

**In the United States Court of Federal Claims**

**OFFICE OF SPECIAL MASTERS**

**No. 18-1705V**

Filed: May 30, 2024

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 JUSTIN FISHER, on behalf of A.F., \*  
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 Petitioner, \*  
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 v. \*  
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 SECRETARY OF HEALTH AND \*  
 HUMAN SERVICES, \*  
 \*  
 Respondent. \*  
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*Mark Sadaka*, Law Offices of Sadaka Associates, LLC, Englewood, N.J., for Petitioner  
*Voris Johnson*, U.S. Department of Justice, Washington, DC, for Respondent

**DECISION ON ENTITLEMENT<sup>1</sup>**

**Oler**, Special Master:

On November 2, 2018, Justin Fisher (“Petitioner” or “Mr. Fisher”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. § 300aa-10, *et seq.*<sup>2</sup> (the “Vaccine Act” or “Program”) on behalf of his minor daughter, A.F. The petition alleges that A.F. developed acute disseminated encephalomyelitis (“ADEM”) that was either caused-in-fact or significantly aggravated by one or more of the vaccines she received on November 3, 2015. Pet. at 1, ECF No. 1.

<sup>1</sup> Because this Decision 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 Decision 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.

<sup>2</sup> 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).

Upon review of the evidence in this case, I find that Petitioner has not established by preponderant evidence that the vaccines A.F. received caused her condition. The petition is accordingly dismissed.

### **I. Procedural History**

Mr. Fisher filed his petition on November 2, 2018. Pet. at 1. He filed medical records (Exs. 1-8) followed by a statement of completion on February 21, 2019. ECF No. 12.<sup>3</sup> Respondent submitted his Rule 4(c) Report on June 13, 2019, stating that “petitioner is not entitled to compensation under the terms of the Act.” Resp’t’s Rep. at 2, ECF No. 15.

Respondent identified several missing medical records and requested that Petitioner file those documents. ECF No. 16. Petitioner filed additional medical records on August 20, 2019 and December 16, 2019. Exs. 9-12.

The parties then filed expert reports in support of their respective positions. (Ex. 13, Expert Report from Dr. David Younger; Exs. A and C, Responsive Expert Reports from Dr. Gregory Holmes and Dr. You-Wen He).

After these filings, I requested additional information from the parties. As a result, they submitted additional expert reports. (Ex. E, Expert Report from Dr. Holmes, Ex. 22, Expert Report from Dr. Alberto Martinez-Arizala, Ex. F, Responsive Expert Report from Dr. Holmes). Subsequent to these filings, I conducted a Rule 5 Conference where I tentatively found that A.F.’s ADEM was more likely caused by her preceding viral infection than by the November 3, 2015 vaccinations. ECF No. 55. I suggested that Petitioner’s counsel speak with Mr. Fisher about dismissing his petition. I gave counsel 30 days to discuss my preliminary findings with his client and then submit a status report. *Id.*

On May 10, 2022, Petitioner filed a status report requesting a decision on the evidentiary record. ECF No. 59. I set a briefing schedule based on this request. *See* Scheduling Order dated May 11, 2022. However, on August 8, 2022, Petitioner filed a status report contending that A.F. displayed indications of encephalopathy with no documented signs of infection. Petitioner asked, “Does the Court want to hear from the petitioner’s expert on this matter?” ECF No. 63 at 3. I granted the parties additional time to file expert reports on this issue. Petitioner filed an expert report from Dr. Martinez-Arizala. Ex. 41. Respondent elected not to respond and instead filed a Motion for a Ruling on the Record. ECF No. 68. Petitioner responded, and both parties filed

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<sup>3</sup> On November 19, 2018, Petitioner filed an amended petition which alleged that A.F. additionally suffered an intussusception as a consequence of the vaccines she received on November 3, 2015. Amended Pet. at 1. ECF No. 9. During a status conference on August 1, 2019, I informed the parties that it appeared from my review of the medical records that A.F. did not experience six months of sequela following her intussusception. Subsequent to that, none of Petitioner’s experts have opined in support of an intussusception claim, and Petitioner did not brief that A.F. suffered from intussusception in his Response to the Motion for a Ruling on the Record or in his Sur-Reply. Accordingly, I have not analyzed this issue.

rebuttal briefs. ECF Nos. 73, 74, 76. The parties filed a joint status report indicating the record was complete on June 13, 2023. ECF No. 77. This matter is now ripe for an adjudication.

## II. ADEM

ADEM is an inflammatory demyelinating disease of the central nervous system that is typically monophasic and most often affects the pediatric population. Cole et al., *Acute Disseminated Encephalomyelitis in Children: An Updated Review Based on Current Diagnostic Criteria*, 100 PEDIATRIC NEUROLOGY, 26-34, 26 (2019) (filed as Ex. A, Tab 4) (hereinafter “Cole”) ADEM presents with encephalopathy and multifocal neurologic symptoms and is preceded by viral infection or fever in a high percentage of cases. First Holmes Rep. at 12; Murthy et al., *Acute Disseminated Encephalomyelitis in Children*, 110 PEDIATRICS 2, 1-9, (2002) (filed as Ex. A, Tab 10) (hereinafter “Murthy”). The diagnostic criteria for ADEM, updated by the International Pediatric Multiple Sclerosis Study Group in 2012, are as follows:

Pediatric ADEM (All are required)
<b>A first polyfocal, clinical CNS event with presumed inflammatory demyelinating cause</b>
<b>Encephalopathy that cannot be explained by fever</b>
<b>No new clinical and MRI findings emerge three months or more after the onset</b>
<b>Brain MRI is abnormal during the acute (three month) phase.</b>
<b>Typically on brain MRI:</b>
<b>Diffuse, poorly demarcated, large (&gt;1–2 cm) lesions involving predominantly the cerebral white matter</b>
<b>T1 hypointense lesions in the white matter are rare</b>
<b>Deep grey matter lesions (e.g. thalamus or basal ganglia) can be present</b>

First Holmes Rep. at 13; Krupp et al., *International Pediatric Multiple Sclerosis Study Group criteria for pediatric multiple sclerosis and immune-mediated central nervous system demyelinating disorders: revisions to the 2007 definitions*, 19 MULTIPLE SCLEROSIS JOURNAL 10, 1261-67, 1262 (2013) (filed as Ex. A, Tab 16).

## III. Medical Records

A.F. was born on July 10, 2015 pursuant to a normal delivery with no complications. Ex. 1 at 2-11. A.F. was discharged from Meriter Hospital in Madison, Wisconsin on July 12, 2015. *Id.* She had a bilirubin level of 10.5 which required clinical monitoring for jaundice. *Id.* at 5.

On July 30, 2015, A.F. visited Dr. Sumita Ram for “fussiness.” Ex. 2 at 46-47. A.F.’s parents reported fussiness for the past 7-9 days, especially at night. *Id.* at 46. Dr. Ram’s impression was “possible reflux,” and the plan was for A.F. to start Zantac<sup>4</sup> and probiotics. *Id.* at 47. A.F.’s parents were told that gripe water or gas drops were okay to use and to follow up in 1-2 weeks. *Id.*

<sup>4</sup> Zantac: trademark for preparations of ranitidine hydrochloride. DORLAND’S MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=53991> (last accessed on May 9, 2024); Ranitidine hydrochloride: the hydrochloride salt of ranitidine, used to inhibit gastric acid secretion in the prophylaxis and treatment of gastric and duodenal ulcer, gastroesophageal reflux disease, and conditions that cause gastric hypersecretion; administered orally, intravenously, or intramuscularly. DORLAND’S

A.F. returned to Dr. Ram on August 7, 2015 for continued fussiness. Ex. 2 at 54-55. A.F.'s mother reported that the fussiness was not worse but had not improved with Zantac, gripe water, or gas drops. *Id.* at 54. A.F.'s mother reported that A.F. was feeding well but would become fussy 15-20 minutes after and was spitting up a lot. *Id.* Dr. Ram noted that A.F.'s weight gain was adequate but lower than expected. *Id.* at 55. Dr. Ram prescribed Prevacid<sup>5</sup> and recommended that A.F.'s mother try to avoid milk and soy. *Id.* Dr. Ram also recommended supplementation with Alimentum to ensure A.F. was eating enough.

On August 14, 2015, A.F. visited Dr. Daniel O'Connell, a pediatric gastroenterologist, at the American Family Children's Hospital, with a chief complaint of fussiness, with possible reflux or milk protein intolerance. Ex. 4 at 5-7. Dr. O'Connell noted that A.F.'s mother was one week into a milk/soy elimination diet but he would expect results in two weeks in A.F. *Id.* at 7. He was not concerned as A.F. was gaining weight consistently and expressed that it was "difficult to determine exactly what is causing her to cry – protein intolerance, colic, gas, or other non-GI problems, but in general I am reassured by her growth and development so far." *Id.*

On August 28, 2015, A.F. returned to Dr. Ram at Meriter Hospital. Ex. 2 at 63-64. A.F.'s parents reported that A.F.'s fussiness was improving. *Id.* Dr. Ram recommended that A.F.'s mother continue the current plan of the elimination diet and supplementation with Alimentum. *Id.* Dr. Ram recommended genetic testing for ankylosing spondylitis and provided a referral to a pediatric ophthalmologist. *Id.* at 64.

On September 8, 2015, A.F. had her two month well-child visit. Ex. 2 at 72-75. A.F.'s mother reported that A.F. experienced more gas during feedings. *Id.* at 72. A.F. had normal growth and development. *Id.* at 73. A.F. experienced improvement with Prevacid. *Id.* at 74-75, 80. A.F. received her scheduled vaccines. *Id.* at 75.

On October 8, 2014, A.F. visited the pediatric after-hours clinic at Meriter Hospital. Ex. 2 at 85-87. A.F. had fallen off a couch while her mother's head was turned. *Id.* at 85. A.F. was found lying on her back still crying with spit up. *Id.* A.F. had a history of GERD but no vomiting. *Id.* A.F. was not injured and was released with a recommendation to take acetaminophen as needed for fever or pain. *Id.* at 86.

On October 22, 2014, A.F. returned to the Meriter Pediatric After Hours Clinic, because she had been screaming inconsolably for the last few hours. Ex. 2 at 100-03. A.F.'s fussiness resolved during this visit. *Id.* at 101. A.F.'s mother was concerned about an ear infection because

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MEDICAL DICTIONARY ONLINE, <https://www.dorlandsonline.com/dorland/definition?id=102068> (last accessed on May 9, 2024) ("DORLAND'S").

<sup>5</sup> Prevacid: trademark for a preparation of lansoprazole. DORLAND'S, <https://www.dorlandsonline.com/dorland/definition?id=27578> (last accessed on May 9, 2024); Lansoprazole: a substituted benzimidazole that acts as a proton pump inhibitor; used to inhibit the secretion of gastric acid for the symptomatic treatment of duodenal and gastric ulcers and gastroesophageal reflux disease and for the long-term treatment of hyperchlorhydria; administered orally. DORLAND'S, <https://www.dorlandsonline.com/dorland/definition?id=27578> (last accessed on May 9, 2024).

she had started daycare and had been tugging at her right ear. *Id.* A.F. was negative for redness, swelling, and fever. *Id.*

A.F. presented for her four-month wellness visit on November 3, 2015. Ex. 2 at 105-13. During this visit, the medical record notes that she was congested, and that over the past two days she had been spitting up more than normal and her stools had been green in color. *Id.* at 110. She did not have a fever and was noted to be feeding well. *Id.* A.F. was diagnosed with a viral illness, reflux, and milk protein intolerance. *Id.* at 112. She received the allegedly causal DTaP, Hep B, IPV, Hib, rotavirus, and PCV vaccinations during this visit. *Id.*

On November 24, 2015, A.F. visited Dr. Janet Kowalski. The medical records note that A.F. had recently started attending daycare and that she had been experiencing cold symptoms for more than four weeks. Ex. 11 at 3. These symptoms included cough, congestion, and wheezing. *Id.* A.F. had no fever, had a normal appetite, and was sleeping well. *Id.* A.F. had been to the doctor 1.5 weeks into her illness and her caregivers were advised that she had a viral illness that would “run its course.” *Id.* A.F.’s mother and grandmother brought her back to the doctor because she was not getting better. *Id.* During the physical exam, Dr. Kowalski observed “left TM [tympanic membrane] with pus superiorly” and nasal congestion. *Id.* at 4. Dr. Kowalski diagnosed A.F. with acute otitis media of the left ear without perforation of the ear drum and nasopharyngitis (common cold). *Id.* at 5. Dr. Kowalski prescribed a 10-day course of amoxicillin. *Id.*

Petitioner brought A.F. to the doctor on December 12, 2015. Ex. 2 at 125. The medical record documents that she was a little fussier than normal and had re-developed some congestion over the past one and one half days, although there was no change in her eating. *Id.* at 125. The records note that A.F. “has a [history of] ear infection for which she was treated with amoxicillin” that she finished about eight days ago. *Id.* at 125. “Her main symptom[] at that time was congestion which cleared immediately with the amoxycillin.” *Id.* A.F.’s temperature was measured at 98.5°F. *Id.* at 126. The physical exam conducted on December 12 documented that A.F. was “well-appearing, smiling and interactive.” *Id.* She fussed a little but was easily consolable. *Id.* A.F. was diagnosed with a “probable ear viral illness.” *Id.* at 126.

A.F. returned to the pediatrician (Dr. Miller) on Thursday, December 17, 2015. Her mother reported that she was notified by daycare that A.F. had a fever of 101.8°F. Ex. 2 at 138. The medical record documents that in the beginning of December, A.F. had congestion that cleared after she was treated with amoxycillin. *Id.* A.F.’s mother reported that A.F.’s current symptoms began six days prior, and for the past few days, her “fussiness had actually improved.” *Id.* At the visit on the 17<sup>th</sup>, A.F. was congested, but was otherwise well appearing. *Id.* She was eating well. *Id.* A.F. was diagnosed with a fever (measured at 99.9°F) with a likely viral etiology. *Id.* at 138-39. The doctor discussed otitis media with A.F.’s mother, and directed that A.F. begin antibiotics only if she did not improve in a couple of days. *Id.* at 139. Dr. Miller prescribed cefdinir. *Id.*

On Sunday, December 20, 2015, A.F. returned to the pediatrician. Ex. 2 at 153. The record documents that on Thursday (December 17), she started with a fever and an ear infection. *Id.* For the past three days, A.F. was “very fussy (screaming, crying), not eating, not sleeping, not coughing, little bit of rattling breathing, spitting up a little more than normal, red face, fever, not diarrhea.” *Id.* A.F. began taking the cefdinir that Dr. Miller prescribed on Saturday, December 19,

and had taken three doses at the time of her appointment on the 20th. *Id.* A.F.'s physical exam noted that she was alert and interactive. *Id.* The exam documented several shallow ulcers in the posterior pharynx and papules on her chest and back as well as 50% clear fluid bilaterally in the ears. *Id.* Her temperature was measured at 98.6°F. *Id.* She was diagnosed with herpangina<sup>6</sup> and a bilateral middle ear effusion. *Id.* The doctor noted it was okay to stop cefdinir. *Id.*

A.F. visited the emergency room in the morning on December 21, 2015 with a chief complaint of a fever. Ex. 1 at 13. Her temperature was measured at 100.5°F. *Id.* at 14. The ED provider notes document the following:

This 5 m.o. female patient presents to the ER for multiple symptoms. Parents first noted child not acting right 10 days ago, was lethargic for 2-3 days. Diminished appetite. No vomiting. No tactile fever. Patient was checked in clinic and diagnosed a viral syndrome. Child seems better from Monday through Wednesday of last week. Last Thursday, the child developed a fever of 101.8. Again, appetite diminished, increased fussiness and difficult to console. Seen on Thursday and diagnosed with pink ears, prescribed antibiotic to start if symptoms did not improve over 24 hours. Advised have not yet been started. Yesterday child was fussy, diminished appetite, seen at after hours clinic and diagnosed with hand-foot-and-mouth disease. Advised by the doctor there to use ibuprofen, one dose given this morning at 5:45 AM. New since awakening this morning, family feels the child has disconjugate gaze with the left eye deviating preferentially to the right. Child took a first bottle during this interview in the emergency department, drank 2 ounces. 2 episodes of vomiting at home earlier this morning. Mother noted one loose stool that was dark red in color yesterday.

Ex. 1 at 14-15. A.F.'s lab results were positive for respiratory syncytial virus ("RSV"). *Id.* at 18. She was admitted to the hospital; Dr. Bendegom's impression was RSV, likely sepsis, and VI cranial nerve palsy on the left side. *Id.* at 19.

Upon admission, the HPI portion of the medical record documents the following:

10-day history of intermittent fevers and diarrhea and consulted for abnormal eye movements. Mother reports over the last approximately 10 days she has been ill, what she describes as having intermittent diarrhea, intermittent fevers, poor p.o.<sup>7</sup> intake, being more fussy, and more sleepy than normal. Her mother reports,

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<sup>6</sup> Herpangina: "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. Called also *aphthous pharyngitis*, *vesicular pharyngitis*, and *herpes angina*. DORLAND'S, [www.dorlandonline.com/dorland/definition?id=22347](http://www.dorlandonline.com/dorland/definition?id=22347) (last visited Nov. 7, 2023). Herpangina is a viral infection that spreads quickly among children, especially in a day care setting. It is closely related to hand, foot, and mouth disease. [www.my.clevelandclinic.org/health/diseases/22508-herpangina](http://www.my.clevelandclinic.org/health/diseases/22508-herpangina) (last visited May 10, 2024).

<sup>7</sup> Per os: by mouth. DORLAND'S, [www.dorlandonline.com/dorland/definition?id=38144&searchterm=per+os](http://www.dorlandonline.com/dorland/definition?id=38144&searchterm=per+os) (last visited Nov. 8, 2023).

however, yesterday she noticed that her left eye could not look outward so she was brought to an outside emergency room.

Ex. 4 at 139. A.F. had an MRI while she was hospitalized, which led to a diagnosis of ADEM. *Id.* at 137. Upon review of the MRI, one of her treating physicians commented that “most cases of ADEM have an antecedent infection, which AF seems to have had several possible recent infections. She is also RSV +.” *Id.* During a consult on December 22, 2015, a treating neurologist opined as follows: “At this time given her prodromal illness, most likely diagnosis is a postinfectious process most consistent with acute disseminated encephalomyelitis or ADEM.” *Id.* at 140. She was started on methyl prednisone. *Id.*

On December 24, 2015, attending physician Dr. Shannon Dean noted that A.F. was exhibiting signs of hypothermia and bradycardia, as well as “decreased perfusion of the lower extremities likely due to autonomic instability secondary to ADEM.” Ex. 4 at 119. An NJ tube was placed to help ensure adequate nutrition. *Id.* A.F. remained very irritable. *Id.* Dr. Dean opined as follows:

ADEM is a clinical and radiologic diagnosis. With her preceding apparent viral illness with fever and non-specific symptoms, this does seem to be the best fit diagnosis. Parents did ask about immunizations as a culprit. She received her 4 month shots on 11/3/15. I indicated that I did not think the time course fit with that as an etiology and favored a viral illness as etiology.

*Id.*

On December 26, 2015, Dr. Dean noted that A.F. had shown improvement in tracking objects, and was neurologically stable. Ex. 4 at 100.

On December 28, 2015, an MRI documented “Rapidly progressive largely symmetrical destructive process centered at grey-white matter junction, most likely infectious or parainfectious demyelination with reactive edema in the central white matter.” *Id.* at 25. A.F. continued to improve and was discharged from the hospital on December 31, 2015. *Id.* at 25-26.

A.F. had a follow-up neurology visit on January 5, 2016. Ex. 4 at 463. A.F.’s grandmother reported that A.F. had made dramatic improvement and that her eyes seem almost back to normal. *Id.* The neurologist noted a “dramatic improvement in mood and behavior since admission.” *Id.* at 464.

A.F. visited a pediatric neurologist on January 26, 2016, and was noted to be back to her baseline with no deficits. *Id.* at 575.

No other medical records necessary to my resolution of this matter have been submitted.

#### **IV. Expert Opinions and Qualifications**

##### **A. Petitioner’s Expert: Dr. David Younger, M.D.**

Dr. Younger received his bachelor's degree from the University of Michigan in 1976 and his medical degree from Columbia University in 1981. Ex. 14 ("Younger CV") at 1. He completed residencies in internal medicine in 1981 and neurology in 1984. *Id.* Dr. Younger is a professor of neuroscience at City University Medical School. *Id.* He is board-certified in internal medicine, clinical neurophysiology, neurology, and electrodiagnostic medicine. *Id.*

Dr. Younger submitted one expert report. Ex. 13 (hereinafter "Younger Rep."). He described ADEM as "a monophasic, immune-mediated central nervous system (CNS) demyelinating disorder that predominates among children following specific viral infections including measles, rubella, and mumps, especially in the spring and winter months, and after vaccine immunization." Younger Rep. at 3. Dr. Younger noted that after vaccination, A.F. suffered from an interim RSV infection and an ear infection before developing ADEM. *Id.*

Dr. Younger characterized A.F.'s condition as a progressive illness. Younger Rep. at 4. He noted that her illness began with "GI symptoms, congestion, spitting up, and green stools, milk protein intolerance, and reflux" and that it progressed to "a fever of 101.8 degrees followed by fussy, crying, coughing, feverish, rattling breathing, insomnia, and loss of appetite with shallow ulcers in the posterior pharynx and papules on her chest and back." *Id.* He opined this then resulted in "left eye deviation, VI cranial nerve palsy on the left side and the necessity of steroids for emergent spastic paraparesis and altered limb tone due to ADEM noted on brain MRI." *Id.* Dr. Younger did not explain how all these signs and symptoms constituted a progressive disease course.

Dr. Younger opined that A.F.'s clinical course was more likely than not, caused by the Hepatitis B vaccine. Younger Rep. at 4. He stated that "The disease is due to a heightened immune response to exogenous stimulation associated with vaccination including activation of polyclonal B-cells, and explains the proximate effect of the claimant's vaccination and its ensuing sequence of events that included acute, subacute and chronic neurological findings..." *Id.* Specifically, Dr. Younger opined that the Hep B vaccine provoked the activation of B cells, which resulted in an "aberrant response" and an "upregulation of antibody production directed against host self-antigens." *Id.* Dr. Younger further opined that "post-vaccination demyelinating encephalomyelitis is more serious and immune-based when it is amplified by concomitant infection as in this child." *Id.*

Dr. Younger discussed the timing of A.F.'s condition, and stated the following: "Within the first 48 hours of vaccination with subunit portion of the microbe as antigen for immune surveillance to confer immunity, the claimant developed systemic symptoms as the initial manifestation of vaccine injury as expected from the physiology of vaccination." Younger Rep. at 5. It is difficult to understand to which systemic symptoms Dr. Younger refers. In response to the question, "please explain when the injury onset occurred", Dr. Younger replied:

Vaccination promotes an immediate activation of polyclonal B-cells pursuant to presentation of the vaccination antigen in the trimolecular complex which also includes naïve T-cells and CD68 macrophage antigen presenting cell in the presence of main histocompatibility (MHC) type 2 molecules. It is the exposure of

a vulnerable host to an antigenic challenge multiplied by protective host immunity and conditioned by genetic factors that causes protective host immunity to become the source of host autoimmunity and the source of progressive disabling neurological conditions such as ADEM in this patient.

*Id.* at 5-6. Dr. Younger concluded his report by stating that all three of the *Althen* prongs had been met. *Id.* at 6.

### **B. Petitioner’s Expert: Dr. Alberto Martinez-Arizala, M.D.**

Dr. Martinez-Arizala graduated with a B.S. from Florida State University and a medical degree from the University of Miami School of Medicine. Ex. 23 (“Martinez-Arizala CV”) at 1. He completed an internship at the Walter Reed Army Medical Center and a residency in neurology in the Letterman Army Medical Center in San Francisco. *Id.* He is a board certified neurologist and a Professor of Clinical Neurology at the University of Miami Miller School of Medicine. *Id.* at 1, 2.

Dr. Martinez-Arizala submitted two expert reports in this case. Ex. 22 (“First Martinez-Arizala Rep.”); Ex. 41 (“Second Martinez-Arizala Rep.”). Dr. Martinez-Arizala opined that A.F.’s ADEM was likely caused by the vaccinations she received on November 3, 2015, specifically the Hep B vaccine. First Martinez-Arizala Rep. at 1, 6. He provided four reasons for this opinion. First, he stated that the time between vaccination and onset of symptoms was within the interval one would expect for vaccine causation. *Id.* at 6. Dr. Martinez-Arizala noted that vaccination was on November 3, 2015, and that onset of A.F.’s ADEM was on December 12, 2015 where she was noted to have a low-grade fever and was observed to be a little fussier than normal. *Id.* He stated, “Although this could also have been associated with her viral illnesses, the timing of the onset of her symptoms implicates the vaccine. By her 12/20/2015 visit to Dr. Kreckman, infant Fisher was worse, and by 12/21/2015 she had clearly developed a neurological disorder (dysconjugate gaze).” *Id.* Second, Dr. Martinez-Arizala noted that A.F. had comprehensive imaging studies and these studies did not reveal another etiology for her condition. *Id.* Third, he stated that “the time for progression and resolution was well within what has been reported for ADEM.” *Id.* And finally, Dr. Martinez-Arizala stated that A.F.’s treating physicians all agreed with the diagnosis of ADEM. *Id.*

Dr. Martinez-Arizala described ADEM as “a demyelinating disease of the central nervous system that usually presents as a monophasic disorder associated with multifocal neurologic symptoms and encephalopathy.” First Martinez-Arizala Rep. at 6. He opined that the most common causes are an infection or a vaccine and that neurologic symptoms follow “days to weeks after an infection or vaccination.” *Id.* at 6-7. Dr. Martinez-Arizala noted that encephalopathy is a required finding in ADEM cases and that encephalopathy typically develops rapidly, in conjunction with other neurologic deficits. *Id.* at 7.

Dr. Martinez-Arizala opined that molecular mimicry is the likely causal mechanism whereby ADEM would develop after vaccination. He described that molecular mimicry occurs “where components of the vaccine possess sequence similarities between it and specific human proteins that results in the cross-activation of autoreactive T or B cells.” First Martinez-Arizala

Rep. at 7. Dr. Martinez-Arizala referenced the 1976 swine flu vaccine leading to an increased risk of Guillain Barré syndrome (GBS) as an example of vaccination resulting in disease via molecular mimicry. *Id.* Dr. Martinez-Arizala stated it is theorized that post-vaccination ADEM results from molecular mimicry between infectious agents and self-antigens. *Id.* In support of this assertion, Dr. Martinez-Arizala cited to Azumagawa. Azumagawa et al., *Post-vaccination MDEM associated with MOG antibody in a subclinical Chlamydia infected boy*, 38 BRAIN AND DEVELOPMENT 690-93 (2016) (filed as Ex. 18) (hereinafter “Azumagawa”). Azumagawa described a case report of a young boy who developed multiphasic disseminated encephalomyelitis after vaccinations for measles and rubella, and the booster immunization for Japanese encephalitis. He tested positive for both anti-myelin oligodendrocyte glycoprotein (MOG) antibodies and Chlamydia pneumoniae antibodies. First Martinez-Arizala Rep. at 7; Azumagawa at 690.

In discussing the logical sequence of cause and effect, Dr. Martinez-Arizala stated:

The Hepatitis B vaccine contains components that triggered the ADEM. The onset of her neurological symptoms was well within the expected time boundaries of the vaccine administration. There was no evidence from the medical records that infant Fisher was suffering from any neurological disorder prior to the vaccination in question. In fact, the contemporaneous medical records are consistent in placing the start of her neurological symptoms after the vaccination.

First Martinez-Arizala Rep. at 9. With regard to timing, Dr. Martinez-Arizala opined that it was consistent with the medical literature. *Id.* He concluded his report by stating that the weight of the evidence supports his position that the Hep B vaccine caused A.F. to develop ADEM. *Id.*

Unlike in his first expert report, in his second report, Dr. Martinez-Arizala opined that the onset of A.F.’s ADEM was December 10, 2015. Second Martinez-Arizala Rep. at 1. He further opined that “Assuming that infant Fisher’s ADEM was post-viral, then it is quite plausible the vaccine worsened her disease.” *Id.* In support of this position, Dr. Martinez-Arizala analogized this case to MS, where it is recommended that vaccines not be administered close in time to a flare of MS to avoid worsening disease symptoms. *Id.*

### **C. Respondent’s Expert: Dr. Gregory Holmes, M.D.**

Dr. Holmes received his medical degree from Washington and Lee University, and he holds an honorary medical degree from Harvard Medical School. Ex. B (hereinafter “Holmes CV”) at 1. He completed his residency in pediatrics at the Yale University School of Medicine and another residency in neurology at the University of Virginia School of Medicine. *Id.* He is board certified in pediatrics, neurology with special competence in child neurology, and clinical neurophysiology. *Id.* Dr. Holmes has also held various academic appointments, including his current positions as professor of neurology and pediatrics at Dartmouth Medical School and Chair of Neurological Sciences at the University of Vermont. *Id.* at 2. Dr. Holmes is on the editorial board for a number of medical and scientific journals including the Journal of Epilepsy, Brain & Development, Pediatric Neurology, Annals of Neurology, and Neurotherapeutics. *Id.* at 5. Dr. Holmes has published over 300 peer-reviewed articles, 76 books and book chapters, and over 400 abstracts. *Id.* at 40-65, 79-84, 85-115.

Dr. Holmes authored three expert reports in this case. Ex. A (hereinafter “First Holmes Rep.”); Ex. E (hereinafter “Second Holmes Rep.”); and Ex. F (hereinafter “Third Holmes Rep.”).

Dr. Holmes provided an extremely thorough recitation of A.F.’s medical history. First Holmes Rep. at 1-11. Dr. Holmes next provided a summary of ADEM. He stated that ADEM, synonymous with postinfectious encephalomyelitis, is a “demyelinating disease of the central nervous system that typically presents as a monophasic disorder associated with multifocal neurologic symptoms and encephalopathy.” *Id.* at 12. Dr. Holmes elaborated that ADEM is mostly preceded by febrile or viral infections affecting young adults and children and an antecedent fever or infection is found in approximately 75% of children with ADEM. *Id.* Dr. Holmes added that neurological symptoms usually appear 4-13 days after the antecedent infection. *Id.* The diagnostic criteria for ADEM in children was developed in 2007 and updated in 2012, with major criteria being: 1) a polyfocal clinical attack of CNS demyelinating disease, 2) encephalopathy that cannot be explained by fever, systemic illness, or postictal symptoms, 3) the absence of clinical and MRI findings three or more months after onset, 4) an abnormal brain MRI during the acute phase with diffuse, poorly demarcated, large lesions in the white matter, and deep gray matter lesions. *Id.* at 11-12. Dr. Holmes stated that the diagnostic criteria require an “absence of new clinical and MRI findings three months or more after onset” because ADEM is typically monophasic and improvement occurs quickly with treatment. Second Holmes Rep. at 2. Recurrent or multiphasic ADEM is rare and constitutes a separate diagnosis; this issue is not relevant because A.F. suffered from a single attack of ADEM. *Id.*

Dr. Holmes opined that A.F.’s ADEM began on December 21, 2015, almost seven weeks after her November 3, 2015 vaccination. First Holmes Rep. at 13-14. Dr. Holmes cited A.F.’s treater Dr. Dean, who also believed her 4-month vaccinations did not temporally fit as an etiology. *Id.* at 14; *see also* Ex. 4 at 118-20. A.F. received her next round of vaccinations in February 2016 without incident. First Holmes Rep. at 14; *see also* Ex. 2 at 180-83.

Dr. Holmes provided his opinion regarding Dr. Younger’s theory of causation. Dr. Holmes stated that there are studies which demonstrate no relationship between vaccinations and ADEM, including the Hepatitis B vaccine. First Holmes Rep. at 15. Dr. Holmes contended that the medical literature submitted by Dr. Younger did not support his causation theory. *Id.* at 16. Dr. Holmes opined that Dr. Younger has not submitted any evidence that the Hepatitis B vaccines has a molecular mimic with the brain. *Id.*

In Dr. Holmes’ final report, he responded to Dr. Martinez-Arizala’s report. Dr. Holmes reiterated that Dr. Martinez-Arizala, similar to Dr. Younger, espouses a theory of molecular mimicry but also has not provided any homology between the Hepatitis B vaccine and any brain peptide. Third Holmes Rep. at 1-2. Dr. Holmes also criticized Dr. Martinez-Arizala’s use of the Rojas paper, as the paper discusses four major criteria to support a molecular mimicry theory, which Dr. Martinez-Arizala did not address. *Id.* at 2. Dr. Holmes last discussed Dr. Martinez-Arizala’s *Althen* prong three analysis, and noted that none of his medical literature supported an onset of either 39 or 48 days after an antecedent event, nor does his cited literature support Hepatitis B virus causing ADEM. *Id.* at 2-3.

### **D. Respondent's Expert, Dr. You-Wen He, M.D., Ph.D.**

Dr. He has been a Professor of Immunology in the Department of Immunology at Duke University Medical Center since 1986. Ex. D (hereinafter "He CV") at 1. Dr. He received his medical degree from the Fourth Military Medical University and his Ph.D. from the University of Miami School of Medicine. He CV at 1. His research areas include innate and adaptive viral and bacterial immunity; he directed research on human immune responses to viral infections including influenza, HIV, HBV, and HCV. *See generally id.* at 5-7. Dr. He has published over 100 peer-reviewed articles. *Id.* at 8-15.

Dr. He authored one expert report in this case. Ex. C (hereinafter "He Rep."). Dr. He opined that he did not believe the Hepatitis B vaccine that A.F. received caused her ADEM. *Id.* at 5. A.F. suffered from a number of infections such as an ear infection, hand, foot, and mouth disease, and RSV prior to her development of ADEM, and there is "overwhelming evidence" of a connection between infections and ADEM. *Id.* Dr. He disagreed with Dr. Younger's assertion that A.F. suffered from repeat challenge from the Hepatitis B vaccine, which increased her risk of CNS inflammatory disease or post-vaccination demyelination encephalomyelitis. *Id.* at 6. Dr. He also disputed Dr. Younger's reliance on the Huynh paper, arguing the 2012 IOM publication was a more recent and comprehensive analysis on vaccine safety. *Id.*

Dr. He stated that A.F.'s vaccinations on July 12, 2015, September 8, 2015, and November 3, 2015 could not temporally connect to A.F.'s ADEM. He Rep. at 7. Dr. He cited to A.F.'s multiple infections in November 2015 as more likely to have caused her neurological symptoms. *Id.* A.F. was treated for an ear infection from November 24-December 4, 2015; the time frame of A.F.'s ear infection occurred between 2-21 days before the onset of her neurological symptoms, which better correlates than the Hepatitis B vaccines. *Id.* Dr. He opined that the immune response from A.F.'s infection was more robust than the immune reaction from her vaccinations. *Id.* at 8.

## **V. Applicable Law**

### **A. Petitioner's Burden in Vaccine Program Cases**

Under the Vaccine Act, a petitioner may prevail in one of two ways. First, a petitioner may demonstrate that a vaccinee 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 or 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, petitioner 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.

Petitioner 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).

## **B. 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.

### C. 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”).

#### **D. 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, his claim is classified as “off-Table.” As noted above, to prevail on an “off-Table” claim, Petitioner must prove by preponderant evidence that A.F. suffered an injury and that this injury was caused by the vaccination at issue. *See Capizzano*, 440 F.3d at 1320.

#### **A. Althen Prong One**

Although Dr. Younger and Dr. Martinez-Arizala have articulated a theory describing how the vaccines A.F. received can cause ADEM, I need not reach that question. My factual findings, discussed in the next section, that A.F.’s viral infection was the more likely than not cause of her condition, make analysis of Petitioner’s causal theory unnecessary. *See, e.g., Hibbard v. Sec’y of Health & Hum. Servs.*, 698 F.3d 1355, 1365 (Fed. Cir. 2012); *Holmes v. Sec’y of Health & Hum. Servs.*, 115 Fed. Cl. 469, 488 (2014); *Vaughan v. Sec’y of Health & Hum. Servs.*, 107 Fed. Cl. 212, 222 (2012). Accordingly, in my analysis of *Althen* prongs two and three, I have assumed, but have not decided that Petitioner has established a medical theory causally linking the flu vaccine to ADEM.<sup>8</sup>

#### **B. Althen Prongs Two and Three**

*Althen* prong two requires Petitioner to establish a logical sequence of cause and effect demonstrating that the vaccination did cause A.F.’s condition. *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

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<sup>8</sup> As discussed later in this decision, I do not find persuasive Dr. Martinez-Arizala’s brief discussion involving the purported interplay between vaccination and a viral infection which occurred approximately one month later.

as particularly trustworthy evidence, since 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).

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).

1. A.F. had at least one and likely multiple infections before she developed ADEM

Petitioner contends that A.F.’s ADEM began on December 10, 2015, and further, that her medical records documented “little to no evidence of a viral infection” before that time. Pet’r’s Reply at 1. As discussed below, I do not find Petitioner’s position to be persuasive.

It is clear that A.F. had one or more infections in the month prior to her onset of ADEM. On November 24, 2015, A.F. went to the doctor because she had been sick for four weeks and was still experiencing congestion. Ex. 11 at 3. Dr. Kowalski observed pus in A.F.’s left tympanic membrane and diagnosed A.F. with acute otitis media of the left ear without perforation of the ear drum and nasopharyngitis. *Id.* at 5. Dr. Kowalski prescribed a 10 day course of amoxicillin. *Id.*

On December 12, 2015, A.F. was presented to the pediatrician because she had completed her course of amoxicillin about eight days prior, but had redeveloped some congestion over the past one and one half days. Ex. 2 at 125. The doctor diagnosed A.F. with a “probable ear viral illness.” *Id.* at 126.

Dr. Martinez-Arizala contended that A.F. did not have a viral infection at the time of the December 12 visit. Second Martinez-Arizala Rep. at 1. He stated as follows: “Dr. Ram also documented that her main symptom at the time of her [ear infection] was congestion, which cleared immediately after completing the amoxicillin. This indicates that [A.F.] had recovered from the congestion/illness that she had prior to the onset of her excessive sleepiness/fussiness on or about December 10, 2015.” Second Martinez-Arizala Rep. at 1. Dr. Martinez-Arizala’s opinion is difficult to square with the medical record. Indeed, one and one half days before this appointment, A.F. “redeveloped some congestion.” Ex. 2 at 125. This point suggests that A.F. had not “recovered from her congestion”, as Dr. Martinez-Arizala argued, but that she was sick; A.F.’s congestion supports her treating physician’s diagnosis of probable viral ear illness.

A.F. returned to the pediatrician on December 17, 2015. Her mother reported that she was notified by daycare that A.F. had a fever of 101.8°F. Ex. 2 at 138. At the visit on the 17<sup>th</sup>, A.F. was congested. *Id.* Her left and right tympanic membranes were observed to be erythematous and dull. *Id.* A.F. was diagnosed with a fever, measured at 99.9°F, with a likely viral etiology. *Id.* at 138-39. Dr. Miller discussed otitis media with A.F.’s mother and recommended that A.F. begin antibiotics if she did not improve in one week. *Id.* at 139.

On Sunday, December 20, 2015, A.F. returned to the pediatrician. Ex. 2 at 153. The record documents that for the past three days, A.F. had been very fussy. *Id.* A.F.’s physical exam

documented several shallow ulcers in the posterior pharynx and papules on her chest and back as well as 50% clear fluid bilaterally in the ears. *Id.* Her temperature was measured at 98.6°F. *Id.* She was diagnosed with herpangina and a bilateral middle ear effusion. *Id.*

These medical records clearly document the existence of one and likely more than one infection. The existence of an infection is significant because the medical literature states that ADEM has an infectious etiology in a high percentage of cases. In fact, ADEM is also referred to as postinfectious encephalomyelitis. *See* Cole at 26 (observing that 55% to 86% of pediatric ADEM cases are preceded by symptoms of a viral illness); Lotze & Chadwick, *Acute disseminated encephalomyelitis (ADEM) in children: Pathogenesis, clinical features, and diagnosis*, UPTODATE, 1-17, 4 (2020) (filed as Ex. A, Tab 19) (noting that approximately 75% of children with ADEM have an antecedent fever or infection); Paolilo et al., *Acute Disseminated Encephalomyelitis Current Perspectives*, 7 CHILDREN 210, 1-15, 4 (2020) (filed as Ex. C, Tab 6) (stating that a preceding infection is observed in 70%-80% of ADEM cases).

I acknowledge that Petitioner is not required to eliminate other potential causes of ADEM in order to be entitled to compensation in the Vaccine Program. *See Walther v. Sec’y of Health & Hum. Servs.*, 485 F.3d 1146, 1149-52 (Fed. Cir. 2007) (concluding a petitioner does not bear the burden of eliminating alternative independent potential causes). However, I find it appropriate to consider other possible sources of injury in making a determination pursuant to *Althen* prong two. *See Stone v. Sec’y of Health & Hum. Servs.*, 676 F.3d 1373, 1379-80 (Fed. Cir. 2012); *see also Winkler v. Sec’y of Health & Hum. Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023), *pet. for panel rehearing and rehearing en banc denied*, No. 22-1960 (Mar. 28, 2024). A.F.’s illness or illnesses are a likely source of her injury.<sup>9</sup>

## 2. Treating physicians

In weighing evidence, special masters are expected to consider the views of treating doctors. *Capizzano*, 440 F.3d at 1326. The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom

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<sup>9</sup> In his second expert report, Dr. Martinez-Arizala dedicated one paragraph to a new theory. He stated, “Assuming that infant Fisher’s ADEM was post-viral, then it is quite plausible the vaccine worsened her disease.” Second Martinez-Arizala Rep. at 1. He cited two articles involving multiple sclerosis as support for his theory, noting that “[i]n MS it is recommended that vaccines not be administered close to an exacerbation to avoid worsening the relapse.” *Id.* Dr. Martinez-Arizala’s new theory is unpersuasive. First, the two articles he filed were about MS, and not ADEM. Second, these articles note that neurologists typically do not give prophylactic vaccines (like Hep B) during a “significant relapse” of MS (defined as “one that causes motor symptoms or severe sensory symptoms that have affected the patient’s usual ability to carry out daily activities”), because “the vaccination might cause side effects, such as fever, that could worsen the relapse.” Ex. 44 at 19. A.F. did not have ADEM at the time of vaccination, and thus was not experiencing a relapse. Finally, Dr. Martinez-Arizala did not explain how a vaccination administered on November 3 could linger in the body and interact with a subsequent infection or infections and result in the onset of ADEM 48 days later. This proposed mechanism was left completely unexplained. As such, I do not find that this causal theory is persuasive or that there is support in the record that it happened in A.F.’s specific case.

they are diagnosing. *See McCulloch v. Sec’y of Health & Hum. Servs.*, No. 09-293V, 2015 WL 3640610, at \*20 (Fed. Cl. Spec. Mstr. May 22, 2015).

Several of A.F.’s treating physicians documented that A.F.’s condition was likely caused by an infection. Dr. Samuel Dzodzomenyo, A.F.’s treating neurologist opined: “At this time given her prodromal illness, most likely diagnosis is a post-infectious process most consistent with ADEM.” Ex. 4 at 140. Pediatrician Dr. Mary Ehlenbach opined as follows: “MRI findings along with minimal nucleated cells in the CSF and neurologic symptoms are consistent with a diagnosis of acute demyelinating encephalomyelitis (ADEM). Most cases of ADEM have an antecedent infection, which [A.F.] seems to have had several possible recent infections. She is also RSV +.” Ex. 4 at 137. Dr. Shannon Dean, one of A.F.’s pediatricians noted the following in the medical record: “My assessment is 5 month-old with bilaterally cranial nerve 6 palsies and MRI findings suggestive of ADEM. ... With her preceding apparent viral illness with fever and non-specific symptoms, this does seem to be the best fit diagnosis. Parents did ask about immunizations as a culprit. She received her 4 month shots on 11/3/15. I indicated that I did not think the time course fit with that as an etiology and favored a viral illness as an etiology.” Ex. 4 at 118-20. None of A.F.’s treating doctors ascribed causation of her ADEM to the vaccines she received.

These opinions are persuasive evidence and help establish that A.F.’s ADEM was more likely than not, caused by an infection.

### 3. Onset of A.F.’s ADEM

Initial symptoms of ADEM are described in the literature as highly variable. Cole at 27. That being said, most children present with a fever, headache, and nausea. *Id.* By definition, all children must have an encephalopathy in order to meet the diagnostic criteria. *Id.* Encephalopathy in young children can present as irritability, sleepiness, confusion, lethargy, or coma. *Id.* at 28. Cranial nerve deficits are also observed in 18%-39% of ADEM cases. *Id.*

Petitioner presented different positions on the onset of A.F.’s ADEM. Dr. Younger contended that the “initial manifestation of vaccine injury” occurred within the first 48 hours of vaccination. Younger Rep. at 5. This position finds no support in the medical records and will not be discussed further. Dr. Martinez-Arizala initially opined that “the onset of the illness most likely dates to her 12/12/2015 visit with Dr. Ram, where she was noted to have a low-grade fever and being a little fussier than usual. Although this could also have been associated with her viral illnesses, the timing of the onset of her symptoms implicates the vaccine.” First Martinez-Arizala Rep. at 6. Dr. Martinez-Arizala did not clarify why he believed the vaccine was causal if the timing of onset implicated the viral illness. However, in his second report, Dr. Martinez-Arizala argued that A.F.’s lethargy and fussiness on December 10, 2015 marked the beginning of her ADEM. Second Martinez-Arizala Rep. at 1. Petitioner advocates this third position in his briefs. *See e.g.*, Pet’r’s Reply at 7. While it is true that lethargy and fussiness can be present in ADEM, these are non-specific symptoms that also exist in many other conditions, including viral infections. Dr. Holmes opined that A.F. experienced the onset of her condition between December 17 and December 21, 2015. Second Holmes Rep. at 2; Third Holmes Rep. at 2. Dr. Holmes further opined that it is “highly unlikely” that A.F. developed ADEM on December 12, 2015. Third Holmes Rep. at 2.

In reviewing the medical records, I conclude that Petitioner's presentation on December 10, December 12, December 17, and December 20 can be explained by the illness or illnesses she was experiencing. While she was described as fussy on each of these dates, I do not find this description preponderantly supports the onset of ADEM.

For example, on December 10<sup>10</sup> and 12, 2015 A.F. was described as "a little fussier than normal", and the medical record notes that her parents brought her to the doctor because she had been more lethargic than normal for the past 36 hours and had re-developed some congestion during this 36 hour period of time. However, there was no change in her eating, she was "easily consolable" and was noted to be "well-appearing, smiling and interactive" on physical exam. Ex. 2 at 125. In the context of the overall medical record, it appears that A.F. was likely still battling an infection.

On December 17, 2015 A.F. had a fever, was congested, and was fussy. Ex. 2 at 138. Her left and right tympanic membranes were observed to be erythematous and dull. *Id.* A.F. was diagnosed as having a fever with a likely viral etiology. *Id.* at 138-39. Although A.F. was fussy during this visit, she also had what appeared to be the continuation of an ear infection.

On Sunday, December 20, 2015, A.F. was "very fussy" and had been for the past three days. Ex. 2 at 153. A.F.'s physical exam documented several shallow ulcers in the posterior pharynx and papules on her chest and back as well as 50% clear fluid bilaterally in the ears. *Id.* She was diagnosed with herpangina and a bilateral middle ear effusion. *Id.* A.F.'s extreme fussiness was likely attributable to her continued ear infection and her new diagnosis of herpangina.

It is difficult to distinguish between A.F.'s viral illness which likely caused lethargy and fussiness and the precise onset of her ADEM. However, based on the above, I conclude there is not preponderant evidence that the fussiness and lethargy A.F. experienced before December 21, 2015, constituted the onset of her condition. I find there *is* preponderant evidence that A.F.'s fever, repeated vomiting, and disconjugate gaze, which began the morning of December 21, 2015 represent the onset of her disease course.

#### 4. Onset interval makes it more likely that the infection was causal

The medical literature describes that when patients have prodromal illness, the latency between infection and onset of ADEM can be measured in days to weeks. For example, Murthy et al. found that 72% of the children studied had an upper respiratory tract infection between two days and four weeks prior to onset of ADEM. Murthy at 2. Murthy concluded that on average, 10 days separated the URI from onset of neurologic symptoms. *Id.* Cole et al. noted that "The latent period between an inciting viral infection and onset of symptoms is typically about 12 days." Cole at 27. Menge et al. observed, "Typically, the latency between a febrile illness and the onset of neurological symptoms is 7–14 days." Menge et al., *Acute disseminated encephalomyelitis: an*

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<sup>10</sup> Although there is no medical visit for December 10, the visit on the 12<sup>th</sup> refers to symptoms that began 36 hours prior.

*acute hit against the brain*, 20 CURRENT OPINION IN NEUROLOGY, 247-254, 247 (2007) (filed as Ex. A, Tab 29). Given the fact that A.F. had symptoms of one or more infections during the 30+ days before the onset of ADEM, I conclude the timing of A.F.'s illness persuasively connects them with her development of ADEM.

Further, the fact that A.F. developed ADEM 48 days after vaccination, reduces the likelihood of the vaccine's causal role. Indeed, Petitioner's own literature describes onset of ADEM within days to weeks of vaccination. Huynh et al. discussed the onset of symptoms in ADEM. They stated: "Depending on the inciting agent, the onset of symptoms may vary slightly: from 1 to 14 days with non-neural vaccines ... and 1 to 3 weeks after rabies vaccination." Huynh et al., *Post-vaccination encephalomyelitis: Literature review and illustrative case*, 15 JOURNAL OF CLINICAL NEUROSCIENCE, 1315-22, 1319 (2008) (filed as Ex. 19) (hereinafter "Huynh"). Pavone et al. described that the interval between vaccination and onset of ADEM was seven days. Pavone et al., *Acute Disseminated Encephalomyelitis: A Long-Term Prospective Study and Meta-Analysis*, 42 NEUROPEDIATRICS 1-10, 3 (2011) (filed as Ex. 28). The longest interval is described by Dale et al., who noted that the mean latency between an illness or vaccination and the onset of neurological signs was 13.0 days, with a range of two to 31 days. Dale at 2410.

These findings regarding the timing of the infection versus the vaccination are in accord with the opinion of Dr. Dean, one of A.F.'s treating physicians, who noted that she "did not think the time course fit with [vaccination] as an etiology and favored a viral illness as etiology." Ex. 4 at 119; *see also White v. Sec'y of Health & Hum. Servs.*, No. 20-1319V, 2023 WL 4204568, at \*18 (Fed. Cl. Spec. Mstr. June 2, 2023) (opining that an infection was more likely causal than vaccination when the infection was closer to the onset of disease than vaccination); *mot. for rev. denied*, 168 Fed. Cl. 660 (2023); *appeal docketed*, No. 2024-1372 (Fed. Cir. Jan. 23, 2024). The existence of this other source of injury, an infection, weakens the persuasiveness of Petitioner's prong two showing in that it reduces the likelihood of the vaccine's causal role.

In summary, A.F. experienced at least one and likely multiple illnesses in the four weeks prior to the onset of her condition. The existence of these illnesses, coupled with the opinions of her treating physicians and the opinion of Dr. Holmes prevent her from establishing that the vaccines she received "did cause" her condition. Petitioner has not presented preponderant evidence in support of the second or the third *Althen* prongs.

## VII. Conclusion

Upon careful evaluation of all the evidence submitted in this matter, including the medical records, the affidavits, as well as the experts' opinions and medical literature, I conclude that Petitioner has not shown by preponderant evidence that he is entitled to compensation under the Vaccine Act. **His petition is therefore DISMISSED. The clerk shall enter judgment accordingly.**<sup>11</sup>

## IT IS SO ORDERED.

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<sup>11</sup> Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment by each filing (either jointly or separately) a notice renouncing their right to seek review.

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