at 12.

On September 24, 2008, Isabela was seen in her pediatrician's office. It was noted by history that she "started having seizures within 24 hours of last vaccine given." Pet'r's Ex. 4 at 22.

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[7] Hypotonia is "a condition of diminished tone of the skeletal muscles, so that they have diminished resistance to passive stretching and are flaccid." Dorland's at 907.

[8] ACTH is an abbreviation for "adrenocorticotropic hormone." Dorland's at 21.

[9] This record indicated the immunization was a "Hepatitis A Vaccine." This evidently is an error as the vaccination record does not list a Hep A vaccine as having been given to Isabela, see Pet'r's Ex. 5; Tr. 39, 147-48 (Hep B).

Over the next months Isabela was weaned off Prednisone and Keppra, and her Topamax was increased. She continued to have episodes of stiffening upon awakening. Pet's Ex. 8 at 7-8. Her development was delayed and she had recurrent spasms. Pet'r's Ex. 8 at 5-6. She was taking Depakote, another antiepileptic medication. Id. at 6. Her diagnosis of infantile spasms remained unchanged. See, e.g., Pet'r's Ex. 8 at 3.

C. Infantile Spasms

Infantile spasms ("IS"), also known as West syndrome, is a recognized epileptic condition. See Resp't's Ex. E at 3, Institute of Medicine, Adverse Effects of Pertussis and Rubella Vaccines 65 (1991).[10] The term IS encompasses more than the occurrence of seizures. See generally Resp't's Ex. C. "An epileptic syndrome is a disorder that manifests one or more specific seizure types and has a specific age of onset and a specific prognosis." Nelson's Textbook of Pediatrics 2013 (19th ed. 2011). West syndrome "consists of a triad of infantile spasms that usually occur in clusters (particularly in drowsiness or upon arousal), developmental regression, and a typical EEG picture called hypsarrhythmia[,] . . . a high-voltage, slow, chaotic background with multifocal spikes." Nelson's at 2024. "Patients with cryptogenic (sometimes called idiopathic) disease have normal development before onset . . . ." Id. The syndrome is a "major cause of pediatric morbidity." Pet'r's Ex. 18 at 2, Michael Goodman, et al., Temporal relationship modeling: DTP or DT immunizations and infantile spasms, 16 Vaccine 225 (1998).[11]

West syndrome typically commences in infancy. Nelson's at 2020, Table 586-7. The "vast majority of studies report a peak onset between ages 4 and 6 months." Resp't's Ex. E at 2. "The spasms, characterized by sudden flexion of the arms, forward flexion of the trunk, and extension of the legs, last only a few seconds and are often repeated many times per day." Pet'r's Ex. 18 at 2. Spasms may be "overlooked by parents and by physicians, being mistaken for startles due to colic or for other benign" syndromes. Nelson's at 2024.

IS is considered an epileptic encephalopathy. Nelson's at 2015, Table 586-2. Encephalopathy is defined as "a degenerative disease of the brain." Dorland's Illustrated Medical Dictionary 614 (32nd ed. 2012). Epileptic encephalopathy indicates a syndrome in which "the severe EEG abnormality is thought to result in cognitive and other impairments." Nelson's at 2013. IS has been associated with a variety of

[10] The pages of both Respondent's and Petitioner's exhibits were not properly individually numbered. Accordingly, references will be to the numbers assigned by the CM/ECF system, which are imprinted at the top of each filed document page, rather than to the numbering original to the document.

[11] Petitioner did not assign exhibit numbers to the two articles submitted pursuant to the Post-Hearing Order, which issued on March 30, 2011. See Notice of Filing Articles Referenced by Experts, Apr. 4, 2011, ECF No. 29. Accordingly, the undersigned designates the first article submitted, written by David Geier, as Petitioner's Exhibit 17, and the second article, written by Michael Goodman, as Petitioner's Exhibit 18. See Vaccine Rules, Supp. to App. B, Rule 10(b)(i) (exhibits should "be consecutively numbered").

antecedent disorders or accidents, including tuberous sclerosis complex and perinatal hypoxia. Resp't's Ex. E at 4. Approximately "65 percent of children with infantile spasms will go on to have other types of seizures." Id. at 3.

IS has been categorized into three types: idiopathic, which is a genetic or presumed genetic condition "in which there is no underlying disorder," symptomatic, in which IS is "caused by an underlying brain disorder," and cryptogenic, "in which there is a presumed underlying brain disorder causing the epilepsy and affecting neurologic function, but the underlying disorder is not known." Nelson's at 2013. Patients with cryptogenic disease have "development [that is] essentially normal prior to onset." Resp't's Ex. E at 4.

Infantile spasms typically are treated with ACTH. Nelson's at 2027. Although initial response to ACTH may be positive, relapse can occur "[d]uring the tapering period, and especially in symptomatic patients." Id. "The majority of patients have a poor prognosis despite ACTH[,]" although cryptogenic cases have a "better chance for a response." Id.

According to the Institute of Medicine ("IOM"), there are no epidemiological studies that indicate "an association between acellular pertussis vaccine and infantile spasms." Ct. Ex. 1 at 1, IOM, Adverse Effects of Vaccines: Evidence and Causality 464 (2011). Also according to the IOM, there is a lack of evidence to support a mechanism linking vaccines containing DTaP vaccines with infantile spasms. Id. at 2. The IOM has concluded that the evidence is inadequate to accept or reject a casual relationship between DTaP and infantile spasms. Id.

D. Vaccine Injury Table

To prove a Table injury, a petitioner must show that he suffered an injury listed on the Vaccine Injury Table and that such injury first manifested within the period listed on the Table. Shalala v. Whitecotton, 514 U.S. at 274 (citing § 300aa-11(c)(1)(C)(i)); 42 U.S.C. § 300aa-14(a); see 42 C.F.R. § 100.3(a) (2010) (Vaccine Injury Table). The injuries listed on the Table are further defined by the Secretary's Qualifications and Aids to Interpretation ("QAI"). See § 300aa-14(b); § 100.3(b).

Petitioner here alleged the Table injury of encephalopathy resulting from administration of the DTaP and other vaccines to Isabela on March 28, 2008. A Table encephalopathy occurs only if the vaccine recipient "manifests, within the applicable period, an injury meeting the description . . . of an acute encephalopathy, and then a chronic encephalopathy persists in such person for more than 6 months beyond the date of vaccination." 42 C.F.R. § 100.3(b)(2). For vaccines containing acellular pertussis toxin, including the DTaP vaccine, the applicable time period for manifestation of an acute encephalopathy is within 72 hours of vaccination. § 100.3(a)(II)(B).[12]

[12] Among the vaccines that were administered on March 28, 2008, the only one (other than DTaP) for which there is an associated injury is IPV. 42 C.F.R. §100.3(a)(VII). There is no allegation that Isabela suffered a Table Injury from her IPV vaccination.

The QAI defines an acute encephalopathy as "one that is sufficiently severe so as to require hospitalization (whether or not hospitalization occurred)." 42 C.F.R. § 100.3(b)(2)(i). The QAI further specifies criteria for evaluating symptoms that may or may not indicate acute encephalopathy. § 100.3(b). For children younger than eighteen months who present following a seizure, the Secretary's definition of an "acute encephalopathy" requires a "significantly decreased level of consciousness" that "persists beyond 24 hours and cannot be attributed to a postictal state (seizure) or medication." § 100.3(b)(2)(i)(A).[13] A "significantly decreased level of consciousness" is

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

§ 100.3(b)(2)(i)(D).[14] The QAI also states, "[t]he following clinical features alone, or in combination, do not demonstrate an acute encephalopathy or a significant change in . . . level of consciousness as described above: Sleepiness, irritability (fussiness), high-pitched and unusual screaming, persistent inconsolable crying, and bulging fontanelle." § 100.3(b)(2)(i)(E). The guidance states further that "[s]eizures in themselves are not sufficient to constitute a diagnosis of encephalopathy." Id. "In the absence of other evidence of an acute encephalopathy, seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy." Id.

E. Petitioner's Case

1. Petitioner – Ms. Kelly Arango

Petitioner testified that Isabela appeared to be developing normally up until the time of her four-month well-baby visit, when she received the vaccinations. Tr. at 7-8. She was vaccinated at around noon on Friday, March 28, 2008. Id. On the morning of Saturday, March 29, 2008, Petitioner noticed a single episode of Isabela's eyes turning sideways for a "quick second" during which the child appeared "dazed" before she "came back" to a normal state. Tr. at 9-10, 17-18. On the next day, Sunday, and the

[13] Postictal means "occurring after a seizure or sudden attack." Dorland's at 1502.

[14] Sections (b)(2)(ii)–(iv) of the QAI include guidance for determining whether a Table injury has been established when an encephalopathy may have been caused by factors other than vaccination. 42 C.F.R. § 100.3(b)(2)(iii). It is not necessary to evaluate alternative factors here, because Petitioner has not carried her burden to show evidence of an acute encephalopathy within 72 hours of vaccination.

following day, Monday, the same thing happened "only a few times over the weekend." Tr. at 10-11. Isabela was taking food over the weekend, but more slowly than usual. Tr. at 16.

The episodes continued until, on the following Thursday, Isabela suffered a convulsion. Tr. at 12. She "looked much worse." Id. Petitioner took Isabela to the office of her pediatrician, Dr. Jennifer Henkind. At the doctor's office, Isabela suffered another convulsion and was immediately taken to the emergency room. Tr. at 12-13. She was diagnosed, after about one month of testing and evaluation, with infantile spasms. Tr. at 14. Thereafter, Isabela received treatment at Montefiore Hospital. See Pet'r's Ex. 7.

2. Petitioner's Expert – Dr. Jennifer Henkind

Dr. Henkind is a practicing pediatrician who is board certified in general pediatric practice. Tr. at 21-23. She treated Isabela from birth. Tr. at 20. She "believes very strongly in vaccines" and her practice insists that children be vaccinated. Tr. at 24-25. She has been personally acquainted with Petitioner for many years. Tr. at 26.

Dr. Henkind recalled seeing Isabela for her well-baby check up on the day she received the vaccinations. Tr. at 26. Isabela was "a beautiful, delicious, developing, and gorgeous four-month-old . . . and everything was going fine." Id. Dr. Henkind had "no concerns about the baby whatsoever" at any time prior to the four-month well-baby check up. Tr. at 26-27.

Dr. Henkind did not recall speaking with Petitioner on the Thursday following the vaccinations, when Isabela experienced her first convulsion. Tr. at 27-28. Had she been informed over the weekend of Isabela's symptoms "I with fairly good certainty would have admitted her into the hospital," tr. at 30, "at a minimum for a basic workup and observation." Tr. at 32.

Dr. Henkind testified that the behavior Isabela exhibited over the weekend following her vaccination (i.e., "child's eyes are deviating," "not responding . . . to the parents the way they used to") "would be alarming" but would not necessarily indicate that the child was having seizures. Tr. at 35-36. "So Kelly wasn't describing anything that sounded like the child was in imminent danger that I needed to send her to the emergency room or that she was having a continuous type of medical situation that needed to be attended to as an emergency at that particular moment." Tr. at 36.

Dr. Henkind decided only in retrospect that Isabela had suffered a vaccine reaction; "it was not the initial presentation." Tr. at 37-38. She recounted that "as things started stabilizing with Isabela" she recommended that the child receive additional vaccinations one at a time, "so that if something happens we can see." Tr. at 39.

> So . . . I don't remember the dates and the exact vaccines . . . but we gave her a vaccine, I believe the hepatitis B vaccine . . . and she seemed to tolerate it fine. We subsequently gave her . . . a couple of weeks later . . . we gave her something called a Prevnar pneumococcal vaccine . . . . And soon thereafter . . . I believe it was within hours or within a day, she started having her spasms again. And she had been really relatively well controlled and fairly seizure free at that point. We vaccinated her, and the whole thing started up again. . . . it was after that happened that in my mind firmly I truly believed that the vaccines had caused this problem.

Id.; see Pet'r's Ex. 4 at 1 (noting Isabela "developed an increase in seizure activity after . . . HIB and Prevnar boosters").

3. Petitioner's Expert – Dr. Philip Overby

a. Dr. Overby's Expert Report

In his expert report dated May 24, 2010, Dr. Overby described the onset of Isabela's seizures and subsequent clinical course. Pet'r's Ex. 11 at 1. He discussed infantile spasms and the difference between "symptomatic" and cryptogenic" IS. Id. at 1-2. "The significance of the distinction lies primarily in the observation that cryptogenic cases typically, but by no means uniformly, have better outcomes in terms of seizure control and development." Id. at 2.

Dr. Overby stated that "some instances of infantile epileptic encephalopathy have been associated with a Na channel mutation, specifically an SCN1a mutation." Id. at 2. He stated further that Isabela was tested for that mutation and was negative. Id.

Dr. Overby described a long-standing association between seizures and the immune system. Id. He also noted a form of unremitting seizures in children "which presents in the setting of fever, without an identifiable infectious etiology." Id.

Dr. Overby noted "a clear temporal association between the administration of her 4 month vaccines and the beginning of her neurological symptoms which culminated in [Isabela's] encephalopathy." Id. at 2-3.

Dr. Overby concluded that Isabela's normal development up to the age of 4 months places her in the category of children with cryptogenic infantile spasms. Id. at 3. He noted that despite her initial response to treatment with ACTH, her development was impaired and she continued to suffer seizures. Id. "[A] reasonable case can be made that the inciting event that provoked Isabella's infantile spasms was her 4 month vaccines." Id.

b. Dr. Overby's Testimony

Dr. Overby treated Isabela from the time she first developed IS and is an expert in pediatric neurology. Tr. at 44-47. He did not initially suspect that vaccination caused Isabela's infantile spasms, "the vaccine did not come up until later." Tr. at 51.

On direct examination, he was asked "whether or not there is a causal connection between the vaccine and the onset of Isabela Orozco's condition?" Tr. at 53. Dr. Overby did not answer affirmatively. Instead, he appeared to deny an opinion that the vaccine was the cause of Isabela's condition, and instead to testify that there was a temporal relationship between vaccination and the onset of her seizures.

> There's no, I don't think that's what this is about. I don't think that's, [t]o demonstrate causality within science is, it's a pretty high bar, higher than I think is generally appreciated. And I think what this is about is it's understood that there will be a temporal relationship, if there's a temporal relationship between one event and another and there's, my opinion on the vaccine compensation quarter is basically I think it's a very – that's what you're asking me, right?

Id.

Continuing his direct examination, Petitioner's counsel asked whether it was Dr. Overby's opinion "that the symptoms experienced by Isabela within 72 hours of being vaccinated by a listed vaccine are, eventually result in her diagnosis with infantile spasms." Tr. at 54. In response, Dr. Overby stated, "I think it's plausible, I think it's plausible." Id.[15] As to causation, Dr. Overby again declined to ascribe causation to the vaccinations.

> And but again to say there's, it's one cannot say in either direction with full medical certainty that it's causal here, but that's I don't think what we're trying to establish here. We're trying to establish that a process began within 72 hours culminating in an encephalopathy, and I think that's all we can say.

Tr. at 54-55.

On further questioning, Dr. Overby alluded to a theory that vaccination could have caused an inflammatory response leading to seizures, and that seizures could lead to further seizures. Tr. at 55. As "more of an aside," he described "clinical

[15] To be clear, on the record before me, it is undisputed that the seizures Isabella experienced within 72 hours of her vaccination were the first symptoms of the condition eventually diagnosed as infantile spasms. Lacking from this record, however, is any reliable evidence, including from Dr. Overby, that the vaccinations caused the seizures that eventually were diagnosed as infantile spasms.

phenomena . . . having to do with NMDA receptors and how they can, antibodies directed against those can cause severe seizure[] encephalopathies." Tr. at 89.[16]

> So for whatever reason it seems, in certain instances it seems plausible to me that with inflammation you could derange that [brain] system and cause severe seizures.
>
> . . . .
>
> That's very loose, it's very loose, but it's, because again I don't, I'm not saying I understand the, it's a potential just general way one could connect a vaccine and these sorts of seizures.

Id. Dr. Overby agreed there was no evidence of an inflammatory process in Isabela's case. Tr. at 90.

Dr. Overby's testimony was clear on the point that the episodes noted by Kelly Arango over the weekend following Isabela's vaccination were seizures. Tr. at 58 ("I think those eye deviations were seizures."); Tr. at 85 ("I think she had seizures, we can say that she had seizures within 72 hours.").

On cross-examination, Dr. Overby confirmed that therapy with the drug ACTH may "initially cause remittance of the seizures but then they will begin again after the course is finished." Tr. at 67. He stated, "It's, our success rate, yeah, it's not infrequent unfortunately, yeah, you can have some success and then it will stop working." Id.

Dr. Overby referred to an epidemiological study which, he conceded, concluded that there was no association between vaccination and infantile spasms. Tr. at 73-76 ("Yeah, I think, yeah, that was the conclusion of the paper.").[17] He referred to another report, by David Geier.[18] Dr. Overby was not aware that Mr. Geier and his father, with whom Mr. Geier authored a number of purported studies involving vaccines, have been discredited. Tr. at 91-92. See note 20, infra.

In response to questions from the Court, Dr. Overby again declined to express the opinion that vaccinations cause infantile spasms. "I don't know, I think it's possible," he testified. Tr. at 82 ("A reasonable degree of medical certainty? I don't know what causes infantile spasms, so no I can't say that.").

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[16] NMDA is an abbreviation for "*N*-methyl-D-aspartate," which is "a neurotransmitter similar to glutamate, found in the central nervous system; a synthetic preparation is used experimentally to study the excitatory mechanisms of glutamate transmitters." Dorland's at 1152.

[17] The report referred to by Dr. Overby eventually was filed as Pet'r's Ex. 18.

[18] The study referred to by Dr. Overby eventually was filed as Pet'r's Ex. 17, David A. Geier & Mark R. Geier, An evaluation of serious neurological disorders following immunization: a comparison of whole-cell pertussis and acellular pertussis vaccines, 26 Brain & Develop. 296 (2004).

Dr. Overby testified that he did not know whether Isabela suffered an allergic response or an autoimmune response to her vaccinations. Tr. at 84. He explained that immunology is "beyond my expertise really." Id.

He testified that the time frame for an immune response following vaccination would begin "almost immediately." Tr. at 83.

Dr. Overby stated that it is not clear whether the seizures that characterize infantile spasms cause brain damage or "if they're more consequence, they're more of a phenomenon of a very abnormal brain." Tr. at 86. Dr. Overby continued to decline to draw a connection between vaccination and brain abnormality in the case of a child with infantile spasms, other than "a temporal association between the seizures that culminated in the encephalopathy." Tr. at 86-87.

4. Petitioner's Medical Literature[19]

Petitioner submitted an article purporting to compare whole-cell pertussis and acellular pertussis vaccines. Pet'r's Ex. 17, David A. Geier & Mark R. Geier, An evaluation of serious neurological disorders following immunization: a comparison of whole-cell pertussis and acellular pertussis vaccines, 26 Brain & Develop. 296 (2004). The article analyzed data from the Vaccine Adverse Event Reporting System ("VAERS"), a compilation of data maintained by the Centers for Disease Control ("CDC"). Id. at 1.[20]

[19] Petitioner's medical literature was not submitted in advance of the hearing, as required. See Pre-Hr'g Order, Dec. 17, 2010, ECF No. 21.

[20] David A. Geier, co-author of the article cited by Petitioner (Pet'r's Ex. 17) does not possess any advanced medical or scientific degrees. "The only degree David Geier possesses is a Bachelor of Arts in Biology." Riggins v. Sec'y of Dep't of Health & Human Servs., No. 99-382V, 2009 WL 3319818 at *6 (Fed. Cl. Spec. Mstr. June 15, 2009). On May 16, 2011, the Maryland State Board of Physicians (the "Board") charged David Geier with practicing medicine without a license. See In re David A. Geier, Charges Under the Maryland Medical Practice Act, Case Nos. 2008-0022, 2009-0318 (May 16, 2011), http://www.mbp.state.md.us/pages/recent_alerts.html (last visited Aug. 8, 2012). On July 30, 2012, the Board concluded that David Geier practiced medicine in Maryland without being licensed and imposed a $10,000 civil fine for the violation. See In re David A. Geier, Unlicensed, Final Decision and Order, Case Nos. 2008-0022, 2009-0318 (July 30, 2012), http://www.mbp.state.md.us/pages/disciplinary.html (last visited Aug. 8, 2012).

David Geier is the son of Mark R. Geier, M.D., the other co-author of Pet'r's Ex. 17. On April 27, 2011, the Board summarily suspended Dr. Geier's license to practice medicine in Maryland on the grounds that the public health, safety, or welfare imperatively required such action. See In re Mark R. Geier, Order for Summary Suspension of License to Practice Medicine, Maryland State Board of Physicians, Case Nos. 2007-0083, 2008-0454, 2009-0308 (Apr. 27, 2011), http://www.mbp.state.md.us/pages/recent_alerts.html (last visited Aug. 8, 2012). Six other states, including California, Indiana, Kentucky, New Jersey, Virginia and Washington subsequently suspended Dr. Geier's license to practice medicine, pending the outcome of the discipline in Maryland. See Medical Board of California, License Look-up System, http://www2.mbc.ca.gov/LicenseLookupSystem/PhysicianSurgeon/Lookup.aspx?licenseType=G&licenseNumber=88736 (last visited Aug. 8, 2012). The State Medical Board of Ohio initiated similar action with

Apart from the unreliability of the authors, see note 20, it is difficult to see how the Geier article supports Petitioner's case. The article concluded that acellular pertussis vaccine was "safer and at least equally efficacious" as compared to the older whole-cell form of pertussis immunization. Pet'r's Ex. 17 at 4. That Isabela received a safer form of the pertussis vaccine than was used to inoculate children in the past does not seem to advance Petitioner's cause. The use of a less reactogenic form of the pertussis vaccine reduces the chances that she was injured by her vaccination.

Petitioner also submitted an article concerning the temporal relationship between DTP or DT immunizations and infantile spasms. Pet'r's Ex. 18 (Goodman). This article does not lend weight to Petitioner's causation argument, for several reasons. First, the authors discussed data concerning an immunization that Isabela did not receive: whole cell pertussis. Second, the Goodman article does not support the proposition that pertussis vaccine causes infantile spasms. The authors noted a "statistically significant" temporal shift in cases of infantile spasms following DPT or DT immunization. Id. at 5. "[T]he cases are more likely to be reported as having been exposed during the week immediately preceding infantile spasms onset than during the other 3 weeks of that preceding month." Id. The authors were quick to disclaim that this data indicated a causative association between vaccination and infantile spasms.

On the contrary, their interpretation was "precisely" consistent with the view that "immunization brings out a neurologic event that would have occurred anyway or calls attention to an event that is already occurring." Id. at 6 (internal quotation marks omitted). It may readily be appreciated that, as the authors pointed out, reports by parents of vaccination in the days immediately preceding seizures may in actuality be

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respect to Dr. Geier's pending licensure application based on Maryland's licensing board suspension, concluding:

> [T]hat the public health, safety, and welfare imperatively required emergency action based on the determination that doctor's treatment for autistic children included exposing children to needless risk of harm resulting from misdiagnoses, failing to conduct adequate physical examinations prior to starting treatment, and treating with therapies not supported by evidence-based studies.

State Medical Board of Ohio, Monthly Formal Actions, July 2011, http://med.ohio.gov/professionals-mfal.htm (last visited Aug. 8, 2012).

On March 22, 2012, following a lengthy appeals process, the Maryland Board upheld the suspension of Dr. Geier's license to practice medicine. See In re Geier, Final Decision And Order, Maryland State Board of Physicians, Case Nos. 2007-0083, 2008-0454, 2009-0308 (Mar. 22, 2012), http://www.mbp.state.md.us/pages/disciplinary.html (last visited Aug. 8, 2012).

I do not give probative weight to any evidence based on the work of the Geiers because they lack appropriate medical credentials and have been found by competent authorities to have engaged in unprofessional conduct. Their work product is not reliable. See Daubert v. Merrell Dow Pharm. Inc., 509 U.S. 579, 597 (1993) (trial judge must ensure that expert's testimony rests on a reliable foundation). A special master may use Daubert "as a tool or framework for conducting the inquiry into the reliability of the evidence." Terran ex rel. Terran v. Sec'y of Dep't of Health & Human Servs., 195 F.3d 1302, 1316 (Fed. Cir. 1999). See Fed. R. Evid. 201(b).

unrelated to vaccine causation. Id. at 5 (noting that the "precise date of onset for an insidious disease such as infantile spasms is difficult to determine" and the "earliest manifestations" of the disorder "may be easily missed").[21]

Third, the IOM in its most recent report on vaccine injuries reviewed and discussed the Goodman study. Ct. Ex. 1 at 1. The IOM stated that it "has limited confidence" in the epidemiologic evidence in the Goodman study, which "lacked validity and precision to assess an association between diphtheria toxoid or tetanus toxoid vaccine and infantile spasms." Id. Specifically with respect to the acellular pertussis vaccine and infantile spasms, the IOM concluded, "The epidemiologic evidence is insufficient or absent to assess an association between acellular pertussis vaccine and infantile spasms." Id.

F. Respondent's Case

1. Respondent's Expert – Dr. Mary Anne Guggenheim

a. Dr. Guggenheim's expert report

Dr. Guggenheim reviewed Isabela's history, the onset of her disorder and her treatment. Resp't's Ex. A at 2. She noted that Isabela has had persistent impairment of motor and cognitive functions. Id. She noted the diagnosis of cryptogenic infantile spasms and stated that Isabela's treating physicians did not initially indicate that her vaccinations on March 28, 2008, were causative. Id. at 3.

Dr. Guggenheim noted that Dr. Overby's expert report appeared to equate Isabela's epileptic encephalopathy with the term "acute encephalopathy" as used in the Vaccine Injury Table. Id. at 3-4. She reviewed the Secretary's guidelines regarding Table injuries and concluded that an epileptic encephalopathy, such as infantile spasms, is not covered by the Table. Id.

Dr. Guggenheim stated that, although there is a large body of medical literature relating seizures to immune function, "no data (experimental or human) establishes a causative link between vaccinations, immunologic factors and the onset of early onset childhood seizures." Id. at 4. She agreed with Dr. Overby that the cause of Isabela's condition "remains unknown." Id.

b. Dr. Guggenheim's testimony

Dr. Guggenheim is an expert in pediatric neurology. Tr. at 96. She described the difference between symptomatic and cryptogenic infantile spasms. Tr. at 98-101

[21] At most, the Goodman findings "suggested the possibility that vaccination may have triggered an earlier onset of spasms in children who were beginning to develop the disorder, or (as seems more likely) that spasms were detected earlier by heightened vigilance of parents following the immunization procedure." Ct. Ex. 2 at 3, James D. Frost, Jr., Infantile Spasms Diagnosis, Management and Prognosis 131 (2003) (discussing the National Childhood Encephalopathy Study ("NCES")).

("cryptogenic infantile spasms is the adjective for when we do not have an identifiable cause for the onset of this severe epilepsy"). She also differentiated the term "epileptic encephalopathy" from the term "acute encephalopathy," which is used in the Secretary's regulations. Tr. at 103-04. An acute encephalopathy, she testified, is "a medical emergency full bore of what's causing this, and it's a severe change in the child's ability to interact, to make eye contact, to be aware of their environment, to feed, very sick child." Tr. at 105. Acute encephalopathy is a different condition from that of a child who is unresponsive during seizure episodes and then returns to a normal state. Tr. at 105, 129-32.

Dr. Guggenheim testified that many children experience an "initial remission from their spasms with ACTH treatment," and then suffer "breakthrough seizures" when the medication is tapered. Tr. at 106. Relapse is "a poor prognostic sign." Tr. at 107.

According to Dr. Guggenheim, there is no convincing data that "activation of the immune system initiates the epileptic process in children." Tr. at 108. She testified that "inflammation in the brain is caused by seizure occurring, does not cause it per se but is caused by [it]." Tr. at 112. Dr. Guggenheim commented that experiments involving animals "very clearly show that the inflammation is a consequence of the induction of seizures, not the cause of it." Id. She also disputed the idea that the response to ACTH, which is an anti-inflammatory agent, indicates that inflammation initiates seizure disorders such as IS. Tr. at 115-16. She explained that the mechanism underlying the therapeutic effect of ACTH in cases of IS is not well understood. Tr. at 116. Dr. Guggenheim testified that the medical record did not disclose evidence of an inflammatory process before Isabela's seizures began. Tr. at 119.

She stated that Isabella did not experience an "acute encephalopathy" following her vaccinations. Tr. at 120. She also testified that "there is no statistical association between" immunizations and infantile spasms. Tr. at 120-21.

Dr. Guggenheim questioned whether the time frame between the alleged vaccine injury and the onset of Isabela's seizures was appropriate. A study she co-authored, see Resp't's Ex. F, Mary Anne Guggenheim et al., Time interval from a brain insult to the onset of infantile spasms, 38 Pediatr. Neurol. 34 (2008), indicated that the time between injury and acute encephalopathy in cases of symptomatic IS was "always" several months. Tr. at 134, 136-37. She asserted that temporal proximity and the onset of seizures "in no way establishes causation." Tr. at 148. She distinguished between an allergic reaction that could occur within hours of a precipitating event and an immune response, which is necessarily "delayed" by the time it takes the body to produce antibodies. Tr. at 150-51.[22]

Dr. Guggenheim disputed the proposition that Isabela suffered a challenge/rechallenge response to vaccination. Tr. at 147-48. She noted that Isabella had had additional immunizations after her initial seizures, "Hib and the Prevnar, and nothing happened." Id.

[22] Dr. Guggenheim cautioned that she is not an immunologist. Tr. at 151.

2. Respondent's Medical Literature

Respondent submitted an article describing various features of early childhood epileptic encephalopathies. Resp't's Ex. C, Jean Aicardi, Epileptic encephalopathies of early childhood, 5 Curr. Opin. Neurol. Neurosurg. 344 (1992). The article described West syndrome as one of the "generally recognized" syndromes of epileptic encephalopathy. Id. at 2. According to Aicardi, "The mechanisms responsible for the epileptic encephalopathies remain poorly understood." Id. at 4. The article noted that "the natural course of infantile spasms is unpredictable and spontaneous remissions are not rare." Id.

Respondent submitted an article discussing the development of epilepsy following an initial insult to the brain. Resp't's Ex. D, Sanjay N. Rakhada & Frances E. Jensen, Epileptogenesis in the immature brain: emerging mechanisms, 5 Nat. Rev. Neurol. 380 (2009). The article noted the "enhanced seizure susceptibility" of the immature brain. Id. at 2. The authors described in detail the many complex changes that may occur in the sequence of epileptic events that follows an initial insult. Id. at 7 - 11. Among these changes is inflammation, which occurs "after" seizures. Id. at 9.

Respondent submitted an excerpt from the 1991 IOM Report on adverse effects of pertussis and rubella vaccines. Resp't's Ex. E. The article reviewed various classifications of infantile spasms, including cryptogenic, i.e., "those for whom there is no known cause of infantile spasms and whose development was essentially normal prior to the onset of spasms." Id. at 4. The article noted the history of suspected association between IS and pertussis vaccines and reviewed the pertinent studies. Id. at 5-14. Among the studies reviewed was the British National Childhood Encephalopathy Study ("NCES") by Bellman, et al. Id. at 11-12. (The data analyzed by Goodman was derived from this same study. See Pet'r's Ex. 18 at 1.).

The IOM concluded, "The evidence does not indicate a causal relation between DPT vaccine or the pertussis component of DPT and infantile spasms." Id. at 15. The IOM noted that "[g]iven the insidious onset," it is "difficult to establish a temporal sequence" between vaccination and the onset of seizures "with certainty." Id. The IOM commented, "there are no other aspects of the clinical presentation that suggest a relation to DPT immunization." Id. The IOM noted that there were "no data bearing on mechanisms [of possible causation] or biologic plausibility." Id.

Respondent submitted an article reporting on the timing interval from a known brain insult to the onset of IS. Resp't's Ex. F (Guggenheim). The article noted that the proportion of cases in which the cause of West syndrome is known is "approaching 90%," and that it is "not unreasonable to assume that there is an underlying brain pathology in all infants who develop infantile spasms." Id. at 3. Thus, it may be expected that "the current diagnostic categories of 'idiopathic' and 'cryptogenic' will eventually disappear." Id. The article noted the relevance of the "timing between vaccine administration and possible adverse effects" for the Vaccine Program, and the authors attempted to determine the "time interval between a clearly identified

encephalopathic event in an . . . otherwise normal child and the clinical onset of infantile spasms." Id.

The study noted "a latent period of at least several weeks, and usually many months, between an event or condition which alters brain function and the onset of infantile spasms." Id. at 5. The latency period, according to the authors, "is correlated with a progressive development of underlying pathologic processes" that eventually result in IS. This finding "preclude[s] claims that the onset of infantile spasms" can occur "within hours or days of immunization." Id.

III. DISCUSSION

A. Table Injury

1. Overview

The Vaccine Act provides streamlined procedures as well as standards of proof for petitioners claiming vaccine injuries. Whitecotton, 514 U.S. at 269-70. While a claimant may present a case of entitlement to compensation by introducing proof of actual causation, the claimant also may obtain compensation by meeting the conditions set forth in the Vaccine Injury Table. Id. at 270. Under the statute, a claimant makes out a case of entitlement by showing that he:

> sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with [a] vaccine . . . and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition . . . occurred within the time period after vaccine administration set forth in the Vaccine Injury Table.

Id. (internal quotation marks omitted) (citing and quoting 42 U.S.C. § 300 aaa-11(c)(1)(C)(i)); see also de Bazan v. Sec'y of Dep't of Health & Human Servs., 539 F.3d 1347, 1351 (Fed. Cir. 2008). As the Court in Whitecotton observed, the rules governing Table injury cases "turn[] the old maxim on its head by providing that if the post hoc event happens fast, ergo propter hoc." 514 U.S. at 270. When a Table injury is established, causation is presumed and the petitioner is entitled to compensation, unless Respondent can establish alternative causation. See Whitecotton, 514 U.S. at 275-76. [23]

As discussed below, this record is devoid of credible evidence of a Table injury.[24]

[23] Injuries not listed on the Table or injuries suffered outside the specified times following vaccination are deemed off-Table injuries, and causation is not presumed. de Bazan, 539 F.3d at 1351.

[24] Because Isabela did not suffer from an acute, post-vaccination encephalopathy, I do not address whether her vaccination caused a chronic encephalopathy, as also required by the Secretary's regulation.

2. Insufficient Proof of Acute Encephalopathy

To constitute an "acute encephalopathy," the vaccinee's condition must be sufficiently severe to require hospitalization, whether or not hospitalization occurs. 42 C.F.R. § 100.3(b)(2)(i). The Secretary's regulations state that an acute encephalopathy "is indicated by a significantly decreased level of consciousness," § 100.3(b)(2)(i)(A), with clinical signs including

> [d]ecreased or absent response to environment (responds, if at all, only to loud voice or painful stimuli); . . . [d]ecreased or absent eye contact (does not fix gaze upon family members or other individuals); or . . . [i]nconsistent or absent responses to external stimuli (does not recognize familiar people or things).

§ 100.3(b)(2)(i)(D)(1)-(3). "In determining whether or not an encephalopathy is a condition set forth in the Table, the Court shall consider the entire medical record." § 100.3(b)(2)(iv). A special master may consider all the evidence presented, including that of Respondent, in determining whether petitioners have met their burden of proof. de Bazan, 539 F.3d at 1353-54; see Doe 11 v. Sec'y of Dep't of Health & Human Servs., 601 F.3d 1349, 1357-58 (Fed. Cir. 2010).

The facts adduced here concerning Isabela's condition, as described by Petitioner, clearly do not meet the requirements of the Secretary's regulations on acute encephalopathy within 72 hours of vaccination. Isabela was vaccinated on a Friday. On the Saturday morning, Petitioner noticed a single episode of Isabela's eyes turning sideways for a "quick second" during which Isabela appeared "dazed" before she "came back" to a normal state. Tr. 9-10, 17-18. The same thing happened the following day, Sunday, and the day after that. These "few times over the weekend," tr. 10-11, when Isabela suffered seizures did not meet any of the criteria for an acute encephalopathy set forth in the Secretary's regulations. See supra; see also Tr. at 103-05, 129-32.

The expert neurologists agreed that Isabela's episodes over the weekend following her vaccination were seizures. See Tr. at 58, 85 (Dr. Overby); Tr. at 118-19 (Dr. Guggenheim).[25] Under the Secretary's regulations, "[s]eizures in themselves are not sufficient to constitute a diagnosis of encephalopathy." 42 C.F.R. § 100.3(b)(2)(i)(E). Per the Secretary's guidance, "seizures shall not be viewed as the first symptom or manifestation of the onset of an acute encephalopathy." Id. Since the onset of seizures within 72 hours, leading to an acute encephalopathy, is precisely the theory proposed by Petitioner, she cannot prevail under the theory that Isabela suffered a Table Injury. See Tr. at 54-55 (Dr. Overby: "We're trying to establish that a process began within 72 hours culminating in an encephalopathy[.]"). The testimony of Petitioner and her experts, as well as Dr. Guggenheim, indicates that Isabela did not suffer an acute encephalopathy in the 72 hours following her vaccination; she suffered seizures.

[25] Dr. Henkind, a pediatrician but not a neurologist, testified that Isabela's symptoms were "alarming" but were not necessarily seizures. Tr. at 35-36.

Experts for both parties testified that Isabela might have been admitted to the hospital for testing and observation if her seizures had been noted and reported as such over the weekend. See Tr. at 30, 32-33 (Dr. Henkind), Tr. at 130-31 (Dr. Guggenheim). The experts also agreed, however, that Isabela's condition was not so severe as to require hospitalization, and as a result to meet the Secretary's definition of an encephalopathy. See 42 C.F.R. § 100.3(b)(2) (i). Compare Tr. at 36 (Dr. Henkind: "Kelly wasn't describing anything that sounded like the child was in imminent danger that I needed to send her to the emergency room"), with Tr. at 105 (Dr. Guggenheim: an acute encephalopathy is "a medical emergency full bore").

Dr. Overby's testimony also failed to demonstrate a Table injury. He opined only that the process that led eventually to a chronic encephalopathy began within 72 hours of Isabela's vaccination. See, e.g., Tr. at 57 ("that's the case I'm making is that this process which culminated in an encephalopathy began when the seizures began or around the time that those seizures began"). The Vaccine Injury Table requires that the actual encephalopathy occur within 72 hours of vaccination. See 42 C.F.R. § 100.3 (a)(II)(B) (injuries following administration of pertussis antigen-containing vaccines). Dr. Overby's testimony in this respect is entirely consistent with the facts: Isabela suffered the initial onset of seizures over the weekend. Those seizures were diagnosed as West syndrome, which led to a chronic encephalopathy. Isabela's condition, as described by Dr. Overby, does not fall within the coverage of the Vaccine Injury Table.

B. Causation-in Fact

Petitioners seeking to prove causation-in-fact must show by a preponderance of the evidence that but for vaccination they would not have been injured, and that vaccination was a substantial factor in bringing about the injury. Cedillo v. Sec'y of Dep't of Health & Human Servs., 617 F.3d 1328, 1338 (Fed. Cir. 2010); Shyface v. Sec'y of Dep't of Health & Human Servs., 165 F.3d 1344, 1352 (Fed. Cir. 1999). Proof of actual causation must be supported by a sound and reliable "medical or scientific explanation that pertains specifically to the petitioner's case, although the explanation need only be 'legally probable, not medically or scientifically certain.'" Moberly ex rel. Moberly v. Sec'y of Dep't of Health & Human Servs., 592 F.3d 1315, 1322 (Fed. Cir. 2010) (quoting Knudsen by Knudsen v. Sec'y of Dep't of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994).

Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." Knudsen, 35 F.3d at 548. A petitioner may use circumstantial evidence to prove the case, and "close calls" regarding causation must be resolved in favor of the petitioner. Althen, 418 F.3d at 1280.

Petitioner's burden is to show that the vaccination brought about her 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 showing of a proximate temporal relationship between vaccination and injury." Althen, 418 F.3d at 1278. Respondent, "like any defendant, is permitted to

offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief." Stone v. Sec'y of Dep't of Health & Human Servs., 676 F.3d 1373, 1380 (Fed. Cir. 2012) (quoting de Bazan, 539 F.3d at 1353).[26]

If Petitioner succeeds in satisfying the elements necessary to prove the case-in-chief, the burden then shifts to Respondent to prove alternative causation by a preponderance of the evidence. Althen, 418 F.3d at 1278. If Petitioner fails to establish her case-in-chief, the burden does not shift. Doe 11, 601 F.3d at 1357-58; see also Cedillo, 617 F.3d at 1335 ("Once a petitioner establishes a prima facie case, the government then bears the burden of establishing alternative causation by a preponderance of the evidence." (citing Walther v. Sec'y of Dep't of Health & Human Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007)).

Because each case must be judged on its own facts, the conclusion in each case reflects not only the weight of the evidence in that case under each of the Althen prongs, but the weight of the evidence in the context of the entire record. See Capizzano v. Sec'y of Dep't of Health & Human Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006) (noting that evidence under Prongs 1 and 3 may increase the probative value of evidence relating to Prong 2). Seemingly inconsistent results may permissibly occur as a result of this case-by-case adjudication process. See Hanlon v. Sec'y of Dep't of Health & Human Servs., 40 Fed. Cl. 625, 630 (1998) (indicating decisions are not binding on special masters except in the same case), aff'd, 191 F.3d 1344 (Fed. Cir. 1999); see also Stone, 676 F.3d at 1380 ("the special master is entitled to consider the record as a whole in determining causation").

1. Althen Prong 1

Under Althen prong 1, a petitioner must set forth a medical theory explaining how the vaccine could cause the complained-of injury. This requirement has been interpreted as "can [the] vaccine(s) at issue cause the type of injury alleged?" Pafford v. Sec'y of Dep't of Health & Human Servs., 451 F.3d 1352, 1356 (Fed. Cir. 2006) (quoting Pafford v. Sec'y of Dep't of Health & Human Servs., No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004)). Although the theory of causation need not be corroborated by medical literature or epidemiological evidence, the theory must be sound, reliable, and reputable – in other words, the theory need not be scientifically certain, but it must have a scientific basis. See Knudsen, 35 F.3d at 548 (finding actual causation "must be supported by a sound and reliable medical or scientific explanation").

[26] In the context of the Vaccine Program, "prima facie case" and "case-in-chief" have distinct meanings, although they are sometimes used interchangeably in practice. As used by the Federal Circuit in Doe 11, the requirements of a prima facie case are statutory, see 42 U.S.C. § 300aa-11(c)(1), while a petitioner's case-in-chief on actual causation also requires a preponderance of evidence on the three Althen factors. See Doe 11, 601 F.3d 1349.

In evaluating whether a petitioner has presented a legally probable medical theory, "the special master is entitled to require some indicia of reliability to support the assertion of the expert witness." Cedillo, 617 F.3d at 1339 n.3 (quoting Moberly, 592 F.3d at 1324). A special master is not required to rely on a speculative opinion that "'is connected to existing data only by the ipse dixit of the expert.'" Snyder ex rel. Snyder v. Sec'y of Dep't of Health & Human Servs., 88 Fed. Cl. 706, 743 (2009) (quoting Gen. Elec. Co. v. Joiner, 522 U.S. 136, 146 (1997)); accord, Perreira v. Sec'y of Dep't of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir.1994) ("An expert opinion is no better than the soundness of the reasons supporting it.").

Assessing the reliability of an expert opinion in Vaccine Act cases can be challenging, because often there is little supporting evidence. See Althen, 418 F.3d at 1280 (noting that the "field [is] bereft of complete and direct proof of how vaccines affect the human body"). Most expert opinions extrapolate from existing data and knowledge. The weight to be given to an expert's opinion is based in part on the size of the "gap between the data and the opinion proffered." Cedillo, 617 F.3d at 1339 (internal quotation marks omitted) (quoting Joiner, 522 U.S. at 146).

In the case at bar, Dr. Overby, Petitioner's medical expert, actually did not present a theory that Isabela's vaccinations could have caused her IS. Dr. Overby's testimony simply endorsed a temporal relationship between Isabela's vaccinations and her seizures. See Tr. at 53 ("what this is about is it's understood that there will be a temporal relationship, if there's a temporal relationship between one event and another"). He agreed that "the symptoms experienced by Isabela within 72 hours of being vaccinated by a listed vaccine are, eventually result in her diagnosis with infantile spasms." Tr. at 54. At other points, his testimony was even more equivocal. See, e.g., Tr. 54-55 ("We're trying to establish that a process began within 72 hours culminating in an encephalopathy, and I think that's all we can say."); Tr. at 54 (as to causation, "one cannot say in either direction"); Tr. at 87 ("I don't think we're going to settle here [whether] this is causal or not since no one knows what causes infantile spasms.").

As noted above, during one portion of his testimony, Dr. Overby appeared to present the theory that vaccination could have caused an inflammatory response leading to seizures, and that seizures could lead to further seizures. He did not, however, endorse that theory as an explanation for how Isabela's epileptic syndrome, IS, could have been caused by vaccination. As "more of an aside," he described how antibodies against NMDA receptors can cause severe seizure encephalopathies. Tr. at 89. But he agreed there was no evidence of an inflammatory process in Isabela's case. Tr. at 90.

A fair reading of Dr. Overby's testimony does not add up to a reliable medical opinion that vaccinations can cause IS. "I don't know, I think it's possible," Dr. Overby testified. Tr. at 82. "A reasonable degree of medical certainty? I don't know what causes infantile spasms, so no I can't say that." Id. He conceded that immunology is "beyond my expertise really." Tr. at 84.

To determine whether Petitioner has met her burden under Prong 1, all the evidence must be weighed.[27] Against the weak (really nonexistent) causation theory presented by Dr. Overby, I must weigh the Secretary's contrary evidence, which is formidable. Dr. Guggenheim's presentation evidenced a thorough understanding of the syndrome Isabela suffered. This included her testimony that IS, even the cases that are deemed cryptogenic, in all likelihood is caused by underlying brain dysfunction. Further, Dr. Guggenheim's testimony showed that it is highly unlikely that inflammation resulting from vaccination leads to the syndrome of IS. In addition, in cases where the cause of West syndrome is known, a latency period of weeks or months has been observed, not hours or days. The record contains no refutation of Dr. Guggenheim's testimony.

On this record, Petitioner did not present preponderant evidence under Althen Prong 1. I proceed to the second prong of the Althen test for the sake of judicial economy and to provide additional context for my decision.

2. Althen Prong 2

The second prong of Althen requires a petitioner to prove "a logical sequence of cause and effect showing that the vaccination was the reason for the injury." Andreu ex rel. Andreu v. Sec'y of Dep't of Health & Human Servs., 569 F.3d 1367,1374 (Fed Cir. 2009) (internal quotation marks omitted) (quoting Althen, 418 F.3d at 1278). The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." Knudsen, 35 F.3d at 548-49. Along those lines, a petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second Althen factor. Id. at 1325-26; see Andreu, 569 F.3d at 1375-77. Further, evidence used to satisfy one prong of the Althen test may overlap to satisfy another prong. Capizzano, 440 F.3d at 1326.

"[T]reating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect shows[s] that the vaccination was the reason for the injury.'" Capizzano, 440 F.3d at 1326 (quoting Althen, 418 F.3d at 1280); see Andreu, 569 F.3d at 1375-76. The testimony of treating physicians concerning vaccine injury therefore is afforded extra weight when balancing the evidence. See Andreu, 569 F.3d at 1375-76. A special master may find that a petitioner has proven causation based on a treating physician's opinion that a vaccination was causally linked to the vaccinee's injury, if the special master finds the opinion to be both reliable and persuasive. See Moberly, 592 F.3d at 1323 (citing Capizzano, 440 F.3d at 1326); Andreu, 569 F.3d at 1375-76. On the other hand, the opinions of treating physicians are not conclusive of the issue. See 42 U.S.C. §300aa-13(b)(1) ("Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special

[27] For the reasons explained above, Petitioner's medical literature does not add weight to the arguments presented in favor of causation.

master or court."); Broekelschen v. Sec'y of Dep't of Health & Human Servs., 618 F.3d 1339, 1346-49 (Fed. Cir. 2010) (affirming special master's finding that Petitioner's injury was not transverse myelitis, notwithstanding the diagnosis of treating physician); Cedillo, 617 F.3d at 1348 ("The Special Master did not err in failing to afford significant weight to the opinions of [the] treating physicians.").

In Andreu, the Federal Circuit found that treating physician testimony was sufficient to set forth a logical sequence of cause and effect. The physician in that case, a pediatric neurologist, testified "unequivocally" that he believed the vaccination caused the injury alleged—a seizure disorder—and he explained the rationale for his conclusion: he could identify the cause of seizures in 70 to 75 percent of his patients, but he was unable to find a cause for the vaccinee's seizures. Andreu, 569 F.3d at 1375-76. He further explained that the timing was consistent with a vaccine-caused seizure, which led him to conclude that the vaccine caused the seizure. Id. at 1376. A second treating physician explained that some evidence supported finding that the vaccine caused the seizure, but he was reluctant to attribute causation to the vaccine. Id. at 1376-77.

The underlying facts in Moberly were very similar to Andreu. In Moberly, the Federal Circuit found the treating physicians' opinions were insufficient to prove causation. The Federal Circuit upheld the lower courts' findings that none of the vaccinee's treating physicians offered a reliable statement that the vaccine caused the injury. The Moberly court contrasted Andreu, stating that "there was direct testimony from Andreu's treating physicians stating 'unequivocally' that the [vaccination] caused his seizures," whereas in Moberly "there was no treating physician evidence that supported the claim of causation." Moberly, 592 F.3d at 1324-25. Instead, the notations in the "medical records regarding the temporal proximity of the [vaccination] to the seizures were all speculative." Id. at 1323.

Based on the Federal Circuit's decision in Andreu, Petitioner theoretically could satisfy Prong 2 of Althen by presenting the testimony of a treating physician. Andreu, however, was a case where there was strong evidence of causation under Prongs 1 and 3. See Moberly, 592 F.3d at 1324-25; see also Andreu, 569 F.3d at 1377 n.4 (petitioners presented evidence from a well-qualified medical expert in support of prong 1). As discussed herein, the evidence in this case, in contrast, is lacking on Prongs 1 and 3. [28] In this case, the testimony of treating physicians did not provide the evidence

[28] The Federal Circuit has held that a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury. See Grant v. Sec'y of Dep't of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992). Neither does the absence of other identified causes necessarily implicate vaccines. "[T[he absence of alternative causes for a condition does not alone suffice to ascribe causation to the vaccine." Lampe v. Sec'y of Dep't of Health & Human Servs., 219 F.3d 1357, 1361 (Fed. Cir. 2000) (citing Grant, 956 F.2d at 1149). In Capizzano, the Federal Circuit stated that the "fact that these physicians' diagnoses may have relied in part on the temporal proximity of [the petitioner's] injuries to the administration of the vaccine is not disqualifying." 440 F.3d at 1326. This statement from Capizzano was in turn relied upon by the Federal Circuit in Andreu, where the Circuit

necessary to prove a case of vaccine causation, under well-established precedent. "[N]either a mere showing of a proximate temporal relationship between vaccine and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." Moberly, 592 F.3d at 1323 (internal quotation marks omitted) (quoting Althen, 418 F.3d at 1278).

As noted above, testimony from treating physicians at hearing must be carefully considered. In this respect, Dr. Henkind and Dr. Overby merit highest marks. Both are well-qualified to render an opinion: they are specialists who have pertinent experience as well as training, and they had the opportunity to observe Isabela's illness and progress first-hand. At hearing, they were candid and helpful, and stayed within the bounds of their expertise. Beyond all of these factors, it was evident that they cared deeply about Isabela and her plight. I have the greatest respect for these physicians and their efforts in this case.[29]

Dr. Overby apparently was not prepared to testify to vaccine causation, but only to a temporal relationship between vaccination and the onset of seizures. During the course of his testimony, he declined several times to ascribe causation to the vaccination. Thus, I can hold without doubt that Dr. Overby's testimony did not establish a logical cause and effect between vaccination and injury—it was clear based on his testimony that it was not intended to do so.

I consider the opinion of Dr. Henkind even more carefully because, unlike Dr. Overby, she appeared actually to believe that vaccination caused Isabela's injury. If the subjective belief of one treating pediatrician is sufficient to satisfy prong 2 of Althen, then prong 2 of Althen has been satisfied in this case. Like the treating physician in Andreu, Dr. Henkind's testimony was unequivocal: the child was well before vaccination, the child became ill after vaccination, and there is no other explanation in the medical record than vaccination. Therefore, Dr. Henkind, concluded, vaccination was the cause. See Tr. at 40.

Dr. Henkind's testimony is insufficient to satisfy Prong 2, for the following reasons. First, unlike Andreu, where there was strong evidence on Prongs 1 and 3, the evidence in this case on those prongs is weak. See Andreu, 569 F.3d at 1375 ("If a claimant satisfies the first and third prongs of the Althen standard, the second prong can be met through medical opinion testimony." (citing Capizzano, 440 F.3d at 1326)); Id. at 1377 n.4 (petitioners presented evidence from a well-qualified medical expert in support of Prong 1). The Federal Circuit in Moberly expressly indicated that the context of a treating physician's opinion is important. See Moberly, 592 F.3d at 1324-25.

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cited and quoted Capizzano, "A treating physician may rely on the close temporal proximity between a vaccine and an injury in concluding that there is a logical sequence of cause and effect between the vaccine and the injury." 569 F.3d at 1376. In light of the decision in Moberly, it appears that treating physician statements based on temporal proximity and the absence of evidence of another cause must be considered; but whether such statements satisfy Prong 2 of Althen depends on the weight of the other evidence of record.

[29] I express the same appreciation for Dr. Guggenheim's participation.

Second, Dr. Henkind is not a neurologist. In her career as a pediatrician, she understandably has had less experience treating children with West syndrome than pediatric neurologists like Dr. Overby and Dr. Guggenheim. Where the specialists' testimony clearly weighs against a finding of causation under Prong 2, it would be incongruous to conclude that the testimony of a non-specialist prevails. See, e.g., Ellis v. Hartford Life and Acc. Ins. Co., 594 F.Supp. 2d 564, 569 (E.D. Pa. 2009) ("[I]f [a] consultant's conflicting opinion is based on reliable evidence, it can support a determination contrary to that of a treating physician, especially if the consultant is a specialist and the treating physician is not." (internal quotation marks omitted) (citing and quoting Addis v. Limited Long-Term Disability Program, 425 F. Supp.2d 610, 617 (E.D. Pa. 2006))).

Third, Dr. Henkind's analysis depends on the concept of challenge/rechallenge. On one occasion after the initial onset of seizures, Dr. Henkind re-vaccinated Isabela (with Hep B vaccine, not pertussis). Pet'r's Ex. 4 at 26; Pet'r's Ex. 5 at 1. This vaccination was followed within hours by the recurrence of spasms. Tr. at 40. See Pet'r's Ex. 4 at 93. As Dr. Guggenheim pointed out, however, on another occasion when Isabela was vaccinated following the initial onset of infantile spasms, she did not suffer a recurrence of seizures. See Tr. at 147-48 (Isabela had immunizations after the onset of her IS and "nothing happened"); see Pet'r's Ex. 5 at 1 (Hib vaccine), Pet'r's Ex. 4 at 27 (smiling and interactive, without further seizure activity).

Logically, it follows that vaccination was likely not the cause of the recurrence of seizures, and the theory of challenge/rechallenge does not explain what happened to Isabela. Petitioner's own expert, Dr. Overby, confirmed that recurrences of spasms are common in cases of West syndrome even after a period of abatement following treatment with ACTH. Tr. at 67. On this record, the likelihood is that the recurrence of spasms following the one instance of Hep B vaccination was a coincidence. On balance, I do not accept Dr. Henkind's testimony as sufficient under Althen Prong 2.

Petitioner indicates that a physician's recommendation to withhold vaccinations can be indicative of a belief in vaccine causation. See supra; see also Pet'r's Post-Trial Br. at 18. In this case, Dr. Henkind's notation is consistent with her opinion at hearing, as to which no inference is needed – she testified clearly that in her opinion this is a rare instance of vaccine injury causation. The notation in the file does not add to the weight of her opinion which, for the reasons discussed above, does not furnish preponderant evidence in Petitioner's favor. The notation from Dr. Overby's files, see Pet'r's Ex. 8 at 14, is even less persuasive, given the reluctance he expressed at hearing to ascribe causation to Isabela's vaccination.

The treating physician opinions therefore provide insufficient evidence of a logical connection between vaccination and injury. As discussed herein, even if Prong 2 were satisfied, Petitioner still has not met the burden of presenting preponderant evidence under Prongs 1 and 3.

3. Althen Prong 3

To show causation, a petitioner must establish that the injury occurred within a time frame that is consistent with the theory of causation set forth. See Pafford, 451 F.3d at 1358. A proximate temporal relationship must be within a "medically acceptable" timeframe. de Bazan, 539 F.3d at 1352. What constitutes an appropriate temporal association is a question of fact and will vary with the particular theory of causation advanced. See Pafford, 451 F.3d at 1358; de Bazan, 539 F.3d at 1352.

It is undisputed that Isabela's seizures commenced shortly after her vaccinations. Petitioner has not presented a theory that is consistent with the onset of infantile spasms within a day of vaccination.

Petitioner seems to rely, although without any explanation, on the Goodman study. See Pet'r's Post Trial Br. at 20; Pet'r's Ex. 18.[30] As discussed above, that study has not been interpreted by the IOM to indicate a causal relationship between seizures and vaccination. See Ct. Ex. 1 at 1. The report itself denies such an association. See Pet'r's Ex. 18 at 5. The Goodman study noted a temporal phenomenon—that the onset of seizures was more likely to be reported within a time period closer to vaccination. See Tr. at 142 ("approximately two weeks"). The authors recognized that a cluster in reports of infantile spasms following vaccination does not signify that vaccination actually caused the spasms that were reported.

I allow for the possibility of a hitherto undiscovered causal relationship between vaccination and the onset of infantile spasms. What the effect would be on this decision if such a relationship were known is beyond my ability to predict. All I can say is that no reliable evidence of such a relationship appears in the record before me.[31]

Evidence of a causally appropriate temporal association as required by Althen Prong 3 therefore is not established by the Goodman report. On the contrary, perhaps the most reasonable conclusion from the Goodman report at this point is that it was an extremely limited study of very few individuals which, if anything, shows no causal association between vaccination and infantile spasms. See Tr. at 143-44.

On the strength of Dr. Guggenheim's testimony, the period of time between vaccination and the onset of Isabella's seizures was too short to be consistent with a

[30] This study was not filed into the record until after the hearing. See Notice of Filing, Apr. 4, 2011, ECF No. 29. The tardy filing not only violated the pre-hearing order, but more importantly deprived the Secretary of a fair opportunity to respond to this evidence. See Tr. at 142, 155-56; Vaccine Rule 8(c).

[31] In a recent decision concerning another seizure disorder, Dravet's syndrome, the Secretary conceded that vaccination precipitated the vaccinee's seizures by causing a febrile reaction. See Deribeaux v. Sec'y of Dep't of Health & Human Servs., No. 05-306V, 2011 WL 6935504 (Fed. Cl. Spec. Mstr. Dec. 9, 2011), aff'd, --- Fed. Cl. ---, 2012 WL 2367037 (June 4, 2012). In that case, there was no evidence that the onset of seizures, even if accelerated by vaccination, changed the tragic outcome of the disorder. 2011 WL 6935504 at *45-46. In this case, without evidence of a causal link between the commencement of seizures and vaccination, the issue addressed in Deribeaux does not arise.

causative relationship. Rather, it appears that the onset of Isabela's seizures was related only coincidentally to her vaccinations.

IV. CONCLUSION

Petitioner has not presented preponderant evidence to support her claim under the Vaccine Act that vaccinations were the cause of Isabela's injuries. Accordingly, she is not entitled to compensation under the Vaccine Act, and her Petition must be **DISMISSED**. In the absence of a timely motion for review filed pursuant to Vaccine Rule 23, the Clerk is directed to enter judgment according to this decision.

IT IS SO ORDERED.

s/ Dee Lord
Dee Lord
Special Master