In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 09-0585V

(Filed: June 5, 2013)

(Reissued for Redaction and Amended Caption: June 19 and 21, 2013)[1]

* *		
LAMONA DODD, parent of S.S., a minor,	*	PUBLISHED
Petitioner,	*	Entitlement, Seizure Disorder, Epilepsy, MMR Vaccination, Insufficient Proof of Causation
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	
* *		

Ronald C. Homer, Conway, Homer & Chin-Caplan, P.C., Boston, MA, for petitioner.

Voris E. Johnson, United States Department of Justice, Washington, DC, for respondent.

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[1] When this decision was originally issued, the parties were notified that the decision would be posted on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2006)). The parties were also notified that they may seek redaction pursuant to 42 U.S.C.A. § 300aa-12(d)(4)(B); Vaccine Rule 18(b). Petitioner made a timely request for redaction, and this decision was reissued on June 19, 2013, with the name of the minor child redacted to initials and the birth date of the minor child redacted to the year only. Two days later, petitioner moved to amend the caption as she is no longer married to S.S.'s father and has changed her name back to Lamona Dodd. The decision was reissued on June 21, 2013 with the amended caption, and petitioner's name was corrected throughout the decision. Except as noted in this footnote, no other substantive changes have been made.

DECISION

On September 4, 2009, Lamona Dodd ("petitioner" or "Ms. Dodd") filed a petition under the National Childhood Vaccine Injury Act ("Vaccine Act")[2] on behalf of her minor son, alleging that the injuries S.S. sustained were caused by the vaccinations he received on October 1, 2007. Petition at 1. In particular, petitioner attributed S.S.'s epilepsy and developmental delay to the measles-mumps-rubella ("MMR") and Diphtheria-Tetanus-acellular-Pertussis ("DTaP") vaccines administered on October 1, 2007.[3] Id. Petitioner requested a ruling on the record or alternately, summary judgment in her favor. Id. at 27-28; See Vaccine Rule 8(d) (which incorporates the procedures set forth in Rule 56 of the Rules of the U.S. Court of Federal Claims ("RCFC")).

The chief difficulty with the asserted claim is that petitioner's theory of vaccine-related causation turned on a type of seizure that S.S. did not have when his disorder first presented. For this reason, as more fully explained below, petitioner's claim cannot stand.

I. Procedural History

On September 18, 2009, two weeks after filing her petition, petitioner filed (1) her affidavit; (2) S.S.'s medical records, including a list of the vaccines he had received; (3) a Vaccine Adverse Event Reporting System ("VAERS") report filed on S.S.'s behalf; and (4) S.S.'s school records. See Pet'r's Exs. 1-17. Petitioner asserted that the "documents provide[d] preponderant evidence … [that S.S.'s] vaccines were the likely cause of his epilepsy, and subsequent developmental delay." Petition at 18.

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[2] The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et. seq. (2006). Hereinafter, individual section references will be to 42 U.S.C.A. § 300aa of the Vaccine Act.

[3] Although petitioner identified both the MMR and DTaP vaccines in her petition as the causal agents, her subsequently retained expert opined that the MMR vaccine singularly provoked S.S.'s injuries. See Petitioner's Exhibits ("Pet'r's Exs.") 18 at 5 (Expert Report of Dr. Kinsbourne filed June 3, 2010); 20 at 4 (Supplemental Expert Report of Dr. Kinsbourne filed December 21, 2010). Consistent with her expert's opinion, petitioner focused her attention in the post hearing briefing on the MMR vaccine alone. See Petitioner's Post Hearing Brief ("Pet'r's Br."), Jun. 10, 2011, at 1; Petitioner's Reply to Respondent's Post Hearing Brief ("Pet'r's Reply to Resp't's Br."), Aug. 12, 2011, at 1.

Respondent filed her Rule 4(c) report in December of 2009, recommending against compensation because the medical records upon which petitioner relied did not establish that she was entitled to Program compensation. Respondent's Report ("Resp't's Report") at 2, 8-9. Respondent asserted that "if the Special Master were to rule upon petitioner's Motion for a Ruling on the Record, the appropriate ruling would be dismissal of the Petition for a failure of proof." Id. at 1 n.1.

The formerly assigned special master held a status conference in December of 2009, affording the parties an opportunity to discuss settlement options before ordering petitioner to file an expert report. Order, Dec. 10, 2009. The parties failed to reach a settlement, and the then-assigned special master ordered petitioner to file "an expert report, [the] curriculum vitae of the opining expert, and copies of any articles of medical literature relied upon [by the expert] in forming the [offered] opinion." Order, Jan. 6, 2010. Petitioner requested and received several extensions of time to comply with the order. See, e.g., Order, Mar. 23, 2010.

In March 2010, the case was reassigned to the undersigned. Three months later, on June 3, 2010, petitioner filed an expert report from Dr. Marcel Kinsbourne, a pediatric neurologist. Accompanying the expert report was his curriculum vitae and nine articles upon which he had relied in forming his opinion. See Pet'r's Exs. 18 (including Tabs A-I); 19. Dr. Kinsbourne posited that the MMR vaccine S.S. received on October 1, 2007, caused an encephalopathy that manifested first as a seizure disorder, and later as developmental delay and hyperactivity with attention deficits. Pet'r's Ex. 18 at 4.

In July 2010, the undersigned held a status conference with the parties to clarify whether S.S.'s initial seizures were accompanied by fever. See Order, Sept. 14, 2010. Petitioner's counsel indicated that S.S.'s presenting seizures were without fever. Id. At that time, the undersigned afforded the Secretary sixty days to file her responsive expert report. Id.

In September 2010, respondent filed the expert report and curriculum vitae of Dr. John McDonald, a pediatric neurologist. See Respondent's Exhibits ("Resp't's Exs.") A; B. Respondent also filed several supporting articles to which Dr. McDonald cited in his report. See Resp't's Ex. A (Tabs 1-3). Dr. McDonald disagreed with Dr. Kinsbourne's opinion of vaccine-related causation. Resp't's Ex. A at 3. He attributed S.S.'s seizure disorder, developmental delay and attentional problems to an "underlying genetic basis," but he acknowledged that the results of any standardized genetic and metabolic testing were not included in the filed medical records. Id. at 4.

In a subsequently filed status report, petitioner clarified that she was not alleging an encephalopathy as defined by the Vaccine Injury Table and had discussed the afebrile nature of S.S.'s seizures with Dr. Kinsbourne. She asked to file a supplemental expert report to describe petitioner's theory more clearly. Petitioner's Status Report, Oct. 22, 2010, at 2. The undersigned granted petitioner's request. First Order, Oct. 28, 2010.

Petitioner filed her supplemental expert report from Dr. Kinsbourne in December 2010. Pet'r's Ex. 20 (including Tabs A-E). In his supplemental report, Dr. Kinsbourne asserted that S.S. had not suffered an encephalopathy--as defined by the Program's Vaccine Table Injury--but instead had suffered a medical encephalopathy, as more broadly defined by the Institute of Medicine ("IOM"). Pet'r's Ex. 20 at 1; compare 42 C.F.R. § 100.3(b)(2) with Pet'r's Ex. 18, Tab G (1994 IOM report)[4] at 137. Dr. Kinsbourne further asserted that when a seizure occurs within a medically reasonable time frame after an MMR immunization, it need not be accompanied by fever to establish vaccine-related causation. Pet'r's Ex. 20 at 2.

Petitioner filed additional medical records in February and March 2011, further to a subpoena issued by the undersigned. See First Order, Feb. 28, 2011; see also, e.g., Pet'r's Exs. 23; 24 (Medical Records filed Mar. 21, 2011).

On March 18, 2011, the undersigned heard the testimony of the experts. Thereafter, the parties filed post-hearing briefing.

The claim is now ripe for a ruling.

II. S.S.'s Medical History

S.S. was born in 2003. Pet'r's Ex. 3 at 19. He was delivered without complications at 37 weeks, weighing seven pounds. His head circumference measured 19.5 inches, and he displayed no observable abnormalities. Id. at 19. His Apgar score was 9 at both one and five minutes.[5] Both his hearing and

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[4] Kathleen R. Stratton, et al., Adverse Events Associated With Childhood Vaccines: Evidence Bearing on Causality, Institute of Medicine 1-464 (1994).

[5] An Apgar score is "a numerical expression of the condition of a newborn infant . . . [determined by] the sum of points gained on assessment of the heart rate, respiratory effort, muscle tone, reflex, irritability, and color." Dorland's Illustrated Medical Dictionary 1682 (32nd ed. 2012). The scale ranges from 0 (the lowest score) to 10 (the highest score). U.S. National Library of Medicine, MedlinePlus, Apgar,

metabolic screening tests were satisfactory. Id. at 23, 29. S.S. and his mother were discharged from the hospital two days after his birth. Id. at 26.

From birth until four years of age, S.S. received the scheduled complement of routine childhood vaccinations. See Pet'r's Ex. 13 at 1. He also experienced common childhood ailments, including runny noses, coughing, sore throats, diarrhea, fevers, and ear infections. His doctors attributed these various ailments to either upper respiratory infections or allergies. E.g., Pet'r's Exs. 3 at 56; 5 at 3. S.S. also contracted strep pharyngitis once and conjunctivitis (often referred to as pink eye) twice. Pet'r's Ex. 5 at 1, 10, 11.[6]

In August of 2005, at 23 months of age, S.S. required emergent care for a fall during which he bumped his head. See Pet'r's Ex. 3 at 86-102. The records from the emergency room visit appear to indicate that S.S. exhibited "confusion" after his head injury, but admittedly the term "confusion" is not clear in the records. Id. at 92. S.S. was discharged with instructions to petitioner to return if her son's symptoms persisted or worsened after three days. Id. at 98.

Nearly seven months later, at two and one half years of age, S.S. began attending daycare. Pet'r's Ex. 16 at 1. He exhibited no health problems. Pet'r's Ex. 10 at 1.

S.S. began attending pre-kindergarten at four years of age, in August 2007. See Pet'r's Ex. 11 at 1. An early screening test administered shortly after he started school showed that his articulation skills were "fair." Id. at 3. His progress reports, however, showed a decrease in his abilities between the second and third quarters--as evidenced by the change in his skill category rankings from "in progress" to "non-mastered" in a number of areas. Id. at 7.

On October 1, 2007, S.S. received the MMR and DTaP vaccinations of which petitioner has complained in this vaccine claim. See Pet'r's Ex. 13 at 1. In the VAERS report petitioner filed on S.S.'s behalf, she stated that one week after his vaccinations, S.S. developed a cough and fever of approximately 100 degrees, but "continued" to attend school. Pet'r's Ex. 12 at 1.

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http://www.nlm.nih.gov/medlineplus/ency/article/003402.htm (last visited on April 17, 2013).

[6] S.S. also suffered a foot injury in January 2006; it resolved independently after a week of rest. Pet'r's Ex. 5 at 6-7.

On October 15, 2007, two weeks after S.S.'s vaccinations, he was not feeling well again. Although he did not have a fever, he did have a headache, abdominal pain, nausea with vomiting, and an episode of diarrheal incontinence during the day. Pet'r's Ex. 3 at 169. Later that day, S.S. experienced a left-sided, focal tonic-clonic seizure that prompted petitioner to seek care at the hospital.[7] Pet'r's Ex. 16 at 2; accord. Pet'r's Ex. 3 at 167, 169, 177-178.

On admission to the hospital, S.S. was examined by Dr. Phillip Norsworthy, the attending emergency room physician. See Pet'r's Ex. 3 at 169. Dr. Norsworthy administered a dose of Ativan, an anti-epileptic medication, to S.S. and ordered several tests, including a computed tomography ("CT") scan of S.S.'s head.[8] Id. S.S.'s test results returned as normal, but were suggestive of sinus disease. Id. After discussions with Dr. Hemant Agarwal, a specialist in pediatric critical care, Dr. Norsworthy transferred S.S. to the pediatric intensive care unit "for . . . further evaluation" and an electroencephalogram ("EEG").[9] Id.

Dr. Agarwal observed and treated S.S. until his discharge (the day after his admission). Pet'r's Ex. 3 at 167. During his hospital admission, S.S. experienced left-sided weakness that resolved. Id. His seizures were managed by the two anti-

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[7] The record evidence offers conflicting accounts regarding when S.S. first began feeling ill. Compare Pet'r's Ex. 16 at 2 (petitioner's affidavit indicating S.S. stayed home from school), with Pet'r's Ex. 3 at 177 (pediatric records indicating that S.S. vomited at school, necessitating an early school pickup by his grandmother), and Pet'r's Ex. 3 at 169 (hospital's records indicating S.S. became sick that evening). But each of the accounts consistently state that S.S. first experienced multiple staring spells followed by seizure activity on the evening of October 15, 2007. See, e.g., Pet'r's Ex. 3 at 169.

[8] A CT scan produces a three-dimensional view of body structures by "passing x-rays through the body organs at many angles through 360 degrees." Mosby's Manual of Diagnostic and Laboratory Tests 1030 (4th ed. 2010). "Each degree of density is given a numeric value called a density coefficient, which is digitally computed into a shade of gray." Id. A head CT scan will give a "well imaged" view of the brain. Id. at 1080. It "is useful in the diagnosis of brain tumors, infarction, bleeding and hematomas." Id.

[9] "The EEG is a graphic recording of the electrical activity of the brain." Id. at 573. It "is invaluable in the investigation of epileptic states." Id. "[S]eizure activity is characterized by rapid, spiking waves," while "[p]atients with cerebral lesions (e.g. tumors, infarctions) will have abnormally slow EEG waves." Id.

seizure medications--Ativan and fosphentoin--the combination of which appeared to assist S.S.'s return to "normal" before his discharge. Id.

After consulting with pediatric neurologists at Vanderbilt Children's Hospital, Dr. Agarwal placed S.S. on Keppra, another anti-seizure medication, to be administered twice daily. Pet'r's Ex. 3 at 167. Dr. Agarwal also prescribed Diastat, an additional anti-epileptic medication, to be administered rectally in the event of a seizure lasting more than five minutes. Id. S.S. was discharged on October 16, 2007, with a referral to the Pediatric Neurology Clinic at Vanderbilt Children's Hospital for a follow-up visit. Id.

The results of S.S.'s EEG, dated one week later, showed that he had experienced subtle slowing throughout his right cerebral hemisphere. Pet'r's Ex. 3 at 207. But, it did not show any seizure activity. Id.

Nearly six weeks later, on December 9, 2007, petitioner took S.S. back to the emergency room for a second seizure episode. Pet'r's Ex. 3 at 240. Dr. Geoffrey Fleming, the examining physician during that emergency room visit, noted that S.S. presented following an "approximately 45-minute generalized tonic-clonic seizure [that] requir[ed] multiple medications" to control. Id.

Petitioner explained that S.S. had been napping on her lap during a church meeting when he awakened, "stiffened and drooled for a while." Pet'r's Ex. 3 at 252. Once back at home, S.S. returned to his nap and could not be awakened. Again, he stiffened and "vomited several times." Id. Concerned about S.S.'s presentation, petitioner took him to the hospital for evaluation. Id.

"En route to the emergency room, he went from tonic to clonic convulsive movements." Pet'r's Ex. 3 at 252. He still was convulsing when he arrived at the hospital, and he required anti-epileptic medication "to break his seizure." Id. S.S. was noted to be afebrile. His head CT scan and laboratory results were normal. Id. at 240. He slowly returned to his neurologic baseline after a two-day hospital stay. Id.

Petitioner acknowledged during that hospital visit that she had stopped giving S.S. the medication he began taking after his first seizure event in October because it made him "very dizzy and restless."[10] Pet'r's Exs. 3 at 281; 16 at 2.

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[10] As mentioned in Dr. Fleming's notes, petitioner complained that the medication made S.S. sleepy. Pet'r's Ex. 3 at 240. Also mentioned in the notes of the case worker--who observed S.S. and conferred with petitioner during the December hospitalization--was petitioner's concern that the prescribed seizure

Petitioner further acknowledged that she had not taken S.S. for his follow-up visit, as directed, after his first seizure episode. Pet'r's Ex. 3 at 252, 281. Dr. Fleming, the attending physician during S.S.'s hospitalization following his second seizure event, urged petitioner to continue to administer S.S.'s seizure medication and to schedule an appointment for S.S. with Dr. Ahmad Alhamda, a pediatric neurologist affiliated with a facility preferred by petitioner. Id. at 240, 253, 281.

Two weeks later, on December 21, 2007, petitioner took S.S. to see Dr. Alhamda. Dr. Alhamda made note of S.S.'s two earlier emergency room visits and his "family history" of "epilepsy in an aunt," whose seizure disorder began in early childhood.[11] Pet'r's Ex. 8 at 10. Dr. Alhamda described S.S. as "a 4 year old with [a] history consistent with generalized secondary epilepsy." Id. He ordered an EEG and a magnetic resonance image ("MRI") of S.S.'s brain. Id. He also increased S.S.'s dosage of Keppra, and provided petitioner with a calendar to track S.S.'s seizure activity. Id.

Two weeks later, on January 9, 2008, petitioner again sought emergent care for S.S. for his hourly episodes of minute-long, tonic-clonic seizures. Pet'r's Ex. 7 at 46. The attending physician, Dr. Kathryn McVicar, made note of a family history of epilepsy in an aunt and ordered both an MRI and an EEG. Id. at 4. The MRI was normal, but S.S.'s EEG showed seizure activity in his fronto-temporal region. Pet'r's Exs. 7 at 46, 48-49; 8 at 7. Two medications, Ativan and fosphenytoin, were administered to halt the seizures, and the anti-epileptic Zonegran was added to S.S.'s prescription regimen for better seizure control. Pet'r's Ex. 7 at 46.

Nearly one week later, on January 15, 2008, S.S. saw Dr. Alhamda for a follow-up visit. Pet'r's Ex. 8 at 5. Dr. Alhamda noted S.S.'s emergency room visit earlier in the month and observed that S.S.'s gait was still slightly unsteady. Id. Without comment, Dr. Alhamda recorded the impression of S.S.'s parents that the prescribed anti-epileptic medication had exacerbated S.S.'s seizures. Id. Similarly, he recorded Ms. Dodd's belief that S.S.'s seizure disorder began shortly after his vaccinations and the concern of S.S.'s parents regarding immunizations.

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medicine was contributing to S.S.'s dizziness. Id. at 281. The case worker reported that she too had observed S.S.'s dizziness and unsteady gait. Id.

[11] Dr. Fleming's notes from S.S.'s October visit to the emergency room also made reference to S.S.'s aunt's seizure condition. Pet'r's Ex. 3 at 169. Although Dr. Agarwal, another attending physician during that same hospital stay, noted that there was "no family history of seizures," Id. at 17, the records contain a number of indications that S.S., in fact, had an aunt with epilepsy. See Pet'r's Exs. 7 at 4; 14 at 4, 17 (referencing S.S.'s great aunt who had epilepsy.)

Id. Dr. Alhamda observed that S.S.'s "[s]eizures seem[ed] to be consistent with [a]frontal [lobe-]type epilepsy," a type of seizure condition accompanied by behavioral changes. Id. at 6; see also, Pet'r's Ex. 7 at 46 (the EEG results show S.S. suffered approximately seven seizures). Dr. Alhamda increased the dosage of S.S.'s anti-seizure medications. Id. He asked to see S.S. regularly and indicated that he was eager to arrange for a "comprehensive epileptic evaluation" of S.S. Id.

The next week, Dr. Alhamda noted a decrease in the number of S.S.'s seizures. He was experiencing only two episodes a day, but the seizures were now longer in duration. Pet'r's Ex. 8 at 3. Although Dr. Alhamda found S.S.'s restlessness to be suggestive of Attention Deficit Hyperactivity Disorder ("ADHD"), he acknowledged that some of S.S.'s attentional issues may have emerged as a "side effect" of the seizure medication. Id. at 3-4. Dr. Alhamda adjusted the dosage and combination of S.S.'s medications. Id.

S.S. returned to Dr. Alhamda one month later. His seizures had ceased, and his hyperactivity was diminished. Pet'r's Ex. 8 at 1. Dr. Alhamda indicated in his notes that since S.S.'s last visit, petitioner had stopped administering the Keppra, had continued to administer the prescribed dosage of Zonegran, and had failed to add the Topamax he had prescribed. Id. Dr. Alhamda increased S.S.'s prescription for Zonegran and urged petitioner to consult with him before altering S.S.'s seizures medications. Id. at 1-2.

Nearly six weeks later, on April 10, 2008, S.S. saw another neurologist, Dr. Eric Pina-Garza at the Vanderbilt Children's Hospital. Pet'r's Ex. 14 at 17. Dr. Pina-Garza noted that S.S. was taking a daily dosage of Zonegran and had last seized ten days earlier. Id. He recorded a family history of seizures in a maternal great aunt and described S.S.'s epilepsy as having an "unclear etiology." Id. He started S.S. on Depakote, another anti-epileptic medication, and ordered an EEG. That EEG, which was performed two weeks later, was normal. Id. at 13.

S.S. continued to see Dr. Pina-Garza. See, e.g., Pet'r's Ex. 23 at 19. He also received more regular care at the East Jackson Family Medical Center. See Pet'r's Ex. 6. Although his seizures were well-managed, the administered medications made S.S. drowsy and caused him to sleep during school. Id. at 11. S.S. also began to exhibit serious behavioral problems. Id. at 15.

Four months after Dr. Pina-Garza began to treat S.S., he added a new anti-epileptic medication, Trileptal, to S.S.'s prescriptive regimen and began to decrease S.S.'s dosage of Depakote. Pet'r's Ex. 14 at 11. Three months later, Dr. Pina-Garza reported that S.S. was no longer experiencing seizures, id. at 4, and was no longer sleeping at school. Pet'r's Ex. 6 at 7. In addition, he was behaving much better. Id. Notwithstanding the noted improvement, S.S. was directed into a

special education placement at school and was encouraged to repeat pre-kindergarten. Pet'r's Ex. 15 at 27.

Two years later, S.S. began taking Adderall, on the recommendation of his treating physicians, to manage his hyperactivity. See, e.g., Pet'r's Ex. 21 at 11.

III. Expert Reports and Testimony

The parties offered the opinions of expert witnesses.

A. Petitioner's Expert

1. His Professional Qualifications

Petitioner offered the expert opinion of Marcel Kinsbourne, M.D., a pediatric neurologist. Transcript of Testimony ("Tr.") at 18. Dr. Marcel Kinsbourne was educated at Oxford University and received his medical degree in 1955. Pet'r's Ex. 19 at 1 (Curriculum Vitae of Dr. Kinsbourne). He continued his education at Oxford, earning additional degrees in the fields of neurology and pediatrics. In 1967, he received his medical license from the state of North Carolina and became an associate professor of neurology and pediatrics at the Duke University Medical Center and a Senior Research Associate at the Center for the Study of Aging and Human Development. Id. In 1974, Dr. Kinsbourne moved to Canada, accepting appointments as a professor of psychology at the University of Waterloo and a professor of pediatric neurology at the University of Toronto. Id. He returned to the United States in 1980 to become the Director of the Behavioral Neurology Department at the Eunice Kennedy Shriver Center. Id. at 1, Tr. at 5. He currently is a professor of psychology at the New School located in New York City. Id.

At the New School, Dr. Kinsbourne teaches graduate students in clinical psychology and oversees a laboratory employing twelve research assistants. Tr. at 6. Although he often sees children during the course of his research and did so during his work at the Eunice Kennedy Shriver Center, Dr. Kinsbourne does not provide active care. Tr. at 32. His work does not "involve the diagnosis or treatment of seizure disorders." Tr. at 32-33.

During his testimony, Dr. Kinsbourne acknowledged that the focus of his work has been on behavioral disorders and not on seizure disorders. He further acknowledged that he has not "seen a pediatric patient on an acute basis for the diagnosis and treatment of a neurological illness, other than a behavioral disorder, since at least 1981" (now more than 30 years ago) Tr. at 34. Dr. Kinsbourne

indicated that approximately fifty-five to sixty percent of his income comes from medical work in legal cases. Tr. at 31.

Based on Dr. Kinsbourne's documented training and experience, the undersigned accepted his tendered expertise as a medical consultant on issues of pediatric neurology, specifically involving behavioral disorders. Id.

2. His Opinion of Causation

Dr. Kinsbourne prepared an initial and a supplemental expert report. See Pet'r's Ex. 18 (Expert Report filed June 3, 2010); Pet'r's Ex. 20 (Supplemental Expert Report filed December 21, 2010). He opined that the MMR vaccine administered to S.S. on October 1, 2007, caused him to develop a seizure disorder and in turn, led to his severe hyperactivity and developmental delay. Pet'r's Ex. 18 at 3, 5. Alternatively, Dr. Kinsbourne asserted that the seizures S.S. first experienced on October 15, 2007, led to a lowering of his seizure threshold and allowed his subsequent injuries to develop. Pet'r's Exs. 18 at 4; 20 at 1; Tr. at 83-84.

a. The Triggering of S.S.'s Seizure Disorder

Dr. Kinsbourne held the MMR vaccine S.S. received in October 2007 responsible for the onset of his seizure disorder. He reasoned that S.S. experienced his first seizure event two weeks after his MMR immunization, which is an acceptable time frame for an adverse reaction to the MMR vaccine--particularly if there is no other explanation for seizure onset. Pet'r's Ex. 18 at 2; Tr. at 28.

Admitting that he could not describe the particular mechanism by which the administered MMR vaccine caused S.S.'s seizure disorder,[12] Dr. Kinsbourne identified S.S.'s first seizure episode on October 15, 2007, as the beginning of his epileptic condition. Tr. at 25, 43, 87. Dr. Kinsbourne posited that because the wild measles virus can cause seizures, the measles vaccine (an attenuated but live viral vaccine) also can cause seizures, albeit "far less frequently." Pet'r's Ex. 18 at 3; accord. Tr. at 19-20. He theorized that the mechanism by which the measles virus and the measles vaccine could trigger seizures would be the same. Tr. at 43.

Citing several studies and 1994 IOM report, Dr. Kinsbourne averred that "[s]eizures after MMR vaccination have been repeatedly documented [and] [t]heir

[12] Dr. Kinsbourne testified that "[i]t's not believed that the measles virus actually invades the brain." Tr. at 25.

peak incidence [occurs] within the second week after vaccination."[13] Pet'r's Ex. 18 at 3. He observed that S.S.'s seizure event on October 15, 2007, occurred during the second week after his MMR immunization and thus, implicated that particular vaccine. Tr. at 42. But, Dr. Kinsbourne conceded that timing alone is not sufficient to prove causation. Tr. at 49-50.

To bolster his opinion of vaccine-related causation, Dr. Kinsbourne averred that no other cause for S.S.'s seizure event existed. Pet'r's Ex. 18 at 2. Discounting the record evidence of a "distant relative" with epilepsy, Dr. Kinsbourne dismissed the likelihood that a genetic underpinning was primarily responsible for S.S.'s seizure condition. Dr. Kinsbourne instead insisted that adverse environmental factors--specifically, the administered vaccines--acted in concert with S.S.'s latent genetic predisposition to trigger the expression of a seizure condition. Tr. at 24, 28.

Dr. Kinsbourne unwaveringly pointed to the MMR vaccine as the causal trigger for S.S.'s initial afebrile seizure event. Referencing several case reports of seizures occurring in afebrile subjects with gastrointestinal illnesses,[14] he asserted

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[13] The studies and report by the IOM were filed with Petitioner's Exhibit 18 as:

Tab A: R. Alderslade et al., The National Childhood Encephalopathy Study 79-183 (1981).
Tab D: Philip J. Landrigan, M.D., et al., Neurologic Disorders Following Live Measles-Virus Vaccination, 223(13) JAMA 1459-62 (1973).
Tab G: Kathleen R. Stratton, et al., Adverse Events Associated With Childhood Vaccines: Evidence Bearing on Causality, Institute of Medicine 1-464 (1994).
Tab I: Robert E. Weibel, M.D., et al., Acute Encephalopathy Followed by Permanent Brain Injury or Death With Further Attenuated Measles Vaccines: a Review of Claims Submitted to the National Vaccine Injury Compensation Program, 101 (13) Pediatrics 383-87 (1998).

[14] These studies were filed with Petitioner's Exhibit 20 as:

Tab C: Wei-Ling Lee, et al., Afebrile Seizures Associated with Minor Infections: Comparison with Febrile Seizures and Unprovoked Seizures, 31(3) Pediatric Neurology 157-164 (2004).
Tab D: Hassib Narchi, Benign afebrile cluster convulsions with gastroenteritis: an observational study, published at www.biomedcentral.com/1471-2431/4/2 (an open access site) on MBC Pediatrics 4:2 (2004).

that seizures do not occur solely as a "reaction to a rise in body temperature." Pet'r's Ex. 20 at 1-2. He acknowledged, however, that fever and rash are the two most common symptoms that accompany wild measles viremia[15]--which reaches its peak two weeks after a measles infection. Tr. at 61. He further acknowledged that this is the first instance in which he has "offered the opinion that the MMR vaccine caused an afebrile seizure." Tr. at 30.

Dr. Kinsbourne recognized that neither fever nor rash--"the most prominent clinical symptoms"--during the peak period, of measles viremia, Tr. at 61, were present at the time of S.S.'s October 15, 2007 seizure event, Tr. at 39-40, not even in the milder form of presentation that might appear after an administration of the attenuated viral measles vaccine. In an effort to explain the absence of the most common symptoms of measles-associated viremia in S.S.'s case, Dr. Kinsbourne offered that "neither of [the symptoms] are seen" in cases involving a measles-induced inflammation known as measles encephalitis, which can lead to serious brain damage and death. Tr. at 61; See also Robert M. Kliegman et. al., Nelson Textbook of Pediatrics 1072 (19th ed. 2011) (describing the "unfavorable outcomes" in children afflicted with measles encephalitis).

Dr. Kinsbourne posited that the fever S.S. is alleged to have developed[16] (one week before his seizure event on October 15, 2007) was attributable to the MMR vaccine and thus, furnished "evidence of viremia." Pet'r's Ex. 20 at 1; Tr. at 61. He did not address, however, the subsequent symptoms of vomiting and diarrhea that S.S. developed shortly before his first seizure event; such symptoms may have been associated with a gastrointestinal illness.

b. Allegations of a Seizure-Induced Encephalopathy

In Dr. Kinsbourne's view, S.S.'s initial seizure was a vaccine-precipitated event that caused brain damage and led to a seizure disorder. He posited that the MMR vaccine S.S. received caused the first seizure event in October 2007, and effectively, lowered S.S.'s seizure threshold, which allowed him to experience seizures more easily.

Dr. Kinsbourne clarified that S.S. did not suffer an encephalopathy as defined by the Vaccine Injury Table. Pet'r's Ex. 20 at 1. Rather, Dr. Kinsbourne

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[15] Viremia is "the presence of viruses in the blood." Dorland's at 2058.

[16] Petitioner claimed in the VAERS report she filed on S.S.'s behalf, that S.S. developed a fever a week after his vaccination. See Pet'r's Ex. 12 at 1.

explained, S.S. suffered an encephalopathy, as more broadly defined by the IOM. According to the IOM, an encephalopathy is "any acute or chronic, acquired abnormality of, or injury to, or impairment of function of the brain." Pet'r's Ex. 18, Tab G (1994 IOM report), at 137.

Citing several filed articles,[17] Dr. Kinsbourne asserted that "prolonged or recurrent seizure activity . . . can irreversibly alter the way the immature brain develops." Pet'r's Ex. 18 at 4. But, he admitted that the seizures S.S. first experienced on October 15, 2007, could not be characterized as the type of prolonged seizure capable of causing brain damage. As he described S.S.'s initial seizure event, it involved staring spells lasting less than a minute, followed by a later episode lasting only a few minutes. Tr. at 37. Although the episode was unsettling to petitioner, it was not protracted.

Dr. Kinsbourne also relied on the results of S.S.'s earliest EEG (the day after his first seizure event) to support his theory of vaccine-related causation. Pet'r's Ex. 20 at 1. That EEG showed "a right hemisphere abnormality." Id. But, Dr. Kinsbourne conceded--when questioned further--that the EEG results were "consistent with a postictal state" following seizure and were not dispositive of permanent damage. Tr. at 41-42. After more questioning, Dr. Kinsbourne acknowledged that S.S. behaved "normally" and showed "no neurological symptoms" the day after his first seizure episode. Tr. at 39.

Dr. Kinsbourne posited that after S.S.'s first seizure event, he was merely in "an abnormal neurological state." Tr. at 86. However, after his subsequent seizure episode on December 9, 2007, S.S. "began to experience . . . severe

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[17] These articles were filed with Petitioner's Exhibit 18 as:

Tab B: Bruce Hermann, et al., The Neurodevelopmental Impact of Childhood-onset Temporal Lobe Epilepsy on Brain Structure and Function, 43(9) Epilepsia 1062-71 (2002).

Tab C: Gregory L. Holmes and Yehezkiel Ben-Ari, The Neurobiology and Consequences of Epilepsy in the Developing Brain, 49 (3) Pediatric Research 320-25 (2001).

Tab F: Carl E. Stafstrom, Assessing the behavioral and cognitive effects of seizures on the developing brain, 135 Progress in Brain Research 377-390 (2002).

Tab H: Thomas P. Sutula, Mechanisms of epilepsy progression: current theories and perspectives from neuroplasticity in adulthood and development, 60 Epilepsy Research 161-171 (2004).

epilepsy" that radically changed his behavior and school achievements.[18] Tr. at 13. Dr. Kinsbourne explained that the first seizure episode left S.S. ostensibly still "within the mainstream" because there was no mention in the medical records of any change in his conduct. Tr. at 22-23. It was only after his second seizure event and subsequent seizure episodes that S.S.'s developmental delay and hyperactivity manifested. Id.

c. The Emergence of S.S.'s ADHD and Developmental Delay

Dr. Kinsbourne also opined that S.S.'s hyperactivity and his developmental delay were caused either by his vaccine-induced epilepsy or the seizure-related medication he was prescribed. Pet'r's Exs. 18 at 4-5; 20 at 3-4. Comparing S.S.'s condition before and after he received the MMR vaccine, Dr. Kinsbourne averred that the MMR vaccine S.S. received impaired his normal functioning and left him performing at "a special education level." Tr. at 66. But when directly questioned about S.S.'s intellect before his vaccination, Dr. Kinsbourne acknowledged that accurate IQ testing cannot be performed prior to "the fourth year of life." Tr. at 62-64. The record indicates that S.S. was four years old when his seizure disorder first manifested, see Pet'r's Ex. 3 at 19; at the same time, he reached the appropriate age for intelligence testing.

d. Pondering the Genetic Influences on S.S.'s Condition

Dr. Kinsbourne commented that no "underlying genetic disorder" had been established in S.S.'s case. Pet'r's Ex. 20 at 3. He noted that as a former clinical pediatric neurologist, he would not have recommended genetic testing for a child who--similar to S.S.--had presented "with a seizure disorder, a low IQ and [hyperactivity]" because such testing would not have informed the child's treatment. Tr. at 59-60. Nonetheless, the undersigned notes that such testing could provide a better understanding of the nature of S.S.'s seizure disorder.

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[18] S.S. experienced behavioral problems at school. Pet'r's Ex. 6 at 15. In addition, his performance decreased from "in progress" to "non-mastered" in a number of the skills that were assessed between the second and third quarters of the school year. Pet'r's Ex. 11 at 8. On December 15, 2008, S.S.'s Individual Education Program ("IEP") team recommended a special education placement for him. Pet'r's Ex. 15 at 27.

B. Respondent's Expert

1. His Professional Qualifications

Respondent offered John McDonald, M.D., as an expert in the field of pediatric neurology. Dr. McDonald was educated at the University of Michigan. Resp't's Ex. B at 1 (Curriculum Vitae of Dr. McDonald). After two years of service in the United States Navy, Dr. McDonald attended medical school at the University of Miami. Id. He is board certified in pediatric neurology. Tr. at 89.

Dr. McDonald is currently an Assistant Professor at the University of Minnesota Medical School, Department of Pediatrics. Resp't's Ex. B at 1. He testified that his duties include monitoring hospitalized patients one week each month, staffing the pediatric neurology clinic twice a week, occasionally assisting at the bone marrow clinic, teaching medical students, and conducting research. Tr. at 90. Dr. McDonald's patients range from the unborn to eighteen years of age. Tr. at 91. He estimated seeing between 30 and 50 patients each week. Id. As an integral part of his clinical practice, he diagnoses and treats children with seizure disorders and instructs medical students about such conditions. Tr. at 92.

The undersigned accepted Dr. McDonald as an expert in pediatric neurology who actively treats children with seizure disorders. Tr. at 94.

2. His Opinion Regarding Causation

Dr. McDonald disagreed with Dr. Kinsbourne's view that S.S.'s seizure disorder resulted from the immunizations he received on October 1, 2007. Resp't's Ex. A at 3. Dr. McDonald observed that the medical records contain no evidence, other than timing, to link the two events. Resp't's Ex. A at 3; Tr. at 102. None of S.S.'s "treating physicians associated the immunizations directly with [his] seizures or developmental delays/ADHD." Resp't's Ex. A at 3. Nor is there evidence suggesting that an acute encephalopathy occurred after S.S.'s vaccinations. Tr. at 95-96.

a. Challenging the Vaccine-Relatedness of S.S.'s Seizure Disorder

Dr. McDonald acknowledged that the "natural measles disease can cause seizures." Tr. at 124. He indicated that although he has seen seizures occur in patients with measles encephalitis, an often debilitating (and occasionally fatal) condition caused by brain inflammation that develops as a patient recovers from a measles infection, id., there is no evidence of measles encephalitis, in this case.

Tr. at 95, 99. Dr. Kinsbourne agreed with respondent's assertion that S.S. showed no signs of having contracted measles encephalitis. Tr. at 87-88.

Dr. McDonald explained that the measles vaccine "is an attenuat[ed] version of the natural measles virus" and thus bears a substantially diminished viral load; due to its significantly reduced virulence, it is much less likely than wild measles virus to cause seizures. Tr. at 125. Dr. McDonald criticized the studies relied upon by Dr. Kinsbourne for the proposition that the measles vaccine could provoke seizure events because those studies involved small, poorly defined groups. Id.

Dr. McDonald also questioned whether, in fact, S.S.'s seizure disorder may have begun to be expressed before he received the MMR vaccine in October of 2007, See Resp't's Ex. A. Pointing to the record evidence of S.S.'s unwitnessed fall on August 19, 2005, id. at 2-3, Dr. McDonald observed that "many children with epilepsy are found to have episodes of suspicious seizure activity that predate their first hospital admission [after] a witnessed seizure," id. at 2.

b. Refuting the Allegations of a Seizure-Induced Encephalopathy

Refuting Dr. Kinsbourne's theory that S.S.'s vaccine-induced seizures caused irreversible brain damage, Dr. McDonald stated that the IOM's definition of encephalopathy is a very broad one. Tr. at 130-32. He explained that, as the term is understood more narrowly by neurologists who evaluate seizure patients, an encephalopathy refers to any damage that persists beyond the seizure event and the attendant recovery period. Tr. at 132. Dr. McDonald observed that "convulsions and . . . [the transient] post-convulsive effects" are distinguishable from those functional disruptions that produce mental changes, but are unrelated to a seizure event. Id.

Pointing to S.S.'s EEG on October 16, 2007--the day following his first recognized seizure--Dr. McDonald stated that the test results showed "very subtle slowing, . . . [but] not an ongoing epileptic process." Tr. at 97. He added that such results were not "consistent with an encephalopathy" when found in a seizure patient. Tr. at 99.

Challenging petitioner's assertion that S.S. suffered an encephalopathy, Dr. McDonald addressed the investigators' findings in the 2001 Holmes article--filed by petitioner and cited by Dr. Kinsbourne. The authors of the 2001 Holmes study determined that "the immature brain is less vulnerable to seizure-induced injury than the mature brain." Resp't's Ex. A at 3 (quoting the 2001 Holmes article, filed

as Pet'r's Ex. 18, Tab C).[19] But, the authors observed that "seizures in the developing brain [could] result in irreversible alterations in neuroma connectivity, and thereby affect brain functioning." Tr. at 116.

Building upon the observations of the authors in the 2001 Holmes study, Dr. McDonald stated that repetitive seizures (as occur in a patient with status epilepticus) can cause additional seizure activity by lowering a patient's seizure threshold --which allows for increased susceptibility to seizures. Tr. at 117. Dr. McDonald explained that a lowered seizure threshold can result from seizure-induced brain damage caused either by alterations to nerve pathways or by changes in the nerve impulse transmissions that protect against seizures. Tr. at 117-18. Although certain seizure activity can result in the lowering of a subject's seizure threshold, he asserted that S.S. did not experience that type of activity during his first seizure event in October of 2007. Tr. at 134.

c. The Emergence of S.S.'s ADHD and Developmental Delay

Dr. McDonald expressed the view similarly expressed by at least one of S.S.'s treaters, that the prescribed anti-epileptic medication could have caused S.S.'s attentional and behavioral issues. Tr. at 106. Dr. McDonald also considered the possibility that S.S.'s developmental delay and attentional problems were co-morbid conditions "unrelated to his epilepsy." Resp't's Ex. A at 2. He added that most likely, S.S.'s diminished intellectual skills and his hyperactivity were genetically-triggered. Tr. at 105, 133. But, even if S.S.'s various conditions were not genetically-based, Dr. McDonald noted that none of S.S.'s treaters associated his health issues with the MMR vaccination he received. Tr. at 105.

d. Pondering the Genetic Influences on S.S.'s Condition

Dr. McDonald asserted that S.S.'s seizure disorder most likely arose from "an underlying genetic basis." Resp't's Ex. A at 4; accord. Tr. at 105. Although convinced of a genetic underpinning, Dr. McDonald recognized that without results from "standardized genetic and metabolic testing," the relevant genetic influences could not be established. Resp't's Ex. A at 4; accord. Tr. at 134.

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[19] Holmes, supra note 17, at 320-25.

IV. Applicable Legal Standards

Under the Vaccine Act, a petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). § 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. § 14(a). If petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. § 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence.[20] § 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing Hellebrand v. Sec'y of Health & Human Servs., 999 F.2d 1565, 1572-73 (Fed. Cir. 1993).

The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." Shyface v. Sec'y of Health & Human Servs., 165 F.3d 1344, 1351 (Fed. Cir 1999). Id. at 1352. The received vaccine, however, need not be the predominant cause of the injury. Id. at 1351.

The Circuit Court has indicated that petitioners "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. Shyface, 165 F.3d at 1352-53 (quoting Grant v. Sec'y of Health & Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical

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[20] Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. Section 11(c)(1) contains additional vaccine claim requirements concerning the type of vaccination received and where it was administered, the duration or significance of the injury, and the lack of any other award or settlement. See § 11(c)(1)(A),(B),(D) and (E).

sequence of cause and effect showing that the vaccination was the reason for the injury.'" Id.

The Federal Circuit subsequently reiterated these requirements in its Althen decision. See 418 F.3d at 1278. Althen requires a petitioner

> to show by preponderant evidence 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.

Id. All three prongs of Althen must be satisfied. Id. "Unlike an on-Table case, proof of causation in an off-Table case must comprise more than just a literal temporal association between the onset of the injury and the vaccination." Pafford v. Sec'y of Health & Human Servs., 64 Fed.Cl. 19, 24 (Fed. Cl. 2005); see also Grant, 956 F.2d at 1148.

The Federal Circuit has instructed that a petitioner may satisfy her evidentiary burden by relying either on "medical records or medical opinion." Althen, 418 F.3d at 1279 (emphasis in original). Any offered expert testimony must be scientifically reliable and may be analyzed using the four factors enumerated by the Supreme Court in Daubert. Terran v. Sec'y of Health & Human Servs., 195 F.3d 1301, 1316 (Fed. Cir. 1999) (referring to Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993)). Circumstantial evidence also might be used. Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1325-26 (Fed. Cir. 2006). Evidence that satisfies one prong might assist in proving another prong as well. Id. at 1326.

The Vaccine Act further requires "that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition." § 13(a)(1)(B). Thus, even if a petitioner satisfies the three-pronged Althen test, compensation cannot be awarded if respondent establishes an alternate cause of injury, not related to the administered vaccine. To defeat petitioner's recovery once petitioner has met her evidentiary burden, respondent must prove, by preponderant evidence, that an alternate cause of injury exists. Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994).

The Federal Circuit has stated that "close calls regarding causation are resolved in favor of injured claimants." Althen, 418 F. 3d at 1280.

V. Evaluating Petitioner's Claim

A. Summary of Petitioner's Theory of Causation

Petitioner alleges that the MMR vaccine administered on October 1, 2007, caused S.S. to develop epilepsy, developmental delay, and hyperactivity.[21] Petitioner asserts that the seizure episode S.S. suffered on October 15, 2007, signaled the onset of his seizure disorder. Petitioner's expert, Dr. Kinsbourne, contends that because the onset of S.S.'s seizures occurred within two weeks of his receipt of the MMR vaccine, the resultant seizure condition is likely vaccine-related. Dr. Kinsbourne reasons that S.S. suffered first his seizure during the period of increased viremia associated with the attenuated measles component in the MMR vaccine. Pet'r's Exs. 18 at 2; 20 at 1-2; Tr. at 25-26.

To explain S.S.'s later seizures, Dr. Kinsbourne asserted that S.S.'s initial seizure event caused sufficient brain damage to lower S.S.'s seizure threshold and increase S.S.'s susceptibility to another seizure event two months later, on December 9, 2007 and thereafter, with increasing frequency. See Pet'r's Ex. 20 at 1; Tr. at 65-66, 83-84. Dr. Kinsbourne added that the later seizures caused further brain damage that resulted in S.S.'s developmental delay and hyperactivity.

Dr. Kinsbourne's arguments--although forcefully presented--lack coherence. Dr. Kinsbourne focused solely on the seizures that S.S. experienced on October 15, 2007, when discussing whether the measles vaccine could cause seizures in the same manner as the measles infection during the two week period following vaccine exposure. Tr. at 12, 42-43. But, he focused specifically on the seizure events that occurred on December 9, 2007, and later when discussing the seizures that allegedly caused the brain damage that resulted in S.S.'s developmental delay and attentional issues. Tr. at 66-67.[22]

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[21] In her petition and later filings, petitioner asserts that S.S.'s epilepsy and developmental delay were vaccine-caused. See, e.g., Pet'r's Br. at 18. However, during his testimony and in his supplemental expert report, Dr. Kinsbourne also describes S.S.'s hyperactivity as a vaccine-caused injury. Pet'r's Ex. 20 at 3; Tr. at 27.

[22] Dr. Kinsbourne testified that "after" the seizure event S.S. suffered on December 9, 2007, "he began to experience a really severe epilepsy with seizures multiple times every day." Tr. at 13.

Dr. Kinsbourne's circular logic, that one event was caused by another simply because the second event occurred, is also unavailing. In support of his assertion that the seizures S.S. experienced on October 15, 2007, led to a lowering of his seizure threshold and caused him to suffer seizure events on December 9, 2007 (and thereafter), Dr. Kinsbourne relies heavily on the fact that the later seizures occurred. Tr. at 83-84. In addition, in support of his assertion that S.S. experienced severe brain damage as a result of his seizures, Dr. Kinsbourne pointed to S.S.'s diminished mental capacity as evidence of earlier brain damage. Tr. at 66.

As discussed further below, although the individual components of Dr. Kinsbourne's theory seem medically sound, the combination of the components underlying his theory of causation is not. Nor does the cobbled theory of causation provide a logical connection between the received vaccination and S.S.'s injuries. For these reasons, petitioner's claim cannot stand.

B. The Filed Medical Literature Does Not Assist Petitioner[23]

Essential to Dr. Kinsbourne's theory is the postulate that similar to a natural measles virus, the attenuated viral measles vaccine can reach a sufficient viral load (that is, peak viremia) within the two-week period after vaccination to provoke seizures, and that it did so in S.S.'s case. To account for S.S.'s later seizure events, Dr. Kinsbourne asserts that the seizure episode S.S. experienced on October 15, 2007, was adequately severe to lower his seizure threshold and thus, allow the subsequent seizure events to occur. In support of this particular assertion, Dr. Kinsbourne cites a number of studies. Pet'r's Ex. 18 at 4. The undersigned addresses, in turn, the studies on which petitioner primarily depended.

1. The 1973 Landrigan Study and 1998 Weibel Study

In the 1973 Landrigan study, the authors evaluated 84 cases of neurologic disorders that appeared within one month of receipt of a live measles-virus vaccine and were reported between the years of 1963 and 1971. Pet'r's Ex. 18, Tab D (1973 Landrigan study), at 1460. The cases were intended to provide epidemiologic detail about the relationship between neurologic disorders, the measles vaccine, and the risks posed by vaccination. Id. at 1459. The cases were divided into four groups based on the reported clinical and laboratory findings. Id. at 1460.

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[23] The parties submitted a total of 17 articles and studies; only those articles on which the parties appeared to rely most heavily are discussed in detail in this section.

The findings presented for Group 3 and Group 4 are the most relevant here. Subjects in Group 3 who had experienced episodes of brief, generalized convulsions with fever--but had no other clinical or laboratory evidence of cerebral infection or intoxication, and had no sequelae--were deemed to have suffered febrile convulsions. Id. (emphasis added). Eleven patients in Group 3 met the criteria for febrile convulsions, and the authors speculated that the convulsions were related to the subjects' febrile response to the administered vaccine. Id. These eleven patients had a convulsive onset within 6 to 13 days after the MMR vaccination, which was a period of time that fell within the expected timeframe for a febrile response.[24] Id.

The subjects in the largest group, Group 4, experienced seizures with no identified cause and suffered more extensive or permanent neurologic effects than did those in Group 3. Id. Some of the subjects in Group 4 were diagnosed with either encephalomyelitis, aseptic meningitis, spinal cord disorders, or disorders of the peripheral nervous system. Id. at 1461. Of the 59 subjects in Group 4 with serious neurologic disorders, five of the disorders were fatal. Id. at 1460.

Symptoms of the various neurologic disorders began to manifest between 1 and 25 days after vaccination. Id. Forty-five subjects in Group 4 had symptom onset between 6 and 15 days after vaccination, the period of time during which viral replication is at its height.[25] Id.

Thirty-six subjects in Group 4 were deemed to have suffered an encephalopathy. Id. at 1461. Twenty-seven of those subjects had convulsions that were either prolonged or focal. Id. Twenty-four subjects in this group were younger than two years old. Id.

The interval between vaccination and symptom onset ranged between 2 and 25 days, but 72% of the group (26 subjects) experienced onset between 6 and 15 days. Id. Follow-up data for 31 subjects in the group showed that five died, ten

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[24] The median age of Group 3 patients was two years, and the group consisted of eight girls, two boys, and one patient whose sex was not reported. Pet'r's Ex. 18, Tab D (1973 Landrigan study), at 1460. Follow-up data was obtained from eight of the participants. All patients had a full recovery, with no ongoing seizure problems and no residual neurologic impairment. Id.

[25] In the Group 4 cases reported between 1963 and 1964, the median age of the subjects was seven years; between 1965 and 1966, the median was three years of age, and between 1967 and 1971, the median was one year of age. Id. There were 53 girls, 20 boys, and 4 patients whose sex was not reported. Id.

recovered fully, and sixteen were left with neurologic residua that ranged from mild hyperactivity to profound retardation. Id.

The authors of the 1973 Landrigan study were unable to establish a causal relationship in any single case between vaccination and the subsequent neurologic disorder. Id. at 1462. Although the epidemiologic evidence suggested that some of the cases may have been causally related to the vaccine administration, the study's authors concluded that the cause of the disorders was "not clear" and "more thorough investigation might demonstrate agents other than measles" caused the observed injuries. Id.

Dr. Kinsbourne appeared initially to rely on the study for the proposition that the measles vaccine could cause seizures. But, on cross examination, he limited the scope of his reliance on the 1973 Landrigan study, asserting only that the study established the time frame within which neurologic injury might appear after vaccination. Tr. at 50-51.

In the 1998 Weibel study filed by petitioner, the authors examined pediatric cases of encephalopathy following MMR vaccination--whether "with or without an inflammatory response." Pet'r's Ex. 18, Tab I (1998 Weibel study), at 383. Of the 403 reviewed cases, the authors determined that only 48 of the children met the criteria for an acute encephalopathy between the 2nd and 15th day after vaccination, id. at 384, and fever preceded onset "by several hours to several days in forty-three of [the] forty-eight children." Id. at 385 (emphasis added). In the majority of the children (32 of 34), who experienced either generalized or focal seizures, the seizures were associated with fever. Id. In one case, a seven month old girl developed a rash and a fever seven days after she received an MMR vaccination. Id. She was hospitalized for recurring seizures (status epilepticus) with a fever of 106 degrees three days later (which was approximately 10 days after vaccination). Id.

Here, the parties do not dispute that S.S.'s initial seizures occurred without fever. The VAERS report filed on March 28, 2008 indicated that S.S. experienced a slight fever seven days prior to his first seizure event but not during his seizure episode. See Pet'r's Ex. 12 at 1. Because the 1998 Weibel study focused on the incidence of febrile seizures, it does not lend significant support to petitioner's theory that the MMR vaccine S.S. received caused him to develop a seizure disorder because his brief, initial seizure event was not associated with fever.

Of note, the authors of the 1973 Landrigan study and the authors of the 1998 Weibel study concluded that "the incidence of reported neurologic disorders following live, attenuated measles-virus vaccination is extremely low." Pet'r's Ex. 18, Tab D (1973 Landrigan study), at 1642; accord. Pet'r's Ex. 18, Tab I

(1998 Weibel study), at 387. The authors also observed that "the lack of controlled studies that distinguish[ed] background rates of encephalopathy of undetermined cause in unvaccinated populations" made an assessment of potential vaccine-related causation difficult. Pet'r's Ex. 18, Tab I (1998 Weibel study), at 386; accord. Pet'r's Ex. 18, Tab D (1973 Landrigan study), at 1642.

2. The 2004 Ong Study and the 2004 Narchi Study

Petitioner did file two articles involving the onset of afebrile seizures; but both the 2004 Ong study and the 2004 Narchi study focused on children who had developed severe seizures after suffering gastrointestinal illnesses. Pet'r's Exs. 20 at Tab C (2004 Ong study), at 157; 20 at Tab D (2004 Narchi study), at 1. The authors of the 2004 Narchi study specifically observed that "the occurrence of afebrile seizures during viral gastroenteritis without dehydration or electrolyte imbalance is little known in Western countries," Pet'r's Ex. 20 at Tab D (2004 Narchi study), at 3 (emphasis added), and the authors of both studies concluded that afebrile seizure events that occur in the context of a gastrointestinal illness are typically "benign . . .and carry an excellent prognosis." Id. at 4; accord. Pet'r's Ex. 20 at Tab C (2004 Ong study), at 161, 164.

The records suggest that S.S. may have experienced his critical seizure event in the context of a gastrointestinal illness because he was reported to have symptoms of nausea, vomiting, and diarrhea before he began seizing. Pet'r's Ex. 3 at 169. However, he was not shown to be dehydrated or suffering from an electrolyte imbalance. And contrary to Dr. Kinsbourne's suggestion, the literature petitioner filed indicates that S.S.'s initial, brief, afebrile seizure event was much more likely than not to have been benign in its impact on S.S.'s neurologic health.

3. The 1994 IOM Report

As previously discussed, the authors of the 1994 IOM report defined the term encephalopathy broadly, and they drew a careful distinction between the expansive definition accorded an encephalopathy and the more narrow definition of an encephalitis. Pet'r's Ex. 18, Tab G (1994 IOM report) at 122. As the authors explained, an "[e]ncephalitis refers to an encephalopathy caused by an inflammatory response in the brain." Id. Observing that "the occurrence of encephalitis following a natural measles virus infection is well described," id. at 123, the authors turned to examine the encephalopathic effects of the attenuated measles vaccine.

While acknowledging that "[t]here is demonstrated biological plausibility that measles vaccine might cause [an] encephalopathy," Id. at 129 (emphasis added), the authors concluded that "the [incidence] rates quoted are impossible to

distinguish from background rates." Id. The authors specifically lamented the lack of "[g]ood case control or controlled cohort studies of these conditions in similar unvaccinated populations, which are necessary for determining the casual relationship between measles and mumps and encephalopathy and encephalitis." Id. at 129-30 (emphasis added). The authors found that "no conclusive evidence of the occurrence of encephalopathy or encephalitis resulting from the administration of the measles vaccine [had been] identified." Id. at 130.

4. The 1981 NCES Study

The 1981 NCES study filed by petitioner was a case-control study. Its primary purpose was to identify potential adverse events following a pertussis immunization. Pet'r's Ex. 18, Tab A (1981 NCES study), at 80. Dr. Kinsbourne argued that the portion of the study which addressed the potential adverse effects of the measles vaccine was a meaningful part of the study. He further argued that the authors' advisory concerning the possible over-reporting of cases applied only to the conclusions involving the pertussis vaccine. Tr. at 52, 75-76; see Pet'r's Ex. 18, Tab A (1981 NCES study), at 145.

The majority of the considered cases involved seizures associated with fever, and consistent with the guidelines provided to physicians, case referrals were limited to children who had suffered a convulsion lasting more than 30 minutes, or a convulsion followed by a two or more hour-long coma, or a convulsion followed by paralysis or other neurological event lasting 24 or more hours. Pet'r's Ex. 18, Tab A (1981 NCES study), at 157. As Dr. Kinsbourne acknowledged, S.S.'s case did not meet this criteria. Tr. at 54-55.

As noted in the NCES study, 16 children developed illness seven to ten days after vaccination. Pet'r's Ex. 18, Tab A (1981 NCES study) at 140. Of the 16 children, two had prior abnormalities. Of the remaining 14 children, nine had experienced "simple or febrile convulsions . . . and [had suffered either an] encephalitis or encephalopathy." Id. "All but two children with mild defects . . . made an apparently complete neurological recovery when followed up." Of the two others, each had a febrile convulsion on a later occasion." Id. (emphasis added). The authors of the NCES observed that the serious neurologic reactions "associated with the measles vaccine are thought to [have been] caused by a mechanism similar to that responsible for post-infectious encephalitis." Pet'r's Ex. 18, Tab A (1981 NCES study), at 142. The NCES study was criticized later in the 1994 IOM report for its observation about the measles vaccine because "a separate analysis of those diagnosed with encephalitis and encephalopathy was not performed." Pet'r's Ex. 18, Tab G (1994 IOM report), at 144; see also Pet'r's Ex, 18, Tab I (1998 Weibel study), at 384 (the authors noted that the 1981 NCES study did not separate convulsions from cases of acute encephalopathy).

The recorded seizure events in the 1981 NCES study were accompanied by fever and were more prolonged or severe than those suffered by S.S. In addition, the subjects of the 1981 NCES study enjoyed substantial recoveries; the outcome for those subjects was materially different from S.S.'s.

5. The 2001 Holmes article

The authors of the 2001 Holmes study discussed the long-term consequences of seizures in the developing versus the mature brain. Pet'r's Ex. 18, Tab C (2001 Holmes study), at 320. Pointing to animal models, the authors observed that adult animals have greater deficits in learning, memory, and behavior following seizure activity, id. at 322, but the authors allowed that significant deficits can occur as a result of seizure activity in neonatal subjects. Id. at 324. The results of the animal study led the authors to conclude that "prolonged or recurrent seizure activity . . . can irreversibly alter the way the immature brain develops and forms synapses." Id.

The authors specifically identified "precipitating factors such as fever" as the agents likely to trigger seizures in children. Id. at 322. Although the authors concluded that the immature brain is more susceptible to seizures, they found that the immature brain was less vulnerable to long-term consequence of these seizures. Id.

When questioned at the hearing about the 2001 Holmes study, Tr. at 115-23, Dr. McDonald stated that the findings of the "pretty convincing" animal model study showed that repetitive seizures can cause "actual alterations in nerve pathways in the brain." Tr. at 117. He explained that repetitive seizures could cause brain damage and lead to more seizures by harming the "nerve cells and chemicals that may help to dampen a seizure." Tr. at 116-17. But he observed that the authors of the 2001 Holmes article had determined that the immature brain is "relatively resilient," Tr. at 120, and thus, cannot be harmed as readily as the mature (or adult) brain. Tr. at 116.

The 2001 Holmes article, as discussed by Dr. MacDonald, helpfully delineates those circumstances in which seizures could lead to the type of brain damage petitioner claims that S.S. suffered. But such circumstances were absent when S.S. first began seizing and thus, the 2001 Holmes article furnishes modest support for petitioner's claim that the received vaccine caused S.S.'s injuries.

6. Conclusion Regarding the Filed Medical Literature

The medical literature submitted by petitioner provides little or no evidentiary support for her theory of causation as applied to S.S.'s circumstances.

The authors of the 1973 Landrigan study, 1998 Weibel study, and 1994 IOM report acknowledged they could not establish a causal connection between the measles vaccine and neurologic disorders, encephalopathy or encephalitis. See Pet'r's Ex. 18, Tab D (1973 Landrigan study), at 1642; Pet'r's Ex. 18, Tab I (1998 Weibel study), at 386-87; Pet'r's Ex. 18, Tab G (1994 IOM report) at 130. The authors of the 2001 Holmes study concluded that although more likely to experience seizures, the immature brain is less susceptible to the long term consequences of seizures. Pet'r's Ex. 18, Tab C (2001 Holmes study), at 322.

In the 1998 Weibel and 1981 NCES studies, the investigators considered cases of seizure onset that was accompanied by fever or was more prolonged and severe than the seizure events suffered by S.S. Pet'r's Ex. 18, Tab I (1998 Weibel study), at 385; Pet'r's Ex. 18, Tab A (1981 NCES study), at 157. The authors of the 2004 Ong and 2004 Narchi studies determined that afebrile seizure that occur in the context of gastrointestinal illnesses, are generally benign. Moreover, the authors of the 2004 Ong and 2004 Narchi studies found that afebrile seizures caused by viral gastroenteritis do not occur in the Western countries unless accompanied by dehydration or electrolyte imbalance. Even if S.S. was shown to have suffered a gastrointestinal illness, the records do not indicate that he exhibited either of the accompanying conditions of dehydration or electrolytic imbalance. And unlike the subjects of the 2004 Ong and 2004 Narchi studies, S.S. required ongoing medical attention for his seizures.

As the Federal Circuit held in Moberly, "studies provide no evidence pertinent to persons not within the parameters of the test group." Moberly, 592 F.3d at 1324. Because the literature petitioner filed does not pertain to the factual circumstances of S.S.'s case, it merits limited evidentiary weight.

C. The Three-Pronged Althen Test

To prove vaccine causation, petitioner must satisfy all three prongs of the Althen test. Althen, 418 F.3d at 1278. Respondent does not dispute that petitioner has established a temporal relationship between the administered MMR vaccine and thus, has satisfied the third Althen prong. Respondent argues, however, that because "petitioner's claim rests on nothing more than a temporal relationship, [it] is legally insufficient to establish vaccine causation." Resp't's Br. at 1.

Even if the undersigned were to conclude that petitioner has satisfied the third prong of Althen, respondent has correctly asserted that proving timing alone is not enough. See Grant, 956 F.2d at 1148. Petitioner contends she has established the first and second prongs of the Althen test. Pet'r's Br. at 34; Pet'r's Reply to Resp't's Br. at 13. Respondent disagrees, insisting that "[p]etitioner has failed to provide [both] a reliable medical theory of causation and . . . adequate proof of a logical sequence of cause and effect linking [Sheik's] vaccinations and his injuries." Resp't's Br. at 24.

To evaluate petitioner's claim properly, the undersigned turns now to consider the first and second prongs of the Althen analysis.

1. Considering the First and Second Althen Prongs

The analyses under the first and second prongs of the Althen test may involve a review of the same evidence to examine different aspects of the causation issue. See Doe 93 v. Sec'y of Health & Human Servs., 98 Fed. Cl. 553, 567 (Fed. Cl. 2011). The first prong focuses on general causation, that is whether the administered vaccine can cause the particular injury which the vaccinee suffers[26] and, the second prong focuses on specific causation, that is whether the administered vaccine did cause the injury.[27] See Pafford, 451 F.3d at 1355-56;

2. First Althen Prong

To satisfy the first prong of the Althen test, petitioners must provide "a medical theory casually connecting the vaccination and the injury." Althen, 418 F.3d at 1278 (quoting Grant, 956 F.2d at 1148). Petitioners must show that it is more likely than not that the received vaccine can cause the alleged injury.

The offered medical theory must be reputable, reliable, and biologically plausible. See, e.g., Pafford, 451 F.3d at 1355 (reputable); Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1324 (Fed. Cir. 2010) (reliable); Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1375 (Fed. Cir. 2009) (biologically plausible). Petitioners must prove this prong by preponderant evidence. Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1350 (Fed. Cir. 2010).

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[26] See generally, Veryzer v. Sec'y of Health & Human Servs., 100 Fed. Cl. 344 (Fed. Cl. 2011) (petitioner failed to satisfy the first Althen prong).

[27] See generally, Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355 (Fed. Cir. 2012) (petitioner failed to satisfy the second Althen prong).

Dr. Kinsbourne offered a theory of causation, based on a few critical components. First, he asserted that the measles vaccine can cause seizures during the period of peak viremia which occurs two weeks after vaccination. Pet'r's Ex. 18 at 3; Tr. at 19-20. Unable to identify the exact mechanism involved--and not required to do so, see Knudsen, 35 F.3d at 549, Dr. Kinsbourne averred that the measles vaccine could cause harm in the same manner that the wild measles virus does. Tr. at 43. Respondent's expert, Dr. McDonald, did not disagree with Dr. Kinsbourne, and he stated that he was "willing" to accept as biologically plausible the proposition that the measles vaccine could cause seizures under certain circumstances--particularly those involving fever and gastrointestinal illness. Tr. at 130.

When discussing the seizures that S.S. experienced during the period of peak viremia after he received the measles vaccine, Dr. Kinsbourne posited that S.S.'s initial seizure event could have caused sufficient brain damage to lower his seizure threshold and make him more susceptible to future seizure events. See Pet'r's Ex. 20 at 1; Tr. at 65-66, 83-84. Dr. McDonald acknowledged that certain types of seizures could lead to additional seizure activity, but emphasized such seizures must be prolonged or repetitive to lower a seizure threshold. Tr. at 116-17.

Finally, Dr. Kinsbourne maintained that epileptic seizures--such as those S.S. experienced on December 9, 2007 and thereafter--could cause brain damage and lead to developmental delay and hyperactivity. Pet'r's Exs. 18 at 4; 20 at 3-4. Dr. McDonald challenged this aspect of Dr. Kinsbourne's testimony, asserting that S.S.'s seizures, developmental delay, and hyperactivity were mostly likely part of the same underlying genetic disorder, if related at all to each other. Resp't's Ex. A at 4; Tr. at 133.

Based on careful consideration of the record evidence, the undersigned finds that in rare circumstances, the measles vaccine can trigger--within fourteen days of administration--seizures if accompanied by fever or in the context of a gastrointestinal illness. A finding that prolonged or repetitive seizures can result in the lowering of a seizure threshold and lead to additional seizures as well as developmental delay is also supported by the expert testimony and filed literature introduced here. Although the record contains some evidence that hyperactivity can result from seizure medications, the undersigned is not persuaded on the weight of this record that hyperactivity can result from MMR vaccine-induced seizure activity.

To prevail on her vaccine claim, however, petitioner also must prove that the MMR vaccine S.S. received in October of 2007 caused his injuries in the manner proposed by Dr. Kinsbourne.

3. Second Althen Prong

To satisfy the second prong of the Althen test, petitioner must establish a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Althen, 418 F.3d at 1278. In other words, petitioner must show that it is more likely than not that the received vaccine caused the alleged injury. See Capizzano, 440 F.3d at 1326. The sequence of cause and effect need only be "logical and legally probable, not medically or scientifically certain." Knudsen, 35 F.3d at 548-49; accord. Capizzano, 440 F.3d at 1326. Testimony from a treating physician may assist petitioner in meeting her burden of proof under the second Althen prong. Capizzano, 440 F.3d at 1326.

Petitioner contends that she has "demonstrated that the MMR vaccine caused [S.S.'s] epilepsy and subsequent developmental delay," Pet'r's Br. at 25, that S.S.'s "injury occurred within a medically appropriate time frame after the MMR vaccine" and that "no other likely cause of [S.S.'s] injury [has been] identified." Id. at 26.

Petitioner's claim that S.S.'s treating physicians attributed his injuries to his vaccination does not persuade. The only mention in the medical records of a possible causal connection between S.S.'s injuries and MMR vaccine originated with petitioner who questioned whether such a connection might exist. See e.g., Pet'r's Ex. 8 at 5. S.S.'s treating physicians did not know the cause of S.S.'s epilepsy. See, e.g., Pet'r's Ex 14 at 17.

Moreover, the theory advanced by Dr. Kinsbourne is not supported by the facts of this case.[28] Even with the undersigned's acceptance of Dr. Kinsbourne's theory that the measles vaccine can cause seizures in rare circumstances involving fever on gastrointestinal illness and that prolonged or repetitive seizures can result in the lowering of a person's seizure threshold and additional seizure activity, petitioner has failed to prove, and the evidence of record is insufficient to show, that either event occurred in this case.

Dr. Kinsbourne admitted that the seizure event S.S. experienced on October 15, 2007, consisted of several "staring spells, each lasting for less than a minute"

[28] Even if the first Althen prong is met or assumed to be met, the proposed theory must be applicable to the facts in the case in order to satisfy the second Althen prong. See Hibbard, 698 F.3d at 1362-63.

and a seizure that lasted a few minutes. Tr. at 37. Moreover, Dr. Kinsbourne acknowledged that S.S. was "behaving normally and had no neurological symptoms the day after his hospital admission, and that this EEG was consistent with a postictal state and showed no evidence of seizure activity or brain damage. Tr. at 37-39, 41-42. As Dr. McDonald testified, and the undersigned similarly finds, S.S.'s brief seizure and staring spells on October 15, 2007, were not of the prolonged and repetitive nature needed to lower S.S.'s seizure threshold. Tr. at 113.

Other than the temporal relationship, there is nothing to suggest that the seizures S.S. suffered on October 15, 2007, were caused by the measles vaccine. S.S. experienced a slight fever of 100 degrees on October 8, 2007. Dr. Kinsbourne agreed that fever and rash are the two most common symptoms of measles viremia. Tr. at 61. However, S.S.'s fever occurred and abated seven days prior to his October 15, 2007 seizures. The studies relied upon by Dr. Kinsbourne mentioned fever occurring a few days prior to and usually continuing during the time of the seizure. See Pet'r's Ex. 18, Tab I (1998 Weibel study), at 4; Tab A (1981 NCES study), at 63. And as previously mentioned, none of S.S.'s treating physicians causally associated the measles vaccine with S.S.'s seizures.

Although "the Vaccine Act does not require [a] petitioner to bear the burden of eliminating alternative causes where the other evidence on causation is sufficient to establish a prima facie case," a petitioner "may be required to eliminate potential alternative causes where the petitioner's other evidence on causation is insufficient." Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1149-50 (Fed. Cir. 2007) (citing Pafford, 451 F.3d at 1359). Here, petitioner asserts that no alternate explanation exists for S.S.'s injury. Yet, as reflected in his medical records, S.S. had a maternal great aunt with epilepsy, see supra note 11, and thus, a likely genetic predisposition to have a seizure condition.

While petitioner has proposed a theory by which the MMR vaccine could cause injuries such as those suffered by S.S., petitioner has failed to establish a logical sequence of cause and effect--consistent with her proposed theory--proving that the measles vaccine S.S. received on October 1, 2007 did cause his injuries. Thus, petitioner has failed to satisfy the second prong of the Althen test.

VI. Conclusion

The Federal Circuit stated in Althen that "neither a mere showing of a proximate temporal relationship between vaccination and injury, nor a simplistic elimination of other potential causes of the injury suffices, without more, to meet the burden of showing actual causation." 418 F.3d at 1278. In this case, petitioner relied primarily on a proximate temporal relationship which she proved and her

dubious claim that no other potential cause for S.S.'s injuries existed. For the reasons more fully detailed above, the undersigned is persuaded that petitioner has satisfied the first and third prongs of the Althen test but finds that petitioner has failed to establish the requirements of the second Althen prong on a factual record that is not close. Because petitioner cannot establish a logical causal sequence, petitioner's claim must be denied.

Petitioner has failed to prove that she is entitled to compensation under the Vaccine Program. The petition for compensation **SHALL BE DISMISSED, and the Clerk of Court shall enter judgment consistent with this decision.**[29]

IT IS SO ORDERED.

s/Patricia E. Campbell-Smith
Patricia E. Campbell-Smith
Chief Special Master

[29] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of notice renouncing the right to seek review.