In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Filed: December 17, 2019

ANDREA FULLER, on behalf of her Minor Child, B.F.,	*	PUBLISHED
Petitioner,	*	No. 15-1470V
v.	*	Special Master Nora Beth Dorsey
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Entitlement; Diphtheria-Tetanus-Acellular-Pertussis (DTaP) Vaccine; Measles Mumps Rubella (MMR) Vaccine; Febrile Seizures; Epilepsy.
Respondent.	*	

Curtis R. Webb, Twin Falls, ID, for petitioner.
Adriana R. Teitel, U.S. Department of Justice, Washington, DC, for respondent.

RULING ON ENTITLEMENT[1]

I. INTRODUCTION

On December 4, 2015, Andrea Fuller ("petitioner"), on behalf of her minor child, B.F., filed a petition under the National Vaccine Injury Compensation Program ("Vaccine Act" or "the Program"), 42 U.S.C. § 300aa-10 et seq. (2012).[2] Petitioner alleges that as a result of receiving a diphtheria-tetanus-acellular-pertussis ("DTaP") vaccine on March 12, 2014, B.F. suffered from complex febrile seizures and developed epilepsy, and a measles mumps rubella ("MMR")

[1] Because this Ruling contains a reasoned explanation for the action in this case, the undersigned is required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (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, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

[2] The National Vaccine Injury Compensation Program is set forth in Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C. §§ 300aa-10 to -34 (2012). All citations in this decision to individual sections of the Vaccine Act are to 42 U.S.C. § 300aa.

vaccine B.F. received on September 18, 2014 significantly aggravated B.F.'s condition. Amended Petition ("Am. Petition") at 2 (ECF No. 132). Respondent argued against compensation, stating that "this case is not appropriate for compensation under the terms of the Act." Respondent's Report ("Resp. Rept.") at 2 (ECF No. 15).

After carefully analyzing and weighing the evidence presented in this case in accordance with the applicable legal standards, the undersigned finds that petitioner provided preponderant evidence that the DTaP vaccine B.F. received on March 12, 2014 caused her to develop complex febrile seizures and epilepsy, which satisfies her burden of proof under Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1280 (Fed. Cir. 2005). Accordingly, petitioner is entitled to compensation.

II. BACKGROUND

A. Procedural History

Petitioner filed her claim on December 4, 2015, and she filed various medical records on January 12, 2016. See Petitioner's Exhibits ("Pet. Exs.") 1-13. She also filed a Statement of Completion with the medical records. (ECF No. 10). On April 22, 2016, respondent filed a Rule 4(c) Report, in which he recommended against compensation. Resp. Rept. at 2. Emphasizing that "temporal proximity alone is insufficient to establish specific causation," respondent maintained that petitioner failed to provide a reputable scientific theory that supports the claim that B.F. experienced seizures as a result of the DTaP vaccination she received and failed to address why the vaccination was more likely than not the cause of B.F.'s condition. Id. at 13. Respondent also stated that petitioner had yet to provide an expert report in support of her claim. Id.

On July 21, 2016, the undersigned granted the petitioner's motion to substitute counsel from Andrew Downing to Curtis Webb. Order dated July 21, 2016 (ECF No. 26). A status conference was held with Mr. Webb on August 16, 2016. Petitioner subsequently filed updated medical records on October 17, 2016. Pet. Exs. 14-20. Petitioner then filed an expert report from Dr. Marcel Kinsbourne on November 30, 2016, as well as several articles referenced in Dr. Kinsbourne's report on December 6, 2016. Pet. Exs. 21-32. Respondent filed responsive expert reports from Dr. Gregory Holmes and Dr. Hayley Gans on May 19, 2017, along with related medical literature on October 19, 2017. Respondent's Exhibits ("Resp. Exs.") A-D. Dr. Kinsbourne filed a supplemental expert report with supporting medical literature on November 13, 2017. Pet. Exs. 33-47.

During a status conference on January 30, 2018, the undersigned provided the parties with her preliminary opinions in the case. Rule 5 Order dated Jan. 31, 2018 (ECF No. 72). She stated that she found two positions set forth in petitioner's expert report compelling: that the vaccine was a substantial factor in triggering the onset of seizures, and that the subsequent MMR vaccine was a significant aggravation of B.F.'s. condition. Id. at 1. She encouraged the parties to consider settlement, but when the parties did not reach an agreement, she instead scheduled an entitlement hearing for October 16-18, 2018. Order dated Mar. 5, 2018 (ECF No. 78). In response to Dr. Kinsbourne's second report, respondent filed a supplemental report from Dr.

Holmes on April 6, 2018. Resp. Ex. E. Respondent also filed a supplemental report from Dr. Gans on April 10, 2018. Resp. Ex. F. On July 2, 2018, petitioner filed Dr. Kinsbourne's responses to the supplemental reports of Dr. Holmes and Dr. Gans. Pet. Exs. 51-52. Respondent filed second supplemental reports from Dr. Holmes and Dr. Gans on October 1, 2018. Resp. Exs. G-H.

Prior to the scheduled entitlement hearing, pre-hearing submissions were filed by petitioner on August 31, 2018 (ECF No. 99), and by respondent on October 1, 2018 (ECF No. 106). The parties then filed their joint prehearing submission on October 3, 2018. (ECF No. 108). During the hearing on October 16-17, 2018, petitioner, Dr. Kinsbourne, Dr. Holmes, and Dr. Gans each testified. Transcript ("Tr.") 3. Following the hearing, petitioner filed a post-hearing brief on January 2, 2019. (ECF No. 116). Petitioner also filed B.F.'s updated medical records and her school records on January 15, 2019, as requested during the hearing. Pet. Exs. 69-74. Respondent subsequently filed a post-hearing brief on May 3, 2019. (ECF No. 123). Petitioner then filed a reply brief on June 13, 2019, as well as an amended petition on July 3, 2019. (ECF Nos. 128, 132).

This matter is now ripe for adjudication.

B. Summary of Relevant Facts[3]

B.F. was born at thirty-five weeks on May 31, 2013, with no noted complications. Pet. Ex. 68 at 2. She was seen by her pediatrician, Dr. Robert Parkey, for routine well baby checks on June 3, June 14, July 1, and August 1, 2013. Pet. Ex. 3 at 43-55. At her four-month well check on November 13, 2013, Dr. Parkey noted that B.F. had good growth and development for her age. Id. at 62-64. She received Prevnar, rotavirus, Hib, DTaP, and IPV vaccinations at this visit. Id. at 64.

Petitioner took B.F. to the pediatrician on February 18, 2014, with complaints of eye irritation and drainage, cough, fever, and a runny nose for ten days. Pet. Ex. 3 at 67. She was diagnosed with an ear infection and conjunctivitis and prescribed an antibiotic. Id. at 69. B.F. had her nine-month well check on March 12, 2014. Id. at 71-73. Dr. Parkey noted that she was doing well developmentally and an examination of her nose, throat, ears, and chest was normal. Id. at 71-72. She received her third set of vaccinations during this visit, including DTaP, Hib, IPV, Hepatitis B, and Prevnar. Id. at 73.

On March 15, 2014, B.F. had a generalized febrile seizure while at a restaurant with her family. Pet. Ex. 3 at 74. This was her first seizure and she was subsequently seen in the St. Joseph's Regional Medical Center Emergency Room. Id. B.F.'s records from the emergency room indicate that her seizure "lasted for about ten minutes." Id. B.F. was described as being

[3] The parties set forth a Stipulation of Facts in their Joint Prehearing Submission. See Joint Prehr'g Submission, filed Oct. 3, 2018 (ECF No. 108). Most of the stipulated facts have been incorporated into this summary. The undersigned notes that "[a]lthough the parties agree on most of the facts relevant to the [p]etitioner's claim, they disagree on the medical and legal significance of those facts." Id. at 7.

postictal. Id. According to her mother, B.F.'s seizure activity "lasted between 10-15 minutes." Pet. Ex. 67 at 2. At the hospital, B.F. had a rectal temperature of 100.2°F, and it was noted that she had about a month of nasal congestion that had increased over the past few days, along with a cough. Pet. Ex. 3 at 74. A CAT scan was normal, but a chest x-ray showed evidence of bronchiolitis and a swab taken to test for respiratory syncytial virus ("RSV") was positive. Id. at 74, 76.

B.F. had a second febrile seizure on April 29, 2014, at 2:00 a.m., while she was sleeping. Pet. Ex. 3 at 108; Pet Ex. 67 at 3. Her parents heard gagging sounds and found her seizing in bed. Pet. Ex. 3 at 108. B.F. had a temperature of 100.5°F. Id. The total duration of the seizure is unknown, but the observed portion was five minutes and generalized. Id. Later that day, B.F. was seen by Dr. Parkey for upper respiratory symptoms including fever, runny nose, and a six-day history of vomiting. Id. at 96. Petitioner informed Dr. Parkey of the seizure that occurred during the night. Id.

B.F. had a third seizure while being bathed on April 30, 2014, and was again taken to the St. Joseph's Regional Medical Center ER, where she was noted to have a fever of 102.7°F. Pet. Ex. 3 at 88; Pet. Ex. 67 at 3. The seizure lasted for approximately thirty minutes in total, beginning fifteen minutes before she arrived at the hospital and continuing for fifteen to twenty minutes in the ER. Pet. Ex. 3 at 88-89. Her seizure stopped after administration of rectal Valium. Id. at 89. B.F. was admitted overnight for observation and an initial EEG study, and she was prescribed Tegretol for seizures. Id. at 115-16. The EEG performed on May 1 was interpreted by Dr. Arif Chowdhury, who described the result as an "[a]bnormal EEG recording due to asymmetry in the right frontotemporal area with sharp contouring activity suggestive of possible seizure." Id. at 100. B.F. was diagnosed with prolonged febrile seizures. Id. at 89. In the hospital discharge note on May 1, 2014, Dr. Parkey wrote that B.F. was admitted after "prolonged, presumptive atypical febrile seizure. . . . [She] had a similar prolonged initial febrile seizure on 03/15/2014." Id. at 115.

On May 2, 2014, B.F. was seen for follow-up by Dr. Parkey, who noted that B.F.'s first seizure "[w]as > 10 minutes in duration." Pet. Ex. 3 at 101-02. B.F.'s diagnosis was recurrent seizures. Id. at 103. Dr. Parkey ordered an MRI and neurology referral. Id. Dr. Parkey noted that "seizures seem atypical and are concerning for more than just simple febrile seizures." Pet. Ex. 3 at 104. After her most recent seizure, B.F. was described as tired and a little unsteady. Id.

B.F. was seen by neurologist Dr. Gregory MacDonald on May 6, 2014. Pet. Ex. 3 at 107. Dr. MacDonald wrote, "[B.F.] has had one, and possibly 2, complex (prolonged) febrile seizures. . . . She has a 40% risk of another febrile seizure after each one - complexity of prior one raises the risk that another one might be complex (prolonged, focal, or recurrent within 24 hours)." Id. The results of the MRI were "essentially normal." Id. Dr. MacDonald's record indicates that B.F.'s lifetime risk of epilepsy was low at 7%. Id. He stopped Tegretol and recommended that B.F. use Diastat as needed for prolonged or repetitive seizures. Id.

On May 11, 2014, B.F. had a forty-minute seizure that required three doses of Valium to be administered. Pet. Ex. 3 at 117-18. Her temperature was 100.8°F when the seizure began. Id. at 117. B.F. had a chest x-ray and was diagnosed with early pneumonia by the ER physician.

Id. at 118. The next day, petitioner took B.F. to see Dr. Parkey for a follow-up. Id. at 125. Petitioner stated that this seizure was different than previous ones because B.F. "seemed to know it was going to happen." Id. Because the seizure was very long and there did not appear to be a fever associated with it, Dr. Parkey concluded that it was reasonable to start AED therapy (an anti-epileptic drug) and prescribed Keppra. Id. at 128. B.F. was diagnosed with a seizure disorder. Id. at 127.

On June 5, 2014, petitioner sought a second opinion at Seattle Children's Hospital. Pet. Ex. 3 at 139-40. B.F. was seen in the hospital's Neurology Clinic and an EEG was performed. Id. The EEG showed "[n]o epileptiform discharges." Id. at 139. Dr. John Kurantani, the interpreting physician, noted that "[t]his EEG does not rule out diagnosis of epilepsy," and recommended clinical correlation. Id. After evaluating B.F., Drs. Michah Brasseur and James Owens concluded that "[i]t would not be unreasonable to continue to treat [her] with Keppra for short-term," but that Keppra would likely not prevent her from having additional febrile seizures. Id. at 143-44.

B.F. had another seizure accompanied by a fever on June 29, 2014, that lasted fifty minutes. Pet. Ex. 3 at 153; Pet. Ex. 11 at 24. She was taken to the ER and given two doses of Diastat to stop the seizure. Pet. Ex. 11 at 24. She was prescribed an antibiotic for her fever and cough and discharged from the hospital. Id. at 24-25. After this seizure, B.F was seizure free for almost three months, from June 29, 2014 to September 25, 2014.

At B.F.'s fifteen-month well check on September 18, 2014, Dr. Parkey noted that B.F. was doing well with an increased dose of Keppra and that her development and growth were normal. Pet. Ex. 3 at 154, 157. During this visit, B.F. received her fourth Hib and Prevnar vaccinations and her first MMR vaccination. Id. at 156. On September 25, 2014, petitioner called Dr. Parkey's office to inform him that B.F. had a febrile seizure that morning. Id. at 158. Petitioner had to administer two doses of Diastat to stop the seizure.[4] Id. About two months after, on November 23, 2014, B.F. was seen in the ER after having another seizure at home. Id. at 162. In the ER, her temperature was 101°F and her parents reported that she had a "croupy cough." Id. Her chest x-ray showed bronchiolitis and interstitial pneumonitis; she was prescribed an antibiotic for pneumonia and discharged. Id. at 162-64.

B.F. had her eighteen-month well check with Dr. Parkey on December 11, 2014. Pet. Ex. 3 at 166. Dr. Parkey noted that B.F. had approximately seven seizures over the past three months which "typically start[ed] with a 'scream', gurgling noise, facial twitching, eye deviation, some ext twitching." Id. Otherwise, B.F. demonstrated good growth and development for her age. Id. Petitioner was instructed to increase B.F.'s dose of Keppra and return for a two-year well check. Id. at 169.

[4] B.F.'s "parents had been instructed to administer [Diastat] if a seizure lasted more than five minutes, and to administer a second dose [] if the first dose did not stop the seizure. [B.F.'s] September 25, 2014 seizure did not stop until [her] mother had given her two doses of [Diastat]." Joint Prehr'g Submission at ¶ 42 (citing Pet. Ex. 14 at 54).

B.F. was seen by her neurologist, Dr. MacDonald, on March 31, 2015. Pet. Ex. 3 at 189. He noted that B.F. had 25 or more seizures in the past year, including some while taking Keppra and some that occurred in the absence of a fever or illness. Id. at 190. Dr. MacDonald diagnosed her with unspecified epilepsy. Id. at 189. Because B.F. was still having seizures on Keppra and experiencing side effects, Dr. MacDonald and petitioner decided to start B.F. on Zonegran in addition to Keppra. Id.

Between April and July 2015, petitioner called Dr. MacDonald's office several times to notify him that B.F. was having breakthrough seizures and more frequent seizures in general. See generally Pet. Ex. 5 at 93-113. B.F.'s medications were changed and adjusted periodically during this time. Id.

B.F. was seizure free for 127 days, until February 1, 2016, when petitioner called Dr. MacDonald's office to report that B.F. had two febrile seizures within twenty-four hours. Pet. Ex. 19 at 14. B.F. had her annual follow-up appointment with Dr. MacDonald shortly after, on March 11, 2016. Id. at 23. He reported that her general health was good and her development was normal. Id. at 24. Dr. MacDonald instructed petitioner that B.F. should remain on Topamax twice daily to manage her seizures. Id. at 22. Dr. MacDonald's goal was for B.F. to go at least one year without seizures, at which point he would consider a trial period without medication. Id.

B.F. had six seizures between her 2016 annual appointment with Dr. MacDonald and her 2017 annual appointment on March 20, 2017. Pet. Ex. 48 at 31. She had one febrile seizure in April 2016 but was then seizure free for 256 days until January 2017, when she had five seizures during the month. Id. All five of the January 2017 seizures were associated with illness and fever, and none required rescue medication. Id. Dr. MacDonald's report from the March 20, 2017 visit indicates that B.F. likely has "an idiopathic focal epilepsy, with secondarily generalized focal seizures with impairment of awareness" that "manifested as clinically generalized convulsive seizures." Id. at 29. He also stated that "genetic generalized epilepsy remains possible and would be more consistent with her breakthroughs with fever. GEFS+ [genetic epilepsy with febrile seizures plus] might be considered, but there is no corroborative family history." Id. Dr. MacDonald's diagnosis was refractory focal epilepsy. Pet. Ex. 48 at 30.

Throughout the summer of 2017, B.F. "had increased unprovoked seizures . . . as often as twice per week" and was "[i]ncontinent of urine and feces with several of them." Pet. Ex. 48 at 92. Dr. MacDonald increased her topiramate dosage in response, and as of her November 1, 2017 appointment with Dr. MacDonald, B.F. had been seizure free since the end of September 2017. Id. At the November 1, 2017 appointment, Dr. MacDonald changed B.F.'s medication from Topamax (topiramate) to Depakote. Id. at 89-90.

In late November 2017, B.F. had a series of seizures associated with an ear infection. Pet. Ex. 48 at 137. Within the first few weeks of December 2017, she had three seizures lasting less than five minutes each. Tr. 21-22. She had another seizure in March 2018 in the setting of a fever and respiratory virus that required petitioner to administer Klonopin. Id. at 22.

At the time of the hearing, B.F.'s most recent seizure had occurred on June 9, 2018. Pet. Ex. 70 at 56; Tr. 22. She started kindergarten in the fall of 2018 and was adjusting well to the traditional classroom setting. Tr. 22-23. Petitioner testified that B.F.'s doctors had not raised any concerns about developmental or cognitive delays, but there was a 504 Education Plan in place at B.F.'s school to provide necessary accommodations for her seizure disorder. Tr. 29-30. As of her December 5, 2018 appointment with her neurologist, B.F. was still taking Depakote to control seizure activity. Pet. Ex. 70 at 56.

C. Petitioner's Testimony

During the entitlement hearing, petitioner testified regarding her own experiences and the course of B.F.'s condition. Petitioner is a registered nurse who currently works as a case management supervisor. Tr. 6. B.F. was healthy when she received her vaccinations on March 12, 2014 and did not show any symptoms of a cold or other illness. Tr. 7. Petitioner indicated that B.F. seemed "a little bit tired" the morning before she experienced her first seizure, and on the day of the seizure, B.F. had "just a little tiny cough . . . , but nothing of alarm." Id. When B.F. experienced her first seizure on March 15, 2014, petitioner was feeding B.F. lunch at a restaurant when petitioner noticed that B.F.'s "eyes kind of fluttered back into the back of her head, and then she went limp." Tr. 8. Petitioner's aunt, who is an EMT and was also at the restaurant, helped care for B.F. and transport her to the hospital. Id. B.F. was still seizing upon arrival at the hospital but stopped shortly after she arrived. Id. Petitioner estimated that this first seizure was "between 10 and 15 minutes" in duration. Tr. 9.

Petitioner stated that B.F had several seizures throughout the spring before she began to improve in May 2014. Tr. 10. B.F. had another seizure on June 29, 2014, after which she was prescribed Tegretol, which was later switched to Dilantin. Tr. 14-15. B.F. had a seizure-free period until September 25, 2014, when petitioner testified that B.F. had a seizure that was "a little bit more intense," and required the administration of Diastat to stop seizure activity. Tr. 16-17. Petitioner described the effect of the Diastat on B.F., stating that it made her "very upset, very whiny, clingy." Tr. 17. B.F. received an MMR vaccination one week prior to this seizure, on September 18, 2014. Tr. 15.

Petitioner testified that B.F. continued to have seizures at varying frequency over the next few years, with the most recent occurring in June 2018. Tr. 18. With the advice of a speech therapist, petitioner began to keep a journal of B.F.'s seizures in order to determine potential causes or stressors. Tr. 20. Petitioner stated that while B.F. has seizures with and without illness, illness is one of her "major stressors." Tr. 24-25. B.F. started kindergarten in the fall of 2018 and "is tolerating school well," but petitioner expressed concerns about the impact of B.F.'s seizures on her "long-term future" and her ability to "learn as everybody else can." Tr. 22-23, 26. B.F. is in a mainstream classroom and has a 504 Plan in place with her school, but no Individualized Education Program ("IEP") at this time. Tr. 29. Petitioner stated that there are no concerns about developmental or cognitive delays at this time and Dr. MacDonald has not raised the issue of genetic testing. Tr. 30.

D. Febrile Seizures and Epilepsy

Febrile seizures occur in 2-5% of children under the age of five. Resp. Ex. A, Tab 31 at 1.[5] A febrile seizure is defined as "a seizure occurring in childhood after one month of age, associated with a febrile illness that is not caused by an infection of the central nervous system." Id. at 2. There are two types of febrile seizures: simple and complex. Id. Most febrile seizures are simple, and only approximately 20-30% are complex. Id. There is a disagreement between the parties here as to the definition of a complex febrile seizure, specifically as to the duration of the seizure, discussed more fully below.

Epilepsy is defined as "two unprovoked seizures." Tr. 144. Evidence shows "[febrile seizures] are associated with an increased risk of subsequent epilepsy, and that epilepsy develops in 2 to 4% of children with a history of [febrile seizures]." Resp. Ex. A, Tab 31 at 7. "[T]he risk of developing epilepsy can be as great as 57% in children with focal, prolonged, and recurrent [febrile seizures]." Id. The causes of febrile seizures are multifactorial and include "inflammation, brain pH, and genetic factors." Pet. Ex. 28 at 481-82.[6]

Febrile seizures have a "major genetic predisposition." Resp. Ex. A, Tab 29 at 2.[7] While multiple genes have been implicated, a "genetic tendency is clearly insufficient in itself to cause febrile seizures." Id. Due to the increased risk of long-term consequences attendant to complex seizures, there has been an effort to distinguish simple from complex febrile seizures. "Complex febrile seizures are followed by epilepsy in 4-15%" of children, whereas "simple febrile seizures have a risk of subsequent epilepsy of 2-3%." Id. at 3.

E. Expert Reports

1. Petitioner – Dr. Marcel Kinsbourne, M.D.

a. Background and Qualifications

Dr. Kinsbourne earned his B.A. from Christ Church at Oxford University. Pet. Ex. 22 at 1. He earned his Bachelor of Medicine (B.M.) and Bachelor of Surgery (B.Ch.) from Oxford University Medical School. Id. He also earned an M.A. and a Doctor of Medicine (D.M.) from Oxford University. Id. From 1974 to 1980, he was the Senior Staff Physician at the Hospital for Sick Children in Toronto, and also the Director of the Behavioral Neurology Unit at Boston University's Sargent College of Allied Health Professions from 1973 to 1982. Id. at 2. Dr.

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[5] Syndi Seinfeld & John M. Pellock, Recent Research on Febrile Seizures: A Review, 4 J. Neurology & Neurophysiology 1 (2013).

[6] Bo Feng & Zhong Chen, Generation of Febrile Seizures and Subsequent Epileptogenesis, 32 Neuroscience Bull. 481 (2016).

[7] Peter Camfield & Carol Camfield, Febrile Seizures and Genetic Epilepsy with Febrile Seizures *Plus* (GEFS+), 17 Epileptic Disorders 124 (2015).

Kinsbourne also served as the Director of the Behavioral Neurology Department at the Eunice Kennedy Shriver Center from 1980 to 1991. Id. Throughout his career, Dr. Kinsbourne has held teaching positions at various institutions. Id. He is currently a Research Professor at Tufts University's Center for Cognitive Studies. Id. Dr. Kinsbourne is licensed to practice medicine in the United Kingdom, Canada, North Carolina, Massachusetts, and Virginia. Id. at 1. Dr. Kinsbourne has served and is currently serving on a number of editorial boards, including Archives of Clinical Neuropsychology and Cognitive Neuropsychiatry. Id. at 3. He has authored or co-authored more than 400 publications. Id. at 5-39.

b. Opinion

Dr. Kinsbourne explains that vaccines activate the innate immune system by stimulating the release of pro-inflammatory cytokines, and such release "is a necessary condition for the genesis of the adaptive immunity which vaccination is intended to engender." Pet. Ex. 21 at 4. While pro-inflammatory cytokine release stimulated by a vaccine is almost always "perfectly normal," in certain individuals "the flow of cytokines is excessive . . . [and] initiates seizure activity." Tr. 35. Here, the vaccines stimulated or overstimulated the innate immune system in a child with unusual sensitivity, causing seizures. Tr. 35-36. Dr. Kinsbourne alleges that this cytokine release mechanism was "operative" in B.F.'s case, because "her onset seizure occurred within seventy-two hours of the vaccinations and it is the innate immune system that can mount so rapid a response." Pet. Ex. 21 at 4. Dr. Kinsbourne states that B.F.'s March 15, 2014 seizure was "within a medically reasonable temporal interval for seizure caused by DTaP," and thus, the vaccine was "a substantial factor in triggering the onset seizure, and most likely. . . the sole cause." Id. at 3-4.

On cross-examination, Dr. Kinsbourne was questioned whether B.F.'s first seizure occurred beyond three days of vaccination,[8] or outside the recognized time frame for a vaccine-related seizure associated with the DTaP vaccine. Dr. Kinsbourne testified that the day a vaccine is administered is considered "day zero." Tr. 59; see also Resp. Ex. F, Tab 1 at 3 ("The day of vaccination was defined as day 0.").[9] B.F. received her DTaP vaccine on March 12, 2014, and had her first seizure on March 15, 2014, "day three" after vaccination. Pet. Ex. 3 at 71-74. Dr. Kinsbourne cited the Braun et al. study to support his testimony. In Braun, "[o]f the 33 infants with known interval from vaccination to seizure, 11 (33%) had seizures the same day as vaccination, and 20 (61%) had seizure[s] 1 to 3 days after vaccination." Pet. Ex. 36 at 4.[10]

[8] Medical records show that B.F. had her March 12, 2014 vaccinations at approximately 8:30 a.m. and her first seizure occurred at approximately 12:30 p.m. on March 15, 2014. Pet. Ex. 3 at 71; Pet. Ex. 11 at 184.

[9] 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 JAMA 823 (2012).

[10] M. Miles Braun et al., Infant Immunization with Acellular Pertussis Vaccines in the United States: Assessment of the First Two Years' Data from the Vaccine Adverse Event Reporting

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On re-cross, Dr. Kinsbourne testified that DTaP vaccinations were sufficient to cause febrile seizures three days after vaccination. Tr. 94. The Institute of Medicine ("IOM") supports Dr. Kinsbourne's position that the temporal association between B.F.'s vaccination and first seizure is appropriate. The IOM discusses a study by Huang et al.,[11] which evaluated the risk of seizures in 433,654 children who received a total of 1,343,067 doses of DTaP. Pet. Ex. 45 at 540-41.[12] In this study, "[t]he exposed person-time period was defined as 0 to 3 days after DTaP vaccination." Id. at 540.

Although Dr. Kinsbourne acknowledges that B.F. tested positive for RSV, he argues that her "[RSV] did not cause any seizure activity" because her RSV infection was "quite longstanding," and she had a seizure only after vaccination. Pet. Ex. 21 at 3. There is no doubt, according to Dr. Kinsbourne, that B.F.'s vaccines contributed to her initial seizure. Tr. 33. Dr. Kinsbourne agrees that B.F. tested positive for RSV and had upper respiratory symptoms which were attributable to RSV. Tr. 44. He concedes that RSV could have played a role in the cause of B.F.'s first seizure but testified that RSV was not the sole cause. Id. Dr. Kinsbourne also opined that the combined effect of her underlying illness (her RSV infection) and vaccination caused B.F.'s first seizure. Tr. 81-82. Petitioner filed an article by Le Saux et al., which supports Dr. Kinsbourne's opinion as to concurrent viral infections in children with febrile seizures. In Le Saux, the authors examined the incidence of hospitalization for children with febrile seizures after receipt of pertussis and MMR vaccines. Pet. Ex. 41 at e348.[13] For purposes of the study, the authors "included children who had concurrent identification of common viral infections, which may have contributed to the seizure." Id. at e352.

Dr. Kinsbourne suggests that seizures lasting longer than ten minutes should be classified as complex, and therefore B.F.'s first seizure on March 15, 2014, which lasted at least ten minutes, is classifiable as a complex febrile seizure. Tr. 33; Pet. Ex. 21 at 4. Dr. Kinsbourne identified three reasons to support his opinion that B.F.'s first seizure was a complex febrile seizure. First, citing data in Hesdorffer et al., the median duration of a first seizure was approximately four minutes, and B.F.'s was certainly longer. Pet. Ex. 39 at 4.[14] Second, B.F.'s

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System (VAERS), 106 Pediatrics 1 (2000).

[11] Wan-Ting Huang et al., Lack of Association Between Acellular Pertussis Vaccine and Seizures in Early Childhood, 126 Pediatrics e263 (2010). Respondent filed this study as Respondent's Exhibit F, Tab 2.

[12] Comm. to Review Adverse Effects of Vaccines, Inst. of Med., Adverse Effects of Vaccines: Evidence and Causality (Kathleen Stratton et al. eds., 2011).

[13] 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).

[14] Dale C. Hesdorffer et al., Distribution of Febrile Seizure Duration and Associations with

(. . . continued)

treating physicians described her initial seizure as atypical, and later described it as complex. Pet. Ex. 3 at 75, 97, 107. Third, in studies, prolonged febrile seizures have been defined as lasting ten minutes. See, e.g., Pet. Ex. 39 at 6; Resp. Ex. E, Tab 5 at 1-2.[15]

Dr. Kinsbourne cites the Hesdorffer article to support his position that a seizure lasting ten minutes should be classified as complex. Hesdorffer studied the duration of first febrile seizures in 158 children. The median duration of first febrile seizures was approximately four minutes. Pet. Ex. 39 at 4. Using this data, the researchers determined cut off times for simple and complex febrile seizures by identifying a group with short first febrile seizures, and another with prolonged first febrile seizures. The data supported a definition of using ten minutes as the upper limit for simple febrile seizures. Id. at 6. They applied a more data driven approach, which Dr. Kinsbourne asserts should override the older clinical approach. Tr. 93. Trinka et al. also supports Dr. Kinsbourne's position as to seizure duration. The authors in Trinka state, "[o]bservations from a [] pediatric population show . . . two subgroups [], one with . . . brief seizures (<5 min) and the other . . . more prolonged seizures. In this study, a seizure that lasted >7 min was likely to be prolonged." Resp. Ex. A, Tab 21 at 3.[16]

According to Dr. Kinsbourne, a complex febrile seizure contributes to the probability of epilepsy. Tr. 39. He opines that B.F.'s March 15, 2014 seizure likely contributed to B.F.'s epilepsy because "[c]omplex febrile seizures have a much more significant risk of being followed by more febrile seizures and then afebrile seizures, meeting the definition of epilepsy." Tr. 38-39. The adage that "seizures beget seizures" still holds true in a subset of children, "whose first seizure causes changes in the brain, making neurons hyperexcitable and more prone to generate seizures than is normal." Tr. 40-41. Dr. Kinsbourne explained the mechanism underlying this process as follows. Vaccination triggers the release of chemicals (cytokines), which signal the brain to generate fever. Tr. 43. Neurons and glial cells emit more cytokines which cause inflammatory changes. Id. Inflammatory changes "can have the effect of permanently raising the level of excitability of neurons, particularly in the hippocampus, which is the main risk area for seizure generation." Id. Moreover, Dr. Kinsbourne opined that there is a cumulative effect each time a seizure occurs. Id.

Dr. Kinsbourne cites the Feng and Chen article in support of his theory. Inflammation, specifically the release of pro-inflammatory cytokines during fever, are thought to trigger febrile seizures. "[F]ever induces the production and release of [the cytokine] IL-1β, which subsequently triggers seizures. Seizures occur when the balance of neuronal excitation and inhibition is altered by neuronal inflammation." Pet. Ex. 28 at 482. "In turn, the seizure itself leads to inflammatory responses. Evidence from clinical observations and experiments shows that IL-1β contributes not only to the generation of [febrile seizures], but also to the epileptogenesis thereafter." Id. Thus, as Feng and Chen determined, the cytokine "IL-1β is a

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Development, 70 Annals Neurology 1 (2011).

[15] Anne T. Berg & Shlomo Shinnar, Complex Febrile Seizures, 37 Epilepsia 126 (1996).

[16] Eugen Trinka et al., A Definition and Classification of Status Epilepticus – Report of the ILAE Task Force on Classification of Status Epilepticus, 56 Epilepsia 1515 (2015).

substantial factor in the initiation of seizures and it also plays a role in the aftermath of prolonged [febrile seizures]." Id.

Dr. Kinsbourne also cites notes by Dr. MacDonald, B.F.'s treating neurologist, in support of his theory. Dr. MacDonald wrote that "each complex seizure makes it more likely that one has another such seizure." Tr. 43-44 (citing Pet. Ex. 16 at 4). Dr. Kinsbourne believes that a complex seizure can change the course of a child's seizure disorder and increase the risk of epilepsy. Dr. Kinsbourne cites a number of articles in support of his theory of causation. Vezzani et al. explains that "[s]eizures, the hallmarks of epilepsy, originate from synchronized aberrant firing of neuronal populations due to underlying hyperexcitability phenomena." Pet. Ex. 32 at 1281.[17] Clinical and experimental studies suggest that proinflammatory cytokines "contribute to aberrant neuronal excitability underlying seizures." Id. In animal studies, transient inflammation caused by seizures during "early life can alter neuronal excitability long-term." Id. at 1286. That is, "brain inflammation . . . appears to be responsible for these long-term neurological changes." Id. The "epileptic process" is described "as a disturbance of neuronal networks." Pet. Ex. 23 at 33.[18] Studies by Birca et al. and others "favor[] the hypothesis that connectivity changes are a consequence of atypical febrile seizures." Id. at 37.

Respondent's expert, Dr. Holmes, co-authored an article with Dr. Yehezkel Ben-Ari, which Dr. Kinsbourne also cites in support of his causal theory. The authors state that "increasing experimental animal data strongly suggest that frequent or prolonged seizures in the developing brain result in long-lasting sequelae." Pet. Ex. 34 at 1055.[19] During febrile seizures, pro-inflammatory cytokines increase, and these cytokines are thought to play a role "in febrile-seizure-induced changes in the brain." Id. at 1056. Experimental studies show that prolonged febrile seizures may cause "long-standing increased excitability." Id. Thus, the traditional idea that "seizures beget seizures" has received modern support. Id. at 1059-60.

In addition to opining that B.F.'s March 12, 2014 DTaP vaccine triggered the onset of B.F.'s seizure disorder, Dr. Kinsbourne also asserts that the MMR vaccine B.F. received on September 18, 2014 significantly aggravated her epilepsy disorder. Pet. Ex. 52 at 3. Prior to her MMR vaccine, B.F. had a three-month seizure-free interval. Id. He states that B.F.'s case meets the criteria for a significant aggravation because "prior to the administration of the MMR vaccine, [B.F.'s] seizures had been controlled by anti-epileptic monotherapy," but following the MMR vaccine, she had six seizures over a three-month period, and "her seizures became harder to control . . . to the point that her epilepsy was declared 'intractable.'" Pet. Ex. 21 at 2, 5; see also Pet. Ex. 52 at 3; Tr. 45-46.

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[17] Annamaria Vezzani et al., IL-1 Receptor/Toll-like Receptor Signaling in Infection, Inflammation, Stress and Neurodegeneration Couples Hyperexcitability and Seizures, 25 Brain Behav. & Immunity 1281 (2011).

[18] A. Birca et al., Enhanced EEG Connectivity in Children with Febrile Seizures, 110 Epilepsy Res. 32 (2015).

[19] Yehezkel Ben-Ari & Gregory L. Holmes, Effects of Seizures on Developmental Processes in the Immature Brain, 5 Lancet Neurology 1055 (2006).

Dr. Kinsbourne argues that there is a "causal relationship" between B.F.'s September 18, 2014 MMR vaccine and her September 25, 2014 seizure because "the risk interval for a seizure after MMR has been considered to be the second week after vaccination," and the seven-day period between B.F.'s vaccination and seizure is "within the acknowledged risk interval." Pet. Ex. 51 at 3; see also Tr. 48. He concludes that because "[t]he MMR vaccination initiated a sequence of events not explicable by any other factor," B.F.'s September 18, 2014 MMR vaccination "cause[d] the significant aggravation of [B.F.'s] seizure disorder by inducing a complex seizure." Pet. Ex. 21 at 5.

With regard to B.F.'s current condition, Dr. Kinsbourne opines that she has focal epilepsy, and that her EEG from November 2017 shows a primary epileptogenic focus in the right hemisphere with secondary generalization. Tr. 77-78, 87-90; see Pet. Ex. 48 at 92.

2. Respondent – Dr. Gregory Holmes, M.D.

a. Background and Qualifications

Dr. Holmes earned his B.S. from Washington and Lee University and his M.D. from the University of Virginia School of Medicine. Resp. Ex. B at 1. From 1979 to 1986, Dr. Holmes was a Staff Neurologist at Newington Children's Hospital and John Dempsey Hospital. Id. at 2. He became the Director of the Pediatric Epilepsy Program at Talmadge Hospital in 1986 and remained in there until 1988. Id. From 1988 to 2002, Dr. Holmes held a number of positions at Boston Children's Hospital, including Director of the Clinical Neurophysiology Laboratory and Epilepsy Program and Director of the Center for Research in Pediatric Epilepsy. Id. He is currently the Physician Leader of the Neurology Health Care Service at Fletcher Allen Health Care. Id. Dr. Holmes is board certified in pediatrics, clinical neurophysiology, and psychiatry and neurology, with special competence in child neurology. Id. at 1. Dr. Holmes is licensed in Connecticut, Georgia, Massachusetts, New Hampshire, and Vermont. Id. He is active in a number of professional organizations and serves on several editorial boards, including Epilepsy & Behavior and Epileptic Disorders. Id. at 7, 11-13. Dr. Holmes has written extensively on a number of topics; his CV lists him as the author or co-author of more than 300 publications and nearly 400 abstracts. Id. at 39-112.

b. Opinion

Dr. Holmes begins by explaining that "[t]he medical record does not support the idea that [B.F.'s] epilepsy was caused by vaccines," particularly because B.F. tested positive for RSV at the time of her initial seizure and RSV is "well known to cause febrile seizures." Resp. Ex. A at 11. He further alleges that there is "no indication in the medical record that vaccines exacerbated [B.F.'s] condition." Id. Dr. Holmes opines that "it is not unusual for the cause of the epilepsy to be unknown," as he believes it is in B.F.'s case. Id. He also notes that "none of [B.F.'s] caretakers endorsed the idea that [her] epilepsy is secondary to vaccination." Id. Dr. Holmes agrees with Dr. Kinsbourne that B.F. has focal epilepsy with secondary generalization, but

believes the etiology is probably genetic[20] and thus, her condition pre-existed the vaccinations at issue. Tr. 143.

Dr. Holmes addresses each of Dr. Kinsbourne's assertions individually. He first states that Dr. Kinsbourne "provide[d] no evidence that a vaccination resulted in the febrile seizure in [B.F.] or that a 10-minute febrile seizure resulted in epilepsy." Resp. Ex. A at 11. Similarly, Dr. Holmes finds "no evidence that the vaccinations [B.F.] received had any relationship to the subsequent development of epilepsy." Id. He notes that "[t]he link between DTaP and seizures of any type is weak," and it is unlikely that the vaccine would result in febrile seizures. Id. According to Dr. Holmes, even if B.F.'s vaccinations did in fact cause a febrile seizure, "there is no evidence that this seizure would cause epilepsy." Id. Dr. Holmes concludes that "even if one uses 10 minutes to define a complex febrile [seizure] there is no evidence that a 10 minute febrile seizure[] would cause epilepsy." Id. at 12. He defines a complex seizure as fifteen minutes in duration, focal,[21] or two or more seizures in twenty-four hours. Tr. 145.

Dr. Holmes opines that febrile seizures do not cause epilepsy unless they are focal or 30 minutes or longer (status epilepticus). Tr. 145-46, 162. Dr. Holmes states that the risk of developing epilepsy after a simple febrile seizure is only 2%. Tr. 146 (citing Resp. Ex. A, Tab 10 at 1-2).[22] However, if a child has a complex febrile seizure, the risk of epilepsy is higher. Tr. 147. He agrees that fever reduces the seizure threshold, but points to other triggers such as decreased sleep that also reduce the threshold. Tr. 156. While Hesdorffer uses ten minutes as the cutoff for a complex seizure, Dr. Holmes opines that the majority of physicians use a fifteen-minute cutoff. Tr. 157. He explained that "biologically, there is no evidence that a ten-minute seizure is any different than a 15-minute seizure." Tr. 160. Dr. Holmes concludes that B.F. had a simple febrile seizure lasting approximately ten minutes, and that it is biologically implausible for a seizure lasting ten minutes to cause brain damage or epilepsy. Tr. 159, 162, 170.

Dr. Holmes agreed with Dr. Kinsbourne that there can be functional changes after a seizure, but that does not mean that a child will develop epilepsy. Tr. 173. He believes that only prolonged or frequent seizures affect the neuronal network. Tr. 174-75. Quoting Berg and Shinnar, Dr. Holmes concludes that "brief seizures . . . do not appear to result in an escalating progressive syndrome leading to a permanent epileptic focus." Tr. 179 (quoting Resp. Ex. G, Tab 6 at 10).[23] Moreover, he opines that the simple seizure B.F. experienced on March 15, 2014

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[20] During the pendency of this claim, respondent was asked to consult with his expert, Dr. Holmes, as to whether genetic testing should be performed. Order dated July 11, 2017 (ECF No. 49). Dr. Holmes and petitioner's treating physician, Dr. MacDonald, agreed that genetic testing was not indicated in this case. Resp. Status Rept., filed Aug. 10, 2017, at 1.

[21] A focal seizure is a partial seizure. Dorland's Illustrated Medical Dictionary 1688 (32d ed. 2012).

[22] Karen B. Nelson & Jonas H. Ellenberg, Predictors of Epilepsy in Children Who Have Experienced Febrile Seizures, 295 New Eng. J. Med. 1029 (1976).

[23] Anne T. Berg & Shlomo Shinnar, Do Seizures Beget Seizures? An Assessment of the Clinical (. . . continued)

was probably caused by RSV, not vaccination. Tr. 185-86. Dr. Holmes testified that if B.F.'s initial seizure was partial or focal, her seizure would have met the criteria for a complex seizure. Tr. 204. He agrees that some of the seizures she had in 2014 could have been focal with secondary generalization. Tr. 203-04.

Next, Dr. Holmes responds to the significant aggravation claim. He concedes that "[t]he MMR vaccine is associated with an increased risk for febrile seizures, and it is possible that the febrile seizure on 9/25/14 was related to the immunization." Resp. Ex. A at 13. However, he highlights that "[B.F.] had multiple febrile seizures not associated with immunizations." Id. He also notes that Dr. Kinsbourne did not provide any "epidemiologic or mechanistic evidence" that a complex febrile seizure can significantly aggravate epilepsy. Resp. Ex. E at 3. Dr. Holmes explains that studies have "found no increased rate of epilepsy among children who had febrile seizures after MMR," as compared to those who had febrile seizures unrelated to vaccinations. Resp. Ex. A at 13 (quoting Resp. Ex. A, Tab 42, at 5).[24]

Dr. Holmes also opines that although B.F. had a febrile seizure seven days after receiving the MMR vaccine, she did not have another seizure for almost two months, and thus "there is no record of exacerbation." Resp. Ex. A at 13. Critically, Dr. Holmes notes that "fluctuations in seizure frequency is common in epilepsy," and do not necessarily indicate a causal connection between the MMR vaccine and the subsequent seizure. Resp. Ex. E at 3.

3. Respondent – Dr. Hayley Gans, M.D.

a. Background and Qualifications

Dr. Gans earned her B.A. from Connecticut College and her M.D. from SUNY Health Science Center at Syracuse. Resp. Ex. D at 1. Dr. Gans completed her post-graduate training at Stanford University School of Medicine in 1998 and has remained at Stanford since that time. Id. at 1-2. She is currently a Clinical Associate Professor in the Department of Pediatrics. Id. at 2. Dr. Gans is a licensed physician in the state of California, and she is board-certified in pediatrics and pediatric infectious diseases. Id. at 1. Dr. Gans has authored or co-authored nearly thirty peer reviewed articles and more than twenty abstracts. Id. at 4-6.

b. Opinion

Dr. Gans opines that B.F.'s March 12, 2014 vaccination did not cause or substantially contribute to her initial febrile seizure or epilepsy. Tr. 99. Instead, Dr. Gans believes B.F.'s RSV infection "is more probable as the cause of the neurologic disease than the immunization which would only be temporally related and even this timing is not supported." Resp. Ex. C at 5. Dr. Gans describes the potential mechanisms through which RSV can cause seizure activity,

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Evidence in Humans, 14 J. Clinical Neurophysiology 102 (1997).

[24] Mogens Vestergaard et al., MMR Vaccination and Febrile Seizures: Evaluation of Susceptible Subgroups and Long-Term Prognosis, 292 JAMA 351 (2004).

explaining that "[RSV] can activate mediators of inflammation, including cytokines . . . which have been shown to have direct and indirect effects on neuronal activity and to be correlated with neurological complications, including seizures." Id. at 6. Dr. Gans also explains that B.F.'s "normal neurological evaluations" and "mildly abnormal EEG" after her initial seizure were "very consistent with the seizures and diagnostic testing results seen with RSV infection." Id. at 7.

Dr. Gans disputes the claim that the DTaP vaccine may cause a febrile seizure three days after administration. Resp. Ex. C at 7. She states that "[i]n studies that have shown a temporal association with [febrile seizures and DTaP,] these have all occurred within 2 days and mostly on [the] day of vaccine administration." Id. Dr. Gans highlights that B.F. received "non-live" viral vaccines on March 12, 2014 and experienced a "complex (10 minute) febrile seizure" on March 15, 2014, three days later, "which is beyond the range for the risk period for seizures associated with these vaccines." Id. Dr. Gans also notes that B.F. "received the same vaccines at 2 and 4 months of age prior to 9 month administration without incident," and "[a]dverse events typically occur after the primary dose and not after several doses have been given without any reaction." Id.

While the studies cited by Dr. Gans showed no increased risk for seizures three days after DTaP vaccination, these findings were subject to limitations and confounding factors: misclassification and incomplete data for febrile seizures; the size of the study population; use of automated data that was sometimes inconsistent with medical records; the presence of fever that was poorly documented, thus febrile seizures were not completely and accurately documented; and increased use of acetaminophen/paracetamol, used to reduce fever after vaccination. Resp. Ex. F, Tab 1, at 6-8; Resp. Ex. F, Tab 2, at 5-6; Resp. Ex. F, Tab 3 at 6.[25]

During the hearing, Dr. Gans stated that she would "leave it to the neurologist [Dr. Holmes]" to discuss the epilepsy aspect of B.F.'s case. Tr. 119. However, Dr. Gans opines that "there is no evidence in the studies associating seizures with immunization to support the subsequent diagnosis of epilepsy." Resp. Ex. C at 8. Dr. Gans disagrees that the MMR vaccine B.F. received aggravated her seizure disorder, because she "suffered many seizures mostly associated with acute illnesses . . . with or without the administration of vaccines," and thus any "temporal association of vaccination with any given seizure event would be arbitrary." Id.; see also Tr. 99. Dr. Gans posits that the fact that "BF developed epilepsy and subsequently had many additional seizures often incited by infectious etiologies" is a "common event" that could "be predicted by [B.F.'s] risk factors alone," independent of any vaccinations. Resp. Ex. H at 3; Resp. Ex. C at 8.

On cross-examination, Dr. Gans testified that she could not say whether RSV, fever, or the combination caused B.F.'s first seizure on March 15, 2014. Tr. 122-23. Dr. Gans also agreed that the DTaP vaccine causes fever. Tr. 128. The mechanism by which DTaP causes

[25] Nick Andrews et al., Post-licensure Comparison of the Safety Profile of Diphtheria/Tetanus/Whole Cell Pertussis/Haemophilus Influenza Type B Vaccine and a 5-in-1 Diphtheria/Tetanus/Acellular Pertussis/Haemophilus Influenza Type B/Polio Vaccine in the United Kingdom, 28 Vaccine 7215 (2010).

fever is due to the immune response to the vaccine, which includes pro-inflammatory cytokines, and is "highly associated with fever." Tr. 128-29. She opines that RSV triggers fever in the same way. Tr. 129.

III. DISCUSSION

A. Standards for Adjudication

The Vaccine Act was established to compensate vaccine-related injuries and deaths. § 300aa-10(a). "Congress designed the Vaccine Program to supplement the state law civil tort system as a simple, fair and expeditious means for compensating vaccine-related injured persons. The Program was established to award 'vaccine-injured persons quickly, easily, and with certainty and generosity.'" Rooks v. Sec'y of Health & Human Servs., 35 Fed. Cl. 1, 7 (1996) (quoting H.R. Rep. No. 908 at 3, reprinted in 1986 U.S.C.C.A.N. at 6287, 6344).

Petitioner's burden of proof is by a preponderance of the evidence. § 300aa-13(a)(1). The preponderance standard requires a petitioner to demonstrate that it is more likely than not that the vaccine at issue caused the injury. Moberly v. Sec'y of Health & Human Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010). Proof of medical certainty is not required. Bunting v. Sec'y of Health & Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, petitioner must prove 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 & Human Servs., 165 F.3d 1344, 1352-53 (Fed. Cir. 1999)); see also Pafford v. Sec'y of Health & Human Servs., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner who satisfies this burden is entitled to compensation unless respondent can prove, by a preponderance of the evidence, that the vaccinee's injury is "due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B).

B. Factual Issues

A petitioner must prove, by a preponderance of the evidence, the factual circumstances surrounding her claim. 42 U.S.C. § 300aa–13(a)(1)(A). To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See Burns v. Sec'y of Health & Human Servs., 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See Cucuras v. Sec'y of Health & Human Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." Sanchez v. Sec'y of Health & Human Servs., No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing Blutstein v. Sec'y of Health & Human Servs., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

There are situations in which compelling 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 & Human Servs., 69 Fed. Cl. 775, 779 (2006) ("[L]ike 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 v. Sec'y of Health & Human Servs., No. 03-1585V, 2005 WL 6117475, at *19 (Fed. Cl. Spec. Mstr. Dec. 12, 2005) ("[W]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." (quoting Murphy v. Sec'y of Health & Human Servs., 23 Cl. Ct. 726, 733 (1991), aff'd per curiam, 968 F.2d 1226 (Fed. Cir. 1992))). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. Andreu v. Sec'y of Health & Human Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); Bradley v. Sec'y of Health & Human Servs., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

Despite the weight afforded medical records, special masters are not bound rigidly by those records in determining onset of a petitioner's symptoms. Valenzuela 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. 90-1754V, 1994 WL 67704, at *3 (Fed. Cl. Spec. Mstr. Feb. 18, 1994) (Section 13(b)(2) "must be construed so as to give effect also to § 13(b)(1) which directs the special master or court to consider the medical records (reports, diagnosis, conclusions, medical judgment, test reports, etc.), but does not require the special master or court to be bound by them").

C. Causation

To receive compensation through the Program, petitioner must prove either (1) that B.F. suffered a "Table Injury"—i.e., an injury listed on the Vaccine Injury Table—corresponding to a vaccine that she received, or (2) that B.F. suffered an injury that was actually caused by a vaccination. See §§ 300aa-13(a)(1)(A), 11(c)(1); Capizzano v. Sec'y of Health & Human Servs., 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Because petitioner does not allege that B.F. suffered a Table Injury, she must prove that a vaccine B.F. received caused her injury. To do so, she must establish, by preponderant evidence: (1) a medical theory causally connecting the vaccine and B.F.'s injury ("Althen Prong One"); (2) a logical sequence of cause and effect showing that the vaccine was the reason for B.F.'s injury ("Althen Prong Two"); and (3) a showing of a proximate temporal relationship between the vaccine and B.F.'s injury ("Althen Prong Three"). § 300aa–13(a)(1); Althen, 418 F.3d at 1278.

The causation theory must relate to the injury alleged. The petitioner must provide a sound and reliable medical or scientific explanation that pertains specifically to this case, although the explanation need only be "legally probable, not medically or scientifically certain." Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioner cannot establish entitlement to compensation based solely on her assertions; rather, a vaccine claim must be supported either by medical records or by the opinion of a medical doctor. § 300aa-13(a)(1). In determining whether petitioner is entitled to compensation, the special master shall consider all material in the record, including "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation." § 300aa-13(b)(1)(A). The undersigned must weigh the submitted evidence and the testimony of the parties' proffered experts and rule in petitioner's favor when the evidence weighs in her favor. See Moberly, 592 F.3d at 1325-26 ("Finders of fact are entitled—indeed, expected—to make determinations as to

the reliability of the evidence presented to them and, if appropriate, as to the credibility of the persons presenting that evidence."); Althen, 418 F.3d at 1280 (noting that "close calls" are resolved in petitioner's favor).

D. Analysis of Factual Issues

In their joint prehearing submission, the parties identify a number of issues that require resolution. Generally, these issues will be resolved in the causation analysis discussion below. However, one issue is factual in nature, and will be discussed here: whether the 10-minute seizure that B.F. suffered on March 15, 2014 was a "complex" seizure. The undersigned finds that the seizure B.F. suffered on March 15, 2014 was a "complex" seizure based on expert opinion, medical literature, medical records, and records of treating physicians.

Both Dr. Kinsbourne and B.F.'s treating physicians classify B.F.'s March 15, 2014 seizure as complex. Dr. Kinsbourne suggests seizures that last at least ten minutes, like B.F.'s March 15, 2014 seizure, are complex. Tr. 33; Pet. Ex. 21 at 4. Although Dr. Kinsbourne acknowledged that "the cut-off point between a simple and a complex febrile seizure has often been set at 15 minutes, recent studies have favored a shorted time span." Pet. Ex. 33 at 2. For example, articles by Hesdorffer and Trinka found prolonged, complex seizures are more than ten and seven minutes respectively, supporting Dr. Kinsbourne's position. Pet. Ex. 39 at 6; Resp. Ex. A, Tab 21 at 3.

In her expert report, Dr. Gans cites to notes from treating physicians, Dr. MacDonald and Dr. Robert Parkey, which label B.F.'s March 15, 2014 seizure as complex. Resp. Ex. C at 4. Specifically, Dr. MacDonald assessed B.F. with complex febrile seizures and Dr. Parkey noted B.F.'s "prolonged initial febrile seizure on [March 15, 2014]" during a later visit. Pet. Ex. 3 at 107, 115. Dr. Parkey noted B.F.'s "seizures seem atypical." Id. at 104. Dr. Theodore Krisher, the emergency room consulting physician on March 15, 2014, also noted B.F.'s seizure was atypical and "prolonged." Id. at 75.

Although Dr. Holmes opines that B.F.'s initial seizure on March 15, 2014 was a simple febrile seizure, the undersigned finds the evidence does not support his opinion. According to Dr. Holmes, most physicians use a fifteen-minute cutoff. However, as Dr. Holmes testified, "biologically, there is no evidence that a ten-minute seizure is any different than a 15-minute seizure." Tr. 160. In fact, in a supplemental report, Dr. Holmes cites an article by Berg and Shinnar, which notes that both ten and fifteen minutes have been used to describe complex seizures. Resp. Ex. E, Tab 5 at 1. However, Berg and Shinnar chose to define "[a] seizure [as] prolonged if it lasted [more than or equal to] 10 min[utes]." Id. at 2.

Although both ten and fifteen minutes have been used to differentiate between a simple and complex seizure, recent studies have used ten minutes. Because B.F.'s initial seizure was approximately ten minutes in length, and described as atypical and prolonged, the undersigned concludes that B.F. suffered a complex seizure on March 15, 2014.

E. Causation Analysis

1. Althen Prong One

Under Althen Prong One, petitioner must set forth a medical theory explaining how the received vaccine could have caused the sustained injury. Andreu, 569 F.3d at 1375; Pafford, 451 F.3d at 1355-56. Petitioner's theory of causation need not be medically or scientifically certain, but it must be informed by a "sound and reliable medical or scientific explanation." Knudsen, 35 F.3d at 548; see also Veryzer v. Sec'y of Health & Human Servs., 98 Fed. Cl. 214, 223 (2011) (noting that special masters are bound by both § 13(b)(1) and Vaccine Rule 8(b)(1) to consider only evidence that is both "relevant" and "reliable"). If petitioner relies upon a medical opinion to support her theory, the basis for the opinion and the reliability of that basis must be considered in the determination of how much weight to afford the offered opinion. See Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1347 (Fed. Cir. 2010) ("The special master's decision often times is based on the credibility of the experts and the relative persuasiveness of their competing theories."); Perreira v. Sec'y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir. 1994) (stating that an "expert opinion is no better than the soundness of the reasons supporting it" (citing Fehrs v. United States, 620 F.2d 255, 265 (Ct. Cl. 1980))).

Petitioner has proffered preponderant evidence of a plausible medical theory. The first tenet of Dr. Kinsbourne's medical theory is that vaccination can cause the release of pro-inflammatory cytokines, which can trigger complex febrile seizures. Petitioner provided current medical support for this theory. To summarize, Dr. Kinsbourne explains that "[v]accinations activate the innate immune system, which enables adaptive immunity to develop," by stimulating the release of pro-inflammatory cytokines. Pet. Ex. 21 at 4. When the cytokine release is excessive, seizures can occur. Tr. 35. Vaccine-associated release of pro-inflammatory cytokines is operative in a case where the seizure occurs within a medically reasonable temporal interval. Pet. Ex. 21 at 3-4. Dr. Kinsbourne testified DTaP vaccination is operative in a case where a seizure occurs within three days after the date of administration, which is defined as day zero. Tr. 33-35.

The second tenet of Dr. Kinsbourne's theory is that "seizures beget seizures." In a subset of children, the first seizure causes changes in the brain, such that further seizures may be more likely. In support of this theory, Dr. Kinsbourne cites Dr. MacDonald's notes, in which he wrote that with each complex seizure, it is more likely that another such seizure will occur. Tr. 43-44 (citing Pet. Ex. 16 at 4). Dr. Kinsbourne also cites various articles in support of his theory that seizures beget seizures, which can eventually lead to epilepsy. See, e.g., Pet. Exs. 23, 28, 32, 34, 39. For example, Hesdorffer writes "prolonged febrile seizures are associated with an increased risk of developing epilepsy." Pet. Ex. 39 at 6. Feng and Chen explain that the release of cytokines "contribute[] not only to the generation of [febrile seizures], but also to the epileptogenesis thereafter." Pet. Ex. 28 at 482. In their article, Ben-Ari and Holmes quote William Gowers, a distinguished neurologist, who stated, "[t]he tendency of the disease [epilepsy] is to self-perpetuation; each attack facilitates the occurrence of another, by increasing the instability of the nerve elements." Pet. Ex. 34 at 1059. Ben-Ari and Holmes provide support that prolonged febrile seizures may cause "long-standing increased excitability." Id. at 1056.

While respondent relies heavily on statistical significance in arguing against Dr. Kinsbourne's theory, the undersigned is not bound by statistical data in this context where B.F. was ultimately diagnosed with epilepsy. Accordingly, the undersigned finds Dr. Kinsbourne credible, and with Dr. MacDonald's notes and supporting medical literature, petitioner has set forth a sound and reliable medical theory, satisfying Althen Prong One.

2. Althen Prong Two

Under Althen Prong Two, petitioner must prove by a preponderance of the evidence that there is a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278). "Petitioner must show that the vaccine was the 'but for' cause of the harm . . . or in other words, that the vaccine was the 'reason for the injury.'" Pafford, 451 F.3d at 1356 (internal citations omitted).

In evaluating whether this prong is satisfied, the opinions and views of the vaccinee's treating physicians are entitled to some weight. Andreu, 569 F.3d at 1367; Capizzano, 440 F.3d at 1326 ("[M]edical 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 trustworthy evidence, since they are created contemporaneously with the treatment of the vaccinee. Cucuras, 993 F.2d at 1528. The petitioner need not make a specific type of evidentiary showing, i.e., "epidemiologic studies, rechallenge, the presence of pathological markers or genetic predisposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." Capizzano, 440 F.3d at 1325. Instead, petitioner may satisfy her burden by presenting circumstantial evidence and reliable medical opinions. Id. at 1325–26.

The experts agree that the first seizure was triggered by a fever. Tr. 43 (Dr. Kinsbourne), 214-15 (Dr. Holmes). However, Dr. Kinsbourne opines the DTaP vaccine contributed to B.F.'s seizure, while Dr. Holmes believes the RSV infection likely caused the initial seizure. As a foundational matter, it is important to note that "respondent accepts that the DTaP vaccine can cause a fever, which in turn can cause a febrile seizure." Resp. Posthr'g Br., filed May 3, 2019, at 19 (citing Resp. Ex. A at 11); see also Tr. 117-18, 128-29. The issue here is whether the DTaP vaccination was a substantial contributing factor to B.F.'s initial seizure.

The undersigned finds petitioner provided preponderant evidence that the DTaP vaccination B.F. received on March 12, 2014 was a substantial contributing factor to her initial seizure on March 15, 2014. Dr. Kinsbourne opines, and the medical literature supports, that DTaP vaccinations can cause febrile seizures three days after administration. Tr. 33-35, 94; see

Pet. Exs. 36, 37,[26] 40,[27] 41, 61;[28] Resp. Ex. F, Tab 1 at 5 tbl.2. As discussed above, the date of vaccination is considered "day zero," which is supported by medical literature presented by both petitioner and respondent. See Pet. Ex. 36 at 4; Resp. Ex. F, Tab 1 at 3. Thus, B.F.'s initial seizure on March 15, 2014 occurred on "day three." Because B.F.'s initial seizure occurred on day three, Dr. Kinsbourne argues that the vaccination was a substantial contributing factor to B.F.'s initial seizure since it occurred in a medically reasonable temporal interval. Pet. Ex. 21 at 3-4.

Dr. Holmes opines that the RSV infection likely caused B.F.'s initial seizure. Dr. Holmes notes RSV is well known to cause febrile seizures. Resp. Ex. A at 11. Dr. Gans adds that "[RSV] can activate mediators of inflammation, including cytokines," similar to the inflammatory response that occurs after vaccination. Resp. Ex. C at 6; Tr. 128-29. However, as Dr. Gans testified, it is impossible to differentiate the exact cause of the first seizure "when a child presents with an infection that has neurologic complications as well as a fever." Tr. 122-23. Dr. Kinsbourne concedes that RSV could have played a role in the cause of the first seizure but opines that it is not the sole cause because the RSV infection was longstanding, and B.F. had her initial seizure only after vaccination. Tr. 44; Pet Ex. 21 at 3. He believes that the combined effect of the underlying RSV infection with the vaccination caused B.F.'s initial seizure. Tr. 81-82. Although B.F. did not appear sick on the date of vaccination, Dr. Gans testified that an RSV infection can be asymptomatic. Tr. 125.

The undersigned finds B.F.'s DTaP vaccination was a substantial factor in causing B.F.'s initial seizure. See Shyface, 165 F.3d at 1352-53 (finding petitioner must prove "that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury"). In Shyface, although the petitioner did not prove the vaccine to be the sole cause of the injury, "the requirements of the Vaccine Act [were] met *prima facie* upon proof of the substantial factor criterion." Id. at 1353. Thus, petitioner does not need to prove the DTaP vaccine was the sole cause of B.F. condition, only that it was a but-for cause as well as a substantial factor in bringing about B.F.'s condition.

[26] Dennis A. Conrad & Hal B. Jensen, Using Acellular Pertussis Vaccines for Childhood Immunization: Potential Benefits Far Outweigh Potential Risks, 105 Postgraduate Med. 165 (1999).

[27] 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 Combines with Diphtheria and Tetanus Toxoids, 21 Pediatric Infectious Disease J. 781 (2002).

[28] M.A. Überall et al., Severe Adverse Events in a Comparative Efficacy Trial in Germany in Infants Receiving Either the Lederle/Takeda Acellular Pertussis Component DTP (DTaP) Vaccine, the Lederle Whole-Cell Component DTP (DTP) or DT Vaccine, 89 Dev. Biological Standardization 83 (1999).

Regardless of whether the RSV infection attributed to B.F.'s initial seizure, it is not the sole cause. As petitioner explained, B.F.'s initial seizure occurred only after administration of the DTaP vaccine and within a medically recognized time frame. The DTaP vaccine is known to cause seizures within three days of administration, which occurred here. Simply because B.F. tested positive for RSV on the date of vaccination does not preclude the finding that the vaccine was a substantial contributing factor in B.F.'s initial seizure. Although the March 12, 2014 vaccination was B.F.'s third dose of DTaP, and B.F. had no adverse reactions from previous vaccinations, studies have shown "[r]ates of fever [are] highest after DTaP [is] given as the third and fourth doses." Pet. Ex. 40 at 783. Petitioner has demonstrated a "logical sequence of cause and effect showing that the vaccination was the reason for the injury." Capizzano, 440 F.3d at 1324 (quoting Althen, 418 F.3d at 1278).

As discussed previously under Althen Prong One, Dr. Kinsbourne opines that seizures beget seizures, which can lead to epilepsy. He argues that B.F.'s initial seizure likely contributed to her epilepsy because complex febrile seizures are more likely to lead to more seizures and epilepsy. Tr. 38-39. Dr. Holmes agrees that the "risk of epilepsy following a febrile seizure is higher than in children without febrile seizures." Resp. Ex. G at 1; see also Resp. Ex. A, Tab 10 at 1 (noting that "[a]ll relevant studies agree that children who have had one or more febrile seizures are more likely to become epileptic than children who have had no febrile seizures"). Dr. Holmes also agrees that there can be functional changes after a seizure. Tr. 171-73. He testified that "seizures can change the brain and perhaps make them more susceptible to seizures, but it doesn't necessarily lead to epilepsy." Tr. 210. Dr. Holmes believes that only prolonged or frequent seizures affect the neuronal network. Tr. 173-74. He also argues that some no longer view complex febrile seizures as the cause of the development of epilepsy. Tr. 146-48.

However, as briefly discussed in Althen Prong One, numerous medical articles describe febrile seizures as a potential cause of epilepsy. As Dr. Holmes testified, risk of epilepsy follows a simple febrile seizure, but the risk is higher after a child has a complex febrile seizure. Tr. 146-47. In fact, Dr. Holmes stated, "[i]f you have one prolonged febrile seizure, you may have another prolonged febrile seizure." Tr. 149. As the undersigned has already determined, B.F.'s initial seizure was complex. Additionally, the medical records show that B.F. suffered other complex, prolonged seizures. See Pet Ex. 3 at 88-89, 117; Pet. Ex. 11 at 24.

The undersigned found petitioner's Althen Prong One theory persuasive and now finds petitioner, by preponderant evidence, has shown that the DTaP vaccine was the reason for B.F.'s initial seizure and epilepsy. Accordingly, petitioner has satisfied Althen Prong Two.

3. Althen Prong Three

Althen Prong Three requires petitioner to establish a "proximate temporal relationship" between the vaccination and the injury alleged. Althen, 418 F.3d at 1281. That term has been equated to mean a "medically acceptable temporal relationship." Id. The petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disease'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). The explanation for what is a medically acceptable time frame must also coincide with the

theory of how the relevant vaccine can cause the injury alleged (under Althen Prong One). Id.; Koehn v. Sec'y of Health & Human Servs., 773 F.3d 1239, 1243 (Fed. Cir. 2014); Shapiro v. Sec'y of Health & Human Servs., 101 Fed. Cl. 532, 542 (2011), recons. den'd after remand, 105 Fed. Cl. 353 (2012), aff'd mem., 503 F. App'x 952 (Fed. Cir. 2013).

The undersigned finds petitioner provided preponderant evidence of a proximate temporal relationship between B.F.'s March 12, 2014 DTaP vaccination and B.F.'s March 15, 2014 complex febrile seizure. As discussed above, DTaP vaccinations can cause febrile seizures three days after administration. Because B.F.'s initial seizure occurred on day three, the undersigned finds petitioner established a medically acceptable time frame.

F. Alternative Causation

Because the undersigned concludes that petitioner has established a prima facie case, petitioner is entitled to compensation unless respondent can put forth preponderant evidence "that [B.F.'s] injury was in fact caused by factors unrelated to the vaccine." Whitecotton v. Sec'y of Health & Human Servs., 17 F.3d 374 (Fed. Cir. 1994), rev'd on other grounds sub nom., Shalala v. Whitecotton, 514 U.S. 268 (1995); see also Walther v. Sec'y of Health & Human Servs., 485 F.3d 1146, 1151 (Fed. Cir. 2007). As discussed above, the undersigned found the RSV infection was not the sole cause of B.F.'s condition, and that B.F.'s DTaP vaccination was a but-for cause as well as a substantial factor in bringing about her condition. See Shyface, 165 F.3d at 1352-53. Thus, respondent did not prove by a preponderance of evidence that B.F.'s injury is "due to factors unrelated to the administration of the vaccine." § 300aa-13(a)(1)(B).

G. Significant Aggravation Claim

Because the undersigned finds petitioner provided preponderant evidence under Althen that the DTaP vaccine B.F. received on March 12, 2014 caused her to develop complex febrile seizures and epilepsy, petitioner is entitled to compensation. Thus, the undersigned does not need to address whether petitioner is entitled to compensation under the claim that the MMR vaccine administered on September 18, 2014 significantly aggravated B.F.'s condition since the undersigned has already determined petitioner is entitled to compensation.

IV. CONCLUSION

For the reasons discussed above, the undersigned finds that petitioner has established by preponderant evidence that she is entitled to compensation. A separate damages order will issue.

IT IS SO ORDERED.

s/Nora Beth Dorsey
Nora Beth Dorsey
Special Master