In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-1565V

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LAURA SURACE,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

* *

Chief Special Master Corcoran

Filed: August 11, 2025

Phyllis Widman, Widman Law Firm LLC, Linwood, NJ, for Petitioner.

Madelyn Weeks, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On July 12, 2021, Laura Surace filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petitioner alleges that a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine she received on July 18, 2019, caused and/or significantly aggravated numerous alleged conditions, including "vestibular/balance dysregulation/difficulty walking, myalgia, malaise, markedly declined functioning, severe pre-menstrual dysphoric disorder ["PMDD"] and other neurological impairments." Petition (ECF No. 1) at 1.

I have opted to decide the claim on the basis of the filed records, and the parties have submitted briefs in support of their respective positions. Petitioner's Brief, dated Oct. 14, 2024 (ECF No. 67) ("Br."); Respondent's Opposition, dated Nov. 22, 2024 (ECF No. 68) ("Opp."); Reply, dated Jan. 15, 2025 (ECF No. 72) ("Reply"). Now, for the reasons set forth below, I deny

[1] Under Vaccine Rule 18(b), each party has fourteen 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] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) ("Vaccine Act" or "the Act"). Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

entitlement. No cognizable vaccine injury has been established, nor has it been shown that the constellation of symptoms Petitioner experienced before receiving the Tdap vaccine likely worsened due to receipt of that vaccine.

I. Medical History

Pre-Vaccination History

Petitioner's pre-vaccination medical history includes a number of features relevant to her claim. For example, she had a history of treatment for anxiety and depression. *See, e.g.,* Ex. 3 at 26-27 (March 2017 wellness visit). Prior to beginning college in the fall of 2017, Petitioner requested a number of personal accommodations (primarily associated with her residence or testing/exam conditions) based on reported disabilities. Ex. 21 at 3, 5. During the summer of 2017, Petitioner received psychiatric treatment for panic attacks and weekly "meltdowns" characterized by episodes of "tearful[] shakes[] [and] screams," that lasted twenty to forty-five minutes. Ex. 5 at 10. And Petitioner underwent a neuropsychological evaluation in December 2017, at which time it was noted that she had a "lifelong history of difficulties with sensory processing, executive functioning, and overall self-regulation, and organization," as her "nervous system [wa]s exquisitely sensitive[,] and she ha[d] great difficulty ignoring distracting or unpleasant sensory experience[s]." Ex. 12 at 9. The psychologic evaluator proposed that a diagnosis of Attention Deficit-Hyperactivity Disorder was warranted, and that some of her sensitivity to stimuli echoed the kinds of symptoms seen with nervous system regulation disorders. *Id.* at 8, 10.

Ms. Surace began college as planned but transferred to a different university in the winter of 2018. There, she was deemed eligible or the same kind of accommodations she had requested earlier. Ex. 24 at 78-79. That May, she had a wellness visit with her primary care provider ("PCP"), Dr. Sandra Voremberg. Ex. 3 at 20. She reported at this time some issues reflective of premenstrual syndrome ("PMS"), and her sensory disorder and anxiety were also noted. *Id.* at 22, 24.[3]

Vaccination and Purported Adverse Events

On July 18, 2019, Ms. Surace (now 20 years old) saw Dr. Voremberg again for a wellness visit. Ex. 3 at 15. Treatments (which included occupational therapy ("OT") and psychologic counseling) Petitioner was receiving for her anxiety and sensory issues were noted. *Id.* at 18. Other than displaying an anxious mood, Petitioner had a normal exam, and she received the Tdap vaccine at this time, as well as a prescription for an oral contraceptive. *Id*. at 11, 16, 19.

One week later (July 25, 2019), Petitioner returned to Dr. Voremberg reporting what she perceived to be vaccination-associated weakness. Ex. 3 at 10, 14. She informed Dr. Voremberg

[3] The records from this visit also note the fact that Petitioner's mother privately informed Dr. Voremberg about Petitioner's earlier neuropsychiatric evaluation, and that in a separate call mentioned the possibility that Ms. Surace was on the autism spectrum disorder ("ASD"). Ex. 3 at 23.

that she had awoken the day after receiving the Tdap vaccine with "severe exhaustion [and a] fever," and that it was "hard to move [her arms and legs] that day." *Id*. at 13. She also became dizzy over the next few days, although her fever diminished and it became somewhat easier to walk despite some lingering pain. *Id.* at 13, 14.

Dr. Voremberg's "main concern [was] to rule out post vaccine Guillain-Barré Syndrome" associated with the vaccination. Ex. 3 at 14. But Petitioner's neuromuscular exam was deemed normal, featuring 5/5 strength in all extremities and normal balance, although Petitioner reported feeling weak and tired climbing stairs, knee locking, and gait difficulties. *Id*. at 14. Dr. Voremberg proposed to file a VAERS[4] report on Petitioner's behalf, and also arranged for a same-day neurology consultation with pediatric neurologist Matthew McCarthy, M.D. *Id*.

At the consultation, Petitioner provided Dr. McCarthy with a history comparable to what she had given to Dr. Voremberg. Ex. 4 at 7, 10. But after examination, Dr. McCarthy opined that "[g]iven [her] normal strength and reflexes and lack of any sensory complaints there [wa]s no concern for an autoimmune post-vaccine demyelinating process." *Id.* at 11. Instead, Dr. McCarthy proposed that Petitioner's symptoms represented "a post-vaccine reaction with flu-like symptoms which seem[ed] to be improving." *Id*.

Two days later, on July 27, 2019, Petitioner went with her mother to a hospital emergency department complaining of "severe pain in her legs that worsened [that day]." Ex. 6 at 31. She now reported continued leg heaviness and knee pain and locking while walking and climbing stairs, and rated her pain a 7/10. *Id*. at 31, 38. Yet Petitioner was "re-evaluated multiple times during the evaluation and was able to walk normally. *Id*. at 34, 36. And other than a test showing low hemoglobin, petitioner's exam and laboratory testing, yielded results within normal limits. *Id*. at 33-36. Even Petitioner's test for C-reactive proteins[5] ("CRP")—a biomarker for inflammation—came back as 3.6 mg/L (within the "normal" reference range of 0.0–9.0). *Id.* at 35. Petitioner was discharged with a diagnosis of "pain in both lower extremities," and advised to consult with her PCP about her oral contraceptive. *Id*. at 36, 67.

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[4] The Vaccine Adverse Event Reporting System ("VAERS") is a national warning system designed to detect safety problems in U.S.-licensed vaccines. *See About VAERS*, VAERS, https://vaers hhs.gov/about.html (last visited July 7, 2025). It is managed by both the CDC and the FDA. VAERS monitors and analyzes reports of vaccine related injuries and side effects from both healthcare professionals and individuals. But it has been observed in the Program that VAERS data is not particularly probative of causation unless supplemented with other reliable evidence—since a VAERS report only establishes a temporal, post-vaccination occurrence. *See also Vig v. Sec'y of Health & Human Servs.*, No. 01–198V, 2013 WL 6596683, at *17 (Fed. Cl. Spec. Mstr. Nov. 14, 2013) ("VAERS is a stocked pond, containing only reports of adverse events after vaccinations but no data about the number of vaccines administered or the occurrence of the same adverse event in individuals who have not been vaccinated").

[5] C-Reactive Proteins are pentameric proteins synthesized by the liver in response to inflammation. B. Singh et al., *C-Reactive Protein: Clinical Relevance and Interpretation*, StatPearls (Jan. 2025), https://www.ncbi.nlm.nih.gov/books/NBK441843/ (last visited Aug. 5, 2025).

Later that summer, Petitioner received some initial physical therapy ("PT") for treatment of muscle weakness (which she continued to attribute to the Tdap vaccine). Ex. 16 at 4, 5, 10. (Her mother acknowledged, however, that a "neurologist ruled out neuro[logical] conditions and fe[lt] the issue [was] purely orthopedic at th[at] point and suggested strengthening in [PT]." *Id*. at 10). On exam, Ms. Surace displayed decreased bilateral arm and leg strength and range of motion "consistent with generalized weakness and pain secondary to vaccine reaction." *Id*. at 5-6. Although additional PT was discussed, Petitioner did not follow through with it at this time.

Petitioner had planned to return to college that fall, but apparently opted instead to take some time off. She saw her psychiatrist in early September 2019, and reported PMDD, along with some anxiety and depression. Ex. 5 at 8. The treater's impression was major depression, generalized anxiety, and PMDD, and Petitioner was prescribed antidepressants. *Id*. She also that month underwent genetic testing to investigate gene/drug interactions. Ex. 8 at 39-43.

Toward the end of September, Petitioner again saw Dr. McCarthy for a new neurological evaluation of recent headaches, dizziness, tinnitus, and sensitivity to light and sound. Ex. 4 at 5. On exam, petitioner had pain and tenderness with palpation throughout her neck muscles but was otherwise normal. *Id*. at 5-6. Dr. McCarthy opined that Petitioner's current symptoms could reflect migraines, adding that the contraceptives she used as well as her personal levels of stress and anxiety were likely cofactors (although he also proposed that cessation of symptoms required better control of anxiety). *Id*. at 6. She also went back to Dr. Voremberg at this time. Ex. 3 at 9. The records from this visit note that Petitioner's prior ASD diagnoses were mentioned, and Dr. Voremberg agreed to contact Petitioner's psychiatrist to discuss those diagnoses, with an eye toward helping Petitioner obtain social support treatment assistance at other educational institutions or places. *Id*. at 8-10.

In November-December 2019, Ms. Surace received additional treatment for PMDD. Ex. 15 at 8. She also obtained another PT evaluation. Ex. 7 at 2. The history section from this evaluation repeats Petitioner's assertion that she experienced unusual aches and pains after receipt of the Tdap vaccine, and that the symptoms had evolved ("from acheyness [sic] to instability, dizziness, ringing in ears, [and] [headache]"), although she had been cleared by a neurologist. *Id*. An exam performed at this time was deemed "consistent with [left] sided vestibular hypofunction resulting in dizziness and unsteadiness on [her] feet." *Id*. at 4. The therapist recommended PT twice weekly for four weeks. *Id*. at 6.

Treatment in 2020 and Beyond

Petitioner has filed many additional records setting forth her treatment over the past several years, and associated efforts to ascertain an explanation for her differing symptoms. But these records shed almost no light all on the issues to be resolved in this case.

During the winter of 2020, for example, Petitioner continued to participate in PT. Ex. 7 at 90. She deemed it beneficial despite fatigue after the sessions were completed. *Id.* at 52, 92. Her psychiatrist later speculated that the vestibular dysfunction that the PT was aimed at addressing probably represented a congenital condition. Ex. 5 at 3 (noting that petitioner was in weekly PT for vestibular dysfunction that she had "prob[ably] had since birth"). She also continued to seek treatment for PMDD, sensory sensitivities, and anxiety, noting to treaters that she bore a diagnosis of "high functioning autism" her "mom th[ought] [was] due to having her inoculations." Ex. 8 at 4-5. She informed other treaters that winter and early spring of her belief that she had experienced a vaccine reaction. *See, e.g.*, Ex. 15 at 6 (March 2020 visit to allergist); Ex. 10 at 7 (March 2020 visit with optometrist); Ex. 9 at 3 (May 27, 2020 visit with otolaryngologist).

In March 2020, Ms. Surace underwent a neuro-optometric rehabilitation analysis due to her complaints that she was "having difficulty understanding her body's position in space." Ex. 10 at 7. No abnormalities were identified, but the treater nevertheless proposed that Petitioner had experienced signs and symptoms of vestibular dysfunction following a "bad reaction" to the vaccine, and subsequently diagnosed her with "visual-vestibular integration dysfunction" and "esophoria."[6] *Id.* at 7–9. She was referred for additional evaluation to an otolaryngologist. Ex. 9 at 3.

Through May and June of 2020, Petitioner visited that treater, Dr. Laura Downey, to be evaluated for sound sensitivity. *See generally* Ex. 9. Petitioner complained that she would become a "little lightheaded" sometimes or after walking for a long time, but it "var[ies] by day." *Id.* at 3. She added that this was "after the Tdap booster," and that she was diagnosed with "autistic spectrum disorder." *Id.* Dr. Downey also noted that the Petitioner claimed that she had sensitive ears "forever" and that she had used musician's ear plugs and noise canceling headphones to manage her sensitivity. *Id.* Dr. Downey conducted an exam and found nothing abnormal, and discussed possible hydrops[7] or semicircular dehiscence syndrome[8] as the cause of her dizziness.

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[6] "Vestibular dysfunction is a disturbance in the body's balance system due to an insult to the vestibular system of the inner ear, the central nervous system processing centers, or both." J. Dougherty et al., *Vestibular Dysfunction*, StatPearls (Jan. 2025), https://www.ncbi.nlm.nih.gov/books/NBK558926/ (last visited Aug. 8, 2025). Esophoria is "a form of heterophoria in which there is a deviation of the visual axis of an eye toward that of the other eye after the visual fusional stimuli have been eliminated." *Esophoria*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=17374&searchterm=esophoria (last visited Aug. 8, 2025).

[7] Hydrops, also known as Edema, is the "presence of abnormally large amounts of fluid in the intercellular tissue spaces of the body, usually referring to subcutaneous tissues." *Edema*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=15589 (last visited Aug. 8, 2025).

[8] "Superior semicircular canal dehiscence is a condition in which there is a hole in the part of the inner ear that controls balance." *Superior Canal Dehiscence Syndrome*, Johns Hopkins Medicine, https://www.hopkinsmedicine.org/health/conditions-and-diseases/superior-canal-dehiscence-syndrome-scds (last visited Aug. 8, 2025).

On July 28, 2020, psychotherapist Elizabeth Hanifin, L.C.S.W., wrote a letter advising that she had been "seeing [Petitioner] for individual psychotherapy sessions for the last three years" (although medical record evidence of this purported treatment relationship was not filed in this case). Ex. 11 at 1. Ms. Hanifin purported that she witnessed petitioner's "functioning decline[] markedly" after the July 2019 vaccination, and noted that petitioner "need[ed] to take months to work toward baseline functioned [sic]." *Id*. at 1-2. Ms. Hanifin further claimed that Petitioner's overall functioning was compromised, that she had light sensitivity, and experienced "balance dysregulation and severe [PMDD]" that had yet to subside. *Id*. at 1.

In the fall of 2020, Ms. Surace underwent another PT evaluation at a different provider for "visual-vestibular deficits secondary to vestibular dysfunction." Ex. 31 at 221-24. The physical therapist transferred to petitioner to OT for "vision therapy involving yoked prisms." *Id*. at 224. She obtained the OT evaluation and attended sessions through January 2021. Ex. 31 at 6, 164.

In May 2021 (two months before this claim's initiation – and nearly two years post-vaccination), Petitioner was treated by the neurologist who offers an expert opinion in this case on her behalf, Dr. Georges Ghacibeh, M.D., for purported reaction to her July 2019 vaccination. Ex. 13 at 19.

Dr. Ghacibeh documented Petitioner's reported history, noting that she had "always had some sensory issues, mostly to sound and sight" but had attended college. After receiving the Tdap vaccine, however, she developed a "low grade fever" and, two days later she "could not move her legs or arms," and "required help walking and going up the stairs." Ex. 13 at 9. Since then, Petitioner continued to experience tinnitus, persistent headaches, vision issues, sensitivity to stimuli, imbalance issues, and muscle weakness. *Id.* Dr. Ghacibeh also stated (contrary to the evidence discussed above, which suggests Petitioner likely was considered for an ASD diagnosis well before vaccination) that Petitioner was only diagnosed with an ASD "when all of the symptoms started after the vaccine," adding that she "fe[lt] that she always had [a]utism, high functioning, but now [her] symptoms [were] worse." *Id*. at 20.

Petitioner's physical examination was normal. Ex. 13 at 21-22. But Dr. Ghacibeh opined that it was "very likely" that her many symptoms were "secondary to DTaP booster," as a result of "a systemic inflammatory reaction to the vaccine." *Id.* at 20. He proposed that Petitioner's "sensitivity to vaccines alone with the mild autism and early speech delay point[ed] to a possible underlying metabolic, specifically mitochondrial, dysfunction." *Id*. He recommended a lab work up but noted that lab "abnormalities m[ight] only appear during periods of high physiological stress." *Id.*

Extensive lab testing was ordered, including a complete blood count, iron panel, amino acid profile, thyroid function, vitamin B12 level, and Lyme antibody. Ex. 13 at 20. But it is not

evident from the filed medical records what the results were of this testing. May 6, 2021 blood work, however, revealed additional evidence of elevated inflammation biomarkers. *Id*. at 5.

II. Expert Reports

A. *Petitioner's Expert – Dr. Georges Ghacibeh*

Dr. Ghacibeh, a neurologist and medical professor, prepared two written reports on Petitioner's behalf. Report, dated June 14, 2023, filed as Ex. 27 (ECF No. 47-2) ("First Ghacibeh Rep."); Report, dated June 13, 2024, filed as Ex. 32 (ECF No. 62) ("Second Ghacibeh Rep.").

Dr. Ghacibeh received his medical degree from the Lebanese University, Faculty of Medical Sciences, in Beirut, Lebanon in 1997, and a Masters of Science in Clinical Investigation from the University of Florida in 2007. Curriculum Vitae, filed as Ex. 27 (ECF No. 47-1) ("Ghacibeh CV") at 1. He then completed internships at Lebanese University and Staten Island University, followed by his residency in Neurology at New York University, Bellevue Medical Center. Ghacibeh CV at 1. Thereafter, Dr. Ghacibeh completed fellowships in Behavioral and Cognitive Neurology, and Clinical Neurophysiology at the University of Florida. *Id.* He is currently an Assistant Professor in the Department of Neurology at Seton Hall-Hackensack Meridian School of Medicine, as well as Chief of the Division of Neurology and Medical Director of the Primary Stroke Center at Pasacack Valley Medical Center and Hackensack Meridian Health. *Id.* He is board certified by the American Board of Psychiatry and Neurology and the American Board of Clinical Neurophysiology. *Id.* at 2.

First Report

Dr. Ghacibeh began his first report with a review of Ms. Surace's medical history and records pre- and post-vaccination. From this, he offered the opinion that the Tdap vaccine caused Ms. Surace's acute neurological and musculoskeletal symptoms, and significantly aggravated her pre-existing sensory sensitivity, visual processing disorder, and emotional dysregulation. First Ghacibeh Rep. at 5–6.

Dr. Ghacibeh theorized that the Tdap vaccine could have caused Petitioner's new symptoms by bringing about acute myositis and acute arthritis that developed into a diffuse and persistent inflammatory response, such as encephalopathy and cranial neuropathy affecting the vestibular nerve (cranial nerve 8). First Ghacibeh Rep. at 5. He based this conclusion on Petitioner's development of a fever and body aches within the first twenty-four hours of receiving the vaccine. *Id.* at 2. From there, the reaction developed into weakness in the legs, knee pain, and trouble ambulating over the next few days— which caused Petitioner to go to the hospital. *Id.* Dr. Ghacibeh opined that there is a direct causal relationship between the vaccine and Petitioner's ailment because the onset and development of progressively worse symptoms occurred within days after vaccination. *Id* at 5.

In addition, Dr. Ghacibeh proposed that the Tdap vaccine significantly aggravated a pre-existing mitochondrial medical condition in the Petitioner. First Ghacibeh Rep. at 5. Based on Petitioner's history of early speech delay, mild symptoms of neurodevelopmental dysfunction, inflammatory reactions caused by vaccines in the past, and emotional regulation difficulties, Dr. Ghacibeh opined that Petitioner likely had suffered from an underlying metabolic disorder before the vaccine at issue. *Id.* If this were the case, then the vaccine severely exacerbated that underlying condition, to the point where it impacted the Petitioner's ability to attend college and form social relationships. *Id.* at 6. (Notably, however, the Petitioner has never been formerly diagnosed with a metabolic disorder by any of her providers).

Dr. Ghacibeh proposed two theories of how the vaccine could have triggered these reactions: molecular mimicry and overstimulation of the immune system (although he supported them with little in the way of corroborative independent evidence). First Ghacibeh Rep. at 6. Molecular mimicry, he opined, results in the phenomenon of autoimmunity that affect the joints, muscles, peripheral nerves, cranial nerves, and central nervous system – consistent with what the Petitioner experienced after her vaccine. *Id.* at 2–3, 6. Overstimulation of the immune system is also common in vaccines, as they "are generally formulated with the primary purpose of activating the immune system so that the body mounts a lasting immune response. . . ." *Id.* at 6. Claiming that such overstimulation can result in the immune system failing to function correctly, Dr. Ghacibeh maintained that this imbalance could present itself as febrile illness or muscle aches after a vaccine. *Id.*

Dr. Ghacibeh's causation theory also relied on the assumption that the "TDaP vaccination is known to cause [an] acute systemic inflammatory response." First Ghacibeh Rep. at 6. Dr. Ghacibeh suggested that people with underlying metabolic, immune, or neurological dysfunction are less likely to handle vaccines well than their healthy counterparts. *Id.* The Tdap vaccine could trigger more severe and persistent reactions. *Id.* Dr. Ghacibeh offered many articles as support for a causal link between various adverse effects and Tdap vaccine, including some that he maintained established a "possible causal relationship between the DTP [whole cell pertussis] vaccine and acute encephalopathy." *Institute of Medicine*, *Adverse Effects of Pertussis and Rubella Vaccines*, 48, 53 (Christopher P. Howson et al., eds. 1991), filed as Ex. 35 (ECF No. 64-3) ("1991 IOM Report"); L. Cowan et. al., *Acute Encephalopathy and Chronic Neurological Damage After Pertussis Vaccine*, 11 Vaccine 14 (1993), filed as Ex. 34 (ECF No. 64-2) ("Cowan"). The IOM Report and the Cowan article looked at the possible relationship between the whole-cell pertussis DTP vaccine and encephalopathy. *See* 1991 IOM Report; Cowan at 1. However, the Petitioner in the present case received the *acellular* pertussis formulation of the Tdap vaccine, rendering such studies of limited relevance.

Another article was cited as evidence of the specific kinds of symptoms that might be experienced due to the Tdap vaccine. *See, e.g.,* L. Fortuna et al., *Enhanced Post-Licensure Safety Surveillance of a New Recombinant Acellular Pertussis Vaccine Licensed as a Monovalent (aP, Pertagen® and Tetanus, Reduced-Dose Diphtheria Combination (TdaP, Boostagen®) Vaccine for*

Immunization of Adolescents and Adults in Thailand, 38 Vaccine 8194 (Dec. 3, 2020) filed as Ex. 33 (ECF No. 64-1) ("Fortuna"). Fortuna conducted a study to surveil the safety of the recombinant acellular pertussis vaccines (including Tdap). *Id.* at 8195. It took note of any adverse reactions reported after receiving the vaccine, such as pain at the injection site, muscle pain, lymphadenitis, etc. *Id*. at 8196. But Fortuna did not find significant concerns. The incidence rate of recipients experiencing myalgia (muscle pain), for example, was only 0.33%—not 3.3% as Dr. Ghacibeh suggests. *Id.* at 8196–97; First Ghacibeh Rep. at 6. In addition, Fortuna observed that all adverse events observed were "mild," and had "resolved within a few days without any sequelae." Fortuna at 3. Dr. Ghacibeh nevertheless proposed that this stood as reliable evidence that the vaccine could cause severe and long-lasting reactions—like those experienced by the Petitioner. *Id.* at 7.

Dr. Ghacibeh referenced other evidence that he proposed established that the TDaP vaccine has been associated with long lasting neurological complications, like seizures and encephalopathy. First Ghacibeh Rep. at 7; E. Woo et al., *Motor Palsies of Cranial Nerves (excluding VII) After Vaccination: Reports to the US Vaccine Adverse Event Reporting System*, 10 Hum. Vaccine Immunother. 301 (2014), filed as Ex. 40 (ECF No. 64-8) ("Woo").[9] But Dr. Ghacibeh acknowledged that the number of adverse effects was "low," and that "most adverse effects . . . are local irritation or self limited flu-like symptoms." *Id*. Woo, for example, focused on cranial nerve palsies reported to VAERS after receipt of routinely-administered vaccines like Tdap. Woo at 1. But Woo observed only 14 such instances post-Tdap vaccine, out of 68 reports of cranial nerve paresis or paralysis. *Id.* Woo deemed this finding to possibly be "purely coincidental," adding that "[p]assive surveillance data cannot be used to assess causality." Woo at 3.

Other items of literature similarly addressed injuries or symptoms dissimilar to Petitioner's complaints. *See, e.g.*, P. Brazis, *Isolated Palsies of Cranial Nerves III, IV, and VI*, 29 Semin. Neurol. 14 (Feb. 12, 2014), filed as Ex. 39 (ECF No. 64-7) ("Brazis") (providing an overview of the palsies of cranial nerves III, IV, and VI, but failing to discuss vaccines or a relationship between vaccines and cranial nerve palsies). Dr. Ghacibeh opined that the Petitioner was suffering from

[9] Dr. Ghacibeh also refers to study that the Petitioner lists as "Exhibit 36" in this case. *See* First Ghacibeh Rep. at 7, 9, (citing M. Uberall et al., *Severe Adverse Events in a Comparative Efficacy Trial in Germany in Infants Receiving Either the Lederle/Takeda Acellular Pertussis Component DTP (DTaP) Vaccine, the Lederle Whole-Cell Component DTP (DTP) or DT Vaccine*, 89 Dev. Biol. Stand. 83 (1997), ("Uberall")); *see also* Petitioner's Updated Exhibit List, dated Feb 7, 2025, (ECF No. 78) ("Pet. Final Ex. List") at 3 (listing the Uberall study as exhibit 36). However, the Petitioner does not appeart to have filed Uberall, and instead filed Chapter 10 of the 2012 IOM report as Exhibit 36—which does mention the purpose and findings of the Uberall study. *See* COMMITTEE TO REVIEW ADVERSE EFFECTS OF VACCINES AND INSTITUTE OF MEDICINE, ADVERSE EFFECTS OF VACCINES: EVIDENCE AND CAUSALITY (Kathleen Stratton, et. al., eds., 2012), filed as Ex. 36 (ECF No. 64-4) ("2012 IOM Report"). Similarly, Dr. Ghacibeh cited to the Lloyd study and Petitioner's counsel listed Lloyd as exhibit 37. *See* First Ghacibeh Rep. at 7, 9 (citing J. Lloyd et al., *Adverse event reporting rates following tetanus-diphtheria and tetanus toxoid vaccinations: data from the Vaccine Adverse Event Reporting System (VAERS), 1991-1997*, 21 Vaccine 3746 (Sep. 8, 2003) ("Lloyd")); Pet. Final Ex. List at 3 (listing Lloyd study as exhibit 37). In actuality, Exhibit 37 is an article that discusses studies that have analyzed adverse neurological events in association with DTP or DTaP vaccines. D. Geier & M. Geier, A Review of the Vaccine Adverse Event Reporting System Database, 5 Expert Opinion on Pharmacotherapy 691, (2004), filed as Ex. 37 (ECF No. 64-5).

"vestibular neuropathy (cranial nerve 8)," but the articles offered do not assess the relationship between Tdap and that condition. Woo did not include harm to that nerve as an adverse issue to be evaluated, and Brazis only looks at nerves 3, 4, and 9. *See* Woo at 1; Brazis at 1.

Second Report

Dr. Ghacibeh's supplemental report endeavored to both respond to Dr. Sriram's report and also reaffirm his causation theory. Second Ghacibeh Rep. at 2. However, it mostly featured attribution of Petitioner' symptoms and onset to a "biphasic" presentation, emphasizing the mostly subjective evidence and little objective evidence presented in this case to support the theory.

Dr. Ghacibeh contended that Petitioner's presentation of symptoms was biphasic, meaning the Petitioner experienced both an acute reaction and chronic symptoms thereafter. *Id.* This also explained, he reasoned, why the acute symptoms disappeared less than six months after vaccination, but the Petitioner continued to suffer from vaccine related symptoms. *Id.* at 2–4. Respondent's experts had noted that Dr. Ghacibeh did not cite any credible evidence linking Petitioner's dizziness, instability and tinnitus to vaccination, but in reaction he pointed to his biphasic theory, adding that no laboratory tests or other objective measures establishing that Respondent's proposed explanations—hydrops or semicircular dehiscence syndrome—existed either. *Id.* at 4.

Dr. Ghacibeh further defended his position that the lack of objective support in the medical record did not disqualify the propriety of a neurological illness diagnosis. Second Ghacibeh Rep. at 3. He maintained that neurologic conditions, such as headaches, can be diagnosed on the basis of subjective complaints by a patient, and therefore Petitioner's subjective complaints did not lack evidentiary validity. In addition, Dr. Ghacibeh noted the existence of objective evidence that he felt supported his neurologic condition diagnosis, including (1) proof of elevated CRP levels (as revealed in testing performed July 27, 2019 and May 6, 2021), (2) objective deficits measured by therapists, and (3) Petitioner's neuropsychological profile showing decline post vaccination. *Id.* (referring to testing found in Ex. 6 at 35, Ex. 13 at 14). From this, Dr. Ghacibeh opined that a neurologic diagnosis based on the evidence was proper.

Dr. Ghacibeh concluded his supplemental report reiterating that the immediate post-vaccine symptoms Petitioner reported, followed by chronic neurological complications, were fully supportive of a vaccine-associated cause – here, the Tdap vaccine she received in July 2019. Second Ghacibeh Rep. at 5.

B. *Respondent's Expert – Dr. Subramaniam Sriram*

Dr. Sriram, a neurologist, supplied a single expert report for Respondent. Report, dated October 24, 2023, filed as Ex. A (ECF No. 52-1) ("Sriram Rep.").

Dr. Sriram received a Bachelor of Medicine and a Bachelor of Surgery from the University of Madras in Madras, India. Curriculum Vitae, filed as Ex. B (ECF No. 52-3) ("Sriram CV") at 1. He then served as an intern and resident at Wayne State University and completed a residency in neurology at Stanford University, where he also served as chief resident and eventually completed a post-doctoral fellowship in neuroimmunology. *Id*. He is board-certified in both neurology and internal medicine. *Id*. He also holds academic positions as a professor of experimental neurology and therapeutics as well as an associate professor in molecular biology and immunology. *Id.* 2. Dr. Sriram is heavily involved in clinical work as he directs the Multiple Sclerosis Clinic at Vanderbilt University Medical Center where he sees roughly 1450 patients a year. Sriram Rep at 1. In addition, he runs a basic science laboratory looking at pathways that promote neurologic repair. https://www.vumc.org/neurology/person/subramaniam-sriram-mbbs (last visited July 8, 2025). In addition, Dr. Sriram has published numerous articles on various aspects of clinical and immune mediated diseases of the nervous system. Sriram CV at 9–21; Sriram Rep. at 1.

Dr. Sriram's report began with a summary of the Petitioner's medical record. Sriram Rep. at 2–8. From this, he concluded that there does not appear to be a "cogent, unifying diagnosis" put forward by the Petitioner that could possibly be associated with the Tdap vaccine. *Id*. at 9. Indeed, Dr. Sriram noted, Dr. Ghacibeh had largely conceded that there is no diagnosis that fits Petitioner's symptoms. *Id.* at 10. At most, Dr. Ghacibeh proposed theories of how the vaccine could have caused Petitioner's symptoms, but Dr. Sriram deemed them to lack a biologic basis, or any other independent support. *Id.* at 12.

Dr. Ghacibeh also proposed diagnostic explanations for Petitioner's presentation that lacked objective record support. Sriram Rep. at 10–11. For example, Dr. Ghacibeh had opined that Petitioner had an undiagnosed metabolic disorder that allowed her to experience severe post-vaccine complications—in this case, her febrile illness—that later impacted her vital organs. First Ghacibeh Rep. at 6. But Petitioner had never been diagnosed with a metabolic disorder, and lab and exam results that might corroborate such a diagnosis were normal. Sriram Rep. at 10. Accordingly, it was speculative to proposed metabolic dysfunction as an explanation for Petitioner's symptoms. *Id.*

Dr. Sriram disputed Dr. Ghacibeh's claim that the sequence of events set forth in Petitioner's medical history established a direct, causal relationship between the vaccine and Petitioner's injuries. Petitioner claims that she experienced muscle stiffness and pain, joint pain, brain fog, and fever after her July 2019 vaccination. Sriram Rep. at 10. The record demonstrated that those symptoms had largely disappeared by Petitioner's first PCP appointment several days later. *Id.* In addition, the neurologic symptoms she reported, such as headache and tinnitus, had been present before Petitioner received the vaccine. *Id.* The evaluation provided by Dr. McCarthy, a neurologist, obtained only a week after the vaccine, also did not show any neurologic or neuromuscular abnormality. *Id.* In fact, And Petitioner's vestibular dysfunction was considered to be caused by either hydrops or semicircular dehiscence syndrome. *Id.* at 7, 12.

Similarly, Dr. Sriram challenged the legitimacy of Dr. Ghacibeh's belief that Petitioner's "severe" reaction resulted in secondary, diffuse impact on several major organs. Sriram Rep. at 11. While Petitioner did experience a febrile reaction after her vaccine, the medical records also established that this had resolved after a few days, rendering it only a transient occurrence. *Id.* Subsequent, post-vaccination lab testing revealed no impairment to Petitioner's vital organs. *Id.* It was thus objectively implausible to contend that the vaccination resulted in greater systemic harm. *Id.*

Dr. Ghacibeh had further failed to substantiate his theories with reliable independent medical or scientific proof. The 1991 IOM Report, for example, not only involved a different Tdap vaccine formulation, but associated the whole cell pertussis component only with adverse events like encephalopathy – a diagnostic classification completely irrelevant to Ms. Surace, whose medical records did not at all support such a diagnosis. Sriram Rep. at 11. And a more recent of the IOM Report on vaccine adverse reactions concluded that there was inadequate evidence to accept or reject a causal relationship between the TDaP vaccines, and others like it, with encephalopathy. *Id.* at 11–12 (*citing* Committee to Review Adverse Effects of Vaccines and Institute of Medicine, *Adverse Effects of Vaccines: Evidence and Causality* 25 (K. Stratton et. al., eds., Aug. 2011), filed as Ex. A Tab 1 (ECF No. 52-2) ("2011 IOM Report")).

Dr. Ghacibeh had similarly failed to offer any credible independent support connecting Petitioner's joint and muscle pain or vestibular dysfunction (dizziness, instability, and tinnitus) to the Tdap vaccine. Sriram Rep. at 12. There was simply insufficient evidence to come to the conclusion that the Petitioner either suffered a neurological injury from the vaccine, or that the Tdap vaccine could result in such harm. *Id.*

III. Procedural History

This claim was initiated four years ago. After the filing of documents (overseen by the "pre-assignment review" process) was completed, the Petition was activated in April 2022 and originally assigned to a different special master. Respondent filed his Rule 4(c) Report opposing compensation in August 2022, and then (while Petitioner obtained additional records needed for assessment of the claim) the case was reassigned to me in the winter of 2023. I subsequently ordered expert reports to be filed, and when that process was completed, set a schedule for briefing of a ruling on the filed record. The matter has been ripe for resolution since February of this year.

IV. Parties' Arguments

Petitioner

Petitioner maintains that she has provided sufficient evidence to support one or both of her theories for her claim that her Tdap vaccine caused and/or significantly aggravated her vestibular dysfunction, difficulty walking, myalgia, malaise, decline in functioning, severe premenstrual dysphoric disorder, inability to concentrate, visual-vestibular deficits, esophoria, acute myositis,

acute arthritis, encephalopathy, cranial neuropathy affecting the vestibular nerve, and emotional distress. The six-prong test to satisfy a significant aggravation claim is described in *Loving v. Sec'y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 144 (2009). The first three *Loving* prongs are unique to a significant aggravation claim, while the last three prongs are identical to the requirements of a causation-in-fact claim as laid out in *Althen v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Petitioner begins her argument by addressing the significant aggravation claim. She notes the first two *Loving* prongs, which look at an injured party's condition before and after the vaccine. Br. at 9. The record establishes that she had a history of depression, anxiety, and sensory processing disorder before administration of the Tdap vaccine. Ex. 3 at 9; Ex. 4 at 11; Ex. 12 at 10. She then references her lengthy, post-vaccination medical history of visits to her PCP, neurologists, physical therapist, advanced practice nurse, otolaryngologist, therapists, optometrist, psychiatrist, neuropsychologist, and others. Br. at 3–7. She was seen for a litany of issues, including trouble ambulating, trouble with focusing, visual-vestibular dysfunction, mood outbursts, anxiety, depression, and premenstrual dysphoric disorder. *Id.* Dr. Ghacibeh specifically noted that the Petitioner's "symptoms had changed dramatically after the vaccination," and that she "developed depression and exacerbated anxiety." *Id.* at 10 (quoting First Ghacibeh Rep. at 3).

Based on these records, notes, and observations taken down by doctors, the Petitioner argues that she has sufficiently established her condition both before and after receiving the TDaP vaccine. And she maintains she has satisfied *Loving* prong three by offering both medical records and her academic performance as evidence that the vaccine worsened her prior conditions to the point that it substantially affected her life. Br. at 10. She claims her providers recognized at least a temporal relationship between vaccination and the decline in her physical and mental abilities. *Id.* at 10–11. Dr. Ghacibeh specifically reported that "[h]er pre-existent symptoms were exacerbated, including sound hypersensitivity, visual processing disorder, . . . emotional dysregulation[, and] mild neurodevelopmental disorder" to the point where it impacted the Petitioner's "ability to attend college and form normal relationships." *Id.* at 10. And Dr. Ghacibeh was not the only provider to notice this shift, since Communicare, Positive Development, Kessler Rehabilitation, and JFK Johnson Rehabilitation Institute all record significant aggravation of her afflictions after vaccination. *Id.* (*citing* Second Ghacibeh Rep.). (Of course, in many of these instances Petitioner specifically sought care for an alleged, self-reported post-vaccination reaction, reducing the evidentiary value of those diagnostic statements somewhat). *See generally* Ex. 28 (ECF No. 57-1); Ex. 29 (ECF No. 57-2); Ex. 7 (ECF No. 8-7); Ex. 31 (ECF No. 60-1); Ex. 28 (ECF No. 57-1) at 11.

In addition to the medical records, Petitioner also references her declining academic performance post-vaccination as evidence of significant aggravation. She argues that cognitive tests taken before and after the vaccine show a decline in cognitive performance. *Cf.* Ex. 12 and Ex 14. Pre-vaccination, Petitioner was able to complete college level coursework—whereas after

she struggled, opting to take the semester off and enroll in a university closer to home. *See* Br. at 11; Ex. 14 at 2.

Petitioner next contends she was able to show the Tdap vaccine "can cause" the symptoms she experienced (whether deemed worsening under *Loving* prong four, or new-onset symptoms under *Althen* prong one). Dr. Ghacibeh had proposed that Petitioner suffered a biphasic, inflammatory response to the vaccine that impacted her nervous system and several of her organs, joins, and muscles. Br. at 12. (quoting Second Ghacibeh Rep. at 3). In turn, he also contended that Ms. Surace had an underlying, undiagnosed metabolic disorder that was the root cause of all her pre-vaccination dysfunctions. *Id.*

The cascade of symptoms and aggravation of pre-existing conditions was triggered by the vaccine activating the metabolic disorder. Br. at 12. Upon receiving the vaccine, Petitioner experienced an acute immediate inflammatory reaction presenting as a febrile illness. *Id.* at 13. Then, she developed a chronic reaction resulting in muscle stiffness, muscle and joint pain, fatigue, tinnitus, vestibular disfunction, dizziness, brain fog, and sensitivity to light and sound. *Id.* Proof of this immunologic response comes from evidence of a inflammatory reaction and resulting injury, as corroborated by presence of inflammatory biomarker testing results, which "suggests the presence of a systemic inflammatory response" post-vaccination. *Id.* at 12–13.

Petitioner further argues that she has established that the Tdap vaccine "did cause" her injuries/worsening, and in a medically-acceptable timeframe (as required by *Loving* prongs five and six/*Althen* prongs two and three). Dr. Ghacibeh asserts that symptoms Petitioner displayed - developmental delay, neurodevelopmental dysfunction, and repeated reactions to vaccines in the past - points to the existence of an undiagnosed metabolic disorder. Br. at 13–14. In addition, the severe reaction and cacophony of ailments Petitioner experienced after the Tdap vaccine at issue and supported by the medical records was a clear exacerbation of pre-existing symptoms and emergence of new symptoms. *Id.* at 14–15.

On reply, Petitioner attempted to rebut some of Respondent's arguments. She opines that Respondent ignores treating provider medical notes that state the Petitioner had a "vaccine adverse reaction," even if they did not expressly mention the Tdap vaccine. Reply at 2. Petitioner also offers three points from Dr. Ghacibeh's treatment medical notes to support her causation theory and temporal proximate relationship between the vaccine and the onset and aggravation of symptoms. *Id.* at 2–4. Thus, Dr. Ghacibeh noted on August 20, 2021, that since taking the "mito[chondrial] cocktail" in May, Petitioner had "experienced marked improvement in her day to day function," and notes from March 8, 2022, further observed her improvement, although "she still fatigues very easily," and offered a diagnosis of an underlying mitochondrial metabolism disorder. *Id.* at 3. Otherwise, Petitioner stresses that the relevant standard for her to prevail on *Loving* and *Althen* is not medical certainty, but instead only requires her to show enough evidence to show onset, causation, exacerbation, and temporal relationship by a preponderance of the evidence. *Id.* at 4.

Respondent

Respondent contends at the outset that Petitioner has not put forward a cognizable injury supported by medical evidence. Opp. at 31. Indeed, in Respondent's view the medical record is unsupportive of any of the injuries offered in Dr. Ghacibeh's expert report—encephalopathy, cranial neuropathy affecting the vestibular nerve, a metabolic disorder, and vestibular dysfunction. *Id.* at 32. Petitioner has instead only offered a myriad of symptoms without a unifying diagnosis, which is insufficient to establish a cause of action under the Vaccine Act. *Id.* at 31 (quoting *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1349 (Fed. Cir. 2010) ("[A] 'vaccine-related injury,' i.e., illness, disability, injury or condition, has to be more than just a symptom or manifestation of an unknown injury")). Without a cognizable, evidentiarily-supported injury, Petitioner's claim must fail.

Respondent also goes through an *Althen* and *Loving* analysis as further support of why Petitioner cannot prevail on her claim. Opp. at 34. Focusing on the first three *Loving* prongs, Respondent contests whether Petitioner experienced a significant aggravation of her pre-existing conditions following the Tdap vaccine. Although Petitioner's pre-existing conditions of PMDD, anxiety, depression, and sensory processing disorder were well established in the medical record, symptoms experienced after her vaccination reflect a continuation of those prior concerns. *Id.* at 45. But the Vaccine Act requires a "markedly greater disability, pain, or illness accompanied by substantial deterioration of health" to show significant aggravation, not merely a "change for the worse in a pre-existing condition." *Id.* at 44 (citing 42 U.S.C. § 300aa-33(4); *Martin v. Sec'y of Health & Hum. Servs.,* No. 13-486V, 2020 WL 6865931, at *10 (Fed. Cl. Spec. Mstr. Oct. 27, 2020) (citing H.R. Rep. 908, 99th Cong.2d Sess. 1, reprinted in 1986 USCCAN 6287, 6356)).

The core *Althen* prongs (*Loving* prongs four to six) are also unsatisfied. First, Petitioner's theory of causation lacks reliable scientific/medical support, and is instead vague and mostly dependent on temporal proximity. Opp. at 34. Dr. Ghacibeh also proposes a number of potential biologic mechanisms, such as molecular mimicry and polyclonal B cell activation, but does not develop them sufficiently. *Id.* at 34–35. In addition, Dr. Ghacibeh failed to illustrate a connection between the vaccine and the specific symptoms in this case, relying heavily instead on the temporal relationship between the vaccination and Petitioner's symptoms. *Id.* at 38.

Respondent also questions the evidentiary value of the items of scientific literature that Dr. Ghacibeh offers in support of Petitioner's causation theory. Resp. Opp. at 35–38. Dr. Ghacibeh misinterpreted the findings of Fortuna, for example, reading the incidence rate of subjects experiencing myalgia as ten times higher than what was reported in the study. *Compare* First Ghacibeh Rep. at 6, *and* Fortuna at 8196–97. Fortuna actually found a low incidence of reported adverse effects after receipt of acellular pertussis vaccine, and concluded that acellular pertussis vaccines are safe for adolescents and adults. Fortuna at 8198. Other articles, like Woo or Lloyd, rely on VAERS data, which has limited causation value. The 1991 IOM Study involved adverse events associated with whole cell pertussis—not the acellular component now found in the

vaccine. Brasis and Woo do not discuss the proposed injuries in this case. Opp. at 35–38. The medical literature submitted by the Petitioner has little overall relevance to the alleged injuries in her case. *Id.* at 38.

Second, with respect to *Loving* prong five/*Althen* prong two, Respondent emphasizes that Petitioner's expert employs a kind of *post hoc ergo propter hoc* reasoning that is not accepted in Program cases. Opp. at 39 (citing *Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1323 (Fed. Cir. 2010). Respondent pointed out that Dr. Ghacibeh mainly relies on temporal association between Petitioner's low grade fever and "more severe systemic complications" to establish a "logical progression" of an adverse reaction in response to the vaccination. *Id.* (quoting First Ghacibeh Rep. at 7). Otherwise, Dr. Ghacibeh points to test results suggesting the presence of biomarkers of inflammation test results—for example, contending that Petitioner's CRP levels were repeatedly elevated. But Respondent observes that CRP testing performed nine days after vaccination (July 27, 2019) yielded results in the "normal" range, and only CRP levels measured on May 6, 2021—almost two years after the vaccination—were elevated, and minimally at best. Opp. at 40 (CRP normal levels are 0.0–9.0 mg/L, and Petitioner first CRP test resulted in levels of 3.6 mg/L (within the "normal" range), while her second test showed levels of 12.3 mg/L (outside the "normal range"). Ex. 6 at 35, Ex. 13 at 14.

In addition, Respondent questions the probative value of treating physician notes from medical care providers who saw the Petitioner well after receipt of the vaccination, and whose understanding of her baseline or pre-vaccination condition was based on "[P]etitioner's own subjective reports of her symptoms." Opp. at 41. In addition, those providers never note or mention their individual view of the Tdap vaccine as causal, outside of their transcription of Petitioner's medical history. *Id.* By contrast, Respondent notes that the views of the most contemporary care providers - Drs. Voremberg, McCarthy, and Hartman - deserve more evidentiary weight, since they saw her within three months of vaccination. *Id.* at 41–42. Even if some of these three providers accepted the possibility that Petitioner had a transient reaction to vaccination, none of them attributed her overall complaints to the Tdap vaccine. *Id.* at 42. And although Dr. Ghacibeh was also one of Petitioner's direct treaters, Respondent notes that the opinions of treating providers are not "sacrosanct," and that medical record as a whole can undermine a treating physician's opinion. Resp. Opp. at 43.

Respondent concludes by arguing that Petitioner has to show a proximate temporal relationship between the vaccination and her injury or its worsening (*Althen* prong three/*Loving* prong six). Dr. Ghacibeh has not established a condition tied to her symptoms that has an scientifically-understood timeline for when onset would begin post-vaccination. Opp. at 43. Dr. Ghacibeh similarly has failed to establish a medically acceptable timeframe for "chronic symptoms" following Tdap. *Id.* at 44. Rather, Dr. Ghacibeh only offers a timeframe of complications "within weeks" of vaccination, but without showing why symptoms would be expected to occur in that time period. *Id.*

V. Applicable 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*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[10] There is no Table claim for the injury (really a collection of symptoms possibly associated with Petitioner's underlying psychologic issues) alleged in this matter.

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*, 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 v. Sec'y of Health & Hum. Servs*., 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(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."

[10] 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. Appx. 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).

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

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or even a generally accepted medical theory. *Andreu*, 569 F.3d at 1378–79 (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. 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.*, 107 Fed. Cl. 280, 245 (2012).

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.*, No. 24-1281, slip op. at 9 (Fed. Cir. July 29, 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 Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (unpublished). 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 a 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. *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 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 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 v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[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.

C. *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*, 618 F.3d at 1347 (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").

D. *Consideration of Medical Literature*

Both parties filed numerous items of 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 in this case, 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").

E. *Determination to Resolve Case without a Hearing*

I have opted to decide entitlement in this case based on written submissions and evidentiary filings, including the expert reports filed by each side. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers rather than via evidentiary hearing, where (in the exercise of their discretion) they conclude that the former means of adjudication will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The choice to do so has been affirmed on appeal. *See D'Toile v. Sec'y of Health & Human Servs.*, No. 15-85V, 2018 WL 1750619, at *2 (Fed. Cir. Apr. 12, 2018); *see also Hooker v. Sec'y of Health & Human 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 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. *See Hovey v. Sec'y of Health & Human Servs.*, 38 Fed. Cl. 397, 402-03 (1997) (special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417.

ANALYSIS

I. Petitioner Has Not Identified a Cognizable Vaccine Injury

Vaccine Program claims must establish the underlying existence of an injury that could be attributable to a prior vaccination. An inability to establish an injury by preponderant evidence can be fatal to a claim (especially where the causation theory presented is based on a proposed outcome consistent with that alleged injury). *Broekelschen*, 618 F.3d at 1346, 1349. It is thus often necessary at the outset of analyzing a Vaccine Act claim to determine whether a given alleged injury has been preponderantly established in the first place. *Locane v. Sec'y of Health & Hum. Servs*., 685 F.3d 1375, 1381 n.3 (Fed. Cir. 2012); *Lombardi v. Sec'y of Health & Hum. Servs*., 656 F.3d 1343, 1353 (Fed. Cir. 2011).

This case features a lengthy, ample medical record that strongly establishes that Petitioner sought medical treatment both before and after her vaccination for a myriad of reasons. Out of this evidence, the Petitioner distills an alleged injury of "vestibular/balance dysregulation/difficulty walking, myalgia, malaise, marked declined functioning, severe PMDD, and other neurological impairments." However, many of these are merely symptoms. Of course, special masters are not medical experts, and are unqualified to diagnose illnesses (nor are they so tasked). *Contreras*, 121

Fed. Cl. at 292–93. But special masters are also not called upon to construct a vaccine-related injury on the basis of nonspecific symptoms or complaints that do not otherwise coalesce into a recognized diagnosis.

When "'the question of causation turns on which injury [the petitioner] suffered,' the special master is permitted to choose between two competing diagnoses of dissimilar diseases as a first step in the causation analysis." *Id.* at 293 (quoting *Broekelschen*, 618 F.3d at 1346). But in this matter, there are not two conflicting diagnoses. Instead, the Petitioner presents a "kitchen sink" of symptoms and diagnoses to the Court. I find that none, collectively or individually, form a cognizable injury (at least for purposes of an *Althen* analysis)—either because they lack record corroboration, or reflect nonspecific concerns that do not "add up" to a cognizable injury that could be proposed to be vaccine-associated.

For example, Petitioner proposes she variously experienced an encephalopathy, cranial neuropathy affecting the vestibular nerve, and a metabolic disorder. But there is no record evidence Petitioner *received* such diagnoses—let alone that any would be appropriate on the basis of Petitioner's medical history. Dr. Ghacibeh himself did not mention any of these as a possibility in any of his treating provider notes, although his expert report proposes them. First Ghacibeh Rep. at 1, 5.

Program petitioners have succeeded in establishing a vaccine-caused encephalopathy (sometimes resulting in developmental regression). But this has usually occurred in the context of Table claims (where claimants are held to exacting factual showings if causation is to be presumed), and the facts in such unique cases underscore the importance of evidence of acute and/or immediate encephalopathy precipitated by a close-in-time vaccination. *See, e.g.*, *Wright v. Sec'y of Health & Human Servs.,* No. 12-423V, 2015 WL 6665600, at *10 (Fed. Cl. Spec. Mstr. Sept. 21, 2015) (child with developmental regression symptoms experienced a Table encephalopathy, where child convulsed and vomited during car ride home after receiving vaccinations (possibly evincing a brief seizure), then became listless, unresponsive, and "basically catatonic" by the following day); *Bast v. Sec'y of Health & Human Servs.,* No. 01-565V, 2012 WL 6858040, at *35-36 (Fed. Cl. Spec. Mstr. Dec. 20, 2012) (discussing case report involving a successful Vaccine Program claimant who alleged a Table encephalopathy claim for her autism-type symptoms; child had developed a high fever, inconsolable crying, irritability, and lethargy, and refusal to walk within forty-eight hours after vaccination), *mot. for review den'd,* 117 Fed. Cl. 104 (2014), *aff'd,* 579 F. App'x 1001 (Fed. Cir. 2014). This case does not establish (nor does it attempt to establish) Table liability, and the Petitioner has not shown by a preponderance that any of these diagnoses are appropriate.[11]

[11] To the extent it is Petitioner's intent to plead an injury of exacerbation of autism symptoms (perhaps by contending that the Tdap vaccine lead to learning issues in college)ASD, comparable such claims have been uniformly rejected. *See, e.g.*, *Sturdivant v. Sec 'y of Health & Human Servs*., No. 07-788V, 2016 WL 552529, at *20 (Fed. Cl. Spec. Mstr.

The contention that Petitioner experienced a metabolic disorder (or had a preexisting one that was vaccine-worsened) is also speculative. No treater (other than perhaps Dr. Ghacibeh in offering an expert report in this case) so opined, and the record in this matter does not provide the kind of objective evidence that would substantiate such an injury.[12] Yet Dr. Ghacibeh proposed that many of Petitioner's symptoms stem from this otherwise-uncorroborated diagnosis. First Ghacibeh Rep. at 5; Ex. 14. And his proof for its existence is by relying on nonspecific or subjective complaints, like headache. Br. at 13.

Neither vestibular dysregulation nor dysfunction have been shown by Petitioner to be recognized diagnoses. Rather, vestibular dysfunction is a general term that describes a disturbance in the body's balance system that has multiple etiologies and presentations, but it typically accompanied by symptoms of vertigo, nausea, and instability.[13] Here, Petitioner only listed complaints of dizziness and instability on July 31, 2019—thirteen days after her vaccination and after multiple visits to other providers. Ex. 16 at 2; Ex. 4 at 7–11. She thereafter continued to complain of dizziness, headaches, and instability at multiple provider visits, but none diagnosed her with any vestibular deficit until December 23, 2019. Ex. 7 at 2. And that appears to have been mostly based on the subjective evidence of Petitioner's self-reported symptoms. Ex. 7 at 4. Also concerning is how the Petitioner' s injury appears transient, varying day-to-day. And it is well established from Petitioner's pre-vaccination history of extreme sensory sensitivity that she had experienced similar symptoms in the past, and yet they were never attributed to vestibular dysfunction. I thus cannot on this record deem these symptoms to constitute a cognizable injury, and one that arose only post-vaccination.

Overall, there is no real injury that can be gleaned from this record that might encompass the Petitioner's litany of post-vaccination concerns. The record establishes only that the Petitioner experienced vaccine-related malaise, but it was transient, and therefore could not be the basis of a claim given the Act's requirement for proof of six months of injury sequelae. *See, e.g.*, *Hinnefeld v. Sec'y of Health & Hum. Servs.*, No. 11-328V, 2012 WL 1608839, at *4-5 (Fed. Cl. Spec. Mstr.

Jan. 21, 2016) (footnote omitted) (discussing the history of autism cases in the Vaccine Program and how those cases have consistently fallen "far short of plausibility" since the OAP concluded (emphasis in original)); *Rogero v. Sec'y of Health & Human Servs.*, No. 11-770V, 2017 WL 4277580, at *4-5 (Fed. Cl. Spec. Mstr. Sept. 1, 2017) (citing eighteen unsuccessful post-Omnibus Autism Proceeding autism claims that went to hearing, and thirteen post-Omnibus Autism Proceeding autism claims that were rejected without a hearing), *mot. for review denied,* slip op. (Fed. Cl. Jan. 11, 2018), *aff'd,* 748 F. App'x 996 (Fed. Cir. 2018). Indeed, special masters have reasonably questioned whether such autism injury claims even possess reasonable basis at this juncture. *See, e.g.*, *Hashi v. Sec'y of Health & Human Servs.,* No. 08-307V, 2016 WL 5092917 (Fed. Cl. Spec. Mstr. Aug. 25, 2016); *Sturdivant,* 2016 WL 552529, at *20.

[12] It is also worth noting that claims that vaccines can cause these kinds of disorders (whether or not they also result in developmental concerns or ASD issues) have almost never met with success. *See, e.g.*, *Gaiter v. Sec'y of Health & Hum. Servs.*, No. 17-1040V, 2018 WL 3991229, at *1 (Fed. Cl. Spec. Mstr. July 6, 2018).

[13] J. Dougherty et al., *supra* note 6.

Mar. 30, 2012) (dismissing case where medical history revealed that petitioner's injury resolved less than two months after onset).

(Of course, Petitioner has identified *some* preexisting issues that might serve as an injury that could have been worsened, such as her purported severe PMDD. This is evident from the discussion with her treating physician and her Yaz prescription being refilled on the day of her vaccination. *See* Ex. 8 (ECF No. 8-3) at 11. I address those symptoms or conditions as the basis for a significant aggravation claim below.).

II. Petitioner Has Not Carried Her *Althen* Burden of Proof

Ignoring Petitioner's inability to substantiate a cognizable injury, I would also find that the *Althen* test has not been preponderantly met.

First, Petitioner has not established, on a "more likely than not" basis, that the Tdap vaccine "can cause" the constellation of symptoms she alleges experiencing. Petitioner's causation theory, as enunciated by Dr. Ghacibeh, is speculative, vague, and largely unsupported by sufficient scientific evidence. That theory requires acceptance of multiple, unsubstantiated assumptions, and takes logical leaps from there that also lack independent support. Dr. Ghacibeh only offers evidence that the Tdap vaccine is known to cause an acute systemic inflammatory response. First Ghacibeh Rep. at 6. But it is a considerable jump from that to the conclusion that the Tdap vaccine trigged a *systemic* inflammatory reaction in the musculoskeletal system. *Id.* at 7. The only evidence in Dr. Ghacibeh's favor is the temporal proximity between the vaccine and the onset of mild fever and malaise after vaccination.

The individual items of literature offered to flesh out this aspect of the causation opinion were also unsupportive of the theory. For example, Cowan and the 1991 IOM Report only look at the whole-cell pertussis vaccine and its relationship to encephalitis. *See* Cowan at 1; 1991 IOM Report. They do not propose associations with the relevant acellular component at issue in this case. Dr. Ghacibeh cites to Fortuna as support for a connection between Tdap and an inflammatory reaction targeting the musculoskeletal system, but that article actually established only that reported myalgia after receiving the Tdap vaccine was rare, and that the adverse reactions observed "were mild in severity" and resolved within days. *Id.* at 3.

Other literature offered by the Petitioner on this point relies mainly on VAERS data, which involves personal reports of a temporally-observed relationship with a vaccine—enough to propose the subject warrants further research, but not enough to support causation. *Howard v. Sec'y of Health & Hum. Servs.*, No. 16-1592V, 2022 WL 4869354, at *21, n.15 (Fed. Cl. Spec. Mstr. Aug. 31, 2022), *mot. for review den'd*, 2023 WL 4117370 (Fed. Cl. May 18, 2023), *aff'd*, 2024 WL 2873301 (Fed. Cir. June 7, 2024) (noting "it has been observed in the Program that VAERS data is not particularly probative of causation unless supplemented with other reliable evidence—since a VAERS reports only establishes a temporal, post-vaccination occurrence, and thus shines no light on the possibility of causation itself").

Some literature had nothing to do with any possible injuries alleged in this matter. For example, Uberall (which was only referenced in another filed item of literature) appears to have assessed the profiles of multiple tetanus toxoid vaccines, including the acellular Tdap vaccine, against the risk of seizures. *See* 2012 IOM Rep. at 18, 74 (discussing Uberall). But the Petitioner in this case has not been diagnosed with seizures, nor does the record establish that she ever experienced any post-vaccination. In addition, the 2012 IOM Report noted that Uberall's authors relied on temporal association as evidence for causation between the two, and could not establish a biologic mechanism between the vaccine and the seizures. *See id.* at 18 (critiquing the Uberall study). Similarly (and based on Dr. Ghacibeh's unsubstantiated opinion that the Petitioner was suffering from "vestibular neuropathy (cranial nerve 8),"), Petitioner offered Woo and Brazis as connecting vestibular neuropathy with Tdap vaccine. First Ghacibeh Rep. at 7. But neither proposed an association with the vaccine and harm to the relevant cranial nerve. *See* Woo at 1; Brazis at 1.

Second, Petitioner has failed to satisfy *Althen* prong two by establishing, via a logical sequence of cause and effect, that the Tdap vaccine "did cause" the symptoms she experienced. Here, Dr. Ghacibeh mainly relies on temporal proximity to satisfy this prong, emphasizing that Petitioner experienced a transient vaccine reaction that he alleges developed into "more severe systemic complications" as proof of a "logical progression" of an adverse reaction. First Ghacibeh Rep. at 7. In support, Petitioner also offers both CRP test results and notes from treating providers to bolster her claim. Second Ghacibeh Rep. at 3.

Yet test results taken *nine days after vaccination* do not indicate the presence of existing inflammation. Ex. 6 at 35. Any results more supportive of this argument were obtained on May 6, 2021—over 21 months after vaccination (making it exceedingly difficult to link them to that prior vaccine). And even theses slightly elevated CRP results are not by themselves strong evidence for the existence of an autoimmune inflammatory disease that began nearly two years prior.[14] If Petitioner's reaction were in fact related to the inflammatory stimuli from the vaccine, it would be expected that the CRP levels would be elevated beyond the normal level *during the first CRP test*. But since the levels were within the normal range at that time, the only explanatory options are that either there was no inflammatory stimuli, or any trigger had resolved within nine days of vaccination. Regardless, the CRP test results do not further Petitioner's specific causation showing.

In addition, Petitioner relies heavily on other treating practitioners' medical record notes linking Tdap with her symptoms. As a general matter, however, statements of treating physicians do not *per se* bind the special master to adopt the conclusions of such an individual. Section 13(b)(1). Rather, their opinions and diagnoses are only as reasonable as their suppositions or bases. And here, it is clear from the record that the majority of the Petitioner's treating physicians do not

[14] *See* Ex. 13 at 14; *see also* B. Singh et al., *C-Reactive Protein: Clinical Relevance and Interpretation*, StatPearls (Jan. 2025), https://www.ncbi.nlm.nih.gov/books/NBK441843/ (last visited Aug. 5, 2025) (explaining that CRP levels are highly reactive to inflammatory stimuli and increase rapidly and decrease quickly upon the resolution of the underlying trigger).

reflect their own conclusions that the Tdap vaccine is linked to the Petitioner's ailments, but are mere memorialized statements made to them *by Petitioner* or her family about her purported medical history. *See, e.g.,* Ex. 7 at 2; Ex. 13 at 165; Ex. 28 at 10.

Ultimately, Petitioner's causation showing largely relies on *post hoc ergo propter hoc* reasoning, which is not regarded as sound law or logic—whether in the Vaccine Program or anywhere else. *Fricano v. United States*, 22 Cl. Ct. 796, 800 (1991) (citing *Loesch v. United States*, 227 Ct. Cl. 34, 45, 645 F.2d 905, 914 (post hoc ergo propter hoc approach to causation is unpersuasive), *cert. denied*, 454 U.S. 1099, 102 S.Ct. 672, 70 L.Ed.2d 640 (1981); *Baskett v. United States*, 8 Cl. Ct. 201, 210–11 (1985), *aff'd*, 790 F.2d 93 (Fed. Cir.), *cert. denied*, 478 U.S. 1006, 106 S.Ct. 3300, 92 L.Ed.2d 714 (1986)); *see also Young v. Burton*, 567 F. Supp.2d 121, 140 (D. D.C. 2008), *aff'd*, 354 F. App'x 432 (D.C. Cir. 2009) (Rejecting physician's testimony drawing conclusions based *on post hoc ergo propter hoc* in a toxic tort case involving alleged mold exposure); *Doe/34 v. Sec'y of Health & Hum. Servs.*, 2009 WL 1955140, at *10 (Fed. Cl. Mar. 4, 2009), *aff'd sub nom. Jane Doe*34 v. Sec'y of Health & Hum. Servs.*, 87 Fed. Cl. 758 (2009) (citing *Grant v. Sec'y of Health & Hum. Servs*, 956 F.2d 1144, 1148 (Fed.Cir.1992) ("[T]he inoculation is not the cause of every event that occurs within the ten day period.... Without more, this proximate temporal relationship will not support a finding of causation")).

While there is evidence of Petitioner experiencing malaise, low grade fever, and other symptoms after her vaccination, that alone was too transient a reaction, and has not been persuasively linked to Petitioner's larger complaints.

III. Petitioner Has Not Shown the Tdap Vaccine Significantly Aggravated any Preexisting Condition

As discussed above, *Loving* prongs three through six largely duplicate the three *Althen* prongs. *See Hooker v. Sec'y of Health & Hum. Servs*., No. 02-472V, 2016 WL 3456435, at *45 (Fed. Cl. May 19, 2016). Here, a significant aggravation claim has not been established, even if I focus solely on conditions Petitioner clearly had experienced pre-vaccination, like PMDD.

Loving prong four requires a petitioner to provide a medical theory demonstrating that the type of vaccination in question can cause a significant worsening of the type of preexisting condition of the vaccine. Petitioner failed to establish, however, that the Tdap vaccine "can cause" exacerbation of injury, or did so here, for many of the same reasons set forth above relating to causation.

For example, Dr. Ghacibeh unconvincingly assumed that Petitioner had a preexisting metabolic disorder (despite the absence of proof corroborating this) that the Tdap vaccine could worsen, leading to a host of other kinds of problems, including Petitioner's ability to attend college and form social relationships. First Ghacibeh Rep. at 6. As stated above, the Petitioner has never been assessed for or diagnosed with a metabolic disorder. However, even if she had been, Dr. Ghacibeh's theory is that the metabolic disorder allowed the vaccine to cause severe post-vaccine

complications that impacted her vital organs. *Id.* at 5. Dr. Ghacibeh did not put forward evidence as to the biomechanics of how this would occur or why the vaccine would worsen her reaction. And, bio-inflammatory markers measured soon after her vaccination show that her vital organs were not inflamed, thus undermining his theory. Ex. 6 at 35.

Under *Loving* prong five, a claimant must show that it is "more probable than not" that the Tdap vaccination *did* aggravate her pre-existing neurodevelopmental dysfunctions or one of her other pre-existing ailments, like anxiety and PMDD. But as discussed above, Petitioner's treating physicians did not come to the conclusion on their own, based on objective record evidence, that the Tdap vaccine aggravated any such conditions. Rather, any statements seeming to embrace aggravation were mainly based on Petitioner's subjective beliefs and self-reporting, rendering their opinion less-reliable. I thus do not give much credit to the providers from Communicare, Positive Development, Kessler Institute for Rehabilitation, JFK Johnson Physical Therapy, and other providers that did not evaluate the Petitioner before her vaccination, who claim significant aggravation of symptoms after the vaccine. Second Ghacibeh Rep. at 1. It is clear that these providers did not examine the Petitioner before the vaccine, and thus could not accurately determine Petitioner's baseline outside of relying on Petitioner's subjective reports of her own symptoms. *See* Ex. 7 at 2; Ex. 31 at 164; Ex. 29 at 23; Ex. 28 at 10–11; Ex. 9 at 3; Ex. 10 at 7.

Accordingly, the Petitioner has failed to satisfy both *Althen* prong two and *Loving* prong five, thus precluding her from succeeding on her claim.

CONCLUSION

Petitioner has not met her burden of proof. 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.[15]

IT IS SO ORDERED.

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

[15] 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.