In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 16-140V

Filed: February 7, 2024

PAULA HEILIG, *mother of I.H.*,	*	TO BE PUBLISHED
Petitioner,	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Richard Gage, Richard Gage, PC, Cheyenne, WY, for Petitioner
Mark Hellie, U.S. Department of Justice, Washington, DC, for Respondent

RULING ON ENTITLEMENT[1]

Oler, Special Master:

On January 29, 2016, Paula Heilig ("Petitioner") filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*[2] (the "Vaccine Act" or "Program") on behalf of her minor daughter, I.H. The petition alleges that I.H. developed a seizure disorder as a result of the DTaP, hepatitis B, inactivated polio ("IPV"), *haemophilus*

[1] Because this Ruling contains a reasoned explanation for the action 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 Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 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, I agree that the identified material fits within this definition, I will redact such material 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 (2012).

influenzae type b ("Hib"), rotavirus, and pneumococcal conjugate ("PCV") vaccines she received on March 6, 2013. The petition further alleges that "[t]he drug treatment that I.H. received for her seizure disorder has caused the development of neutropenia."[3] Pet. at 1, ECF No. 1.

Upon review of the evidence in this case, I find that Petitioner has preponderantly demonstrated that the DTaP vaccine I.H. received caused her to develop epilepsy.

I. Procedural History

Petitioner filed her petition on January 29, 2016. Pet. She filed medical records in support of her petition on April 15, 2016 (Exs. 1-6) and on September 7, 2016 (Ex. 8).

Respondent filed his Rule 4 Report on October 24, 2016 recommending that entitlement be denied. Resp't's Rep. at 1; ECF No. 26.

The parties then filed expert reports from their respective neurologists. On February 27, 2017, Petitioner filed an expert report from Dr. Marcel Kinsbourne along with Dr. Kinsbourne's CV. Exs. 9, 10. Petitioner filed the medical literature associated with Dr. Kinsbourne's report on March 3, 2017. Exs. 11-27. On August 1, 2017, Respondent filed an expert report from Dr. Shlomo Shinnar (Ex. A) Dr. Shinnar's CV (Ex. B) and the medical literature associated with his report (Exs. A.1-A.18). The parties filed responsive reports from each expert. Ex. 28, Ex. C, Ex. 50.

I conducted an entitlement hearing on December 9 and 10, 2021, after which the parties filed post hearing briefs. ECF Nos. 90, 92, 94. This matter is now ripe for an adjudication.

II. Medical History

I.H. was born on September 7, 2012. Ex. 1 at 4. Prior to the allegedly causal vaccinations, she was generally in good health, was developing normally, and had no adverse reactions to previous vaccinations. *Id*., Ex. 8 at 5-15.

On January 22, 2013, Petitioner brought I.H. to her pediatrician, Tatyana Ledovsky, M.D., with chief complaints of cough, runny nose, and bronchiolitis for the past two days. Ex. 8 at 14-15. Dr. Ledovsky noted that I.H. had nasal congestion and wheezing; her assessment was acute bronchiolitis due to infection. *Id.*

On March 6, 2013, I.H. received DTaP, hepatitis B, IPV, Hib, rotavirus, and PCV vaccines at her six-month well child appointment. Ex. 8 at 17-18. Dr. Ledovsky noted that her development was normal. *Id.* at 17.

[3] Although Petitioner alleges that I.H. developed neutropenia as a result of her epilepsy medication, she appears to have abandoned this aspect of her claim. Petitioner did not discuss neutropenia in her expert reports, her pre- or post-hearing briefs, or during the entitlement hearing. As a result, I have not analyzed this issue.

On March 7, 2013, Petitioner brought I.H. postictal[4] to the emergency room ("ER") reporting that I.H. had been shaking and vomiting that morning. Ex. 1 at 65. ER staff assessed I.H.'s condition as a 13 out of 15 on the Glasgow Coma Scale ("GCS")[5] and noted that she began crying in the exam room. *Id.* Petitioner reported that I.H. had a seizure that morning lasting 30 minutes that included tonic-clonic movement and staring to one side without eye rolling, urinary or stool incontinence, or frothing. *Id.* at 87-88. I.H. had a temperature of 100.8˚F or 100.9˚F in the ER, but Petitioner reported that her temperature was normal at home. *Id.*; *id.* at 100. Petitioner denied cough, diarrhea, earache, and upper respiratory symptoms. *Id.* Petitioner stated that I.H. received Tylenol the previous evening because she was cranky but not febrile after her vaccinations. *Id.* at 88. The emergency physician's assessment was "seizure disorder, first episode, without fever[6] – cause to be evaluated." *Id.* at 89.

During her hospitalization, I.H.'s blood tested positive for respiratory syncytial virus ("RSV"). Ex. 1 at 85. Her head CT was normal, and her EEG was abnormal, showing "generalized spike and wave discharge indicative of generalized epilepsy." *Id.* at 94, 98, 133.

On March 8, 2013, I.H. had a consult with neurologist Nirmala Mitra, M.D. Ex. 1 at 216. Dr. Mitra noted that I.H. had a "generalized tonic-clonic seizure and was afebrile," and that her neurological and developmental exam was "completely normal." *Id.* Dr. Mitra declined to start I.H. on anti-seizure medications. *Id.* at 179. I.H. was discharged from the hospital on March 9, 2013, with a diagnosis of febrile convulsions (simple), unspecified, and acute bronchiolitis due to RSV. *Id.* at 66.

On March 11, 2013, Petitioner brought I.H. to Dr. Ledovsky for a follow-up. Ex. 8 at 20-21. I.H. had no fever or cough and was generally in a good state of health. *Id.* at 20. She had no neurological symptoms and Dr. Ledovsky noted that she was active and alert. *Id.*

---

[4] Postictal refers to the phase "occurring after a seizure or sudden attack." DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=40528 (last visited Dec. 29, 2023) ("DORLAND'S").

[5] The GCS is "a standardized system for assessing response to stimuli in a neurologically impaired patient; reactions are given a numerical value in three categories (eye opening, verbal responsiveness, and motor responsiveness), and the three scores are then added together. The lowest values are the worst clinical scores." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=104938 (last visited Dec. 29, 2023).

[6] The medical record of this visit contains contradictory notations as to fever. Ex. 1 at 89 (noting a temperature of 100.8˚F on arrival in the ER and describing I.H.'s first seizure episode as "without fever."). A similar discrepancy appears in the record of I.H.'s neurology consult with Dr. Mitra on March 8, 2013. *Id.* at 216. I.H.'s temperature on admission on March 7 was consistently documented as being either 100.8˚F or 100.9˚F, both of which are within the fever range for a six-month-old. *See Id.* at 65, 89, 100; RECOGNIZING AND RESPONDING TO INFANT FEVERS, https://www.mayoclinichealthsystem.org/hometown-health/speaking-of-health/dont-ignore-infant-fevers (last visited Jan. 30, 2024) ("A fever is a single temperature reading of 100.4 degrees Fahrenheit or greater."). The fact that I.H. had a fever on March 7, 2013 is not disputed by either side, therefore, I conclude that I.H.'s first seizure was a febrile seizure.

On April 13, 2013, Petitioner brought I.H. to Dr. Ledovsky for earache and acute rhinitis, reporting two days of nasal congestion and low-grade fever. Ex. 8 at 22-23.

On April 16, 2013, I.H. presented in the ER having had a seizure lasting four to five minutes. Ex. 3 at 6. I.H. was afebrile, alert, and active on arrival with a GCS of 15 out of 15. *Id.* Petitioner reported that during the seizure, I.H.'s skin felt warm to the touch and her temperature was 99.7˚F. *Id.* Petitioner reported no fever or runny nose but that I.H. had been cranky. *Id.* I.H. exhibited some left sided stiffness on exam but was otherwise improving. *Id.* I.H. was discharged the same day and the primary impression was seizure disorder. *Id.* at 8.

On May 22, 2013, Petitioner brought I.H. to Dr. Ledovsky with thrush and received a prescription for nystatin.[7] Ex. 8 at 26-27.

On June 10, 2013, I.H. saw Dr. Ledovsky for her nine-month well child visit. Ex. 8 at 28-29. I.H.'s examination was normal, including normal tone and motor development, sensory system and reflexes, and cranial nerves. *Id.* at 28. I.H.'s white blood cell count was low and Dr. Ledovsky later diagnosed I.H. with neutropenia[8] and lymphocytosis[9] and referred her to a hematologist. *Id.* at 28, 33.

On June 17, 2013, I.H. saw hematologist Birte Wistinghausen, M.D. Ex. 2 at 1-4. Dr. Wistinghausen also diagnosed I.H. with neutropenia; tests for Epstein-Barr virus, cytomegalovirus, quantitative IgGs, and neutrophil antibodies were negative. *Id.* at 4, 7-9. At a follow-up on June 26, Dr. Wistinghausen noted that I.H.'s absolute neutrophil count ("ANC") was still low and recommended weekly complete blood counts ("CBC's") to rule out cyclic neutropenia. *Id.* at 10-13. Dr. Wistinghausen also recommended a bone marrow biopsy if I.H.'s neutropenia continued. *Id.*

On June 28, 2013, I.H. returned to the ER after having one-minute seizures earlier that day and the previous evening. Ex. 1 at 227-28. At both times, I.H. recovered within one to two minutes with no post-ictal phase. *Id.* 261. I.H.'s temperature in the ER was 101.7˚F; the emergency physician noted that I.H. had had two previous febrile seizures and had neutropenia. *Id.* at 230, 261, 689. I.H. had another seizure later that evening that lasted for two minutes. *Id.* at 279. The emergency physician's notes state that "[i]n view of repeated seizures and abnormal EEG it looks

---

[7] Nystatin is "a polyene antifungal agent produced by the growth of *Streptomyces noursei*, effective against *Candida albicans* and other *Candida* species; used in the treatment of vaginal, intestinal, oropharyngeal, and cutaneous candidal infections, administered orally and topically." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=34567 (last visited Jan. 30, 2024).

[8] Neutropenia is "an abnormal decrease in the number of neutrophils [a type of white blood cell] in the blood." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=33915 (last visited Jan. 30, 2024).

[9] Lymphocytosis is an "excess of normal lymphocytes [a type of white blood cell] in the blood or in any effusion." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=29034 (last visited Jan. 25, 2024).

more like a seizure disorder precipitated by fever rather than febrile seizure." *Id.* It was also noted that I.H.'s father and uncle had a history of febrile seizures. *Id.* at 711.

On July 1, 2023, I.H. underwent a repeat EEG, which was abnormal due to a "paroxysmal burst of delta activity indicative of underlying cortical dysfunction" and "wave discharge indicative of generalized epilepsy" and "asymmetry between left and right side indicative of an underlying structural lesion." *Id.* at 368. On July 2, she underwent a brain MRI that revealed a three-to-four millimeter abnormality in the frontal lobe. *Id.* at 669. The notes indicate that this abnormality was nonspecific and could have a neoplastic, post-inflammatory, or postinfectious etiology. *Id.*

On July 12, 2013, I.H. had a follow-up appointment with Dr. Wistinghausen, who noted that she was stable and that her rash and diarrhea were improving, and that she had mild rhinorrhea and dry cough but was in no acute distress. Ex. 2 at 19. He recommended a bone marrow biopsy to determine the etiology of her neutropenia. *Id.*

On July 15, 2013, I.H. saw neurologist Arash Fazl, M.D. Ex. 2 at 22-24. Dr. Fazl noted that I.H.'s development was fine, even advanced with regard to language and motor skills. *Id.* at 23. He also noted that I.H.'s father and paternal grandmother had a history of febrile seizures. *Id.* He opined that I.H.'s seizures were less likely to be febrile seizures and might in fact be epilepsy. *Id.* at 24.

On July 17, 2013, I.H. underwent a bone marrow biopsy and the results were normal. Ex. 2 at 26-28, 33.

On August 12, 2013, I.H. had a follow-up with Dr. Wistinghausen, who noted that she was doing well. Ex. 2 at 60-63. Dr. Wistinghausen noted that I.H.'s neutropenia was most likely autoimmune. *Id.* at 61.

On August 26, 2013, I.H. saw neurologist Jose Montes-Rivera, M.D. Ex. 2 at 65-66. Dr. Montes-Rivera noted that I.H. was doing well on clonazepam and that her examination was normal. *Id.* at 66.

On August 30, 2013, Petitioner brought I.H. to Dr. Ledovsky for viral conjunctivitis. Ex. 8 at 43-44. I.H. received a flu vaccination at this appointment. *Id.* at 44.

On September 7, 2013, I.H. reported to the ER because she was bitten on her face by the family dog. Ex. 2 at 75-78. I.H. also suffered a seizure lasting 30 seconds after skipping a dose of her medication. *Id.* at 76. Her parents reported that her temperature had been 101.8˚F. *Id.* at 80. She was admitted to the hospital and discharged on September 9. *Id.* at 81.

On October 5, 2013, Petitioner brough I.H. to Dr. Ledovsky for her one year well child exam. Ex. 8 at 48-49. Her examination was normal, and she received flu and varicella vaccinations. *Id.* at 49.

On October 7, 2013, I.H. saw neurologist Elaine Brown, M.D., for a follow-up. Ex. 2 at 214-15. Dr. Brown noted that I.H.'s seizures may be febrile, but that her abnormal EEG and MRI raised epilepsy as a possible concern. *Id.* at 215. At a follow-up with Dr. Wistinghausen that same day, I.H. was noted to be doing well with no seizures, fevers, or other complaints. *Id.* at 209-11.

On November 4, 2013, Petitioner brought I.H. back to Dr. Wistinghausen reporting a 30-second seizure three weeks earlier. Ex. 2 at 217-20. Petitioner had brought I.H. to the ER at that time, where I.H. received a diagnosis of herpangina.[10] I.H. had had a total of seven seizures and Petitioner reported that her seizures always happened "after vaccinations." *Id.* at 217.

Over the following months, I.H. was seen for various minor complaints (e.g., cough, cold, upper respiratory infection) and follow-ups, and was noted to be developing normally without seizures. *E.g.*, Ex. 2 at 223-36, 229-32, 248-49; Ex. 8 at 62-63, 69-70.

On July 2, 2014, Petitioner brought I.H. to Dr. Ledovsky reporting that I.H. had experienced seizures on June 29 and 30 and a fever of 100.6˚F. Ex. 8 at 75-76. Dr. Ledovsky diagnosed I.H. with pharyngitis and recommended acetaminophen and ibuprofen. *Id.* at 76.

On August 11, 2014, Petitioner brought I.H. to neurologist Chelsea Hesterman, M.D. Ex. 2 at 273-74. Petitioner reported that, since her last neurology appointment in February 2014, I.H. had a seizure in March, four in June, two in one day in July, and one in August. *Id.* at 273. Petitioner reported that I.H.'s seizures seemed to correlate with febrile illnesses and exposure to hot weather. *Id.* Dr. Westerman examined I.H. and found her to be neurologically and developmentally normal. *Id.*

On August 31, 2014, I.H. presented in the ER after a breakthrough seizure that lasted for 20 minutes. Ex. 3 at 29. Her father stated that she had been playing and "suddenly began laughing and moving strangely, responding initially, although slowly, then her eyes fixated to the left and she lost muscle tone, followed by [r]ight side shaking." *Id.* I.H. had a second seizure in the ambulance and was actively seizing on arrival in the ER. *Id.* I.H. was discharged the following day as she was awake, alert, and oriented, and was interactive with her parents and hospital staff. *Id.* at 31.

On September 5, 2014, I.H. underwent an EEG with normal results. Ex. 4 at 10. Medical records over the following years reflect that I.H. continued to have a seizure approximately every several months. *E.g.*, Ex. 89 at 1, 11-13, 15-16, 20, 33, 39. Most recently, I.H. saw Dr. Ledovsky for a well-child visit on September 7, 2021. *Id.* at 43. Dr. Ledovsky noted that I.H.'s exam and development were normal. *Id.*

No other relevant medical records have been filed.

[10] Herpangina is "an acute infectious disease caused by either group A or group B coxsackievirus or by echoviruses, chiefly affecting young children in the summer; characteristics include vesiculoulcerative lesions on the mucous membranes of the throat, dysphagia, vomiting, and fever." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=22347 (last visited Dec. 29, 2023).

III. Petitioner's Affidavit and Testimony

A. Petitioner's Affidavit

Petitioner signed her affidavit on February 2, 2016. ECF No. 8. In it, she averred that I.H. was a healthy baby when she received her six-month vaccines. *Id.* at 1. One day after vaccination, I.H. suffered a seizure. *Id.* Petitioner stated that I.H. was diagnosed with neutropenia in June of 2013 and that she has suffered multiple seizures since vaccination. *Id.*

B. Petitioner's Testimony

Petitioner, I.H.'s mother, testified at the entitlement hearing. Tr. at 6. I.H. was born via cesarian section due to her breach position but was otherwise normal and healthy. *Id.* at 6-7. I.H. had bronchitis when she was four-and-one-half months old; during this illness, she had a runny nose, cough, and some trouble breathing. *Id.* at 7-8. This resolved within a week to a week and one half with saline treatment. *Id.* at 9.

Petitioner testified that on the day of I.H.'s six-month vaccinations, she was in good health. Tr. at 10. That evening, I.H. became fussy and refused to eat. *Id.* Petitioner gave her Tylenol and she slept well. *Id.* The next day, I.H. was playing when she suddenly began to shake, vomit, and foam at the mouth, and her lips turned blue. *Id.* at 11. Petitioner and her brother-in-law took I.H. to the hospital. *Id.* Petitioner was unable to recall whether she took I.H.'s temperature but testified that she felt warmer than usual to the touch. *Id.* at 12.

Petitioner testified that I.H. became more responsive and started to cry during the examination in the ER and that she had a fever on admission. Tr. at 12. Just after the seizure, I.H. seemed dizzy and disoriented, but she returned to normal after that. *Id.* at 13. ER staff performed an EEG and a lumbar puncture. *Id.*

Petitioner testified that I.H. had a second seizure with the same type of presentation in April 2013. Tr. at 14. Petitioner brought her to the hospital for more tests. *Id.*

Petitioner testified that all of I.H. seizures have been grand mal seizures. Tr. at 14. They are generalized, affecting her whole body, and are characterized by shaking arms and legs, staring up or to the side, and loss of consciousness. *Id.* Petitioner stated that every time I.H. gets a fever, she has a seizure. *Id.* at 15. She also has seizures when she does not have a fever. *Id.* Petitioner estimated that I.H., aged nine at the time of hearing, had experienced a total of 50 seizures over her lifetime. *Id.* at 15-16.

Petitioner stated that I.H. attended pre-K, but that they stopped sending her there because of seizures. Tr. at 16. Other children made fun of her for having to wear a helmet at recess and she had several seizures at school. *Id.* at 16-17. I.H. was in fourth grade and was being homeschooled at the time of the hearing. *Id.* at 18.

Petitioner testified that I.H. has taken phenobarbital, clonazepam, Keppra, and Topamax at various times over the years and that these were not effective and had negative side effects. Tr. at 18-19. I.H. is no longer taking anticonvulsive medication. *Id.* at 19.

Petitioner testified that I.H. had a febrile seizure in January 2021, but her seizures are not more frequent than when she was taking Topamax. Tr. at 21.

On cross-examination, Petitioner testified that I.H.'s father had one febrile seizure in childhood. Tr. at 23. I.H.'s paternal grandmother and maternal uncle also have a history of febrile seizures. *Id.* at 23-24.

IV. Expert Opinions and Qualifications

A. Dr. Marcel Kinsbourne, M.D.

1. Qualifications

Dr. Kinsbourne is board certified in pediatrics. Tr. at 82. He received his medical degree in England, and he has been licensed to practice medicine in North Carolina since 1967. Ex. 10 ("Kinsbourne CV") at 1. From 1967 to 1974, Dr. Kinsbourne served as an associate professor in pediatrics and neurology and a senior research associate at Duke University Medical Center before holding a series of academic positions, including professorships in pediatrics, neurology, and psychology. *Id*. at 2. His clinical experience includes serving as a senior staff physician in Ontario, Canada, from 1974 to 1980, and a clinical associate in neurology at Massachusetts General Hospital from 1981 to 1991, although many years have passed since he regularly saw patients. I recognized him as an expert in pediatric neurology. Tr. at 27.

2. Expert Reports and Testimony

Dr. Kinsbourne authored three expert reports and testified at the entitlement hearing. Exs. 9 ("First Kinsbourne Rep."), 28 ("Second Kinsbourne Rep."), 50 ("Third Kinsbourne Rep.").

Dr. Kinsbourne testified that the acellular pertussis and PCV vaccines I.H. received caused her first seizure. Tr. at 28. He opined that the other vaccinations I.H. received on March 6, 2013, "don't have a significant record of causing seizures." *Id.*

Dr. Kinsbourne described that the development of seizures involves a genetic susceptibility followed by a trigger. First Kinsbourne Rep. at 1-2; Tr. at 67 (citing Radwa Badawy et al., *Capturing the epileptic trait: cortical excitability measures in patients and their unaffected siblings*, 136 BRAIN 1177-91 (2013) (filed as Ex. 55) ("Badawy") (finding that non-epileptic children have similar cortical excitability to their epileptic siblings)).

I.H. had a three to four millimeter hyperintense area in the subcortical white matter of the left frontal operculum. Dr. Kinsbourne stated that this "may be a tiny patch of dysgenesis, [which] could still be the area in which seizure threshold is lowered and which begins to emit paroxysmal discharges when triggered by a 'second hit' such as an infection or a vaccination." First Kinsbourne

Rep. at 2. He further opined that the cortical dysgenesis alone would not have triggered I.H.'s seizures, emphasizing the importance of the second hit. *Id.* He cited Fauser, et al., in support of this position. Susanne Fauser et al., *Clinical characteristics in focal cortical dysplasia: a retrospective evaluation in a series of 120 patients*, 19 BRAIN 129, 1907-16 (2006) (filed as Ex. 15) (hereinafter "Fauser"). Fauser described 120 patients with epilepsy related to cortical dysplasia where the onset their disease began between the ages of less than one year and 60. Fauser at 1909. Fauser noted that "it could be assumed that cortical dysplasia can exist for prolonged periods of time without giving rise to clinically manifest seizures." *Id.* at 1913.

Dr. Kinsbourne also cited Tezer-Filek, et al., who reported a case of a man with cortical dysplasia who did not develop signs until he was 74 years old. Irsel Tezer-Filek et al., *A case with an asymptomatic malformation of cortical development diagnosed in eighth decade of life*, 111 BRATISLAVA MED. J. 467-68 (2010) (filed as Ex. 23) (hereinafter "Tezer-Filek"). Dr. Kinsbourne quoted the Najm article, which states that "[d]ata from human studies suggest that some patients with congenital/perinatal dysplastic lesions do not express epilepsy till later in life and if they do, epilepsy appears after some type of trigger." First Kinsbourne Rep. at 5 (quoting Imad M. Najm et al., *Pathophysiological Mechanisms of Focal Cortical Dysplasia: A Critical Review of Human Tissue Studies and Animal Models*, 48 EPILEPSIA 21-32 (2007) (filed as Ex. 64) (hereinafter "Najm"). Ultimately, Dr. Kinsbourne opined that "the very small abnormality in [I.H.]'s left frontal lobe, by no means 'predestines the patient to have epilepsy.' In many cases, an additional insult (a second hit) is needed before the first seizure occurs." First Kinsbourne Rep. at 5. He opined that I.H. most likely has more than one such abnormality based on the focal features of the seizures she has experienced. Tr. at 50.

Dr. Kinsbourne opined that vaccines are potential triggers of seizure disorders. First Kinsbourne Rep. at 5. He noted that vaccination activates the innate immune system, whose "IL-1R/TLR signaling mediates change in neuron ion channels that lower seizure thresholds chronically." *Id.* He further opined that because I.H. had received the DTaP and PCV vaccines previously, the anamnestic[11] response she necessarily experienced resulted in the rapid production of cytokines (IL-1 beta and IL-6). *Id.* at 6. Ultimately, he opined that onset of a seizure approximately 18 hours after vaccination was a medically reasonable temporal interval. *Id.*

Dr. Kinsbourne specifically discussed the pertussis component of the DTaP vaccine, noting that the "acellular vaccine is a purified formulation of the previously used whole-cell pertussis vaccine." Second Kinsbourne Rep. at 6. He noted that purifying the vaccine dramatically reduced the frequency of seizures caused by the vaccine, but that it did not eliminate them altogether. *Id.* at 6; Tr. at 60 (citing Lisa A. Jackson et al., *Retrospective population-based assessment of medically attended injection site reactions, seizures, allergic responses and febrile episodes after acellular pertussis vaccine combined with diphtheria and tetanus toxoids*, 21 PEDIATRIC INFECTIOUS DISEASE J. 781-85 (2002) (filed as Ex. 37)). Dr. Kinsbourne noted that between January 1, 1995, and June 30, 1998, the number of VAERS reports of seizures following whole

[11] Anamnesis refers to recollection or memory, and in the context of immunology, it refers to "the capacity of the immune system to respond more rapidly and strongly to subsequent antigenic challenge than to the first exposure." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=88760 (last visited Jan. 25, 2024).

cell pertussis was 203 and following acellular pertussis was 96. Second Kinsbourne Rep. at 6. He cited to Le Saux, et al., who reported a 79% decrease in febrile seizures when acellular pertussis was substituted for whole cell pertussis. *Id.* (citing 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 348-53 (2003) (filed as Ex. 39) (hereinafter "Le Saux"). Dr. Kinsbourne cited the Sun article, which provides epidemiological evidence of an increased risk of seizures after DTaP vaccination. Tr. at 62 (citing Yuelian Sun et al., *Risk of Febrile Seizures and Epilepsy After Vaccination With Diphtheria, Tetanus, Acellular Pertussis, Inactivated Poliovirus, and* Haemophilus Influenzae *Type b*, 307 J. AM. MED. ASSN. 823-831 (2012) (filed as Ex. 86) (hereinafter "Sun")).

Dr. Kinsbourne noted that a 1997 issue of the CDC's Morbidity and Mortality Weekly Report found that seizures "generally occurred less frequently among infants who received acellular pertussis vaccines than among those vaccinated with whole-cell DPT." Second Kinsbourne Rep. at 7. He also cited the CDC's Vaccine Information Statement for the DTaP vaccine from 2007, which states that about one child out of 14,000 may experience a seizure. *Id.* (citing CTRS. FOR DISEASE CONTROL & PREVENTION, VACCINE INFO. STATEMENT: DTAP VACCINE (2007) (filed as Exs. 32, 73) ("VIS")). Dr. Kinsbourne cited Sun, who concluded that "DTaP-IPV-Hib vaccination was associated with an increased risk of febrile seizures on the day of the first 2 vaccinations given at 3 and 5 months, although the absolute risk was small." Second Kinsbourne Rep. at 7 (citing Sun). Sun also concluded that "[v]accination with DTaP-IPV-Hib was not associated with an increased risk of epilepsy." *Id.* at 823.

Dr. Kinsbourne noted that children with genetic abnormalities that result in lowered seizure threshold are more at risk of developing an early onset of epilepsy. Second Kinsbourne Rep. at 7. He opined that febrile seizures can alter central nervous system ("CNS") excitability to lower the seizure threshold in the long term. *Id.* He described that "postictal accumulation of inflammatory mediators … progressively lower the seizure threshold." *Id.* at 8. He referenced Ben Ari and Holmes, who stated "seizure-induced changes in the young brain substantially increase the risk of subsequent injury by a second, induced seizure—the so called 'two hit model.' Similarly, while the incidence is low, children with early-life seizures have an increased risk of developing epilepsy." *Id.* at 8, *citing* Yehezkel Ben-Ari & Gregory L. Holmes, *Effects of seizures on developmental processes in the immature brain*, LANCET NEUROLOGY (2006) (filed as Ex. 29) (hereinafter "Ben-Ari and Holmes").

Dr. Kinsbourne acknowledged that I.H. tested positive for RSV but noted that her lower respiratory tract and chest were clear. First Kinsbourne Rep. at 6. In fact, Dr. Kinsbourne stated that "the medical records are completely incompatible with an on-going bronchiolitis." Second Kinsbourne Rep. at 3. Based on this, Dr. Kinsbourne opined that "[b]ronchiolitis as an alternate causation cannot be substantiated on the record." First Kinsbourne Rep. at 6.

With respect to RSV, Dr. Kinsbourne further noted that I.H.'s treating physicians did not link her seizure to RSV, and that a positive RSV culture is not the equivalent of clinical disease. Second Kinsbourne Rep. at 1, 3.

Dr. Kinsbourne discussed the nature of I.H.'s first seizure, opining that she suffered from a complex[12] febrile seizure. Second Kinsbourne Rep. at 3; Tr. at 44-45 (noting that I.H.'s first seizure was inconsistent with the criteria for a simple benign seizure). He noted that I.H.'s first seizure was too long to be considered simple. Second Kinsbourne Rep. at 4. He also stated that this seizure was focal[13] with a left sided onset, then generalizing. *Id.* According to Dr. Kinsbourne, "a focal seizure is very consistent with a cortical dysplasia." *Id.* Dr. Kinsbourne opined that I.H.'s cortical dysplasia cannot be disassociated from her epilepsy, but that they constitute "a single disorder." *Id.* He referenced an EEG performed on March 8, 2013. Ex. 1 at 133-35. The impression was, "[t]his is an abnormal record because of the presence of generalized spike and wave discharge indicative of generalized epilepsy." *Id.* at 133.

Dr. Kinsbourne also testified that the fact that I.H.'s temperature was not seriously elevated at the time of her first seizure is not material because it is the proinflammatory cytokines and not the fever itself which triggered the seizure. Tr. at 68-69. He opined that her family history of seizures lowered her seizure threshold, and each subsequent seizure lowered it further. *Id.* at 69. He also opined that her RSV infection around age four-and-one-half months did not trigger a seizure because her seizure threshold had not yet been lowered by vaccination. *Id.* at 79. He opined that her March 6, 2013, vaccinations were a stronger immune challenge than she had experienced previously. *Id.*

Dr. Kinsbourne referenced Sun, which concluded that seizures brought on by vaccinations tend to occur within 24 hours. Tr. at 75 (citing Sun). He noted that the DTaP package insert and VIS advise caution when administering either vaccine to a patient who has previously had seizures following previous vaccinations. Tr. at 76-78 (citing Ex. 93 at 4; VIS at 1). He opined that the 18 hours that elapsed between I.H.'s vaccinations and her first seizure is an appropriate timeframe from which to infer causation. *Id.* at 76-77.

Dr. Kinsbourne acknowledged that I.H. did not have an adverse reaction to her first two doses of DTaP vaccine. Tr. at 93. He opined that some children begin having seizures after the first dose, some after the second, and some after the third. *Id.* He was unaware of literature predicting that seizures will begin to occur at a particular age. *Id.* at 94.

---

[12] A complex seizure is "a type of partial seizure characterized by varying degrees of impairment of consciousness; the patient performs automatisms and later may be amnesic for them." DORLAND'S, https://www.dorlandsonline.com/dorland/definition?id=105404 (last visited Jan. 30, 2024).

A simple seizure is "the most localized type of partial seizure, with a discharge that is predominantly one-sided or that presents localized features, and without loss of consciousness…Symptoms are varied, including motor, somatosensory, autonomic, and psychic." DORLAND'S, https://www.dorlandsonline.com /dorland/definition?id=105422 (last visited Jan. 30, 2024).

[13] A focal (as opposed to generalized) seizure affects a particular area of the brain and is also known as a partial seizure. CTRS. FOR DISEASE CONTROL & PREVENTION, TYPES OF SEIZURES, https://www.cdc.gov/epilepsy/about/types-of-seizures.htm (last visited Jan. 30, 2024).

B. Dr. Shlomo Shinnar, M.D., Ph.D.

1. Qualifications

Dr. Shinnar is currently the Director of the Montefiore/Einstein Epilepsy Management Center in New York. Ex. B (hereinafter "Shinnar CV") at 1. He attended Columbia University and the Albert Einstein College of Medicine where he received an M.D. and a Ph.D. in neurophysiology. Shinnar CV at 1. He completed his residency and fellowships in general pediatrics and neurology at Johns Hopkins Hospital in Baltimore, Maryland. *Id.* Dr. Shinnar is board certified in neurology with special competence in child neurology and added qualifications in clinical neurophysiology and epilepsy. *Id.* at 2**.** He currently works as a Professor of Neurology, Pediatrics and Epidemiology, and Population Health at Albert Einstein College of Medicine. *Id.* Dr. Shinnar serves as the Hyman Climenko Professor of Neuroscience Research and the Director of the Comprehensive Epilepsy Management Center at Montefiore Medical Center and the Albert Einstein College of Medicine. *Id.* Moreover, as the Director of the Comprehensive Epilepsy Management Center, he has treated and supervised the treatment of thousands of children suffering from seizure disorders. *Id.* Dr. Shinnar has also been awarded grants by the National Institutes of Health to research childhood afebrile seizures as well as childhood onset epilepsy. *Id.* I recognized him as an expert in pediatrics and neurology with subspecialty expertise in epilepsy. Tr. at 100.

2. Expert Reports and Testimony

Dr. Shinnar authored two expert reports and testified at the entitlement hearing. Exs. A ("First Shinnar Rep."), C ("Second Shinnar Rep.").

Dr. Shinnar noted that the definition of epilepsy is "[t]he occurrence of two or more unprovoked seizures separated by more than 24 hours." First Shinnar Rep. at 5. He further stated the "[f]ebrile seizures are seizures occurring in a child in the context of a febrile illness." *Id.* He stated that children who go on to develop epilepsy are at higher risk of experiencing febrile seizures when they are in the "developmental risk period." *Id.*

Dr. Shinnar opined that I.H.'s seizure disorder would be classified as having a structural cause due to her cortical dysplasia. First Shinnar Rep. at 5. He stated that I.H.'s febrile seizures were likely due to her family history of febrile seizures and her cortical dysplasia. *Id.* Dr. Shinnar attributed I.H.'s seizures to her cortical dysplasia and febrile illnesses. Tr. at 101. He opined that a family history of seizures was a key risk factor for seizures in I.H.'s case. *Id.* at 103.

Dr. Shinnar noted that I.H.'s first seizure occurred in the context of a febrile illness. First Shinnar Rep. at 5. He stated that because I.H. had a fever and was vomiting, this was inconsistent with a post-vaccine reaction and more consistent with a viral illness. *Id.* Dr. Shinnar indicated that I.H.'s treating physicians diagnosed the seizure as a febrile seizure secondary to acute bronchiolitis due to RSV. *Id.* Dr. Shinnar opined that I.H.'s clinical course was consistent with this diagnosis. *Id.* He noted that her breathing rate was elevated, but that this was nonspecific. Tr. at 109 (citing Ex. 1 at 90-91). He acknowledged that I.H. did not have any other symptoms of bronchiolitis at

the time. *Id.* at 118. He also noted that regardless of the cause, any bronchiolitis associated with a fever can produce a febrile seizure. Second Shinnar Rep. at 2.

Dr. Shinnar discussed I.H.'s subsequent seizures and noted that they were also febrile seizures. First Shinnar Rep. at 5. He opined that I.H.'s epilepsy was due to her cortical dysplasia. *Id.* at 6. He noted that "[c]ortical dysplasias are widely recognized as one of the most common causes of epilepsy that does not fully respond to medications." *Id.* He stated that "the focal cortical dysplasia made this child more susceptible to febrile seizures and was also responsible for the development of epilepsy at a later age." Second Shinnar Rep. at 3.

The hallmarks of epilepsy associated with autoimmune disorders are intractable seizures and "a markedly abnormal and encephalopathic EEG with slowing as well as epileptiform activity." First Shinnar Rep. at 6. Dr. Shinnar noted that I.H.'s EEG and MRI findings do not meet these criteria. *Id.* He opined that an abnormal EEG is common after a patient has had several febrile seizures, and that this does not necessarily indicate epilepsy. Tr. at 105. He also disagreed with Dr. Kinsbourne's opinion that seizures often lower the seizure threshold, saying that it is possible for this to occur, but it is rare. *Id.* at 118.

Dr. Shinnar acknowledged that although I.H. did have her initial seizure within 24 hours of her third DTaP vaccination, this seizure was in the context of an RSV infection. First Shinnar Rep. at 6. He acknowledged that a fever caused by a vaccination could lead to a seizure, especially in an infant. Tr. at 105. He opined that vaccines do not cause epilepsy. *Id.* He noted the RSV infection was much more likely to be the cause of the seizure as opposed to I.H.'s vaccination. First Shinnar Rep. at 6. He also stated that I.H. did not have a reaction to either of her other two DTaP vaccinations. Second Shinnar Rep. at 3. Regardless of what caused the initial febrile seizure (bronchiolitis or vaccine), Dr. Shinnar opined that I.H.'s epilepsy was caused by her cortical dysplasia. *Id.* at 4. He acknowledged that pro-inflammatory cytokines can cause seizures, but added that they do so by causing a fever. Tr. at 116.

With respect to timing, Dr. Shinnar opined that there is weak evidence associating seizures with acellular pertussis and no evidence associating it with epilepsy. First Shinnar Rep. at 9. He noted that viral bronchiolitis (unlike acellular pertussis vaccine) is a common cause of fever and febrile seizures. *Id.* He further noted that cortical dysplasia "is one of the most common causes of intractable epilepsy in children." *Id.* at 9-10. "[I]f a child develops a seizure disorder and the imaging shows a dysplasia [it] is assumed to be the cause." Second Shinnar Rep. at 3. Such a finding will terminate a diagnostic workup for a cause. *Id.* He also stated that "if seizures prove to be refractory to medications, surgical removal of the dysplasia will typically result in seizure freedom…" *Id.*

Ultimately, Dr. Shinnar concluded that "I.H., a child with a strong family history of febrile seizures, started out having febrile seizures in the context of a viral illness. Then, as a consequence of her cortical dysplasia, she developed epilepsy which has not been fully controlled on medications." Second Shinnar Rep. at 4. He opined that none of I.H.'s febrile seizures or her epilepsy are related to the DTaP vaccine. *Id.*

V. Applicable Law

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that she suffered a "Table" injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the time period provided in the Table. § 11(c)(1)(C)(i). "In such a case, causation is presumed." *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed in the Vaccine Injury Table, a petitioner may demonstrate that she suffered an "off-Table" injury. § 11(c)(1)(C)(ii).

For both Table and non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010); *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs., 931 F.2d 867, 873* (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records of by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Secretary of Health and Human Services*. 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that petitioner establish by preponderant evidence that the vaccinations he received caused 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.

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs*., 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378-79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325-26). Special Masters, despite their expertise, are not empowered by statute to conclusively resolve what are complex scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the

laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras v. Sec'y of Health & Hum. Servs*., 121 Fed. Cl. 230, 245 (2015) ("[p]lausibility … in many cases may be enough to satisfy *Althen* prong one" (emphasis in original)), *vacated on other grounds,* 844 F.3d 1363 (Fed. Cir. 2017). But this does not negate or reduce a petitioner's ultimate burden to establish her overall entitlement to damages by preponderant evIdence. *W.C. v. Sec'y of Health & Hum. Servs*., 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as 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'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing … that mandates that the testimony of a treating physician is sacrosanct–- that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should also be weighed against other, contrary evidence also present in the record–- including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs*., 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Caves v. Sec'y of Health & Hum. Servs*., No. 06-522V 2011 WL 1935813 at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 Fed. App'x 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs*., 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must also coincide with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs*., 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand on other grounds,* 105 Fed. Cl. 353 (2012), *aff'd without op.,* 503 F. App'x 952 (Fed. Cir. 2013). *Koehn v. Sec'y of Health*

& Hum. Servs., No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for review den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

A. Law Governing Analysis of Fact Evidence

The process for making factual determinations in Vaccine Program cases begins with analyzing the medical records, which are required to be filed with the petition. Section 11(c)(2). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 413, 417 (Fed. Cir. 1993) (it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

Medical records created contemporaneously with the events they describe are generally trustworthy because they "contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions," where "accuracy has an extra premium." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378 (Fed. Cir. 2021) citing *Cucuras*, 993 F.2d at 1528. This presumption is based on the linked proposition that (i) sick people visit medical professionals; (ii) sick people honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) *mot. for rev. denied*, 142 Fed. Cl. 247, 251-52 (2019), *vacated on other grounds and remanded*, 809 Fed. Appx. 843 (Fed. Cir. Apr. 7, 2020).

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03-1585V, 2005 WL 6117475 at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are generally found to be deserving of greater evidentiary weight than oral testimony–- especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; see also *Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, there are situations in which compelling oral testimony may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475 at *19 ("[w]ritten

records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent and compelling." *Sanchez*, 2013 WL 1880825 at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611 at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *LaLonde v. Sec'y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

B. Analysis of 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 & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594-96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (*citing Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). "The *Daubert* factors for analyzing the reliability of testimony are: (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community." *Terran*, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592-95).

The *Daubert* factors play a slightly different role in Vaccine Program cases than they do when applied in other federal judicial fora. *Daubert* factors are employed by judges to exclude evidence that is unreliable and potentially confusing to a jury. In Vaccine Program cases, these factors are used in the weighing of the reliability of scientific evidence. *Davis v. Sec'y of Health & Hum. 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"). The flexible use of the *Daubert* factors to evaluate persuasiveness and reliability of expert testimony has routinely been upheld. *See*, e.g., *Snyder*, 88 Fed. Cl. at 743. In this matter, (as in numerous other Vaccine Program cases), *Daubert* has not

been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts of his own in order to rebut a petitioner's case. 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 v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, 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*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). A "special master is entitled to require some indicia of reliability to support the assertion of the expert witness." *Moberly*, 592 F.3d at 1324. Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Id.* at 1325-26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

C. Consideration of Medical Literature

Finally, although this decision discusses some but not all of the medical literature in detail, I have reviewed and considered all of the medical records and literature submitted in this matter. *See Moriarty v. Sec'y of Health & Hum. 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 & Hum. 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 Petitioner does not allege an injury listed on the Vaccine Injury Table, her claim is classified as "off-Table." As noted above, to prevail on an "off-Table" claim, Petitioner must prove by preponderant evidence that I.H. suffered an injury and that this injury was caused by the vaccinations at issue. *See Capizzano*, 440 F.3d at 1320.

A. *Althen* Prong One

In the context of the Program, "to establish causation, the standard of proof is preponderance of evidence, not scientific certainty." *Langland v. Sec'y of Health & Hum. Serv.*, 109 Fed. Cl. 421, 441 (2013). Petitioner's burden under *Althen*'s first prong is to provide a medical theory causally connecting the vaccination and the injury. *Id.* This theory must be sound and reliable. *Boatmon*, 941 F.3d at 1359.

Petitioner's theory of causation is that the vaccines[14] I.H. received on March 6, 2013, caused I.H. to develop a fever, which led to a febrile seizure. This febrile seizure lowered the seizure threshold in conjunction with I.H.'s underlying cortical dysplasia, which resulted in the subsequent seizures she experienced and an ultimate diagnosis of epilepsy (the so-called "second hit" theory). Respondent urges that the medical literature does not support a causal link between the DTaP vaccine and either epilepsy or seizures more generally. ECF No. 92 at 9-10.

The parties do not dispute that I.H. suffers from epilepsy or that she has a cortical dysplasia. First Kinsbourne Rep. at 3-4; First Shinnar Rep. at 6. There is also no dispute that I.H. suffered her first seizure within about 18 hours of the allegedly causal vaccinations on March 6, 2013. First Kinsbourne Rep. at 2; First Shinnar Rep. at 5.

1. Cortical Dysplasia and Epilepsy

Cortical dysplasias are malformations in the development of the brain that "are characterized by a disruption of the normal lamination of the [cerebral] cortex." Najm at 21. These malformed areas of the brain "are frequently recognized as the etiology of epilepsy in children." Heather Olson et al., *Epileptogenic Cerebral Cortical Malformations*, *in* PELLOCK'S PEDIATRIC EPILEPSY: DIAGNOSIS & THERAPY 111, 111 (John M. Pellock et al., eds.) (filed as Ex. A-14) ("Olson"). The degree of cortical malformation varies widely, with consequent variation in the probability of epilepsy onset, the age at which onset occurs, and disease severity. *Id.* at 111-12. If enough data is available, a cortical dysplasia can be categorized according to the stage of brain development during which the disruption occurred. *Id.* at 113; *see generally Akers v. Sec'y of Health & Hum. Servs.*, No. 15-597V, 2021 WL 3560069, at *18-20 (Fed. Cl. Spec. Mstr. July 6, 2021) (providing a thorough discussion of cortical development and the classification scheme for cortical dysplasias).

2. Petitioner's Second Hit Theory

Theories implicating a vaccine as a trigger for epilepsy onset in the context of an underlying cortical dysplasia have been litigated twice before in the Vaccine Program, with different results. *See Akers*, 2021 WL 3560069, at *36 (rejecting the petitioner's theory that cytokines generated during the systemic response to vaccination crossed the blood-brain barrier and overactivated the already susceptible cortical dysplasia);[15] *Reilly v. Sec'y of Health & Hum. Servs.*, No. 09-489V,

[14] At the entitlement hearing, Dr. Kinsbourne narrowed the focus of his causation analysis to the DTaP and PCV vaccines. Tr. at 28.

[15] I note that the facts of the instant case are distinguishable from those in *Akers* in several respects. For example, the course of epilepsy in the child in *Akers*, A.A., was more severe than that of I.H, with more frequent seizures and global developmental delay. *Akers*, 2021 WL 3560069, at *4-5, 14. A.A.'s epilepsy was sufficiently severe that she underwent two surgical resections to remove her cortical dysplasia. *Id.* at 9, 14. Once the malformed area of her brain was removed, histopathological analysis revealed that A.A's cortical dysplasia was very serious. *Id.* at 23-24. The special master acknowledged the literature supporting the theory that a second hit is required in some cases, but concluded based on A.A.'s clinical, imaging, and histopathological records that "these findings were more than enough to cause the severe epileptic condition that A.A. experienced without implicating her four-month vaccines as a trigger or second hit." *Id.* at 31.

2016 WL 3456844, at *13-15 (Fed. Cl. Spec. Mstr. May 31, 2016) (accepting petitioner's theory that the pertussis component of the DTaP vaccine acted as a "second hit," causing onset of infantile spasms where the child had a focal cortical dysplasia).

Here, Dr. Kinsbourne opined that, at least in some cases, cortical dysplasia alone is not sufficient to cause epilepsy. Rather, he testified that development of epilepsy involves an underlying genetic susceptibility paired with an environmental trigger. First Kinsbourne Rep. at 1-2; Tr. at 67. Petitioner filed medical literature supporting her contention that, in at least some cases, cortical dysplasia only becomes epileptogenic after being triggered by some other insult, a so-called "second hit."

First, Petitioner filed Najm, which states that "much evidence has suggested to many that not all dysplastic lesions are epileptic. Only parts of some dysplastic lesions show in situ epileptogenicity." Najm at 25. Najm continues, stating that "[d]ata from human studies suggest that some patients with congenital/perinatal dysplastic lesions do not express epilepsy [until] later in life and if they do, epilepsy appears after some type of trigger." *Id.* at 28. Najm cites a study in which rats that had been exposed to radiation in utero did not develop epilepsy in vivo until they had received a dose of proconvulsant medication. *Id.* (citation omitted). Najm remarked that these results "mirror the natural history in a significant number of patients with [cortical dysplasias]…in whom the epileptic phenotype does not develop [until] an otherwise nonepileptic stressor such as trauma, acute infection, stress, sleep deprivation…leads to the transformation of a nonepileptic pathology into an epileptic phenotype." *Id.*

Petitioner also cited at article by Widdess-Walsh, et al. Peter Widdess-Walsh et al., *Electro-clinical and imaging characteristics of focal cortical dysplasia: Correlation with pathological subtypes*, 67 EPILEPSY RSCH. 25-33 (2005) (filed as Ex. 87) ("Widdess-Walsh"). Here, the authors reviewed 145 cases of patients with cortical dysplasias who underwent surgery between 1990 and 2002. *Id.* at 25. The age of epilepsy onset ranged from under one to 47 years. *Id.* at 28. The authors note that "a 'second hit' to an already dysplastic area may facilitate eventual epileptogenesis." *Id.* at 31.

Petitioner also filed three articles providing evidence that among patients with cortical dysplasias, the onset of epilepsy can occur at any point over the span of decades. First, Kasper, et al., reviewed the cases of 47 patients with refractory[16] temporal lobe epilepsy who had undergone surgical resection. Burkhard S. Kasper et al., *Temporal Lobe Microdysgenesis in Epilepsy Versus Control Brains*, 58 J. NEUROPATHOLOGY & EXPERIMENTAL NEUROLOGY 22-28, 22 (1999) (filed as Ex. 78) ("Kasper"). Kasper noted that the mean age at which epileptic onset occurred was 13.8 years, and that the range of ages at the time of onset was from one to 39 years. *Id.* at 23. Likewise, Fauser described 120 patients with epilepsy related to cortical dysplasia where the onset of their disease began between the ages of less than one year and 60. Fauser at 1909. Fauser noted that "it could be assumed that cortical dysplasia can exist for prolonged periods of time without giving

[16] "Patients are considered to have refractory epilepsy if disabling seizures continue despite appropriate trials of two antiseizure drugs, either alone or in combination." Jerome Engel, Jr., *Approaches to refractory epilepsy*, 17 ANN. INDIAN ACAD. NEUROLOGY S12-S17, S12 (2014).

rise to clinically manifest seizures." *Id.* at 1913. Finally, Tezer-Filek reported the case of a patient whose cortical dysplasia had been asymptomatic until his first seizure at the age of 74. Tezer-Filek at 467-68. The wide range of ages at which seizures begin in patients with cortical dysplasias provides some support for the idea that structural abnormality alone does not always trigger the onset of epilepsy.

Dr. Shinnar disagreed that the medical literature supports Dr. Kinsbourne's theory. First Shinnar Rep. at 6-7. Instead, he argued that I.H.'s cortical dysplasia is sufficient on its own to explain her clinical course without a second hit. *Id.* However, during his testimony, Dr. Shinnar acknowledged that a fever caused by a vaccination could lead to a seizure, especially in an infant. Tr. at 105.

On review of the evidence and testimony in the record, I conclude that Petitioner has shown that, at least in some cases, epilepsy in a patient with a cortical dysplasia is not a foregone conclusion but requires a second hit in order for clinical signs and symptoms to manifest.

3. DTaP Vaccine as Second Hit

In light of the foregoing, it remains to be determined whether the DTaP vaccine can be the second hit necessary to trigger clinical epilepsy in some cases. I find that it can.

Petitioner filed medical literature supporting the contention that the DTaP vaccine can cause febrile seizures. Sun conducted a large cohort study of more than 378,000 children born in Denmark between 2003 and 2008 to determine whether the increased risk of febrile seizures known to be associated with the whole-cell pertussis vaccine also applied to the acellular pertussis vaccine. Sun at 823. Sun concluded that "DTaP-IPV-Hib vaccination[17] was associated with an increased risk of febrile seizures on the day of the first 2 vaccinations given at 3 and 5 months, although the absolute risk was small." *Id.* They also found an increased risk of febrile seizures in children who received the pneumococcal vaccine along with the DTaP-IPV-Hib vaccine within one to three days of the second vaccination and on the day of the third vaccination. *Id.* at 827.

Respondent's own medical literature supports the idea that, in some cases, febrile seizures correlate with the development of epilepsy. In a book chapter, Dr. Shinnar stated that

> [f]ebrile seizures lasting longer than 20 minutes, however, although not causing cell death, are associated with long-lasting changes in h-channels. The h-channel is the hyperpolarization-activated cation channel, also known as the pacemaker channel, which can be either "excitatory" or "inhibitory". These changes are associated with increased susceptibility to seizures, although not with spontaneous seizures.

Shlomo Shinnar, *Febrile Seizures, in* SWAIMAN'S PEDIATRIC NEUROLOGY: PRINCIPLES & PRACTICE 790, 792 (Kenneth F. Swaiman et al. eds., 2012) (filed as Ex. A-1) (internal citations omitted). Two studies "found that prolonged febrile seizures (i.e., febrile status epilepticus) were

[17] Sun notes that DTaP, IPV, and Hib are administered as a combined vaccine in Denmark and that the acellular pertussis vaccine replaced the whole-cell variant in 2002. Sun at 823.

associated with an increased risk of subsequent epilepsy above that for a complex febrile seizure that was less prolonged." *Id.* at 794. "Whether febrile seizures are simply an age-specific marker of future seizure susceptibility or have a causal relationship with the subsequent epilepsy remains a matter of controversy." *Id.*

Dr. Shinnar elaborated on this theme as a co-author of a later edition of the same chapter, stating that two factors support the theory that febrile seizures are an age-specific marker of epilepsy rather than its cause.

> There is no increased incidence of epilepsy in populations with a high cumulative incidence of febrile seizures (e.g., 10% in Tokyo, Japan). Second, no evidence exists that treatment of febrile seizures alters the risk of subsequent epilepsy. However, newer data suggest that, while in most cases the link is not causal, there is a causal link between very prolonged febrile seizures, or febrile status epilepticus, and subsequent hippocampal injury, mesial temporal sclerosis, and temporal lobe epilepsy.

Syndi Seinfeld et al., *Febrile Seizures*, *in* SWAIMAN'S PEDIATRIC NEUROLOGY: PRINCIPLES & PRACTICE 505, 507 (Kenneth F. Swaiman et al. eds., 2017) (filed as Ex. A-2) (internal citations omitted).

Petitioner also filed medical literature in support of the theory that febrile seizures can alter neurological structures in such a way that subsequent seizures and epilepsy become more likely. Badawy stated that:

> [t]he relationship of neuronal plasticity to epilepsy is complex, with evidence that seizures themselves can alter ion channel gene expression and subunit stoichiometry, and that resistance to anti-epileptic drugs might be associated with alteration in the function of various channels. Further support for this comes from our recent findings of progressive changes in cortical excitability associated with refractory seizures.

Badawy at 1189. Further, Vezzani, et al., note that "pro-epileptogenic injuries" activate certain inflammatory pathways that cause seizures to recur, and additionally, that experiments which induce CNS inflammation mimicking infection cause a change in brain excitability and increase the likelihood that additional seizures will ensue. Annamaria Vezzani et al., *IL-1 receptor/Toll-like receptor signaling an infection, inflammation, stress and neurodegeneration couples hyperexcitability and seizures*, 25 BRAIN, BEHAVIOR, & IMMUNITY 1281-89, 1282 (2011) (filed as Ex. 26) (hereinafter "Vezzani"). The authors state that "[t]his set of experimental evidence is concordant with the clinical observations that inflammatory processes are induced in [the] brain following infection, … febrile seizures, status epilepticus, which are all events associated with the occurrence of symptomatic seizures and with an increased risk of developing epilepsy." *Id.*

Based on this evidence, I find that in some cases, a prolonged febrile seizure can lead to the development of epilepsy in a person with a cortical dysplasia. Accordingly, I find that

Petitioner has provided a sound and reliable medical theory by which the DTaP vaccine can cause a febrile seizure that leads to epilepsy. She has thus satisfied her burden under prong one of *Althen*.

B. *Althen* Prong Two

Under *Althen's* second prong, a petitioner must "prove a logical sequence of cause and effect showing that the vaccination was the reason for the injury." *Althen*, 418 F.3d at 1278. The sequence of cause and effect must be "'logical' and legally probable, not medically or scientifically certain." *Id.* A petitioner is not required to show "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* (omitting internal citations). *Capizzano v. Sec'y of Health & Hum. Servs*., 440 F.3d 1317, 1325 (Fed. Cir. 2006). Instead, circumstantial evidence and reliable medical opinions may be sufficient to satisfy the second *Althen* prong. *Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 U.S. Claims LEXIS 1023 at *75 (Fed. Cl. Spec. Mstr. July 30, 2012), *aff'd* 108 Fed. Cl. 743 (Fed. Cl. 2013).

The parties dispute the cause of I.H.'s first febrile seizure. Petitioner contends it was vaccine induced; Respondent's position on this issue has evolved. Respondent initially alleged that I.H.'s fever resulted from acute bronchiolitis due to RSV. *See* First Shinnar Rep. at 5, 10 (attributing I.H.'s fever to a viral illness); Second Shinnar Rep. at 2 (same); Resp's Pre-Hearing Brief at 21 ("Based on her initial diagnosis of RSV bronchiolitis and her fever upon admission, Dr. Shinnar concluded that I.H.'s RSV bronchiolitis was a febrile illness that triggered her initial febrile seizure."); Tr. at 100-01 (Dr. Shinnar testifying that "On March 7, 2013, you have an infant who we now know had a cortical dysplasia and who had an acute illness, and that combination is the cause of the seizure.").

The medical record does not support this interpretation. I.H. did have bronchiolitis that began two days before a medical visit on January 22, 2013. Ex. 8 at 14. Further, she tested positive for RSV on March 7, 2013, the day she was admitted to the hospital. Ex. 1 at 85, 89. However, this test does not indicate that I.H. had an active infection. Dr. Shinnar acknowledged at the entitlement hearing that these antibodies could have been a result of her illness six weeks prior. Tr. at 118. Further, I.H. was not described or assessed as a sick child on March 7, 2013. *See e.g.*, Ex. 1 at 88 ("Mother denies fever, cough, vomiting, diarrhea, ear ache, URI symptoms." … "Review of constitutional symptoms negative. Review of respiratory symptoms negative."). Additionally, when I.H. presented for her six-month well child exam the day before, on March 6, 2013, she was healthy; she did not have any signs or symptoms of a viral illness. Ex. 8 at 17-18. Her lungs were clear and her temperature was 97.1˚F. Ex. 8 at 17.

While Dr. Shinnar initially contended that I.H.'s acute illness plus her cortical dysplasia caused her to develop a fever (Tr. at 100-01), he later testified as follows:

> **Q.** In your opinion, what was the more likely than not cause of I.H.'s febrile seizure on March 7, 2013?
>
> **A.** A fever in the context of a strong family history of febrile seizures and a cortical dysplasia.

Tr. at 113. In his post hearing brief, Respondent argued as follows:

> Dr. Shinnar testified that I.H.'s first febrile seizure was caused by a fever in the context of a strong family history of febrile seizures and her cortical dysplasia. HT 113:21-101:2. Dr. Shinnar further testified that, although the DTaP vaccine was not a more-likely-than-not cause of I.H.'s initial febrile seizure, he could not completely rule it out because vaccines are known to sometimes cause a fever. *Id.* at 113:5-11. Regardless, Dr. Shinnar testified that the more likely cause of I.H.'s first febrile seizure was her family history of febrile seizures and her cortical dysplasia. HT 113:21-101:2. Accordingly, petitioner has not met her burden to produce preponderant evidence that I.H.'s DTaP vaccination caused her first febrile seizure.

Resp't's Post Hearing Brief at 11.

While it is uncontested that I.H.'s family history of febrile seizures and her cortical dysplasia made it more likely that she would suffer a febrile seizure, something still needed to cause the fever. As discussed above, the medical record does not support the notion that I.H. had a viral illness on March 7, 2013. Further, Dr. Shinnar conceded that vaccines can cause a fever, and that "anything that causes a fever in a young child can cause a febrile seizure…" Tr. at 105. Dr. Kinsbourne opined that I.H.'s DTaP vaccine caused her initial seizure on March 7, 2013. Second Kinsbourne Rep. at 3. There is no other source of fever documented in the medical record. Accordingly, I find there is preponderant evidence that the DTaP vaccine caused I.H.'s fever, which in turn caused her febrile seizure on March 7, 2013.

I.H.'s initial febrile seizure lasted for approximately 30 minutes. Ex. 1 at 87. The seizure "was focal, with a left sided onset, and then generalizing." Second Kinsbourne Rep. at 4. The seizure resulted in I.H. becoming limp and quiet for some period of time after the seizure, which Dr. Kinsbourne described as a "postictal" state. Tr. at 34, 72. Medical literature supports the point that status epilepticus[18] is associated with an increased risk of subsequent epilepsy. I.H.'s EEG performed on March 7, 2013 was abnormal "because of the presence of generalized spike and wave discharge indicative of generalized epilepsy." Ex. 1 at 133. The seizure was not a simple febrile seizure, and thus, according to Dr. Kinsbourne, "the onset seizure cannot be dissociated from the epilepsy that followed." Second Kinsbourne Rep. at 4. The evidence in this case is in accord with Petitioner's causal theory. A preponderance of the evidence demonstrates that I.H.'s postvaccination initial complex febrile seizure constituted the onset of her epilepsy. Petitioner has preponderantly demonstrated that I.H.'s DTaP vaccination "did cause" her seizure disorder and has thus established the second prong of *Althen*.

[18] Status epilepticus is "a prolonged series of seizures without return to full consciousness between them; the two major types are *convulsive s. epilepticus*, which is life-threatening, and *nonconvulsive s. epilepticus*, which is serious but not usually life-threatening." DORLAND'S, https://www.dorlandsonline.com /dorland/definition?id=108327 (last visited Jan. 30, 2024).

C. *Althen* Prong Three

The timing prong contains two parts. First, a petitioner must establish the "timeframe for which it is medically acceptable to infer causation" and second, he must demonstrate that the onset of the disease occurred in this period. *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542-43 (2011), *recons. denied after remand on other grounds*, 105 Fed. Cl. 353 (2012), *aff'd without op.*, 503 F. App'x 952 (Fed. Cir. 2013).

It is undisputed that I.H.'s initial seizure began within 24 hours of her DTaP vaccination. Joint Pre-Hearing Submission at 1. The Sun article demonstrates that there is an increased risk of febrile seizures on the day of DTaP vaccination. Specifically, Sun concluded that children who received the pneumococcal vaccine in conjunction with the DTaP-IPV-Hib vaccine "had an increased risk of febrile seizures …on the day of the third vaccination." Sun at 827. Dr. Kinsbourne testified that this is the case (Tr. at 76-77), and this point was not meaningfully contested by Dr. Shinnar. Taken together, this constitutes preponderant evidence that the timing of I.H.'s vaccine reaction, approximately 18 hours after DTaP vaccination, is medically appropriate. Petitioner has presented preponderant evidence in support of the third *Althen* prong.

VII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the affidavits and testimony, as well as the experts' opinions and medical literature, I conclude that Petitioner has established entitlement to compensation. An order regarding damages will issue shortly.

IT IS SO ORDERED.

s/ Katherine E. Oler
Katherine E. Oler
Special Master