In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 22-399V

AMANDA WILES,	*	Filed: December 9, 2025
Petitioners,	*	
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Chris J. Webb, Black McLaren PC, Memphis, TN, for Petitioner.

Ryan Pyles, U.S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On April 7, 2022, Amanda Wiles[2] filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Program"). Petition (ECF No. 1) ("Pet.") at 1. Petitioners alleges that she developed a seizure disorder after receipt of tetanus-diphtheria-acellular pertussis ("Tdap") and influenza ("flu") vaccines on October 3, 2019, or that her condition (to the extent it predated vaccination) was significantly aggravated by these vaccines. Pet. at 1.

I deemed the matter reasonably resolved via ruling on the record, and the parties have now briefed their respective positions. Petitioner's Motion for Ruling on the Record, dated March 3, 2025 (ECF No. 46) ("Br."); Respondent's Brief, dated April 17, 2025 (ECF No. 48) ("Opp."); Reply, dated May 2, 2025 (ECF No. 55) ("Reply"). For the reasons set forth below, I deny

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] Petitioner has married since the case's initiation, and the caption was amended to account for her name change (from "Amanda Seigel")—although the medical record evidence refers to her maiden name.

entitlement. It has not been preponderantly demonstrated that the vaccines Petitioner received, alone or in concert, could or did cause aggravation of her likely preexisting seizure disorder.

I. Fact Background/Medical History

Vaccination and Early Symptoms

Petitioner's pre-vaccination medical history largely does not bear on her claim (although as discussed below, she later reported some earlier symptoms that might be associated with her purported injury—and seems primarily to allege a significant aggravation claim). She did have a history of juvenile rheumatoid arthritis that was believed to have resolved, plus a family history of maternal hypothyroidism. Ex. 2 at 11, 19, 34.

Petitioner (then 24 years old) received doses of the Tdap and flu vaccines on October 3, 2019, during an annual examination. Ex. 2 at 12–14. 25. At this time, a "nodularity [of the left] radial forearm" was noted, and Petitioner was told to contact her treater if any unspecified symptoms she had reported did not improve. *Id*. at 26. There is no contemporaneous medical record evidence of any close-in-time reaction to these vaccines.

A week and a half later (October 12, 2019), Ms. Wiles took herself to an emergency room, where she complained of seizure-like activity that had begun early that morning. Ex. 3 at 13. In particular, she reported recent confusion, and "several episodes during the previous week in which she felt somewhat hazy and [disoriented] however she never lost consciousness and recalls those events." *Id.* She also complained of stiffened muscles when she turned her head. *Id.* Petitioner expressed the view that the vaccines she had recently received may have caused her symptoms. *Id.* at 6, 13–14. A CT scan performed at this time yielded normal results, and Petitioner was discharged but instructed to consult with a neurologist. *Id.* at 17–19.

On October 17, 2019, Petitioner saw neurologist Rachel Rosenbaum, D.O. Ex. 2 at 166. She informed Dr. Rosenbaum that within hours of the October 3rd vaccinations, she began to experience "memory issues," and subsequently felt unwell for several days. *Id.* In addition, she represented that around the time she sought emergency care (October 11–12, 2019), she woke shaking, with clenched fists and arms bent, and that she was foaming at the mouth. *Id.* She otherwise was feeling and acting confused and unwell, although, since the seizure activity, had felt better. *Id.*

Dr. Rosenbaum prescribed anti-seizure medication and ordered an MRI and EEG.[3] Ex. 2 at 166. The EEG was performed that same day, and it revealed epileptiform activity interpreted to evidence "an increased risk for focal seizure." Ex. 3 at 93. But the imaging (cervical and brain) performed a week later revealed nothing of concern. Ex. 6 at 126–27.

Petitioner returned to Dr. Rosenbaum on November 4, 2019, reporting that she had missed a medication dose and had felt "hot/clammy with a sensation of [déjà vu]"—something she recalled experiencing the year before (and hence long pre-vaccination). Ex. 2 at 161. Dr. Rosenbaum opined that Petitioner's symptoms were "likely epileptic (focal seizure vs aura)," and she proposed that Petitioner was suffering from "localization-related epilepsy" that would require persistent medication to treat. *Id.*

Treatment in 2020 and Beyond

The next records filed in this case relating to Petitioner's alleged vaccine injury are from the winter of 2020. On February 10, 2020, Ms. Wiles returned to Dr. Rosenbaum for evaluation of an intermittent hand tremor that she reported had persisted for one month. Ex. 2 at 152. Petitioner was again assessed with localization-related symptomatic epilepsy, and it was noted she had experienced at least one prior tonic-clonic seizure, and that she would require medication for her "very fine" hand tremor. *Id*. at 154–55.

Six months later, during an August 3, 2020, neurology follow-up with nurse practitioner Jennifer Edgar, Petitioner reported experiencing no additional seizures since March (and that was attributed to a missed medication dose), although she had experienced a recurrence of déjà vu symptoms the month before, in connection with a return to school. Ex. 6 at 79. Treaters discussed the need to change up medications due to reported side effects. *Id*. at 79, 82.

That fall (November 19–23, 2020), Ms. Wiles was hospitalized after having a witnessed seizure at work, then three additional seizures once at the hospital without waking and which required sedation and intubation. Ex. 3 at 112. A continuous video-EEG revealed an abnormal "pattern of severe encephalopathy consistent with spindle coma," but without epileptiform discharges or seizures. *Id*. at 149. Petitioner did, however, experience some focal seizures once extubated. *Id.* A November 21, 2020, brain MRI now revealed a "[v]ery small T2 hyperintense [right] frontal white matter focus, unchanged from 2019." *Id*. at 193. Petitioner returned to baseline thereafter, although she continued to complain of déjà vu/aura seizure feelings. *Id.* at 219.

[3] An electroencephalogram ("EEG") is defined as "a recording of the potentials on the skull generated by currents emanating spontaneously from nerve cells in the brain." *Electroencephalogram*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15813 (last visited Dec. 2, 2025).

Petitioner consulted with a different neurologist in December 2020. Ex. 11 at 158. In providing a medical history, she noted that before her first seizure on October 11, 2019, she had experienced "intermittent episodes that she called [déjà] vu for the previous year," that "consisted of a feeling of nausea with a weird and overwhelming feeling in her head that would pass within 30–45 seconds without impairment of awareness or responsiveness." *Id.* The neurologist assessed Petitioner with "presumed focal aware seizures (episodes of [déjà] vu) preceded [petitioner's] first [focal to bilateral tonic-clonic seizure (FBTCS)] by approximately a year." *Id.* at 160.

Petitioner has filed additional records reflecting treatment she received for her epilepsy in 2021–22, but substantively they add little in resolving her vaccine injury claim. Over time, her diagnosis was refined to localization-related, intractable/medically-refractory epilepsy. *See, e.g.*, Ex. 11 at 22, 25. There is no evidence from this period in which treaters explored vaccine causation, or opined that a vaccine was a possible explanation for Petitioner's condition.

II. Expert Opinions

A. Petitioner's Experts

1. *Dr. M. Eric Gershwin* – Dr. Gershwin prepared two written reports for Petitioner. Report, dated May 22, 2024, filed as Ex. 18 (ECF No. 35-1) ("First Gershwin Rep."); Report, dated November 20, 2024, filed as Ex. 58 (ECF No. 44-1) ("Second Gershwin Rep.").

Dr. Gershwin is a Distinguished Professor of Medicine in the Division of Rheumatology/Allergy and Clinical Immunology at the University of California Davis School of Medicine. Curriculum Vitae, dated May 31, 2024 (ECF No. 35-22) at 1. Before his current role, he served as the Chief of the same division for nearly forty years. *Id.* Dr. Gershwin received his medical degree from Standford University before completing his residency at Tufts-New England Medical Center. *Id.* He is triple board-certified with boards in internal medicine, allergy-immunology, and rheumatology. *Id.* at 2. In addition to seeing patients, Dr. Gershwin serves as an editor for several autoimmunity and allergy journals, and his research has led to the publication of over a thousand peer-reviewed articles. *Id.* 5–142.

First Report

Dr. Gershwin's initial report was quite succinct, and provided a listing of medical records reviewed rather than his own summary of their contents (although he did review these items in preparing his opinion). First Gershwin Rep. at 1. With respect to Petitioner's diagnosis, Dr. Gershwin deferred to Petitioner's expert neurologist (Dr. Justin Willer). But he opined generally that "there was evidence of a seizure disorder prior to the vaccination," and that the sole

environmental factor that could have "caused or contributed to the changes in seizure activity" that Petitioner experienced were the flu and Tdap vaccines she received. *Id.* at 2, 3.

Dr. Gershwin framed around his causation theory a discussion of the "blood brain barrier" ("BBB")—a tightly-connected layer of endothelial cells found inside blood vessels around the brain that control what is allowed to permeate into the brain.[4] First Gershwin Rep. at 2. He noted that medical science (which once thought of the brain as "a perfect immunologically privileged site") now understood the BBB is not "impenetrable," but instead can allow the transfer of a variety of cells and blood components into the brain—including immune cells like cytokines (which can actually impact the BBB's filtering function). *Id.*

The central nervous system ("CNS") generally "plays an active role" in defending the brain from pathogens. First Gershwin Rep. at 2. Even if the brain itself is not a likely place where "antigen-specific adaptive immune response" (meaning production of antibodies in reaction to foreign antigens) occurs, the brain has many "resident" immune cells that aid in its immunologic protection. *Id.* However, these brain-specific innate responses cannot always prevail against certain kinds of pathogenic attack, such as in the context of a viral-caused encephalitis. *Id.* at 3.

A vaccine can affect the BBB's permeability, Dr. Gershwin maintained, through its immune impact. First Gershwin Rep. at 2. In particular, he maintained that there is a "potential for migration of activated immune cells into the brain." *Id.* at 3; M. Bradl & A. Flugel, *The Role of T Cells in Brain Pathology*, 265 Current Topics in Microbiology and Immunology 141, 150–52 (2002), filed as Ex. 27 (35-10) ("Bradl & Flugel"). The BBB would normally prevent T cells from entry, but certain conditions could activate them sufficiently to breach it, and Dr. Gershwin outlined several possibilities. *Id.* T cells activated by a foreign antigen that *also* had amino acid sequential similarity (via molecular mimicry) to a CNS antigen could then initiate an autoimmune disease, as corroborated by animal model experiments involving induction of autoimmune CNS disease. *Id.*; B. Dittel et al., *Presentation of the Self Antigen Myelin Basic Protein by Dendritic Cells Leads to Experimental Autoimmune Encephalomyelitis*, 163 J. Immunology 32, 32 (1999), filed as Ex. 37 (ECF No. 53-1); G. Fossati et al., *Triggering a Second T Cell Receptor on Diabetogenic T Cells Can Prevent Induction of Diabetes*, 190 J. Exp. 577, 577 (1999), filed as Ex. 38 (ECF No. 35-21). The activation could occur in response to receipt of a vaccine as well, in Dr. Gershwin's opinion (although he cited no literature specific to the proposed impact of a vaccine). First Gershwin Rep. at 3.

[4] The "Blood Brain Barrier" is defined as "the barrier system separating the blood from the parenchyma of the central nervous system. Its anatomic component consists of unique endothelial cells in the brain capillaries, having tight junctions without fenestrations and with few microvilli and few vesicles for fluid transport." *Blood-brain barrier*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=60232 (last visited Dec. 4, 2025).

Second Report

Dr. Gershwin's supplemental report solely reacted to the opinion offered by Respondent's immunology expert, Dr. You-Wen He. Dr. Gershwin maintained that his causation theory (arising from his own expertise as an immunologist) centered on two questions: "whether cytokines alter the blood brain barrier and whether cytokines released during vaccination are sufficient to alter this barrier." Second Gershwin Rep. at 1. Dr. He, however, had not in Dr. Gershwin's estimation addressed these matters, instead simply denying in blanket form any vaccine association, and ignoring "the well-established fact that cytokines do modulate the blood brain barrier." *Id.* He also contended that Dr. He addressed matters not relevant to this case (such as the degree to which the immune response was the same for vaccines as for a wild infection). *Id.*

Dr. Gershwin then went on to reiterate the opinion set forth in his first report. Second Gershwin Rep. at 2–3. Cytokines generated in response to a vaccination, he maintained, were an important reasons vaccines "work," and are rapidly upregulated after a vaccine's administration. *Id.* at 2. BBB cytokine levels have, in studies about its disruption, been shown to be comparably high (although how the peripherally-induced cytokines would impact the BBB *at the same time as vaccination,* or even within a day thereafter, was not addressed in the literature offered to support this contention). J. Brown et al., *Metabolic Consequences of Inflammatory Disruption of the Blood-Brain Barrier in an Organ-On-Chip Model of the Human Neurovascular Unit*, 13 J. Neuroinflammation 1, 5–14 (2016), filed as Ex. 60 (ECF No. 44-3).

Thus, Dr. Gershwin seemed to suggest that vaccine-induced cytokine increases could impact the BBB and allow immunologic harm to the brain. In support, he offered a series of block quotes from some other articles (although they involved different vaccines, addressing the epilepsy injury in this case only indirectly). Second Gershwin Rep. at 2–3 (citing S. Eslait-Olaciregui et al., *Serious Neurological Adverse Events Following Immunization Against SARS-CoV-2: A Narrative Review of the Literature*, 14 Therapeutic Advances in Drug Safety 1, 14 (2023), filed as Ex. 66 (ECF No. 44-9) ("Eslait-Olaciregui") (a literary review assessing certain neurological adverse effects occurring after the COVID-19 vaccine); A. Yarlagadda et al., *The Blood Brain Barrier and the Role of Cytokines in Neuropsychiatry*, 6 Psychiatry 1, 1–4 (2009), filed as Ex. 67 (ECF No. 44-10)). None stood as robust evidence for the conclusion that *vaccination* is sufficient to cause breach of the BBB and lead to seizures.

2. *Dr. Justin A. Willer* – Dr. Willer is a clinical neurologist, and he offered one report on Petitioner's behalf. Report, filed May 31, 2024, as Ex. 40 (ECF No. 35-23) ("Willer Rep."). Dr. Willer maintained that the two vaccines Petitioner received on October 3, 2019, acted in combination to substantially aggravate a preexisting seizure disorder. Willer Rep. at 31.

Dr. Willer received his undergraduate degree from Columbia College of Columbia University and his medical degree from the University of Health Sciences/The Chicago Medical School. Curriculum Vitae, dated May 31, 2024, filed as Ex. 57 (ECF No. 35-40). He has held hospital appointments at University Hospital, Long Island College Hospital, Maimonides Hospital Medical Center, and Kings County Medical Center. *Id.* He has also held academic appointments as a Neuromuscular Consultant and Assistant Professor of Clinical Neurology at the State University of New York, HSC at Brooklyn. *Id.* He is licensed to practice medicine in New York, New Jersey, and Florida, and is board certified by the American Board of Psychiatry and Neurology, with added qualifications in clinical neurophysiology, and American Board of Electrodiagnostic Medicine. *Id.* at 3.

Dr. Willer's report included a lengthy initial review of Petitioner's relevant medical history. Willer Rep. at 2–15. Throughout this section, he underscored the fact that Petitioner had reported some initial, neurologic-like symptoms, such as confusion and memory issues, in the timeframe between vaccination and first seizures. *Id.* at 2. And he noted medical treatment evidence that Petitioner's disorder likely predated vaccination, with instances of feelings she referred to as a sensation of "deja vu." *Id.* at 7, 12.

Dr. Willer then discussed epilepsy as a general matter. Willer Rep. at 16. He defined epilepsy to be "a disorder of the brain characterized by an enduring predisposition to generate epileptic seizures, and by the neurobiologic, cognitive, psychological, and social consequences of this condition." *Id.* (citing R. Fisher et al., *A Practical Definition of Epilepsy*, 55 Epilepsia 475, 475 (2014), filed as Ex. 41 (ECF No. 35-24) ("Fisher"). A current diagnostic understanding of epilepsy requires evidence of at least two unprovoked seizures within more than a 24-hour period, with a risk of recurrence thereafter over ten years. Willer Rep. at 16; Fisher at 475.

Seizures, Dr. Willer noted, could be triggered by a variety of environmental factors—including vaccination—and he offered a number of case reports in which this had purportedly occurred (although many are facially distinguishable—involving either different diseases that featured an initial seizure, or febrile seizures in a pediatric population). *See, e.g.*, N. Nakamura et al., *Neurologic Complications Associated with Influenza Vaccination: Two Adult Cases*, 42 Internal Medicine 191, 193–94 (2003), filed as Ex. 42 (ECF No. 35-25) (instances of transverse myelitis and acute disseminated encephalomyelitis after receipt of flu vaccine); D. Craiu et al., *Vaccination and Childhood Epilepsies*, 36 Eur. J. Paediatric Neurology 57, 57 (2002), filed as Ex. 43 (ECF No. 35-26) ("Craiu"); J. Duffy et al., *Febrile Seizure Risk After Vaccination in Children 6 to 23 Months*, 138 Pediatrics 1, 5–8 (2016), filed as Ex. 44 (ECF No. 35-27) ("Duffy").

Dr. Willer maintained that receipt of several vaccines at once, as here, could cause greater CNS inflammation than would be experienced due to a single vaccine alone. Willer Rep. at 16. He offered some medical literature demonstrating how seizure activity was associated with

upregulation of certain kinds of proinflammatory cytokines. A. Vezzani et al., *Experimental and Clinical Evidence*, 46 Epilepsia 1724, 1728 (2005), filed as Ex. 45 (ECF No. 35-28) ("Vezzani"); Y. Paudel et al., *Role of Inflammation in Epilepsy and Neurobehavioral Comorbidities: Implication for Therapy*, 837 Eur. J. Pharmacology 145, 146 (2018), filed as Ex. 46 (ECF No. 35-29). In addition, seizure threshold could be reduced inside the brain (impacting the native CNS immune protections) by inflammation that managed to penetrate the BBB. Willer Rep. at 17–18; K. Rogers et al., *The Cortical Innate Immune Response Increases Local Neuronal Excitability Leadings to Seizures*, 132 Brain 2478, 2478 (2009), filed as Ex. 47 (ECF No. 35-30). Thus, inflammation-driven exacerbation of a seizure disorder could "change the level of future seizure activity," causing more frequent and damaging seizures later. Willer Rep. at 32.

Otherwise, a number of articles Dr. Willer offered more specifically linked vaccination to recurrence or aggravation of seizure activity (although again more often than not the literature cited involved children or a distinguishable vaccine). R. Zhang et al., *Influenza Associated Neurologic Complications in Children from an H3 2 Outbreak in Shenzhen, China during COVID-19 Lockdown*, 134 I. J. Infectious Diseases 91, 91–92 (2023), filed as Ex. 48 (ECF No. 35-31) ("Zhang"); J. Murphy et al., *Recurrent Seizures After Diptheria, Tetanus, and Pertussis Vaccine Administration*, 138 AJDC 908, 909 (1984), filed as Ex. 50 (ECF No. 35-33) ("Murphy"); E. Pang et al., *COVID-19 Vaccination-Related Exacerbation of Seizures in Persons with Epilepsy*, 138 Epilepsy & Behavior 1, 2–3 (2023), filed as Ex. 52 (ECF No. 35-35) ("Pang").

Petitioner's own record, Dr. Willer contended, was consistent with the conclusion that her epileptic disorder had been vaccine-aggravated. Willer Rep. at 22–31. Most of this section of Dr. Willer's report simply repeated his prior medical history review. But he emphasized again that Petitioner's condition (mainly characterized by nonspecific seizure-like instances of feelings of nausea/déjà vu) predated vaccination. *Id.* at 22. Dr. Willer defined these episodes as "epileptic auras," or "simple partial seizures. *Id.* at 31.

By contrast, after receipt of the two vaccines, Petitioner experienced some alarming feelings of confusion coupled with physical symptoms, which began either the day of vaccination (reflected by "memory issues") or a week later, based on reports Petitioner made at the time of her October 12, 2019, emergency room visit. Willer Rep. at 22–23, 26. (Dr. Willer seemed to find reports of partial seizure activity very close-in-time to vaccination to be unreliable. *Id.* at 32–33). Regardless, she had actual seizures after the vaccinations, which became more intractable by November 2019, a month post-vaccination. *Id.* at 33. Hence, her seizure disorder/epilepsy had worsened in the subsequent timeframe.

B. Respondent's Experts

1. *Dr. Elaine Wirrell* – Dr. Wirrell is a pediatric neurologist and epileptologist, and she offered a single written report for Respondent. Report, filed July 29, 2024, as Ex. A (ECF No. 36-1) ("Wirrell Rep.").

Dr. Wirrell is board-certified in both pediatrics and neurology and has practiced as a pediatric neurologist, treating thousands of patients. Wirrell Rep. at 1–2; Curriculum Vitae, dated July 29, 2024, filed as Ex. B (ECF No. 36-2) ("Wirrell CV") at 1–2. She obtained her M.D. at the University of British Columbia, Vancouver, and attended the IWK Hospital for Children in Halifax, Nova Scotia to complete her Residency and Fellowship. Wirrell CV at 1. Dr. Wirrell currently serves as the Chair of Child Neurology and the Child and Adolescent Neurology Clinic Director at the Mayo Clinic in Rochester, MN—a position that he has held since 2022. *Id.*; Wirrell Rep. at 1. Dr. Wirrell has published over 250 peer-reviewed articles, book chapters, and reviews regarding pediatric epilepsy and seizure disorders. *Id.* at 51–97.

Like Dr. Willer, Dr. Wirrell conducted her own medical record review, summarizing it in the first section of her report. Wirrell Rep. at 2–9. She deemed Petitioner's first "recognized" seizure to have occurred On October 13, 2019—the incident that led to the emergency room visit. *Id.* at 3. But at later consultations with neurologic experts, Petitioner reported her *pre-vaccination* intermittent episodes, leading Dr. Wirrell to agree with Dr. Willer that Petitioner's epilepsy likely predated receipt of the flu and Tdap vaccines. *Id.* at 4. Based on the records, Dr. Wirrell opined that Petitioner could be properly diagnosed with "drug-resistant focal epilepsy," and that it likely began before vaccination, albeit with more subtle episodes (a "not uncommon" occurrence, she proposed). *Id.* at 9–10, 14.

Dr. Wirrell next discussed some known etiologic bases for epilepsy, and how Petitioner's history corresponded to them. Wirrell Rep. at 10–11 (citing E. Wirrell, *Evaluation of First Seizure and Newly Diagnosed Epilepsy*, 28 Continuum 230, 232–35 tbl. 1-1, (2022), filed as Ex. A Tab 18 (ECF No. 39-8) ("Wirrell")). Dr. Wirrell could not affirmatively embrace a structural/brain malformation explanation for Petitioner's condition (despite some slight brain MRI findings that were suggestive of a "focal cortical dysplasia"),[5] and metabolic/infectious testing had not resulted in any explanatory results. Wirrell Rep. at 10. A genetic cause was also unlikely, given Petitioner's lack of a family history of epilepsy. *Id.* An autoimmune explanation had some plausibility, since Petitioner and her family had a demonstrated history of other autoimmune diseases, but testing had

[5] "Focal cortical dysplasias consist of abnormal cortical lamination in a discrete area of cortex. High-resolution, thin-section MRI can reveal these areas sometimes in the setting of drug-resistant epilepsy." *Nelson Textbook of Pediatrics* 2809 (R. Kliegman et al. eds., 20th ed. 2016).

been mostly inconclusive. *Id.*[6] Otherwise, a third to one-half of all epilepsy cases are deemed idiopathic (although Dr. Wirrell did not firmly express the view that this best explained the cause of Petitioner's epilepsy). *Id.* at 11; Wirrell at 245.

The Tdap and flu vaccines, by contrast, were not likely causal of epilepsy, in Dr. Wirrell's view. Wirrell Rep. at 11–13. Regarding the Tdap vaccine, Dr. Wirrell acknowledged some literature support for an increased risk of *febrile* seizures (meaning seizures in the context of, or attributable to, a vaccine-induced fever) within a few days of vaccination, and particularly for infants or young children. M. Daley et al., *Safety of Diphtheria, Tetanus, Acellular Pertussis and Inactivated Poliovirus (DTaP-IPV) Vaccine*, 32 Vaccine 3019, 3019 (2014), filed as Ex. A Tab 4 (ECF No. 38-4). But several studies performed in the last 15 years found no comparable risk of *afebrile* seizures. Y. 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, 823 (2012), filed as Ex. A Tab 15 (ECF No. 39-5). Similar determinations were made in studies involving the flu vaccine. S. Haberg et al., *Epilepsy in Children After Pandemic Influenza Vaccination*, 141 Pediatrics 1, 1 (2018), filed as Ex. A. Tab 10 (ECF No. 38-10); A. Kawai et al., *Febrile Seizures After 2010–11 Trivalent Inactivated Influenza Vaccine*, 136 Pediatrics 848, 848 (2015), filed as Ex. A Tab 13 (ECF No. 39-3).

More to the point, Dr. Wirrell maintained, it could not be demonstrated with citation to independent literature or studies that the vaccines at issue could likely *worsen* existing epilepsy. Wirrell Rep. at 13–14. She allowed that transient exacerbation (consistent with findings about vaccination and fever-associated seizure activity) occurs, but denied that reliable studies showed "that persons with epilepsy who have had a vaccine-proximate seizure have a poorer long-term outcome with higher rates of drug resistance or more frequent seizures" than unvaccinated individuals. Wirrell Rep. at 13.

Dr. Wirrell offered several items of literature offering indirect support for this contention, since they involved child samples or known genetically-caused seizure disorders. *See, e.g.*, A. McIntosh et al., *Effects of Vaccination on Onset and Outcome of Dravet Syndrome: A Retrospective Study*, 9 Lancet Neurol 592, 596–97 (2010) filed as Ex. A Tab 14 (ECF No. 39-4) (finding no reasonable basis the DTP vaccinations cause Dravet syndrome); K. Top et al., *Risk of Seizures After Immunization in Children with Epilepsy: A Risk Interval Analysis*, 18 BMC Pediatrics 134, 134 (2018), filed as Ex. A Tab 16 (ECF No. 39-4). But at least one study a bit more on point supported the conclusion that receipt of a vaccine comparable to the version at issue did not result in worsening of epilepsy. L. Arnheim-Dalhstrom et al., *Risk of Presentation to Hospital with Epileptic Seizures after Vaccination with Monovalent ASO3 Adjuvanted Pandemic A/HlNl*

[6] At best, Dr. Wirrell speculated, Petitioner might meet the criteria for a diagnosis of "Steroid Responsive Encephalopathy Associated with Thyroid Disease"—although Petitioner was never treated with steroids in the first place, and otherwise there is insufficient evidence in the record to embrace this diagnostic explanation. Wirrell Rep, at 10–11.

2009 Influenza Vaccine (Pandemrix): Self Controlled Case Series Study, 345 BMJ 1, 1 (Dec. 28, 2012), filed as Ex. A Tab 1 (ECF No. 38-1) ("Arnheim-Dahlstrom").

Given all of the above, Dr. Wirrell did not deem Dr. Willer's opinion persuasive. To begin with, she criticized Dr. Willer for eliding the difference between epilepsy and a seizure (which is a "symptom of epilepsy"), noting that transient worsening of epileptic symptoms was not consistent with a larger-scale worsening of epilepsy as a condition. Wirrell Rep. at 14. Dr. Wirrell again deemed there to be a substantive difference between worsening of epilepsy overall versus a transient flare in seizure activity in response to some environmental stimulation that did not persist.

Dr. Wirrell next pointed out deficiencies in the probative value of literature Dr. Willer had cited in support of causation. *Id.* at 15–17. Craiu, for example, focused on the risk of *febrile* seizures, a concern limited to pediatric patients under the age of six (and hence wholly inapplicable to Petitioner, who was a young adult at the time of vaccination), and otherwise did not establish a true risk of vaccine-caused worsening. *Id.* at 15; Craiu at 57. Duffy was similarly focused on infant patients and the risk of febrile seizures. Wirrell Rep. at 15; Duffy at 5–7. Murphy (which Dr. Wirrell noted was 40 years old) not only involved infants, but a whole-cell pertussis version of a Tdap-like vaccine no longer administered (and also had methodologic weaknesses). Wirrell Rep. at 16; Murphy at 909. And Pang not only involved a different vaccine (COVID-19 vaccine), but at best supported transient exacerbation close-in-time to vaccination. Wirrell Rep. at 17; Pang at 2–3.

2. *Dr. You-Wen He* – Dr. He is a medical doctor and immunologist who authored a single written report commenting on primary causation questions raised by Petitioner's claim. Report, dated September 4, 2024, filed as Ex. C (ECF No. 40-1) ("He Rep.").

Dr. He received his M.D. from the Fourth Military Medical University in Xian, China, and his Ph.D. in Microbiology and Immunology from the University of Miami School of Medicine in Miami, Florida. Curriculum Vitae, dated Sep. 6, 2024, filed as Ex. D (ECF No. 40-2) at 1. Dr. He is currently a Professor of Immunology at the Department of Immunology at Duke University Medical Center. *Id.* During the course of his career, Dr. He has reviewed National Institutes of Health ("NIH") studies, serves on editorial boards, and has authored or co-authored numerous publications. *Id.* at 2–17. Dr. He's research focuses on His research areas include "innate and adaptive immunity against viral and bacterial infections[,] as well as tumors." He Rep. at 1. He has conducted research on human immune responses to viral infections and is currently a Co-Principal Investigator for clinical trials focusing on cancer immunotherapy. *Id.*

Although Dr. He did not offer an opinion as to interpretation of diagnostic or medical facts, he reviewed Petitioner's medical history and wrote up a summary of her condition, agreeing with the other experts that she was properly understood to have epilepsy. He Rep. at 2–5. Dr. He also accepted the definition of epilepsy that other experts embraced. *Id.* at 5–6.

Dr. He next turned to the aspect of Dr. Gershwin's opinion focusing on the BBB and how its breach could spark an attack on CNS tissues in the brain, resulting in epilepsy. He Rep. at 6–7. Although Dr. He accepted Dr. Gershwin's general definition of the BBB and its function, and allowed that wild infections can disrupt it (causing neuroinflammatory brain injuries like encephalitis or bacterial meningitis), he denied that reliable evidence existed suggesting the either of the vaccines at issue could have the same impact resulting in a disease with seizure as a symptom. *Id*. at 7.

Specifically, Dr. He acknowledged (consistent with Dr. Gershwin's contention) that current science no longer viewed the BBB as impenetrable—and that in fact regulation of CNS homeostasis *required* some permeability in it. He Rep. at 9. But he deemed the argument that vaccination could impact the function of the BBB to lack support, noting that Dr. Gershwin had offered no evidence to support the idea. *Id.*

The same was true, Dr. He maintained, for the follow-on component of Dr. Gershwin's theory, in which immune cells activated due to vaccination would migrate from the periphery, through the BBB and into the CNS, causing injury. He Rep. at 10–18. And he disputed each separate element of Dr. Gershwin's argument.

For example, Dr. He denied the existence of evidentiary support for the idea that vaccination could induce T cell migration (in the manner discussed in Bradl & Flugel, which involved T cell migration solely in the context of wild infections or experimentally-induced encephalomyelitis). He Rep. at 10; Bradl & Flugel at 149–52. He contested the idea that these migrating T cells would have cross-reactive potential in the CNS (due to their mimicry with foreign antigens and CNS structures), noting that (a) no homology had been demonstrated between these vaccines' components and any CNS proteins, and (b) it was not established that Petitioner had ever been diagnosed with an autoimmune form of epilepsy in any event (rendering theories about cross-reactivity due to molecular mimicry moot). He Rep. at 10–11. And he contended that there were sound scientific and medical reasons to doubt that molecular mimicry was a likely mechanism generally for autoimmune diseases, given the frequency of homology in nature, and accompanying cross-reactivity without disease. *Id.* at 11–13.

Dr. Gershwin's theory also, Dr. He maintained, inadequately took into account the extent to which the human immune system's regulatory "checks and balances" were able to prevent autoimmune injury. He Rep. at 13–14. Because of these safeguards, "the critical determinant of autoimmune disease development upon antigen stimulation is the strength/extent of the immune activation" at issue, as opposed to the possibility of cross-reactivity due to mimicry alone. *Id.* at 14. While wild infectious processes could be robust enough to overcome immune tolerance, this was not also the case for vaccinations, which (due to their formulation, more limited antigenic

nature, and controlled impact in prompting an immune response) were far less likely to provoke autoimmune disease in the same manner. *Id.* at 15–17. And animal model studies designed to simulate encephalitic injuries intentionally employed powerful adjuvants (in order to render the experiments useful in their observations) that were not comparable in effect to a vaccine. *Id.* at 17.

More specific to the allegations in this case, Dr. He questioned whether an association between the flu and Tdap vaccines and seizures could be substantiated. He Rep. at 7–8. He noted generally, for example, that publications on adverse vaccine effects from the former Institute of Medicine[7] had not observed an association between the flu or Tdap vaccines and seizures. *Adverse Effects of Vaccines: Evidence and Causality, Institute of Medicine* (K. Stratton et al., eds. 2012), filed as Ex. C Tab 6 (ECF No. 41-6). A more recent, systemic review article similarly observed no studies linking these vaccines to epilepsy. M. Dudley et al., *The State of Vaccine Safety Science: Systematic Reviews of the Evidence*, 20 Lancet Infect. Dis. e80, e84 (2020), filed as Ex. C Tab 7 (ECF No. 41-7). But the literature offered by Dr. Willer was inapt (involving different vaccines, injuries, or febrile seizures in an infant/pediatric population), with Dr. He repeating many of the same criticisms voiced by Dr. Wirrell. He Rep. at 18–21.

III. Procedural History

By August 2022, Petitioner had filed all relevant and outstanding medical records. ECF No. 19. Respondent thereafter filed a Rule 4(c) Report on April 25, 2023, arguing that the Petition should be dismissed as Petitioner had "not provided an expert report, nor other preponderant medical evidence supporting causation sufficient to meet her burden of proof." Respondent's Report, dated Apr. 25, 2023 (ECF No. 27). I held a status conference on May 4, 2023, after which I ordered Petitioner to file her expert report on or before July 31, 2023. *See* Docket Entry Order dated May 4, 2023. Thereafter, Petitioner requested extensions of time twice, which I granted. *See* ECF Nos. 28 and 29. After Petitioner filed a third motion for extension on November 11, 2023, I scheduled a status conference with the parties on November 16, 2023. *See* Docket Entry Order, dated Nov. 13, 2023. Petitioner noted at that time that she was considering dismissal of the claim, given her difficulty in retaining an expert opinion, and also considering whether to proceed *pro se* or retain new counsel. By January 2024, however, existing counsel appeared for Petitioner. Thereafter, the aforementioned expert reports were filed by both sides, and I set a schedule for briefing entitlement to a damages award via ruling on the record. *See* Docket Entry Order, dated Dec. 2, 2024. The briefing was completed by May of this year, and the claim is ripe for resolution.

[7] The Institute of Medicine is now known as the "National Academy of Sciences, Engineering, and Medicine."

IV. Party Arguments

Petitioner

Petitioner acknowledges her claim alleges significant aggravation of a pre-vaccination seizure disorder, and she attempts to show how she can meet the test for such a claim as established in *Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 144 (2009). Br. at 14. She contends the initial three *Loving* prongs are satisfied. Br. at 15–23. Petitioner had a preexisting, if undiagnosed, seizure disorder prior to vaccination, and characterized by episodes of seizure auras. *Id.* at 15–16. After vaccination, however, she actually began to undergo true seizures as recognized by medical science and her own treaters, requiring significant treatment for them in response. *Id.* at 16–18. Her post-vaccination overall health was facially worse than before, and thus met the test for a "significant aggravation." *Id.* at 18–23.

Petitioner also maintains that the last three *Loving* prongs (which correspond to the test for direct causation-in-fact as established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005)) have been satisfied. Br. at 23–39. First, she asserts that it has been preponderantly established that the flu and Tdap vaccines can cause aggravation of a seizure disorder. Br. at 23 ("the combination of the vaccinations created acute inflammation which impacted Petitioner's central nervous system function (via Dr. Gershwin's mechanism), resulting in the rapid and significant aggravation of Petitioners preexisting, primarily asymptomatic seizure disorder (as explained by Dr. Willer)"). Dr. Gershwin demonstrated that vaccine-induced cytokine production can impact the BBB, allowing immune cells (in particular, those reacting to antigens that are mimics of CNS tissue structures) to cross into the CNS and potentially cause autoimmune harm. *Id.* at 24–30. This could induce an encephalopathy sufficient to secondarily impact seizure activity. *Id.* at 30–31. And Dr. Willer independently established that inflammation (often attributable to proinflammatory cytokines) can worsen seizure activity—and that such inflammation can be vaccine-induced (especially if two vaccines are administered at the same time, as here). *Id.* at 31–36 (referencing Vezzani; Craiu; Duffy).

Second, Petitioner contends that she has successfully demonstrated that the vaccines at issue did worsen her epilepsy. Br. at 37–38. In support, she primarily references the obvious change between the nature of her pre-vaccination partial seizures and what came later, claiming that the transition was unlikely but for vaccination. *Id.* Thus, she had established a sequence of events consistent with the theory that the vaccines worsened her epilepsy. *Id.* at 38. And she argues that the sixth *Loving* prong is met as well, since the onset of her worsened seizure activity likely occurred between two and nine days post-vaccination—a medically acceptable timeframe for the vaccines to impact her existing but less-severe epilepsy. *Id.* at 39.[8]

[8] Petitioner's brief also argues that Respondent has not established a sufficient "factor unrelated" to explain Petitioner's injury (Br. at 40), but the obligation to so prove only arises in cases where Petitioner's success in

On reply, Petitioner reaffirms that she has satisfied all the *Loving* prongs and emphatically rejects Respondent's arguments that Petitioner has failed to satisfy her burden. *See generally*, Reply. Citing her medical records, her expert witnesses' opinions, and offered medical literature, Petitioner claims that these items show the existence of her condition, it's frequency, and severity after vaccination and satisfy *Loving* prong one, two, and three. *Id.* at 3–11. Further, Petitioner claims that Respondent does not dispute/has conceded her success in satisfying *Loving* prongs one, two, three, and six. *Id.* at 10, 32. When discussing *Loving* prongs four and five, Petitioner echoes the arguments laid out in her Brief. *See id.* at 11–33. Specifically, Petitioner claims that Respondent and his experts' theories and arguments are unsuccessful, as Respondent's experts refused to acknowledge or consider generally accepted scientific and medical data and theories put forward by Petitioner and her experts. *See id.* at 15–23, 26. In addition, Petitioner claims that Respondent is impermissibly seeking to heighten Petitioner's burden to that of scientific certainty, and require that Petitioner produce epidemiologic evidence in her favor to prevail. *See id.* at 11–14, 23.

Respondent

Respondent agrees that Petitioner likely had a pre-vaccination seizure disorder, but contests Petitioner's success in satisfying the *Loving* prongs for a significant aggravation claim (focusing in particular on the three *Loving* prongs comparable to the *Althen* elements). *See generally* Opp. at 12–30. He notes initially that Petitioner's *form* of epilepsy, as reflected by the medical evidence, is not likely one that could be considered autoimmune in nature. *Id.* at 14–15. Ultimately, there was no evidence generated in the course of Petitioner's treatment that this was the case, and Petitioner's experts either lacked the qualifications to propose such a diagnosis or failed to do so. *Id.* at 15–16. Respondent also stresses that Dr. Willer relied on numerous items of literature involving febrile seizures in children—a context completely irrelevant to this case. *Id.* at 16–17.

The first relevant *Loving* prong (prong four, an analog to *Althen* prong one) has not been met, Respondent argues. Opp. at 17–25. Many items of evidence offered in favor of causation, like Craiu, involved pediatric seizures, and did not otherwise stand for the proposition that *afebrile* seizures can be vaccine–induced. *Id.* at 18. By contrast, Respondent's experts offered ample persuasive articles and studies showing no risk of seizures in the context relevant to this case. *Id.* In fact, as Dr. Wirrell established, epilepsy exacerbation was unlikely *even* in the context of children experiencing febrile seizures. *Id.* at 18–19 (citing Wirrell Rep. at 14).

Petitioner also did not establish that an innate immune response to vaccination, resulting in increased cytokine production, could likely provoke a worsening of an existing seizure

establishing the prima facie elements of her claim causes the burden of proof to shift—and, as noted below, I do not find that Petitioner has carried her initial burden.

disorder—while Petitioner's experts at the same time also assumed an autoimmune process was contributing to Petitioner's injury, even though the argument was speculative and overbroad (in assuming that the intended effect of vaccination becomes pathologic). Opp. at 19–24. And insufficient reliable evidence had been offered to establish that vaccines have been shown capable of provoking such a harmful cytokine response resulting in this specific kind of injury that is CNS-oriented. *Id.* at 24–25.

The remaining two *Loving* prongs (corresponding to *Althen* prongs two and three) had also not been established. Opp. at 25–29. *Loving* prong five (requiring Petitioner to show that the Tdap and flu vaccines likely did worsen her epilepsy) was unmet because Petitioner has not shown that her post-vaccination status was inconsistent with the usual course of epilepsy, or more reflective of a form of worsening associated with vaccination. *Id.* at 26. There was nothing in the actual medical record that corroborated Petitioner's theory that overproduction of cytokines due to vaccination had caused a BBB breach (given the absence of evidence that Petitioner ever experienced a systemic kind of inflammation). *Id.* at 27. Petitioner's treaters found in their testing no results suggestive of CNS inflammation. *Id.* And Petitioner's onset of seizure worsening, in the two to ten day post-vaccination period, had not been shown by her experts to be medically acceptable, with Petitioner over-relying on evidence specific to the irrelevant context of febrile seizures in children. *Id.* at 28–29.

V. Relevant Legal Standards

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

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[9] No Table claim is alleged, nor is there a Table claim for epilepsy as a defined vaccine injury.

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

[9] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *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, 1352–53 (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*, 418 F.3d at 1278: "(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 proximate temporal relationship between vaccination and injury."

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

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny 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. Distinguishing between "preponderant evidence" and "medical certainty" is important because special masters must take care not to impose an evidentiary burden that is too high. *Bunting*, 931 F.2d at 873 ("The standard of proof required by the [Vaccine] Act is simple preponderance of evidence; not scientific certainty.... [I]t is not plaintiff's burden to disprove every possible ground of causation suggested by defendant nor must the findings of the court meet the standards of the laboratorian.") (citations and internal quotation marks omitted).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Cerrone v. Sec'y of Health & Hum. Servs.*, 146 F.4th 1113, 1122 (Fed. Cir. 2025); *Kalajdzic v. Sec'y of Health & Hum. Servs.*, No. 2023-1321, 2024 WL 3064398, at *2 (Fed. Cir. June 20, 2024) (arguments "for a less than preponderance standard" deemed "plainly inconsistent with our precedent" (*citing Moberly*, 592 F.3d at 1322)); *Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also Demore v. Sec'y of Health & Hum. Servs.*, No. 20-1265V, 2024 WL 4542934 (Fed. Cl. Spec. Mstr. Sept. 26, 2024), *aff'd*, No. 20-1265V, 2025 WL 868902, at *4 (Fed. Cl. Mar. 20, 2025) (rejecting the argument that a petitioner's burden is to prove that a causation theory is *plausible* and instead requiring petitioner to prove the theory by a preponderance of the evidence) (emphasis added). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

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; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *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, 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).

Medical records and statements of a treating physician, however, 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 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); *Veryzer v. Sec'y of Dept. 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 F. Appx. 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 medically acceptable timeframe must align 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. Den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 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 rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Elements of Significant Aggravation Claim*

Where a petitioner alleges significant aggravation of a preexisting condition, the *Althen* test is expanded, and the petitioner has additional evidentiary burdens to satisfy. *Loving*, 86 Fed. Cl. at 144. In *Loving*, the Court of Federal Claims combined the *Althen* test with the test from *Whitecotton v. Sec'y of Health & Hum. Servs.*, 81 F.3d 1099, 1107 (Fed. Cir. 1996), which related to on-Table significant aggravation cases. The resultant "significant aggravation" test has six components, which require establishing:

> (1) the person's condition prior to administration of the vaccine, (2) the person's current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person's current condition constitutes a 'significant aggravation' of the person's condition prior to vaccination, (4) a medical theory causally connecting such a significantly worsened condition to the vaccination, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) a showing of a proximate temporal relationship between the vaccination and the significant aggravation.

Loving, 86 Fed. Cl. at 144; *see also W.C.*, 704 F.3d at 1357 (holding that "the *Loving* case provides the correct framework for evaluating off-table significant aggravation claims"). In effect, the last three prongs of the *Loving* test correspond to the three *Althen* prongs.

C. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11I(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 415, 417 (Fed. Cir. 1993) (determining that 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).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to 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); *Cucuras*, 993 F.2d at 1525 ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

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 often 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. United States 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, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) 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. *La Londe 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.

D. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his 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). Under *Daubert*, the 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).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *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 the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. 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 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. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). 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. *Moberly*, 592 F.3d 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").

E. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

F. *Resolution of Case Without Hearing*

I am resolving Petitioner's claim on the filed record. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *21 n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs*., 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

The parties agree that Petitioner was properly diagnosed with focal epilepsy that likely began prior to vaccination, making this a proper significant aggravation claim to be analyzed under the *Loving* factors. Nevertheless, two aspects of Petitioner's injury warrant highlighting. First, the relevant medical record does not preponderantly support the conclusion that Petitioner likely experienced an *autoimmune* form of epilepsy, driven by autoantibodies. *See Agarwal v. Sec'y of Health & Hum. Servs*., No. 16-191V, 2020 WL 5651683 (Fed. Cl. Spec. Mstr. Aug. 31, 2020)

(child developed autoimmune limbic encephalitis (ALE) with intractable seizures after receiving Tdap and meningococcal vaccines); *McCulloch v. Sec'y of Health & Hum. Servs*., No. 09-293V, 2015 WL 3640610 (Fed. Cl. Spec. Mstr. May 22, 2015) (human papillomavirus vaccine caused minor child to develop autoimmune encephalitis, intractable epilepsy, and subsequent developmental delays). Petitioner never tested positive for any putatively-causal antibodies, and no treaters appear to have deemed her epilepsy to be an autoimmune type. Nor did testing suggest she was experiencing some kind of neuroinflammatory injury. As a result, causation theories involving cross-reacting antibodies and the harm they would do to Petitioner are far less tenable. (In fact, since Petitioner's epilepsy existed pre-vaccination, it becomes even harder to conceive of a theory in which a non-autoimmune form of epilepsy is worsened *due* to an autoimmune process that is not itself reflected by the diagnosis of a separate autoimmune disease). This lack of corroborative proof outweighs the more ambiguous evidence that Petitioner or her family members had a demonstrated propensity for autoimmune conditions.

Second (and independent from the fact that it cannot be ascertained from this record what instigated Petitioner's seizure-like aura symptoms, in the months to a year before the vaccinations at issue), there is no evidence that Petitioner suffered a fever from the two vaccines she received on October 3, 2019—or, more importantly, that such a fever caused Petitioner to experience a post-vaccination seizure. And the literature filed in this case associating vaccine-induced febrile seizures to seizure exacerbation (or more directly suggesting that vaccination can provoke a febrile seizure) does not at all apply to an adult like Ms. Wiles. *See Stone v. Sec'y of Health & Hum. Servs.*, 676 F.3d 1373 (Fed. Cir. 2012) (denying compensation in the matter of two children developing post-vaccination fevers that induced a single, isolated seizure in each child where petitioners failed to make a prima facie case that the DTaP vaccine caused each child to develop severe myoclonic epilepsy of infancy). Thus, arguments involving febrile seizures in a pediatric population have very little probative value in resolving this claim.

Looking at the six *Loving* prongs, the first three can be easily resolved in Petitioner's favor. The record preponderantly establishes she likely was already experiencing epilepsy before her vaccinations. After them, she had her first diagnosed seizures. And her post-vaccination medical history amply supports the conclusion that her overall condition had worsened. But the last three *Loving* prongs (analogs for *Althen* prongs one to three) are not met—in particular, prong four (and the failure to meet even one such prong is properly fatal to the entire claim).[10] For it has not been preponderantly established that the flu and/or Tdap vaccines, alone or together, can cause worsening of focal, non-autoimmune epilepsy in an adult.

A fundamental flaw in Petitioner's theory is the extent to which it invokes the oft-rejected concept of vaccine-induced cytokine overproduction, leading to aberrant consequences. I have, in

[10] All prongs of the *Althen* test, which are also the last three prongs of the *Loving* test, must be satisfied to grant entitlement. *Dobrydnev v. Sec'y of Health & Hum. Servs*., 566 Fed. Appx. 976, 980 (Fed. Cir. 2014).

many prior cases, criticized this theory as speculative, and as attempting to convert what is expected of a vaccine into something pathologic—but without the corroborative evidence needed to suggest this is likely. *See, e.g.*, *Putman v. Sec'y of Health & Hum. Servs*., No. 19-1921V, 2022 WL 600417, at *21 (Fed. Cl. Spec. Mstr. Jan. 31, 2022); *Martin v. Sec'y of Health & Hum. Servs*., No. 17-250V, 2020 WL 4815840, at *27 (Fed. Cl. Spec. Mstr. July 17, 2020). The fact that vaccines do cause transient upregulation of cytokines does not also mean it likely that these cytokines cause injury, or are comparable in degree or effect to cytokine increases in the context of an active wild infectious process. The same goes for the idea that vaccine-induced cytokines likely breach the BBB. It does not follow that because cytokines are *associated* with BBB breaches, vaccines likely lead to such breaches. And nothing was offered to support the contention that the risk of this kind of innate-driven aberrant response increases simply because *two* vaccines are administered at the same time.

The next leg of Petitioner's theory—that the vaccines she received not only produced a means of breaching the BBB, but then could harm the CNS, likely due to some kind of vaccine-caused process—was even less well-substantiated. Little to no reliable evidence was offered to show what components of the two vaccines at issue might have the capacity to cross-react with CNS nerve tissues, or how that kind of autoimmune process would drive worsening of existing epilepsy. Worse, and as noted above, the record does not substantiate that Petitioner even *had* an autoimmune form of seizure disorder, greatly reducing the probative value of causation evidence assuming an autoimmune pathogenic process caused her worsening.

Evidence offered that was purportedly specific to a vaccine-seizure association was comparably unpersuasive in the context of the facts of this case. Some such evidence involved other vaccines or conditions. *See, e.g.*, Eslait-Olaciregui at 1 (discussing the COVID-19 vaccine); Pang at 1 (discussing COVID-19 vaccines); Murphy at 909 (discussing a version of the Tdap vaccine no longer administered). Much of it involved febrile seizures experienced by infants and children, a context considerably removed from the present circumstances. *See* Duffy; Zhang. By contrast, Respondent offered some epidemiologic evidence supporting the conclusion that vaccines are not in fact associated with afebrile seizures or worsening of a seizure disorder. *See* Arnheim-Dahlstrom at 1. Although petitioners are never compelled to offer this kind of evidence to support their claim, ample Program authority speaks to its relevance in assessing causation, and the fact that its existence can undermine a claimant's entitlement showing.[11]

The balancing out of the persuasive value of each sides' experts favored Respondent as well. Dr. Gershwin's reports had a cursory quality to them, relying on broad points about

[11] For this reason, I give little weight to the argument many experts (including Dr. Gershwin herein (*see* Second Gershwin Rep. at 2)) make about how the rarity of vaccine injuries reduces the probative value of epidemiologic studies. *See Ulysse v. Sec'y of Health & Hum. Servs*., No. 15-451V, 2022 WL 2115248, at *18 (Fed. Cl. Spec. Mstr. May 19, 2022).

immunization or the context of BBB breaches without establishing a sufficient connection from one causation component to the next. While Dr. Gershwin critiqued Dr. He for a similar deficiency, in fact Dr. He's larger-picture points—about the low likelihood of molecular mimicry generally, for example—were actually highly probative. Dr. Willer's contentions were effectively rebutted by Dr. Wirrell, who possessed probably overall the best combination of expertise on the topic of epilepsy and its causes to offer an opinion in this case. She provided reliable scientific and medical evidence supporting her position, and her overall opinion—that she personally, and based on her considerable experience as Mayo Clinic Director of Child and Adolescent Neurology, was unaware of views in the medical community that vaccination could likely provoke worsening of an existing epileptic condition—warranted weight, and offered even more grounding for my finding that causation was not demonstrated in this matter.[12]

This case ultimately presents circumstances in which an adult's existing epileptic disorder in fact worsened within approximately two weeks of receipt of two vaccines—but with no evidence she experienced an unusual vaccine reaction, or the kind of vaccine-provoked symptoms (fever especially) that are associated with seizure activity in a distinguishable patient population. And that temporal association alone is an insufficient basis to find vaccine causation. Petitioner's causation showing did not rise to a level of preponderance.

CONCLUSION

Because Petitioner has not carried her burden of proof, she is not entitled to damages. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[13]

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[12] Dr. Wirrell's competence as a medical expert on the topic of pediatric neurology has been recognized in other cases. *See Ellis v. Sec'y of Health & Hum. Servs.*, No. 13-336V, 2018 WL 4846547, at *25 (Fed. Cl. Spec. Mstr. Sept. 6, 2018).

[13] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.