In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 15-08V

Filed: March 28, 2024

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WILLIAM DAVIS, *and* NICOLE DAVIS *on behalf of Z.D.*

Petitioners,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* * * * * * * * * * * * *

Mark Sadaka, Esq., Law Offices of Sadaka Associates, LLC, Englewood, NJ, for petitioners.
Emilie Williams, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

Roth, Special Master:

On January 5, 2015, William and Nicole Davis ("petitioners") filed a petition on behalf of their minor child, Z.D., for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, et seq.[2] (the "Vaccine Act" or "Program"). The petition alleged that Z.D. received DTaP, IPV, Hib, and flu vaccinations on January 12, 2012, and thereafter developed a seizure disorder. Petition at 1, ECF No. 1.

An entitlement hearing was conducted on July 30 and 31, 2020 via videoconferencing. Following careful review and analysis of all of the documentary evidence and testimony submitted

[1] Because this decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned finds that the identified material fits within this definition, such material will be redacted from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

in this case by both petitioners and respondent and in accordance with the applicable legal standards, I find that petitioners have not proffered preponderant evidence demonstrating that any of the vaccinations Z.D. received on January 12, 2012 caused-in-fact or otherwise contributed to his seizure disorder and/or epilepsy. Accordingly, I find that petitioners are not entitled to compensation and the petition must be dismissed.

I. Issues to be Determined

The first issue is whether Z.D.'s initial seizure constituted non-convulsive status epilepticus ("NCSE") or a simple febrile seizure. Next, it must be determined whether preponderant evidence exists to establish a reliable medical theory, a logical sequence of cause and effect, and a medically appropriate temporal relationship between vaccination and Z.D.'s initial seizure—either NCSE or simple febrile seizure—and his subsequent seizure disorder. Thus, the appropriate diagnosis of Z.D.'s first seizure as well as all three *Althen* prongs are in dispute.

II. Procedural History

Petitioners filed their petition on January 5, 2015. ECF No. 1. The matter was initially assigned to Special Master Dorsey. ECF No. 4. Petitioners filed medical records on January 20, 2015 and March 23, 2015. Petitioners' Exhibits ("Pet. Ex.") 1-16, ECF Nos. 6, 9-12. Additional medical records and petitioners' affidavits were filed on May 21, 2015. Pet. Ex. 17-21, ECF Nos. 13-17.

Respondent filed his Rule 4(c) Report on September 3, 2015, advising the case was not appropriate for compensation. ECF No. 21. The parties filed a joint status report on October 8, 2015, advising that respondent was not willing to engage in settlement discussions. ECF No. 25. Additional medical records and expert reports were ordered. ECF No. 26.

This case was reassigned to me on October 19, 2015. ECF No. 27-28.

Additional medical records and affidavits were filed throughout 2016. Pet. Ex. 22-29, 47-49, ECF Nos. 29-33, 35-37, 40-41, 43. Petitioners filed an expert report from Marcel Kinsbourne, M.D. Pet. Ex. 28-29, ECF No. 37. Respondent filed his expert report from John Zempel, M.D. and medical literature on June 20, 2016. Respondent's Exhibits ("Resp. Ex.") A-B, ECF No. 42.

Petitioners were ordered to and filed a supplemental expert report. Pet. Ex. 50-58, ECF Nos. 44, 46, 48-49. Respondent filed a responsive report and a status report, advising that informal resolution remained unlikely, on February 27, 2017. Resp. Ex. C, ECF Nos. 50-51.

Petitioners continued filing medical records through 2017. Pet. Ex. 59-64,[3] ECF Nos. 53-54, 56, 58, 60, 62, 117-18. Petitioners filed a supplemental expert report on December 22, 2017. Pet. Ex. 65-66, ECF Nos. 64-65.

Respondent filed a supplemental report and medical literature on March 5, 2018. Resp. Ex. D-D Tab 3, ECF No. 66.

[3] Petitioners refiled Pet. Ex. 62 after the entitlement hearing. ECF Nos. 117-18.

Additional medical records, a supplemental expert report, and medical literature were filed in 2018. Pet. Ex. 67-69, ECF Nos. 67, 69-70. Respondent also filed a supplemental expert report. Resp. Ex. E, ECF No. 73.

An entitlement hearing was scheduled for July 30 and 31, 2020. ECF No. 75. Petitioners filed a motion for interim fees and costs on June 28, 2019, which was granted on July 29, 2019. ECF Nos. 76-81.

Additional medical records, medical literature, and an expert report were filed by petitioners in 2020. Pet. Ex. 70-80, ECF Nos. 83-87, 90-91, 95, 99, 107, 109. Respondent advised that he did not intend to file further expert reports. ECF No. 98.

Petitioners and respondent filed their pre-hearing and joint prehearing submissions. ECF Nos. 100-06.

The entitlement hearing took place on July 30 and 31, 2020. Based on testimony during the course of the hearing, petitioners were ordered to file an EEG sleep study performed on April 28, 2014 and any videos or reports of Z.D.'s absence seizures in 2014. ECF. No. 111. By way of status report filed on October 26, 2020, petitioners advised that they did not record any of Z.D.'s seizures and that the EEG sleep study was previously filed as Pet. Ex. 11 at 45. ECF No. 116.[4] No further report was filed from Dr. Kinsbourne addressing the EEG results.

After several joint motions for extension of time, the parties filed their post-hearing briefs on June 11, 2021. ECF Nos. 119-25.

This matter is now ripe for decision.

III. The Factual Record

A. Z.D.'s Medical History Prior to the Vaccinations

Z.D. was born on June 7, 2010 at 38 weeks by repeat cesarean section following an uncomplicated pregnancy. Mrs. Davis had a seizure during a 1999 pregnancy with eclampsia. Z.D. was 7 lb. 2.8 oz. A hepatitis B vaccine was administered on that date. Pet. Ex. 6 at 191-93. He passed a hearing screen. *Id*. at 212. Z.D. was noted to have hypospadias at birth which was surgically corrected in October of 2010. Pet. Ex. 6 at 191; Pet. Ex. 1 at 14-15. Upon discharge, a referral for post-partum newborn home visit was ordered due to Mrs. Davis' history of post-partum depression. Pet. Ex. 6 at 209.

Z.D. had normal development and routine childhood illnesses with fever in the first year and a half of life. He received all vaccines without event. *See generally* Pet. Ex. 3.

[4] This was an outpatient EEG performed on April 28, 2014, and the first EEG Z.D. underwent. As more specifically discussed below, this EEG was interpreted as bursts of generalized spike and wave discharges without clinical accompaniment. "This EEG is indicative of a lowered seizure threshold with a propensity toward primary generalized seizures." Pet. Ex. 11 at 45.

At his 15-month well baby visit on October 4, 2011, Z.D. was developing normally. Pet. Ex. 4 at 16-17. He had a fever of unknown origin. *Id*. at 17. He received hepatitis A and preservative free influenza split virus vaccines without event. *Id*.

Z.D. was presented for his 18-month-old well child check up at 19 months old on January 12, 2012. His diet was noted to be insufficient for meats, fruits, and vegetables, and he had an abnormal sleep pattern. Pet. Ex. 3 at 26. His mother was "…concerned about speech dad not has 10-15 words." *Id*. BabyNet[5] was offered to the parents who declined because they may be moving back to the beach. *Id*. at 27. Physical examination was normal with no delayed milestones noted on the Developmental Questionnaire. *Id*. Z.D. received the subject preservative free influenza and DTaP-Hib-IPV (Pentacel) vaccines. *Id*. at 27-28. This was the third Pentacel vaccine Z.D. had received. *Id*. at 28, 97.

B. Z.D.'s Medical Records after the Vaccinations

On January 13, 2012, an ambulance was called to the Davis household at 15:27 (3:27pm). Pet. Ex. 19 at 1. Upon arrival, EMS recorded Z.D. to be verbal with pupils equal. He was noted to be alert at 15:45 (3:45pm) and again at 15:50 (3:50pm). *Id*. His grandmother reported she was watching Z.D. and that he had been running a fever for several hours then "he became difficult to rouse." He had "an episode of seizure like activity lasting several seconds with [patient] being unresponsive initially following the activity." *Id*. at 2. Z.D. was physically examined while being held by his grandmother. He was "initially responsice (sic) to loud verbal by opening eyes and staring blankly to R side." He was flushed, and his skin was warm. He became more responsive and was able "to follow simple commands and acts age appropriate." He continued "to appear somewhat lethargic, but remains awake and alert throughout transport." *Id*. Grandmother reported several vaccinations the day before. She had not given him any medication. The parents arrived and confirmed vaccinations the day before with no significant medical history. EMS documented that "PT gradually becomes more responsive throughout transport and acts age appropriate." *Id*.

Z.D. was presented to Lexington Medical Center Emergency Department at approximately 16:15 (4:15pm). History of illness included "1 Year Old Male Patient Presents with seizure diffuse for 1 hour(s). The Onset is acute. The symptoms are Moderate. Additional Symptoms or Pertinent History also involve had seizure today and fever this afternoon. had multiple immunizations yest. NO recent URI sx, n/v, cough etc. NO sick contacts." Pet. Ex. 19 at 1; Pet. Ex. 5 at 3. Nursing notes at 16:24 (4:24pm) noted doctor at bedside to discuss with family, patient fussy, slower to respond than normal, appears post ictal with fever of 103.3 status post immunizations yesterday. Pet. Ex. 5 at 7. He was tachycardic, hot to the touch, and face flushed. *Id*. Physical examination performed at 16:35 (4:35pm) documented NAD (meaning no abnormality detected, no apparent distress, or no appreciable disease), sleepy, warm to touch. *Id*. at 3. The remainder of the examination was normal/negative. *Id*. at 3-4. Once his fever was reduced with Motrin and Tylenol, he was noted at 17:37 (5:37pm) to be aroused, given juice/Pedialyte, drinking with a straw,

[5] BabyNet is an early intervention system for infants and toddlers in South Carolina for those with developmental delays. *BabyNet*, South Carolina Department of Health and Human Services, https://www.scdhhs.gov/resources/programs-and-initiatives/babynet (last visited Mar. 13, 2024).

smiling, appears more bright/alert. *Id*. at 7. Twenty minutes later, he was sleeping in his mother's arms, skin was cooler, he was sweating less, and his face was less flushed. He was kept for monitoring and observed to have no further seizures at 19:45 (7:45pm). *Id*. At 19:57 (7:57pm), laboratory and other testing was normal with no focal source of infection noted, and his fever was suspected to be from immunizations. *Id*. at 3. His pertinent history was noted as "Pt c febrile seizure, got 3 immunizations yesterday. Fever spiked, no hx fever this am". *Id*. at 8. He was discharged at 21:07 (9:07pm) with a diagnosis of febrile seizure (simple) and with instructions to follow up with pediatrician in two days. *Id*. at 5, 12.

There were no records for any follow up visits following discharge from the ER.

Two months later, on March 5, 2012, Z.D. was presented to the pediatrician. Pet. Ex. 3 at 64. Mrs. Davis reported pulling/holding his ears, can't stand loud noises, not sleeping, and crying at night. *Id*. The family was moving back from Columbia. Z.D. was noted to have 8 words, made eye contact, and pointed at things. "He had a febrile seizure 18 [months] imm/sib ill about a month ago". *Id*. A speech and hearing evaluation was ordered due to speech delay and loud noises bothering him. *Id*.

Z.D. was presented to Young Talkers, LLC for speech evaluation on March 21, 2012. He was found to have mildly delayed receptive language skills and moderately delayed expressive language skills in comparison to others his age. Pet. Ex. 3 at 71-72, 74. He would leave off the ends of words. A hearing assessment was recommended. His history included one febrile seizure and surgery for hypospadias. He was not currently toilet trained. *Id*. at 71. He was developmentally appropriate. He communicated mostly by gestures such as pointing or grunting. *Id*. "The family reported that [Z.D.] says about 20 different words" but recently became concerned about his speech. *Id*.

Z.D. was examined by his pediatrician on April 3, 2012 for complaints that his tongue/mouth hurt and was red as per parents. He was not eating but was drinking well. He had diarrhea 3-4 days before and had 2 episodes per day for 4 days. Oral intake of fluids was good. He had no other symptoms. His immunizations were up to date and past medical history was noncontributory. Pet. Ex. 3 at 75. No other issues were reported. He was well nourished, alert, in no distress, and interacted with parents appropriately for his age. *Id*. at 76. Examination was normal, and he was diagnosed with gastroenteritis and instructed to eat a bland diet. *Id*.

Z.D. was seen by an ear nose and throat specialist on April 11, 2012. He had severe wax in his ears that was cleaned out. Pet. Ex. 3 at 78.

On May 24, 2012, Mrs. Davis took her daughter to the pediatrician and during the visit expressed concern about Z.D.'s upcoming 2-year-old visit and shots due to his seizure after his 15-month checkup and because he "has been regressing developmentally, wants him to be referred to neuro." Pet. Ex. 3 at 79.

Dr. Walsh, a neurologist, examined Z.D. on June 5, 2012. Pet. Ex. 1 at 42. Dr. Walsh documented the history as a "brief seizure followed by several minutes of drowsiness" in January—one day after his 18-month routine vaccinations with a fever of 103. "The parents report

comes from his grandmother—a nurse—who witnessed it." Pet. Ex. 1 at 42. He was seen in the ER with no etiology found. He was discharged home with round the clock antipyretics and gradually recovered over four days or so. He has had no subsequent seizures. The family relocated to a new home. Z.D. was found to be behind in speech and is undergoing speech therapy once a week. He does not use language well and has learned to sign. His hearing screen was "ok", and he demonstrates good intelligence. *Id*. Family history includes mother with one seizure thought to be a complication of an epidural with her first child's delivery. *Id*. at 43. "He does not chew or swallow well but does not seem to have aspirated or been ill because of it." The remainder of the examination was normal/negative. Dr. Walsh agreed with the ER doctors that Z.D. had a febrile seizure, with no other signs of mental or physical skill loss and no development of other symptoms or signs. *Id*. at 44. "I am reluctant to attribute his speech problems to the seizure or an underlying developing or progressive neurological disorder. I would not pursue further neurologic testing at this time. Because most seizure (sic) after immunization are related to fever—and he did have fever with no other cause identified—I would probably pre-treat with an anti-pyretic during future immunizations. I would not start an anti-seizure medicine at this time and I do not think it likely an EEG will add useful information to our decision making." *Id*. Dr. Walsh discussed the risks of febrile seizures with the family, stating that he did not believe the risk from febrile seizures was different from the usual 1-2% chance of epilepsy and maybe a 50% chance of recurrence. *Id*.

At his June 8, 2012 2-year-old well child visit, he reportedly coughed with exertion, his speech had improved, but he choked a lot. Pet. Ex. 3 at 82. All milestones were reached with the exception of using more than 50 words, speaking in 2-3 word phrases, and naming 2 body parts. *Id*. He had a past medical history of speech therapy at Young Talkers and "Convulsions, Febrile" after Pentacel. *Id*. He was assessed to be a well child, with "exercised induced cough" and speech delay. *Id*. at 85. M-CHAT filled out that day was normal. *Id*. at 80, 85. Parents refused immunizations that visit because of a party that night. *Id*. at 85. Parents to call with progress report on use of albuterol for cough. *Id*. A prescription for an evaluation of oral motor skills for eating was sent to Young Talkers. *Id*. at 86.

At speech therapy on June 13, 2012, petitioners reported that Z.D. was evaluated by a neurologist who did not think there was anything neurological secondary to his seizure and that his speech delay may be due to a motor speech disorder or apraxia.[6] Pet. Ex. 3 at 90. On June 20, 2012, his parents noted that his gagging and coughing during eating and drinking had decreased this week after a week of nebulizer treatment for possible activity induced asthma. *Id*. at 91. Observation of food and liquids showed adequate mastication, mature chew, and preparation for swallowing. *Id*.

Z.D. received a hepatitis A vaccination on July 13, 2012. Pet. Ex. 3 at 92. Mrs. Davis called the pediatrician that afternoon to report that Z.D. had 101 fever and she was concerned due to febrile seizure after his last immunizations in March.[7] *Id*. at 93. She was instructed to rotate Tylenol and Motrin every three hours and take him to the ER if his fever reaches above 104. *Id*.

[6] Apraxia of speech is a speech disorder due to the mouth and neck muscles' loss of ability to carry out familiar, purposeful movements in the absence of paralysis or other motor or sensory impairment. *Dorland's Illustrated Medical Dictionary* 119 (33rd ed. 2019) [hereinafter "*Dorland's*"].

[7] The vaccination and seizure were both in January 2012. *See generally* Pet. Ex. 3; Pet. Ex. 5; Pet. Ex. 19.

On July 30, 2012, Mrs. Davis called the pediatrician to find out when Z.D. had received the Pentacel vaccine. She was advised that he received them on August 10, October 12, and December 16 of 2010. Pet. Ex. 3 at 97.

In August 2012, Z.D. tested positive for salmonella with a fever of 102, diarrhea, abdominal pain, and weight loss. Pet. Ex. 3 at 100, 105; Pet. Ex. 6 at 176, 186. He was to be kept well hydrated, rotating Motrin and Tylenol to control fever, and given a simple diet. Pet. Ex. 3 at 100-04, 109, 111. His history of "Convulsions, Febrile" after Pentacel was noted. *Id*. at 100. He was also receiving Albuterol by nebulizer three times a day for asthma. *Id*. at 119. The salmonella resolved by August 28, 2012 but he continued to have diarrhea and stomach pain at his September 4, 2012 follow visit. He was eating normally. *Id*. at 123, 126; Pet. Ex. 6 at 176. No seizures were reported. Pet. Ex. 3 at 126.

Z.D. was meeting his speech therapy goals and therapy continued. Pet. Ex. 3 at 131; Pet. Ex. 7 at 7-10.

Z.D. had a seizure on September 15, 2012 and was presented to the ER. Pet. Ex. 6 at 140. Mrs. Davis reported that he woke from his nap complaining of mouth pain with a fever of 99.8. Later that day, he fell off the couch and was shaking with seizure activity. *Id*. A prior febrile seizure was noted. A fever of 103.1 was noted in the ER and he was given Motrin. The fever persisted and he was given Tylenol. *Id*. at 140-42. On examination, he was neurologically intact, alert, and consolable. *Id*. at 141. A chest x-ray revealed perihilar opacities most likely secondary to subsegmental atelectasis[8]; however, central airway inflammation and atypical infection could not be excluded. *Id*. at 161. He was diagnosed with a febrile seizure and discharged home in stable condition. *Id*. at 145.

Mrs. Davis called the pediatrician the next day to advise that Z.D. had a second febrile seizure and went to the ER last night with "jerking". Pet. Ex. 3 at 133.

Z.D. was seen by the pediatrician on September 17, 2012. He still had a high fever with upper respiratory infection and barky cough. Pet. Ex. 3 at 133-37. Mrs. Davis reported that he had a seizure after he got very hot on September 15, 2012. *Id*. at 134. He was diagnosed with croup and prescribed Orapred. *Id*. at 137. Upon re-examination on September 21, 2012, he reportedly still had a URI, a rash, and was not acting like himself. *Id*. at 139. He was noted to be alert and well appearing. *Id*. at 141. He was assessed with allergic rhinitis and prescribed Zyrtec. *Id*. at 142. He had no further seizures.

Mrs. Davis called the pediatrician to report Z.D. being fussy, lethargic, and crying on September 20, 2012, with no fever. Pet. Ex. 3 at 138. She brought him to the pediatrician on September 21, 2012, with a rash around his mouth and his skin looked "webby". *Id*. at 139. He was well appearing and diagnosed with allergic rhinitis. *Id*. at 141-42.

Mrs. Davis called the pediatrician on September 26, 2012 to report that Z.D. had red lips and sores in his mouth. She was advised that hand, foot, and mouth was going around and was instructed to watch for fever and increased symptoms. Pet. Ex. 3 at 147.

[8] Atelectasis refers to incomplete expansion of a lung or portion of a lung. *Dorland's* 168.

A month later, Z.D. was presented to the ER with fever, runny nose, and cough. Pet. Ex. 6 at 123. He was noted to be a two-year-old with two febrile seizures in the past, but no seizure activity reported at this time. *Id*. He had a fever of 101.7 with an ear infection on examination. *Id*. at 125. He was prescribed amoxicillin and discharged. *Id*. Tylenol and Ibuprofen for fever were to be given as directed. *Id*. at 126.

The same day, Mrs. Davis called the pediatrician to report that she took Z.D. to the ER because he had a fever and was concerned about the possibility of him having a seizure. He had a fever of 102, now 101.5. She was advised if his fever was not a "spikey" fever, it was less likely to cause seizures. She was again advised on proper Tylenol/Motrin dosing. Pet. Ex. 3 at 148.

On November 5, 2012, Z.D. was transported by ambulance to the ER for a febrile seizure. Pet. Ex. 6 at 90. The EMT report documented a two-year-old found on the couch at the fire station. Z.D. had a one minute seizure in the car. *Id*. at 94. Mrs. Davis reported a febrile seizure a month ago and one in February.[9] Mrs. Davis reported that Z.D. had a fever that morning of 99.5 and was given Motrin. At 12:30 he had a fever of 101 but she did not give him any further medication. *Id*. She further reported Z.D. had a seizure after which he was initially unresponsive but then awake and alert to verbal commands. He became more alert during transport to the ER. *Id*. At the ER, he was noted to have apraxia. *Id*. at 90. Chest X-ray showed some minimal left base streaky atelectasis. Pet. Ex. 3 at 154; Pet. Ex. 6 at 109. He was given Motrin and Tylenol. Pet. Ex. 6 at 121. He was discharged with a diagnosis of febrile seizures with acute febrile illness. *Id*. at 92.

Mrs. Davis called the pediatrician later that day concerned about this most recent seizure, being the third since February and the second in a month. She wanted a referral to Medical University of South Carolina ("MUSC"). Pet. Ex. 3 at 149.

Z.D. was presented to the pediatrician on November 6, 2012 for follow up of a one-minute seizure. Pet. Ex. 3 at 150. Mrs. Davis reported passing a fire station when Z.D. had a seizure so she stopped, and an ambulance took Z.D. to the ER. *Id*. He had a fever of 104 upon arrival at the ER and a postictal period of 30-45 minutes. *Id*. He reportedly had a barky cough since Sunday with bumps and a little swelling of his top lip which he gets with the febrile seizure. *Id*. Mr. Davis expressed concern for Z.D.'s immune system. *Id*. at 153. Febrile seizures were discussed with the parents. The parents expressed concern that his speech delay was related to the seizures. A return to the neurologist if seizures continued was recommended. The use of Tylenol and Motrin to treat fevers was again advised. *Id*.

That same day, Z.D. was presented to the ER for fever and cough that started a few days ago but was now gone. He had a seizure yesterday that was brief and was presented to the ER. Mrs. Davis was concerned he was going to have another seizure, and she reported that yesterday was his third. Pet. Ex. 9 at 13-14. Z.D. was noted to be active, playful, alert, attentive, smiling, and making eye contact. *Id*. at 13. He also saw the PCP earlier today and was diagnosed with croup and herpangina. *Id*. at 14. He had no new seizures or fever. He looked well. A long discussion was had with the mother. *Id*.

[9] At this point, Z.D. had suffered two febrile seizures, one in January 2012 and one in September 2012. Pet. Ex. 5 at 6-7; Pet. Ex. 6 at 140-42, 145.

Z.D. returned to Dr. Walsh on November 13, 2012 reporting "additional febrile seizures and the family wishes to revisit management options." Pet. Ex. 1 at 46. Dr. Walsh described Z.D.'s initial seizure as "brief, generalized tonic clonic in context of post immunization fever-met criteria for simple febrile seizure and management was based on the expected prognosis and risk of the seizures vs the chance or (sic) recurrence and treatment options." *Id*. He has had two more seizures with the same semiology, all with fever, and the family's concern has risen. *Id*. Other than developing some allergies, there was no change in his general heath and no new symptoms or signs to suggest an additional underlying diagnosis. *Id*. Examination was negative/normal *Id*. at 46-47. Dr. Walsh noted nothing in the history or assessment that day showed evidence of regression that would suggest an additional or new diagnosis. *Id*. at 47. It was unclear that an EEG or neuroimaging would provide a clear idea of prognosis or management choice, so "we have elected not to do any studies at this time." The natural history of febrile seizures and treatment options were discussed. The parents expressed concern with responding quickly enough to treat fever and avoid seizures. "After full discussion of various daily anti-seizure options, we've elected a therapeutic trial of Keppra – about 20mg/kg/d in divided doses." *Id*.

Z.D. was seen by his pediatrician on November 14, 2012, due to a high blood pressure reading at Dr. Walsh's office. His blood pressure was normal on examination. Pet. Ex. 3 at 163-66.

A speech therapy report for the fall of 2012 documented that Z.D. had attended 16 of 24 scheduled visits and was making consistent progress. Pet. Ex. 7 at 13.

Z.D. received a flu vaccine on December 4, 2012, without event. Pet. Ex. 3 at 176.

Two weeks later, on December 19, 2012, Z.D. was presented to the ER at South Strand Regional for fever, cough, sore throat, and runny nose since yesterday. Pet. Ex. 9 at 33. He had a fever of 103 treated with Tylenol prior to arrival. He was taking Keppra for about a month. Z.D. was noted to be sitting up, drinking, and not ill appearing or toxic. *Id*. He had an oral temperature of 101.5. *Id*. at 34. The parents were instructed to give him Motrin and Tylenol to control his fever. He was discharged in stable condition. *Id*.

Later that day, an ambulance was called to the Davis house. Pet. Ex. 6 at 57. Upon arrival, the EMTs noted a two-year-old sitting on the couch alert and oriented. Mrs. Davis reported that Z.D. was sick since yesterday, had a fever last night of 103, was seen in the ER earlier today, given Motrin, and sent home with instructions to rotate Tylenol and Motrin. *Id*. He had a history of febrile seizures. The parents reportedly had not given him the Tylenol and Motrin as instructed at the ER earlier that day and he was walking around and shaking. *Id*. They wanted him transported to Waccamaw ER for evaluation. Z.D. complained of being cold and was placed on the stretcher with blankets. His temperature was 101.5. He remained alert and oriented during transport. *Id*. Once at the ER, Z.D. was noted to have an ear infection with fever. *Id*. at 52-53. His temperature on arrival was 104.1. *Id*. at 72. He was given Tylenol, Motrin, Pedialyte, and amoxicillin. He was discharged. *Id*. at 54, 60.

On December 22, 2012, Z.D. was presented to the pediatrician for three days of fever, rash,

chills, poor appetite, and swelling of the upper lip post-ER visit on Wednesday. Pet. Ex. 3 at 179. He was taking Keppra for a prior medical history of "Convulsions, Febrile." His rash had worsened with amoxicillin. His sister had the same symptoms without the rash and tested positive for RSV. *Id*. He was ill appearing but non-toxic. *Id*. at 181. He tested negative for both RSV and flu. *Id*. at 182. The assessment was URI and dermatitis. *Id*.

Z.D. saw the pediatrician again two days later due to 101 fever the night before. Pet. Ex. 3 at 185. His lips were dried and cracked. He had a faint rash since the fever went away with some macular rash on the right eye. *Id*. The parents advised they were seeing an immunologist in January and questioned if he had bacteria in his blood. *Id*. at 188. They were assured his blood was normal. *Id*.

The following day, December 25, 2012, Z.D. was presented to the ER with fever, cough, and red eye. Pet. Ex. 3 at 196. He was taking Keppra. *Id*. He was reported to have a fever for one week and a facial rash and swelling for two weeks and had been seen by the pediatrician. Pet. Ex. 6 at 37-38. His fever and painful facial swelling continued. His lips were swollen and cracked. An IV was started. He tested positive for RSV and was given Keflex. *Id*. at 38.

Z.D. returned to the pediatrician on December 26, 2012 following his ER visit the night before for 101.7 fever. He had tested positive for RSV. Pet. Ex. 3 at 190. He was diagnosed with bronchiolitis RSV, impetigo, r/o cellulitis of the right eye. *Id*. at 193. He was seen again on December 28, 2012 due to spitting up after taking Keflex. *Id*. at 199. He had no seizures with this recent illness. *Id*.

Mrs. Davis requested a Keppra level check on January 15, 2013. She reported that Z.D. did not sleep the night before and was "pitching really huge fits." Pet. Ex. 3 at 203. Following testing, Keppra dosage was changed to 1.5 ml twice daily. *Id*. at 206. Keppra levels were routinely checked over the next several months. He continued to have rashes and sleep disturbances. His parents reported him to be sick. Pet. Ex. 3 at 206, 209, 211. At his next pediatrician visit, he was noted to be well-nourished, well developed, alert, and appropriate for his age. *Id*. at 213. He was assessed with keratosis pilaris.[10] *Id*. at 214.

A February 2013 report from his speech therapist documented a 2 year, 8-month-old with apraxia of speech who had made consistent progress with one therapy session a week since March of 2012. Pet. Ex. 7 at 16. He was discharged due to family moving out of state. His records should be requested when the family settles to continue individualized speech therapy. *Id*.

Z.D. was re-evaluated on March 1, 2013 for continued speech therapy and noted to be above average in receptive language skills and below average in expressive language skills. Overall, he was within average range in comparison to others his age. He had made significant progress over the past year and was age appropriate for fluency, pragmatic skills, and vocal parameters. He no longer choked when eating or drinking, although he was still difficult to understand. Pet. Ex. 3 at 223.

[10] Keratosis pilaris is a common, benign condition in which hyperkeratosis occurs around hair follicles, usually on the exterior surfaces of the thighs and arms, but sometimes elsewhere. *Dorland's* 970.

On March 11, 2013, he was assessed for URI and weight loss of 20 ounces in 7 days. Pet. Ex. 3 at 215, 218. He returned to the pediatrician on March 20, 2013, for a rash that began a day ago with papules and erythema. *Id*. at 219. He had no other symptoms. He would only sleep at night if his mom laid next to him and would get up and cry if he awoke and she was gone. He would fall asleep immediately when in the car. The parents had stopped giving him melatonin when Keppra was started. He still slept in a crib. *Id*. He was assessed with unspecified sleep disturbance. *Id*. at 222.

At an April 10, 2013 pediatric visit, his parents reported feeding problems. He was picky, only ate very small bites at a time, did not like meat and would spit it out, but would eat cheese and fruits and drink milk. He ate better when taking Zyrtec but the combination with Keppra made him drowsy, so the Zyrtec was stopped. He constantly put his hands in his mouth and therapist expressed concern for oral aversion. He had been examined by a dentist several times and all was normal. Allergy and neurology appointments were scheduled for May. He had shortness of breath with exertion; Nebulizer treatment alleviates it. Pet. Ex. 3 at 227. The assessment on that date was failure to thrive, allergic rhinitis, questionable exercise induced asthma, and "seizures, NOS" (not otherwise specified). *Id*. at 228. He has speech delays and oral aversions. *Id*.

Z.D. remained in speech therapy through May 30, 2013 with consistent progress. His parents reported when his rate of speech was not too fast, his overall intelligibility had increased. Z.D. was noted to have characteristics consistent with apraxia of speech negatively affecting expressive language skills and functional communication. Pet. Ex. 7 at 19.

On May 20, 2013, Z.D. was examined by Dr. Drosieko, an allergist. He had a history of exercise induced cough and SOB over the past year and used albuterol by nebulizer every few weeks. Since March, he has had chest pain and SOB. He was prescribed a Ventolin inhaler with spacer and facemask every day. He had frequent URIs in the past requiring albuterol several times daily but had been healthy for the past six months. Zyrtec enhanced the side effects of Keppra. Pet. Ex. 11 at 40. The assessment was asthma, rhinitis, and febrile seizures. *Id*. at 42.

Dr. Walsh examined Z.D. on May 22, 2013 for follow up. He had a "brief, generalized tonic clonic [seizure] in context of post immunization fever", which met the criteria for a simple febrile seizure. Pet. Ex. 11 at 38. Management was based on the expected prognosis and recurrence and treatment options. He then had more seizures, all with fever, and the family became concerned. There have been no changes in his general health but for allergies and no symptoms or signs suggesting an underlying diagnosis, but after discussion with the parents, a trial of Keppra was initiated. He has not had a seizure since and tolerates the medicine well but for some "behavior issues". There are no new complaints. *Id*. Examination was normal/negative and Z.D. was noted to be alert, in no acute distress, with good eye contact and no involuntary movements. *Id*. at 38-39. No change to treatment was to be made, and the family agreed. *Id*. at 39.

Petitioners completed a developmental questionnaire for McLeod Rehabilitative Services in November of 2013. They documented that Z.D. stood, walked, and crawled early, held his head up, rolled over and sat without support as normal; fed himself with a spoon, babbled or jabbered, spoke first words, used one-to-two-word phrases, and spoke in sentences. Pet. Ex. 12 at 6. He had seizures with high fevers and woke during the night about 3 to 4 times per week. *Id*. at 7. He was

in speech therapy with good progress but still had trouble expressing himself and would get frustrated. *Id*. Mrs. Davis described him as anxious, easygoing, active, talkative, imaginative, and cooperative, needing little discipline. If he gets frustrated, he will get mad or cry. *Id*. at 8. He received occupational services and progressed well. *See generally Id*.

At a return visit with Dr. Walsh on December 9, 2013, Z.D. was reported to have no further seizures while on Keppra and the parents had no complaints or interest in changing his medication at that time. Pet. Ex. 11 at 36. He was noted to be alert and cooperative with no mood, thought, affect disorder or involuntary movements. *Id*. at 37. Dr. Walsh wrote "I believer (sic) these are febrile seizures and [Z.D.] is likely to outgrow them." *Id*.

Z.D. was seen by Dr. Drosieko on January 9, 2014 for exercise induced asthma, rhinitis, cough, and SOB for the past year and a half. Pet. Ex. 11 at 30. He used albuterol by nebulizer when needed but since March has had persistent issues and was prescribed Ventolin by inhaler which he has needed daily. Allergy testing was normal in the past. Flovent worked but then he developed a URI and now seems more tired, using albuterol several times daily with Flovent. He takes Keppra for febrile seizures. A chest x-ray was suggestive of viral process or reactive airway disease. *Id*. at 33. The assessment was asthma with recent exacerbation of symptoms, rhinitis, and febrile seizures. *Id*.

Dr. Drosieko referred Z.D. to Dr. Streck for asthma follow up, who saw him that same day. Pet. Ex. 11 at 30. An in-depth history was documented, including his SOB and chest pain following activity, coughing which wakes him at night, febrile seizures, and family history of seizures in mother and asthma in a maternal aunt. *Id*. at 30-31. His examination was normal but for infrequent dry cough. *Id*. at 31. He had asthma with exacerbation of symptoms due to URI, and azithromycin was prescribed. *Id*. at 33.

At an evaluation for speech therapy at One Stop Therapy on January 13, 2014, Z.D.'s history was reported as not using speech until 20 months of age and a diagnosis of apraxia. Significant progress has been achieved. Pet. Ex. 10 at 9. He suffered a seizure at 18 months following Pentacel vaccine with two subsequent seizures before being prescribed Keppra. He had no further seizures in the past year. He takes 6 mg of Keppra and two puffs of Advair for asthma daily. Evaluation revealed severe phonological delay and delay of expressive language skills with much attributed to phonological delay. *Id*. Prognosis was listed as good based on his stimulability and cooperation. *Id*. at 11.

A second evaluation was done at One Stop Therapy on January 16, 2014 due to the parents' concerns with his overall coordination. Pet. Ex. 10 at 1. Mrs. Davis reported that Z.D. was a typical pregnancy born at 38 weeks and met all milestones. He had a seizure at 18 months old following Pentacel vaccine and two additional seizures related to high fevers. He had been seizure free for the past year. He was on medication to control his seizures which affects his motor coordination and strength. He also has asthma. He takes Keppra and "two puffs" for asthma daily. He receives speech therapy for apraxia of speech. Z.D. was cooperative and well engaged throughout the evaluation. *Id*. The impression was weakness in the areas of upper extremities, trunk stability, praxis, pencil grasp, cutting skills, in hand manipulation skills, and poor sensory processing. *Id*. at 4. Occupational therapy was recommended to best prepare him for school and social interaction.

Id. He began occupational therapy. *See generally id*.

At his follow up with Dr. Drosieko on February 20, 2014, his condition remained the same for asthma and rhinitis. Prevacid was prescribed for suspected reflux. Pet. Ex. 11 at 23, 26-27.

Z.D. was presented to the ER at Grand Strand on March 10, 2014, for cough, low grade temperature, and wheezing for 3 to 4 days. Pet. Ex. 9 at 75. He was taking Keppra, well appearing, smiling, playing on an iPad, and non-toxic. *Id*. at 76-77. He was diagnosed with acute bronchitis and asthma exacerbation then discharged home. *Id*. at 77. He was prescribed prednisolone and amoxicillin. *Id*. at 88. He had not had a seizure in well over a year.

Z.D. returned to Dr. Drosieko on March 14, 2014 for follow up for bronchitis. Pet. Ex. 11 at 18. His reflux was better with Prevacid. He was active and playful but coughed frequently. The impression was asthma with cough, rhinitis, probable reflux, and febrile seizures. *Id*. at 21-22.

On April 14, 2014, Z.D. was presented to the ER at Grand Strand for shortness of breath and febrile seizure of 5 second duration. Pet. Ex. 9 at 97, 99. He was a three-year-old with febrile seizures and low-grade fever for the past three days that spiked earlier in the day. He had difficulty breathing then had a 5 second seizure, after which he was alert and responsive. His last seizure was a year and a half ago. *Id*. Over the past year he had fevers without seizures. He had a negative strep test at the pediatrician's office earlier that day. *Id*. He takes Keppra. *Id*. at 100. A chest x-ray revealed airway thickening without infiltrate. *Id*. at 103, 125. Tylenol and Ibuprofen were given. *Id*. at 104. He was diagnosed with bronchitis and a febrile seizure and was discharged. *Id*. The discharge instructions included seizure with high fever as common in children up to the age of 7 with 1 in 10 children having febrile seizures and some having several. *Id*. at 130. The seizures are not usually caused by a disorder of the nervous system like epilepsy or a brain infection and studies show that there is no serious nerve damage or decrease in intelligence in children with febrile seizures. The parents were instructed on the importance of treating infections that cause fevers to prevent further seizures. They were advised that repeated febrile seizures may indicate neurological problems. *Id*.

The following week, the parents presented Z.D. to the ER at MUSC reporting that he had cold hands and facial and hand numbness which were a sign of an oncoming seizure. He did not have a seizure. Pet. Ex. 11 at 13. He had a fever in the morning and was given Tylenol and Motrin. *Id*. at 13-14. The history provided by the parents included "febrile seizures with tonic clonic characteristics" in 2012 and the use of Keppra. He had no further seizures until two weeks ago. *Id*. The assessment was a viral illness with intermittent, mild cough. *Id*. at 16. He was otherwise well appearing. *Id*. His parents "adamantly request[ed] 'blood work' to 'diagnose bacterial infection'"; it was explained that blood work would unnecessarily cause pain to Z.D. and would not change his treatment since white blood cell count would be elevated in both viral and bacterial infections. *Id*. at 16-17. His parents left without discharge paperwork, stating they would take Z.D. to Mt. Pleasant ED.[11] *Id*. at 17.

Z.D. underwent EEG testing on April 28, 2014 which revealed bursts of generalized spike and wave discharges without clinical accompaniment. Pet. Ex. 11 at 45. The findings were

[11] There was no record of an ED visit at Mt. Pleasant that day.

"indicative of a lowered seizure threshold with a propensity toward primary generalized seizures." *Id*.

A chest x-ray also performed that day showed "prominent bronchovascular markings and perihilar interstitial opacities consistent with viral process or reactive airway disease." Pet. Ex. 11 at 48.

Z.D. was presented to Dr. Walsh on April 29, 2014 following a 30 second seizure two weeks prior with body stiffening, eyes rolling back, and 2-3 minutes of unresponsiveness afterward. Pet. Ex. 11 at 4. Dr Walsh noted that a Keppra level was drawn and was low "per parental report (however, I do not see anything confirming this[])". Keppra had been increased to 400 mg twice a day without a seizure since the increase, even though he had a fever last night for which he was presented to the ER as a precaution. *Id*. He has complained of one-sided facial weakness, which almost always happens after his seizures. He touches his face during these episodes. The parents voiced concern with chewing motions, staring episodes, and lips puckered to one side which he will stop if his name is called. *Id*. Following examination, the assessment was a 3-year-old with simple febrile seizures. *Id*. at 7. An MRI for facial numbness was suggested. The parents were directed to consult with Z.D.'s pulmonologist about sedation in light of his asthma. *Id*. Further, the parents were counseled that presenting to the ER was not necessary when Z.D. has a fever unless he has a prolonged seizure or a seizure without fever. *Id*.

That same day, Z.D. had a pulmonary examination for recurrent febrile illnesses of unclear origin. Pet. Ex. 11 at 9-11. His chest x-ray was "pretty benign." *Id*. at 11. Medication for reflux was prescribed. His father "adamantly" requested an antibiotic to travel back to Myrtle Beach. In response, Augmentin was prescribed but documented as unclear for what was being treated. *Id*. A Respiratory Viral Panel ("PCR") performed was positive for parainfluenza Type 1 and adenovirus. Pet. Ex. 11 at 51. His Keppra level was low. *Id*. at 53.

Z. D. was examined by Dr. Kraus on May 22, 2014 on referral from Dr. Walsh for increased light sensitivity and right eye pain. He had several months of URIs and fever with increased seizures. After a recent seizure he complained of eye pain and with facial numbness and chewing problems. Pet. Ex. 11 at 1. Examination was normal, with mild hyperopia and no glasses necessary. *Id*. at 2.

At his allergy visit on June 9, 2014, Z.D. was noted to be tolerating Prevacid. Pet. Ex. 15 at 1. He was a 4-year-old with asthma, GERD, allergic rhinitis, and seizures. He was positive for parainfluenza Type 1 and adenovirus in April which caused a high fever and seizure. *Id*. at 2. Neurology ordered a brain MRI. He was on iron supplements for anemia. He had issues with speech and now was getting feeding therapy. *Id*.

Z.D. returned to the allergist on July 23, 2014 with reports of gasping and snoring. Pet. Ex. 15 at 15. His symptoms were thought to be secondary to nasal obstruction. *Id*. He was to continue Advair and start Nasonex. *Id*. At his September 10, 2014 visit, he was doing well on Flonase which seemed to alleviate the gasping episodes. *Id*. at 15-16.

Dr. Walsh examined Z.D. on September 10, 2014, as well. Pet. Ex. 15 at 20. His parents

believed he may have had a brief "truncated seizure" in the spring, but he was very sick at the time. They described him sitting up in bed, staring up briefly, and appearing unresponsive, but it resolved quickly and "they are not convinced it was a seizure – abbreviated or not." *Id*. He tolerated Keppra, was progressing in therapy, and his speech therapy diagnosis was changed from apraxia to a phonological problem. His allergies were markedly improved. He had not regressed or lost any previously acquired function. *Id*. On examination, he was alert, oriented, with normal strength, no tremor, no cranial nerve or sensory deficit, normal muscle tone, sits, stands, and walks. *Id*. at 21. His coordination and gait were normal. *Id*. He had no regression and no need for further testing. *Id.* at 21-22. "From a neurological viewpoint, I am hopeful his seizures were febrile and related to his immunization–as opposed to immunization induced directly." *Id*. at 22.

A developmental assessment on December 10, 2014 showed a 4-year 6-month-old with average receptive language skills, significant expressive language delay consistent with verbal apraxia. Pet. Ex. 18 at 6-7. He was at risk for learning difficulties and would need psychoeducational testing at age 6. *Id*. at 7. He had fine motor dyspraxia and mild asymmetry with right toe walking. He held his arm in abduction with slight shoulder extension and flexion at the elbow. He was followed by neurology for seizure disorder and took Keppra. *Id*. His "parents report[ed] 'vaccine injury- MMR caused febrile illness' for which he has a lawyer in New York." *Id*. at 3.[12] He did not meet the criteria for Autism Spectrum Disorder. *Id*. at 7.

On December 22, 2014, Z.D. was presented for second opinion to neurologist, Dr. Turner. Pet. Ex. 16 at 29. He was a 4-year 6-month-old with a history of febrile seizures, abnormal EEG, and expressive language delays. His first seizure was at 18 months following a post-immunization fever, and he was diagnosed with a febrile seizure. "Reportedly initial event was febrile status epilepticus."[13] *Id*. He had four more seizures—all occurring with fever and illness—and was ultimately placed on Keppra in November of 2012. An EEG obtained in April 2014 showed generalized spike and wave discharges without clinical accompaniment. "Therefore, his previous seizure were (sic) likely illness related seizure and due to a decreased seizure threshold in the context of primary generalized epilepsy." *Id*. His last seizure was a year ago. His parents check his Keppra levels monthly and become very concerned when the levels are low despite seizure control. *Id*. The parents report significant concerns regarding seizure recurrence but are pleased with the improvements he has made over the past year. *Id*. at 29. He has some mild speech dyspraxia and has been referred to a new speech therapist to assist with this. *Id*. His parents do not think he is progressing as he should in speech therapy and are interested in other therapies. *Id*. Dr. Turner ordered an EEG and qEEG. *Id*. at 31; *see also* Pet. Ex. 25. The assessment was primary generalized epilepsy, dyspraxia of developmental speech, post-immunization reaction, developmental delay, abnormal EEG, and immunization not carried out because of contraindication. Pet. Ex. 16 at 30-

[12] Z.D. did not receive the MMR vaccine on January 12, 2012; he received DTaP, IPV, Hib, and flu vaccinations, which are the allegedly causal vaccinations for petitioners' claim. *See* Petition; Pet. Ex. 3 at 27-28.

[13] Petitioners' motion for interim fees reveals that counsel was retained in June 2012, 5 months after Z.D.'s first febrile seizure, and counsel appears to have engaged Dr. Kinsbourne as petitioners' expert in April 2014. By December 2014—when this visit took place—petitioners' counsel had had several conversations with Dr. Kinsbourne, who opined that Z.D. suffered from status epilepticus. *See* Motion for Interim Fees at 9, 13-14, ECF No. 76. The parents then started reporting Z.D.'s history as status epilepticus rather than simple febrile seizures.

31.

EEG and qEEG functional brain mapping were performed on December 29, 2014. Pet. Ex. 16 at 21. His prior seizure events were noted to be associated with illness and fever. There was some concern for left sided facial numbness. *Id*. The EEG was abnormal in the awake state due to "1) Rare essentially generalized spike wave discharges, maximal frontal, and 2) Asymmetry of waking background, relative amplitude suppression RIGHT hemisphere." *Id*. at 22. The EEG clinical correlation suggested a "lowered seizure threshold with a propensity toward generalized or focal seizures, as well as possible cortical/subcortical dysregulation over the right hemisphere, and clinical correlation is required. *Id*. The qEEG interpretation and clinical correlation was similar to the EEG results, also suggesting cortical and subcortical regional, focal, and/or global dysregulation. *Id*. at 26.

Petitioners and Z.D. met with Dr. Turner on December 30, 2014 to discuss the EEG and qEEG results. Pet. Ex. 16 at 1. Dr. Turner documented his review of the available medical records and details from the parents of Z.D.'s history, including location, quality, severity, timing, duration, context, modifying factors, and associated signs and symptoms. *Id*. The parents wanted a brain MRI and to pursue neuromodulation training. *Id*. Dr. Turner seemingly had all of Z.D.'s neurological and allergy records since his first seizure. *Id*. at 2-18. Examination that day was normal. *Id*. at 18. Assessments included dyspraxia of development of speech, epilepsy undetermined as to focal or generalized, left facial numbness, post immunization reaction; abnormal EEG, developmental delay, primary generalized epilepsy, and immunizations not carried out because of contraindication. *Id*. Dr. Turner wrote that Z.D. was a 4-year, 6-month-old with history of initial febrile seizure within 24 hours of vaccination followed by recurrent febrile seizures and development of abnormal EEG warranting further evaluation including brain MRI. *Id*. at 18-19. His EEG demonstrated maximal bi-frontal and asymmetry of background with relative amplitude decease over the right hemisphere, consistent with his history of recent left facial numbness. *Id*. at 19. The parents noted some pre-ictal events with funny sensations over his right face and mouth area, slurred speech, and thickened saliva during seizure. Taken as a whole, a focal epileptogenic process is likely and MRI was warranted. Neuromodulation was to be discussed after completion of the MRI. *Id*.

On January 13, 2015, an MRI of Z.D.'s brain without contrast was normal. Pet. Ex. 16 at 34.

In a follow up with Dr. Turner on April 6, 2015, leg and left hip pain and transient inability to walk last week were reported. Pet. Ex. 25 at 33. On examination he had confirmed mild leg length discrepancy with left leg 0.5 mg shorter than his right. *Id*. at 34. At his return visit to Dr. Turner on June 18, 2015, Z.D. was then five years old. *Id*. at 36. His parents reported a normal orthopedic examination with a shoe insert which alleviated his knee and hip pain. He has had no seizures reported and remained on Keppra without side effects. *Id*. The parents expressed interest in getting Z.D. a seizure dog. *Id*. He was to remain on Keppra. *Id*. at 37.

Z.D. had no further seizures through December 2015. Pet. Ex. 25 at 47-49.

A 2015 speech evaluation noted moderate to severe childhood apraxia of speech ("CAS")

defined as "a neurological childhood (pediatric) speech sound disorder in which the precision and consistency of movements underlying speech are impaired in the absence of neuromuscular deficits (e.g. abnormal reflexes, abnormal tone). CAS may occur as a result of known neurological impairment, in association with complex neurobehavioral disorders of known or unknown origin, or as an idiopathic neurogenic speech sound disorder. The core impairment in planning and/or programming spatiotemporal parameters of movement sequences results in errors in speech sound production and prosody." Pet. Ex. 24 at 3.

Z.D. was presented to Dr. Krishnamurthy on February 13, 2017 for consult of seizures. Pet. Ex. 63 at 1. They were still trying to secure prior medical records from Dr. Turner. *Id*. He was on Keppra. *Id*. at 1-2. He was reported to have seizures since the age of 18 months, most associated with fever and "head jerking" with unresponsiveness up to an hour. *Id*. at 2. His last seizure was 2-3 years prior. *Id*. at 3. He stares off when tired and stressed. Keppra was started soon after first seizure. MRI was normal. EEG was abnormal per parental report. He has no learning problems and is developing normally. His brother has been diagnosed with seizures recently. Exam that day was normal. *Id*.

An EEG performed on April 5, 2017 was abnormal and consistent with a seizure disorder. Pet. Ex. 75 at 33.

The record indicates that from April 28, 2017 onward, Mrs. Davis was calling Dr. Krishnamurthy's office with questions about Keppra and Z.D. having staring spells, behavior issues, and GI problems. Pet. Ex. 62 at 11. A discussion was apparently had with Dr. Krishnamurthy about changing from Keppra to Depakote because staring spells were getting worse. *Id*. at 10. She called again on May 24, 2017 to report that Z.D. was throwing up and she knew it was the medication. *Id*. at 8. She called back later to advise that Z.D. "looked whacky" since starting Depakote last Friday. *Id*. at 9. She was told to take him to the ER. *Id*.

In May 2017, Z.D. was presented to Dr. Krishnamurthy for generalized seizure disorder and long-term drug use. Pet. Ex. 62 at 4. The record indicates that Z.D. was switched to Depakote due to behavioral problems with Keppra and because it did not control his seizures. *Id*. at 4-5. He has had seizures since age 18 months associated with fever and consisting of head jerking. *Id*. at 5. His last seizure was 2-3 years ago. He does have frequent staring off episodes usually when tired and stressed. *Id*. He is developing normally and has no learning problems. *Id*. at 6. Brother has been recently diagnosed with seizures. *Id*. He had a follow up with Dr. Krishnamurthy in June 2017 and Depakote sprinkles were renewed and being tolerated. *Id*. at 1-2.

On November 19, 2017, Z.D. had a tonic clonic seizure without fever and was apparently seen in the Grand Strand ER. Pet. Ex. 75 at 4-5. He saw Dr. Krishnamurthy for follow up the following day. This was his first seizure since being switched to Depakote sprinkles. *Id*. at 5. An EEG performed on that date was normal but limited due to increased patient movement artifact. *Id*. at 31. "The back ground (sic) activity is well organized, consistent with chronological age of patient." *Id*. Z.D. followed up with Dr. Krishnamurthy on December 19, 2017 and February 19, 2018. *Id*. at 2-3.

Z.D. underwent biofeedback/neurofeedback/neuromodulation/NMD training with

"dramatic and noticeable improvements". Pet. Ex. 74 at 6.

Updated medical records show that Z.D. struggles with anemia, febrile viral illnesses, low WBC levels, developmental speech delay, constipation, asthma, and reactive airway disease. Pet. Ex. 17; Pet. Ex. 62; Pet. Ex. 63; Pet. Ex. 71; Pet. Ex. 72.

The last medical records filed in 2020 show that Z.D.'s seizures are referred to as "[e]pilepsy, unspecified, not intractable, without status epilepticus." Pet. Ex. 73 at 15; Pet. Ex. 67 at 8. He is thought to have absence seizures that are afebrile and very brief with staring spells and flickering of eyelids for a few seconds. Pet. Ex. 70 at 2. The impression is generalized seizures and primary generalized epilepsy, which is well but not perfectly controlled. *Id*. at 3.

Z.D.'s brother has been diagnosed with photosensitive seizures. Pet. Ex. 70 at 5. Genetic testing performed has not identified an underlying cause for Z.D.'s clinical features. Pet. Ex. 60; Pet. Ex. 64.

C. Petitioners' Affidavits and Testimony

1. Affidavit and Testimony of William Davis

Mr. Davis is the father of Z.D. and two other children. He is married to Nicole Davis. Pet. Ex. 20 at 1.

Mr. Davis attended Z.D.'s January 12, 2012 well child visit. Tr. 73. He had no concerns with Z.D.'s speech at the time and thought Z.D. was healthy and developing normally. Tr. 73. Z.D. could clearly say 10-15 words at that time. Tr. 74. He recalled commenting to his wife that he couldn't believe how many vaccines Z.D. received. Tr. 77-78.

Mr. Davis did not recall anything unusual about Z.D.'s behavior on the morning of January 13, 2012. Tr. 75. His mother-in-law came to visit that day to watch the three children so he and his wife could go to a movie that afternoon. Pet. Ex. 20 at 1.

He and his wife arrived at the theatre at approximately 1:38pm and around 3:00 or 3:15pm, his wife went to take a phone call out in the hall. When she returned, she told him Z.D. was seizing and unresponsive and "my mom thinks we're going to lose him." Pet. Ex. 20 at 2; Tr. 76. When they arrived home, his mother-in-law was on the couch holding Z.D. who was still seizing and unresponsive with his eyes rolled back and appeared "lifeless". Pet. Ex. 20 at 3; Tr. 77, 79.

Mrs. Davis went outside to call the pediatrician to find out which vaccines Z.D. received the day before while EMS was treating Z.D. Pet. Ex. 20 at 3; Tr. 77-79.

The hospital was a half hour away. Pet. Ex. 20 at 3. He followed the ambulance and Mrs. Davis rode with Z.D. in the ambulance. *Id*.; Tr. 80. Upon arrival at the hospital, Z.D. "was still out of it," his eyes closed, unresponsive and he still had a fever. Pet. Ex. 20 at 3. When questioned about the ER record which documented "diffuse one hour seizure", he stated he did not know where the information came from because he "didn't talk to anyone except the doctor." Tr. 80-81.

He recalled that Z.D. seemed lifeless, unresponsive, and "burning up" in the hospital. Tr. 81. Mr. Davis recalled the ER doctors saying Z.D. had a seizure and was postictal. Tr. 82.

They remained at the hospital until 9pm when Z.D.'s fever stabilized. When they left the hospital, Z.D. was still looking off to the side and unresponsive. Pet. Ex. 20 at 3; Tr. 83-84. He would not describe Z.D. as being "alert". Tr. 85. Between the January 2012 event and November of 2012, Z.D. did not have any issues with staring off or not focusing; his only problem was his speech. Tr. 120-21. However, after that first seizure, he could never get Z.D.'s attention. Tr. 107.

Mr. Davis recalled Z.D.'s next doctor appointment on March 5, 2012, at which time he could not tolerate loud noises, was fussy, wanted to be held all the time, stopped playing and was no longer affectionate. Tr. 88; Pet. Ex. 3 at 64. Mr. Davis was unable to understand the words Z.D. was saying. Tr. 89. His communication essentially revolved around pointing and grunting. Tr. 90.

Mr. Davis recalled seeing Dr. Walsh on June 5, 2012 for the first neurology appointment because this was the first referral they could get. Tr. 91. Dr. Walsh assured them the first seizure was an isolated event and not to worry. Tr. 91.

Mr. Davis described Z.D.'s second seizure on September 15, 2012. He walked over, knocked something off the table, dropped to the floor and had a seizure with his eyes rolled back. Tr. 91-92; Pet. Ex. 6 at 140-63. An ambulance took Z.D. to the hospital. Tr. 92-93. At the hospital, Z.D. looked postictal with his eyes off to the side. Tr. 93. He was diagnosed with a seizure but was not given medication. Tr. 93.

Z.D.'s third seizure was on Mr. Davis's birthday, November 5, 2012. Tr. 93. They were in the car when Z.D. had a seizure and when he looked in the rearview mirror, he saw Z.D.'s head tilted back, eyes off to the side, and head shaking. He was unresponsive. He pulled into a nearby fire station to get medical attention. Tr. 94. An ambulance arrived at the fire station and Mrs. Davis rode with Z.D. to the hospital and Mr. Davis followed in the family car. Tr. 94-95.

Mr. Davis confirmed that Z.D. had a fever with the first three seizures and all subsided as the fever went down. Tr. 118. He and his wife were instructed to control the fever to prevent seizures. Tr. 118.

At a follow up with Dr. Walsh, they were told Z.D. would grow out of the seizures. Tr. 96. They asked about medication options, and Dr. Walsh prescribed Keppra because it treats febrile seizures. Tr. 97-99; Pet. Ex. 1 at 47. No warning about side effects of Keppra were given. Tr. 98.

Z.D.'s fourth seizure was on April 14, 2014, accompanied by respiratory distress. Tr. 100; Pet. Ex. 9 at 99-105. Z.D.'s eyes were rolled back and his face was twitching. Tr. 101. At another follow up with Dr. Walsh, an EEG was ordered which was abnormal. Tr. 101-02. Keppra was continued. Tr. 102.

Mr. Davis recalled that during a developmental appointment for occupational and physical therapy, the doctor noticed Z.D. messing with his face and referred them to Dr. Turner, another neurologist, for an MRI. Tr. 104-05. They took Z.D. to Dr. Turner in December of 2014 because

they were dissatisfied with Dr. Walsh. Tr. 103, 106; Pet. Ex. 16 at 29-32. Dr. Turner diagnosed Z.D. with epilepsy following an EEG and MRI. Tr. 108.

They then saw Dr. Krishnamurthy while Dr. Turner was on sabbatical. Tr. 109. Dr. Krishnamurthy advised that Z.D. was taking the wrong medication because he did not have febrile seizures—he had absence seizures. Tr. 110, 117. Mr. Davis could not remember if Dr. Krishnamurthy agreed that Z.D.'s initial seizures were febrile seizures and he then developed epileptic seizures or whether all the seizures were related to epilepsy. Tr. 118-19. Mr. Davis believes they are all absence seizures, but he is not a doctor. Tr. 119. They were told that absence seizures involved Z.D. looking away, and Mr. Davis equated staring spells to absence seizures. Tr. 110-11. Dr. Krishnamurthy switched Z.D.'s medication to Depakote and Dr. Turner agreed. Tr. 111.

Mr. Davis said that all Z.D.'s behavioral problems went away once on Depakote and his staring spells subsided. Tr. 123.

Z.D. had another seizure was on November 19, 2017 noted to be tonic-clonic. Tr. 113-14; Pet. Ex. 75 at 4-5. His eyes were rolled back and face was twitching, but he came out of it quickly. Tr. 114.

Z.D. still has seizures, but they are better. Tr. 116, 122. He had one in Charleston, and they took him to the ER. He had another minor seizure in May 2019. Tr. 114-15.

Mr. Davis stated that Z.D.'s older brother had two grand mal seizures, which involved him biting his tongue. Doctors immediately put him on Keppra and diagnosed him with junior myoclonic epilepsy. Dr. Turner believed that video games triggered his seizures. Tr. 124-25. But, unlike his older brother, Z.D. never convulsed. Tr. 126.

2. Affidavits and Testimony of Nicole Davis

Mrs. Davis is Z.D. mother. She and William have three children. She works from home in home design and creating websites. Pet. Ex. 21 at 1. She described the family as very active and Z.D. as a happy, calm, and easy going baby who did not cry a lot. *Id.*; Tr. 15.

Mrs. Davis recalled Z.D.'s check-up on January 12, 2012 when he received his required vaccinations. Pet. Ex. 21 at 1; Tr. 15. He had 10-15 words at that visit. Tr. 15-16. She was concerned about the number of words Z.D. had—not his ability to speak clearly—but her husband was not concerned. Tr. 16, 17. Mrs. Davis did not recall them being referred to BabyNet, and she thought this was perhaps because they did not follow through with speech therapy at that time. Tr. 16. Z.D. was fine that evening after his shots; everything was "routine." Pet. Ex. 21 at 1-2; Tr. 18.

The next day, her mother came to visit, and she and Mr. Davis went to a movie. Pet. Ex. 21 at 2; Tr. 19. Before they left, Z.D. was eating, playing, and acting normally. Pet. Ex. 21 at 2; Tr. 20. The movie started around 1:30pm. Tr. 20. Around 3:00-3:15pm, her mother called that Z.D. was "seizing, he's unresponsive, I think we're going to lose him." Tr. 22; Pet. Ex. 21 at 2. Mrs. Davis was very concerned since her mother was a nurse. Pet. Ex. 21 at 2.

Mrs. Davis went back into the theater to get her husband. Pet. Ex. 21 at 2. She called an ambulance from the car but was told one had already been dispatched to her home. *Id.*; Tr. 23. The ambulance was at the house when they arrived. Tr. 23. She affirmed once inside the house she saw Z.D. unconscious and seizing. Pet. Ex. 21 at 2. At hearing, she stated when they got home, her mother was holding Z.D., his face was twitching, his eyes were rolled back, and his body looked limp. Tr. 23. She then said he was staring blankly to the side. Tr. 26. She called the pediatrician to find out what vaccines he had the day before. Tr. 24. Mrs. Davis rode in the ambulance with Z.D. to the hospital. Pet. Ex. 21 at 2; Tr. 25.

Mrs. Davis disagreed with the EMT record that Z.D. was alert during transport. She agreed he was conscious but was staring off into space. Tr. 26. "I couldn't get him to respond to me or to look at me." Tr. 27. She had affirmed he had a temperature of 103.3 in the ambulance and seized the whole ride to the ER. Pet. Ex. 21 at 2.

Mrs. Davis stated they arrived at the hospital at 4:13pm, and Z.D. was pale, staring off, unresponsive, his face was twitching, and he was feverish. Tr. 28-30; Pet. Ex. 5. Neither she nor her husband provided the information in the hospital record that Z.D. had a diffuse seizure for one hour. Tr. 27-28; *see also* Pet. Ex. 5 at 3. She affirmed the "postictal phase lasted a long time." Pet. Ex. 21 at 2; Pet. Ex. 5 at 3.

According to Mrs. Davis, it took hours to bring his fever down to a safe level so he could be discharged. Pet. Ex. 21 at 3. Even when they left the ER, he was fussy and "in and out". Tr. 31. They were told to control the fever with Tylenol and Motrin. Pet. Ex. 21 at 3. She recalled taking his temperature throughout the evening and giving him Tylenol and Motrin until his fever broke. Tr. 32-33. She stated, "I don't know that he ever went back to normal [after the first seizure]. I mean, he was never the same. He never wanted to play anymore or do anything. He cried, just cried and was fussy all the time." Tr. 33.

Mrs. Davis stated between January 13 and March 5, 2012, Z.D. regressed in terms of speech, could not speak, and would simply grunt and point to communicate. Tr. 34-35. Loud sounds bothered him. Tr. 34. When she took him to the pediatrician on March 5, 2012, she was "very concerned about [Z.D.] having all the issues that he was having and not being able to speak for his age." This was a new pediatrician that recommended Z.D. see a neurologist and go to speech therapy. Tr. 35-37; Pet. Ex. 3 at 63-64.

Mrs. Davis took Z.D. for a speech evaluation on March 21, 2012. Tr. 37; Pet. Ex. 7. He was diagnosed with apraxia of speech. Tr. 37. Mrs. Davis stated that Z.D. did not have difficulty with his speech prior to his first seizure. If he had, she would have mentioned it to his pediatrician. Tr. 38; *but see* Pet. Ex. 3 at 26, where on January 12, 2012, Mrs. Davis expressed concern over Z.D.'s speech to his pediatrician and the record notes a referral to BabyNet.

Mrs. Davis recalled the first appointment with Dr. Walsh on June 5, 2012. Tr. 38; Pet. Ex. 1 at 42. She and her husband were told that Z.D.'s seizure was an isolated event and to not be too concerned. Tr. 38-39. Mrs. Davis stated she told Dr. Walsh about her concern for Z.D.'s choking and trouble swallowing, which started at some point after the first seizure. Tr. 39-40.

She also stated that after the first seizure, Z.D. could barely walk, his feet were turned inward, and he was not able to talk. Tr. 68. She agreed that none of these issues were documented in any medical record or in any developmental questionnaires. Tr. 68-69.

Mrs. Davis recalled Z.D.'s second seizure in September 2012. Tr. 41; Pet. Ex. 6 at 140-63. Z.D. was laying on the floor in his room with his face twitching and his eyes rolled back. Tr. 41-42. "[H]is body was just lifeless". She called 911.Tr. 41-42.

His third seizure occurred on November 5, 2012 while they were in the car. Z.D.'s face began to twitch, his eyes rolled back, and his body went limp. Tr. 43-44; Pet. Ex. 6 at 90-121. They drove to a nearby fire department for medical attention. The seizure lasted around 10 minutes. Tr. 44.

They took Z.D. back to Dr. Walsh in November 2012 and were told Z.D. was having febrile seizures. They were also told that Keppra would combat the seizures, and it was prescribed. Tr. 45.

Mrs. Davis stated that throughout 2013, Z.D. cried excessively, woke during the night, seemed distracted, and was not progressing with his speech. Tr. 46.

Z.D.'s fourth seizure occurred on April 14, 2014 but was different because it involved respiratory arrest. Tr. 46-47; Pet. Ex. 9 at 99-105. Z.D.'s eyes rolled back and his face was twitching. Tr. 47-48. Mrs. Davis called 911 and noticed he was having trouble breathing. Tr. 48.

Dr. Walsh then ordered an EEG, which was performed on April 28, 2014. The results were abnormal. Tr. 49-50; Pet. Ex. 11 at 7, 45.

Mrs. Davis stated they were dissatisfied with Dr. Walsh and sought a second opinion from Dr. Turner on December 22, 2014. Tr. 51-52, 54; Pet. Ex. 16 at 29-34. Dr. Turner diagnosed Z.D. with epilepsy. Tr. 10, 52. They were told Z.D.'s brain was damaged from a lack of oxygen during his seizures. Tr. 65-66.

Mrs. Davis stated when they saw Dr. Krishnamurthy, they were told that Z.D. had generalized seizures and was on the wrong medication. Z.D. was then switched to Depakote. Tr. 52-53.

Z.D.'s had a seizure in November 2017, but it was not as "harsh" as his prior seizures. Tr. 54-55; Pet. Ex. 75 at 4-5. She added that Z.D. was completely different after switching to Depakote. Tr. 56. He no longer had outbursts, and his staring spells were now brief. Tr. 56.

Mrs. Davis stated that her older son has a seizure disorder with grand mal seizures which involve full body flailing and biting his tongue which began in May 2017 while playing football. Tr. 56-57. He had another seizure on Thanksgiving that same year while playing video games. Tr. 57. He has been diagnosed with epilepsy triggered by flashing lights. Tr. 57. Mrs. Davis claims that Z.D.'s seizures are much different because he "never convulsed." Tr. 57.

Mrs. Davis stated that Z.D. has caught up in his development in most areas except for reading. Tr. 64. However, he is not normal and cannot run and play like he used to, he gets overheated and tired easily with periods where he cannot walk. Pet. Ex. 21 at 3. He has "focal seizures where he will just stop what he is doing and will start staring." *Id*.; Tr. 6. She initially recalled the staring spells beginning after the other seizures subsided. Tr. 11. She later could not remember when the staring spells began, but she guesses it was in 2015 when he was in kindergarten. Tr. 42-43.

She stated Z.D. still gagged and choked while eating. Tr. 65. She conceded none of Z.D.'s treaters associated his speech or eating problems with his seizures. Tr. 65. Z.D. has been diagnosed with verbal apraxia, speech dyspraxia, and dyspraxia of fine motor skills. He gets frustrated when he is not understood and must be home schooled because he is not up to date on his vaccinations. Pet. Ex. 21 at 4; Tr. 6.

In a subsequent affidavit, Mrs. Davis affirmed that Z.D. was homeschooled because the public school system was unable to accommodate him for mainstream schooling. His Individualized Education Program results did not "meet the requirements for additional support in mainstream schooling and the services he would need are not available." Pet. Ex. 27 at 1. She believes he needs a personal aid for one-on-one attention, which the school system cannot provide. *Id*. at 2. He also only attends school half a day because he gets fatigued, which can cause seizure activity such as staring spells, facial numbness, and head pain.[14] *Id*.; Tr. 7-8. The medical records indicate that he was homeschooled to prevent exposure to illnesses from other children. *See* Pet. Ex. 16 at 17-18.

3. Affidavit of Lucille Menard[15]

Mrs. Menard provided an affidavit dated December 2015. Mrs. Menard is Z.D.'s grandmother and Mrs. Davis' mother. She was a Licensed Practical Nurse ("LPN") for 25 years and retired in 2010. Pet. Ex. 48 at 1. She described her job as administering medicines, hooking up IVs, giving baths, taking vitals at the hospital, making appointments, giving referrals, and calling in medication at the doctor's office. *Id*. at 1-2.

According to Mrs. Menard, when she arrived at the Davis household around 1pm on January 13, 2012, Z.D. was awake and playful. Petitioners left to see a movie around 1:15pm and she spent some time with Z.D., then put him down for a nap "probably around 2pm". He slept for about an hour while she played with her older two grandchildren and watched TV. Pet. Ex. 48 at 2.

[14] The remainder of the affidavit is not discussed herein as it goes to damages and Mrs. Davis' belief of what accommodations Z.D. would need at school for him to attend.

[15] Mrs. Davis affirmed her mother's mental state at the time she wrote her affidavit in 2015 was fine but her memory began to regress around late 2017 and she was diagnosed with dementia. Tr. 59-61. Mr. Davis also stated Mrs. Menard was fine in 2015 when she signed her affidavit but has become more forgetful in the past year or two. Tr. 127. Mr. Davis testified that Mrs. Menard was a healthcare professional and worked in a family practice. Tr. 128-29.

At around 3pm, she heard Z.D. crying and "walked upstairs to check on him." Pet. Ex. 48 at 2. When she got to his room, he was crying loudly. She touched his forehead. He was "burning up." She took him out of his crib and brought him downstairs. *Id*. Mrs. Davis had left Z.D.'s baby items on the counter in the kitchen including a thermometer. *Id*. at 3. She put it under his arm and it took a few minutes to register. Z.D. was crying the whole time. When the thermometer beeped, she saw Z.D. had a temperature of 103.3. "At the same time, [Z.D.] looked like he was in a trance." She yelled his name, but he did not respond or move. "When he opened his eyes, I noticed his eyes were rolled back. I tried to call his name and lightly shake him, but he was nonresponsive. [Z.D.] did not convulse." *Id*.

Mrs. Menard called her daughter, told her what was happening, that she was scared and worried Z.D. would not make it. She also called 911 then went to the living room and sat on the couch holding Z.D. and waited for help. Z.D. "was motionless in my arms and was unresponsive". Pet. Ex. 48 at 3.

When EMS arrived, Mrs. Menard "explained to them what happened". Pet. Ex. 48 at 3. They evaluated Z.D., gave him oxygen, put him on the gurney, and put him in the ambulance. Her daughter and son-in-law arrived right after EMS did. Her daughter went in the ambulance with Z.D., her son-in-law followed in the car, and she stayed with her other two grandchildren. *Id*.

IV. The Experts' Opinions

A. Petitioners' Expert, Dr. Marcel Kinsbourne

1. Qualifications

Dr. Marcel Kinsbourne graduated from Oxford University in England with a B.M., B.Ch., the equivalent of an American M.D. Pet. Ex. 28 at 1. Dr. Kinsbourne became licensed in the United States in 1967. *Id.* at 1-2. Dr. Kinsbourne served as an associate professor and a senior research associate at Duke University Medical Center before holding a series of academic positions. *Id*. at 2-3. His clinical experience includes serving as a senior staff physician in Ontario from 1974-1980 and a clinical associate in neurology at Massachusetts General Hospital from 1981-1991. *See Fantini v. Sec'y of Health & Human Servs*., No. 15-1332V, 2022 WL 1760730, at *5 (Fed. Cl. Spec. Mstr. May 2, 2022).

Dr. Kinsbourne is well known to the Court having been involved in Vaccine Program cases since the inception of the Program. *See, e.g., Badman v. Sec'y of Health & Human Servs.,* No. 89–89V, 1990 WL 293393, at *1 (Fed. Cl. Spec. Mstr. Mar. 22, 1990).

Dr. Kinsbourne issued five reports in this matter and testified at hearing. Pet. Ex. 29; Pet. Ex. 58; Pet. Ex. 65; Pet. Ex. 68; Pet. Ex. 76.

2. Causation Opinion

i. Dr. Kinsbourne's First Report

Dr. Kinsbourne summarized Z.D.'s medical history as follows: Z.D. received routine 18-month-old vaccinations on January 12, 2012. One day later, he suffered a fever lasting for several hours, followed by him "lapsing into a prolonged lowered level of consciousness," as described by his parents and grandmother, a nurse. Pet. Ex. 29 at 1. His grandmother measured his temperature at 103.3 and put him down for a nap at 2pm. One hour later, he began to "screech uncontrollably", went into a "trance", would not respond, and his eyes were rolled back. *Id*. She called EMS and held him motionless and unresponsive. By this time, he had been running a fever for several hours. *Id*. The grandmother reported "a few seconds of convulsive movements [to EMS], but the grandmother denies having made such an observation." *Id*. EMS found Z.D. responsive to "loud verbal (sic) by opening eyes and staring blankly to R side." *Id*.; *see also* Pet. Ex. 19 at 2. He became more responsive during transport. *Id*.

Dr. Kinsbourne created the following timeline: EMS was called at 3:27pm, arrived at 3:39pm, departed at 3:44pm, arrived at the hospital at 4:13pm, Z.D. was admitted at 4:17pm. Pet. Ex. 29 at 1. At 4:30pm, Z.D. appeared postictal. At 5:31pm, he was fully alert. *Id*. at 1-2. Z.D. was therefore unresponsive for 60 minutes or more before recovering full awareness. *Id*. at 2.

Dr. Kinsbourne continued, stating that Z.D. "uttered his first words no sooner than March 21, 2012, when he was 21 months old, having previously expressed himself by grunting and pointing. At that time, he understood 20 words. His receptive language was at the 10th percentile on the REELT. He was diagnosed with apraxia of speech" and noted to be moderately delayed in speech. Pet. Ex. 29 at 1-2, citing Pet. Ex. 7 at 4[16]. At age four,[17] his verbal ability was that of a 2-year 5-month-old due to severe phonological disorder that compromised the intelligibility of his speech. Pet. Ex. 29 at 2, citing Pet. Ex. 14 at 1. He has fine motor delay and impairment of sensory processing requiring occupational therapy and physical therapy due to seizure disorder with resultant gross motor delay. Pet. Ex. 29 at 3; Pet. Ex. 24 at 3; Pet. Ex. 12 at 11; Pet. Ex. 22 at 29.

1. The Initial Seizure

Dr. Kinsbourne agreed Z.D.'s initial seizure was "clearly febrile," but consisted of a prolonged period of diminished level of consciousness, and therefore was not a "simple febrile seizure." Prolonged stupor with eyes turned upward is consistent with the clinical presentation of nonconvulsive status epilepticus ("NCSE"). Pet. Ex. 29 at 3-4; Pet. Ex. 43.[18] NCSE is a variant of status epilepticus. Pet. Ex. 29 at 4. A formal diagnosis of NCSE requires concurrent EEG validation of paroxysmal discharges. In the absence of EEG testing, clinical presentation informs the diagnosis. Z.D.'s prolonged stupor witnessed by his family and EMS, along with his lengthy and gradual ascent to normal awareness, is common in NCSE. An estimated twenty-five percent of children with status epilepticus do not convulse. *Id*.; Pet. Ex. 44.[19] According to *Jafarpour &*

[16] Although Dr. Kinsbourne stated that Z.D. spoke his first words at 21 months of age, the medical records state that he had 10-15 words on the date of vaccination. Pet. Ex. 3 at 26.

[17] Dr. Kinsbourne wrote that these findings were when Z.D. was at age five; however, the medical records show that he was in fact four years old at this visit. Pet. Ex. 14 at 1.

[18] Simon Shorvon & Eugen Trinka, *Nonconvulsive Status Epilepticus and the Postictal State*, 19 EPILEPSY & BEHAVIOR 172 (2010), filed as "Pet. Ex. 43."

[19] Stacey K.H. Tay et al., *Nonconvulsive Status Epilepticus in Children: Clinical and EEG Characteristics*, 47 EPILEPSIA 1504 (2006), filed as "Pet. Ex. 44."

Loddenkemper, NCSE "is associated with worse clinical outcome". Pet. Ex. 38 at 5.[20] An EEG was not performed at the time of Z.D.'s initial seizure for a formal diagnosis of NCSE, but the two done later were suggestive of atypical absence epilepsy. Pet. Ex. 29 at 4. "The spike and wave pattern of dysrhythmia is the kind of EEG dysrhythmia that is observed in the atonic 'absence' variant of NCSE." *Id*. Z.D.'s staring spells are consistent with absence epilepsy. *Id*.

2. Risk of Seizure After Acellular Pertussis Vaccine and Mechanism of Injury

Dr. Kinsbourne conceded that acellular DTaP is less likely to cause seizures than the whole cell DTP. Pet. Ex. 29 at 4-5; Pet. Ex. 40.[21] However, all vaccinations activate the innate immune system with toll-like receptors releasing proinflammatory cytokines, including interleukin-1 beta which is required to achieve an adaptive immune response. Pet. Ex. 29 at 5; Pet. Ex. 32.[22] DTaP vaccine causes the release of both IL-1beta and IL-6. Pet. Ex. 29 at 5; Pet. Ex. 31 at 5;[23] Pet. Ex. 41.[24] Fever is mediated in part by IL-1beta and has the propensity to cause seizures. Seizures then release additional IL-1beta in the brain which results in a lower seizure threshold. Pet. Ex. 29 at 5; Pet. Ex. 45;[25] Pet. Ex. 33.[26] This occurs because when IL-1beta binds to its receptor, it reduces GABA (A) receptor currents, which reduces inhibition and causes enhanced neuronal excitability from which seizure onset may result. Pet. Ex. 29 at 5.

Vezzani & Baram found that "[f]ever is a systemic host response to infection, inflammation, or stress. Fever provokes convulsions (febrile seizures) in 3-5% of young children". Pet. Ex. 45 at 3.[27] The mechanism by which fever evokes seizures is not fully elucidated, but evidence supports the role of IL-1beta. *Id*. Prolonged febrile seizures are associated statistically with the development of temporal lobe epilepsy. *Id*. Retrospective studies show that roughly 30-70% of those with temporal lobe epilepsy have a history of prolonged febrile seizures early in life.

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[20] Saba Jafarpour & Tobias Loddenkemper, *Outcomes in Pediatric Patients with Nonconvulsive Status Epilepticus*, 49 EPILEPSY & BEHAVIOR 98 (2015), filed as "Pet. Ex. 38."

[21] Nicole Le Saux et al., *Decrease in Hospital Admissions for Febrile Seizures and Reports of Hypotonic-Hyporesponsive Episodes Presenting to Hospital Emergency Departments Since Switching to Acellular Pertussis Vaccine in Canada: A Report from IMPACT*, 112 PEDIATRICS e348 (2003), filed as "Pet. Ex. 40."

[22] Xin Chen et al., *Pertussis Toxin by Inducing IL-6 Promotes the Generation of IL-17-Producing CD4 Cells*, 178 J. OF IMMUNOLOGY 6123 (2007), filed as "Pet. Ex. 32."

[23] Gunnar Carlin & Eila Viitanen, *In Vitro Pyrogenicity of the Diphtheria, Tetanus and Acellular Pertussis Components of a Trivalent Vaccine*, 23 VACCINE 3709 (2005), filed as "Pet. Ex. 31."

[24] Gang Li et al., *Cytokines and Epilepsy*, 20 SEIZURE 249 (2011), filed as "Pet. Ex. 41." This article explained that epilepsy is a common neurological disorder, but its etiology is often unknown. Recent studies have shown a complex relationship between epilepsy and the immune system. Cytokines released through an inflammatory reaction are understood to mediate spontaneous seizures. Pet. Ex. 41 at 1. IL-1 beta, IL-6 and tumor necrosis factor increase quickly after generalized tonic clonic or complex partial seizures and return to baseline after varying time intervals. *Id*. at 5. Seizures induce cytokine expression both in the brain and in the periphery. *Id*. Li et al. points out that IL-1 beta, IL-6 and tumor necrosis factor have been shown to have both pro- and anticonvulsive properties in varying animal studies. *Id*.

[25] Annamaria Vezzani, PhD & Tallie Z. Baram, MD, PhD, *New Roles for Interleukin-1 Beta in the Mechanisms of Epilepsy*, 7 EPILEPSY CURRENTS 45 (2007), filed as "Pet. Ex. 45."

[26] C. Dube et al., *Cytokines: A Link Between Fever and Seizures*, 57 ANNALS OF NEUROLOGY 152 (2005), filed as "Pet. Ex. 33."

[27] Vezzani & Baram, *supra* note 25.

Id. Prolonged or recurrent seizures can irreversibly alter the way the immature brain develops and forms synapses, resulting in changes in expression or operation of functional receptors lowering the seizure threshold for further seizures. Pet. Ex. 29 at 5.[28] The probability and severity of subsequent spontaneous seizures is correlated with the duration of the prolonged febrile seizure. Pet. Ex. 29 at 5; Pet. Ex. 34.[29]

Dr. Kinsbourne opined that Z.D. had an "inferred NCSE" which "contributes to unfavorable outcomes" caused by the vaccinations he received, most likely the acellular pertussis vaccine. Pet. Ex. 29 at 5. Further, the "prolonged nature of the onset seizure," subsequent major seizures, and interictal paroxysmal activity on EEG while on powerful anti-epileptic medication suggests that Z.D.'s epilepsy is unlikely to remit and he probably has atypical absence epilepsy ("AAE") which has impacted his mental development manifesting in speech and language difficulties, as well as gross and fine motor and emotional control difficulties. *Id*. at 4, 6. In support of his opinion, Dr. Kinsbourne relied on literature that describes NCSE as one of two distinct entities: absence status epilepticus or complex partial status epilepticus. Pet. Ex. 38 at 1.[30] Although several definitions exist for NCSE, all include cognitive deficits of at least 30 minutes associated with continuous or near continuous ictal discharges on EEG. *Id*.; *see also* Pet. Ex. 39.[31] Atypical absence status epilepticus is generally seen in children with secondary generalized epilepsy where an EEG shows "slow" spike and wave at <2.5 Hz. Pet. Ex. 39 at 5; *see also* Pet. Ex. 42.[32] *Kaplan* concluded that NCSE represents one of the greatly underrecognized and underdiagnosed epileptic conditions. *Id*. at 16; *see* Pet. Ex. 79 at 3.[33] *Adams et al*. defined NCSE as a "type of seizure characterized by an alteration in cognition, memory, arousal, affect, motor learning, or motor behavior of at least 10- 30 minutes in duration *in the absence of tonic or clonic activity*." Pet. Ex. 79 at 2 (emphasis added).[34]

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[28] Dr. Kinsbourne relied on *Holmes & Ben-Ari* (2001) and *Ben-Ari & Holmes* (2006) to support this statement, but neither were filed.

[29] Celine M. Dube et al., *Epileptogenesis Provoked by Prolonged Experimental Febrile Seizures: Mechanisms and Biomarkers*, 30 J. OF NEUROSCIENCE 7484 (2010), filed as "Pet. Ex. 34." This study examined whether prolonged febrile seizures can cause epilepsy in the absence of genetic or acquired predisposing factors. Pet. Ex. 34. The authors concluded that the answer to that question was unclear. *Id*. at 2. *Dube et al*. noted that while most children who experience febrile status epilepticus do well, some will develop epilepsy and it is not clear why. *Id*. at 13. *Dube et al*. found in their animal study that "seizure duration influenced epileptogenesis augmenting the severity of the resulting epilepsy, measured by duration of the spontaneous seizures and their generalization". *Id*. However, it was also noted on EEG that spontaneous seizures in rats were preceded by interictal activity, which denoted long febrile seizures and resulting hyperexcitable limbic circuit but did not reliably predict frank epilepsy. *Id*.

[30] Jafarpour & Loddenkemper, *supra* note 20.

[31] Peter W. Kaplan, M.B., B.S., FRCP, *Behavioral Manifestations of Nonconvulsive Status Epilepticus*, 3 EPILEPSY & BEHAVIOR 122 (2002), filed as "Pet. Ex. 39."

[32] Melinda Nolan, FRACP et al., *Clinical and Neurophysiologic Spectrum Associated with Atypical Absence Seizures in Children with Intractable Epilepsy*, 20 J. OF CHILD NEUROLOGY 404 (2005), filed as "Pet. Ex. 42." This article discusses atypical absence seizures in the context of intractable epilepsy, which Z.D. does not have. Tr. 316.

[33] Scott J. Adams et al., *Pediatric Absence Status Epilepticus: Prolonged Altered Mental Status in an 8-Year-Old Boy*, 2016 CASE REPORTS IN NEUROLOGICAL MEDICINE 1 (2016), filed as "Pet. Ex. 79."

[34] *Id*.

Dr. Kinsbourne added that *Holmes* provides that "recurrent seizures in the developing brain can result in long-term adverse consequences." Pet. Ex. 35 at 4.[35] However, *Holmes* also provided that many children who develop epilepsy appear to have cognitive deficits that precede the onset of seizures, suggesting that the etiology of the seizures—not the seizures themselves—are responsible for the impaired cognition. *Id*. *Holmes* further discussed conditions that Z.D. did not have. *See generally* Pet. Ex. 35; Pet. Ex. 10 at 11.

Dr. Kinsbourne opined that Z.D.'s NCSE was the cause of his speech difficulties, relying on *Neiman* to show the onset of aphasia between 18 months and 13 years but usually after 4 and before 7 with language deterioration occurring over weeks or months, but with acute onset also described. Pet. Ex. 52 at 1-2.[36] The prevalence of clinical seizures in acquired epileptic aphasia is 70-85% with half of affected children having a seizure as the initial manifestation. In one-third of patients, only a single status epilepticus episode is recorded, and 12% have a family history of epilepsy. *Id*. *Neiman* also discussed language dysfunction in patients with early onset benign childhood occipital epilepsy due to the continuous spike-and-wave discharges during slow-wave sleep. *Id*. at 3. Oromotor apraxia and speech problems may develop or worsen with episodes of sustained spike and wave discharges during sleep. *Id*. at 4.

ii. Dr. Kinsbourne's Second Report

Maintaining that Z.D.'s first seizure was NCSE, not a simple febrile seizure, and that "status epilepticus is quite capable of permanently lowering a child's seizure threshold", Dr. Kinsbourne argued that Z.D.'s first seizure caused his seizure disorder. Pet. Ex. 58 at 1-2. According to Dr. Kinsbourne, Z.D. suffered four major seizures before he was prescribed Keppra, an anti-epileptic. Keppra is not prescribed for benign febrile seizures. *Id*. at 1. Further, the timeframe between Z.D.'s first and second seizure was typical for epilepsy. *Id*. at 2.

In this report, Dr. Kinsbourne described Z.D.'s seizures as a mixed seizure disorder which included convulsive, absence, and minor seizures, with only the convulsive seizures being responsive to his anti-epileptic treatment. Pet. Ex. 58 at 2. EEG showed typical interictal subclinical epileptiform concomitant with his clinically apparent seizures and staring spells. *Id*.

As for his speech delay, Dr. Kinsbourne argued that no language or speech disorder was documented by his pediatrician in the medical record and there was no referral for speech evaluation or therapy prior to his vaccinations. Pet. Ex. 58 at 3. Z.D.'s speech "crashed" after his status epilepticus seizure, causing him to gesture and grunt to make his needs known. *Id*. A language test performed two months after his vaccine-related seizure showed his receptive language as in the 10th percentile but his expressive language in the 1st percentile. *Id*., citing Pet. Ex. 7 at 4.

Dr. Kinsbourne concluded that Z.D. has acquired epileptiform aphasia or AEA. Children with AEA with convulsive disorder start developing language normally but then regress. Pet. Ex.

[35] Gregory L. Holmes, *What is More Harmful, Seizures or Epileptic EEG Abnormalities? Is There Any Clinical Data?*, 16 EPILEPTIC DISORDERS S12 (2014), filed as "Pet. Ex. 35."

[36] Eli S. Neiman, DO, *Acquired Epileptic Aphasia Clinical Presentation*, Medscape (2015), https://emedicine.medscape.com/article/1176568-clinical?form=fpf, filed as "Pet. Ex. 52."

58 at 4. He again referenced *Neiman* to support that primary impairment in AEA is in expressive language, and a seizure is commonly the first manifestation of AEA. *Id*. at 4, 5; Pet. Ex. 52.[37]

iii. Dr. Kinsbourne's Third Report

In this report, Dr. Kinsbourne responded to Dr. Zempel's definition of epilepsy requiring two unprovoked/afebrile seizures arguing that the Keppra "effectively brought his seizures to a halt, leaving him no opportunity to have the two afebrile seizures." Pet. Ex. 65 at 1-2. Further, Dr. Zempel failed to address the subclinical interictal epileptiform discharges seen on Z.D,'s EEG, which were inconsistent with benign febrile seizures. *Id*. Dr. Zempel also discounted Z.D.'s minor seizures, which included staring and chewing motions. *Id*.

Finally, Dr. Kinsbourne argued that Z.D.'s brother having epilepsy sheds no light on Z.D.'s seizure disorder. Pet. Ex. 65 at 3.

iv. Dr. Kinsbourne's Fourth Report

In this report Dr. Kinsbourne acknowledged that a key issue in this case is the appropriate diagnosis for Z.D.'s first seizure arguing that Z.D.'s first seizure was not brief or benign and was followed by a long postictal period. He then submitted that there "was no record of any convulsive phase in [Z.D.]'s onset seizure." Pet. Ex. 68 at 1-2. However, even if there were a few seconds of convulsions, an hour postictal period is inconsistent with a benign febrile seizure. *Id*. at 2. Dr. Kinsbourne cited *Millichap*, which stated that "[c]hildren typically return to baseline quickly after a simple febrile seizure. . . Prolonged drowsiness is not typical for simple febrile seizure and should prompt consideration of an alternative etiology." *Id*., citing Resp. Ex. D Tab 1.[38]

v. Dr. Kinsbourne's Fifth Report

In his fifth report, Dr. Kinsbourne maintained that the "sequence of events that constituted Z.D.'s first seizure clearly map out that Z.D. suffered from a prolonged absence seizure and not a simple febrile seizure." Further, it is "preposterous" to call the sequence of events here a simple febrile seizure. Even several seconds of convulsive movements would not cause a prolonged postictal state. Pet. Ex. 76 at 1-2. Simple febrile seizures last 1-15 minutes and are not preceded by screeching. *Id*. at 2. A child may be groggy or sleepy after a simple febrile seizure, but an extended postictal state is not part of the description of a simple febrile seizure. *Id*. However, the literature relied on by Dr. Kinsbourne shows the aftermath of most seizures is a short period of confusion and sometimes sleep. Pet. Ex. 43 at 3.[39]

In further support of his opinion that Z.D.'s initial seizure was not a simple febrile seizure and was instead his first epileptic seizure, Dr. Kinsbourne concluded that Z.D. has been since been formally diagnosed with primary generalized epilepsy. Pet. Ex. 76 at 2; Pet. Ex. 70 at 2-9.

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[37] *Id*.

[38] John J. Millichap, MD, FAAP, *Clinical Features and Evaluation of Febrile Seizures*, UpToDate (2023), https://www.uptodate.com/contents/clinical-features-and-evaluation-of-febrile-seizures/print?source=see_link, filed as "Resp. Ex. D Tab 1."

[39] Shorvon & Trinka, *supra* note 18.

vi. Dr. Kinsbourne's Testimony

Dr. Kinsbourne testified that Z.D.'s seizure disorder was triggered by the January 12, 2012 vaccinations. Tr. 133. He described the many kinds of seizures including tonic-clonic seizures involving jerking limbs, falling, and biting one's tongue, which is what Z.D.'s half-brother has. Tr. 134-35, 150. Febrile seizures are triggered by fever and are quite common in young children. Tr. 135-36. He stated that simple febrile seizures, which Z.D. was diagnosed with on January 13, 2012, involve tonic-clonic activity, last fewer than fifteen minutes, and cannot possibly be missed because there is nothing subtle about the severe jerking. Tr. 136-37, 174. Twitching of the face is not tonic-clonic, it is myoclonus,[40] which does not occur with simple febrile seizures. Tr. 200-01.

Dr. Kinsbourne maintained that Z.D.'s first seizure did not include tonic-clonic behavior and lasted longer than 15 minutes therefore the diagnosis of simple febrile seizure was wrong. Tr. 137, 141, 330. He interpreted the grandmother's use of "seizure-like activity" as relating to eyes rolling up—not tonic-clonic activity. Tr. 331-32. He conceded that no one knows exactly what she meant. Tr. 333. He added that ER doctors are not neurologists and would not appreciate Z.D.'s presentation with a rather rare form of epilepsy. Tr. 195.

Further, Dr. Kinsbourne stated that Dr. Walsh accepted the wrong diagnosis from the hospital but realized after the third seizure in November of 2012 that Z.D. had epilepsy and prescribed Keppra. Tr. 193-95. "I want to make it really clear no one prescribes Keppra for simple febrile seizures. . . [i]t is incomprehensible to me that he put a child on Keppra and thought that he was still treating simple febrile seizures." Tr. 194-95, 199. Keppra has risks and it is extremely unlikely that Dr. Walsh prescribed it simply because Z.D.'s parents requested medication. Tr. 200. It is more likely, that Dr. Walsh realized the child had epilepsy and prescribed an anti-seizure medication. Tr. 193-95.

Dr. Kinsbourne maintained that Z.D. had absence seizures and epilepsy. Tr. 138, 141, 149, 150. He explained that absence seizures are when a child suddenly stops what they are doing and upon recovery, has no idea what has happened. Tr. 138. They have automatisms, such as the eyes rolling backwards or looking to the side and sudden brief jerks. Tr. 141. Z.D.'s first three seizures included eyes turned up and his face jerking, all clear manifestations of absence seizures. Tr. 149.

Further, absence seizures have adverse consequences on a developing child. Tr. 179-80. He described three types of absence seizures which vary in length. The first is a petit mal seizure where a person stares off and freezes for a few seconds which typically has no negative consequences since they are short. Tr. 139, 143. The second is an atypical absence seizure where a person is unresponsive for a matter of minutes. The third is status epilepticus, which is defined as an abnormal mental state—being not completely unconscious but also not fully awake and alert—for more than thirty minutes. Tr. 139, 143, 145.

Dr. Kinsbourne argued that Z.D.s first seizure was the third type, status epilepticus, longer

[40] Myoclonus is defined as shock-like contractions of a portion of a muscle, an entire muscle, or a muscle group, restricted to one area of the body or appearing synchronously or asynchronously in several areas. *Dorland's* 1205.

than 15 minutes and associated with more negative effects. Tr. 139, 141, 143, 145; *see* Pet. Ex. 5 at 3. He calculated the beginning of the seizure when the grandmother ran upstairs. Tr. 145, 197. From then through the ambulance ride to the hospital was over thirty minutes. Tr. 145, 199. He acknowledged the EMS record documented Z.D. as alert but accepted the mother's testimony that he was conscious but staring off throughout the transport. Tr. 146-48. Therefore, the initial seizure "absolutely lasted more than 10 or 15 minutes". Tr. 199.

Further, Z.D. was described as postictal at the hospital, which is what occurs when a seizure stops. There is "absolutely" a difference between postictal and alert. Tr. 147-48. When asked to reconcile how Z.D. was "alert" during transport but postictal at the hospital, Dr. Kinsbourne reasoned the EMTs merely assessed whether Z.D. was conscious and because he was conscious, they documented that he was alert. Tr. 148.

Regarding *Althen* prong I, Dr. Kinsbourne explained that the innate immune system responds to infection by releasing the pro-inflammatory cytokine IL-1beta, which in turn generates fever and stimulates the immune system. Tr. 168, 170, 171-72, 175; *see also* Pet. Ex. 33.[41] He further explained that "cytokines . . . activate cells in the body and in the brain such as macrophages [], which then produce toxins to kill" the bacteria or virus. Tr. 168, 170, 175-76. Vaccinations like infection evoke a similar response in the body. Tr. 169, 170. In epilepsy, some circuits are overstimulated by the cytokines and over-function manifesting as seizures. Tr. 169, 176. Cytokines exist in the body at low levels all the time but can be produced in excess causing hyperexcitable neurons. Tr. 173-74, 176; *see also* Pet. Ex. 45.[42] Dr. Kinsbourne stated that seizures are triggered by cytokines—not fever; although it is possible that a fever alone could cause a seizure, the fever would have to be very high. Tr. 171. Cytokines, on the other hand, can cause seizures even when fever is low because they cause brain inflammation. Tr. 171-72.

Further, Dr. Kinsbourne stated a seizure with fever is not the same as a simple febrile seizure. Tr. 171. Oftentimes, a child will have a seizure with a fever and doctors are uncertain whether it's epilepsy or not. Tr. 328. Therefore, it is normal for doctors to hold off on diagnosing epilepsy until a child is "old enough to have two afebrile seizures." Thus, the date of diagnosis does not necessarily indicate when the epilepsy first began. Tr. 328.

Dr. Kinsbourne agreed that the vaccinations Z.D. received caused his fever the next day and DTaP vaccine is known to cause fever and inflammation. Tr. 184-85. However, fevers foster activation of seizures by speeding up circuits in the brain. Tr. 164, 166. Circuits may be vulnerable for a variety of reason, including genetics, brain damage, or toxins. Tr. 167-68, 184-85. A fever can trigger the manifestation of an epileptic tendency because certain brain circuits are vulnerable in epileptic patients. Tr. 149-50, 166, 176. Epilepsy is generally due to excessive excitation of neurons. Tr. 159-60, 169. In absence seizures, Gaba neurons in particular are hyperexcitable. Tr. 161, 166, 176.

Here, Z.D.'s epilepsy manifested through absence seizures and was diagnosed by the April 28, 2014 EEG testing which showed interictal epileptiform activity, despite there being no outward symptoms of seizure at that time. Tr. 150, 152-55; Pet. Ex. 11 at 45. The EEG results showed

[41] Dube et al., *supra* note 26.
[42] Vezzani & Baram, *supra* note 25.

Z.D.'s tendency of hyperexcitability. Tr. 154. Dr. Kinsbourne agreed with Dr. Krishnamurthy that Z.D. had absence epilepsy, given his response to Depakote and not Keppra. Tr. 155-56. Further, Dr. Kinsbourne saw no reason to differentiate Z.D.'s first seizure from his later-diagnosed epilepsy. Tr. 150. At young ages, the brain is sensitive to rising temperatures. Fever becomes less a factor as one grows older. Tr. 151, 203. Further, the presentation of epilepsy commonly changes with age, which explains why Z.D. had more petit mal seizures as he got older, as well as one tonic clonic seizure. Tr. 150-51.

Further, Dr. Kinsbourne stated that following his first seizure in January 2012, Z.D. suffered neurological damage that manifested in problems with speech, a common consequence of absence seizures. Tr. 179-83, 334, 337; *see also* Pet. Ex. 57.[43] Generally, speech problems in children happen gradually. "What doesn't happen a lot is regression. Regression is completely a different thing . . . A child precipitously losing [speech] is rare and very alarming and pathological." Tr. 335; *but see* Pet. Ex. 3 at 71, where petitioners reported two months after his first seizure on March 21, 2012 that Z.D. was saying about 20 words.

Dr. Kinsbourne described aphasia as losing words and apraxia as knowing the words but being unable to shape one's lips and throat to say the words correctly. Swallowing difficulty and trouble moving one's mouth is also related to apraxia which is "very neurological" and rarely a temporary problem. Tr. 336-37. "If a child is getting the skills, whatever they are, at some usual rate and then it falls off, something has happened. Something has happened to that child's brain." Tr. 337.

Dr. Kinsbourne claimed that prior to the vaccinations, Z.D. had 10-15 words, which was in the objectively "normal" range. Tr. 178-79, 334. After the vaccinations, he "dropped off a cliff" and was the equivalent to a nine-month-old at nearly two years of age. "But there is no doubt that the abrupt and striking regression in his language development, which is quite unusual, happened soon after the vaccination." The first seizure was "sufficient to cause an adverse effect on brain processes." Tr. 179. He clarified he was not saying Z.D. ever had aphasia. Tr. 338.

According to Dr. Kinsbourne, the time between the vaccinations and the first seizure was reasonable. Tr. 185-86. The time between the first and second seizure—approximately eight months—was also medically reasonable. Tr. 177. "I think it's what happens with epilepsy. The interval between seizures in epilepsy are enormously variable, and there's nothing whatever unusual about eight months intervening between the first and second seizure." Tr. 177-78, 203.

Dr. Kinsbourne agreed DTaP is generally recognized to rarely cause seizures but is far less likely to cause seizures than the whole cell pertussis vaccine DPT. Tr. 207-08; *see also* Pet. Ex. 29 at 5. But he added, DTaP can still cause seizures, even though it's a less frequent occurrence than its predecessor. Tr. 209.

[43] Hannah Cock, *Experimental Evidence of Status-Induced Brain Damage*, filed as "Pet. Ex. 57."

B. Respondent's Expert, Dr. John Zempel

1. Qualifications

Dr. Zempel received his bachelor's degree in molecular biology with honors. Tr. 210. He received his M.D. and Ph.D. from Washington University St. Louis. Tr. 211. He completed his residency in child neurology and had a fellowship in pediatric epilepsy. He actively treats patients as a pediatric neurologist and epileptologist, and he has his own research lab. Tr. 211-12. He testified that most of his patients have intractable pediatric epilepsy. Tr. 211.

2. Causation Opinion

i. Dr. Zempel's First Report

Dr. Zempel agreed NCSE can cause neurological injury but disagreed Z.D. had NCSE. Resp. Ex. A at 7. "Dr. Kinsbourne's interpretation of subsequent events depends on his assumption that Z.D. had NCSE of extended length." *Id*. Dr. Zempel agreed with Z.D.'s treating physicians that his first seizure was a simple febrile seizure. *Id*. at 7-8.

Dr. Zempel explained that if Z.D. presented with what appeared to be more than a simple febrile seizure in January of 2012, he would have been admitted to the hospital, undergone extensive testing, and been prescribed medication. Resp. Ex. A at 8. His course of treatment at the hospital was entirely consistent with a simple febrile seizure. *Id*. at 9. Further, being tired following a seizure, coupled with a high fever and being given medication is not unusual. After several hours of observation and once his fever was lowered, Z.D. was noted to be alert and sent home. Following this event, his parents did not take him to the doctor again for two months and at that time, March of 2012, he was noted to be well, alert, making eye contact, and pointing to things. Concerns with his speech were noted again, but his development was within normal limits. A speech and hearing evaluation was recommended. *Id*. at 4, 8.

Dr. Zempel detailed the EMS observations, emergency room records, Drs. Walsh and Turner's records, and the EEG results concluding there was no support for a diagnosis of NCSE. Resp. Ex. A at 3-7. Dr. Zempel disagreed there was a "prolonged period of stupor with eyes turned upward" evidencing NCSE. He pointed to the ER record as documenting a "postictal period in the presence of fever that improved with the reduction in fever such that Z.D. was discharged after several hours of observation." *Id*. at 8. Z.D.'s course was consistent with a simple febrile seizure. Further, the ER record makes no mention of Z.D.'s eyes being turned upward—only that he was sleeping or not at baseline. *Id*.

There is also no support in the medical records that Z.D. had drug resistant epilepsy. Resp. Ex. A at 8-9. Z.D. was treated for years with a low to moderate dose of one antiseizure medication with few adjustments. There are no records that Z.D. suffered an unprovoked or afebrile seizure necessary for a diagnosis of epilepsy. *Id*. Additionally, his mother reported concerns about his speech at the January 12, 2012 visit, the day of his vaccinations. *Id*. at 9; Pet. Ex. 4 at 12; Pet. Ex. 29 at 1.

In Dr. Zempel's opinion, Z.D. had a simple febrile seizure the day after his vaccinations. Resp. Ex. A at 8, 9. They are referred to as "simple" because they are shorter and typically well tolerated. *Id*. at 9. Complex febrile seizures include multiple prolonged seizures in one day or with focality. *Id*. Febrile seizures are distinguishable from epilepsy and are a pediatric syndrome which occur with acute illness and especially fever. *Id*. at 10.

Dr. Zempel agreed that determining whether a first seizure is a benign febrile seizure or the unmasking of epilepsy is difficult. "Recurrent afebrile seizures make it more likely in retrospect that an earlier seizure that occurred in the context of fever is a part of epilepsy, where the fever lowers seizure threshold, rather than as part of a pediatric febrile seizure syndrome." Resp. Ex. A at 10. An estimated 2-5% of children have febrile seizures, while only 0.5-1% are diagnosed with epilepsy. Some febrile seizures, like complex febrile seizures, are associated with the development of future epilepsy. However, there is no support in current literature for simple febrile seizures causing long term neurological dysfunction, including epilepsy. *Id*. at 10, 11; Resp. Ex. A Tab 1;[44] Resp. Ex. A Tab 6;[45] Resp. Ex. A Tab 7.[46]

Further, a diagnosis of epilepsy depends on the presence of unprovoked seizures as opposed to provoked seizures. Provoked seizures typically result from traumatic brain injury, fever, abnormal blood chemistries such as hypoglycemia (low blood glucose), hyponatremia (low blood sodium), hemorrhages (bleeding), or other acute structural causes. Resp. Ex. A at 10. The guidelines of the International League Against Epilepsy ("ILAE") have broadened the definition of epilepsy to include one unprovoked seizure with a likelihood of further seizures, influenced by genetic, structural, or EEG factors. *Id*. Thus, an abnormal EEG and a single unprovoked seizure under the new guidelines would suggest a diagnosis of epilepsy. The records clearly document Z.D.'s seizures as provoked by fever. *Id*.

Dr. Zempel disagreed that vaccines in general or DTaP specifically can cause epilepsy or did in Z.D. Resp. Ex. A at 10. Dr. Zempel conceded that a child such as Z.D. with an abnormal interictal EEG is at a higher risk of unprovoked seizures, but Z.D.s initial and subsequent seizures were all associated with fever, consistent with a febrile seizure syndrome. *Id*. He agreed with Dr. Walsh that the simple febrile seizures are not themselves, causative of longer-term injury. The initial EEG revealed generalized epileptiform activity consistent with a reduced seizure threshold, therefore it was entirely possible that Z.D. would eventually develop unprovoked seizures and be diagnosed with epilepsy. *Id*. Many children with generalized epileptiform abnormalities have a genetic predisposition to both febrile seizures and epilepsy. *Id*. at 10-11. He would not agree that a simple febrile seizure led to the development of generalized epilepsy or that Z.D. has atypical absence epilepsy. *Id*.

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[44] American Academy of Pediatrics, *Febrile Seizures: Clinical Practice Guideline for the Long-term Management of the Child with Simple Febrile Seizures*, 121 PEDIATRICS 1281 (2008), filed as "Resp. Ex. A Tab 1."

[45] Karin B. Nelson, M.D. & Jonas H. Ellenberg, Ph.D., *Prognosis in Children with Febrile Seizures*, 61 PEDIATRICS 720 (1978), filed as "Resp. Ex. A Tab 6."

[46] Karin B. Nelson, M.D. & Jonas H. Ellenberg, Ph.D., *Predictors of Epilepsy in Children Who Have Experienced Febrile Seizures*, 295 THE NEW ENGLAND J. OF MEDICINE 1029 (1976), filed as "Resp. Ex. A Tab 7."

Dr. Zempel cited to the 2008 American Academy of Pediatrics, which reported that in over 365 medical articles reviewed on simple febrile seizures, there was no association found between simple febrile seizures and long-term neurological disability, except where preexisting abnormalities were present. Resp. Ex. A at 11; Resp. Ex. A Tab 1;[47] Resp. Ex. A Tab 6;[48] Resp. Ex. A Tab 7.[49] Further, neither a decline in IQ, academic performance, or behavioral abnormalities have been shown to be a consequence of recurrent febrile seizures. Resp. Ex. A at 11; Resp. Ex. A Tab 1.

Dr. Zempel conceded he could not provide an explanation for Z.D.'s neurodevelopmental issues, but that does not imply that Z.D.'s vaccination-associated simple febrile seizure caused them. Additionally, Z.D. had documented speech issues prior to his vaccinations, which is not uncommon in children. Resp. Ex. A at 11.

Dr. Zempel concluded that Z.D. suffered a simple febrile seizure one day after his vaccinations. The vaccinations were not related to his subsequent febrile seizures, possible epilepsy, or long-term neurodevelopmental issues. Resp. Ex. A at 11.

ii. Dr. Zempel's Second Report

Dr. Zempel addressed Dr. Kinsbourne's opinion that Z.D.'s first seizure was febrile status epilepticus. He pointed out that Dr. Kinsbourne relied on a medical history provided by the parents years later. Resp. Ex. C at 1. He further pointed out that Dr. Walsh did not characterize the initial seizure as status epilepticus. Even later, Dr. Turner wrote "Epilepsy, unspecified, not intractable, without status epilepticus." *Id.*; Pet. Ex. 25 at 44.

Dr. Kinsbourne characterized Z.D.'s seizures as a mixed seizure disorder with features of convulsive, absence, and minor seizures with only the convulsive seizures responsive to anti-epileptics. Resp. Ex. C at 1-2. Dr. Zempel noted that Z.D. never had an extended EEG video study in which seizures were captured in order to support Dr. Kinsbourne's theory that Z.D had ongoing subclinical (absence) seizures. Z.D. is not being treated for uncontrolled epilepsy. *Id*. at 2-3.

Dr. Zempel pointed out that *Musicco*[50] relied on by Dr. Kinsbourne only discussed unprovoked seizures associated with epilepsy in children and adults and how it can start in many different temporal windows. Resp. Ex. C at 3. Z.D. only had provoked or febrile seizures, so the study is not applicable to this case. *Id*.

Dr. Zempel acknowledged Dr. Kinsbourne taking issue with his reference to Z.D.'s January 2012 seizure as an "isolated" febrile seizure but stated that he failed to provide any support that Z.D.'s seizure was anything more than that. Resp. Ex. C at 4.

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[47] American Academy of Pediatrics, *supra* note 44.
[48] Nelson & Ellenberg, *supra* note 45.
[49] Nelson & Ellenberg, *supra* note 46.
[50] It does not appear this article was filed. Further, Dr. Zempel wrote in his report that this study was from 2007; however, Dr. Kinsbourne's report noted that it was published in 1997. Resp. Ex. C at 3; Pet. Ex. 58 at 2.

Further, Z.D. had a documented speech/language development issue on January 12, 2012—the day of vaccination—and the pediatrician referred petitioners to "BabyNet", South Carolina's early evaluation and intervention program. Resp. Ex. C at 4.

Dr. Zempel agreed that a link exists between epilepsy and speech and language issues in AEA but disagreed that Z.D.'s clinical and electrophysiological features support a variant of AEA. Resp. Ex. C at 4. Z.D. has not been treated for nor undergone any testing for AEA, and his treaters did not consider his subsequent development of epilepsy in the context of AEA. *Id*. Had Dr. Zempel been the treating epileptologist and concerned about uncontrolled seizures or AEA, he would have ordered an overnight EEG video study and initiated treatment beyond a single anti-seizure medication. *Id*. at 5. Further, Z.D.'s EEG results were not consistent with AEA. *Id*. at 5-6. Finally, Dr. Kinsbourne provided no evidence to support that Z.D.'s "febrile seizures or rare/intermittent generalized epileptiform discharges are related to his speech dyspraxia." *Id*. at 6.

iii. Dr. Zempel's Third Report

Dr. Zempel addressed the genetic testing performed on Z.D., stating that the vast majority of patients with epilepsy will not have a genetic cause determined by current testing methodology. Resp. Ex. D at 1. A strong family history, particularly in first degree relatives, supports a genetic cause of a patient's epilepsy. Z.D.'s brother has epilepsy with an abnormal EEG. *Id*. at 2; Pet. Ex. 62 at 6.

Dr. Zempel strongly disagreed that there is no prolonged postictal period following a simple febrile seizure. Resp. Ex. D at 2. He agreed *Bonhoeffer et al*. stated that no postictal state exists after a simple febrile seizure but that "belies obvious daily clinical experience." *Id*.; Pet. Ex. 66.[51] Further, other than *Bonhoeffer et al*., there is no other support for the notion that there is no postictal state after a simple febrile seizure. Resp. Ex. D at 2-3. In fact, recent literature notes that while children typically return to baseline quickly after simple febrile seizures, "[a]s with nonfebrile seizures, the postictal phase can be associated with confusion or agitation and drowsiness." *Id*. at 3. Dr. Zempel recognized that prolonged drowsiness is not typical for a simple febrile seizure and if it exists should prompt further testing. The "presence of a focal neurologic finding that resolves as part of a postictal state would change the classification of a simple febrile seizure to a complex febrile seizure" but that would not indicate that a seizure was status epilepticus. *Id*. at 2.

Dr. Zempel explained that clinical observation is required to distinguish between continued seizure activity, postictal drowsiness, fatigue from fever and illness, and simple sleep. Resp. Ex. D at 2. Where clinical signs of ongoing seizure activity exist, antiseizure medication is given. Where prolonged unresponsiveness exists, an emergent EEG would be ordered. Here, Z.D. was observed and the clinical observations made at the time were of no concern for status epilepticus or ongoing seizures. *Id*. Therefore, he was discharged without the need for testing. Nothing in the record supports anything other than a simple febrile seizure. *Id*. at 2-3. It is common for a post-

[51] Jan Bonhoeffer et al., *Generalized Convulsive Seizure as an Adverse Event Following Immunization: Case Definition and Guidelines for Data Collection, Analysis, and Presentation*, 22 VACCINE 557 (2004), filed as "Pet. Ex. 66."

febrile seizure patient to be kept in the ER for several hours for observation to ensure they return to baseline, which is what happened here. *Id*.

Further, there are explanations for why a child who suffers a febrile seizure may not return to baseline immediately including drowsiness/sleepiness associated with fever/illness or being tired due to the time of day. Resp. Ex. D at 3. The most recent definition of simple febrile seizures from the American Academy of Pediatrics does not include a lack of a postictal state. "Any practicing child neurologist would be surprised that simple febrile seizures would be characterized by lack of a postictal state" because this assertion is not supported in the medical literature or in every day common clinical practice. *Id*.; Resp. Ex. D Tab 3.[52]

iv. Dr. Zempel's Fourth Report

Dr. Zempel pointed out that Dr. Kinsbourne "continues to portray the seizure which occurred on January 13, 2012 differently than the seizure as it is described in the medical record, and he does not rely on the expertise and judgment of the contemporaneous treating physicians." Resp. Ex. E at 1. Dr. Zempel argued that it is appropriate to defer to the interpretations of treating providers because "these issues are difficult to disentangle years later" which is why he has relied extensively on the medical record. *Id*.

As a treating neurologist who specializes in the care of children with intractable epilepsy and as part of larger neurology service, he regularly sees simple and complex febrile seizures, and he recognizes the stress and complexity in determining the length of a seizure. Resp. Ex. E at 1. The postictal period is also complicated by a child being sick or febrile and wanting to rest or sleep. It is the medical providers' role to assess the responsiveness of the child and discern whether there is ongoing seizure activity or focality on examination. While an emergency EEG would certainly clarify if a patient is sleeping or still seizing, that is rarely readily available. *Id*.

Dr. Zempel continued, if there are signs of ongoing seizure, treatment with anti-seizure medication is used. The judgment of the evaluating physician best reflects the state of the patient. Resp. Ex. E at 2. Most pediatric hospitals would admit a child with no history of febrile seizures who presents with a complex febrile seizure (prolonged, recurrent within 24 hours, or demonstrating focality) for observation and further evaluation like EEG or lumbar puncture. *Id*.

Here, Z.D. was observed for several hours in the ER with no focality noted. He was not admitted, there was no further work up and no neuroimaging, all indicating a lack of any concern for anything other than a simple febrile seizure. Resp. Ex. E at 2. Dr. Zempel conceded that without an EEG, it is not possible to determine the actual length of the seizure. *Id*. But based on the treatment provided and the notes contained in the medical records, the initial seizure was a simple febrile seizure with recovery upon abatement of fever. Further, Dr. Walsh's records repeatedly documented the diagnosis of simple febrile seizure, and he counseled the parents on simple febrile seizures at length. *Id*.

[52] American Academy of Pediatrics, *Clinical Practice Guideline—Febrile Seizures: Guideline for the Neurodiagnostic Evaluation of the Child with a Simple Febrile Seizure*, 127 PEDIATRICS 389 (2011), filed as "Resp. Ex. A Tab 2" and "Resp. Ex. D Tab 3."

Dr. Zempel's opinion remained that Z.D. had a simple febrile seizure one day after his vaccinations. The vaccinations were not responsible for his further seizures, possible epilepsy, or long-term neurodevelopment. Resp. Ex. E at 2.

v. Dr. Zempel's Testimony

Dr. Zempel agreed that Z.D. had recurrent febrile seizures and was later diagnosed with epilepsy with unprovoked seizures. Tr. 315.

Dr. Zempel explained that tonic-clonic or convulsive seizures also referred to as grand mal seizures are easily recognizable as opposed to absence seizures where "you're simply not responsive." Tr. 213-14. Febrile seizures have different categories. Simple febrile seizures are generalized convulsive seizures that last less than fifteen minutes and can recur in approximately 30-50% of the pediatric population. Tr. 215, 217. A febrile seizure over 30 minutes long is considered febrile status epilepticus. Tr. 216. Non-convulsive status epilepticus or NCSE is defined as a long seizure with poor responsiveness but no convulsions. Tr. 218-19. NCSE is concerning to pediatric neurologists because ER personnel may not be as concerned as they would be when a patient is violently convulsing. Tr. 219. Even convulsive seizures lasting a minute or two are not concerning. But convulsive seizures lasting 20, 30 or 60 minutes are because they are more likely to cause neurological damage and compromise breathing. Tr. 255-56, 306. Children with simple febrile seizure(s) will sometimes have fever but no seizure. Tr. 217, 247. Nevertheless, there is "no evidence that simple febrile seizures, even recurrent simple febrile seizures, cause long-term neurologic damage." Tr. 218, 263, 264. Further, having simple febrile seizures does not mean the patient will develop epilepsy later. Tr. 220-21.

Dr. Zempel agreed with the ER doctors from January 13, 2012 that Z.D.'s presentation sounded "very much like a simple febrile seizure." Tr. 221-23, 233, 252. Based on the EMT record of "seizure like activity", Z.D.'s first seizure was tonic-clonic. Tr. 240, 242. Most EMT crews consider seizures a major convulsive event. Tr. 240. "I 100 percent agree that it doesn't specifically state that [Z.D. convulsed]. And I do agree that if there wasn't a convulsive event, then this is not likely or is not a simple febrile seizure." Tr. 242. Dr. Zempel acknowledged that Z.D.'s grandmother wrote in her affidavit that he did not convulse, conceding the case becomes more difficult if that is accepted as true. Tr. 241.

However, Z.D.'s condition throughout the EMS transport was typical of a child with fever and simple febrile seizures. Tr. 295-96. He was less responsive in the beginning—whether because he was sleepy or not feeling well—but improved at the ER. Tr. 296. His being noted as postictal in the ER means different things to different people but is generally understood to mean that a person is not normally responsive. Tr. 297. The note that Z.D. was postictal was made slightly over thirty minutes after the ambulance was first called. Tr. 297. However, it is possible that Z.D.'s lack of responsiveness following the seizure was the result of his fever. Tr. 317-18; *see also* Pet. Ex. 5 at 7. Children with high fevers are not themselves and are not always normally responsive. Tr. 317-18.

Dr. Zempel added that, in addition to what is documented, the actions taken are also telling. Tr. 224. In the ER, Z.D. was given medication to bring his fever down and to observe him once

the fever broke. Tr. 231. The record shows once the fever came down, he became more aware and interactive and remained so for the remainder of his time in the ER. Tr. 234. He was observed to ensure he was improving then discharged. Tr. 233. Had there been any concern for ongoing seizure activity, anti-seizure medication would have been administered. Tr. 232. If there was concern for a complex febrile seizure, he would likely have been admitted and observed with testing ordered. Tr. 232, 236. The record that documented Z.D. stable for disposition implies that the ER doctors were not concerned about his trajectory, were treating him for a simple febrile seizure, and determined it was suitable to discharge him home. Tr. 298. Overall, the treatment rendered in the ER on January 13, 2012 was entirely consistent with a simple febrile seizure. Tr. 236. "I don't see anywhere in the medical records that supports the idea that this" was NCSE. Tr. 239. Dr. Zempel conceded it is impossible to disprove a NCSE without testing. Tr. 239.

When asked what he thought of the record documenting a "one-hour diffuse seizure" he reasoned it could be the result of a drop down menu on the hospital computer system as opposed documenting Z.D.'s condition. Tr. 294; *see also* Pet. Ex. 5. He never used that hospital's computer system, so it was his best guess of what the note meant. Tr. 294.

Dr. Zempel agreed ER doctors are not neurologists, but added they see patients having febrile seizures more than neurologists do. Tr. 229-30, 234. Thus, he trusts that ER doctors have the requisite experience to appropriately evaluate and treat febrile seizures. Tr. 296.

Regarding prong I, Dr. Zempel agreed that DTaP is known to have a higher risk for fever and fevers are associated with febrile seizures. Tr. 299. He explained that everyone has a seizure threshold influenced by genetics, delivery, neurologic injury, etc. When that threshold is passed, a seizure occurs. Tr. 214, 246. Fever can lower the seizure threshold. Tr. 243. Dr. Zempel agreed that Z.D.'s vaccine caused the fever "that then gated his propensity for having febrile seizures." Tr. 299. Absent the vaccine, Z.D. would have not likely had his first provoked seizure. Tr. 300.

Epilepsy, however, is defined as having more than one unprovoked seizure and is more than just having seizures. Epilepsy indicates an underlying brain vulnerability, for which seizures are only one symptom. Tr. 214, 215, 266. An EEG is helpful, but not necessary, to diagnose epilepsy and is used less for diagnosis than for classification of the type of epilepsy. Tr. 270, 277, 279, 300. Z.D. had two EEGs, one was abnormal and the second was normal. Tr. 272. Dr. Zempel accepted the diagnosis of the treating neurologists that Z.D. now has epilepsy. Tr. 273.

Dr. Zempel further explained that epilepsy can develop at any age but not typically under the age of two. Tr. 245, 281. Febrile seizures are provoked by fever, while epilepsy is unprovoked seizures. Tr. 218, 314. Dr. Zempel agreed a child can have both febrile seizures and epilepsy. Tr. 218, 321. However, no literature suggests that simple febrile seizures are related to the development of epilepsy. Tr. 281-84, 320, 321-22. Children with simple febrile seizures are at about the same risk of developing epilepsy as the general population. Tr. 323. Children having multiple simple febrile seizures that begin under the age of one with a family history of epilepsy are at a higher risk of developing epilepsy. Tr. 323. There is also some overlap between febrile seizures and epilepsy with the frequency of febrile seizures in the context of other factors increasing the risk of epilepsy. Tr. 324. Further, staring spells in children are not always attributable to epilepsy, making the diagnosis of epilepsy in children who have staring spells

difficult. For example, a child who stares while watching TV is less concerning than a child who is playing and suddenly stops and stares. Tr. 271-72. Finally, many children diagnosed with epilepsy will outgrow it, sometimes without medical intervention. Tr. 305.

Dr. Zempel agreed with Dr. Walsh that the medical records and history supported Z.D. having simple febrile seizures and therefore Dr. Walsh treated Z.D. appropriately. Tr. 249-51. Further, not ordering testing or anti-seizure medication was within the standard of care for simple febrile seizures. Tr. 249; *see also* Pet. Ex. 1 at 42-45.

Dr. Zempel could not say what caused Z.D.'s neurodevelopmental issues or whether "the speech and language problems are associated directly with [Z.D.] having seizures." Tr. 264, 300-01. The records do not document any developmental issues after his first seizure. That does not mean they were not present, "It just means they weren't severe." Tr. 304. It was noteworthy that the mother expressed concern with Z.D.'s speech prior to the vaccination, and a referral for speech therapy was provided. Tr. 265, 301. Dr. Zempel stated he may have ordered testing where a child was presented with choking and trouble swallowing, but that would depend on other symptoms, such as weight loss or pneumonia. Tr. 302.

Dr. Zempel agreed with the medical record that the second seizure on September 15, 2012 was also a simple febrile seizure. Tr. 252. The ER record documents a history that included Z.D. waking from a nap, complaining of mild pain, then having shaking with seizure activity. He had a fever in the ER and was diagnosed with simple febrile seizure. Tr. 252-53; Pet. Ex. 6 at 140-42, 145. Similarly, Z.D.'s third seizure on November 5, 2012 occurred during an acute febrile illness and was considered in the ER to be a simple febrile seizure with no reason to think otherwise. Tr. 252-53; *see also* Pet. Ex. 6 at 90-92. When Dr. Walsh saw Z.D. on November 13, 2012, he noted nothing new in Z.D.'s presentation so no testing was ordered. This is important because neurologists generally are not hesitant to order testing if there is reason to believe something is wrong or could be learned from test results. Tr. 253. Based on the record, Dr. Walsh stood by his initial diagnosis of simple febrile seizure. Tr. 254. The record further shows that the parents expressed concerns with their ability to respond with treatment quickly enough during a febrile illness, so he discussed medication options and the parents elected to try Keppra to treat Z.D.'s seizures. Tr. 286-87.

Dr. Zempel would not have ordered anti-seizure medication at that time for simple febrile seizures. Tr. 254, 259. However, if a family was really concerned or lived far from a hospital, he would have prescribed Diastat for emergency use in the event that the child seized for more than five minutes so the parents could initiate treatment while waiting for EMS to arrive. Tr. 256, 286. He would not prescribe Keppra to treat simple febrile seizures. Tr. 285. "Dr. Walsh kind of did something that I agree with Dr. Kinsbourne that is not typical of most situations these days." Tr. 256. However, there is "…general recommendation. And then there's real life." Tr. 257. It was likely Dr. Walsh prescribed Keppra at this appointment to allay the parents' fears and reduce the risk of future seizures. Tr. 262, 285, 287-88; *see also* Pet. Ex. 1 at 46. However, Keppra is not the standard of care to treat simple febrile seizures. Tr. 288.

Dr. Zempel agreed the time between an initial epileptic and subsequent epileptic seizures can vary widely. "It could be decades after." Tr. 313.

Dr. Zempel discussed Dr. Krishnamurthy's diagnosis and treatment, stating that when sitting in a room and talking with parents, you get more history from them than from a medical record. At that time, based on what the parents were reporting, Dr. Krishnamurthy must have had concerns about Z.D. having staring spells to switch him to Depakote, which has greater risk than Keppra, but less risk than ongoing seizures. Tr. 280-81; Pet. Ex. 62 at 4.

Dr. Zempel and I engaged in an exchange, confirming that it was his opinion that no cause and effect exists between simple febrile seizures and epilepsy, i.e. Z.D.'s febrile seizures and later diagnosis of epilepsy were two separate issues and not a progressive seizure disorder that started with febrile seizures and became epilepsy. Tr. 280-81, 320-22. Dr. Zempel stated that everyone has a seizure threshold. Different genetic components or an injury can change one's likelihood of having a seizure. But there is no literature that supports simple febrile seizures developing into epilepsy or that simple febrile seizures raises the risk of developing generalized epilepsy in any way. Tr. 281-83. Further, there is no epidemiologic or mechanistic data in animals or humans to suggest that simple febrile seizures lead to epilepsy. Tr. 283-84. Dr. Zempel did not disagree that a small subgroup of children may have genetic or developmental predispositions that include both febrile seizures and epilepsy. Tr. 321, 324. But no literature or studies have concluded that febrile seizures can become epilepsy. He agreed that there is an overlap between children who have epilepsy who also have febrile seizures, but the two are not connected. Tr. 321-22. Dr. Zempel stated that it was difficult to answer whether Z.D.'s speech problems were related to his febrile seizures or epilepsy. Tr. 321.

Counsel for petitioner challenged Dr. Zempel's position that no literature or studies have concluded that febrile seizures go on to become epilepsy. He pointed to an article relied on by Dr. Zempel which contained the statement that children with simple febrile seizures have the same risk as the general population of developing epilepsy, but that children who have multiple febrile seizures with the first under the age of 12 months and a family history of epilepsy are at higher risk of developing epilepsy. Counsel suggested this was contrary to Dr. Zempel's testimony. Tr. 322-23; *see* Resp. Ex. A Tab 1 at 2.[53] Dr. Zempel acknowledged the statement, noting that he had highlighted it in the article. He explained again that there is an overlap of people who have febrile seizures and have epilepsy due to their genetics. Tr. 323-25. He agreed that Z.D. had two out of three factors that mark a higher risk of epilepsy; Z.D. has a family history of epilepsy and has had multiple febrile seizures, but his first febrile seizure did not occur before the age of 1. Tr. 325; Resp. Ex. A Tab 1 at 2.

I noted to petitioners' counsel that throughout the pendency of this case, petitioners have argued that Z.D.'s brother's epilepsy diagnosis had no bearing on this case, but he was now suggesting a genetic propensity. Counsel agreed but then deferred to Dr. Kinsbourne to explain. Tr. 325-26. He added that Z.D. does not have a genetic form of epilepsy, but since his brother has epilepsy, there is a family history, "which in common parlance we understand to be an increased risk. It doesn't mean that it's causal, but . . . he has a family history and we can't argue against that." Tr. 325-26. It is notable that the records also note that Mrs. Davis has a history of a seizure. Pet. Ex. 6 at 192.

[53] American Academy of Pediatrics, *supra* note 44.

C. Dr. Kinsbourne's Rebuttal Testimony

In responding to the foregoing exchange between myself and petitioners' counsel, Dr. Kinsbourne stated that there is uncertainty whether children who have seizures with fever also have epilepsy, so an epilepsy diagnosis is withheld until the child is old enough to have two afebrile seizures. However, the time of diagnosis is not necessarily when the epilepsy started. Tr. 328.

Dr. Kinsbourne claimed that the central disagreement between himself and Dr. Zempel was "about these several seconds of seizure-like activity." If they agreed about that, they would agree about everything. Tr. 328-29. Dr. Kinsbourne stated that convulsions would be considered seizure-like behavior; twitching (myoclonus) of the face is seizure-like, but that is not consistent with a simple febrile seizure; jerking of the head, however, would not be referred to as seizure-like behavior. So to state that "seizure-like behavior" means behavior that is benign is "simply unsupportable." Tr. 329. He further stated that Z.D.'s eyes rolling up was "obvious seizure behavior." Tr. 331.

It was noted to Dr. Kinsbourne that his recital of the facts, events and content of the EMS record seemed to be confused. Tr. 330-33. But upon clarification, he argued that since the grandmother, who was a nurse, was unavailable to explain what she meant by "seizure-like behavior", the statement could not be relied upon to support Z.D. having a simple febrile seizure. I agreed but noted that it also could not be used to discount that he had a simple febrile seizure. Tr. 333-34.

Addressing Z.D.'s speech issues being present prior to the vaccinations, Dr. Kinsbourne stated that the parents were not concerned and did not contact BabyNet. Further, his vocabulary was within normal range but "dropped precipitously, just like that" after the vaccination. However, he conceded that "[w]hether the vaccination caused that is another issue. But that . . . should be taken into account." Tr. 334. He agreed that children develop speech problems without seizures, but regression in speech is different and less common. Tr. 334-35. It was pointed out that in January 2012, Z.D. had 10-15 words, and at his first evaluation with a speech therapist in March 2012, he had even more words; with the record unclear as to whether Z.D. lost words or his words became unintelligible, Dr. Kinsbourne stated he then would withdraw his comments. Tr. 335.

I pressed Dr. Kinsbourne on Z.D.'s diagnosis of apraxia—not aphasia—and motor coordination problems with choking in the absence of seizures. He explained that aphasia is losing words, while apraxia is knowing the word but being unable to physically shape your lips and throat to utter it correctly. Apraxia is not an issue with speech itself, but rather is an issue related to the movement of the mouth. It is a motor problem, and he explained that motor problems are neurological. Tr. 335-36. Dr. Kinsbourne stated that if the child is getting skills that then fall off, something happened in the brain. Tr. 337. He agreed it can happen without a seizure stating that "there are multiple reasons why the speech mechanism can go wrong." Tr. 337. Dr. Kinsbourne denied he ever opined that Z.D. had aphasia, but rather he had a speech defect in articulation so that he was unintelligible but that "was not present until a certain time". Tr. 337-38. He stated that phonological problems can happen at any age. Tr. 338-39.

V. Applicable Law

A. Legal Standard Regarding Causation

The Vaccine Act provides two avenues for petitioners to receive compensation. First, a petitioner may demonstrate a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may demonstrate an "off-Table" injury, which requires that the petitioner "prove by a preponderance of the evidence that the vaccine at issue caused the injury." *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii). Initially, a petitioner must provide evidence that he or she suffered, or continues to suffer, from a definitive injury. *Broekelschen v. Sec'y of Health & Human Servs*., 618 F.3d 1339, 1346 (Fed. Cir. 2010). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a "substantial factor" and a "but for" cause of the injury is sufficient for recovery. *See Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

To prove causation for an "off-Table" injury, petitioners must satisfy the three-pronged test established in *Althen v. Sec'y of Health & Human Servs*., 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioners show by preponderant evidence that a vaccination petitioner received caused his or 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*. at 1278. Together, these prongs must show "that the vaccine was 'not only a but-for cause of the injury but also a substantial factor in bringing about the injury.'" *Stone v. Sec'y of Health & Human Servs*., 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Causation is determined on a case-by-case basis, with "no hard and fast per se scientific or medical rules." *Knudsen v. Sec'y of Health & Human Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioners are not required to identify "specific biological mechanisms" to establish causation, nor are they required to present "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities." *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). "[C]lose calls regarding causation are resolved in favor of injured claimants." *Althen*, 418 F.3d at 1280.

Each of the *Althen* prongs requires a different showing. The first *Althen* prong requires petitioners to provide a "reputable medical theory" demonstrating that the vaccines received *can* cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, petitioners' "theory of causation must be supported by a 'reputable medical or scientific explanation.'" *Andreu ex rel. Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1379 (Fed. Cir. 2009) (quoting *Althen*, 418 F.3d at 1278). This theory need only be "legally probable, not medically or scientifically certain." *Id.* at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, "petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature." *LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014).

The second *Althen* prong requires proof of a "logical sequence of cause and effect." *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). In other words, even if the vaccinations can cause the injury, petitioners must show "that it did so in [this] particular case." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). "A reputable medical or scientific explanation must support this logical sequence of cause and effect," *id.* at 961 (citation omitted), and "treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury," *Paluck v. Sec'y of Health & Human Servs*., 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375). Petitioners are not, however, required "to eliminate alternative causes as part of establishing [their] prima facie case." *Doe v. Sec'y of Health & Human Servs.*, 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec'y of Health & Human Servs.*, 485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a "petitioner does not bear the burden of eliminating alternative independent potential causes").

To satisfy the third *Althen* prong, petitioners must establish a "proximate temporal relationship" between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This "requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *De Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, "a petitioner's failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause." *Id.* However, "cases in which onset is too soon" also fail this prong; "in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked." *Id.*; *see also Locane v. Sec'y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) ("[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.").

B. Legal Standard Regarding Fact Finding

The process for making determinations in Vaccine Program cases regarding factual issues begins with analyzing the medical records, which are required to be filed with the petition. § 11(c)(2). Medical records created contemporaneously with the events they describe are generally considered to be more trustworthy. *Cucuras v. Sec'y of Health & Human Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993); *but see Kirby v. Sec'y of Health & Human Servs*., 993 F.3d 1378, 1382-83 (Fed. Cir. 2021) (clarifying that *Cucuras* does not stand for proposition that medical records are presumptively accurate and complete). While not presumed to be complete and accurate, medical records made while seeking treatment are generally afforded more weight than statements made by petitioners after-the-fact. *See Gerami v. Sec'y of Health & Human Servs*., No. 12-442V, 2013 WL 5998109, at *4 (Fed. Cl. Spec. Mstr. Oct. 11, 2013) (finding that contemporaneously documented medical evidence was more persuasive than the letter prepared for litigation purposes), *mot. for rev. denied*, 127 Fed. Cl. 299 (2014). Indeed, "where later testimony conflicts with earlier contemporaneous documents, courts generally give the contemporaneous documentation more weight." *Campbell ex rel. Campbell v. Sec'y of Health & Human Servs*., 69 Fed. Cl. 775, 779 (2006); *see United States v. U.S. Gypsum Co*., 333 U.S. 364, 396 (1948).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining facts such as the onset of a petitioner's symptoms. *Vallenzuela v. Sec'y of Health & Human Servs*., No. 90-1002V, 1991 WL 182241, at *3 (Fed. Cl. Spec. Mstr. Aug. 30, 1991); *see also Eng v. Sec'y of Health & Human Servs*., No. 90-175V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb 18, 1994) (explaining that § 13(b)(2) "must be construed so as to give effect to § 13(b)(1) which directs the special master or court to consider the medical record...but does not require the special master or court to be bound by them"); *see also Burns v. Sec'y of Health & Human Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

There are situations in which compelling oral testimony may be more persuasive than written records. *See Campbell*, 69 Fed. Cl. at 779. When witness testimony contradicts medical records, such testimony must be consistent, clear, cogent, and compelling to be persuasive. *See Sanchez v. Sec'y of Health & Human Servs*., No. 11-685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (vacated on other grounds, *Sanchez by & through Sanchez v. Sec'y of Health & Human Servs*., No. 2019-1753, 2020 WL 1685554 (Fed. Cir. Apr. 7, 2020), *review denied, Sanchez by & through Sanchez v. Sec'y of Health & Hum. Servs*., 152 Fed. Cl. 782 (2021)) (quoting *Blutstein v. Sec'y of Health & Human Servs*., No. 90-2808V, 1998 WL 408611, at *85 (Fed. Cl. Spec. Mstr. June 30, 1998)); *see, e.g., Stevenson ex rel. Stevenson v. Sec'y of Health & Human Servs*., No. 90-2127V, 1994 WL 808592, at *7 (Fed. Cl. Spec. Mstr. June 27, 1994) (crediting the testimony of a fact witness whose "memory was sound" and "recollections were consistent with the other factual evidence"). Special masters may also consider other types of evidence, such as unsworn statements, on the grounds that the Vaccine Program was designed to have "flexible and informal standards of admissibility of evidence." 42 U.S.C. § 300aa-12(d)(2)(B); *see also Munn v. Sec'y of Health & Human Servs*., 970 F.2d 863, 873 (Fed. Cir. 1992).

In short, "the record as a whole" must be considered. § 13(a).

C. Evaluating Expert Testimony

Establishing a sound and reliable medical theory connecting the vaccine to the injury often requires a petitioner to present expert testimony in support of his or her claim. *Lampe v. Sec'y of Health & Human Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). The Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), requires that courts determine the reliability of an expert opinion before it may be considered as evidence. "In short, the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Id*. at 590 (citation omitted). Thus, for Vaccine Act claims, a "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly ex rel. Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010). The *Daubert* factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Human Servs.*, 94 Fed. Cl. 53, 66-67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and

the relative persuasiveness of their competing theories." *Broekelschen*, 618 F.3d at 1347 (citing *Lampe*, 219 F.3d at 1362). And nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 743 (2009) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

D. Consideration of Medical Literature

Finally, although this decision discusses some but not all of the literature in detail, the undersigned reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty ex rel. Moriarty v. Sec'y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) ("We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision."); *Simanski v. Sec'y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) ("[A] Special Master is 'not required to discuss every piece of evidence or testimony in her decision.'" (citation omitted)), *aff'd*, 601 F. App'x 982 (Fed. Cir. 2015).

VI. Analysis

Because petitioners do not allege an injury listed on the Vaccine Injury Table, their claim is classified as "off-Table." As noted above, for petitioners to prevail on an "off-Table" claim, they must show by preponderant evidence that Z.D.'s alleged injury resulted from the vaccinations at issue.[54] *Capizzano*, 440 F.3d at 1320. Doing so shifts the burden to respondent to show that the injury was caused by factors unrelated to the vaccinations. *Deribeaux ex rel. Deribeaux v. Sec'y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013).

A. Diagnosis

The Federal Circuit has instructed that "if the existence and nature of the injury itself is in dispute, it is the special master's duty to first determine which injury was best supported by the evidence presented in the record before applying the *Althen* test to determine causation of that injury." *Lombardi v. Sec'y of Health & Human Servs*., 656 F.3d 1343, 1352 (Fed. Cir. 2011), citing *Broekelschen*, 618 F.3d at 1346. Thus, identification of a petitioner's injury is a prerequisite to the *Althen* analysis.

Petitioners allege that Z.D. suffered a "vaccine-induced prolonged febrile seizure resulting in neurological damage and seizure disorder". Petition at 1. Petitioners' causation theory is contingent on a finding that the initial seizure was status epilepticus and specifically NCSE. Thus, prior to analyzing causation, it must first be determined whether Z.D.'s initial seizure on January 13, 2012 was a prolonged febrile seizure or NCSE, as argued by petitioners, or a simple febrile

[54] Although petitioners initially argued in their petition that the vaccinations at issue caused or, in the alternative, significantly aggravated Z.D.'s condition, petitioners only argued caused-in-fact at hearing. *See* Petition. Further, neither petitioners' pre-hearing submission nor the parties' joint pre-hearing submission argued—or even mentioned—significant aggravation or *Loving*. Accordingly, significant aggravation will not be discussed.

seizure as diagnosed by Z.D.'s treating physicians and agreed to by respondent and his expert.

Dr. Kinsbourne opined that Z.D.'s initial seizure was NCSE. Pet. Ex. 58 at 1; Pet. Ex. 68 at 1. He defined NCSE as prolonged stupor affecting mental status and the ability to interact or respond in the absence of outward manifestations, such as convulsions. Tr. 139, 143, 145; Pet. Ex. 29 at 4; Pet. Ex. 38 at 1-3.[55] A diagnosis of NCSE requires a seizure that lasts thirty minutes or more. Pet. Ex. 38 at 2-3. He described an absence seizure as when a child suddenly stops what they're doing and exhibits automatisms, such as eyes rolling back or to the side. Tr. 138, 141. Upon recovery from an absence seizure, a child will have no idea what has happened. Tr. 138. A simple febrile seizure, on the other hand, lasts 1-15 minutes, involves tonic-clonic or convulsive activity, and cannot be missed because of the severe jerking involved. Tr. 137, 174, 201; Pet. Ex. 76 at 2.

Dr. Kinsbourne created a timeline to support his opinion that Z.D.'s seizure lasted more than 30 minutes and was NCSE. Tr. 145, 199; Pet. Ex. 29 at 1. He relied on Mrs. Davis's testimony that Z.D. was conscious but looking off to the side the entire ambulance ride to the hospital and the ER record documenting Z.D. as postictal on arrival. Tr. 146, 148. He acknowledged the EMS assessment that Z.D. was responsive and alert but concluded they were merely assessing whether Z.D. was conscious, which he was, so they documented him as alert. Tr. 145, 148, 199; Pet. Ex. 29 at 1.

Dr. Kinsbourne further argued that Z.D.'s first seizure was his first epileptic seizure. Pet. Ex. 58 at 1. He submitted that the ER physicians misdiagnosed Z.D. with a simple febrile seizure and all subsequent treaters, including Dr. Walsh, simply repeated the mistake. Tr. 137, 141, 193-94, 195, 330; Pet. Ex. 76 at 1. He suggested that Dr. Walsh realized that Z.D.'s correct diagnosis was epilepsy after his third seizure, at which time Dr. Walsh prescribed Keppra, which no neurologist would prescribe for simple febrile seizures. Tr. 193-95, 199. At that point, Dr. Walsh no longer believed Z.D. had suffered from simple febrile seizures. Tr. 193-95, 199.

Dr. Zempel agreed with the definitions set forth by Dr. Kinsbourne. Tr. 214-16, 218-19. He agreed if a febrile, convulsive seizure lasts longer than thirty minutes, it would be considered febrile status epilepticus. Tr. 216. He also agreed that prolonged seizures are concerning for potential neurologic damage. Tr. 255-56, 306. However, he disagreed that Z.D.'s first seizure was NCSE and agreed with Z.D.'s treating physicians that Z.D. suffered a simple febrile seizure based on the history and clinical observation. He opined that there is no evidence that supports that a simple febrile seizure can cause long term neurologic injury or epilepsy. Resp. Ex. A at 4, 8; Tr. 218, 220-21, 263, 264, 281-84, 320, 321-22.

Dr. Zempel referred to the medical records and Z.D.'s condition during EMS transport as consistent with a simple febrile seizure. Tr. 221-23, 233, 252, 296. He believed what the parents interpreted as not responsive was the result of high fever, not ongoing seizure activity. Tr. 317-18; Pet. Ex. 5 at 7. He added that the medical records reflect Z.D. to be sleeping or not at baseline, contrary to the parents' testimony, accepted by Dr. Kinsbourne, that Z.D.'s eyes were rolled back and he was unresponsive. Resp. Ex. A at 8; Pet. Ex. 19 at 1-2 (EMS record noted upon arrival Z.D.'s pupils were equal and he was responsive "to loud verbal by opening eyes and staring blankly

[55] Jafarpour & Loddenkemper, *supra* note 20.

to R side"); Pet. Ex. 5 at 3, 7 (the hospital record documented that Z.D. was initially sleepy and feverish, then once the fever went down he was drinking with a straw and was "bright/alert").[56]

Further, Dr. Zempel stated that Z.D.'s treatment in the ER was consistent with a simple febrile seizure because he did not require admission or testing. Resp. Ex. A at 9; Tr. 224, 236. His temperature was recorded as 103.3 upon arrival. Pet. Ex. 5 at 7. He was given anti-pyretic medication to reduce the fever and once reduced, he was noted to be interactive and aware throughout his visit. Tr. 231, 234. He was observed with no concern for ongoing seizure activity upon arrival or at any point thereafter. Resp. Ex. D at 1-3; Resp. Ex. E at 2. Once he improved, he was discharged. Tr. 233, 298.

Dr. Zempel agreed, however, that while the records do not support NCSE, there is no way to disprove it since the requisite testing was not performed. Tr. 239.

Dr. Zempel acknowledged that the ER record noted Z.D. to be postictal thirty minutes after the ambulance was called to the Davis home; in his opinion, Z.D.'s postictal period was due to high fever. Once the fever was reduced, he improved. Resp. Ex. A at 7; Tr. 297. He also agreed that *Bonhoeffer et al*. stated there is no postictal state following a simple febrile seizure. However, Dr. Zempel explained that this is not a widespread opinion and is only contained in this single article. Further, it is not what is seen in clinical practice. Resp. Ex. D at 1-3; Pet. Ex. 66.[57]

Dr. Zempel agreed that, based on the history and medical record, Dr. Walsh was also correct in concluding Z.D. had a simple febrile seizure. Tr. 249-51. Dr. Walsh appropriately did not order testing or prescribe anti-seizure medication, which was within the standard of care for treating simple febrile seizures. Tr. 249; *see also* Pet. Ex. 1 at 42-45. Dr. Zempel stated had he been the treating physician, he too would not have ordered anti-seizure medication because Z.D.'s presentation was consistent with a simple febrile seizure. Tr. 254, 259. Dr. Zempel added that Dr. Walsh likely prescribed Keppra after the third febrile seizure to allay the parents' fears and reduce the risk of future seizures. Tr. 262, 285, 287-88; *see also* Pet. Ex. 1 at 46. However, he agreed with Dr. Kinsbourne that Keppra is not the standard of care to treat simple febrile seizures. Tr. 288.

Based on a thorough review and weighing of the medical records, the experts' opinions, and the testimony provided, I find that the evidence supports that Z.D.'s first seizure was a simple febrile seizure. The foregoing finding rests primarily on 1) the evidence of tonic-clonic activity and 2) the duration of the seizure.

1. Evidence of Tonic-Clonic or Convulsive Activity

Mrs. Menard was the only person present when Z.D. had his first seizure but was unable to testify at hearing due to dementia. The medical record shows that she called 911 and when EMS arrived, Mrs. Menard reported to EMS that Z.D. "had been running a fever for several hours when

[56] The medical records are contrary to the parents' affirmations and testimony that Z.D. was still seizing when they arrived home, in the ambulance, and in the ER. The records are also in conflict with the parents' testimony that he was still unresponsive when discharged from the ER. *See* Pet. Ex. 5; Pet. Ex. 20 at 3; Pet. Ex. 21 at 2; Tr. 23, 26-27, 28-30, 31, 77, 79, 81, 83-85.

[57] Bonhoeffer et al., *supra* note 51.

he became difficult to rouse." Pet. Ex. 19 at 2. He then had an "episode of seizure like activity lasting several seconds" and was "unresponsive initially following the activity". *Id*. While the experts interpreted "seizure like activity" differently, they agreed they could only speculate to what Mrs. Menard meant since she was unable to testify and clarify the statement. Tr. 242, 333.

In her affidavit, Mrs. Menard affirmed watching her grandkids on January 13, 2012, as well as putting Z.D. down for a nap around 2:00pm. Pet. Ex. 48. at 2. He slept for an hour and around 3:00pm, she heard him crying. She then "walked upstairs to check on him" and when she got to his room, he was crying loudly. She placed her hand on his forehead, and he was "burning up." She took him out of his crib and brought him downstairs. *Id*. She put a thermometer under his armpit which took a few minutes to register. Z.D. was crying the whole time. *Id*. at 3. When the thermometer beeped, Z.D. had a fever of 103.3. At the same time, Z.D. "looked like he was in a trance." She yelled his name, but he did not move or respond. When he opened his eyes, she noticed his eyes were rolled back. She tried to call his name and lightly shake him, but he was unresponsive. She affirmed that he did not convulse. *Id*. Petitioners, who were not present during Z.D.'s initial seizure, stated the same. Tr. 57, 115, 126.

Mrs. Menard's affidavit, written three years after the events, is inconsistent with what she reported to EMS when they arrived on January 13, 2012. The EMS record from that day shows that Mrs. Menard reported that Z.D. was "running a fever for several hours when he became difficult to rouse." Pet. Ex. 19 at 2. He then had an "episode of seizure like activity lasting several seconds" and was "unresponsive initially following the activity". *Id*. Upon arrival, EMS assessed Z.D. to be responsive. *Id*. In contrast, three years later in her affidavit, Mrs. Menard referred to Z.D. as being in a trance, not moving or responding, and with his eyes rolled back, but he did not convulse. Pet. Ex. 48 at 3.

It is within a special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence such as oral testimony. *Cucuras*, 993 F.2d at 1528. While not infallible, contemporaneous medical records are generally afforded more weight than statements made by petitioners after-the-fact. *Gerami*, No. 12-442V, 2013 WL 5998109, at *4. In the instance where there are inconsistencies between contemporaneous records and later testimony, "courts generally give the contemporaneous documentation more weight." *Campbell*, 69 Fed. Cl. at 779. Due to the inconsistencies detailed above, the contemporaneous medical records reporting what was told to the medical professionals at the time of the events are entitled to more weight.

Mrs. Menard's statements to EMS taken in their entirety do not describe a child in a trance, not moving or responding, eyes rolled back, and who "did not convulse" as later affirmed in her affidavit. Pet. Ex. 48 at 2; Pet. Ex. 19 at 2. Mrs. Menard was repeatedly referred to as being a nurse. As such, she was certainly aware of the importance of accurate reporting to responding emergency personnel.

However, due to her unavailability, consideration of Z.D.'s history reported in the medical records at the time of the events is appropriate bearing in mind that the petitioners were not present during the events of the January 13, 2012 seizure but relied on and repeated the details provided to them by Mrs. Menard. On January 13, 2012, Z.D. was presented to the ER at approximately

4:15pm with a history of seizure and fever that afternoon. Pet. Ex. 19 at 1; Pet. Ex. 5 at 3. Physical examination performed at 4:35pm documented him to be sleepy and warm to touch. Pet. Ex. 5 at 3. After his fever was reduced and around 5:37pm, he was noted to be aroused, drinking juice/Pedialyte with a straw, smiling, and appearing more bright/alert. *Id*. at 7. Twenty minutes later, he was sleeping, his skin was cooler and his face less flushed. He was monitored and observed for several more hours with no sign of ongoing seizure activity. *Id*. He was discharged around 9:00pm with a diagnosis of simple febrile seizure. *Id*. at 6.

At his next medical visit two months later, the record documents that "[h]e had febrile seizure 18 [months] imm/sib ill about a month ago". Pet. Ex. 3 at 64. On June 5, 2012, Dr. Walsh documented a history of a brief seizure, followed by several minutes of drowsiness one day after his 18-month vaccinations with a fever of 103. "The parents report comes from his grandmother—a nurse—who witnessed it." Pet. Ex. 1 at 42. Dr. Walsh agreed that Z.D. had a simple febrile seizure, with no other signs of mental or physical skill loss and no development of other symptoms or signs. *Id*. at 44. He wrote that "[b]ecause most seizure (sic) after immunization are related to fever…I would not start an anti-seizure medicine at this time and I do not think it likely an EEG will add useful information to our decision making." *Id*. At a sick visit on August 6, 2012, the pediatric record included "Convulsions, Febrile" after Pentacel vaccine. Pet. Ex. 3 at 100.

Dr. Walsh's record for November 13, 2012 documented Z.D.'s original seizure as "brief, generalized tonic clonic". Pet. Ex. 1 at 46. Dr. Walsh noted two additional seizures since that time with the same semiology and all with fevers. Pet. Ex. 3 at 168. At a follow up visit for a subsequent illness, he was noted to be taking seizure medication for "Convulsions, Febrile". Pet. Ex. 3 at 179. Dr. Walsh's record for May 22, 2013 again noted his original seizure to be "brief, generalized tonic clonic in context of post immunization fever." He has simple febrile seizures and was started on Keppra with no further seizures. Pet. Ex. 11 at 38.

On April 27, 2014, Z.D. was presented to MUSC for what his parents reported was an oncoming seizure. Pet. Ex. 11 at 13. The history of present illness noted, "*[p]er parents*, he had a [history of] 3 febrile seizures with tonic clonic characteristics prior to starting Keppra in November 2012." *Id*. at 14 (emphasis added).

Analyzing the evidence as a whole and affording appropriate weight to the medical records, Z.D.'s initial seizure as observed by Mrs. Menard and later described by his parents based on what they were told by Mrs. Menard was brief and tonic-clonic/convulsive in the context of fever. This is supported by the contemporaneous records detailed above where his initial seizure was described as "brief, generalized tonic clonic" and he was specifically noted to have a history of "Convulsions, Febrile" seizure. Pet. Ex. 1 at 46; Pet. Ex. 3 at 100, 168, 179; Pet. Ex. 11 at 38. The record from April 27, 2014 is particularly significant, as *the parents* reported his initial three seizures to all be febrile involving tonic-clonic activity. Pet. Ex. 11 at 14.[58] I find no reason to afford more weight to Mrs. Menard's or petitioners' statements made three years after the events that Z.D. did not convulse when the medical records created at the time of the events and when treatment was being sought all recorded his seizures as brief and involving tonic-clonic/convulsive activity in the context of fever. The presence of tonic-clonic activity/convulsions with high fever then returning

[58] Presumably, petitioners provided Z.D.'s history at all medical visits since Z.D. was only a toddler. However, the April 2014 record is the only one to specify that the history was provided by petitioners.

to baseline once the fever subsided supports that Z.D. suffered a simple febrile seizure following his January 12, 2012 vaccinations.

2. Duration of the Seizure

Also in dispute is the duration of Z.D.'s initial seizure and the relevance of the postictal period following that seizure.

Dr. Kinsbourne relied only on the testimony and affirmations of petitioners and Mrs. Menard to establish his proposed duration of the first seizure, concluding that Z.D.'s first seizure was over thirty minutes long. He calculated the onset of the seizure to be when Mrs. Menard "… ran up the stairs to pick [Z.D.] up" with the end of the seizure to be upon arrival at the hospital based on Mrs. Davis's statement that Z.D. continued to seize in the ambulance. Tr. 26-27, 145-48; Pet. Ex. 21 at 2. Included in his calculation were petitioners' claims that when they arrived home, Z.D. was laying in his grandmother's arms unresponsive and staring off to the side. Pet. Ex. 20 at 3; Tr. 23, 26, 77, 79. However, Mrs. Menard's affidavit and petitioners' testimony, which were provided years after the events, are inconsistent with the contemporaneous medical records filed. Accordingly, more weight is afforded to the contemporaneous medical records. *Cucuras*, 993 F.2d at 1528; *Gerami*, No. 12-442V, 2013 WL 5998109, at *4; *Campbell*, 69 Fed. Cl. at 779.

The January 13, 2012 EMS record includes Mrs. Menard's reporting that Z.D. was running a fever for several hours, became difficult to rouse, had an episode of "seizure like activity lasting several seconds" and was initially unresponsive afterward. Pet. Ex. 19 at 2. The 911 call was received at 15:27 and EMS arrived at the scene at 15:39, twelve minutes later. *Id*. at 1. On arrival, Z.D. was noted to be responsive to loud noises, becoming more responsive, and he "remain[ed] awake and alert throughout transport." *Id*. at 2.

The experts agreed that a simple febrile seizure lasts for 1-15 minutes. Tr. 137, 174, 215-16; Pet. Ex. 76 at 2. The medical records support Mrs. Menard reporting that Z.D.'s initial seizure[59] was seconds in duration and within the appropriate timeframe for a simple febrile seizure.

The experts also interpreted the postictal period differently. Dr. Kinsbourne argued that there is no postictal period following a simple febrile seizure but there is one following status epilepticus. Tr. 148; Pet. Ex. 65; Pet. Ex. 66.[60] He relied on *Bonhoeffer et al*., which stated that postictal drowsiness does not follow simple febrile seizures. Pet. Ex. 66 at 558.[61] He also referenced *Millichap*, which stated that "[p]rolonged drowsiness is not typical for simple febrile seizure." Resp. Ex. D Tab 1.[62] However, *Millichap* defined simple febrile seizures as "seizures that are generalized, last less than 15 minutes, and do not recur in a 24-hour period"; the definition does not discuss a postictal period, nor does it require the exclusion of a postictal period to fit the

[59] Likewise, Z.D.'s subsequent seizures in September and November 2012 and April 2014 were reported to be seconds in duration and all in the context of high fever. Following each, Z.D. was alert and responsive once his fever was reduced. Pet. Ex. 3 at 168; Pet. Ex. 6 at 90, 92, 94, 140-42, 145; Pet. Ex. 9 at 97, 99-100, 104; Pet. Ex. 11 at 36-39.
[60] Bonhoeffer et al., *supra* note 51.
[61] *Id*.
[62] Millichap, *supra* note 38.

criteria for a simple febrile seizure. *Id*. at 2, 5. Further, Dr. Kinsbourne submitted *Shorvon & Trinka*, which stated that the aftermath of most seizures is a short period of confusion and sometimes sleep. Pet. Ex. 43 at 3.[63]

Dr. Zempel argued that medical literature and everyday clinical practice support that a lengthy postictal state can and does follow a simple febrile seizure. Tr. 297; Resp. Ex. D at 2, 3. He "strongly disagree[d]" with Dr. Kinsbourne's contention that a 30-45 minute postictal period would be "out of proportion" with a brief benign febrile seizure. Resp. Ex. C at 2; Resp. Ex. D at 2; Pet. Ex. 58 at 1. Dr. Zempel relied on *Allen et al*., which studied 90 children and while they found the median recovery time from febrile seizures was 18 minutes, the authors also stated that "[m]ost children regain consciousness within 30-40 min[utes], although some take many hours". Resp. Ex. D Tab 2 at 1, 3.[64] Further, like *Millichap*, the American Academy of Pediatrics Clinical Practice Guidelines do not include the lack of a postictal state in the current definition of a simple febrile seizure. Resp. Ex. D Tab 3;[65] Resp. Ex. D Tab 1.[66]

The weight afforded to expert testimony is within the discretion of the special master. *Davis*, 94 Fed. Cl. at 66-67; *Moberly*, 592 F.3d at 1325-26. Here, Dr. Kinsbourne chose to rely on statements from Mrs. Menard and petitioners provided years after the events rather than on the contemporaneous medical records and reports to medical professionals at the time of the events. Further, he confused or included facts that simply did not exist in the record. Tr. 331-33. In so doing, he concluded that Z.D. suffered a non-convulsive status epilepticus seizure of over 30 minutes in duration, followed by a lengthy postictal period. *See generally* Pet. Ex. 29; Pet. Ex. 58; Pet. Ex. 65; Pet. Ex. 68; Pet. Ex. 76.

The contemporaneous evidence shows Mrs. Menard reporting seizure like activity of a few seconds followed by brief unresponsiveness in which she could not get his attention. Pet. Ex. 19 at 2. He was responsive upon arrival of EMS. *Id*. Once in the ER, a nurse noted he appeared postictal in the context of a high fever of 103.3. Pet. Ex. 5 at 3, 7. Once the fever abated, he returned to baseline, was noted to be awake and alert, then sleeping, but he was kept for observation until around 9:00pm to ensure he had no further seizure activity. *Id*. at 6-7. The record does not include any signs of a prolonged seizure or lengthy postictal period. Even so, Dr. Zempel has persuasively demonstrated that a postictal period may follow a simple febrile seizure.

3. Conclusion on Diagnosis

As explained at length above, Dr. Kinsbourne maintained that Z.D.'s first seizure was NCSE based on affirmations and testimony provided years after the events which were inconsistent with the contemporaneous medical records. When referring to the medical records, Dr. Kinsbourne either underplayed, misquoted, confused, or disregarded the records entirely. In fact, the summary of the medical history contained in his initial report contains facts not found anywhere in the records filed. *See, e.g.*, Pet. Ex. 29 at 1 (for example, "[s]hortly before 15.00 p.m. he began to

[63] Shorvon & Trinka, *supra* note 18.
[64] J.E. Allen et al., *Recovery of Consciousness After Epileptic Seizures in Children*, 92 ARCHIVES OF DISEASE IN CHILDHOOD 39 (2007), filed as "Resp. Ex. D Tab 2."
[65] American Academy of Pediatrics, *supra* note 52.
[66] Millichap, *supra* note 38.

screech uncontrollably.")

Dr. Kinsbourne argued that the ER doctors misdiagnosed Z.D.'s initial seizure as a simple febrile seizure and Dr. Walsh accepted that incorrect diagnosis. Tr. 193-95, 199. However, Dr. Walsh's records prove otherwise and were based on the parents' reporting at each visit. On June 5, 2012, Dr. Walsh wrote "[a]s described to me, I believe [Z.D.] had a simple febrile seizure perhaps related to his immunization." Pet. Ex. 1 at 42. On November 13, 2012, Dr. Walsh wrote the original seizure was "brief, generalized tonic clonic in context of post immunization fever", consistent with a simple febrile seizure, and "there are no new symptoms or signs to suggest an additional underlying diagnosis." *Id*. at 46. He also documented a discussion with the parents who expressed uncertainty in their ability to respond with treatment quickly enough since Z.D. had two additional febrile seizures; thus, "[a]fter full discussion of various daily anti-seizure options, we've elected a therapeutic trial of Keppra". *Id*. at 47. Based on the parents' reporting at each visit and his clinical findings, Dr. Walsh believed the correct diagnosis to be simple febrile seizures with no new neurological symptoms or need for neuroimaging. He further discussed with the parents Z.D.'s seizures in the context of fever. *Id*. at 46-47. The records also show that Dr. Walsh prescribed Keppra because petitioners were concerned with their ability to act quickly enough to treat a febrile illness and prevent another seizure—not because Dr. Walsh realized he was treating a child with epilepsy, as Dr. Kinsbourne suggested. *Id*.; Tr. 193-95, 199.

Further, Dr. Kinsbourne relied on a December 22, 2014 medical visit, nearly three years after Z.D.'s first seizure, to support his opinion that the first seizure was NCSE. At that visit, Dr. Turner's nurse practitioner wrote, "[r]eportedly initial event was febrile status epilepticus" and "his previous seizure were (sic) likely illness related seizure and due to a decreased seizure threshold in the context of primary generalized epilepsy." Pet. Ex. 68 at 1; Pet. Ex. 67 at 2. While Dr. Kinsbourne correctly quotes the record, this record merely reflects the parents' reporting a history and not the neurologist's impression. Pet. Ex. 67 at 2. The parents' history on this date not only conflicts with the histories provided in all the prior medical records documenting the initial seizures as simple febrile seizures, but also with the April 2014 record, at which time the petitioners reported a history of febrile seizures with tonic-clonic characteristics prior to starting Keppra in November 2012. Pet. Ex. 5 at 6; Pet. Ex. 1 at 42, 46; Pet. Ex. 3 at 168; Pet. Ex. 11 at 7, 14, 38-39. Further, at a subsequent visit in December 2015, Dr. Turner's assessment included "Epilepsy, unspecified, not intractable, *without status epilepticus*" and "immunization not carried out because of patient decision for other reason". Pet. Ex. 25 at 44-49 (emphasis added).

Dr. Zempel maintained that Z.D.'s January 13, 2012 seizure was a simple febrile seizure. He noted that ER doctors regularly see patients with febrile seizures, perhaps even more frequently than neurologists, and therefore have the requisite experience to appropriately evaluate and treat febrile seizures. Tr. 229-30, 234, 296. Again, the opinions of treating physicians are not binding on a special master; however, a special master may afford greater weight to contemporaneous medical records than to other evidence, particularly in circumstances where the proffered evidence is in conflict with the contemporaneous evidence. *Snyder*, 88 Fed. Cl. at 706; *Burns*, 3 F.3d at 417; *Cucuras*, 993 F.2d at 1528; *see also Woods v. Sec'y of Health & Human Servs*., No. 17-897V, 2023 WL 19182, at *1, *11-12 (Fed. Cl. Spec. Mstr. Jan. 3, 2023). As explained at length, the medical records here were entitled to more weight than the conflicting testimony that was later provided.

I find Dr. Zempel's opinion, which was grounded in the medical records and consistent with that of those who treated Z.D., to be more persuasive than Dr. Kinsbourne's opinions, which included an unsupported diagnosis of NCSE and relied on facts not supported by the contemporaneous records.

Dr. Zempel conceded that NCSE cannot be disproven due the lack of EEG on that date. Tr. 239. However, the simple fact that the alleged diagnosis cannot be disproven is not evidence of its accuracy. It is petitioners' burden to prove by preponderant evidence that the vaccinations led to Z.D.'s alleged injuries. Petitioners' causation theory depended entirely on a finding that the initial seizure was status epilepticus, specifically NCSE. They have failed to provide sufficient evidence to support such a finding.

The totality of the evidence shows that on January 13, 2012, a day after his vaccinations, Z.D. developed a high fever, experienced a tonic-clonic/convulsive seizure that was a few seconds long, was responsive to loud noises upon arrival of emergency medical personnel, continued to have a high fever of over 103 in the ER, and was medicated with antipyretics. When his fever dropped, he was alert, observed in the ER for several more hours without further seizure activity, then discharged home. *See generally* Pet. Ex. 5; Pet. Ex. 19. Based on his history and clinical presentation, his treating physicians diagnosed him with a simple febrile seizure. Pet. Ex. 5 at 6-7. Z.D. had additional brief, one to several second, tonic-clonic seizures over the next two years, all in the context of acute illness with high fever. Pet. Ex. 3 at 168; Pet. Ex. 6 at 90, 92, 94, 140-42, 145; Pet. Ex. 9 at 97, 99-100, 104; Pet. Ex. 11 at 36-39.

There is no persuasive evidence in the record to support that Z.D.'s seizure on January 13, 2012 was NCSE or status epilepticus. In conclusion, I find that the evidence supports that Z.D. suffered a brief simple febrile seizure within 24 hours of his January 12, 2012 vaccinations.

B. *Althen* Analysis

Having determined that Z.D. suffered a simple febrile seizure on January 13, 2012, petitioners must prove by preponderant evidence that the vaccinations Z.D. received on January 12, 2012 not only caused his simple febrile seizure the following day, but also caused his subsequent febrile seizures, a seizure disorder and apraxia.

1. *Althen* Prong One: Petitioners Have Not Proffered a Reputable Medical Theory

Dr. Kinsbourne opined that status epilepticus is capable of permanently lowering a child's seizure threshold. Pet. Ex. 58 at 2. Vaccinations stimulate the immune system, causing the release of pro-inflammatory cytokines, one of which is IL-1b. Pet. Ex. 29 at 5; Pet. Ex. 40;[67] Pet. Ex. 32.[68] IL-1b has a propensity to cause both fever and seizures. In turn, seizure activity tends to cause further release of IL-1b in the brain, thus lowering the seizure threshold. Pet. Ex. 29 at 5; Pet. Ex.

[67] Le Saux et al., *supra* note 21.
[68] Chen et al., *supra* note 22.

45;[69] Pet. Ex. 33.[70] Prolonged seizure activity can irreversibly alter the way the immature brain develops and forms synapses. Pet. Ex. 29 at 5; Pet. Ex. 58 at 2.[71] The alterations can result in long term consequences in seizure susceptibility, learning and memory, and risk for subsequent seizure-induced injury. *Id*.; Pet. Ex. 45.[72] Dr. Zempel agreed that NCSE is capable of causing neurological injury. Resp. Ex. A at 7. Thus, the experts agreed that NCSE can lead to later epilepsy or brain damage.

However, neither expert opined that a simple febrile seizure could result in epilepsy or brain damage. According to Dr. Kinsbourne, simple febrile seizures tend to be benign and do not predict later epilepsy. Tr. 163-64. Similarly, Dr. Zempel repeatedly stated that simple febrile seizures are not associated with a greater risk of developing epilepsy. Resp. Ex. A at 10, 11; Resp. Ex. A Tab 1;[73] Resp. Ex. A Tab 6;[74] Resp. Ex. A Tab 7.[75]

Petitioners' theory depended entirely on a finding that Z.D.'s first seizure following his vaccinations was nonconvulsive status epilepticus. They explained how NCSE can lead to epilepsy and other associated injuries or conditions. However, petitioners failed to offer a theory as to how a simple febrile seizure could lead to brain damage, speech delay, a lower seizure threshold, or epilepsy. The causation opinion must relate to the injury alleged. *See Broekelschen*, 618 F.3d at 1344, 1346 (upholding the special master's denial of entitlement when he made a factual determination that the condition that Dr. Broekelschen actually suffered from was not the one for which he had claimed or presented causation evidence); *see also Vinesar v. Sec'y of Health & Human Servs*., No. 18-440V, 2024 WL 1252167, at *1 (Fed. Cl. Mar. 6, 2024). Here, it does not. Accordingly, petitioners have failed to carry their burden on Prong I.

2. *Althen* Prong Two: Petitioners Have Not Provided a Logical Sequence of Cause and Effect

It generally follows that a petitioner's failure to prove Prong I results in a failure to prove Prong II. All agreed that Z.D.'s first seizure was induced by fever a day after his vaccinations. Pet. Ex. 29 at 5; Pet. Ex. 1 at 42, 44; Resp. Ex. A at 11; Tr. 299-300. Dr. Kinsbourne opined that Z.D.'s first seizure was NCSE and was his first epileptic seizure, not a simple febrile seizure. Pet. Ex. 29 at 2; Pet. Ex. 58 at 4; Pet. Ex. 65 at 2. However, he failed to demonstrate that Z.D.'s initial seizure was an epileptic seizure or explain how a simple febrile seizure can cause or lead to epilepsy. He further failed to show how Z.D.'s first simple febrile seizure can or did cause any of Z.D.'s speech problems or other neuromotor conditions.

Dr. Kinsbourne submitted that Z.D.'s initial seizure was "far more severe" than a "benign febrile seizure", was NCSE, and was significant in his development of epilepsy. Pet. Ex. 58 at 4. He wrote, "the initial status epilepticus, more likely than not, lowered [Z.D.'s] seizure threshold."

[69] Vezzani & Baram, *supra* note 25.
[70] Dube et al., *supra* note 26.
[71] *Supra* note 28.
[72] Vezzani & Baram, *supra* note 25.
[73] American Academy of Pediatrics, *supra* note 44.
[74] Nelson & Ellenberg, *supra* note 45.
[75] Nelson & Ellenberg, *supra* note 46.

Pet. Ex. 65 at 2. He cited to Dr. Turner's medical record years later that Z.D. had a lower seizure threshold. Pet. Ex. 29 at 2; Pet. Ex. 25 at 1 (noting Z.D. to have a "decreased seizure threshold in the context of primary generalized epilepsy.").

Z.D. was diagnosed with epilepsy in December 2014—nearly three years after his first febrile seizure. Pet. Ex. 16 at 29-31. When presented to Dr. Turner for a second opinion, petitioners reported a history of an initial seizure in January 2012 at 18-months concurrent with a post-immunization fever of 103, diagnosed as a febrile seizure. *Id*. at 29. At that visit, the nurse practitioner wrote, "[R]eportedly initial event was febrile status epilepticus." *Id*. His subsequent seizures all occurred with fever and illness, and he was placed on Keppra in November 2012 due to frequency of febrile seizures and "increasing concern from [Z.D.'s] parents." An EEG performed in April 2014 noted generalized spike and wave discharges without clinical accompaniment. "Therefore, his previous seizure were (sic) likely illness related seizure and due to a decreased seizure threshold in the context of primary generalized epilepsy." *Id*. This is the only reference in the medical record in which a physician suggested Z.D.'s initial seizure was related to epilepsy and was written in the context of the first seizure reportedly being febrile status epilepticus; still, Dr. Turner refers to the first seizure as occurring "in concurrence with a post immunization fever (103)" and does not suggest that the vaccinations or the initial seizure caused Z.D.'s epilepsy or his speech difficulty.[76] Additionally, Z.D.'s first treating neurologist Dr. Walsh did not attribute his speech difficulty to his initial seizure or to the vaccinations; in fact, he documented the opposite. Pet. Ex. 1 at 44 (Dr. Walsh wrote that "I am reluctant to attribute his speech problems to the seizure or an underlying developing or progressive neurologic disorder.").

Dr. Kinsbourne's opinion was contingent on a finding that Z.D.'s initial febrile seizure was status epilepticus, not a simple febrile seizure. As detailed above, Dr. Kinsbourne's diagnosis of NCSE is contrary to the medical records, and Dr. Kinsbourne failed to explain how a simple febrile seizure lasting only a few seconds, which he defined as "benign", could lead to epilepsy or speech issues. Tr. 163-64. Additionally, the medical records show concern over Z.D.'s speech prior to his first seizure and prior to the vaccinations at issue. Pet. Ex. 3 at 26 (January 12, 2012—the date of vaccination—"Mom concerned about speech dad not has 10-15 words."). Further, Dr. Kinsbourne consistently referred to a regression in Z.D.'s speech, claiming in his second expert report that he had aphasia, specifically acquired epileptiform aphasia (AEA). Pet. Ex. 58 at 4. However, at hearing, he denied ever opining that Z.D. had aphasia. Tr. 336, 337-38. The records show that Z.D.'s speech progressed following the vaccination, although the intelligibility of his speech later became an issue which ultimately led to the diagnosis of apraxia of speech. Pet. Ex. 3 at 71; Pet. Ex. 7 at 16. None of Z.D.'s medical providers associated his apraxia with his vaccinations or with his simple febrile seizures. Petitioners failed to show how Z.D.'s simple febrile seizure caused or was in any way related to his later development of epilepsy or speech issues. As such, petitioners have not demonstrated a logical sequence of cause and effect between the vaccines and the injuries alleged. Accordingly, petitioners have failed to carry their burden on Prong II.

[76] Petitioners were referred to Dr. Turner by the doctor they saw at MUSC for a developmental assessment. Pet. Ex. 18 at 3. Dr. Turner's assessment in December 2014 included a post-immunization reaction. Pet. Ex. 16 at 30. However, he did not mention the vaccine in the context of Z.D.'s seizures or speech difficulty. This can most likely be explained by the referring doctor's record, which documented that petitioners reported that Z.D. had a vaccine injury for which they retained a lawyer. *See* Pet. Ex. 18 at 3; Pet. Ex. 16 at 14.

3. *Althen* Prong Three: Petitioners Have Not Established a Proximate Temporal Relationship

Respondent "acknowledged that Z.D.'s initial febrile seizure occurred in close temporal proximity to his flu and/or Pentacel vaccinations". However, he disputed that Z.D.'s later seizures were temporally related to the subject vaccines. Resp. Pre-Hearing Submission at 12.

The parties agreed that Z.D.'s initial seizure was precipitated by fever within 24 hours of his vaccinations. The experts also agreed that an interval of eight months between a first and second epileptic seizure is not uncommon. Pet. Ex. 58 at 2; Tr. 203, 313-14. However, petitioners failed to establish that Z.D.'s first seizure was anything other than a simple febrile seizure or was in anyway related to his subsequent febrile seizures, his diagnosis of epilepsy three years later, or his speech apraxia. Thus, petitioners failed to demonstrate by preponderant evidence that Z.D.'s subsequent febrile seizures, seizure disorder (epilepsy) and/or speech difficulty were related to the vaccinations he received on January 12, 2012.

VII. Conclusion

When petitioners fail to carry their burden in proving causation, the Secretary is not required to present an alternate explanation for the vaccinee's condition. *De Bazan*, 539 F.3d at 1352. Petitioners in this matter have failed to put forth a prima facie showing of causation; therefore, respondent is not required to demonstrate that a "factor unrelated" was the sole cause of the vaccinee's condition. Accordingly, this case must be dismissed.

In the absence of a timely filed motion for review (see Appendix B to the Rules of the Court), the Clerk shall enter judgment in accordance with this decision.[77]

IT IS SO ORDERED.

s/ Mindy Michaels Roth
Mindy Michaels Roth
Special Master

[77] Pursuant to Vaccine Rule 11(a), if a motion for review is not filed within 30 days after the filing of the special master's decision, the clerk will enter judgment immediately.